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LABORATORIES, INC.

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# CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

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16. Abstract (Limit: 200 words)

The effects of Acid-black-52 (5610640) (AB52) and Yellow-3 (1342296) (Y3) were studied in rats and hamsters. AB52 and Y3 were administered intratracheally to Golden-Syrian-hamsters and Fischer-344-rats once a week for 15 weeks at concentrations of 0.56 to 3.16 milligrams per 0.2 milliliters of saline solution. AB52 and Y3 were administered orally for 27 months, the former at 2 percent and the latter at 0.8 percent in the diet. Animals were observed for clinical symptoms during the experiments. At the end of the experiments, all animals were killed, and complete necropsies and histopathological studies were conducted. AB52 was not found to be oncogenic in either species by either route of administration. Y3 given intratracheally was oncogenic in the adrenal cortex of male hamsters and in the pancreas of male rats. Y3 administered in the diet was oncogenic in the adrenal glands of both sexes of hamsters, in the liver and urinary tract of male rats, and in the endocrine system of female rats. The author concludes that AB52 is noncarcinogenic and Y3 is carcinogenic in rats and hamsters.

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CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3
IN HAMSTERS AND RATS

BLI Project No. 210103

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# I. ABSTRACT

A carcinogenicity study of Acid Black 52 (Amasol Black WA, C.I. 15711) and Yellow 3 (Amaplast Yellow PFC, the crude base of C. I. Disperse Yellow 3, C.I. 11855) was performed at Borriston Laboratories, Inc., by intratracheal instillation and dietary administration. The study was conducted from September 10, 1979 to February 9, 1982.

Treatment groups consisted of 50 male and 50 female Golden Syrian hamsters and Fischer 344 rats. Control groups consisted of 35 males and 35 females/group. Intratracheal administration was performed once weekly for 15 consecutive weeks. Dyes were administered in the diets for 27 months.

Acid Black 52 was administered intratracheally to hamsters at 0.75 mg/0.2 ml saline and to rats at 0.32 mg/0.2 ml saline. Control groups received intratracheal doses of 0.2 ml saline only. Acid Black 52 was administered in the diets of hamsters and rats at 2 percent of the total diet. Control groups received pelleted meal prepared with 1.3 percent corn oil (used as a dust suppressant for all dietary formulations).

Definitive oncogenicity was not observed in hamsters or rats given intratracheal doses or diets containing Acid Black 52.

Acid Black 52 in the diet apparently suppressed the incidence of lymphoma/leukemia in the bone marrow of hamsters and in the hematopoietic/lymphatic system, liver and lungs of rats. A suppressive effect was also suggested for adrenal cortical tumors in treated female hamsters and to a lesser extent in treated male hamsters.

Yellow 3 was administered intratracheally to hamsters and rats at 15.0 mg/0.2 ml saline. Control groups received intratracheal doses of 0.2 ml saline only. Yellow 3 was administered to hamsters and rats at 0.8 percent of the total diet. Control groups received pelleted meal prepared with 1.3 percent corn oil.

Intratracheal administration of Yellow 3 demonstrated oncogenicity in the adrenal cortex of hamsters and pancreas of rats. Dietary administration of Yellow 3 produced oncogenic effects in the adrenals of hamsters. Yellow 3 in the diet was oncogenic to the liver and urinary tract of male rats and the endocrine system (pituitary and thyroid) of female rats.

Yellow 3 given intratracheally apparently suppressed the incidence of neoplasms in the spleen of hamsters and in the prostate, thyroid, and adrenal medulla of rats. Dietary administration of Yellow 3 demonstrated the ability to suppress the incidence of lymphoma/leukemia in treated hamsters and rats.

## II. INTRODUCTION

A carcinogenesis bioassay of C.I. Disperse Yellow 3, a textile dye, was conducted at Battelle Columbus Laboratories, Columbus, Ohio, under a subcontract from Tracor Jitco, Inc., Rockville, Maryland, prime contractor for the NCI Carcinogenesis Testing Program from March 1977 to April 1979[a]. The bioassay was conducted by feeding diets containing 5,000 and 10,000 ppm of the test substance to groups of 50 Fischer 344 rats of either sex for 103 weeks. Similar groups of 50 B6C3F1 mice received diets containing 2,500 and 5,000 ppm of the test substance for 103 weeks. Groups of 50 untreated rats and mice of either sex served as controls.

Throughout the bioassay, mean body weights of dosed rats and mice of either sex were lower than those of the controls. Survival of dosed rats of either sex was significantly greater than that of the corresponding controls. No other compound-related clinical signs or effects on survival were observed.

A significant and dose-related increase in neoplastic nodules of the liver occurred in dosed male rats as compared to controls (controls 1/49, 2%; low-dose 15/50, 30%; high-dose 10/50, 20%).

Stomach tumors, considered rare in Fischer 344 rats, were found only in the dosed male rats. These tumors consisted of one adenocarcinoma and a sarcoma (in the same animal) in the high-dose group and in the low-dose group a squamous papilloma, fibrosarcoma, adenoma, and mucinous adenocarcinoma. The incidence of these tumors was not significantly greater than that in controls; thus, the association between the administration of C. I. Disperse Yellow 3 and the stomach tumors in male rats was not clearly established.

Negative trends in the incidences of certain primary tumors in treated rats included: decreased lymphoma or leukemia in both sexes; decreased malignant mesothelioma and C-cell carcinoma in males; and decreased pituitary adenoma and endometrial polyps in females.

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[a]NIH Publication No. 82-1778; NTP Technical Report on the Carcinogenesis Bioassay of C.I. Disperse Yellow 3 (CAS No. 2832-40-8).

Hepatocellular adenomas occurred in dosed female mice at incidences significantly higher than that in the controls (control 0/50, 0%; low-dose 6/50, 12%; high-dose 12/50, 24%). The incidences of hepatocellular carcinomas were also higher in the dosed female mice than in the controls, but the increased incidences were not statistically significant. A significantly lower incidence of hepatocellular adenomas was detected among low-dose male mice.

Alveolar/bronchiolar adenomas occurred in high-dose male mice at an incidence significantly higher than that in the controls (control 2/50, 4%; low-dose 6/49, 12%; high dose 9/49, 18%). However, the incidence among control male mice was somewhat lower than the historical rate for Battelle Columbus Laboratory, the high-dose effect was not significant when adenomas and carcinomas were combined, and the incidence among low-dose female mice was significantly reduced as compared with controls; thus, the incidence of alveolar/bronchiolar adenomas among males was not clearly related to treatment with C. I. Disperse Yellow 3.

Lymphomas or leukemias occurred in a dose-related trend in female mice and at incidences greater in the high-dose group than that in the controls. However, the increase was not regarded as being related to the administration of C. I. Disperse Yellow 3.

Under the conditions of this bioassay, C. I. Disperse Yellow 3 was found to be a carcinogen as evidenced by an increased incidence of hepatic neoplastic nodules among male rats and an increased incidence of hepatocellular adenomas among female mice. In addition, the stomach tumors found in male rats may have been induced by the administration of C. I. Disperse Yellow 3.

To our knowledge, no additional information regarding the acute or chronic toxicity of Yellow 3 or Acid Black 52 was available prior to the performance of the carcinogenicity study at Borriston Laboratories, Inc.

## III. TEST AND CONTROL MATERIALS

### A. Receipt of Test and Control Materials

Amasol Black WA (Acid Black 52), 164 percent crude, a fine black powder, code 248013, lot 5374, BRL No. 145 and Amaplast Yellow PFC (Yellow 3), a fluffy yellow powder code 6116087, MX558702050, PO. 002414, BRL No. 147, were obtained from American Color and Chemical Corporation, Lock Haven, Pennsylvania. Dyes were kept at room temperature. Normal saline was used as the vehicle for intratracheal instillation and was obtained from Abbott Laboratories, Chicago, Illinois. Mazola® corn oil was used as a dust suppressant in the diet preparation and was supplied by Borriston Laboratories, Inc; the corn oil was purchased as needed throughout the course of the study.

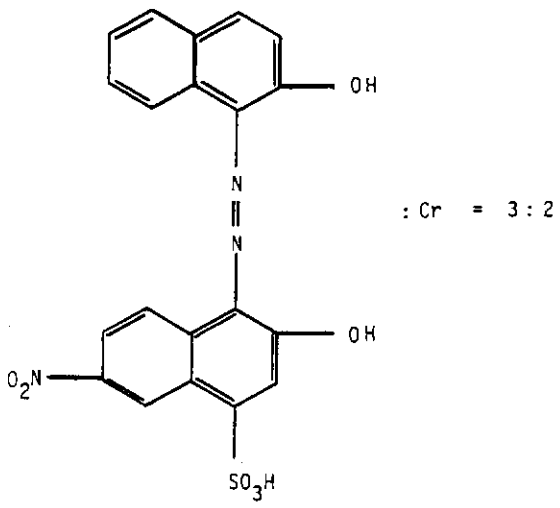
### B. Analyses of the Azo Dyes

Acid Black 52 and Yellow 3 were analyzed for C, H, N, O, S, Na, Cl, and Cr. Infrared scans were performed on nujol, fluorolube mull and KBr pellets. Azo group titration was performed for percentage (%) dyestuff for each dye. Stability of the dye content in diets was determined by analyzing samples stored for two weeks at -20°, 5°, 25°, and 45°C, by using thin layer chromatography (TLC) to determine dye degradation components. Dye degradation was determined by color visualization of the TLC plates under ultraviolet light and iodine staining techniques. Elemental analyses for C, H, N, and O were performed by Galbraith Laboratories, Inc., Knoxville, Tennessee; all other analyses were conducted by Biospherics, Inc., Rockville, Maryland.

Random grab samples of the formulated diets were analyzed for dye content. The percent recovery of each dye was optimized by trial with various solvents and solvent combinations. Extraction of the yellow dye from the feed samples was performed in methanol. Quantitation was achieved colorimetrically against standards of known concentration and absorbance. The black dye was extracted from the feed samples by agitation in methanol:potassium hydroxide. The extraction was filtered and quantitation was achieved colorimetrically versus a standard curve.

Values obtained from the elemental analysis of Black 52 showed considerable divergence from the theoretical values based on the chemical structure, suggesting that the sample was considerably impure. This was substantiated by X-ray powder diffraction patterns showing the presence of NaCl, the detection of 8.48% sodium in the sample, 6.1% chloride and low chromium concentration (3.71%). Acid Black 52 is said to be a chromate complex derived from Mordant Black 1 at a ratio of approximately 2 atoms of chromium to 3 molecules of the monoazo dye as shown below:

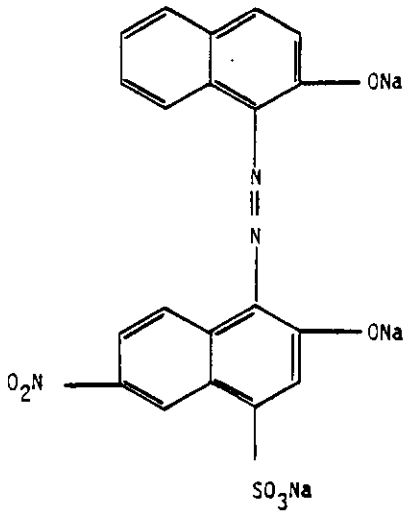
Acid Black 52




Elemental Analysis of Acid Black 52

| | Cr: Azo | Theoretical Values 1:2 | Theoretical Values 2:3 | Analytical Values |
|---|---|---|---|---|
| C | | 51.84% | 50.60% | 38.95% |
| H | | 2.37% | 2.75% | 3.39% |
| O | | 24.19% | 23.65% | 19.56% |
| N | | 9.07% | 8.87% | 6.90% |
| Cr | | 5.61% | 7.32% | 3.71% |
| S | | 6.91% | 6.76% | 6.19% |
| Na | | 0.00% | 0.00% | 8.48% |
| Cl | | 0.00% | 0.00% | 6.10% |
| | | 99.99% | 99.95% | 93.28% |
| | MW | 926 | 1421 | |

The presence of excess sodium (over that equivalent to the Na in the NaCl present) may be attributed to sodium being substituted for the hydrogen on the sulfonic acid moiety ($HO_3S$) as a result of the "salting out" process employed in manufacturing the dye. The low chromium content would indicate the presence of the sodium salt of the phenol component mixed with the normal chromium complex as indicated below:




Two of the above molecules closely approximate the molecular weight of Acid Black and the Azo and nitro equivalents per weight are correspondingly equal.

The Azo group titration performed on four samples of Acid Black 52 during the contract period showed a dyestuff content of 98.6, 97.2, 90.5 and 95.0%.

No attempt was made to further identify the components of Acid Black since the intent of the program was to evaluate the toxic effects of the production dye as used in the industry, and not that of the pure material.

An infrared scan of Acid Black 52 failed to show an absorbance pattern regardless of the phase, as shown in Figures 1 and 2.

FIGURE 1

INFRARED SCAN OF ACID BLACK 52 - NUJOL MULL PHASE

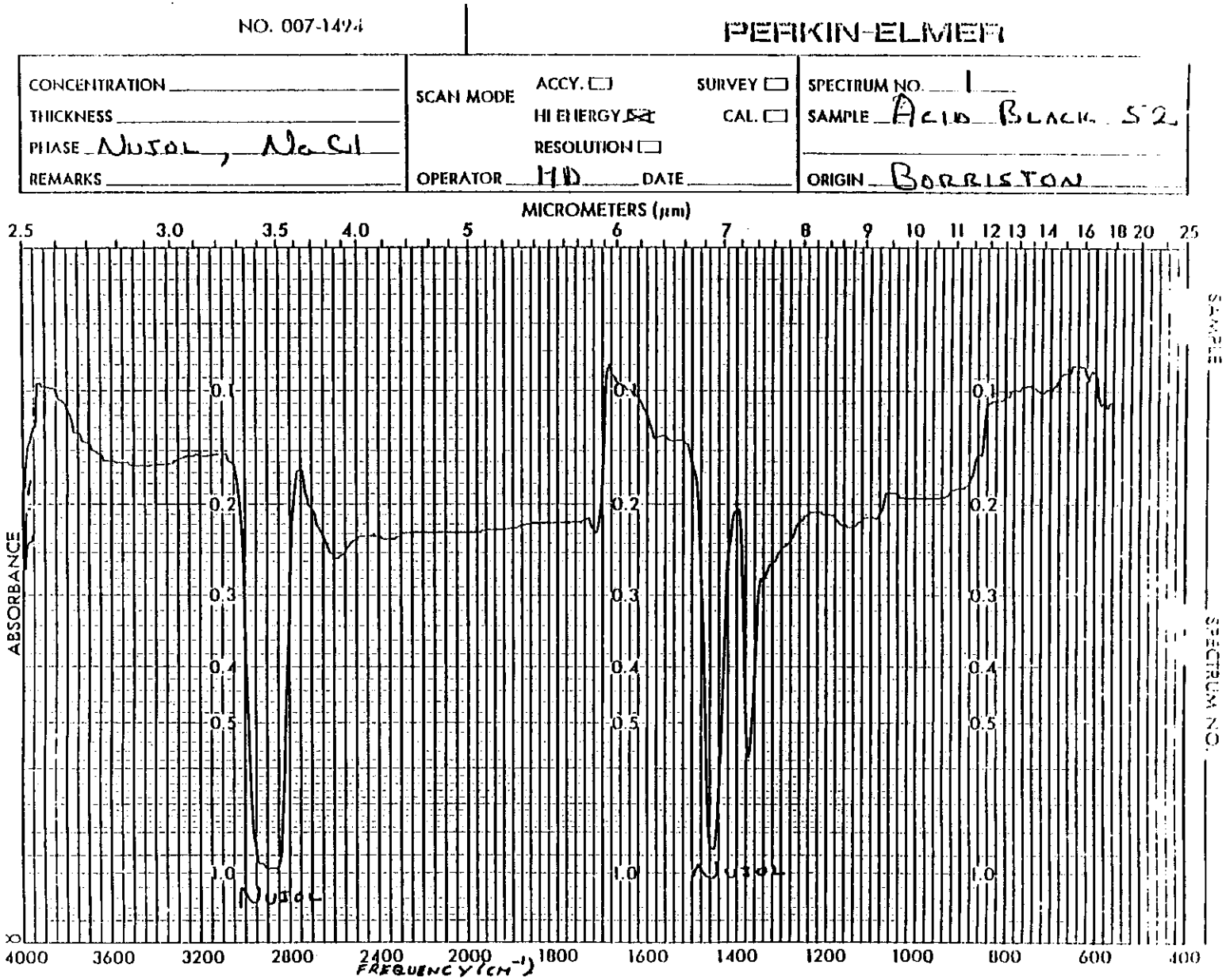
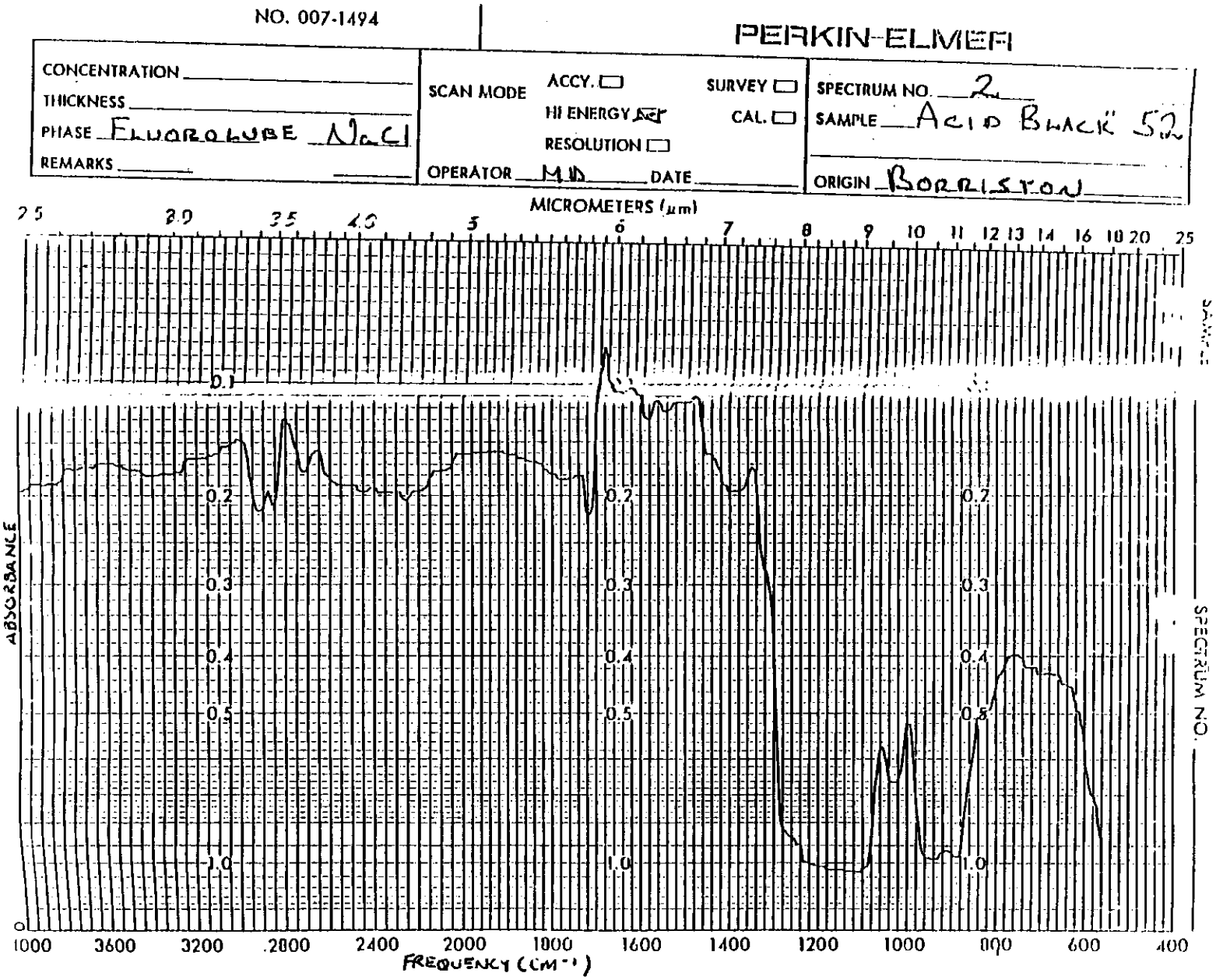


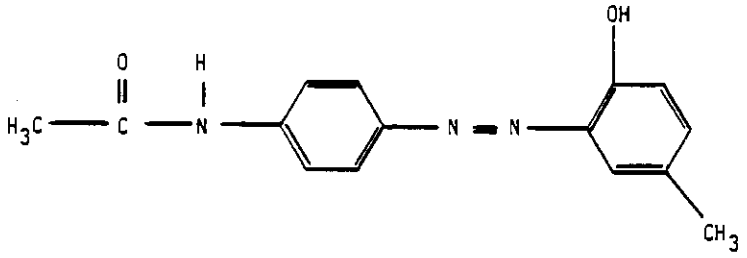
FIGURE 2

INFRARED SCAN OF ACID BLACK 52 - FLUOROLUBE MULL PHASE



The Yellow 3 appeared to be a much purer product as indicated by the elemental analysis shown below:

Yellow 3




Elemental Analysis of Yellow 3

| | Theoretical Values | | Analytical Values |
|---|---|---|---|
| C | 66.91% | | 66.44% |
| H | 5.58% | | 5.76% |
| O | 11.90% | | 12.57% |
| N | 15.61% | | 15.06% |
| | 100.00% | MW = 269 | 99.83% |

Dyestuff analyses of four samples of Yellow 3 using Azo group titration showed results of 94.6, 97.1, 100.0 and 100.0%.

Absorbance bands for Yellow 3 are illustrated in Figures 3 and 4. The Azo group (N=N) of the yellow dye failed to show an absorbance band in the infrared spectrum since its absorbance frequency is in the visual range. The (O-H) group had an absorbance band similar to that of

FIGURE 3

INFRARED SCAN OF YELLOW 3 - NUJOL MULL PHASE

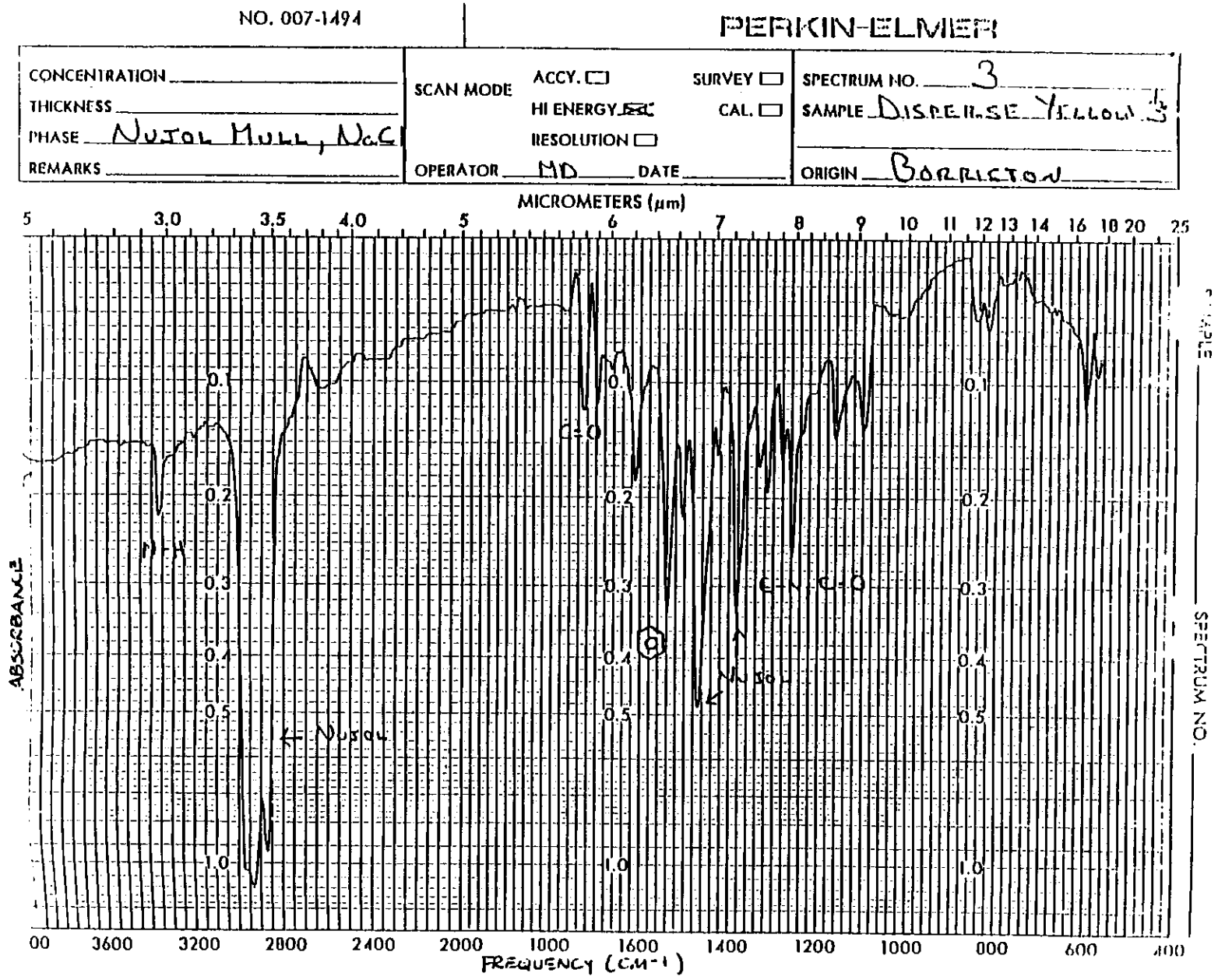
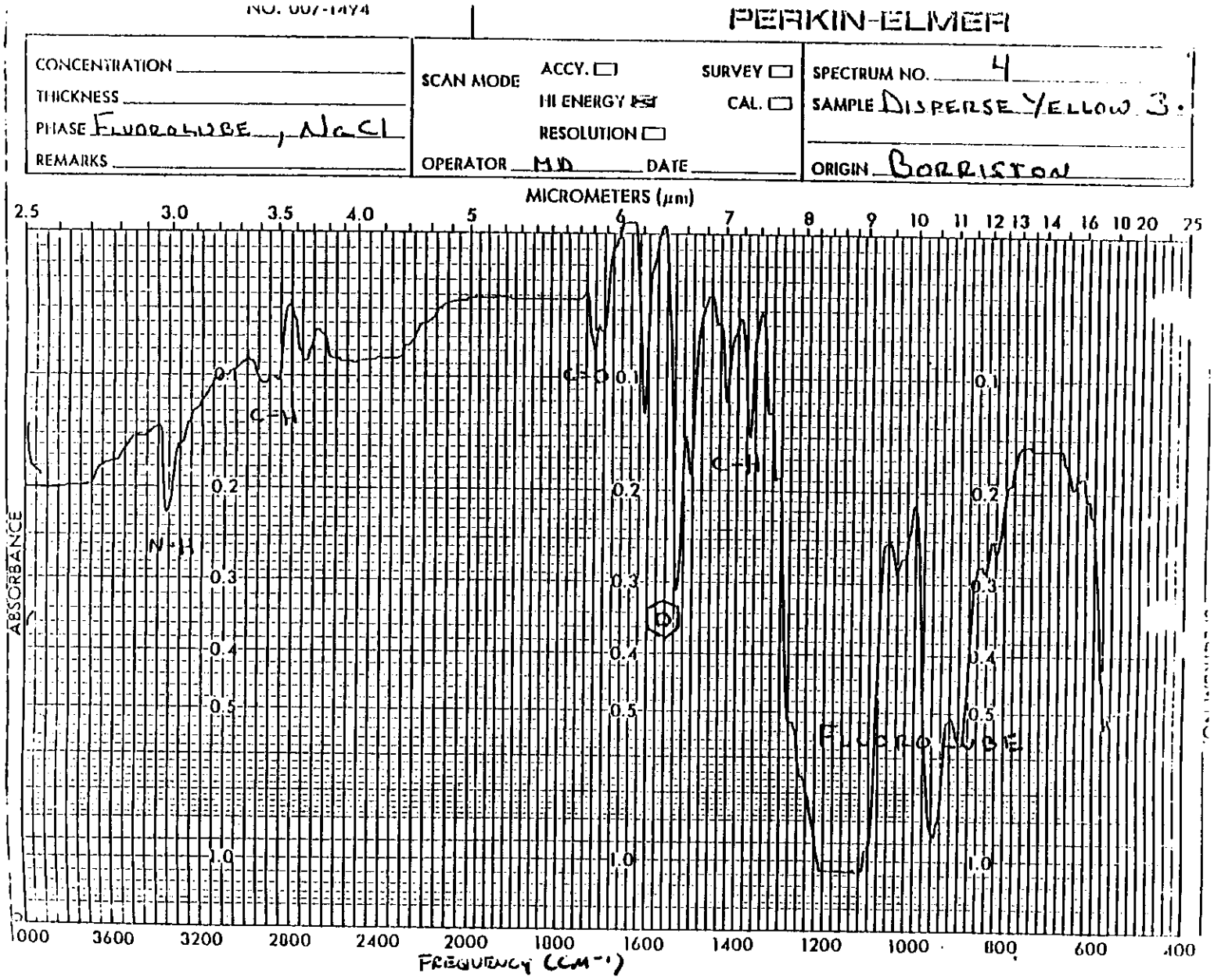


FIGURE 4

INFRARED SCAN OF YELLOW 3 - FLUOROLUBE MULL PHASE



the (N-H) group. Absorbance bands of each phase for Yellow 3 are shown below:

Absorbance Bands - Yellow 3

Phase: Nujol Mull, Spectrum 3

| Bond | Frequency ($cm^{-1}$) |
|---|---|
| N-H | 3370 |
| C-O | 1730 |
| Aromatic Ring | 1610, 1540, 1510 |
| C-N; C-O | 1080-1360 |
| O-H | 3200-3400 |

Phase: Fluorolube Mull, Spectrum 4

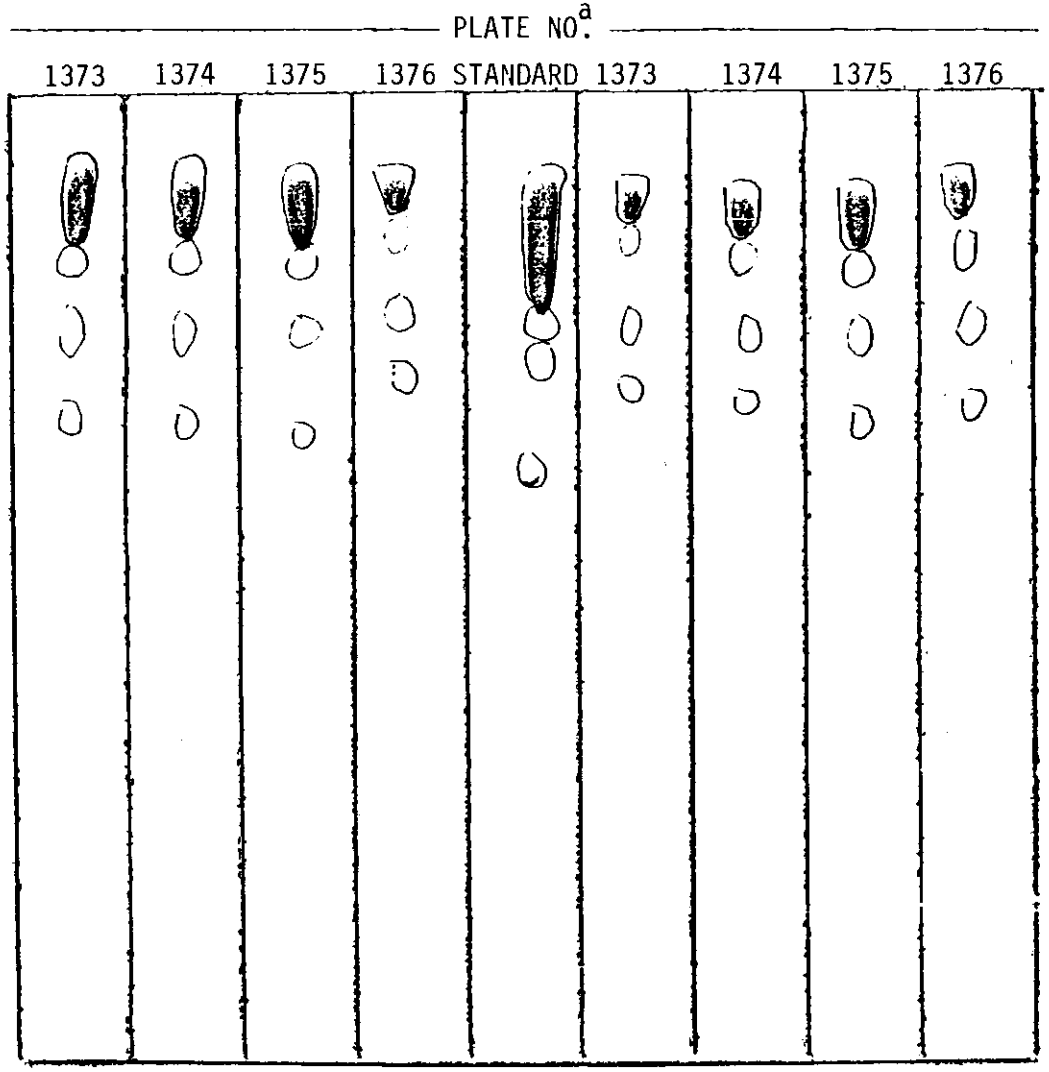
| Bond | Frequency ($cm^{-1}$) |
|---|---|
| N-H | 3360 |
| C-O | 1720 |
| Aromatic Ring | 1610, 1540, 1505 |
| C-H | 1370, 1420 |

Diets containing 5% concentration of each dye were prepared by mixing the appropriate amount of each dye in Purina® Lab Meal using Mazola® corn oil in a Hobart Blender. Samples were stored for two weeks at -20°, 5°, 25°, and 45°C.

Analyses of the diets by thin layer chromatography showed that diets containing Acid Black 52 had four components (see Figure 5). The same components also were found in the Black standard alone further substantiating the impurities previously discussed. Figure 6 shows that feed samples containing Yellow 3 had two components, both found in the Yellow standard. No degradation products detected by visualization technique were found in the diet samples that were not in the reference standard, thus indicating the stability of the dyes in the diets when stored for two weeks at temperatures up to 45°C.

FIGURE 5

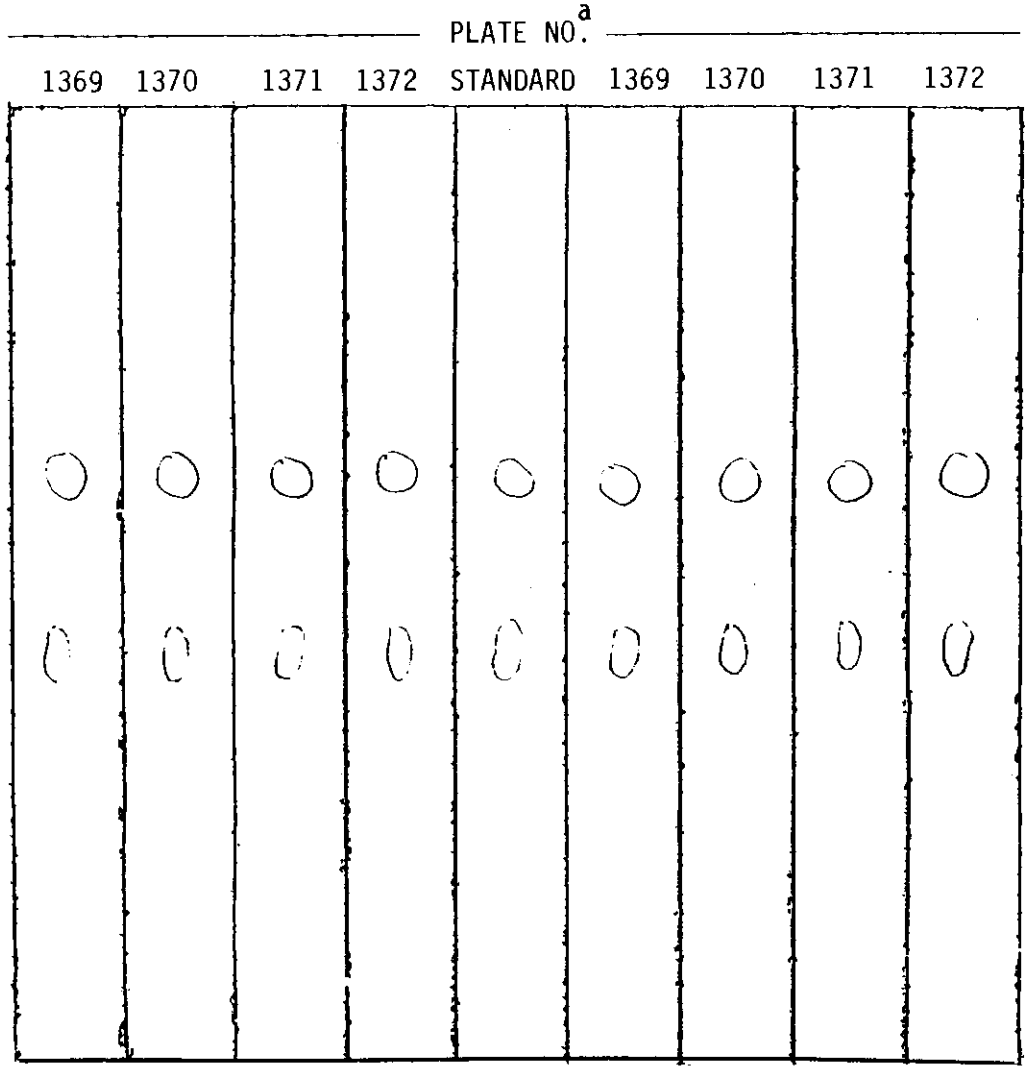
TLC PLATES OF ACID BLACK 52




[a]Plate Nos. 1373, 1374, 1375, and 1376 correspond to diet samples stored at 45, 25, 5, and -20°C, respectively.

FIGURE 6

TLC PLATES OF YELLOW 3




[a]Plate Nos. 1369, 1370, 1371, and 1372 correspond to diet samples stored at 45, 25, 5, and -20°C respectively.

Analyses of the formulated diets during the course of the study indicated the dye-diet mixtures were homogeneous, as well as accurately prepared. Values obtained were as follows:

Diet Analyses - Acid Black 52

| Date Mixed | Date Sent | Theoretical Concentration | % of Dye-stuff |
|---|---|---|---|
| 12-07-79 | 12-21-79 | 2.0% | 1.97 |
| 1-17-80 | 3-22-80 | 2.0% | 2.09 |
| 3-14-80 | 7-27-80 | 2.0% | 1.92 |
| 7-02-80 | 1-05-81 | 2.0% | 1.90 |
| 3-19-81 | 5-08-81 | 2.0% | 2.00 |

Diet Analyses - Yellow 3

| Date Mixed | Date Sent | Theoretical Concentration | % of Dye-stuff |
|---|---|---|---|
| 12-10-79 | 12-21-79 | 0.8% | 0.769 |
| 3-10-80 | 3-22-80 | 0.8% | 0.805 |
| 4-09-80 | 7-27-80 | 0.8% | 0.775 |
| 6-30-80 | 1-05-81 | 0.8% | 0.770 |
| 4-27-81 | 5-08-81 | 0.8% | 0.730 |

## IV. ACUTE AND SUBCHRONIC INTRATRACHEAL AND DIETARY STUDIES

### A. Acute Single-Dose Oral Intubation and Intratracheal Studies

#### 1. Methodology

Single-dose intratracheal instillation and oral intubation studies were performed at the following dose levels:

INTRATRACHEAL INSTILLATION

| Dye | Group No. | No. of Animals Male | No. of Animals Female | Species | Treatment† mg/0.2 ml Saline |
|---|---|---|---|---|---|
| Acid Black 52 | 1 | 5 | 5 | Hamster | 0.56 |
| | 2 | 5 | 5 | Rat | 0.56 |
| | 3 | 5 | 5 | Hamster | 1.0 |
| | 4 | 5 | 5 | Rat | 1.0 |
| | 5 | 5 | 5 | Hamster | 1.78 |
| | 6 | 5 | 5 | Rat | 1.78 |
| | 7 | 5 | 5 | Hamster | 5.62 |
| | 8 | 5 | 5 | Rat | 3.16 |
| | 9 | 5 | 5 | Hamster | 3.16 |
| Yellow 3 | 10 | 5 | 5 | Hamster | 5.6 |
| | 11 | 5 | 5 | Rat | 5.6 |
| | 12 | 5 | 5 | Hamster | 10.0 |
| | 13 | 5 | 5 | Rat | 10.0 |
| | 14 | 5 | 5 | Hamster | 17.8 |
| | 15 | 5 | 5 | Rat | 17.8 |
| | 16 | 5 | 5 | Hamster | 31.6 |
| | 17 | 5 | 5 | Rat | 31.6* |
| | 18 | 5 | 5 | Hamster | 31.6* |

†Dose levels for the black dye were originally set at 5.6, 10.0, 17.8 and 31.6 mg/0.2 ml saline. Since all rats treated at the low dose (5.6 mg) died within ten minutes of instillation, new dose levels (0.56, 1.0, 1.78 and 3.16) were established for both rats and hamsters. Since mortality did not occur in hamsters treated at 1.78 mg, the next highest dose (Group 7) was increased to 5.62 mg. However, all hamsters died after instillation and an additional group (Group 9) was subsequently dosed at 3.16 mg.

*31.6 mg dye/0.2 ml of a 0.2% gelatin-saline suspension.

ORAL INTUBATION

| Dye | Group No. | No. of Animals Male | No. of Animals Female | Species | Dose Level (mg/kg) Volume = 30 ml/kg |
|---|---|---|---|---|---|
| Acid Black 52 | 19 | 5 | 5 | Hamster | 269 |
| | 20 | 5 | 5 | Rat | 269 |
| | 21 | 5 | 5 | Hamster | 519 |
| | 22 | 5 | 5 | Rat | 519 |
| | 23 | 5 | 5 | Hamster | 1000 |
| | 24 | 5 | 5 | Rat | 1000 |
| | 25 | 5 | 5 | Hamster | 1930 |
| | 26 | 5 | 5 | Rat | 1930 |
| | 27 | 5 | 5 | Hamster | 3730 |
| | 28 | 5 | 5 | Rat | 3730 |
| Yellow 3 | 29 | 5 | 5 | Hamster | 269 |
| | 30 | 5 | 5 | Rat | 269 |
| | 31 | 5 | 5 | Hamster | 519 |
| | 32 | 5 | 5 | Rat | 519 |
| | 33 | 5 | 5 | Hamster | 1000 |
| | 34 | 5 | 5 | Rat | 1000 |
| | 35 | 5 | 5 | Hamster | 1930 |
| | 36 | 5 | 5 | Rat | 1930 |
| | 37 | 5 | 5 | Hamster | 3730 |
| | 38 | 5 | 5 | Rat | 3730 |

Animal supplier, housing, care and quarantine were identical to that in the chronic study (see Sections V.A. and V.B).

The procedures for preparation and administration of the dosing suspensions for intratracheal instillation were identical to those used in the chronic study (see Sections V.D. and V.F.).

Dosing suspensions for oral intubation were prepared by mixing an appropriate amount of the dye in saline to achieve the required dose level. The admixture was mixed well with a spatula and agitated for 15 minutes on a magnetic stirrer prior to intubation. All doses were administered as a single oral dose at a constant volume of 30 ml/kg of body weight. Prior to dosing, animals were food-fasted overnight.

Postdosing, food was withheld for one hour after which it was available ad libitum.

Animals were observed for mortality and signs of toxicity at 1, 4 and 24 hours after exposure and daily thereafter for 14 days. Body weights were measured prior to treatment and at the time of death or sacrifice. Complete gross necropsy examinations were performed on all animals upon death or sacrifice.

2. Results

a. Acid Black 52: Acid Black 52 caused a definite toxic effect in the respiratory tract of both hamsters and rats which showed a dose-reponse relationship. In addition, the results indicated that dye was more toxic in rats than hamsters when administered intratracheally.

Hamsters exhibited no signs of breathing difficulty following instillation of Acid Black 52 at the 0.56 and 1.0 mg dose levels. At a dose level of 1.78 mg, hamsters exhibited dyspnea and polypnea for a one-hour period after dosing, followed by a return to normal condition. Hamsters dosed at 3.16 mg experienced extreme respiratory distress, suffocation and gasping; five males and four females died within 20 minutes after instillation. No signs of distress were observed in rats dosed at the 0.56 mg level. Rats dosed at 1.0 mg showed signs of breathing difficulty and sluggishness for a four-hour period after instillation. Extreme respiratory difficulty and suffocation were observed at dose levels of 1.78 and 3.16 mg. Three males and three females from the 1.78 mg dose group died after dosing. Three males and two females from the 3.16 mg dose group died immediately after dosing; additionally, two males and two females from this group died four hours after instillation.

Males and females of both species showed 100% survival rate at the low dose (0.56 mg). At 1.0 mg, 100% survival was observed in females of both species as compared to 60% and 100% in male rats and hamsters respectively. At a dose level of 1.78 mg, 20% of the male and female rats survived in contrast to 20% and 80% in the male and female hamsters, respectively.

In both species receiving Acid Black 52 intratracheally, the concentration of dye deposits observed at necropsy in the lungs after 14 days varied proportionally to the dose instilled. The dye was well distributed in a diffuse manner in all lobes of the lung.

A single oral intubation of Acid Black at the 269, 519, 1000, and 1930 mg/kg dose levels failed to elicit any signs of toxicity in rats and hamsters. However, at 3730 mg/kg, a species difference in toxic response was observed between rats and hamsters receiving Acid Black 52, as evidenced by decreased survival in male and female hamsters (40% and 60%, respectively) when compared to 100% survival in male and female rats.

In both species receiving Acid Black 52 orally, no tissue alterations were seen in hamsters or rats at gross examination.

b. Yellow 3: Yellow 3 produced no toxic effects when instilled intratracheally in either species at any of the dose levels tested. At necropsy, no dye deposition was observed in the lungs of either species at any dose level.

A single oral intubation of Yellow 3 at all dose levels tested failed to show any signs of toxicity in rats or hamsters. No tissue alterations were seen in either species receiving the yellow dye by oral intubation.

## B. Subchronic Intratracheal and Dietary Administration Studies

### 1. Methodology

Intratracheal instillations were given once weekly for 12 weeks and dietary administration was performed for 90 days at the following dose levels:

INTRATRACHEAL INSTILLATION

| Dye | Group No. | No. of Animals Male | No. of Animals Female | Species | Treatment mg/0.2 ml Saline |
|---|---|---|---|---|---|
| Acid Black 52 | 1 | 20 | 20 | Hamster | 0.13 |
| | 2 | 20 | 20 | Hamster | 0.24 |
| | 3 | 20 | 20 | Hamster | 0.42 |
| | 4 | 20 | 20 | Hamster | 0.75 |
| | 5 | 20 | 20 | Rat | 0.08 |
| | 6 | 20 | 20 | Rat | 0.16 |
| | 7 | 20 | 20 | Rat | 0.32 |
| | 8 | 20 | 20 | Rat | 0.61 |
| Yellow 3 | 9 | 20 | 20 | Hamster | 3.16 |
| | 10 | 20 | 20 | Hamster | 5.62 |
| | 11 | 20 | 20 | Hamster | 10.00 |
| | 12 | 20 | 20 | Hamster | 17.80 |
| | 13 | 20 | 20 | Rat | 3.16 |
| | 14 | 20 | 20 | Rat | 5.62 |
| | 15 | 20 | 20 | Rat | 10.00 |
| | 16 | 20 | 20 | Rat | 17.80 |
| Vehicle Control (0.2 ml Saline) | 17 | 15 | 15 | Hamster | 0 |
| | 18 | 15 | 15 | Hamster | 0 |
| | 19 | 15 | 15 | Rat | 0 |
| | 20 | 15 | 15 | Rat | 0 |

DIETARY ADMINISTRATION

| Dye | Group No. | No. of Animals Male | No. of Animals Female | Species | Dietary Level (% Diet) |
|---|---|---|---|---|---|
| Acid Black 52 | 21 | 20 | 20 | Hamster | 0.25 |
| | 22 | 20 | 20 | Hamster | 0.50 |
| | 23 | 20 | 20 | Hamster | 1.00 |
| | 24 | 20 | 20 | Hamster | 2.00 |
| | 25 | 20 | 20 | Rat | 0.25 |
| | 26 | 20 | 20 | Rat | 0.50 |
| | 27 | 20 | 20 | Rat | 1.00 |
| | 28 | 20 | 20 | Rat | 2.00 |
| Yellow 3 | 29 | 20 | 20 | Hamster | 0.13 |
| | 30 | 20 | 20 | Hamster | 0.25 |
| | 31 | 20 | 20 | Hamster | 0.50 |
| | 32 | 20 | 20 | Hamster | 1.00 |
| | 33 | 20 | 20 | Rat | 0.13 |
| | 34 | 20 | 20 | Rat | 0.25 |
| | 35 | 20 | 20 | Rat | 0.50 |
| | 36 | 20 | 20 | Rat | 1.00 |

DIETARY ADMINISTRATION (Continued)

| Dye | Group No. | No. of Animals Male | No. of Animals Female | Species | Dietary Level (% Diet) |
|---|---|---|---|---|---|
| Dietary Control | 37 | 15 | 15 | Hamster | 0 |
| | 38 | 15 | 15 | Hamster | 0 |
| | 39 | 15 | 15 | Rat | 0 |
| | 40 | 15 | 15 | Rat | 0 |

Animal supplier, housing, care and quarantine observations were identical to that in the chronic study (see Sections V.A. and V.B.).

Suspensions for intratracheal instillation were prepared as described in Section V.D. Animals received intratracheal instillations of each dye at the specified dose level once a week for 12 consecutive weeks. The methodology for intratracheal administration is given in Section V.F.

Dye-formulated diets containing the required concentration of each dye were prepared as described in Section V.E.; the resulting mixtures were mixed in a Patterson-Kelly Twinshell blender and were presented as ground feed, whereas in the chronic study, the mixtures were pelletized. Animals received ad libitum amounts of the formulated diets, provided fresh weekly in 9-ounce round glass jars with stainless steel tops, for a 90-day period.

All animals were observed twice daily for mortality and moribundity. Body weights and clincal signs were recorded once weekly, beginning on the first day of treatment. Food consumption was measured weekly in rats exposed to the diets. All surviving animals were sacrificed 90 days after the first treatment. Complete necropsy examinations were performed on each animal at the time of death or sacrifice and tissues were saved for possible histopathologic evaluation.

2. Results

a. Acid Black 52: Following intratracheal administation, Acid Black 52 exhibited a strong toxic effect in the respiratory tract of both hamsters and rats. At similar dose levels administered intratracheally

once a week for 12 consecutive weeks, hamsters and rats showed a striking species difference in toxic response. The black dye was more toxic in rats than hamsters at the higher dose level (0.61 mg rat and 0.75 mg hamster); eight male and two female rats died as compared to only two male hamsters. A dose-related mortality rate was apparent among the male groups of each species; however, no such pattern of mortality was observed in females administered the dye (Table I). Reduced body weight gain was noted in all male and female groups of both species as compared to their controls (except the male group at the 0.16 mg dose level) (Table I). Both hamsters and rats exhibited suffocation, extreme breathing difficulty, and collapse immediately following each release of Acid Black 52 suspension into the lungs.

Similar gross pathology was observed in both hamsters and rats dosed intratracheally with Acid Black 52. Diffuse dye deposits were observed in the lungs in quantities proportional to the dose instilled. Dye deposition extended to the periphery of all lobes of the lungs. Tissues from the control and high dose hamsters were examined microscopically. No significant findings were observed.

A species difference was observed when Acid Black 52 was administered in the diet. The dye was observed to be more toxic in hamsters than rats. Administered diets containing 2% by weight of Acid Black 52 showed a significant increase in mortality in hamsters as compared to control hamsters or rats administered an identical dye concentration. At a dose level of 2% Acid Black 52, deaths occurred in six male and five female hamsters, whereas no deaths occurred in the rats of either sex. Reduced body weight gain was observed in male and female hamsters receiving Acid Black 52 dye at 2% of the total diet as compared to their control groups (Table II).

Hamsters exposed to the dye at 1% and 2% showed compound-colored coat throughout the study. No other compound-related signs of toxicity were observed in hamsters or rats.

Gross pathology of hamsters fed Acid Black 52 at dietary levels of 0.25% and 0.50% showed gray staining of the gastrointestinal tract. At 1% and 2% dietary levels, Acid Black 52 produced gray-blue staining of the gastrointestinal tract, liver, kidneys, testes, and the cecal mucosa.

Similar findings were present in rats given Acid Black 52 at dietary levels of 1% and 2%. Blue-gray staining of the gastrointestinal tract, green stained kidneys, and blue-gray mesenteric lymph nodes were observed in rats fed Acid Black 52 in their diets at the 1% level. Rats receiving 2% of the dye in their diets exhibited blue-black gastrointestinal tracts and greenish kidneys. Tissues from the high dose (2%) rats were examined microscopically. No treatment-related lesions were present.

b. Yellow 3: Yellow 3 administered intratracheally at dose levels of 3.16, 5.62, 10.0, and 17.8 mg, produced no toxic changes in the respiratory tracts of hamsters or rats. No dose-related mortality was noted for hamsters or rats given Yellow 3 (Table III). Reduced body weight gain (as compared to controls) was more pronounced among the male animals of both species (Table III).

At necrospy no dye deposits were observed in the lungs of rats and hamsters dosed intratracheally with Yellow 3. No microscopic examinations were performed on these groups.

When administered in the diet, Yellow 3 produced minimum toxic effects in either species; however, a dose-related decrease in body weight was observed in rats (Table IV). A decrease in body weight was seen in all hamsters being greater in the male animals. Compound-colored coats were seen in hamsters and rats of both sexes during the 90-day period. No other compound-related clinical signs were observed.

No remarkable gross pathology was observed in hamsters fed Yellow 3 at any dietary level tested. Slight yellow staining of the gastrointestinal tract and medulla portion of the kidneys was observed in rats fed Yellow 3 at all dose levels tested. Enlarged thyroids were present in seven male and seven female rats from the high dose (1%) dose group. This finding also was noted in one male, two females, and three males from the 0.13, 0.25, and 0.50% dose groups, respectively, which suggested a dose-related response. Microscopic evaluation was conducted on the thyroids of all control and high dose rats. In addition, the thyroids of five males and five females from the lower dose levels were examined; the rats selected included those which showed thyroid enlargement at necropsy.

Follicular cell hyperplasia of the thyroid was present in a high percentage of the rats examined from all treated groups. This finding was not observed in any of the control rats of either sex. The incidence of this lesion, broken down by severity gradings of minimal to slight and moderate to severe, is shown below:

| Dose (% of Diet) | Sex | Incidence/Number Examined | |
|---|---|---|---|
| | | Minimal to Slight | Moderate to Severe |
| 0.00 | M | 0/14* | 0/14* |
| | F | 0/15 | 0/15 |
| 0.13 | M | 0/5 | 5/5 |
| | F | 3/5 | 2/5 |
| 0.25 | M | 0/3* | 3/3* |
| | F | 1/3* | 2/3* |
| 0.50 | M | 0/4* | 4/4 |
| | F | 1/5 | 4/5 |
| 1.00 | M | 6/12* | 2/12* |
| | F | 2/15* | 7/15* |

*Number examined is decreased due to thyroids which were not available for examination.

Based on these results, thyroid follicular cell hyperplasia was considered to be related to the administration of Yellow 3. The reason for the higher incidence of moderate to severe lesions at the lower dose levels than at the high dose, particularly in the males, is not understood.

## V. CHRONIC/CARCINOGENICITY INTRATRACHEAL AND DIETARY ADMINISTRATION STUDIES

### A. Test Animals

Prior to initiation of the acute study, two separate murine virus antibody determinations were conducted on hamsters obtained from various suppliers as a preliminary assessment of animal quality. The results of the analyses are presented in Appendix III. On both occasions the Charles River hamsters were found to be negative for the five viruses tested. Based on these results, Charles River Breeding Laboratory was chosen as the test animal supplier for this project.

Twenty-one day old Golden Syrian hamsters (405 of each sex) and weanling Fischer 344 rats (410 males and 409 females) were received from Charles River Breeding Laboratory. Each species was isolated and maintained in separate quarters for two weeks prior to initiation of the study. Animal numbers and treatment groups were assigned by a BLI computer randomization procedure.

### B. Animal Maintenance

Hamsters and rats were individually housed in solid bottom polycarbonate cages (Table V) with shredded aspen bedding (Table V). Cages and bedding were changed weekly. All diets (Table V) were available ad libitum in food hoppers and water (Table V) was available in water bottles (filled when necessary). Sanitized hoppers and bottles (Table V) were provided each week. Average temperature of the animal rooms was 72°±4° F. Humidity is not controlled at Borriston but was generally between 30 and 70 percent. Room air ventilation was approximately 10-15 exchanges/hour. Animal rooms were maintained on a 12-hour light/dark cycle. Rats and hamsters were housed separately by species as well as route of administration.

### C. Dose Levels and Study Duration

Based on the results of the 90-day subchronic studies, the maximum tolerated dose (MTD) which could be administered in the chronic/carcinogenic studies without unwanted toxic side-effects was different for each dye, species and route of administration.

Group assignments, dose levels, and duration of exposure for the chronic intratracheal instillation study were as follows:

Group Assignment Intratracheal Instillation

| Group | Species | Dye | Dose (mg) | No. of Animals M | No. of Animals F | Duration In Weeks M | Duration In Weeks F |
|---|---|---|---|---|---|---|---|
| 1 | Hamster | Acid Black 52 | 0.75 | 50 | 50 | 117 | 103 |
| 2 | Rat | Acid Black 52 | 0.32 | 50 | 50 | 117 | 117 |
| 3 | Hamster | Yellow 3 | 15.0 | 50 | 50 | 117 | 103 |
| 4 | Rat | Yellow 3 | 15.0 | 50 | 50 | 117 | 117 |
| 5 | Hamster | Control | 0.0 | 35 | 35 | 117 | 103 |
| 6 | Hamster | Control | 0.0 | 35 | 35 | 117 | 103 |
| 7 | Rat | Control | 0.0 | 35 | 35 | 117 | 117 |
| 8 | Rat | Control | 0.0 | 35 | 35 | 117 | 117 |

Group assigments, dose levels, and duration of exposure for the chronic dietary feeding study were as follows:

Group Assignment Dietary Administration

| Group | Species | Dye | Dose (%) | No. of Animals M | No. of Animals F | Duration In Weeks M | Duration In Weeks F |
|---|---|---|---|---|---|---|---|
| 9 | Hamster | Acid Black 52 | 2.0 | 50 | 50 | 110 | 96 |
| 10 | Rat | Acid Black 52 | 2.0 | 50 | 50 | 109 | 117 |
| 11 | Hamster | Yellow 3 | 0.8 | 50 | 50 | 110 | 96 |
| 12 | Rat | Yellow 3 | 0.8 | 50 | 50 | 109 | 117 |
| 13 | Hamster | Control | 0.0 | 35 | 35 | 110 | 96 |
| 14 | Hamster | Control | 0.0 | 35 | 35 | 110 | 96 |
| 15 | Rat | Control | 0.0 | 35 | 35 | 109 | 117 |
| 16 | Rat | Control | 0.0 | 35 | 35 | 109 | 117 |

D. Intratracheal Preparation

Suspensions of both Azo dyes were prepared weekly prior to treatment. An adequate amount of dye was weighed out into a sterile 50 ml flask into which saline was added. The mixture was sonicated on an ultrasonic vibrator for two to three minutes to obtain a homogeneous suspension and was kept homogeneous by constant stirring on a magnetic

stirrer during each intratracheal instillation. Quantitative particle size determinations were not conducted. However, qualitative observations made prior to dosing indicated that the suspensions were homogeneous; the dye particles appeared to be of a respirable size and no agglomeration was noted. Vehicle control groups received normal saline only. A list of items used in the preparation of suspensions is presented in Table VI.

E. Dietary Preparation

Fresh diets containing the required concentration of each dye were prepared weekly. Prior to the incorporation into the diets, each dye was thoroughly mixed with corn oil (1.3%) used as a dust suppressant. The dye/corn oil mixture was incorporated with the powdered rodent meal (Purina® Rodent Chow # 5001) and mixed in a Patterson-Kelly Twinshell blender for 20 minutes. The mixture was then pelletized. Control diets were prepared at the same time and consisted of the same powdered rodent diet which was mixed with corn oil (1.3%) and pelletized. These control diets were fed to all groups in the intratracheal study as well as to the dietary control groups. A list of items used in the preparation of test diets is presented in Table VI. All diets were prepared with dye and corn oil on a weight-to-weight basis. Formulated diets were stored at room temperature until used. To insure accuracy of diet preparation, random grab samples of formulated diets were analyzed for dye content. All diets were 91-105% of the desired theoretical concentrations.

F. Intratracheal and Dietary Administration

Rats and hamsters received intratracheal instillations of each dye at the specified dose levels in 0.2 ml saline suspensions once a week for 15 consecutive weeks. Before each treatment, the animals were anesthetized with an intraperitoneal injection of 0.4 ml of a 1% solution of Brevital Sodium. Intratracheal doses were administered through a 0.25 ml tuberculin syringe fitted with a blunt 19 gauge needle. The needle was 60 mm long and bent at a 135° angle, 45 mm from the tip. The needle was gently inserted under the epiglottis into the tracheal lumen and the suspension gently injected and the needle withdrawn. Control animals were dosed with 0.2 ml of saline only.

Rats and hamsters received ad libitum amounts of the formulated diets in pellet form and were offered fresh diets weekly in stainless steel feeders. Diets were administered for a continuous period of 27 months.

G. Mortality and Clinical Signs

Animals from both the intratracheal and dietary studies were observed twice daily, seven days per week, for mortality and moribidity. All relevant clinical signs were recorded weekly for all animals.

H. Body Weights and Food Consumption

Body weights were recorded initially and then monthly thereafter. Food consumption was measured weekly for control and treated animals on the dietary study only.

I. Gross Necropsy

Complete gross necropsy was performed for each moribund, found dead, or terminally sacrificed animal. Necropsy included external examination of the following tissues and organs:

| | |
|---|---|
| Skin | Colon |
| Mandibular Lymph Node | Cecum |
| Mammary Gland | Rectum |
| Salivary Gland | Mesenteric Lymph Node |
| Thigh Muscle | Liver |
| Sciatic Nerve | Gallbladder (Hamster) |
| Sternebrae | Pancreas |
| Vertebrae or Femur with Marrow | Spleen |
| | Kidneys |
| Costochondral Junction | Adrenals |
| Rib | Urinary Bladder |
| Thymus | Seminal Vesicles |
| Larynx | Prostate |
| Trachea | Testes |
| Lung and Bronchi | Ovaries |
| Heart | Uterus |
| Thyroid | Nasal Cavity |
| Parathyroids | Brain |
| Esophagus | Pituitary |
| Stomach | Spinal Cord and Eyes (If lesions were present) |
| Duodenum | |
| Jejunum | Tissue masses, suspect tumors |
| Ileum | Gross Lesions |

All tissues and organs were examined *in situ*, dissected from the carcass, and fixed in 10% neutral buffered formalin. Gross lesions were recorded and all tissues were fixed at a thickness of less than 0.5 cm. The trachea and lungs were removed *en masse* and infused with approximately 1 to 2 ml of 10% neutral buffered formalin or until the lungs were filled to normal inspiratory volume. They were then submerged in 10 percent neutral buffered formalin until fixation was complete.

J. Histopathology

After fixation, all tissues harvested from necropsy were embedded in paraffin, sectioned, and stained with hematoxylin and eosin. Histopathological examination was performed on all tissues from all animals from each route of administration.

K. Data Interpretation and Statistical Analysis

The results section which follows in this report presents each dye as an individual entity. All comparisons and conclusions are confined to assessment of data between each treated group and its control counterpart for each dye, species and route of administration. No attempt was made to compare Acid Black 52 to Yellow 3, hamster to rat, or intratracheal instillation to dietary administration. Therefore, each comparison as summarized below was a complete study:

| Acid Black 52 | Yellow 3 |
|---|---|
| 1. Intratracheal instillation in hamsters; treated Group 1 versus control Group 5. | 1. Intratracheal instillation in hamsters; treated Group 3 versus control Group 6. |
| 2. Intratracheal instillation in rats; treated Group 2 versus control Group 7. | 2. Intratracheal instillation in rats; treated Group 4 versus control Group 8. |
| 3. Dietary administration in hamsters; treated Group 9 versus control Group 13. | 3. Dietary administration in hamsters; treated Group 11 versus control Group 14. |
| 4. Dietary administration in rats; treated Group 10 versus control Group 15. | 4. Dietary administration in rats; treated Group 12 versus control Group 16. |

The majority of support data (tables and appendices) are also presented according to dye. Each table or appendix is further divided by species (hamster followed by rat). Within each species subsection, data for intratracheal instillation precedes data for dietary administration and for each route of administration, male data precedes female data.

The number of tumor-bearing animals (as determined by histopathological examination) for each major organ/organ system in each treated group was statistically compared to its control group (of the same sex) using a two-tailed Fisher's exact test.[a] Organ systems compared were: all tissues, endocrine, digestive, respiratory, hematopoietic/lymphatic, cardiovascular, urinary, reproductive, nervous, and muscular/skeletal. Organs compared were: skin/mammary, stomach, lungs, brain, liver, spleen, pancreas, kidney, and miscellaneous structures.

In conducting the Fisher's analyses, a ratio of the number of tumor-bearing animals (numerator) to the effective number of animals at risk (denominator) was formed for each treated group and its control counterpart for each organ or organ system. The number at risk was determined as the number of survivors in the treated and control groups at the time of death of the first animal in either of the two groups which was found (upon subsequent microscopic examination) to have a tumor in the particular organ or organ system. This procedure was used since the diagnosed tumors were nonobservable during the in-life phase of the study and therefore, the time to tumor occurrence could not be determined.

The number of tumor-bearing animals, and corresponding number at risk used in the statistical analyses are presented in Tables XI (Acid Black 52) and XVII (Yellow 3). Data were analyzed by Fisher's exact test at $p \leq 0.05$; therefore, values of $p < 0.05$ were considered to be statistically significant and are so indicated in the aforementioned tables by the symbol "S".

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[a]Zar, J.H, 1974. Biostatistical Analysis Prentice - Hall, Inc., Englewood Cliff, N.J. pp 291 - 295.

# VI. RESULTS

## A. Acid Black 52

### 1. Intratracheal Administration of Acid Black 52 in Hamsters

This evaluation involved comparison between the Acid Black 52 treated hamsters (Group 1) and their control (Group 5) counterparts. Support data for these groups are presented in this report as follows: survival data are presented in Table VII with graphic illustration of survival presented in Figure 7; mean body weights are presented in Table VIII; total tumor incidence for major organs is presented in Table X; Fisher's exact analyses of tumor-bearing animals for major organs and organ systems are presented in Table XI: a group summary of histopathology findings is presented in Table XII; and the individual histopathology findings are presented in Appendix I.

Survival: Survival among the treated male hamsters was noticeably higher than that of their control counterparts throughout the study, e.g., at the mid-point of the study (Week 58), 84% of the treated male hamsters were alive compared to 71% of the male controls. By study end, 16% survival was recorded for the treated male hamsters compared to 11% survival for the control animals. Survival rates of the female control and treated hamsters were comparable for the first 50 weeks of study. During Weeks 51 through 84, survival among the female controls was slightly lower than that observed for the treated female hamsters; 44% survival was noted for the treated female hamsters compared to 40% survival in their control counterparts at Week 84. Survival rates of the control and treated female hamsters then remained comparable up to Week 97 at which point the treated animals had a lower percent survival than the control animals for the remainder of the study.

Body Weight: No noticeable differences in body weight data were observed between the control and treated hamsters of either sex.

Gross Pathology: Obvious gross lesions involving the lung were observed in an appreciable number of treated male and female hamsters. These varied from blue-gray mottling and pinpoint black-gray foci to translucent or white foci or nodules. These lesions were not observed in the control hamsters of either sex.

Atrial thrombosis, renal cortical pitting, and small biliary cysts were frequent gross findings in all groups of hamsters. The treated and control females had a higher incidence of these findings than was seen in the treated and control males. An accumulation of clear or blood-tinged fluid in the thoracic or abdominal cavities was seen in several spontaneous deaths; anasarca often was present in these animals.

Histopathology: The total number of tumor-bearing animals in the males (19/42 at risk) and female (10/42) treated group was slightly lower than that seen in their control counterparts (13/25 and 8/25 for males and females, respectively). No statistically significant differences were observed between treated and control hamsters with respect to the number of tumor-bearing animals for any of the major organs or organ systems.

Although statistical significance was not observed for endocrine system tumors in male hamsters ($p=1.000$), a slight treatment-related increase in the incidence of cortical cell adenomas in the adrenals of the treated males (16/49 examined) was noted when compared to those occurring in the control males (9/35). Adrenal cortical nodular hyperplasia also was present with slightly higher incidence in the treated males (21/49) than in the male controls (13/35). In the female hamsters, a negative trend was noted with respect to the incidence of cortical cell adenomas; these tumors were observed in 5/35 control hamsters, while 0/50 were noted in the treated group. However, the incidence of cortical nodular hyperplasia was much higher in the treated females (11/50) than in the controls (4/35).

Treatment-related pulmonary pathology of various types was marked and occurred in both male and female hamsters receiving Acid Black 52 intratracheally. Pneumonopathy, including histiocytosis with or without intracytoplasmic pigmented particulate material, intra-alveolar acellular eosinophilic masses (referred to as pulmonary alveolar lipoproteinosis elsewhere in the literature), alveolar/bronchiolar cell hyperplasia,

metaplasia, and adenomatosis all occurred to a minimal to severe degree in nearly all of the males (46/50) and females (46/50) receiving Acid Black intratracheally. Pulmonary neoplasms were limited to an alveolar/bronchiolar cell adenoma in one male hamster receiving Acid Black 52 intratracheally and an undifferentiated metastatic carcinoma in one female control hamster.

Pneumonias of various types occurred in both male and female treated and control hamsters, as did alveolar histiocytosis (included with pneumonopathy). In many instances, the latter lesion was secondary to atrial thrombosis, an entity of frequent occurrence in Syrian hamsters.

A few additional non-neoplastic lesions were present in greater number in the hamsters receiving Acid Black 52 intratracheally than in the control hamsters. Proliferating or inflammatory lesions of the ileum occurred more often in the treated female hamsters when compared to controls or males. The incidence of biliary cysts was higher in the treated female and male hamsters than in the controls. Atrial thrombosis appeared more frequently in the treated male hamsters than in the controls. Only a slightly higher incidence of atrial thrombosis in treated female hamsters was observed when compared to the female controls. The incidences of these lesions are summarized below:

| Tissue/Lesion | Sex | Incidence/Number Examined | |
|---|---|---|---|
| | | Treated | Control |
| Ileum | | | |
| Proliferative/inflammatory lesions | Male | 4/49 | 2/35 |
| | Female | 11/50 | 3/35 |
| Liver | | | |
| Biliary cysts | Male | 8/50 | 3/35 |
| | Female | 18/50 | 8/34 |
| Heart | | | |
| Atrial thrombosis | Male | 11/48 | 3/35 |
| | Female | 18/50 | 10/35 |

2. Dietary Administration of Acid Black 52 in Hamsters

This evaluation involved comparison between the Acid Black 52 treated hamsters (Group 9) and their control (Group 13) counterparts. Support data for these groups are presented in this report as follows: survival data are presented in Table VII with graphic illustration of survival presented in Figure 7; mean body weights and mean food consumption data are presented in Tables VIII and IX, respectively; total tumor incidence for major organs is presented in Table X; Fisher's exact analyses of tumor-bearing animals for major organs and organ systems are presented in Table XII; a group summary of histopathology findings is presented in Table XIII; and the individual histopathology findings are presented in Appendix I.

Survival: There appeared to be a treatment-related decrease in survival for both sexes of hamsters administered Acid Black 52 in their diet. Survival at any given interval during the study was lower for the treated groups compared to their respective control counterparts. The first death in the control males occurred during Week 44; in contrast, 20% of the treated males were dead by this interval. By Week 110, 0% survival was reached in the treated males; 30% of the control males were alive at this interval. The first female control death was recorded during Week 31. Survival in the treated group at this interval had decreased to 70%. By Week 90, 18% survival was observed for the treated females compared with 29% for the control females.

Body Weight and Food Consumption: Body weights of the treated male hamsters were equivalent to their control counterparts throughout the duration of the study. Body weights of the treated female hamsters were slightly lower (averaging approximately 9%) than their control counterparts at each body weight interval.

Food consumption data showed that treated hamsters of both sexes consumed more food than their respective control counterparts during the first half of the study. Increased food intake continued throughout the study for the treated males, whereas, food intake of the treated females was equivalent with that of the female controls during the last half of the study.

Gross Pathology: The most frequently occurring gross observation in hamsters fed Acid Black 52 was blue-black staining around body openings and most tissues. The intestinal tracts of treated hamsters which died during the study often were filled with gray-black fluid.

Enlarged lymph nodes, usually the mandibular but occasionally others, often were observed. Atrial thrombosis and renal cortical pitting occurred in all groups of hamsters but appeared more frequently in the controls with a slightly higher incidence in the control females. Small biliary cysts were observed more frequently in the control hamsters of both sexes. In several spontaneous deaths, in treated as well as control hamsters, the thoracic and abdominal cavities contained clear or blood-tinged fluid. Anasarca often was present in these animals.

Histopathology: A significantly greater ($p=0.024$) number of tumor-bearing animals involving the endocrine system was present in the female control hamsters (6/30 at risk) as compared to the treated females (0/30). This was principally due to an increased incidence of adrenal cortical cell adenomas in the female controls (4/35 examined as compared to 0/50 in the treated group). The treated males also had a slightly lower incidence of adrenal cortical cell adenomas (6/50) than did their controls (5/34). In addition, adrenal cortical nodular hyperplasia was seen with slightly higher incidence in the control males and females (14/34 and 5/35) than in the treated animals (15/50 and 4/50).

A negative trend (i.e., greater occurrence in control as compared to treated animals) also was observed for malignant lymphoma of the bone marrow in the male animals (control, 3/35; treated, 0/50).

The number of malignant lymphomas involving the spleen of the treated females (3/50) appeared biologically significant when compared to the controls (0/35). Furthermore, the incidence of hyperplasia in the spleens of the treated male (5/50) and female (5/50) hamsters appeared to be somewhat greater than their respective controls (males, 0/34; females, 2/35). However, no statistical signficance was observed for neoplasms of the spleen in either male or female hamsters ($p=1.000$ and $p=0.119$, repectively).

In the liver of treated females, hepatocellular vacuolation appeared more frequently than in the controls; male treated and control hamsters showed comparable incidences of this lesion. The occurrence of hepatocellular pigmentation in the male and female treated hamsters was greater than in the male and female controls. Siderophagocytosis also was observed more frequently in the treated male and female hamsters than in the controls. The incidences of these lesions are summarized below:

| Lesion | Sex | Incidence/Number Examined | |
|---|---|---|---|
| | | Treated | Control |
| Hepatocellular vacuolation | Female | 16/50 | 6/35 |
| Hepatocellular pigmentation | Male | 26/50 | 2/35 |
| | Female | 8/50 | 0/35 |
| Siderophagocytosis | Male | 17/50 | 4/35 |
| | Female | 30/50 | 9/35 |

Pigment (presumably Acid Black 52) was concentrated in the zona reticularis of the adrenal, proximal tubules of the kidney, hepatocytes, Kupffer's cells, seminiferous tubules and interstitium of the testes, ovary, and various lymph nodes of the treated males and females.

The usual spontaneous lesions of aging hamsters were encountered in this study. Amyloidosis was a frequent finding in the thyroid gland, adrenal, spleen, liver, and kidney of both sexes with the greatest and most severe incidence occurring in the females. Nephrotic lesions consisted of glomerulonephropathy (other than amyloidosis), tubular dilatation, nephrolithiasis, and other degenerative or inflammatory lesions unrelated to dietary administration of Acid Black 52.

Proliferative enteritis, an entity peculiar to hamsters, was present in all groups to a minor degree. An occasional mesenteric lymph node contained ectopic proliferating intestinal epithelium.

3. Intratracheal Administration of Acid Black 52 in Rats

This evaluation involved comparison between the Acid Black 52 treated rats (Group 2) and their control (Group 7) counterparts. Support data for these groups are presented in the tables and appendices previously detailed in Section VI.A.1., "Intratracheal Administration of Acid Black 52 in Hamsters."

Survival: Survival among the control and treated rats was equivalent for both sexes throughout the duration of the study. By study end, 44% of the treated male rats and 62% of the treated female rats were alive compared to 48% and 51% in their control counterparts, respectively.

Body Weights: No noticeable differences in body weight data were observed between the control and treated male rats. Comparable body weight data were recorded between the control and treated female rats during the first half of the study. During the latter half of the study, the treated female rats had slightly lower than control mean body weights at all body weight intervals.

Gross Pathology: The most consistently observed gross observations in both male and female treated rats was the presence of pulmonary lesions. In the majority of the rats, multiple pinpoint dark foci of the lungs were observed. A few white or yellow nodules were scattered throughout the lungs of some of the treated rats of both sexes.

Histopathology: The total number of tumor-bearing animals in the treated male (45/48 at risk) and female (35/47) groups was comparable to that of the controls (males, 31/31; females, 26/33). No statistically significant differences were observed with respect to the number of tumor-bearing animals for any of the major organs or organ systems.

Although statistical significance was not present for liver tumors, the total incidence of proliferative liver lesions in treated female rats exceeded that of the controls as shown below:

| Lesion | Incidence/Number Examined | |
|---|---|---|
| | Treated | Control |
| Neoplastic nodules | 3/50 | 1/35 |
| Eosinophilic foci | 9/50 | 4/35 |
| Basophilic foci | 2/50 | 0/35 |
| Clear cell foci | 3/50 | 0/35 |

A similar pattern was not seen in the male rats; the incidences of proliferative liver lesions were comparable for male treated and control groups.

The incidence of pituitary adenomas in the treated rats (males 8/37 examined; females 18/43) exceeded that observed in the controls (males, 4/29; females, 11/33). A higher incidence of thyroid C-cell adenomas also was noted in the treated females (10/41) as compared to the control group (4/33).

A lesion occurring consistently in treated rats (males, 24/50; females, 38/50) was the presence of numerous intra-alveolar pigment laden macrophages or pigmented histiocytosis in the lungs of both sexes. The pigment was presumably Acid Black 52. The incidence of lesions usually associated with chronic murine pneumonia was more prevalent in the treated males (14/50) than in the treated females (11/50) or in the control rats of either sex (1/35). The number of treated females with lung neoplasms (5/43 at risk) exceeded that seen in the controls (1/30). One alveolar/bronchiolar cell adenoma, one malignant lymphoma, and three leukemias were present in the treated females as compared to one leukemia in the controls.

In the ovaries of the treated females, acute or chronic oophoritis occurred in 5/47 animals examined; similar lesions were not observed in the controls.

A higher incidence of mammary gland tumors was present in the control females (14/30 at risk) than in the treated females (11/43), however, the difference was not statistically significant ($p=0.081$).

Testicular interstitial cell tumors were seen with similarly high incidences in the treated (41/49) and control (29/35) male rats.

The usual incidence of non-neoplastic lesions common to the Fischer rat was observed in both treated and control rats.

4. Dietary Administration of Acid Black 52 in Rats

This evaluation involved comparison between the Acid Black 52 treated rats (Group 10) and their control (Group 15) counterparts. Support data for these groups are presented in the tables and appendices listed previously in Section VI.A.2., "Dietary Administration of Acid Black In Hamsters."

Survival: A treatment-related effect on survival was observed for the treated male rats only and became apparent after Week 68. Survival of the treated and control males was equivalent during the first 68 weeks; thereafter, a steady decline in survival was observed for the treated male rats. By Week 108, 71% of the male controls were alive compared to only 10% for the treated males. Comparable survival rates were observed between female control and treated rats throughout the study.

Body Weight and Food Consumption: Lower than control mean body weights were predominant in the treated male rats, especially after Week 66. Mean body weights of the treated female rats were equivalent to their controls with the exception of somewhat lower mean body weight from Week 83 to Week 117.

Food intake values of the treated male rats were somewhat higher than the male controls for the first 75 weeks of study; thereafter, food consumption fluctuated, being slightly lower, slightly higher or equivalent to those of their control counterparts. Female treated rats in general, maintained slightly higher food intake throughout the duration of the study.

Gross Pathology: All treated rats had black staining on body surfaces. "Thin and hunched" was a frequent gross observation in treated male rats. Pitting of the kidneys was more frequently observed in the treated rats of both sexes than in their respective controls.

Lenticular opacities were frequently observed with the highest incidence occuring in the treated and control female rats. Grossly observed tissue masses were more prevalent in the female rats with a higher incidence in the female controls. Enlargement of the pituitary was a gross finding consistently observed in all rats, with the exception of

the treated males. Gross lesions of the testes were more prominent and numerous in the controls than in the treated male rats.

Gross lesions associated with Fischer rat leukemia (i.e., enlarged spleen, friable yellow-brown swollen liver, and occasional icterus) occurred in greater numbers in the control rats of both sexes.

Histopathology: The total number of tumor-bearing animals in the control males (35/35 at risk) was significantly greater (p=0.009) than that of the treated males (38/47). Significance was apparently attributable to the incidence of tumors of the hematopoietic/lymphatic system (p=0.012) and liver (p=0.003). The number of endocrine tumors, although not statistically significant (p=0.082), was also greater in the controls. The total number of tumor-bearing animals was comparable for the treated and control females. However, the number of females with tumors involving the liver and the hematopoietic system was greater in the control as compared to the treated group.

In the males, the number of animals with liver tumors in the control group (13/29 at risk) greatly exceeded that in the treated group (1/21). Four of the tumors present in the control animals were neoplastic nodules; all others (including the tumor present in the treated male) were diagnosed as leukemia. In addition, other proliferative lesions of the liver such as eosinophilic and clear cell foci were more numerous in the control males (7/35 and 8/35) than in the treated males (3/50 and 10/50). A similar but less pronounced pattern was observed for leukemia and neoplastic nodules in the livers of the females rats; the number of tumor-bearing animals involving the liver in the control females (15/33 at risk) was significantly greater (p=0.005) than that seen in the treated group (7/46).

The significantly (p=0.012) increased number of tumor-bearing animals for the hematopoietic/lymphatic system of the control males was due to the presence of leukemia in the spleens of these animals (control, 10/35 examined; treated, 2/49). Similarly, the incidence of leukemia in the spleens of the control females (9/35) exceeded that seen in the treated females (4/50), although statistical significance was not observed (p=0.148). The incidence of leukemia in the lungs also was higher in the

control males (7/35 examined) and females (4/35) than in the treated rats of either sex (males, 2/50; females, 1/50).

The increased number of endocrine tumors in the control males (17/28 at risk) as compared to the treated males (6/18) was largely due to pituitary adenomas and thyroid C-cell adenomas as summarized below:

| Organ/Lesion | Incidence/Number Examined | |
|---|---|---|
| | Treated | Control |
| Pituitary | | |
| Adenoma | 0/33 | 8/26 |
| Thyroid | | |
| C-cell adenoma | 0/42 | 5/31 |
| C-cell hyperplasia | 1/42 | 6/31 |

The incidence of C-cell hyperplasia in the thyroids of the control males (as indicated in the above table) was similarly increased.

Chronic nephropathy was particularly evident in both treated and control male rats (43/50 and 30/35, respectively). The lesion was observed to a severe degree in all affected treated males, while severe lesions were reported in only six of the affected control males. Chronic nephropathy was often accompanied by fibrous osteodystrophy, parathyroid hyperplasia, and diffuse mineralization in all layers of the stomach.

Periarteritis and myocardiopathy (both spontaneous diseases of laboratory rats) were more prominent and frequent in the dietary Acid Black treated males than in either dietary or intratracheal controls or rats receiving intratracheal doses of either dye.

## B. Yellow 3

### 1. Intratracheal Administration of Yellow 3 in Hamsters

This evaluation involved comparison between the Yellow 3 treated hamsters (Group 3) and their control (Group 6) counterparts. Support data for these groups are presented in this report as follows: survival data are presented in Table XIII with graphic illustration of survival

presented in Figure 8, mean body weights are presented in Table XIV; total tumor incidence for major organs is presented in Table XVI; Fisher's exact analyses of tumor-bearing animals for major organs and organ systems are presented in Table XVII; a group summary of histopathology findings is presented in Table XVIII; and the individual histopathology findings and presented in Appendix II.

Survival: Survival in the control and treated male hamsters was equivalent until Week 47; thereafter, survival for the treated male hamsters was somewhat greater than that of their control counterparts. By study end, 24% of the treated males were alive compared to 17% survival for the male control hamsters. Equivalent survival was observed between the control and treated female hamsters until Week 63; thereafter, and until Week 78, survival of the treated female hamsters was lower than their control counterparts. Following Week 78, slightly lower survival was noted for the female control hamsters; however, by study end, comparable survival was observed for the treated and control females (6% and 8%, respectively).

Body Weight: No noticeable differences in body weight data were observed between the control and treated hamsters of either sex.

Gross Pathology: No consistent treatment-related gross lesions were observed in hamsters receiving intratracheal administration of Yellow 3. Atrial thrombosis and biliary cysts occurred more frequently in female hamsters than in male hamsters. Pitted kidneys and enlarged spleen and lymph nodes occurred more frequently in the treated female hamsters when compared to the female controls.

Histopathology: A treatment-related effect was apparent in the adrenal gland of treated male hamsters. The incidence of cortical cell adenomas (12/50) exceeded that seen in the controls (6/35); however, statistical significance was not observed for tumors involving the endocrine system ($p=0.527$).

The incidence of liver tumors in the treated female hamsters (6/50 examined) was greater than in the female controls (1/35). Four tumors were diagnosed as cholangiomas and a single lymphoma and plasmacytoma each were observed in the treated females. A single cholangioma occurred in

the female controls. The difference in the number of tumor-bearing animals (6/34 at risk versus 1/27) was not statistically significant (p=0.121).

A statistically significant increase (p=0.018) in tumor-bearing animals was present for hematopietic/lymphatic tumors in the control males (4/27 at risk) as compared to the treated males (0/44). This was largely a result of three splenic tumors (two lymphomas and one hemangioma) in the control group; no tumors were present in the spleens of the treated males. Fisher's analysis indicated a value of p=0.051 for splenic tumors.

An increased number of tumor bearing animals involving the lung also was observed in the control males (3/27 at risk) as compared to the treated males (0/44); Fisher's analysis indicated value of p=0.051. Two of the tumors in the lungs of the control males were leukemias and the third was an undifferentiated mesenchymal neoplasm.

Non-neoplastic microscopic lesions occurred in the lungs of the treated hamsters; many were multiple lesions. Pneumonopathy was the term used to described these multiple lesions of the lung which consisted of eosinophilic masses, alveolar/bronchiolar cell proliferation, adenomatosis, metaplasia, and histiocytosis. The incidence of pneumonopathy in the treated male (19/50) and female (26/50) hamsters was greater than that of their respective controls (11/35 and 8/35).

The usual spontaneous lesions of aging hamsters were observed in these groups. Amyloidosis frequently occurred in a variety of organ systems and was seen with greatest incidence in female hamsters. Atrial thrombosis also was observed more frequently in the females.

2. Dietary Administration of Yellow 3 In Hamsters

This evaluation involved comparison between the Yellow 3 treated hamsters (Group 11) and their control (Group 14) counterparts. Support data for these groups are presented as follows: survival data are presented in Table XIII with graphic illustration of survival presented in Figure 8; mean body weights and mean food consumption data are presented in Tables XIV and XV, respectively. Total tumor incidence for major organs is presented in Table XVI; Fisher's exact analyses of tumor-bearing

animals for major organs and organ systems as presented is Table XVII; a group summary of histopathology finding is presented in Table XVIII; and the individual histopathology findings are presented in Appendix II.

Survival: Survival of the treated male hamsters was equivalent to that of the male controls throughout the majority of the study. Following Week 98, however, the male controls experienced a rapid decline in survival; by Week 109, 38% of the treated males were alive compared to 17% survival of the male controls. Treated female hamsters had a somewhat higher survival rate than the female controls until Week 87; thereafter, survival was comparable.

Body Weights and Food Consumption: Mean body weights of both sexes were equivalent to those of their respective control counterparts throughout the duration of the study. The female control hamsters experienced a slight reduction in mean body weight during Week 96 (7% lower body weight from the previous interval).

Treated hamsters of both sexes consumed slightly more food than their control counterparts during the course of the study.

Gross Pathology: No significant treatment-related gross lesions were observed in hamsters administered Yellow 3 in the diet. Small liver cysts, pale pitted kidneys, hemothorax, ascites, and anasarca frequently were observed in these hamsters. A few enlarged or nodular spleens occurred in the females fed Yellow 3.

Histopathology: A slight increase in the incidence of adrenal tumors was present in the treated females (10/49 examined) as compared to the control (4/34); this difference was not statistically significant ($p=1.000$). A similar pattern was not observed for the males; however, the incidence of cortical nodular hyperplasia in the adrenal of the treated males (20/50) exceeded that seen in the controls (8/35).

Statistically significant increases in the number of tumor-bearing animals involving the hematopoietic/lymphatic systems, lung, and liver were seen in the control males as summarized below:

| Organ/Organ System | Incidence/Number at Risk | | p-Value |
|---|---|---|---|
| | Treated | Control | |
| Hematopietic/Lymphatic System | 0/48 | 7/34 | 0.001 |
| Lung | 0/48 | 5/34 | 0.010 |
| Liver | 0/33 | 5/22 | 0.008 |

In each instance, significance was due to the presence of lymphoma/leukemia in these tissues which occurred only in the controls.

Pulmonary histiocytosis (intra-alveolar accumulations of macrophages) occurred in all hamsters on study, particularly those receiving dietary administration of Yellow 3; a higher incidence occurred in both treated and control female hamsters than in male hamsters. Hepatocellular pigmentation occurred with greater incidence in the treated male hamsters (31/50) than in the treated female hamsters (4/50). A minimal incidence of hepatocellular pigmentation was seen in the control male hamsters (4/35) but was probably not biologically significant. Treated female hamsters appeared to have more thyroid follicular cysts (7/45) when compared to the controls (2/34) and the incidence of thyroid amyloidosis was higher in the females than in the males.

The previously mentioned usual spontaneous lesions of aging hamsters were also encountered in these animals. Atrial thrombosis occurred with greater incidence in the treated (16/50) and control females (13/35) as compared to the treated (12/50) or control (4/35) males.

3. Intratracheal Administration of Yellow 3 in Rats

This evaluation involved comparison between the Yellow 3 treated rats (Group 4) and their control (Group 8) counterparts. Support data for these groups also share the tables and appendices described in Section VI.B.1., "Intratracheal Administration of Yellow 3 in Hamsters."

Survival: Survival rates in the control and treated male groups were equivalent until Week 95; thereafter, survival was higher in the treated male rats, especially during the last several weeks of the study. By study end, 66% survival was recorded for the treated male rats compared to 83% survival for their control counterparts. Survival rates in the control and treated female rats were equivalent until Week 109. In contrast to the males, survival was slightly lower in the female control rats after Week 109 and remained so for the duration of the study. By study end, 66% survival was recorded for the treated female rats as compared to 54% survival for the female controls.

Body Weight: Equivalent body weight data were observed between the control and treated male rats until Week 88; thereafter, the control male rats had lower than treated group mean body weights at all body weight intervals. No noticeable differences in body weight data were observed between the control and treated female rats.

Gross Pathology: Lesions typically seen in aging Fischer rats were present in these groups. Female treated rats had more grossly visable thyroid and adrenal lesions than were seen in the controls. Masses involving the small intestine of two female treated rats were observed.

Histopathology; In treated male rats, a treatment-related effect was suggested by the tumor incidence observed in the lungs, kidneys, pancreas, and skin/mammary gland as shown below:

| | Incidence/Number at Risk | |
|---|---|---|
| Organ | Treated | Control |
| Lungs | 11/47 | 5/34 |
| Kidneys | 4/45 | 0/34 |
| Pancreas | 8/41 | 3/34 |
| Skin/mammary | 9/40 | 2/32 |

These differences in tumor incidence were not statistically significant, although a p-value of 0.055 was noted for skin/mammary gland tumors.

In the lungs of the treated males, eight of the tumors were lymphoma/leukemia, one was an alveolar/bronciolar cell adenoma, and three were classified as adenomatosis; other neoplasms were metastases from other sites. Four leukemias, one alveolar/bronchiolar cell adenoma, and one adenocarcinoma were present in the lungs of the control males. The four tumors observed in the kidneys of the treated males consisted of a metastatic adenocarcinoma, a lymphoma, a transitional cell carcinoma, and an undifferentiated sarcoma. Pancreatic tumors in the treated male group were three acinar cell adenomas, three islet cell adenomas, an islet cell carcinoma, an invasive mesothelioma, and a lymphoma. The three pancreatic tumors in the control group were an islet cell adenoma, a lymphoma, and a leukemia. The skin/mammary tumors, although more prevalent in the treated group, were those normally observed in the skin or its adnexa.

Lung and liver tumors were observed with greater incidence in the treated female rats (10/49 and 12/49) than in the controls (6/33 and 6/33), which suggested a possible treatment-related effect. In the lungs, three alveolar/bronchiolar cell adenomas and seven leukemias were present in the treated group; three leukemias and three metastatic tumors were present in the control group. In the livers of the treated females, nine leukemias, three neoplastic nodules, and a single histiocytoma were observed; six leukemias were present in the control group.

A possible treatment-related effect was also observed in the pituitaries of the treated female rats. Pituitary adenomas were present with a much higher incidence in the treated group (25/39 examined) as compared to the control group(11/25).

A greater number of adrenal cortical cell adenomas were observed in the treated male rats (5/48 examined) than in the controls (0/35). At the same time, the incidence of pheochromocytoma was much greater in the male control rats (9/35) than in the treated male rats (1/48). Additionally, a metastatic adenocarcinoma and a malignant lymphoma were present in the treated male rats.

In the adrenals of female rats, the incidence of pheochromocytoma also was greater in the controls (3/35) than in the treated animals (1/50). Cortical nodular hyperplasia (4), a leukemia, and a

ganglioneuroma also were present in the adrenals of the treated female rats; one cortical cell adenoma was present in a female control rat.

Striking differences between treated and control male rats were in evidence in the prostates of these animals. The incidence of prostate tumors (9/35) and prostate hyperplasias (8/35) in the control male rats greatly outnumbered those of the treated male rats (1/50 and 2/50). Interstitial cell tumors of the testes accounted for the majority of tumors observed in the male reproductive system; this tumor was observed with similar incidence in treated (44/50) and control (32/35) rats.

Thyroid neoplasms were more prevalent in the control female rats. Four C-cell carcinomas, two C-cell adenomas and two follicular cell adenomas were present in the control group. By comparison, treated females had one follicular cell adenoma and three C-cell adenomas. C-cell hyperplasia also was present in two control females. Two duodenal neoplasms (a leiomyoma and an undifferentiated sarcoma) were observed in the treated female rats.

Intra-alveolar pigmented histiocytosis was strikingly higher in the treated male (40/50) and female rats (42/50) than in the male (0/35) and female (2/35) controls. Compound-related centrilobular necrosis of the liver was observed in the treated males (4/50); none occurred in the male controls. Enostosis (a sub-periosteal proliferation of bone occuring at the expense of the marrow cavity) of the femur and rib was more prevalent in the treated female rats than in the female controls.

Chronic murine pneumonia and inflammation of the upper respiratory tract were much more prevalent in the male and female controls than in the treated rats.

4. Dietary Administration of Yellow 3 in Rats

This evaluation involved comparison between the Yellow 3 treated rats (Group 12) and their control (Group 16) counterparts. Support data for these groups share the tables and appendices listed previously in Section VI.B.2., "Dietary Administration of Yellow 3 in Hamsters."

Survival: No differences in survival were noted between the treated male rats and their controls, in spite of the uncommonly high survival rate of the male control rats; the first death in this group occurred during Week 100. Survival was equivalent between the female treated and

control rats until Week 90; thereafter, slightly lower survival was noted in the female control rats. By Week 116, 76% of the treated female rats were alive compared to 43% of their control counterparts.

Body Weight and Food Consumption: Mean body weights of the treated male rats were approximately 10% lower than those of the male controls during each interval of the study. Mean body weights of the treated females were somewhat lower (approximately 15% lower) than those of the female controls.

Food consumption values of the treated and control males rats were equivalent. Food intake for the treated females was somewhat lower than their control counterparts throughout the course of the study.

Gross Pathology: Ulcerations of the forestomach were more prevalent in the control rats than in the treated rats. Evidence of leukemia such as enlargement of the spleen, was present in the control rats only; none was observed in the treated rats. All other types of lesions commonly seen in the Fischer rat occurred as expected.

Multiple white foci and occasional raised nodules were seen in most livers of the treated male rats. An occasional nodule was observed in the treated females. A great number of female rats fed Yellow 3 had red-black, thickened ceca.

Histopathology: Lesions of the liver were pronounced in the males and were present in greater numbers in the treated group than in the controls:

| Lesion | Incidence/Number Examined | |
|---|---|---|
| | Treated | Control |
| Clear cell foci | 33/50 | 2/35 |
| Eosinophilic foci | 23/50 | 16/35 |
| Neoplastic nodules | 25/50 | 2/35 |
| Hepatocellular carcinoma | 2/50 | 0/35 |

The number of tumor-bearing animals involving the livers of the treated male rats (27/50 at risk) was statistically significantly higher ($p=0.001$) when compared to that of the male control rats (7/35). Additionally, the

incidence of degenerative lesions, i.e., hepatocellular cystic degeneration, exceeded that seen in the controls (treated, 11/50; controls, 0/35).

A statistically significant increase (p=0.017) in the number of tumor-bearing animals involving the kidneys also occurred in the treated males (7/41 at risk) as compared to the control males (0/31). Kidney adenomas were present in seven treated animals; two transitional cell carcinomas of the urinary bladder were also presented.

The incidence of pituitary adenomas, (treated, 24/39; control, 13/26) and thyroid C-cell adenomas (treated, 6/44; control, 1/35) was high in the female rats fed Yellow 3. An increase in the number of tumor-bearing animals involving the endocrine system of female rats fed Yellow 3 (29/46 at risk) was noted when compared to the controls (16/30); however, this difference was not statistically significant (p=1.000).

A statistically significant negative trend (p=0.0003) in the number of tumor bearing animals with leukemia was noted in the control females (8/30 at risk) as compared to the treated female rats (0/46). A similar pattern occurred in the male rats fed Yellow 3; leukemia was present in 5/35 control male rat spleens, but was not observed in any of the treated males. A statistically significant decrease (p=0.033) in the incidence of lung tumors also was seen in the treated females (1/46 at risk) as compared to the controls (5/30). As with the spleen, this was due to the presence of leukemia in the lungs of the control females; leukemia was not observed in the treated females.

Follicular cell hyperplasias of the thyroid occurred with higher incidence and severity in the treated male rats (15/45) than in the male controls (1/29).

Enteropathy, characterized by some mucosal blunting, a loss of crypt epithelium, and deposition of an acellular material resembling collagen, occurred in a large number of ceca from the treated female group. An occasional inflammatory component was present in the muscularis, serosa, and mesentery.

## VII. DISCUSSION

### A. Acid Black 52

#### 1. Intratracheal Administration of Acid Black in Hamsters

Significant numbers and types of pulmonary lesions occurred in the treated male and female hamsters. In the treated males, the incidence of cortical cell adenomas, as well as cortical nodular hyperplasia, exceeded that observed in the controls. In the treated females, no adrenal neoplasms occurred; the female controls had a 14% incidence of this lesion. The incidence of cortical nodular hyperplasia in the treated female hamsters exceeded that of the controls. Adrenal cortical tumors are frequent findings in hamsters and the moderate number observed in the treated group renders a neoplastic effect somewhat less than clear-cut.

#### 2. Dietary Administration of Acid Black in Hamsters

Most of the gross lesions observed in the hamsters were spontaneous in nature and peculiar to the species. Enlarged lymph nodes (usually the mandibular) found in the older hamsters were caused by proliferation of plasmacytes and occurred primarily in those with extensive amyloidosis. Atrial thrombosis and its attendant sequelae (fluid in the body cavities, passive congestion, and pulmonary histiocytosis) is a frequent syndrome in aging hamsters; however, the reason for its increased incidence in females only was not clear. Amyloidosis, involving multiple organs in all groups, was more intense in the female hamsters. Again, this is a spontaneous lesion of aging hamsters.

A significant negative trend was apparent in the incidence of lymphoma in the bone marrow of the male hamsters. Lymphoma involving the spleen was observed more often in the treated female hamsters than in the controls. In both instances, the number of occurrences was small and biological significance was unclear. Lymphomas are not uncommon tumors in hamsters and some researchers have reported a fairly high incidence of this neoplasm. A negative trend occurred for the number of adrenal cortical tumors in hamsters of both sexes suggesting a tumor suppressive effect in this organ. Hyperplasia of the adrenal cortical cells was slightly higher in the male and female control hamsters when compared to

the incidence which occurred in the treated hamsters; a high incidence of this lesion is frequently observed in hamsters.

The hepatocellular vacuolation observed in the livers of the treated female hamsters may be biologically significant when compared with the controls; however, this remains speculative.

3. Intratracheal Administration of Acid Black in Rats

Treatment-related pulmonary lesions were present in both male and female rats and for the most part, consisted of multiple pinpoint dark foci. These represented multifocal accumulations of pigmented macrophages in the lung parenchyma. The pigment was presumably Acid Black 52.

The total incidence of various types of proliferative liver lesions in the treated females suggested a slight effect on the liver. A similar pattern was not observed in the treated males.

The number of testicular interstitial cell tumors appearing in the control and treated rats, although high in incidence is not considered to be biologically significant. The incidence of this tumor type is variable in Fischer rats and its presence in this case was related to longevity of survival. Similarly, longevity of survival was associated with the apparent treatment-related effect of pituitary adenoma in the male and female rats.

The biological significance of the increased incidence of thyroid C-cell adenomas in the treated females was equivocal.

The increased incidence of pulmonary neoplasms in the treated females was not considered treatment related. Three of the five neoplasms were leukemia and the higher incidence of this tumor was probably related to the slightly increased survival in the treated females.

4. Dietary Administration of Acid Black in Rats

The gross lesions observed in the rats were those normally seen in aging Fischer rats. Lesions associated with Fischer rat leukemia were observed only in the controls of both sexes.

Significantly increased numbers of tumor bearing animals were observed in the control rats of both sexes for tumors involving the hematopoietic/lymphatic system, liver, and lung. These significant negative trends were primarily due to the presence of Fischer rat leukemia in the controls, although the incidence of neoplastic nodules and other proliferative lesions of the liver also was slightly higher in the control males. The decreased incidence of leukemia in rats fed Acid Black 52 strongly suggested a tumor suppressive effect from the dye. Although decreased survival was apparent for the treated males, this factor did not account for the variation in tumor incidence since a similar effect was present in the female rats, for which comparable survival rates were observed throughout the study for the control and treated groups. The possible neoplastic effect for other types of proliferative liver lesions, although suggested, was not as clear cut. The increased incidence of pituitary adenomas and thyroid C-cell adenomas for the control male group was probably related to longevity of survival.

Acid Black 52 appeared to be toxic to the kidney of the male rats. Severe pitting of the kidneys was more prevalent in the treated males and indicated a toxic effect. Chronic nephropathy was most severe in male dietary rats receiving Acid Black 52 compared to all other groups in the study. Chronic nephropathy was accompanied by a high incidence of parathyroid hyperplasia and dystrophic mineralization of the stomach and severe disseminated fibrous osteodystrophy.

B. Yellow 3

1. Intratracheal Administration of Yellow 3 in Hamsters

No biologically significant treatment-related gross lesions were apparent in this group.

A greater incidence of adrenal cortical tumors was present in the treated male hamsters compared to their controls; two of these were carcinomas which supports a positive treatment effect.

Yellow 3 appeared to suppress the incidence of lymphoma/leukemia in the treated male hamsters. This effect was noted in the hematopoietic/lymphatic system (primarily spleen) and the lungs of these animals; lymphoma/leukemia was present in these tissues in the control males only.

The inference of a treatment-related positive neoplastic effect in the liver of the treated females was not valid. These tumors may not in

fact be neoplasms, but rather a more severe expanding and proliferating papillary cystic mass of biliary tissue. In either case they were probably benign.

Treatment-related non-neoplastic pulmonary lesions (termed pneumonopathy) were present in treated hamsters of either sex.

2. Dietary Administration of Yellow 3 in Hamsters

Male control hamsters appeared to have significantly more neoplasms involving the lung, liver, and hematopoietic/lymphatic system (bone marrow and spleen). This significant negative trend was the result of leukemia/lymphoma which occurred only in the controls. Since no differences in survival were observed between the treated and control males, these findings suggested that Yellow 3 suppressed lymphoma/leukemia in the treated males.

A slight increase in the incidence of adrenal tumors occurred in the treated females. Although a similar increase was not observed in the treated males, the incidence of cortical nodular hyperplasia was noted to be higher in the treated males than in the controls.

3. Intratracheal Administration of Yellow 3 in Rats

The inference of a neoplastic effect in the lungs of the treated males and females was not valid since the majority of tumors observed were leukemia. Similarly, the significance of the apparent treatment-related effect in the livers of the treated females was diminished due to the presence of leukemia. The incidence of leukemia in the lung and liver, as well as in other tissues in the treated rats was of little consequence as it is a manifestation of the generalized Fischer rat leukemia. The number of tumor-bearing animals in the treated group for liver and lung did not appear to be significantly higher than the controls if leukemia was not considered.

Neoplastic effect in the kidneys of the treated males, also was considered invalid since only one tumor was a primary neoplasm of the kidney; all others were metastases or invasive. Acinar cell adenoma and islet cell adenoma of the pancreas in the treated male rats, however, appeared to be related to administration of Yellow 3. These pancreatic tumor incidences were higher than the literature indicated.

A treatment-related positive neoplastic effect in the female pituitary was not a certainty but gained some validity in that a similar

effect was in evidence for the Yellow 3 dietary females. In each case, the incidence of adenoma was slightly higher than that seen in the rats receiving Acid Black by either route. However, the Fischer rat has a history of high incidence of this tumor and an accurate assessment of carcinogenicity in this organ would require more striking differences between treated and control animals than was observed in this study.

The increased incidence of thyroid tumors in the control females was biologically significant. Thyroid hyperplasia also was present concomitantly with the tumors in the control rats.

An apparent negative trend was present for the incidence of adrenal medullary tumors (pheochromocytomas) in both male and female rats. The reported incidence of this tumor in the Fischer rat is fairly high (10% in males; 3% in females). A negative trend also was present for tumors and hyperplasias of the prostate.

Neoplasms present in the duodenum of two treated female rats appeared to be biologically significant primarily because duodenal tumors are rare in Fischer rats. Biological significance was refutable since one tumor was a leiomyoma and the other an undifferentiated sarcoma and since no hyperplasias were noted in other treated females.

The incidence of mesothelioma in the treated rats was higher than reported in the literature. This was interpreted to be a biological phenomenon rather than a treatment-related effect.

4. Dietary Administration of Yellow 3 in Rats

Yellow 3 in the diet of rats appeared to be oncogenic to the liver of male rats as evidenced by a statistically significant increase in liver tumors (primarily neoplastic nodules) and other proliferative liver lesions. Yellow 3 also produced oncogenic effects in the urinary tract (particularly the kidneys) of the treated males. In female rats, the dye appeared to be oncogenic to the endocrine system, primarily the pituitary and thyroid.

Cecal lesions in the treated female rats (classified as enteropathy for this study) were the apparent result of Yellow 3. The pathogenesis of the cecal lesions is not understood.

Yellow 3 also suppressed the appearance of Fischer rat leukemia in the treated animals . This was illustrated by the incidence of leukemia in the spleens of the control rats of both sexes and in the lungs of the control females. Leukemia was not present in the treated counterparts.

# VIII. CONCLUSIONS

## A. Acid Black 52

Intratracheal administration of Acid Black 52 to Syrian hamsters and Fischer rats gave no definite indication of oncogenicity in either species and/or sex at dose levels of 0.75 mg (hamsters) or 0.32 mg (rats).

Acid Black 52 fed to Syrian hamsters and Fischer rats was probably not oncogenic to either species at a dose level of 2.0% of the total diet. Dietary administration of Acid Black 52 apparently suppressed the incidence of lymphoma/leukemia in the bone marrow of treated hamsters and in the hematopoietic/lymphatic system, liver, and lungs of treated rats. A suppressive neoplastic effect also was suggested from data involving adrenal cortical tumors in treated female hamsters, and to a lesser extent in treated male hamsters.

## B. Yellow 3

Intratracheal administration (15.0 mg) of Yellow 3 to Syrian hamsters and Fischer rats demonstrated oncogenicity in the adrenal cortex of male hamsters and in the pancreas of male rats. Yellow 3 demonstrated the apparent ability to suppress the incidence of neoplasia in the spleen (hematopoietic system) of male hamsters, prostate of male rats, thyroid of female rats, and adrenal medulla of rats of both sexes.

Yellow 3 fed (0.8% of total diet) to Syrian hamsters and Fischer rats demonstrated oncogenicity in the adrenal of male and female hamsters, liver and kidneys of male rats, and endocrine system (thyroid and pituitary) of female rats. The incidences of follicular cell hyperplasia (males) and cecal enteropathy (females) were increased in the treated rats. Yellow 3 demonstrated the apparent ability to suppress the incidence of lymphoma/leukemia in the treated hamsters and rats.

A carcinogenesis bioassay of C.I. Disperse Yellow 3, a monoazo dye similar to Amaplast Yellow PFC, was conducted by Battelle Columbus Laboratories, Columbus, Ohio (NTP Technical Report, CAS No. 2832-40-8). This study was initated by the NCI Carcinogenesis Testing Program and was conducted from March 1977 to April 1979. The dye was administered in the diet to Fischer 344 rats at dose levels of 5,000 and 10,000 ppm. Certain

similarities and differences between the Battelle and Borriston studies were apparent upon comparison of the results.

A significant incidence of dose-related neoplastic nodules was apparent in the livers of male rats in the Battelle study, as well as at Borriston. Also, a significant negative trend in the incidence of monocytic leukemia was reported for male and female rats in both studies. The results obtained at Borriston showed a significant increase in the incidence of renal neoplasms. While two kidney tumors were observed in the Battelle study they were not considered significant.

An increase in endocrine (thyroid and pituitary) tumors was observed in female rats treated at Borriston; Battelle reported a decreased incidence of thyroid C-cell adenomas and pituitary adenomas in the treated male and female rats, respectively. Similarly, the incidences of follicular cell hyperplasia of the thyroid (males) and cecal enteropathy (females) were increased in the Borriston study; these findings were not reported by Battelle. The gastric neoplasms reported by Battelle were not observed in the Borriston study.

In the Borriston study, Acid Black 52, when instilled intratracheally or when administered in diet did not exhibit a definite carcinogenic effect. Where as, Yellow 3 when instilled intracheally demonstrated to be oncogenic in the adrenal cortex of male hamsters and in the pancreas to male rats. Yellow 3 in the diet was oncogenic in the adrenal of both sexes of hamsters, in the liver and urinary tract of male rats and in the endocrine system of female rats.

Thus, in the study the carcinogenic potential of Azo dyes, Acid Black 52 and Yellow 3 in two species was different depending upon the route of exposure.

Table I: Dosage, Survival, and Mean Body Weights of Hamsters Administered Acid Black 52 Intratracheally, Once A Week for 12 Consecutive Weeks (Subchronic)

| | Dose (mg) | Survival[a] (Week of Death) | Mean Body Weight | | | | | | Weight Change (%)[c] |
|---|---|---|---|---|---|---|---|---|---|
| | | | Initial | | Final | | Change | | |
| | | | $\bar{X}$ | SD | $\bar{X}$ | SD | $\bar{X}$ | SD | |
| Male | 0.00 | 15/15 | 73 | 9 | 122 | 17 | 49 | 15 | - |
| | 0.13 | 19/20 (4) | 73 | 7 | 121 | 14 | 46 | 15 | -6 |
| | 0.24 | 20/20 | 73 | 8 | 116 | 26 | 43 | 29 | -12 |
| | 0.42 | 19/20 (7) | 72 | 10 | 113 | 14 | 41 | 16 | -16 |
| | 0.75 | 17/19[b] (5,7) | 70 | 13 | 114 | 16 | 43 | 18 | -12 |
| Female | 0.00 | 12/15 (2,3,4) | 65 | 8 | 130 | 19 | 60 | 17 | - |
| | 0.13 | 19/20 (3) | 69 | 10 | 124 | 15 | 53 | 16 | -12 |
| | 0.24 | 17/20 (2,3) | 69 | 6 | 125 | 15 | 55 | 15 | -8 |
| | 0.42 | 19/20 (9) | 68 | 8 | 120 | 14 | 51 | 13 | -15 |
| | 0.75 | 21/21[b] | 71 | 6 | 128 | 15 | 56 | 15 | -7 |

[a]Number surviving/number initially in the group. Denominator represents "N" for initial body weight means; numerator represents "N" for final body weight means and mean weight changes.

[b]Group series deviated from protocol due to missexed animal.

[c]Weight change (%) = weight change (dosed group) minus weight change (control group) divided by weight change (control group) x 100.

Table I: Dosage, Survival, and Mean Body Weights of Rats Administered Acid Black 52 Intratracheally, Once A Week for 12 Consecutive Weeks (Subchronic)

| | Dose (mg) | Survival[a] (Week of Death) | Mean Body Weight | | | | | | Weight Change (%)[c] |
|---|---|---|---|---|---|---|---|---|---|
| | | | Initial | | Final | | Change | | |
| | | | $\bar{X}$ | SD | $\bar{X}$ | SD | $\bar{X}$ | SD | |
| Male | 0.00 | 14/15 (7) | 95 | 8 | 304 | 30 | 199 | 37 | - |
| | 0.08 | 18/20 (7,9) | 96 | 12 | 294 | 22 | 198 | 16 | -1 |
| | 0.16 | 16/20 (1,3,7,9) | 99 | 11 | 311 | 27 | 210 | 20 | +6 |
| | 0.32 | 16/20 (1,1,7,12) | 105 | 12 | 308 | 25 | 203 | 27 | +2 |
| | 0.61 | 12/20 (1,1,1,6,6,6,7,12) | 103 | 11 | 303 | 14 | 197 | 14 | -1 |
| Female | 0.00 | 14/15 (2) | 85 | 10 | 197 | 13 | 111 | 14 | - |
| | 0.08 | 19/20 (2) | 81 | 7 | 186 | 13 | 105 | 14 | -5 |
| | 0.16 | 17/20 (4,4,11) | 84 | 6 | 185 | 7 | 101 | 5 | -9 |
| | 0.32 | 17/20 (2,2,6) | 82 | 7 | 183 | 8 | 100 | 10 | -10 |
| | 0.61 | 18/20 (2,12) | 78 | 18 | 186 | 9 | 104 | 9 | -6 |

[a]Number surviving/number initially in the group. Denominator represents "N" for initial body weight means; numerator represents "N" for final body weight means and mean weight changes.

[b]Group series deviated from protocol due to missexed animal.

[c]Weight change (%) = weight change (dosed group) minus weight change (control group) divided by weight change (control group) x 100.

Table II: Dosage, Survival, and Mean Body Weights of Hamsters Administered Acid Black 52 in the Diet for 13 Consecutive Weeks (Subchronic)

| | Dose (% of Diet) | Survival[a] (Week of Death) | Mean Body Weight | | | | | | Weight Change (%)[c] |
|---|---|---|---|---|---|---|---|---|---|
| | | | Initial | | Final | | Change | | |
| | | | $\bar{X}$ | SD | $\bar{X}$ | SD | $\bar{X}$ | SD | |
| Male | 0.00 | 15/15 | 81 | 8 | 122 | 16 | 45 | 12 | - |
| | 0.25 | 20/20 | 77 | 8 | 119 | 19 | 43 | 17 | -4 |
| | 0.50 | 20/20 | 76 | 9 | 122 | 20 | 47 | 18 | +4 |
| | 1.00 | 20/20 | 76 | 9 | 119 | 17 | 44 | 11 | -2 |
| | 2.00 | 14/20 (4,4,6,6, 6,13) | 74 | 17 | 113 | 17 | 36 | 15 | -20 |
| Female | 0.00 | 15/15 | 75 | 10 | 137 | 23 | 63 | 21 | - |
| | 0.25 | 20/20 | 76 | 12 | 129 | 19 | 53 | 14 | -16 |
| | 0.50 | 20/20 | 74 | 10 | 139 | 19 | 65 | 14 | +3 |
| | 1.00 | 19/20 (7) | 76 | 12 | 131 | 18 | 55 | 15 | -13 |
| | 2.00 | 15/20 (4,4,4,7) | 72 | 8 | 118 | 20 | 46 | 17 | -27 |

[a]Number surviving/number initially in the group. Denominator represents "N" for initial body weight means; numerator represents "N" for final body weight means and mean weight changes.

[b]Group series deviated from protocol due to missexed animal.

[c]Weight change (%) = weight change (dosed group) minus weight change (control group) divided by weight change (control group) x 100.

Table II: Dosage, Survival, and Mean Body Weights of Rats Administered Acid Black 52 in the Diet for 13 Consecutive Weeks (Subchronic)

| | Dose (% of Diet) | Survival[a] (Week of Death) | Mean Body Weight | | | | | | Weight Change (%)[c] |
|---|---|---|---|---|---|---|---|---|---|
| | | | Initial | | Final | | Change | | |
| | | | $\bar{X}$ | SD | $\bar{X}$ | SD | $\bar{X}$ | SD | |
| Male | 0.00 | 14/14[b] | 151 | 11 | 324 | 19 | 173 | 13 | - |
| | 0.25 | 19/20 (2) | 144 | 23 | 331 | 24 | 183 | 22 | +6 |
| | 0.50 | 20/20 | 146 | 14 | 334 | 18 | 189 | 17 | +9 |
| | 1.00 | 21/21[b] | 142 | 23 | 319 | 41 | 175 | 32 | +1 |
| | 2.00 | 20/20 | 151 | 14 | 327 | 19 | 176 | 16 | +2 |
| Female | 0.00 | 16/16[b] | 108 | 7 | 189 | 11 | 81 | 7 | - |
| | 0.25 | 20/20 | 108 | 9 | 185 | 11 | 77 | 12 | -5 |
| | 0.50 | 20/20 | 108 | 8 | 188 | 13 | 80 | 12 | -1 |
| | 1.00 | 19/19[b] | 101 | 10 | 181 | 13 | 80 | 17 | -1 |
| | 2.00 | 20/20 | 104 | 9 | 183 | 12 | 79 | 8 | -2 |

[a]Number surviving/number initially in the group. Denominator represents "N" for initial body weight means; numerator represents "N" for final body weight means and mean weight changes.

[b]Group series deviated from protocol due to missexed animal.

[c]Weight change (%) = weight change (dosed group) minus weight change (control group) divided by weight change (control group) x 100.

Table III: Dosage, Survival, and Mean Body Weights of Hamsters Administered Yellow 3 Intratracheally, Once a Week for 12 Consecutive Weeks (Subchronic)

| | Dose (mg) | Survival[a] (Week of Death) | Mean Body Weight | | | | | | Weight Change (%)[c] |
|---|---|---|---|---|---|---|---|---|---|
| | | | Initial | | Final | | Change | | |
| | | | $\bar{X}$ | SD | $\bar{X}$ | SD | $\bar{X}$ | SD | |
| Male | 0.00 | 15/15 | 72 | 9 | 123 | 13 | 49 | 14 | - |
| | 3.16 | 20/20 | 74 | 11 | 122 | 14 | 49 | 17 | 0 |
| | 5.62 | 20/20 | 72 | 14 | 122 | 14 | 50 | 17 | +2 |
| | 10.00 | 20/20 | 75 | 12 | 119 | 16 | 47 | 19 | -4 |
| | 17.80 | 19/19[b] | 71 | 7 | 111 | 15 | 40 | 17 | -18 |
| Female | 0.00 | 15/15 | 73 | 8 | 129 | 16 | 56 | 14 | - |
| | 3.16 | 18/20 (3,3) | 73 | 7 | 132 | 21 | 59 | 19 | +5 |
| | 5.62 | 19/20 (2) | 71 | 9 | 124 | 14 | 53 | 12 | -5 |
| | 10.00 | 16/20 (4,4,4,5) | 69 | 7 | 118 | 12 | 45 | 16 | -20 |
| | 17.80 | 17/21[b] (2,3,6,8) | 72 | 8 | 122 | 12 | 50 | 13 | -11 |

[a] Number surviving/number initially in the group. Denominator represents "N" for initial body weight means; numerator represents "N" for final body weight means and mean weight changes.

[b] Group series deviated from protocol due to missexed animal.

[c] Weight change (%) = weight change (dosed group) minus weight change (control group) divided by weight change (control group) x 100.

Table III: Dosage, Survival, and Mean Body Weights of Rats Administered Yellow 3 Intratracheally, Once a Week for 12 Consecutive Weeks (Subchronic)

| | Dose (mg) | Survival[a] (Week of Death) | Mean Body Weight | | | | | | Weight Change (%)[c] |
|---|---|---|---|---|---|---|---|---|---|
| | | | Initial | | Final | | Change | | |
| | | | $\bar{X}$ | SD | $\bar{X}$ | SD | $\bar{X}$ | SD | |
| Male | 0.00 | 14/15 (7) | 133 | 16 | 302 | 18 | 170 | 20 | - |
| | 3.16 | 17/20 (5,6,11) | 147 | 13 | 300 | 23 | 154 | 21 | -9 |
| | 5.62 | 19/20 (7) | 131 | 18 | 290 | 38 | 159 | 24 | -6 |
| | 10.00 | 16/20 (2,6,7,9) | 146 | 10 | 300 | 19 | 153 | 16 | -10 |
| | 17.80 | 17/20 (2,6,9) | 145 | 16 | 301 | 27 | 154 | 27 | -9 |
| Female | 0.00 | 14/15 (4) | 105 | 8 | 182 | 13 | 76 | 10 | - |
| | 3.16 | 20/20 | 106 | 8 | 187 | 12 | 81 | 10 | +7 |
| | 5.62 | 16/20 (5,5,5,10) | 108 | 10 | 191 | 13 | 81 | 9 | +7 |
| | 10.00 | 18/20 (4,4) | 107 | 8 | 180 | 9 | 73 | 10 | -4 |
| | 17.80 | 18/20 (3,9) | 102 | 15 | 176 | 14 | 74 | 15 | -3 |

[a]Number surviving/number initially in the group. Denominator represents "N" for initial body weight means; numerator represents "N" for final body weight means and mean weight changes.

[b]Group series deviated from protocol due to missexed animal.

[c]Weight change (%) = weight change (dosed group) minus weight change (control group) divided by weight change (control group) x 100.

Table IV: Dosage, Survival, and Mean Body Weights of Hamsters Administered Yellow 3 in the Diet for 13 Consecutive Weeks (Subchronic)

| | Dose (% of Diet) | Survival[a] (Week of Death) | Mean Body Weight | | | | | | Weight Change (%)[c] |
|---|---|---|---|---|---|---|---|---|---|
| | | | Initial | | Final | | Change | | |
| | | | $\bar{X}$ | SD | $\bar{X}$ | SD | $\bar{X}$ | SD | |
| Male | 0.00 | 14/14[b] | 80 | 10 | 134 | 15 | 53 | 10 | - |
| | 0.13 | 20/20 | 80 | 10 | 126 | 21 | 47 | 20 | -11 |
| | 0.25 | 18/20 (3,12) | 80 | 7 | 127 | 16 | 48 | 13 | -9 |
| | 0.50 | 18/20 (2,4) | 79 | 10 | 122 | 15 | 43 | 13 | -19 |
| | 1.00 | 18/20 (4,5) | 75 | 8 | 114 | 11 | 39 | 12 | -26 |
| Female | 0.00 | 16/16[b] | 71 | 8 | 136 | 17 | 65 | 18 | - |
| | 0.13 | 17/20 (2,3) | 71 | 9 | 138 | 15 | 61 | 16 | -6 |
| | 0.25 | 19/20 (3) | 74 | 10 | 133 | 22 | 61 | 18 | -6 |
| | 0.50 | 18/20 (4,11) | 75 | 9 | 139 | 21 | 64 | 16 | -2 |
| | 1.00 | 17/20 (4,6,13) | 73 | 12 | 130 | 19 | 56 | 12 | -14 |

[a] Number surviving/number initially in the group. Denominator represents "N" for initial body weight means; numerator represents "N" for final body weight means and mean weight changes.

[b] Group series deviated from protocol due to missexed animal.

[c] Weight change (%) = weight change (dosed group) minus weight change (control group) divided by weight change (control group) x 100.

Table IV: Dosage, Survival, and Mean Body Weights of Rats Administered Yellow 3 in the Diet for 13 Consecutive Weeks (Subchronic)

| | Dose (% of Diet) | Survival[a] (Week of Death) | Mean Body Weight | | | | | | Weight Change (%)[c] |
|---|---|---|---|---|---|---|---|---|---|
| | | | Initial | | Final | | Change | | |
| | | | $\bar{X}$ | SD | $\bar{X}$ | SD | $\bar{X}$ | SD | |
| Male | 0.00 | 14/15 (13) | 108 | 10 | 329 | 17 | 220 | 15 | - |
| | 0.13 | 19/19[b] | 109 | 15 | 313 | 18 | 202 | 12 | -8 |
| | 0.25 | 20/20 | 108 | 9 | 307 | 18 | 199 | 19 | -10 |
| | 0.50 | 19/20 (4) | 110 | 12 | 300 | 14 | 188 | 12 | -15 |
| | 1.00 | 18/19[b] (3) | 105 | 9 | 263 | 17 | 158 | 13 | -28 |
| Female | 0.00 | 15/15 | 86 | 8 | 188 | 18 | 102 | 15 | - |
| | 0.13 | 21/21[b] | 89 | 8 | 182 | 12 | 94 | 10 | -8 |
| | 0.25 | 20/20 | 88 | 8 | 176 | 11 | 88 | 10 | -14 |
| | 0.50 | 20/20 | 90 | 7 | 168 | 14 | 78 | 12 | -24 |
| | 1.00 | 21/21[b] | 85 | 8 | 148 | 12 | 63 | 9 | -38 |

[a]Number surviving/number initially in the group. Denominator represents "N" for initial body weight means; numerator represents "N" for final body weight means and mean weight changes.

[b]Group series deviated from protocol due to missexed animal.

[c]Weight change (%) = weight change (dosed group) minus weight change (control group) divided by weight change (control group) x 100.

Table V: Specification and Sources of Materials Used For Animal Maintenance

| Item | Specification | Source |
|---|---|---|
| Cages | Solid-Bottom Polycarbonate | Allentown Caging and Equipment Allentown, N.J. |
| Bedding | Shredded Aspen Bedding | American Excelsior Co. Annapolis Junction, Md. |
| Diets | Purina® Lab Chow #5001 | Ralston Purina Co., St. Louis, Mo. |
| Watering System | 16 oz. Glass Bottles<br>#8 Stoppers<br>2-1/2" S/S Sipper Tubes | Allentown Caging and Equipment Allentown, N.J. |

Table VI: Specification and Sources of Materials Used For Intratracheal and Dietary Preparation

| Item | Specification | Source |
|---|---|---|
| Weighing | Mettler p/11N/8<br>Mettler H33AR | Mettler Instrument Corp.<br>Hightston, N.J. |
| Saline | 0.9% Sodium Chloride;<br>Sterile, Pyrogenic | A.J. Buck and Sons<br>Cockeysville, Md. |
| Sonification | Model: W-220F | Ultrasonic Inc.<br>Plainview, New York |
| Stirring | Corning® Magnetic<br>Stirrer | Fischer Scientific Co.<br>Silver Spring, Md. |
| Corn Oil | Mazola® Corn Oil | Major Chain Food Store |
| Blender | Patterson-Kelly<br>Twinshell | The Patterson-Kelly Co., Inc.<br>East Stroudsburg, Pa. |
| Pelleting | CL Type 3 Pellet Mill | California Pellet Mill Co.<br>Crantorsville, Ind. |

TABLE VII

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

SURVIVAL[a] - ACID BLACK 52

| | INTRATRACHEAL | | | | | | | | DIETARY | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | MALE | | | | FEMALE | | | | MALE | | | | FEMALE | | | |
| GROUP | 1 | 5 | 2 | 7 | 1 | 5 | 2 | 7 | 9 | 13 | 10 | 15 | 9 | 13 | 10 | 15 |
| SPECIES (TREATMENT)[b] | H(T) | H(C) | R(T) | R(C) | H(T) | H(C) | R(T) | R(C) | H(T) | H(C) | R(T) | R(C) | H(T) | H(C) | R(T) | R(C) |
| DOSE LEVEL[c] | 0.75 | 0 | 0.32 | 0 | 0.75 | 0 | 0.32 | 0 | 2.0 | 0 | 2.0 | 0 | 2.0 | 0 | 2.0 | 0 |
| Week | | | | | | | | | | | | | | | | |
| 1 | 50 | 35 | 50 | 35 | 50 | 35 | 50 | 35 | 50 | 35 | 49 | 35 | 50 | 35 | 50 | 35 |
| 2 | 50 | 35 | 50 | 35 | 50 | 35 | 50 | 35 | 47 | 35 | 49 | 35 | 47 | 35 | 50 | 35 |
| 3 | 50 | 35 | 49 | 35 | 50 | 35 | 50 | 35 | 45 | 35 | 49 | 35 | 44 | 35 | 50 | 35 |
| 4 | 50 | 35 | 49 | 35 | 49 | 35 | 50 | 35 | 45 | 35 | 49 | 35 | 44 | 35 | 50 | 35 |
| 5 | 50 | 35 | 49 | 35 | 49 | 35 | 50 | 34 | 44 | 35 | 49 | 35 | 38 | 35 | 50 | 35 |
| 6 | 50 | 35 | 49 | 35 | 48 | 35 | 50 | 34 | 44 | 35 | 49 | 35 | 38 | 35 | 50 | 35 |
| 7 | 50 | 35 | 49 | 35 | 48 | 35 | 50 | 34 | 42 | 35 | 49 | 35 | 37 | 35 | 50 | 35 |
| 8 | 50 | 35 | 49 | 35 | 47 | 35 | 50 | 34 | 42 | 35 | 49 | 35 | 37 | 35 | 50 | 35 |
| 9 | 50 | 35 | 49 | 35 | 47 | 35 | 50 | 34 | 40 | 35 | 49 | 35 | 37 | 35 | 50 | 35 |
| 10 | 50 | 35 | 49 | 35 | 47 | 35 | 49 | 34 | 40 | 35 | 49 | 35 | 37 | 35 | 50 | 35 |
| 11 | 50 | 35 | 49 | 35 | 47 | 35 | 49 | 34 | 40 | 35 | 49 | 35 | 37 | 35 | 50 | 35 |
| 12 | 50 | 35 | 49 | 35 | 47 | 35 | 49 | 34 | 40 | 35 | 49 | 35 | 37 | 35 | 50 | 35 |
| 13 | 50 | 35 | 49 | 35 | 47 | 35 | 49 | 34 | 40 | 35 | 49 | 35 | 37 | 35 | 50 | 35 |
| 14 | 50 | 35 | 49 | 34 | 47 | 35 | 49 | 34 | 40 | 35 | 49 | 35 | 37 | 35 | 50 | 35 |
| 15 | 50 | 35 | 49 | 34 | 47 | 35 | 49 | 34 | 40 | 35 | 49 | 35 | 36 | 35 | 50 | 35 |
| 16 | 50 | 35 | 49 | 34 | 47 | 35 | 48 | 34 | 40 | 35 | 49 | 35 | 36 | 35 | 50 | 35 |
| 17 | 50 | 35 | 49 | 34 | 47 | 35 | 48 | 34 | 40 | 35 | 49 | 35 | 36 | 35 | 50 | 35 |
| 18 | 50 | 35 | 49 | 34 | 47 | 35 | 48 | 34 | 40 | 35 | 49 | 35 | 36 | 35 | 50 | 35 |
| 19 | 50 | 35 | 49 | 34 | 47 | 35 | 48 | 34 | 40 | 35 | 49 | 35 | 36 | 35 | 50 | 35 |
| 20 | 50 | 35 | 49 | 34 | 47 | 35 | 48 | 34 | 40 | 35 | 49 | 35 | 36 | 35 | 50 | 35 |
| 21 | 50 | 35 | 49 | 34 | 47 | 35 | 48 | 34 | 40 | 35 | 49 | 35 | 36 | 35 | 50 | 35 |
| 22 | 50 | 34 | 49 | 34 | 47 | 35 | 48 | 34 | 40 | 35 | 49 | 35 | 35 | 35 | 50 | 35 |
| 23 | 49 | 34 | 49 | 34 | 47 | 35 | 48 | 34 | 40 | 35 | 48 | 35 | 35 | 35 | 50 | 35 |
| 24 | 49 | 34 | 49 | 34 | 47 | 35 | 48 | 34 | 40 | 35 | 48 | 35 | 35 | 35 | 50 | 35 |
| 25 | 49 | 33 | 49 | 34 | 47 | 35 | 48 | 34 | 40 | 35 | 48 | 35 | 35 | 35 | 50 | 35 |
| 26 | 49 | 33 | 49 | 34 | 47 | 35 | 48 | 34 | 40 | 35 | 48 | 35 | 35 | 35 | 50 | 35 |
| 27 | 49 | 33 | 49 | 34 | 47 | 35 | 48 | 34 | 40 | 35 | 48 | 35 | 35 | 35 | 50 | 35 |
| 28 | 49 | 32 | 49 | 34 | 47 | 35 | 48 | 34 | 40 | 35 | 48 | 35 | 35 | 35 | 50 | 35 |
| 29 | 49 | 32 | 49 | 34 | 47 | 35 | 48 | 34 | 40 | 35 | 48 | 35 | 35 | 35 | 50 | 35 |
| 30 | 49 | 32 | 49 | 34 | 47 | 35 | 48 | 34 | 40 | 35 | 48 | 35 | 35 | 35 | 50 | 35 |
| 31 | 49 | 32 | 49 | 34 | 47 | 35 | 48 | 34 | 40 | 35 | 48 | 35 | 35 | 34 | 50 | 35 |
| 32 | 49 | 32 | 49 | 34 | 47 | 35 | 48 | 34 | 40 | 35 | 48 | 35 | 35 | 34 | 50 | 35 |
| 33 | 48 | 32 | 49 | 34 | 47 | 35 | 48 | 34 | 40 | 35 | 48 | 35 | 34 | 34 | 50 | 35 |

[a] Number of animals alive on the last day of each week.

[b] Species: Hamster = H, Rat = R; (Treatment): Treated = (T), Control = (C).

[c] Intratracheal doses administered as mg/0.2 ml saline; control animals received 0.2 ml saline without dye. Dietary doses administered as % of total diet; all diets were prepared with 1.3% w/w Mazola® corn oil and control diets consisted of meal plus corn oil (1.3%).

TABLE VII

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

SURVIVAL[a] - ACID BLACK 52

| | INTRATRACHEAL | | | | | | | | DIETARY | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | MALE | | | | FEMALE | | | | MALE | | | | FEMALE | | | |
| GROUP | 1 | 5 | 2 | 7 | 1 | 5 | 2 | 7 | 9 | 13 | 10 | 15 | 9 | 13 | 10 | 15 |
| SPECIES (TREATMENT)[b] | H(T) | H(C) | R(T) | R(C) | H(T) | H(C) | R(T) | R(C) | H(T) | H(C) | R(T) | R(C) | H(T) | H(C) | R(T) | R(C) |
| DOSE LEVEL[c] | 0.75 | 0 | 0.32 | 0 | 0.75 | 0 | 0.32 | 0 | 2.0 | 0 | 2.0 | 0 | 2.0 | 0 | 2.0 | 0 |
| Week | | | | | | | | | | | | | | | | |
| 34 | 48 | 32 | 49 | 34 | 47 | 35 | 48 | 34 | 40 | 35 | 48 | 35 | 34 | 34 | 50 | 35 |
| 35 | 48 | 32 | 49 | 34 | 47 | 35 | 48 | 34 | 40 | 35 | 48 | 35 | 34 | 34 | 50 | 35 |
| 36 | 47 | 32 | 49 | 34 | 47 | 35 | 48 | 34 | 40 | 35 | 48 | 35 | 34 | 34 | 50 | 35 |
| 37 | 47 | 31 | 49 | 34 | 47 | 35 | 48 | 34 | 40 | 35 | 48 | 35 | 34 | 34 | 50 | 35 |
| 38 | 47 | 31 | 49 | 34 | 47 | 35 | 48 | 34 | 40 | 35 | 48 | 35 | 34 | 34 | 50 | 35 |
| 39 | 47 | 31 | 49 | 34 | 47 | 35 | 48 | 34 | 40 | 35 | 48 | 35 | 34 | 34 | 50 | 35 |
| 40 | 46 | 31 | 48 | 34 | 47 | 35 | 48 | 34 | 40 | 35 | 48 | 35 | 34 | 34 | 50 | 35 |
| 41 | 46 | 31 | 48 | 34 | 47 | 35 | 48 | 34 | 40 | 35 | 48 | 35 | 34 | 33 | 50 | 35 |
| 42 | 46 | 31 | 48 | 34 | 47 | 35 | 48 | 34 | 40 | 35 | 48 | 35 | 34 | 33 | 50 | 35 |
| 43 | 46 | 31 | 48 | 34 | 47 | 35 | 48 | 34 | 40 | 35 | 48 | 35 | 34 | 33 | 50 | 35 |
| 44 | 45 | 30 | 48 | 34 | 47 | 34 | 48 | 34 | 40 | 34 | 48 | 35 | 33 | 33 | 50 | 35 |
| 45 | 44 | 28 | 48 | 34 | 46 | 34 | 48 | 34 | 39 | 34 | 48 | 35 | 33 | 33 | 50 | 35 |
| 46 | 44 | 28 | 48 | 34 | 45 | 34 | 48 | 34 | 39 | 34 | 48 | 35 | 33 | 33 | 50 | 35 |
| 47 | 44 | 28 | 48 | 34 | 45 | 34 | 48 | 34 | 39 | 34 | 47 | 35 | 33 | 32 | 50 | 35 |
| 48 | 43 | 28 | 48 | 34 | 45 | 33 | 48 | 34 | 38 | 34 | 47 | 35 | 32 | 32 | 50 | 35 |
| 49 | 43 | 28 | 48 | 34 | 45 | 33 | 48 | 34 | 38 | 34 | 47 | 35 | 31 | 32 | 50 | 35 |
| 50 | 43 | 28 | 48 | 34 | 44 | 32 | 48 | 34 | 37 | 34 | 47 | 35 | 31 | 32 | 50 | 35 |
| 51 | 43 | 27 | 48 | 34 | 44 | 28 | 48 | 34 | 37 | 34 | 47 | 35 | 31 | 31 | 50 | 35 |
| 52 | 42 | 26 | 48 | 34 | 44 | 28 | 48 | 34 | 37 | 33 | 47 | 35 | 31 | 31 | 50 | 35 |
| 53 | 42 | 26 | 48 | 34 | 44 | 28 | 48 | 34 | 37 | 33 | 47 | 35 | 31 | 31 | 50 | 35 |
| 54 | 42 | 25 | 48 | 34 | 44 | 27 | 48 | 34 | 37 | 33 | 47 | 35 | 31 | 31 | 50 | 35 |
| 55 | 42 | 25 | 48 | 34 | 42 | 25 | 48 | 34 | 37 | 33 | 47 | 35 | 30 | 31 | 49 | 35 |
| 56 | 42 | 25 | 48 | 34 | 42 | 25 | 48 | 34 | 37 | 32 | 47 | 35 | 30 | 31 | 49 | 35 |
| 57 | 42 | 25 | 48 | 34 | 42 | 24 | 47 | 34 | 37 | 32 | 47 | 35 | 30 | 31 | 49 | 35 |
| 58 | 42 | 25 | 48 | 34 | 42 | 24 | 47 | 34 | 37 | 32 | 47 | 34 | 30 | 30 | 49 | 35 |
| 59 | 42 | 25 | 48 | 34 | 42 | 24 | 47 | 34 | 37 | 32 | 47 | 34 | 30 | 30 | 49 | 35 |
| 60 | 42 | 25 | 48 | 33 | 42 | 24 | 47 | 34 | 37 | 29 | 47 | 34 | 30 | 30 | 49 | 35 |
| 61 | 42 | 25 | 48 | 33 | 42 | 23 | 47 | 34 | 36 | 29 | 47 | 34 | 30 | 30 | 49 | 35 |
| 62 | 42 | 25 | 48 | 33 | 41 | 23 | 47 | 34 | 36 | 29 | 47 | 34 | 30 | 30 | 49 | 35 |
| 63 | 42 | 25 | 48 | 32 | 41 | 23 | 47 | 34 | 36 | 29 | 47 | 34 | 29 | 29 | 49 | 35 |
| 64 | 42 | 25 | 48 | 32 | 40 | 22 | 47 | 34 | 35 | 29 | 47 | 34 | 28 | 28 | 49 | 35 |
| 65 | 42 | 25 | 48 | 32 | 39 | 21 | 47 | 34 | 34 | 28 | 47 | 34 | 28 | 26 | 49 | 35 |
| 66 | 42 | 25 | 48 | 32 | 38 | 20 | 47 | 34 | 33 | 28 | 47 | 34 | 26 | 26 | 49 | 35 |

[a] Number of animals alive on the last day of each week.

[b] Species: Hamster = H, Rat = R; (Treatment): Treated = (T), Control = (C).

[c] Intratracheal doses administered as mg/0.2 ml saline; control animals received 0.2 ml saline without dye. Dietary doses administered as % of total diet; all diets were prepared with 1.3% w/w Mazola® corn oil and control diets consisted of meal plus corn oil (1.3%).

TABLE VII

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

SURVIVAL[a] - ACID BLACK 52

| | INTRATRACHEAL | | | | | | | | DIETARY | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | MALE | | | | FEMALE | | | | MALE | | | | FEMALE | | | |
| GROUP | 1 | 5 | 2 | 7 | 1 | 5 | 2 | 7 | 9 | 13 | 10 | 15 | 9 | 13 | 10 | 15 |
| SPECIES (TREATMENT)[b] | H(T) | H(C) | R(T) | R(C) | H(T) | H(C) | R(T) | R(C) | H(T) | H(C) | R(T) | R(C) | H(T) | H(C) | R(T) | R(C) |
| DOSE LEVEL[c] | 0.75 | 0 | 0.32 | 0 | 0.75 | 0 | 0.32 | 0 | 2.0 | 0 | 2.0 | 0 | 2.0 | 0 | 2.0 | 0 |
| Week | | | | | | | | | | | | | | | | |
| 67 | 42 | 25 | 48 | 31 | 37 | 19 | 47 | 34 | 33 | 28 | 46 | 34 | 24 | 26 | 49 | 35 |
| 68 | 42 | 25 | 48 | 31 | 37 | 19 | 47 | 34 | 33 | 28 | 46 | 34 | 23 | 26 | 49 | 35 |
| 69 | 41 | 25 | 48 | 30 | 34 | 17 | 47 | 34 | 33 | 28 | 44 | 34 | 22 | 24 | 49 | 35 |
| 70 | 41 | 25 | 48 | 30 | 34 | 17 | 47 | 33 | 33 | 28 | 43 | 34 | 22 | 22 | 49 | 34 |
| 71 | 41 | 25 | 48 | 30 | 33 | 16 | 47 | 33 | 33 | 28 | 43 | 34 | 22 | 21 | 48 | 34 |
| 72 | 39 | 25 | 48 | 30 | 32 | 16 | 47 | 33 | 33 | 28 | 43 | 34 | 22 | 21 | 48 | 34 |
| 73 | 39 | 24 | 48 | 30 | 32 | 16 | 47 | 33 | 33 | 27 | 43 | 34 | 22 | 21 | 48 | 34 |
| 74 | 38 | 24 | 48 | 30 | 31 | 16 | 47 | 33 | 32 | 27 | 43 | 33 | 20 | 21 | 48 | 34 |
| 75 | 38 | 24 | 48 | 30 | 31 | 15 | 47 | 33 | 32 | 27 | 43 | 33 | 19 | 19 | 48 | 34 |
| 76 | 38 | 23 | 48 | 30 | 30 | 15 | 47 | 33 | 31 | 27 | 43 | 33 | 19 | 19 | 48 | 34 |
| 77 | 38 | 23 | 48 | 30 | 30 | 15 | 47 | 32 | 31 | 27 | 42 | 33 | 19 | 19 | 48 | 34 |
| 78 | 37 | 23 | 48 | 30 | 29 | 15 | 47 | 32 | 29 | 27 | 42 | 33 | 19 | 18 | 48 | 34 |
| 79 | 37 | 23 | 48 | 30 | 27 | 15 | 47 | 31 | 29 | 27 | 41 | 33 | 19 | 17 | 48 | 34 |
| 80 | 36 | 23 | 48 | 30 | 26 | 15 | 47 | 31 | 29 | 26 | 41 | 33 | 18 | 17 | 46 | 34 |
| 81 | 36 | 23 | 48 | 30 | 26 | 15 | 47 | 31 | 26 | 26 | 37 | 33 | 16 | 17 | 46 | 33 |
| 82 | 36 | 23 | 48 | 30 | 24 | 15 | 47 | 31 | 25 | 25 | 35 | 33 | 16 | 16 | 46 | 33 |
| 83 | 34 | 23 | 48 | 30 | 24 | 15 | 47 | 31 | 25 | 25 | 35 | 33 | 15 | 15 | 46 | 33 |
| 84 | 34 | 23 | 48 | 30 | 22 | 14 | 47 | 31 | 24 | 24 | 34 | 33 | 15 | 14 | 46 | 33 |
| 85 | 33 | 23 | 48 | 30 | 22 | 13 | 46 | 31 | 24 | 23 | 33 | 32 | 15 | 14 | 46 | 33 |
| 86 | 33 | 23 | 47 | 30 | 22 | 13 | 46 | 31 | 23 | 23 | 33 | 31 | 14 | 14 | 46 | 33 |
| 87 | 32 | 23 | 46 | 30 | 21 | 13 | 46 | 31 | 22 | 23 | 30 | 31 | 13 | 12 | 46 | 33 |
| 88 | 31 | 22 | 46 | 30 | 21 | 13 | 44 | 31 | 22 | 23 | 30 | 31 | 11 | 12 | 45 | 32 |
| 89 | 30 | 21 | 45 | 30 | 20 | 11 | 44 | 31 | 22 | 23 | 30 | 31 | 11 | 12 | 45 | 31 |
| 90 | 28 | 20 | 45 | 30 | 18 | 11 | 44 | 30 | 22 | 23 | 29 | 31 | 9 | 10 | 44 | 31 |
| 91 | 26 | 18 | 45 | 30 | 14 | 9 | 43 | 30 | 22 | 21 | 29 | 31 | 9 | 9 | 44 | 31 |
| 92 | 26 | 17 | 45 | 30 | 13 | 9 | 43 | 30 | 22 | 21 | 28 | 30 | 9 | 9 | 43 | 30 |
| 93 | 26 | 16 | 45 | 30 | 12 | 8 | 41 | 30 | 21 | 20 | 26 | 30 | 8 | 8 | 43 | 30 |
| 94 | 26 | 15 | 45 | 30 | 12 | 8 | 41 | 30 | 21 | 20 | 25 | 29 | 6 | 8 | 43 | 30 |
| 95 | 26 | 15 | 44 | 30 | 11 | 7 | 41 | 29 | 21 | 19 | 25 | 29 | 5 | 5 | 43 | 30 |
| 96 | 26 | 15 | 44 | 30 | 10 | 7 | 41 | 29 | 21 | 19 | 24 | 29 | 0[d] | 0[d] | 43 | 30 |
| 97 | 26 | 14 | 44 | 30 | 8 | 7 | 41 | 29 | 16 | 18 | 21 | 29 | | | 42 | 29 |

[a] Number of animals alive on the last day of each week.

[b] Species: Hamster = H, Rat = R; (Treatment): Treated = (T), Control = (C).

[c] Intratracheal doses administered as mg/0.2 ml saline; control animals received 0.2 ml saline without dye. Dietary doses administered as % of total diet; all diets were prepared with 1.3% w/w Mazola® corn oil and control diets consisted of meal plus corn oil (1.3%).

[d] "0" indicates week of terminal sacrifice for the indicated group, sex and species.

TABLE VII

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

SURVIVAL[a] - ACID BLACK 52

| | INTRATRACHEAL | | | | | | | | DIETARY | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | MALE | | | | FEMALE | | | | MALE | | | | FEMALE | | | |
| GROUP | 1 | 5 | 2 | 7 | 1 | 5 | 2 | 7 | 9 | 13 | 10 | 15 | 9 | 13 | 10 | 15 |
| SPECIES (TREATMENT)[b] | H(T) | H(C) | R(T) | R(C) | H(T) | H(C) | R(T) | R(C) | H(T) | H(C) | R(T) | R(C) | H(T) | H(C) | R(T) | R(C) |
| DOSE LEVEL[c] | 0.75 | 0 | 0.32 | 0 | 0.75 | 0 | 0.32 | 0 | 2.0 | 0 | 2.0 | 0 | 2.0 | 0 | 2.0 | 0 |
| Week | | | | | | | | | | | | | | | | |
| 98 | 26 | 14 | 44 | 29 | 7 | 7 | 39 | 29 | 16 | 18 | 21 | 29 | - | - | 42 | 29 |
| 99 | 26 | 13 | 43 | 28 | 5 | 7 | 38 | 29 | 16 | 16 | 21 | 28 | - | - | 41 | 28 |
| 100 | 25 | 13 | 43 | 27 | 4 | 6 | 38 | 29 | 15 | 15 | 19 | 28 | - | - | 41 | 27 |
| 101 | 25 | 13 | 43 | 27 | 4 | 3 | 38 | 29 | 15 | 15 | 18 | 28 | - | - | 40 | 27 |
| 102 | 23 | 13 | 42 | 27 | 3 | 2 | 38 | 29 | 14 | 15 | 17 | 28 | - | - | 40 | 27 |
| 103 | 22 | 12 | 41 | 27 | 0[d] | 0[d] | 36 | 29 | 14[l] | 15 | 11[l] | 27 | - | - | 40 | 27 |
| 104 | 22 | 12 | 38 | 27 | | | 36 | 25 | 12 | 14 | 9 | 27 | - | - | 38 | 27 |
| 105 | 21 | 11 | 38 | 27 | | | 36 | 24 | 10 | 14 | 7 | 26 | - | - | 36 | 26 |
| 106 | 21 | 11 | 37 | 27 | | | 36 | 24 | 10 | 14 | 6 | 25 | - | - | 36 | 26 |
| 107 | 18 | 10 | 36 | 25 | | | 35 | 24 | 7 | 12 | 5 | 25 | - | - | 36 | 26 |
| 108 | 18 | 10 | 35 | 24 | | | 35 | 24 | 7 | 11 | 5 | 25 | - | - | 35 | 25 |
| 109 | 18 | 10 | 35 | 24 | | | 35 | 24 | 6 | 11 | 0[d] | 0[d] | - | - | 34 | 24 |
| 110 | 16 | 10 | 32 | 24 | | | 35 | 23 | 0[d] | 11 | | | | | 33 | 23 |
| 111 | 16 | 8 | 31 | 22 | | | 34 | 22 | | 0[d] | | | | | 31 | 23 |
| 112 | 15 | 7 | 30 | 20 | | | 34 | 22 | | | | | | | 31 | 23 |
| 113 | 14 | 7 | 28 | 20 | | | 33 | 21 | | | | | | | 30 | 23 |
| 114 | 9 | 6 | 26 | 20 | | | 32 | 21 | | | | | | | 30 | 22 |
| 115 | 9 | 4 | 22 | 20 | | | 32 | 18 | | | | | | | 29 | 22 |
| 116 | 8 | 4 | 22 | 17 | | | 31 | 18 | | | | | | | 29 | 21 |
| 117 | 0[d] | 0[d] | 0[d] | 0[d] | | | 0[d] | 0[l] | | | | | | | 0[d] | 0[d] |

[a] Number of animals alive on the last day of each week.

[b] Species: Hamster = H, Rat = R; (Treatment): Treated = (T), Control = (C).

[c] Intratracheal doses administered as mg/0.2 ml saline; control animals received 0.2 ml saline without dye. Dietary doses administered as % of total diet; all diets were prepared with 1.3% w/w Mazola® corn oil and control diets consisted of meal plus corn oil (1.3%).

[d] "0" indicates week of terminal sacrifice for the indicated group, sex and species.

FIGURE 7
CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTER AND RATS
ACID BLACK 52 - HAMSTERS
MALES

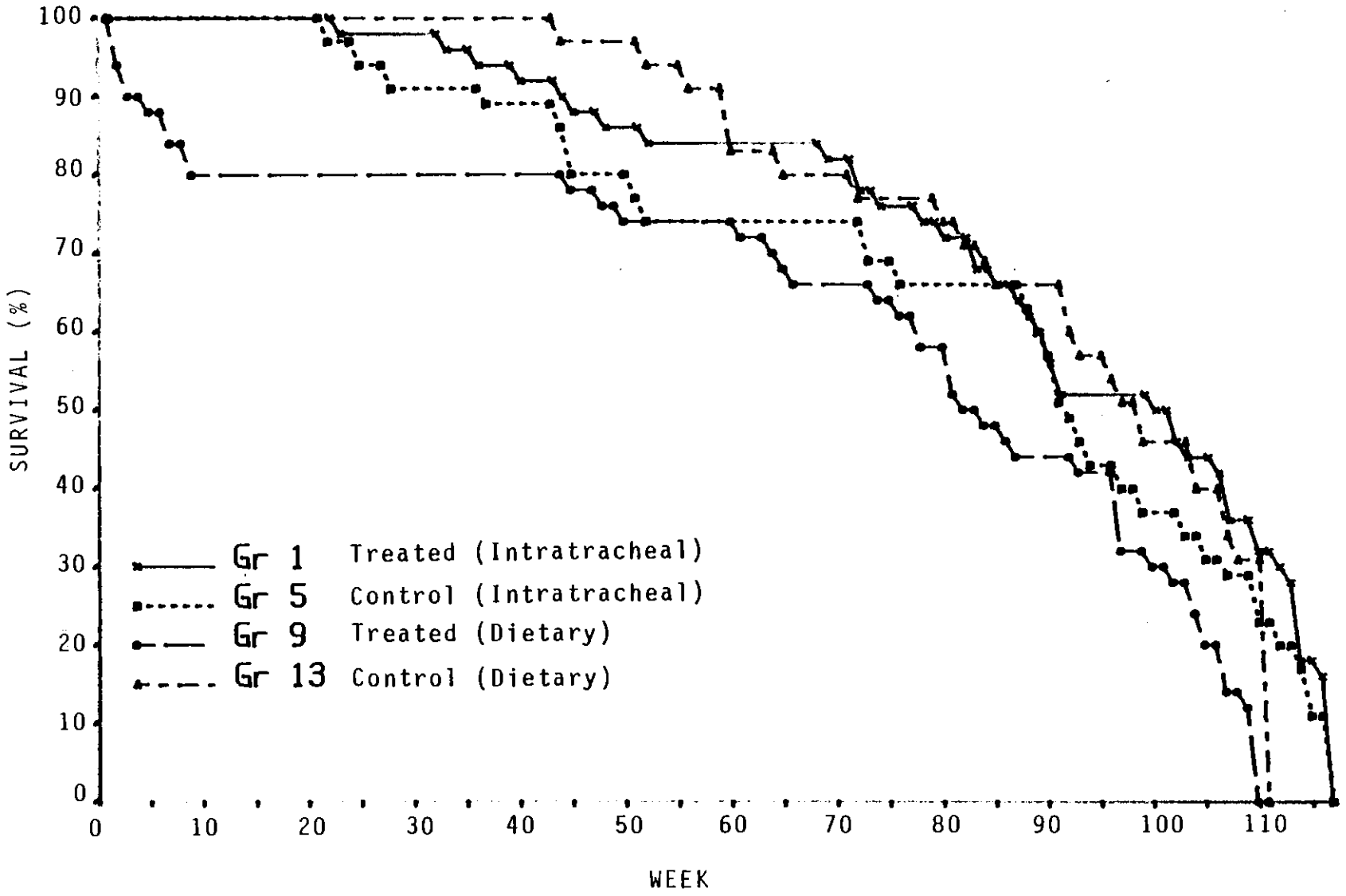

FIGURE 7
CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTER AND RATS
ACID BLACK 52 - HAMSTERS
FEMALES

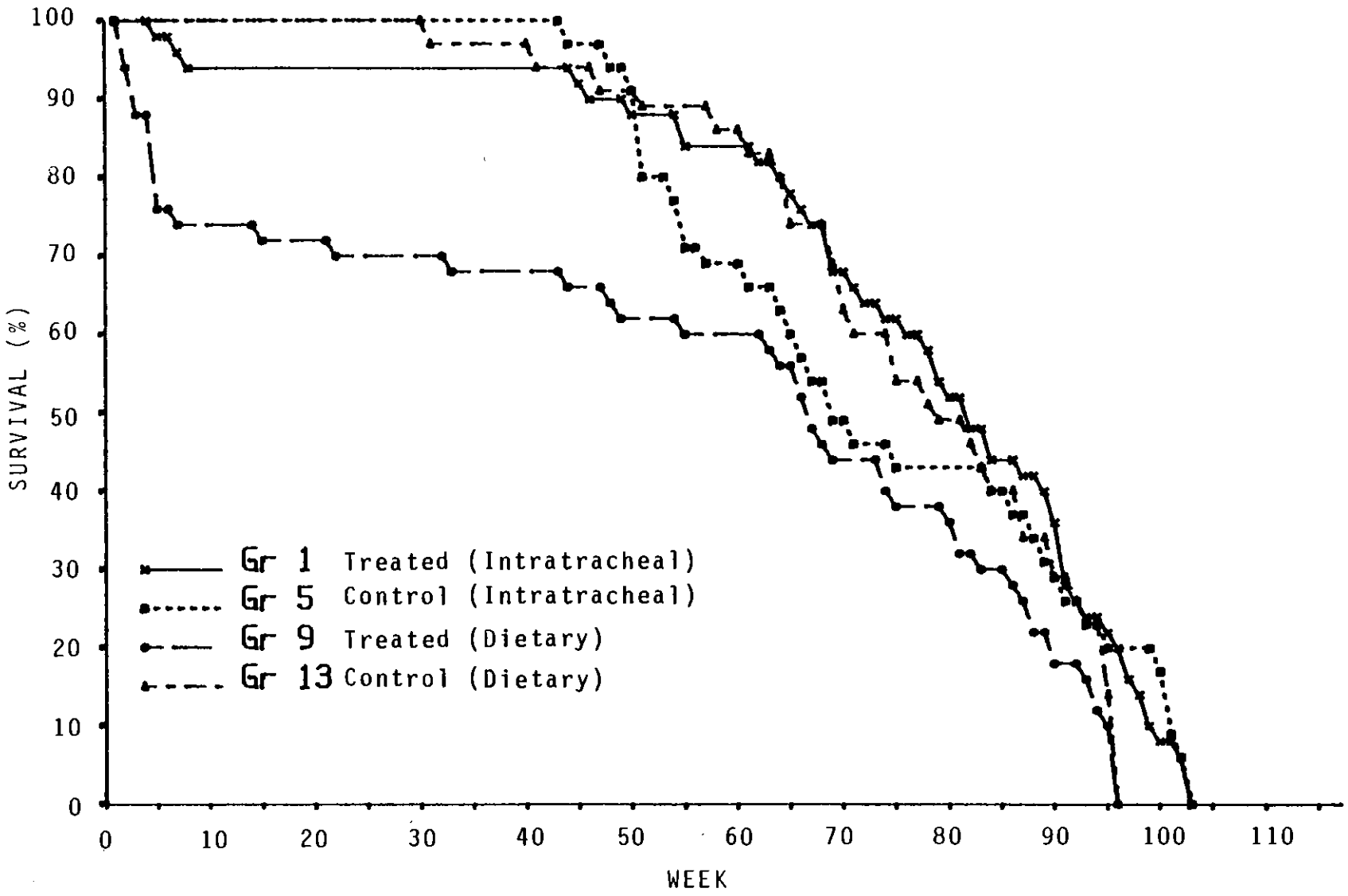

FIGURE 7
CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTER AND RATS
ACID BLACK 52 - RATS
MALES

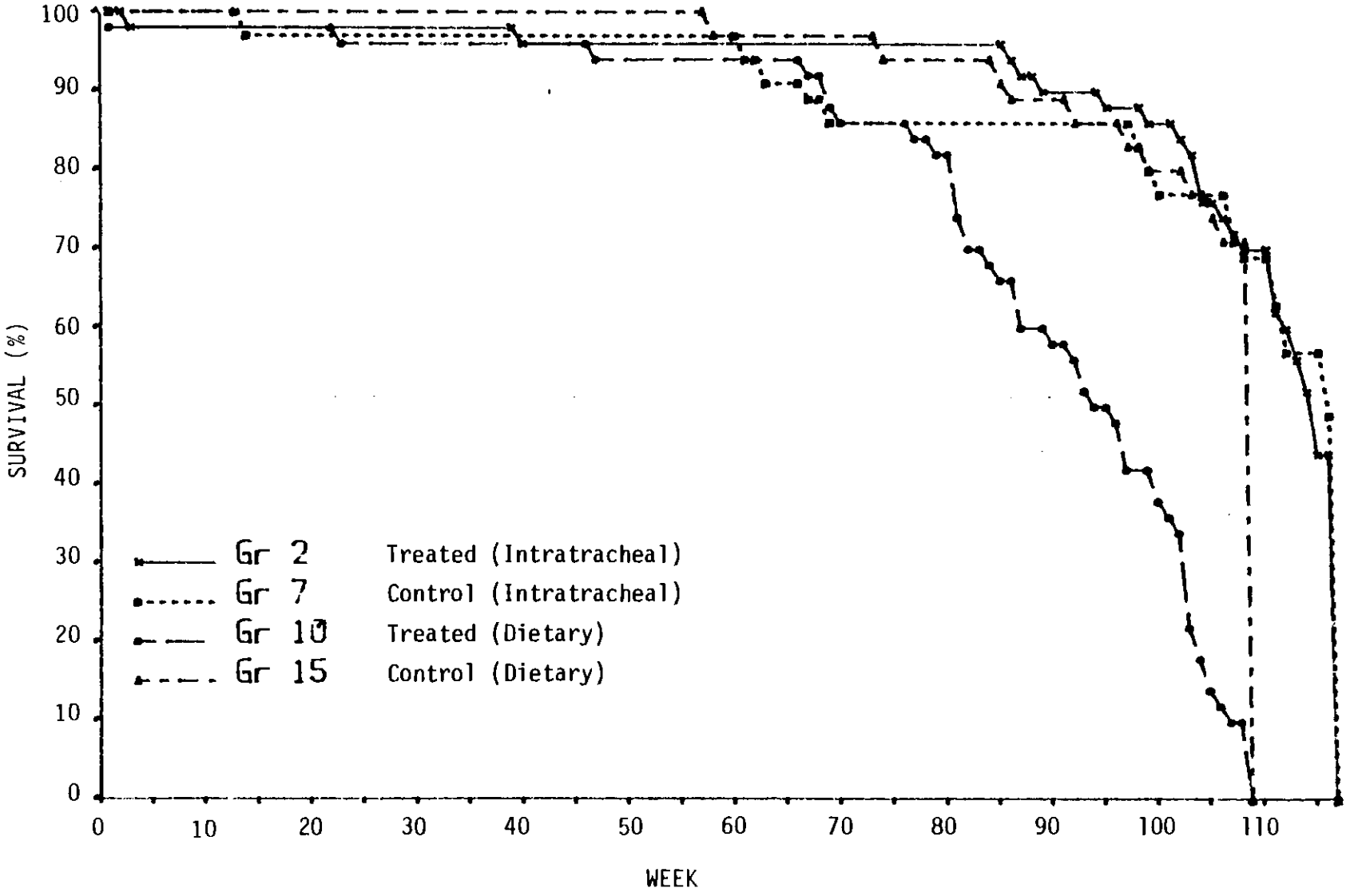

FIGURE 7
CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTER AND RATS
ACID BLACK 52 - RATS
FEMALES

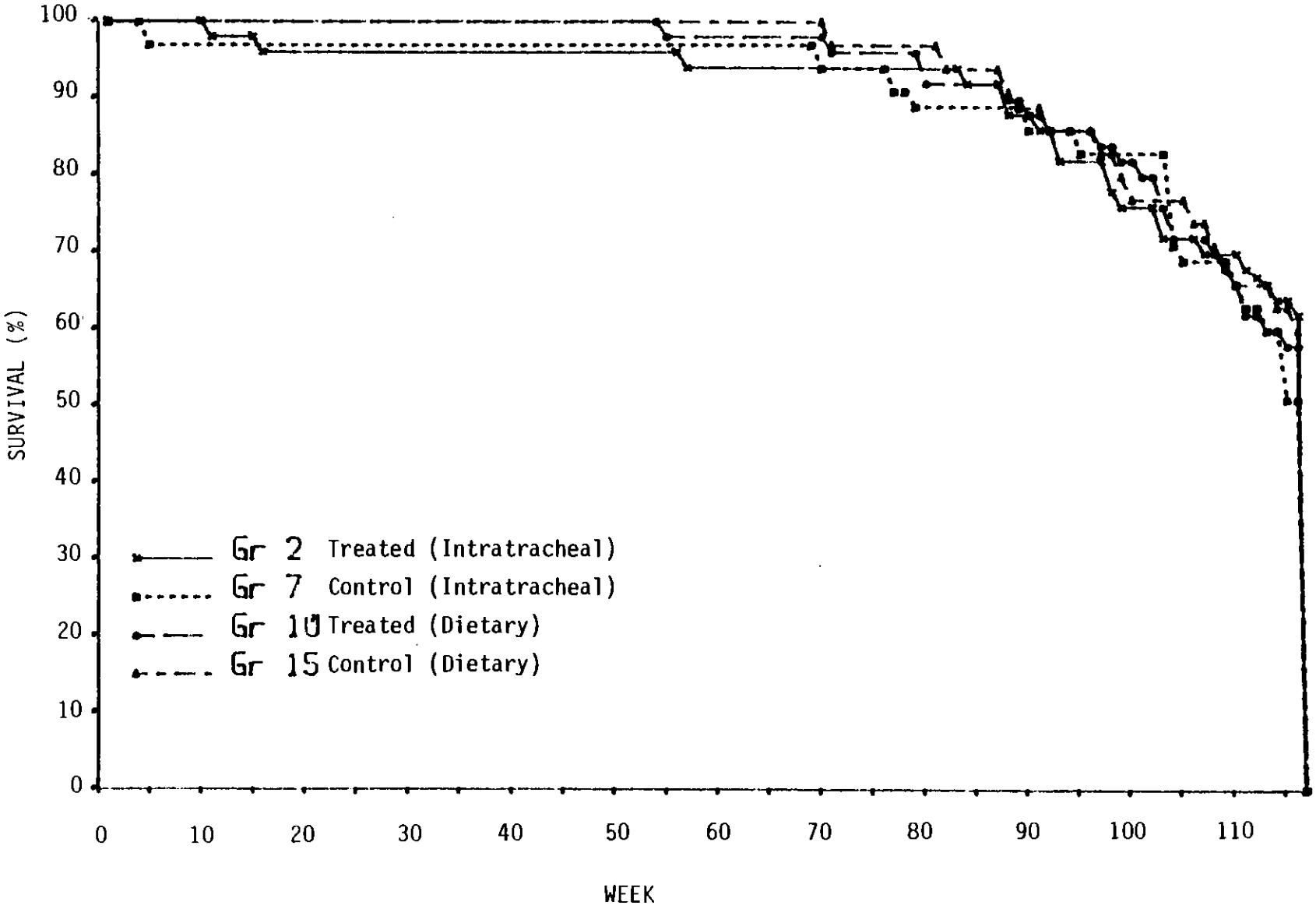

TABLE VIII

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

MEAN BODY WEIGHT DATA WITH STANDARD DEVIATIONS[a]
ACID BLACK 52 - INTRATRACHEAL INSTILLATION

| GROUP | MALES | | | | FEMALES | | | |
|---|---|---|---|---|---|---|---|---|
| | 1 | 5 | 2 | 7 | 1 | 5 | 2 | 7 |
| SPECIES (TREATMENT)[b] | H(T) | H(C) | R(T) | R(C) | H(T) | H(C) | R(T) | R(C) |
| DOSE LEVEL (mg)[c] | 0.75 | 0 | 0.32 | 0 | 0.75 | 0 | 0.32 | 0 |
| Week | | | | | | | | |
| 1 | 82(10) | 79(8) | 110(11) | 110(8) | 79(9) | 83(6) | 93(7) | 96(7) |
| 5 | 93(10) | 94(11) | 236(14) | 236(14) | 95(11) | 107(13) | 154(8) | 157(8) |
| 9 | 101(12) | 105(11) | 283(19) | 285(22) | 106(11) | 120(15) | 174(10) | 179(10) |
| 13 | 113(14) | 117(14) | 304(23) | 307(20) | 116(14) | 133(19) | 181(11) | 187(10) |
| 18 | 117(15) | 120(14) | 326(24) | 330(20) | 121(15) | 130(20) | 195(14) | 201(12) |
| 22 | 121(14) | 122(15) | 347(27) | 349(23) | 126(15) | 130(20) | 208(12) | 213(12) |
| 27 | 120(17) | 119(18) | 367(25) | 366(28) | 125(13) | 120(22) | 217(12) | 222(13) |
| 31 | 122(16) | 122(16) | 376(25) | 376(27) | 126(15) | 123(19) | 222(14) | 225(15) |
| 36 | 128(15) | 127(15) | - | - | 126(16) | 124(20) | - | - |
| 37 | - | - | 391(31) | 394(29) | - | - | 235(16) | 239(16) |
| 40 | 131(15) | 129(15) | 398(29) | 396(30) | 126(17) | 123(15) | 238(19) | 241(17) |
| 44 | 134(14) | 132(15) | - | - | 129(16) | 127(19) | - | - |
| 45 | - | - | 407(29) | 404(29) | - | - | 245(19) | 251(19) |
| 49 | 137(14) | 134(19) | 413(26) | 409(33) | 134(21) | 129(20) | 251(20) | 258(22) |
| 53 | 135(15) | 135(17) | 416(26) | 418(31) | 135(27) | 128(20) | 259(21) | 266(23) |
| 57 | 137(15) | 135(16) | - | - | 129(20) | 131(18) | - | - |
| 59 | - | - | 423(29) | 423(38) | - | - | 268(23) | 276(27) |
| 62 | 134(17) | 132(16) | 422(28) | 426(19) | 127(18) | 127(19) | 270(22) | 278(28) |
| 66 | 131(17) | 130(13) | - | - | 130(16) | 128(16) | - | - |
| 67 | - | - | 410(29) | 423(25) | - | - | 270(23) | 277(26) |
| 70 | 128(15) | 127(14) | - | - | 129(14) | 124(17) | - | - |
| 71 | - | - | 423(29) | 431(28) | - | - | 275(23) | 282(24) |
| 75 | 123(16) | 126(16) | 429(29) | 441(28) | 124(21) | 120(17) | 282(26) | 294(28) |
| 79 | 130(14) | 128(17) | 435(30) | 445(28) | 123(18) | 118(19) | 290(26) | 295(39) |
| 83 | 132(16) | 132(14) | - | - | 120(19) | 119(27) | - | - |
| 84 | - | - | 433(35) | 447(28) | - | - | 297(29) | 307(30) |
| 87 | 135(14) | 134(15) | - | - | 121(21) | 116(18) | - | - |
| 88 | - | - | 433(35) | 440(37) | - | - | 297(38) | 311(36) |
| 92 | 135(15) | 137(13) | - | - | 119(14) | 116(22) | - | - |
| 93 | - | - | 437(36) | 447(30) | - | - | 307(41) | 325(32) |
| 96 | 135(18) | 138(11) | - | - | 122(13) | 119(21) | - | - |

[a] Data are presented as mean (S.D.); data are in grams.

[b] Species: Hamster = H, Rat = R; (Treatment): Treated = (T), Control = (C).

[c] All doses administered in 0.2 ml saline suspensions; control animals received 0.2 ml saline without dye.

"-" Body weight not required at this week for the indicated group and species.

TABLE VIII

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

MEAN BODY WEIGHT DATA WITH STANDARD DEVIATIONS[a]
ACID BLACK 52 - INTRATRACHEAL INSTILLATION

| | MALES | | | | FEMALES | | | |
|---|---|---|---|---|---|---|---|---|
| GROUP | 1 | 5 | 2 | 7 | 1 | 5 | 2 | 7 |
| SPECIES (TREATMENT)[b] | H(T) | H(C) | R(T) | R(C) | H(T) | H(C) | R(T) | R(C) |
| DOSE LEVEL (mg)[c] | 0.75 | 0 | 0.32 | 0 | 0.75 | 0 | 0.32 | 0 |
| Week | | | | | | | | |
| 97 | - | - | 437(42) | 446(29) | - | - | 315(47) | 332(32) |
| 101 | 137(15) | 140(12) | 424(45) | 445(25) | 123(18)[d] | 122(39)[d] | 320(35) | 332(32) |
| 104 | 136(15) | 143(8) | - | - | | | - | - |
| 106 | - | 142(10) | 417(42) | 418(38) | | | 314(38) | 330(24) |
| 109 | 129(14) | - | - | - | | | - | - |
| 111 | - | - | 392(40) | 405(38) | | | 296(41) | 327(13) |
| 114 | 120(21) | 129(14) | - | - | | | - | - |
| 117 | 122(19)[d] | 134(7)[d] | 343(34)[d] | 343(40)[d] | | | 278(43)[d] | 290(33)[d] |

[a] Data are presented as mean (S.D.); data are in grams.

[b] Species: Hamster = H, Rat = R; (Treatment): Treated = (T), Control = (C).

[c] All doses administered in 0.2 ml saline suspensions; control animals received 0.2 ml saline without dye.

"-" Body weight not required at this week for the indicated group and species.

[d] Represents last body weight interval prior to terminal sacrifice.

TABLE VIII

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

MEAN BODY WEIGHT DATA WITH STANDARD DEVIATIONS[a]

ACID BLACK 52 - DIETARY ADMINISTRATION

| | MALES | | | | FEMALES | | | |
|---|---|---|---|---|---|---|---|---|
| GROUP | 9 | 13 | 10 | 15 | 9 | 13 | 10 | 15 |
| SPECIES (TREATMENT)[b]: | H(T) | H(C) | R(T) | R(C) | H(T) | H(C) | R(T) | R(C) |
| DOSE LEVEL (%)[c] | 2.0 | 0 | 2.0 | 0 | 2.0 | 0 | 2.0 | 0 |
| Week | | | | | | | | |
| 1 | 64(6) | 64(6) | 108(8) | 104(6) | 62(6) | 63(6) | 85(7) | 85(6) |
| 5 | 84(9) | 90(9) | 222(16) | 221(36) | 82(9) | 93(9) | 145(11) | 145(8) |
| 9 | 104(10) | 108(10) | 281(23) | 289(13) | 103(13) | 113(14) | 175(12) | 172(18) |
| 13 | 112(13) | 114(12) | 310(31) | 323(18) | 111(13) | 120(17) | 192(11) | 190(12) |
| 18 | 120(13) | 119(13) | 327(34) | 346(23) | 113(16) | 128(21) | 201(13) | 190(12) |
| 23 | 112(20) | 115(13) | 342(31) | 359(30) | 111(16) | 125(22) | 211(13) | 208(13) |
| 27 | 122(30) | 118(12) | 364(26) | 380(23) | 113(11) | 128(21) | 219(13) | 215(13) |
| 31 | 126(13) | 121(13) | 382(26) | 395(26) | 119(16) | 128(22) | 228(13) | 224(14 |
| 36 | 129(12) | 124(15) | 385(26) | 406(25) | 123(16) | 132(21) | 231(14) | 227(18) |
| 40 | 128(15) | 126(16) | 403(24) | 417(27) | 127(17) | 133(21) | 241(15) | 239(17) |
| 44 | 129(17) | 124(16) | 410(24) | 428(29) | 123(21) | 130(19) | 247(16) | 245(18) |
| 48 | 130(13) | 127(14) | 413(23) | 433(30) | 127(16) | 135(16) | 251(16) | 252(19) |
| 52 | 127(19) | 123(16) | 410(23) | 431(32) | 123(16) | 134(18) | 257(17) | 256(20) |
| 56 | 130(14) | 126(13) | - | - | 125(16) | 138(20) | - | - |
| 57 | - | - | 414(24) | 437(33) | - | - | 261(19) | 264(22) |
| 61 | 129(14) | 125(14) | 415(25) | 441(35) | 125(14) | 138(24) | 268(17) | 270(23) |
| 66 | 128(15) | 123(13) | 394(37) | 436(42) | 119(14) | 132(18) | 268(20) | 260(31) |
| 69 | 129(18) | 123(13) | - | - | 120(15) | 134(31) | - | - |
| 70 | - | - | 404(30) | 439(36) | - | - | 268(25) | 276(26) |
| 74 | 131(14) | 126(10) | 404(25) | 451(36) | 118(16) | 131(33) | 280(18) | 287(26) |
| 79 | 129(16) | 126(11) | 398(30) | - | 117(20) | 139(38) | 278(25) | - |
| 83 | 130(18) | 126(12) | 392(37) | 450(36) | 120(18) | 129(22) | 283(20) | 303(31) |
| 87 | 138(14) | 127(14) | 388(40) | 451(31) | 118(15) | 136(19) | 285(28) | 310(38) |
| 91 | 136(14) | 127(18) | - | - | 116(20) | 139(18) | - | - |
| 93 | - | - | 375(43) | 447(34) | - | - | 293(20) | 319(33) |
| 96 | 136(12) | 128(16) | - | - | 115(20)[d] | 123(14)[d] | - | - |
| 97 | - | - | 359(30) | 448(33) | - | - | 290(27) | 324(33) |
| 100 | 136(10) | 127(13) | - | - | | | - | - |
| 101 | - | - | 311(57) | 431(44) | | | 279(35) | 321(131) |
| 104 | 131(19) | 124(17) | - | - | | | - | - |
| 106 | - | - | 329(56) | 416(38)[d] | | | 285(32) | 320(31) |
| 110 | 139(17)[d] | 123(16)[d] | 345(48)[d] | 418(58) | | | 283(32) | 312(42) |
| 113 | | | | | | | 277(29) | 296(39) |
| 117 | | | | | | | 248(42)[d] | 266(39)[d] |

[a] Data are presented as mean (S.D.); data are in grams.

[b] Species: Hamster = H, Rat = R; (Treatment): Treated = (T), Control = (C).

[c] All doses administered as % of total diet; all diets were prepared with 1.3% w/w Mazola® corn oil and control diets consisted of meal plus corn oil (1.3%).

"-" Body weight not required at this week for the indicated groups and species.

[d] Represents the last body weight interval prior to terminal sacrifice.

TABLE IX

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

MEAN FOOD CONSUMPTION DATA WITH STANDARD DEVIATIONS[a]
ACID BLACK 52 - DIETARY ADMINISTRATION

| | MALES | | | | FEMALES | | | |
|---|---|---|---|---|---|---|---|---|
| GROUP | 9 | 13 | 10 | 15 | 9 | 13 | 10 | 15 |
| SPECIES (TREATMENT)[b] | H(T) | H(C) | R(T) | R(C) | H(T) | H(C) | R(T) | R(C) |
| DOSE LEVEL (%)[c] | 2.0 | 0 | 2.0 | 0 | 2.0 | 0 | 2.0 | 0 |
| Week | | | | | | | | |
| 1 | 104(35) | 97(38) | 116(19) | 111(7) | 94(37) | 97(41) | 98(6) | 90(6) |
| 2 | 68(12) | 96(52) | 114(8) | 118(9) | 58(16) | 95(47) | 93(8) | 85(8) |
| 3 | 66(11) | 61(10) | 128(14) | 119(15) | 69(13) | 67(16) | 85(17) | 86(13) |
| 4 | 65(18) | 62(14) | 142(16) | 133(10) | 70(28) | 69(24) | 109(14) | 93(6) |
| 5 | 70(18) | 77(11) | 149(11) | 124(11) | 79(28) | 76(24) | 106(9) | 81(15) |
| 6 | 73(10) | 65(16) | 135(17) | 132(24) | 72(12) | 61(15) | 101(15) | 86(11) |
| 7 | 69(11) | 53(8) | 144(17) | 126(13) | 64(19) | 58(18) | 102(10) | 84(11) |
| 8 | 71(12) | 55(8) | 143(13) | 117(24) | 73(16) | 64(17) | 107(19) | 93(8) |
| 9 | 75(12) | 62(10) | 143(18) | 135(10) | 71(17) | 68(19) | 105(7) | 90(12) |
| 10 | 72(10) | 60(9) | 148(19) | 123(17) | 70(10) | 64(16) | 105(21) | 86(10) |
| 11 | 70(12) | 58(11) | 141(14) | 121(10) | 68(9) | 69(24) | 105(13) | 82(8) |
| 12 | 69(15) | 59(10) | 138(13) | 126(10) | 69(16) | 64(15) | 102(14) | 86(22) |
| 13 | 69(12) | 58(10) | 140(16) | 121(11) | 69(16) | 65(18) | 104(8) | 85(10) |
| 14 | 67(8) | 55(11) | 136(14) | 113(11) | 64(10) | 62(17) | 103(7) | 79(8) |
| 15 | 68(15) | 53(9) | 133(13) | 128(12) | 63(13) | 56(16) | 99(6) | 90(11) |
| 16 | 64(12) | 59(11) | 140(14) | 114(10) | 56(11) | 64(14) | 106(14) | 77(13) |
| 17 | 67(10) | 51(11) | 136(15) | 114(17) | 64(15) | 56(17) | 104(12) | 78(13) |
| 18 | 66(9) | 47(10) | 129(20) | 121(8) | 59(13) | 54(16) | 96(14) | 84(14) |
| 19 | 60(12) | 44(9) | 132(17) | 109(8) | 56(12) | 54(18) | 100(10) | 77(7) |
| 20 | 57(14) | 42(12) | 136(25) | 112(9) | 52(14) | 51(16) | 98(17) | 80(13) |
| 21 | 61(13) | 43(12) | 130(22) | 122(11) | 58(14) | 49(15) | 98(8) | 88(8) |
| 22 | 55(13) | 47(12) | 126(24) | 111(12) | 51(12) | 51(13) | 103(9) | 76(7) |
| 23 | 65(14) | 53(11) | 131(12) | 130(9) | 67(18) | 59(14) | 96(14) | 94(6) |
| 24 | 66(18) | 56(13) | 138(12) | 121(9) | 75(17) | 63(14) | 99(7) | 82(6) |
| 25 | 79(16) | 53(12) | 127(10) | 124(11) | 78(21) | 64(14) | 91(8) | 83(14) |
| 26 | 72(12) | 55(9) | 131(11) | 128(10) | 80(24) | 61(15) | 94(6) | 91(7) |
| 27 | 58(16) | 55(11) | 119(19) | 119(12) | 69(25) | 64(15) | 96(16) | 79(9) |
| 28 | 58(13) | 53(13) | 129(10) | 129(10) | 79(28) | 62(16) | 100(8) | 91(5) |
| 29 | 57(30) | 58(16) | 129(10) | 120(10) | 59(23) | 72(24) | 97(8) | 84(5) |
| 30 | 61(21) | 51(11) | 120(11) | 120(11) | 75(24) | 65(19) | 95(10) | 82(5) |
| 31 | 72(19) | 56(14) | 123(11) | 123(11) | 83(27) | 68(20) | 104(8) | 87(6) |
| 32 | 71(16) | 55(12) | 135(10) | 130(11) | 85(27) | 68(14) | 98(6) | 96(5) |

[a] Data are presented as mean (S.D.); data are in grams.

[b] Species: Hamster = H, Rat = R; (Treatment): Treated = (T), Control = (C).

[c] All doses administered as % of total diet; all diets were prepared with 1.3% w/w Mazola® corn oil and control diets consisted of meal plus corn oil (1.3%).

TABLE IX

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

MEAN FOOD CONSUMPTION DATA WITH STANDARD DEVIATIONS[a]
ACID BLACK 52 - DIETARY ADMINISTRATION

| GROUP | MALES | | | | FEMALES | | | |
|---|---|---|---|---|---|---|---|---|
| SPECIES (TREATMENT)[b] | 9 H(T) | 13 H(C) | 10 R(T) | 15 R(C) | 9 H(T) | 13 H(C) | 10 R(T) | 15 R(C) |
| DOSE LEVEL (%)[c] | 2.0 | 0 | 2.0 | 0 | 2.0 | 0 | 2.0 | 0 |
| Week | | | | | | | | |
| 33 | 74(27) | 63(25) | 131(11) | 131(11) | 98(44) | 79(23) | 98(7) | 88(7) |
| 34 | 82(14) | 60(9) | 134(11) | 138(12) | 83(19) | 64(10) | 97(6) | 94(7) |
| 35 | 79(23) | 59(10) | 145(13) | 135(14) | 81(27) | 64(12) | 100(7) | 97(18) |
| 36 | 78(15) | 61(11) | 142(13) | 144(7) | 89(24) | 70(17) | 106(8) | 109(8) |
| 37 | 82(15) | 64(8) | 137(12) | 130(16) | 90(24) | 67(14) | 101(8) | 96(8) |
| 38 | 88(19) | 62(13) | 138(12) | 120(13) | 97(25) | 67(13) | 98(16) | 90(10) |
| 39 | 81(23) | 57(13) | 143(19) | 128(12) | 99(29) | 65(14) | 102(7) | 92(7) |
| 40 | 85(21) | 59(15) | 137(15) | 131(10) | 96(28) | 74(19) | 104(9) | 95(9) |
| 41 | 92(27) | 59(13) | 143(9) | 134(10) | 93(27) | 72(18) | 106(8) | 97(8) |
| 42 | 96(26) | 61(14) | 145(11) | 124(18) | 95(25) | 71(15) | 106(12) | 89(9) |
| 43 | 98(29) | 64(15) | 140(10) | 136(13) | 102(34) | 75(17) | 104(8) | 96(7) |
| 44 | 94(26) | 62(20) | 151(15) | 138(11) | 89(26) | 83(29) | 113(9) | 99(7) |
| 45 | 112(28) | 84(29) | 143(17) | 136(12) | 114(35) | 105(35) | 109(9) | 100(8) |
| 46 | 81(28) | 70(32) | 154(12) | 135(11) | 92(34) | 90(35) | 111(9) | 111(8) |
| 47 | 93(29) | 67(18) | 154(11) | 140(11) | 100(32) | 95(41) | 115(8) | 105(9) |
| 48 | 105(26) | 79(22) | 154(8) | 139(13) | 108(26) | 97(32) | 114(7) | 101(9) |
| 49 | 99(22) | 74(20) | 140(15) | 138(14) | 104(32) | 95(34) | 113(7) | 104(8) |
| 50 | 97(18) | 68(17) | 144(12) | 142(15) | 91(21) | 83(28) | 107(9) | 104(9) |
| 51 | 99(30) | 78(26) | 149(11) | 138(12) | 94(31) | 96(38) | 115(10) | 108(9) |
| 52 | 98(22) | 77(29) | 170(17) | 167(20) | 98(22) | 87(24) | 136(10) | 123(10) |
| 53 | 100(22) | 64(17) | 140(12) | 133(21) | 100(25) | 82(26) | 104(17) | 99(12) |
| 54 | 99(19) | 69(20) | 135(9) | 135(12) | 100(21) | 80(25) | 99(10) | 100(7) |
| 55 | 90(21) | 64(17) | 143(11) | 125(15) | 90(21) | 80(22) | 111(9) | 94(6) |
| 56 | 88(17) | 65(18) | 140(8) | 127(16) | 83(17) | 79(18) | 113(9) | 93(7) |
| 57 | 92(15) | 68(16) | 140(11) | 144(21) | 80(13) | 82(27) | 108(11) | 109(8) |
| 58 | 82(14) | 73(17) | 128(9) | 132(13) | 87(20) | 79(16) | 99(9) | 99(9) |
| 59 | 79(20) | 61(21) | 136(10) | 112(36) | 77(21) | 84(21) | 103(9) | 85(11) |
| 60 | 86(21) | 71(23) | 131(10) | 127(13) | 84(23) | 79(23) | 113(8) | 99(8) |
| 61 | 89(26) | 65(23) | 123(18) | 120(17) | 83(21) | 81(27) | 107(12) | 87(9) |
| 62 | 87(18) | 65(27) | 141(18) | 140(14) | 81(23) | 70(26) | 107(17) | 102(11) |
| 63 | 87(22) | 53(22) | 135(12) | 131(20) | 83(23) | 73(34) | 103(21) | 96(17) |

[a] Data are presented as mean (S.D.); data are in grams.

[b] Species: Hamster = H, Rat = R; (Treatment): Treated = (T), Control = (C).

[c] All doses administered as % of total diet; all diets were prepared with 1.3% w/w Mazola® corn oil and control diets consisted of meal plus corn oil (1.3%).

TABLE IX

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

MEAN FOOD CONSUMPTION DATA WITH STANDARD DEVIATIONS[a]
ACID BLACK 52 - DIETARY ADMINISTRATION

| | MALES | | | | FEMALES | | | |
|---|---|---|---|---|---|---|---|---|
| GROUP | 9 | 13 | 10 | 15 | 9 | 13 | 10 | 15 |
| SPECIES (TREATMENT)[b] | H(T) | H(C) | R(T) | R(C) | H(T) | H(C) | R(T) | R(C) |
| DOSE LEVEL (%)[c] | 2.0 | 0 | 2.0 | 0 | 2.0 | 0 | 2.0 | 0 |
| Week | | | | | | | | |
| 64 | 89(20) | 63(22) | 148(17) | 131(21) | 85(25) | 74(27) | 119(22) | 102(9) |
| 65 | 81(19) | 66(17) | 142(18) | 138(20) | 80(24) | 74(23) | 120(11) | 101(13) |
| 66 | 85(14) | 65(23) | 133(30) | 132(25) | 99(25) | 79(27) | 110(11) | 97(17) |
| 67 | 79(12) | 60(19) | 121(27) | 126(29) | 69(17) | 65(20) | 102(19) | 99(19) |
| 68 | 68(17) | 63(17) | 130(31) | 125(17) | 52(14) | 65(17) | 112(20) | 104(19) |
| 69 | 77(17) | 65(27) | 139(19) | 129(44) | 77(35) | 72(32) | 118(25 | 120(22) |
| 70 | 73(17) | 69(32) | 141(21) | 131(34) | 69(23) | 64(21) | 107(31) | 107(24) |
| 71 | 77(17) | 67(22) | 137(35) | 137(20) | 82(32) | 72(22) | 106(37) | 102(23) |
| 72 | 80(18) | 67(12) | 140(28) | 132(28) | 68(25) | 80(31) | 117(21) | 96(26) |
| 73 | 92(20) | 69(26) | 140(12) | 128(24) | 80(31) | 68(16) | 109(16) | 97(20) |
| 74 | 82(18) | 61(14) | 144(11) | 138(13) | 73(20) | 70(25) | 113(10) | 104(9) |
| 75 | 72(19) | 60(27) | 133(12) | 133(15) | 73(31) | 69(21) | 104(13) | 104(14) |
| 76 | 86(19) | 61(21) | 130(15) | 144(15) | 84(27) | 88(34) | 99(17) | 115(8) |
| 77 | 79(20) | 76(19) | 122(23) | 139(18) | 80(29) | 98(46) | 91(29) | 109(12) |
| 78 | 83(23) | 74(16) | 131(19) | 136(16) | 74(35) | 104(44) | 103(30) | 104(11) |
| 79 | 85(28) | 61(13) | 124(28) | 131(14) | 70(19) | 82(31) | 99(26) | 96(14) |
| 80 | 74(27) | 58(21) | 139(21) | 141(16) | 66(22) | 74(23) | 119(22) | 104(18) |
| 81 | 93(19) | 68(10) | 136(21) | 137(30) | 90(28) | 92(31) | 121(17) | 114(18) |
| 82 | 94(20) | 69(13) | 138(12) | 120(34) | 95(47) | 98(45) | 108(24) | 104(13) |
| 83 | 84(22) | 71(29) | 137(11) | 136(25) | 68(27) | 72(28) | 110(17) | 101(18) |
| 84 | 91(28) | 66(16) | 135(14) | 135(13) | 78(23) | 73(27) | 109(20) | 105(11) |
| 85 | 81(20) | 57(16) | 135(17) | 136(14) | 82(31) | 69(28) | 109(30) | 106(16) |
| 86 | 91(32) | 60(14) | 129(19) | 127(14) | 84(40) | 82(38) | 114(22) | 101(18) |
| 87 | 80(66) | 66(14) | 141(29) | 135(19) | 66(26) | 81(33) | 108(45) | 106(27) |
| 88 | NA | 70(34) | 133(17) | 126(29) | NA | 70(31) | 109(25) | 110(18) |
| 89 | 110(28) | 67(23) | 125(30) | 133(21) | 75(29) | 81(41) | 111(19) | 113(13) |
| 90 | 75(30) | 55(17) | 114(28) | 129(13) | 72(42) | 70(33) | 110(14) | 102(12) |
| 91 | 92(37) | 68(22) | 118(39) | 130(48) | 63(55) | 63(25) | 115(13) | 100(19) |
| 92 | 86(36) | 62(22) | 120(33) | 129(27) | 62(15) | 59(22) | 112(14) | 108(14) |
| 93 | 93(32) | 75(27) | 113(12) | 120(20) | 76(33) | 68(26) | 102(15) | 103(14) |

[a] Data are presented as mean (S.D.); data are in grams.

[b] Species: Hamster = H, Rat = R; (Treatment): Treated = (T), Control = (C).

[c] All doses administered as % of total diet; all diets were prepared with 1.3% w/w Mazola® corn oil and control diets consisted of meal plus corn oil (1.3%).

NA = Not available due to error.

TABLE IX

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

MEAN FOOD CONSUMPTION DATA WITH STANDARD DEVIATIONS[a]
ACID BLACK 52 - DIETARY ADMINISTRATION

| | MALES | | | | FEMALES | | | |
|---|---|---|---|---|---|---|---|---|
| GROUP | 9 | 13 | 10 | 15 | 9 | 13 | 10 | 15 |
| SPECIES (TREATMENT)[b] | H(T) | H(C) | R(T) | R(C) | H(T) | H(C) | R(T) | R(C) |
| DOSE LEVEL (%)[c] | 2.0 | 0 | 2.0 | 0 | 2.0 | 0 | 2.0 | 0 |
| Week | | | | | | | | |
| 94 | 88(30) | 66(24) | 146(17) | 143(11) | 60(25) | 72(16) | 130(22) | 116(11) |
| 95 | 113(34) | 70(24) | 133(14) | 135(9) | 77(22)[d] | 61(7)[d] | 119(21) | 107(33) |
| 96 | 93(33) | 67(18) | 110(23) | 105(30) | | | 119(19) | 103(28) |
| 97 | 92(19) | 64(17) | 126(8) | 136(9) | | | 116(23) | 101(26) |
| 98 | 91(24) | 67(23) | 143(10) | 139(16) | | | 123(13) | 111(12) |
| 99 | 92(27) | 67(22) | 130(18) | 136(16) | | | 124(16) | 114(23) |
| 100 | 101(29) | 79(32) | 122(25) | 145(23) | | | 138(16) | 125(25) |
| 101 | 92(28) | 83(30) | 147(18) | 137(32) | | | 150(23) | 115(32) |
| 102 | 77(32) | 78(29) | 128(18) | 119(44) | | | 128(18) | 114(16) |
| 103 | 83(36) | 70(13) | 126(22) | 138(21) | | | 126(24) | 130(26) |
| 104 | 75(30) | 62(22) | 116(26) | 129(27) | | | 115(17) | 122(15) |
| 105 | 88(18) | 72(24) | 127(17) | 129(31) | | | 120(16) | 114(14) |
| 106 | 44(17) | 67(19) | 109(30) | 120(20) | | | 115(20) | 106(22) |
| 107 | 76(33) | 41(9) | 134(14)[d] | 120(34)[d] | | | 120(22) | 112(21) |
| 108 | 64(26)[d] | 80(29)[d] | NA | NA | | | NA | NA |
| 109 | NA | NA | NA | NA | | | NA | NA |
| 110 | NA | NA | | | | | NA | NA |
| 111 | | | | | | | NA | NA |
| 112 | | | | | | | 108(20) | 99(26) |
| 113 | | | | | | | 130(21) | 111(32) |
| 114 | | | | | | | 128(24) | 109(27) |
| 115 | | | | | | | 85(27) | 69(25) |
| 116 | | | | | | | 113(15)[d] | 113(18)[d] |
| 117 | | | | | | | 153(13) | 138(35) |

[a] Data are presented as mean (S.D.); data are in grams.

[b] Species: Hamster = H, Rat = R; (Treatment): Treated = (T), Control = (C).

[c] All doses administered as % of total diet; all diets were prepared with 1.3% w/w Mazola® corn oil and control diets consisted of meal plus corn oil (1.3%).

NA = Not available due to error.

[d] Represents the last available food consumption interval prior to terminal sacrifice.

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

TOTAL TUMOR INCIDENCE OF MAJOR ORGANS - ACID BLACK 52

HAMSTERS - INTRATRACHEAL

GROUP 1 MALE (TREATED)

| | |
|---|---|
| SKIN | 0 TUMORS |
| MAMMARY GLAND | 0 TUMORS |
| MUSCLE | 0 TUMORS |
| SALIVARY GLAND | 1 TUMORS |
| MANDIBULAR LYMPH NODE | 1 TUMORS |
| SCIATIC NERVE | 0 TUMORS |
| THYMUS | 0 TUMORS |
| LARYNX | 0 TUMORS |
| THYROID | 0 TUMORS |
| PARATHYROID | 0 TUMORS |
| TRACHEA | 0 TUMORS |
| BRONCHUS | 0 TUMORS |
| ESOPHAGUS | 0 TUMORS |
| ADRENAL | 17 TUMORS |
| STOMACH | 0 TUMORS |
| DUODENUM | 0 TUMORS |
| JEJUNUM | 0 TUMORS |
| ILEUM | 0 TUMORS |
| CECUM | 0 TUMORS |
| COLON | 0 TUMORS |
| RECTUM | 0 TUMORS |
| MESENTERIC LYMPH NODE | 0 TUMORS |
| LUNG | 1 TUMORS |
| LIVER | 1 TUMORS |
| GALLBLADDER | 0 TUMORS |
| SPLEEN | 0 TUMORS |
| PANCREAS | 1 TUMORS |
| KIDNEY | 0 TUMORS |
| HEART | 0 TUMORS |
| URINARY BLADDER | 0 TUMORS |
| SEMINAL VESICLE | 0 TUMORS |
| PROSTATE | 0 TUMORS |
| TESTIS | 0 TUMORS |
| CEREBRUM | 0 TUMORS |
| CEREBELLUM | 0 TUMORS |
| PITUITARY | 0 TUMORS |
| STERNABRAE | 0 TUMORS |
| FEMUR | 0 TUMORS |
| BONE MARROW | 0 TUMORS |
| NASAL CAVITY | 0 TUMORS |
| OTHER | 1 TUMORS |

THERE WERE 19 TUMOR-BEARING ANIMALS; 23 TUMORS AVG.= 1.2

GROUP 5 MALE (CONTROL)

| | |
|---|---|
| SKIN | 1 TUMORS |
| MAMMARY GLAND | 0 TUMORS |
| MUSCLE | 0 TUMORS |
| SALIVARY GLAND | 1 TUMORS |
| MANDIBULAR LYMPH NODE | 1 TUMORS |
| SCIATIC NERVE | 0 TUMORS |
| THYMUS | 0 TUMORS |
| LARYNX | 0 TUMORS |
| THYROID | 0 TUMORS |
| PARATHYROID | 0 TUMORS |
| TRACHEA | 0 TUMORS |
| BRONCHUS | 0 TUMORS |
| ESOPHAGUS | 0 TUMORS |
| ADRENAL | 10 TUMORS |
| STOMACH | 0 TUMORS |
| DUODENUM | 0 TUMORS |
| JEJUNUM | 0 TUMORS |
| ILEUM | 0 TUMORS |
| CECUM | 0 TUMORS |
| COLON | 0 TUMORS |
| RECTUM | 0 TUMORS |
| MESENTERIC LYMPH NODE | 0 TUMORS |
| LUNG | 1 TUMORS |
| LIVER | 2 TUMORS |
| GALLBLADDER | 0 TUMORS |
| SPLEEN | 2 TUMORS |
| PANCREAS | 1 TUMORS |
| KIDNEY | 0 TUMORS |
| HEART | 0 TUMORS |
| URINARY BLADDER | 0 TUMORS |
| SEMINAL VESICLE | 0 TUMORS |
| PROSTATE | 0 TUMORS |
| TESTIS | 0 TUMORS |
| CEREBRUM | 0 TUMORS |
| CEREBELLUM | 0 TUMORS |
| PITUITARY | 0 TUMORS |
| STERNABRAE | 0 TUMORS |
| FEMUR | 0 TUMORS |
| BONE MARROW | 1 TUMORS |
| NASAL CAVITY | 0 TUMORS |
| OTHER | 1 TUMORS |

THERE WERE 13 TUMOR-BEARING ANIMALS; 19 TUMORS AVG.= 1.5

TABLE X

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

TOTAL TUMOR INCIDENCE OF MAJOR ORGANS - ACID BLACK 52

HAMSTERS - INTRATRACHEAL

GROUP 1 FEMALE (TREATED)

| | |
|---|---|
| SKIN | 1 TUMORS |
| MAMMARY GLAND | 0 TUMORS |
| MUSCLE | 0 TUMORS |
| SALIVARY GLAND | 0 TUMORS |
| MANDIBULAR LYMPH NODE | 2 TUMORS |
| SCIATIC NERVE | 0 TUMORS |
| THYMUS | 0 TUMORS |
| LARYNX | 0 TUMORS |
| THYROID | 0 TUMORS |
| PARATHYROID | 1 TUMORS |
| TRACHEA | 0 TUMORS |
| BRONCHUS | 0 TUMORS |
| ESOPHAGUS | 0 TUMORS |
| ADRENAL | 0 TUMORS |
| STOMACH | 0 TUMORS |
| DUODENUM | 0 TUMORS |
| JEJUNUM | 0 TUMORS |
| ILEUM | 0 TUMORS |
| CECUM | 0 TUMORS |
| COLON | 0 TUMORS |
| RECTUM | 0 TUMORS |
| MESENTERIC LYMPH NODE | 1 TUMORS |
| LUNG | 0 TUMORS |
| LIVER | 5 TUMORS |
| GALLBLADDER | 0 TUMORS |
| SPLEEN | 0 TUMORS |
| PANCREAS | 2 TUMORS |
| KIDNEY | 0 TUMORS |
| HEART | 0 TUMORS |
| URINARY BLADDER | 0 TUMORS |
| OVARY | 1 TUMORS |
| UTERUS | 0 TUMORS |
| CEREBRUM | 0 TUMORS |
| CEREBELLUM | 0 TUMORS |
| PITUITARY | 1 TUMORS |
| STERNABRAE | 0 TUMORS |
| FEMUR | 0 TUMORS |
| BONE MARROW | 0 TUMORS |
| NASAL CAVITY | 0 TUMORS |
| OTHER | 0 TUMORS |

THERE WERE 10 TUMOR-BEARING ANIMALS; 14 TUMORS AVG.= 1.4

GROUP 5 FEMALE (CONTROL)

| | |
|---|---|
| SKIN | 1 TUMORS |
| MAMMARY GLAND | 0 TUMORS |
| MUSCLE | 0 TUMORS |
| SALIVARY GLAND | 0 TUMORS |
| MANDIBULAR LYMPH NODE | 0 TUMORS |
| SCIATIC NERVE | 0 TUMORS |
| THYMUS | 0 TUMORS |
| LARYNX | 0 TUMORS |
| THYROID | 0 TUMORS |
| PARATHYROID | 0 TUMORS |
| TRACHEA | 0 TUMORS |
| BRONCHUS | 0 TUMORS |
| ESOPHAGUS | 0 TUMORS |
| ADRENAL | 6 TUMORS |
| STOMACH | 0 TUMORS |
| DUODENUM | 0 TUMORS |
| JEJUNUM | 0 TUMORS |
| ILEUM | 0 TUMORS |
| CECUM | 0 TUMORS |
| COLON | 0 TUMORS |
| RECTUM | 0 TUMORS |
| MESENTERIC LYMPH NODE | 0 TUMORS |
| LUNG | 1 TUMORS |
| LIVER | 1 TUMORS |
| GALLBLADDER | 0 TUMORS |
| SPLEEN | 0 TUMORS |
| PANCREAS | 0 TUMORS |
| KIDNEY | 0 TUMORS |
| HEART | 0 TUMORS |
| URINARY BLADDER | 0 TUMORS |
| OVARY | 1 TUMORS |
| UTERUS | 1 TUMORS |
| CEREBRUM | 0 TUMORS |
| CEREBELLUM | 0 TUMORS |
| PITUITARY | 0 TUMORS |
| STERNABRAE | 0 TUMORS |
| FEMUR | 0 TUMORS |
| BONE MARROW | 0 TUMORS |
| NASAL CAVITY | 0 TUMORS |
| OTHER | 0 TUMORS |

THERE WERE 3 TUMOR-BEARING ANIMALS; 11 TUMORS AVG.= 1.4

TOTAL TUMOR INCIDENCE OF MAJOR ORGANS - ACID BLACK 52

HAMSTERS - DIETARY

GROUP 9 MALE (TREATED)

| | |
|---|---|
| SKIN | 0 TUMORS |
| MAMMARY GLAND | 0 TUMORS |
| MUSCLE | 0 TUMORS |
| SALIVARY GLAND | 0 TUMORS |
| MANDIBULAR LYMPH NODE | 2 TUMORS |
| SCIATIC NERVE | 0 TUMORS |
| THYMUS | 0 TUMORS |
| LARYNX | 0 TUMORS |
| THYROID | 1 TUMORS |
| PARATHYROID | 0 TUMORS |
| TRACHEA | 0 TUMORS |
| BRONCHUS | 0 TUMORS |
| ESOPHAGUS | 0 TUMORS |
| ADRENAL | 3 TUMORS |
| STOMACH | 1 TUMORS |
| DUODENUM | 0 TUMORS |
| JEJUNUM | 0 TUMORS |
| ILEUM | 0 TUMORS |
| CECUM | 0 TUMORS |
| COLON | 0 TUMORS |
| RECTUM | 0 TUMORS |
| MESENTERIC LYMPH NODE | 1 TUMORS |
| LUNG | 1 TUMORS |
| LIVER | 2 TUMORS |
| GALLBLADDER | 0 TUMORS |
| SPLEEN | 2 TUMORS |
| PANCREAS | 0 TUMORS |
| KIDNEY | 0 TUMORS |
| HEART | 0 TUMORS |
| URINARY BLADDER | 0 TUMORS |
| SEMINAL VESICLE | 0 TUMORS |
| PROSTATE | 0 TUMORS |
| TESTIS | 0 TUMORS |
| CEREBRUM | 0 TUMORS |
| CEREBELLUM | 0 TUMORS |
| PITUITARY | 0 TUMORS |
| STERNABRAE | 0 TUMORS |
| FEMUR | 0 TUMORS |
| BONE MARROW | 0 TUMORS |
| NASAL CAVITY | 0 TUMORS |
| OTHER | 0 TUMORS |

THERE WERE 10 TUMOR-BEARING ANIMALS; 14 TUMORS AVG.= 1.4

GROUP 13 (CONTROL)

| | |
|---|---|
| SKIN | 0 TUMORS |
| MAMMARY GLAND | 0 TUMORS |
| MUSCLE | 0 TUMORS |
| SALIVARY GLAND | 0 TUMORS |
| MANDIBULAR LYMPH NODE | 3 TUMORS |
| SCIATIC NERVE | 0 TUMORS |
| THYMUS | 1 TUMORS |
| LARYNX | 0 TUMORS |
| THYROID | 0 TUMORS |
| PARATHYROID | 1 TUMORS |
| TRACHEA | 0 TUMORS |
| BRONCHUS | 0 TUMORS |
| ESOPHAGUS | 0 TUMORS |
| ADRENAL | 6 TUMORS |
| STOMACH | 1 TUMORS |
| DUODENUM | 1 TUMORS |
| JEJUNUM | 1 TUMORS |
| ILEUM | 1 TUMORS |
| CECUM | 1 TUMORS |
| COLON | 1 TUMORS |
| RECTUM | 1 TUMORS |
| MESENTERIC LYMPH NODE | 1 TUMORS |
| LUNG | 1 TUMORS |
| LIVER | 2 TUMORS |
| GALLBLADDER | 0 TUMORS |
| SPLEEN | 2 TUMORS |
| PANCREAS | 0 TUMORS |
| KIDNEY | 0 TUMORS |
| HEART | 0 TUMORS |
| URINARY BLADDER | 0 TUMORS |
| SEMINAL VESICLE | 0 TUMORS |
| PROSTATE | 1 TUMORS |
| TESTIS | 0 TUMORS |
| CEREBRUM | 0 TUMORS |
| CEREBELLUM | 0 TUMORS |
| PITUITARY | 0 TUMORS |
| STERNABRAE | 0 TUMORS |
| FEMUR | 0 TUMORS |
| BONE MARROW | 3 TUMORS |
| NASAL CAVITY | 0 TUMORS |
| OTHER | 0 TUMORS |

THERE WERE 9 TUMOR-BEARING ANIMALS; 18 TUMORS AVG.= 2.1

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

TOTAL TUMOR INCIDENCE OF MAJOR ORGANS - ACID BLACK 52

HAMSTERS - DIETARY

GROUP 9 FEMALE (TREATED)

| | |
|---|---|
| SKIN | 0 TUMORS |
| MAMMARY GLAND | 0 TUMORS |
| MUSCLE | 0 TUMORS |
| SALIVARY GLAND | 0 TUMORS |
| MANDIBULAR LYMPH NODE | 1 TUMORS |
| SCIATIC NERVE | 0 TUMORS |
| THYMUS | 0 TUMORS |
| LARYNX | 0 TUMORS |
| THYROID | 0 TUMORS |
| PARATHYROID | 0 TUMORS |
| TRACHEA | 0 TUMORS |
| BRONCHUS | 0 TUMORS |
| ESOPHAGUS | 0 TUMORS |
| ADRENAL | 0 TUMORS |
| STOMACH | 0 TUMORS |
| DUODENUM | 0 TUMORS |
| JEJUNUM | 0 TUMORS |
| ILEUM | 0 TUMORS |
| CECUM | 0 TUMORS |
| COLON | 0 TUMORS |
| RECTUM | 0 TUMORS |
| MESENTERIC LYMPH NODE | 1 TUMORS |
| LUNG | 0 TUMORS |
| LIVER | 0 TUMORS |
| GALLBLADDER | 0 TUMORS |
| SPLEEN | 3 TUMORS |
| PANCREAS | 0 TUMORS |
| KIDNEY | 0 TUMORS |
| HEART | 0 TUMORS |
| URINARY BLADDER | 0 TUMORS |
| OVARY | 1 TUMORS |
| UTERUS | 3 TUMORS |
| CEREBRUM | 0 TUMORS |
| CEREBELLUM | 0 TUMORS |
| PITUITARY | 0 TUMORS |
| STERNABRAE | 0 TUMORS |
| FEMUR | 0 TUMORS |
| BONE MARROW | 0 TUMORS |
| NASAL CAVITY | 0 TUMORS |
| OTHER | 0 TUMORS |

THERE WERE 7 TUMOR-BEARING ANIMALS; 9 TUMORS AVG.= 1.7

GROUP 13 FEMALE (CONTROL)

| | |
|---|---|
| SKIN | 1 TUMORS |
| MAMMARY GLAND | 0 TUMORS |
| MUSCLE | 0 TUMORS |
| SALIVARY GLAND | 0 TUMORS |
| MANDIBULAR LYMPH NODE | 1 TUMORS |
| SCIATIC NERVE | 0 TUMORS |
| THYMUS | 0 TUMORS |
| LARYNX | 0 TUMORS |
| THYROID | 0 TUMORS |
| PARATHYROID | 0 TUMORS |
| TRACHEA | 0 TUMORS |
| BRONCHUS | 0 TUMORS |
| ESOPHAGUS | 0 TUMORS |
| ADRENAL | 4 TUMORS |
| STOMACH | 0 TUMORS |
| DUODENUM | 0 TUMORS |
| JEJUNUM | 0 TUMORS |
| ILEUM | 0 TUMORS |
| CECUM | 0 TUMORS |
| COLON | 0 TUMORS |
| RECTUM | 0 TUMORS |
| MESENTERIC LYMPH NODE | 1 TUMORS |
| LUNG | 2 TUMORS |
| LIVER | 3 TUMORS |
| GALLBLADDER | 0 TUMORS |
| SPLEEN | 0 TUMORS |
| PANCREAS | 1 TUMORS |
| KIDNEY | 0 TUMORS |
| HEART | 0 TUMORS |
| URINARY BLADDER | 0 TUMORS |
| OVARY | 0 TUMORS |
| UTERUS | 1 TUMORS |
| CEREBRUM | 0 TUMORS |
| CEREBELLUM | 0 TUMORS |
| PITUITARY | 1 TUMORS |
| STERNABRAE | 0 TUMORS |
| FEMUR | 0 TUMORS |
| BONE MARROW | 0 TUMORS |
| NASAL CAVITY | 0 TUMORS |
| OTHER | 1 TUMORS |

THERE WERE 11 TUMOR-BEARING ANIMALS; 13 TUMORS AVG.= 1.1

TABLE X

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

TOTAL TUMOR INCIDENCE OF MAJOR ORGANS - ACID BLACK 52

RATS - INTRATRACHEAL

GROUP 2 MALE (TREATED)

| | |
|---|---|
| SKIN | 8 TUMORS |
| MAMMARY | 3 TUMORS |
| THIGH MUSCLE | 0 TUMORS |
| SALIVARY GLAND | 0 TUMORS |
| BRONCHI | 0 TUMORS |
| TRACHEA | 0 TUMORS |
| LARYNX | 1 TUMORS |
| THYROID | 8 TUMORS |
| PARATHYROID | 0 TUMORS |
| ESOPHAGUS | 0 TUMORS |
| MANDIBULAR LYMPH NODE | 1 TUMORS |
| ADRENALS | 8 TUMORS |
| THYMUS | 0 TUMORS |
| SCIATIC NERVE | 0 TUMORS |
| STOMACH | 0 TUMORS |
| DUODENUM | 0 TUMORS |
| JEJUNUM | 0 TUMORS |
| ILEUM | 0 TUMORS |
| CECUM | 0 TUMORS |
| COLON | 0 TUMORS |
| RECTUM | 0 TUMORS |
| MESENTERIC LYMPH NODES | 0 TUMORS |
| LUNGS (ALL LOBES) | 9 TUMORS |
| LIVER | 13 TUMORS |
| SPLEEN | 9 TUMORS |
| PANCREAS | 2 TUMORS |
| KIDNEYS | 0 TUMORS |
| HEART | 1 TUMORS |
| URINARY BLADDER | 0 TUMORS |
| SEMINAL VESICLE | 0 TUMORS |
| PROSTATE | 1 TUMORS |
| TESTES | 41 TUMORS |
| BRAIN | 0 TUMORS |
| PITUITARY | 8 TUMORS |
| STERNUM/RIB & RIB JUNCTIO | 0 TUMORS |
| FEMUR | 1 TUMORS |
| NASAL CAVITY | 0 TUMORS |
| OTHER | 7 TUMORS |

THERE WERE 45 TUMOR-BEARING ANIMALS; 121 TUMORS AVG.= 2.7

GROUP 7 MALE (CONTROL)

| | |
|---|---|
| SKIN | 6 TUMORS |
| MAMMARY | 2 TUMORS |
| THIGH MUSCLE | 1 TUMORS |
| SALIVARY GLAND | 1 TUMORS |
| BRONCHI | 1 TUMORS |
| TRACHEA | 0 TUMORS |
| LARYNX | 0 TUMORS |
| THYROID | 11 TUMORS |
| PARATHYROID | 0 TUMORS |
| ESOPHAGUS | 0 TUMORS |
| MANDIBULAR LYMPH NODE | 4 TUMORS |
| ADRENALS | 6 TUMORS |
| THYMUS | 2 TUMORS |
| SCIATIC NERVE | 0 TUMORS |
| STOMACH | 1 TUMORS |
| DUODENUM | 0 TUMORS |
| JEJUNUM | 0 TUMORS |
| ILEUM | 0 TUMORS |
| CECUM | 0 TUMORS |
| COLON | 1 TUMORS |
| RECTUM | 0 TUMORS |
| MESENTERIC LYMPH NODES | 3 TUMORS |
| LUNGS (ALL LOBES) | 11 TUMORS |
| LIVER | 14 TUMORS |
| SPLEEN | 9 TUMORS |
| PANCREAS | 4 TUMORS |
| KIDNEYS | 3 TUMORS |
| HEART | 3 TUMORS |
| URINARY BLADDER | 1 TUMORS |
| SEMINAL VESICLE | 1 TUMORS |
| PROSTATE | 1 TUMORS |
| TESTES | 29 TUMORS |
| BRAIN | 1 TUMORS |
| PITUITARY | 5 TUMORS |
| STERNUM/RIB & RIB JUNCTIO | 0 TUMORS |
| FEMUR | 1 TUMORS |
| NASAL CAVITY | 0 TUMORS |
| OTHER | 8 TUMORS |

THERE WERE 31 TUMOR-BEARING ANIMALS; 130 TUMORS AVG.= 4.2

TABLE A

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

TOTAL TUMOR INCIDENCE OF MAJOR ORGANS - ACID BLACK 52

RATS - INTRATRACHEAL

GROUP 2 FEMALE (TREATED)

| | |
|---|---|
| SKIN | 0 TUMORS |
| MAMMARY | 14 TUMORS |
| THIGH MUSCLE | 0 TUMORS |
| SALIVARY GLAND | 1 TUMORS |
| BRONCHI | 0 TUMORS |
| TRACHEA | 0 TUMORS |
| LARYNX | 0 TUMORS |
| THYROID | 10 TUMORS |
| PARATHYROID | 0 TUMORS |
| ESOPHAGUS | 0 TUMORS |
| MANDIBULAR LYMPH NODE | 1 TUMORS |
| ADRENALS | 3 TUMORS |
| THYMUS | 1 TUMORS |
| SCIATIC NERVE | 0 TUMORS |
| STOMACH | 1 TUMORS |
| DUODENUM | 0 TUMORS |
| JEJUNUM | 0 TUMORS |
| ILEUM | 0 TUMORS |
| CECUM | 0 TUMORS |
| COLON | 0 TUMORS |
| RECTUM | 0 TUMORS |
| MESENTERIC LYMPH NODES | 1 TUMORS |
| LUNGS (ALL LOBES) | 5 TUMORS |
| LIVER | 10 TUMORS |
| SPLEEN | 3 TUMORS |
| PANCREAS | 1 TUMORS |
| KIDNEYS | 1 TUMORS |
| HEART | 0 TUMORS |
| URINARY BLADDER | 0 TUMORS |
| OVARIES | 1 TUMORS |
| UTERUS | 3 TUMORS |
| BRAIN | 1 TUMORS |
| PITUITARY | 19 TUMORS |
| STERNUM/RIB & RIB JUNCTIO | 0 TUMORS |
| FEMUR | 0 TUMORS |
| NASAL CAVITY | 0 TUMORS |
| OTHER | 1 TUMORS |

THERE WERE 35 TUMOR-BEARING ANIMALS; 87 TUMORS AVG.= 2.5

GROUP 7 FEMALE (CONTROL)

| | |
|---|---|
| SKIN | 1 TUMORS |
| MAMMARY | 23 TUMORS |
| THIGH MUSCLE | 0 TUMORS |
| SALIVARY GLAND | 0 TUMORS |
| BRONCHI | 0 TUMORS |
| TRACHEA | 0 TUMORS |
| LARYNX | 0 TUMORS |
| THYROID | 5 TUMORS |
| PARATHYROID | 0 TUMORS |
| ESOPHAGUS | 0 TUMORS |
| MANDIBULAR LYMPH NODE | 0 TUMORS |
| ADRENALS | 2 TUMORS |
| THYMUS | 1 TUMORS |
| SCIATIC NERVE | 0 TUMORS |
| STOMACH | 0 TUMORS |
| DUODENUM | 0 TUMORS |
| JEJUNUM | 0 TUMORS |
| ILEUM | 0 TUMORS |
| CECUM | 0 TUMORS |
| COLON | 0 TUMORS |
| RECTUM | 0 TUMORS |
| MESENTERIC LYMPH NODES | 1 TUMORS |
| LUNGS (ALL LOBES) | 1 TUMORS |
| LIVER | 6 TUMORS |
| SPLEEN | 8 TUMORS |
| PANCREAS | 4 TUMORS |
| KIDNEYS | 0 TUMORS |
| HEART | 1 TUMORS |
| URINARY BLADDER | 0 TUMORS |
| OVARIES | 1 TUMORS |
| UTERUS | 4 TUMORS |
| BRAIN | 1 TUMORS |
| PITUITARY | 12 TUMORS |
| STERNUM/RIB & RIB JUNCTIO | 0 TUMORS |
| FEMUR | 1 TUMORS |
| NASAL CAVITY | 0 TUMORS |
| OTHER | 0 TUMORS |

THERE WERE 21 TUMOR-BEARING ANIMALS; 72 TUMORS AVG.= 2.6

TABLE X

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

TOTAL TUMOR INCIDENCE OF MAJOR ORGANS - ACID BLACK 52

RATS - DIETARY

GROUP 10 MALE (TREATED)

| | |
|---|---|
| SKIN | 1 TUMORS |
| MAMMARY | 0 TUMORS |
| THIGH MUSCLE | 0 TUMORS |
| SALIVARY GLAND | 0 TUMORS |
| BRONCHI | 0 TUMORS |
| TRACHEA | 0 TUMORS |
| LARYNX | 0 TUMORS |
| THYROID | 1 TUMORS |
| PARATHYROID | 0 TUMORS |
| ESOPHAGUS | 0 TUMORS |
| MANDIBULAR LYMPH NODE | 0 TUMORS |
| ADRENALS | 1 TUMORS |
| THYMUS | 0 TUMORS |
| SCIATIC NERVE | 0 TUMORS |
| STOMACH | 0 TUMORS |
| DUODENUM | 0 TUMORS |
| JEJUNUM | 0 TUMORS |
| ILEUM | 0 TUMORS |
| CECUM | 0 TUMORS |
| COLON | 0 TUMORS |
| RECTUM | 0 TUMORS |
| MESENTERIC LYMPH NODES | 0 TUMORS |
| LUNGS (ALL LOBES) | 5 TUMORS |
| LIVER | 1 TUMORS |
| SPLEEN | 2 TUMORS |
| PANCREAS | 3 TUMORS |
| KIDNEYS | 0 TUMORS |
| HEART | 0 TUMORS |
| URINARY BLADDER | 0 TUMORS |
| SEMINAL VESICLE | 0 TUMORS |
| PROSTATE | 0 TUMORS |
| TESTES | 37 TUMORS |
| BRAIN | 1 TUMORS |
| PITUITARY | 0 TUMORS |
| STERNUM/RIB & RIB JUNCTIO | 0 TUMORS |
| FEMUR | 0 TUMORS |
| NASAL CAVITY | 0 TUMORS |
| OTHER | 1 TUMORS |

THERE WERE 38 TUMOR-BEARING ANIMALS; 54 TUMORS AVG.= 1.4

GROUP 15 MALE (CONTROL)

| | |
|---|---|
| SKIN | 4 TUMORS |
| MAMMARY | 3 TUMORS |
| THIGH MUSCLE | 0 TUMORS |
| SALIVARY GLAND | 1 TUMORS |
| BRONCHI | 0 TUMORS |
| TRACHEA | 0 TUMORS |
| LARYNX | 0 TUMORS |
| THYROID | 5 TUMORS |
| PARATHYROID | 0 TUMORS |
| ESOPHAGUS | 0 TUMORS |
| MANDIBULAR LYMPH NODE | 1 TUMORS |
| ADRENALS | 3 TUMORS |
| THYMUS | 1 TUMORS |
| SCIATIC NERVE | 0 TUMORS |
| STOMACH | 0 TUMORS |
| DUODENUM | 1 TUMORS |
| JEJUNUM | 0 TUMORS |
| ILEUM | 0 TUMORS |
| CECUM | 0 TUMORS |
| COLON | 0 TUMORS |
| RECTUM | 0 TUMORS |
| MESENTERIC LYMPH NODES | 2 TUMORS |
| LUNGS (ALL LOBES) | 8 TUMORS |
| LIVER | 14 TUMORS |
| SPLEEN | 11 TUMORS |
| PANCREAS | 7 TUMORS |
| KIDNEYS | 1 TUMORS |
| HEART | 1 TUMORS |
| URINARY BLADDER | 1 TUMORS |
| SEMINAL VESICLE | 1 TUMORS |
| PROSTATE | 1 TUMORS |
| TESTES | 32 TUMORS |
| BRAIN | 2 TUMORS |
| PITUITARY | 0 TUMORS |
| STERNUM/RIB & RIB JUNCTIO | 1 TUMORS |
| FEMUR | 1 TUMORS |
| NASAL CAVITY | 0 TUMORS |
| OTHER | 1 TUMORS |

THERE WERE 35 TUMOR-BEARING ANIMALS; 111 TUMORS AVG.= 3.2

TABLE X

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

TOTAL TUMOR INCIDENCE OF MAJOR ORGANS - ACID BLACK 52

RATS - DIETARY

GROUP 10 FEMALE (TREATED)

| | |
|---|---|
| SKIN | 1 TUMORS |
| MAMMARY | 16 TUMORS |
| THIGH MUSCLE | 0 TUMORS |
| SALIVARY GLAND | 0 TUMORS |
| BRONCHI | 0 TUMORS |
| TRACHEA | 0 TUMORS |
| LARYNX | 0 TUMORS |
| THYROID | 8 TUMORS |
| PARATHYROID | 0 TUMORS |
| ESOPHAGUS | 0 TUMORS |
| MANDIBULAR LYMPH NODE | 1 TUMORS |
| ADRENALS | 3 TUMORS |
| THYMUS | 0 TUMORS |
| SCIATIC NERVE | 0 TUMORS |
| STOMACH | 1 TUMORS |
| DUODENUM | 0 TUMORS |
| JEJUNUM | 0 TUMORS |
| ILEUM | 0 TUMORS |
| CECUM | 0 TUMORS |
| COLON | 0 TUMORS |
| RECTUM | 0 TUMORS |
| MESENTERIC LYMPH NODES | 1 TUMORS |
| LUNGS (ALL LOBES) | 3 TUMORS |
| LIVER | 7 TUMORS |
| SPLEEN | 6 TUMORS |
| PANCREAS | 2 TUMORS |
| KIDNEYS | 2 TUMORS |
| HEART | 0 TUMORS |
| URINARY BLADDER | 1 TUMORS |
| OVARIES | 0 TUMORS |
| UTERUS | 6 TUMORS |
| BRAIN | 0 TUMORS |
| PITUITARY | 25 TUMORS |
| STERNUM/RIB & RIB JUNCTIO | 0 TUMORS |
| FEMUR | 0 TUMORS |
| NASAL CAVITY | 0 TUMORS |
| OTHER | 4 TUMORS |

THERE WERE 43 TUMOR-BEARING ANIMALS; 88 TUMORS AVG.= 2.0

GROUP 15 FEMALE (CONTROL)

| | |
|---|---|
| SKIN | 2 TUMORS |
| MAMMARY | 12 TUMORS |
| THIGH MUSCLE | 0 TUMORS |
| SALIVARY GLAND | 0 TUMORS |
| BRONCHI | 0 TUMORS |
| TRACHEA | 0 TUMORS |
| LARYNX | 0 TUMORS |
| THYROID | 5 TUMORS |
| PARATHYROID | 1 TUMORS |
| ESOPHAGUS | 0 TUMORS |
| MANDIBULAR LYMPH NODE | 0 TUMORS |
| ADRENALS | 1 TUMORS |
| THYMUS | 0 TUMORS |
| SCIATIC NERVE | 0 TUMORS |
| STOMACH | 0 TUMORS |
| DUODENUM | 0 TUMORS |
| JEJUNUM | 0 TUMORS |
| ILEUM | 0 TUMORS |
| CECUM | 0 TUMORS |
| COLON | 0 TUMORS |
| RECTUM | 0 TUMORS |
| MESENTERIC LYMPH NODES | 2 TUMORS |
| LUNGS (ALL LOBES) | 5 TUMORS |
| LIVER | 15 TUMORS |
| SPLEEN | 9 TUMORS |
| PANCREAS | 0 TUMORS |
| KIDNEYS | 1 TUMORS |
| HEART | 0 TUMORS |
| URINARY BLADDER | 0 TUMORS |
| OVARIES | 1 TUMORS |
| UTERUS | 5 TUMORS |
| BRAIN | 0 TUMORS |
| PITUITARY | 14 TUMORS |
| STERNUM/RIB & RIB JUNCTIO | 0 TUMORS |
| FEMUR | 0 TUMORS |
| NASAL CAVITY | 0 TUMORS |
| OTHER | 3 TUMORS |

THERE WERE 31 TUMOR-BEARING ANIMALS; 77 TUMORS AVG.= 2.4

TABLE XI

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

FISHER'S ANALYSIS OF TUMOR-BEARING ANIMALS - ACID BLACK 52

HAMSTERS - INTRATRACHEAL

| ORGAN SYSTEM | TREATED GROUP & SEX | TREATED TBA | TREATED AT RISK | CONTROL GROUP & SEX | CONTROL TBA | CONTROL AT RISK | PROBABILITY 1-TAIL | PROBABILITY 2-TAIL |
|---|---|---|---|---|---|---|---|---|
| (ALL TISSUES) | 1M | 19 | 42 | 5M | 13 | 25 | 0.388 | 1.000 |
| (RESPIRATORY SYSTEM) | 1M | 1 | 42 | 5M | 1 | 25 | 0.611 | 1.000 |
| (LUNG) | 1M | 1 | 42 | 5M | 1 | 25 | 0.611 | 1.000 |
| (DIGESTIVE SYSTEM) | 1M | 2 | 30 | 5M | 3 | 21 | 0.331 | 0.637 |
| (LIVER) | 1M | 1 | 30 | 5M | 2 | 21 | 0.366 | 0.561 |
| (HEMATOPOIETIC/LYMPHATIC SYSTEM) | 1M | 1 | 39 | 5M | 3 | 25 | 0.161 | 0.291 |
| (PANCREAS) | 1M | 1 | 30 | 5M | 1 | 21 | 0.659 | 1.000 |
| (ENDOCRINE SYSTEM) | 1M | 18 | 39 | 5M | 11 | 25 | 0.536 | 1.000 |
| (SPLEEN) | 1M | 0 | 30 | 5M | 2 | 21 | 0.165 | 0.165 |
| (MISCELLANEOUS TUMORS) | 1M | 1 | 32 | 5M | 0 | 23 | 0.582 | 1.000 |

TBA = Tumor-bearing animal; M = Male

TABLE XI

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

FISHER'S ANALYSIS OF TUMOR-BEARING ANIMALS - ACID BLACK 52

HAMSTERS - INTRATRACHEAL

| ORGAN SYSTEM | TREATED GROUP & SEX | TREATED TBA | TREATED AT RISK | CONTROL GROUP & SEX | CONTROL TBA | CONTROL AT RISK | PROBABILITY 1-TAIL | PROBABILITY 2-TAIL |
|---|---|---|---|---|---|---|---|---|
| (ALL TISSUES) | 1F | 10 | 42 | 5F | 8 | 25 | 0.325 | 1.000 |
| (REPRODUCTIVE SYSTEM) | 1F | 1 | 21 | 5F | 3 | 13 | 0.145 | 0.274 |
| (RESPIRATORY SYSTEM) | 1F | 0 | 4 | 5F | 1 | 6 | 0.600 | 1.000 |
| (LUNG) | 1F | 0 | 4 | 5F | 1 | 6 | 0.600 | 1.000 |
| (DIGESTIVE SYSTEM) | 1F | 5 | 33 | 5F | 1 | 16 | 0.351 | 0.649 |
| (LIVER) | 1F | 5 | 33 | 5F | 1 | 16 | 0.351 | 0.649 |
| (HEMATOPOIETIC/LYMPHATIC SYSTEM) | 1F | 3 | 12 | 5F | 0 | 8 | 0.193 | 0.242 |
| (PANCREAS) | 1F | 2 | 30 | 5F | 0 | 15 | 0.439 | 0.545 |
| (ENDOCRINE SYSTEM) | 1F | 4 | 42 | 5F | 6 | 25 | 0.106 | 0.157 |

TBA = Tumor-bearing animal; F = Female

TABLE XI

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

FISHER'S ANALYSIS OF TUMOR-BEARING ANIMALS - ACID BLACK 52

HAMSTERS - DIETARY

| ORGAN SYSTEM | TREATED GROUP & SEX | TREATED TBA | TREATED AT RISK | CONTROL GROUP & SEX | CONTROL TBA | CONTROL AT RISK | PROBABILITY 1-TAIL | PROBABILITY 2-TAIL |
|---|---|---|---|---|---|---|---|---|
| (ALL TISSUES) | 9M | 10 | 44 | 13M | 9 | 35 | 0.481 | 1.000 |
| (REPRODUCTIVE SYSTEM) | 9M | 0 | 10 | 13M | 1 | 14 | 0.583 | 1.000 |
| (RESPIRATORY SYSTEM) | 9M | 1 | 44 | 13M | 1 | 35 | 0.693 | 1.000 |
| (LUNG) | 9M | 1 | 44 | 13M | 1 | 35 | 0.693 | 1.000 |
| (DIGESTIVE SYSTEM) | 9M | 2 | 24 | 13M | 2 | 24 | 0.696 | 1.000 |
| (STOMACH) | 9M | 1 | 10 | 13M | 1 | 14 | 0.670 | 1.000 |
| (LIVER) | 9M | 2 | 24 | 13M | 2 | 24 | 0.696 | 1.000 |
| (HEMATOPOIETIC/LYMPHATIC SYSTEM) | 9M | 3 | 31 | 13M | 4 | 27 | 0.421 | 1.000 |
| (ENDOCRINE SYSTEM) | 9M | 7 | 29 | 13M | 7 | 27 | 0.560 | 1.000 |
| (SPLEEN) | 9M | 2 | 29 | 13M | 2 | 27 | 0.667 | 1.000 |

TBA = Tumor-bearing animal; M = Male

TABLE XI

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

FISHER'S ANALYSIS OF TUMOR-BEARING ANIMALS - ACID BLACK 52

HAMSTERS - DIETARY

| ORGAN SYSTEM | TREATED GROUP & SEX | TREATED TBA | TREATED AT RISK | CONTROL GROUP & SEX | CONTROL TBA | CONTROL AT RISK | PROBABILITY 1-TAIL | PROBABILITY 2-TAIL | |
|---|---|---|---|---|---|---|---|---|---|
| (ALL TISSUES) | 9F | 7 | 34 | 13F | 12 | 34 | 0.140 | 0.280 | |
| (REPRODUCTIVE SYSTEM) | 9F | 3 | 28 | 13F | 1 | 26 | 0.334 | 0.334 | |
| (RESPIRATORY SYSTEM) | 9F | 0 | 34 | 13F | 2 | 34 | 0.246 | 0.493 | |
| (LUNG) | 9F | 0 | 34 | 13F | 2 | 34 | 0.246 | 0.493 | |
| (HEMATOPOIETIC/LYMPHATIC SYSTEM) | 9F | 4 | 31 | 13F | 2 | 31 | 0.336 | 1.000 | |
| (PANCREAS) | 9F | 0 | 11 | 13F | 1 | 12 | 0.522 | 1.000 | |
| (ENDOCRINE SYSTEM) | 9F | 0 | 30 | 13F | 6 | 30 | 0.012 | 0.024 | S* |
| (SPLEEN) | 9F | 3 | 31 | 13F | 0 | 31 | 0.119 | 0.119 | |
| (MISCELLANEOUS TUMORS) | 9F | 0 | 30 | 13F | 1 | 31 | 0.508 | 1.000 | |

TBA = Tumor-bearing animal; F = Female

*A significantly higher incidence of tumor-bearing animals was present in the control group as compared to the treated group.

TABLE XI

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

FISHER'S ANALYSIS OF TUMOR-BEARING ANIMALS - ACID BLACK 52

RATS - INTRATRACHEAL

| ORGAN SYSTEM | TREATED GROUP & SEX | TREATED TBA | TREATED AT RISK | CONTROL GROUP & SEX | CONTROL TBA | CONTROL AT RISK | PROBABILITY 1-TAIL | PROBABILITY 2-TAIL |
|---|---|---|---|---|---|---|---|---|
| (ALL TISSUES) | 2M | 45 | 48 | 7M | 31 | 31 | 0.219 | 0.276 |
| (SKIN/MAMMARY GLAND) | 2M | 9 | 44 | 7M | 7 | 29 | 0.462 | 1.000 |
| (MUSCLE/SKELETAL SYSTEM) | 2M | 0 | 48 | 7M | 1 | 31 | 0.392 | 0.392 |
| (LUNG) | 2M | 9 | 44 | 7M | 11 | 30 | 0.102 | 0.182 |
| (RESPIRATORY SYSTEM) | 2M | 10 | 44 | 7M | 11 | 30 | 0.149 | 0.294 |
| (CARDIOVASCULAR SYSTEM) | 2M | 1 | 44 | 7M | 3 | 30 | 0.179 | 0.297 |
| (LIVER) | 2M | 11 | 44 | 7M | 12 | 30 | 0.133 | 0.309 |
| (SPLEEN) | 2M | 9 | 44 | 7M | 9 | 30 | 0.252 | 1.000 |
| (HEMATOPOIETIC/LYMPHATIC SYSTEM) | 2M | 9 | 44 | 7M | 9 | 30 | 0.252 | 1.000 |
| (PANCREAS) | 2M | 2 | 26 | 7M | 3 | 20 | 0.373 | 1.000 |
| (ENDOCRINE SYSTEM) | 2M | 22 | 47 | 7M | 17 | 30 | 0.271 | 1.000 |
| (DIGESTIVE SYSTEM) | 2M | 11 | 44 | 7M | 12 | 30 | 0.133 | 0.309 |
| (STOMACH) | 2M | 0 | 36 | 7M | 1 | 26 | 0.419 | 0.419 |
| (KIDNEY) | 2M | 0 | 36 | 7M | 3 | 26 | 0.069 | 0.069 |
| (URINARY SYSTEM) | 2M | 0 | 36 | 7M | 3 | 26 | 0.069 | 0.069 |
| (BRAIN) | 2M | 0 | 44 | 7M | 1 | 30 | 0.405 | 0.405 |
| (NERVOUS SYSTEM) | 2M | 0 | 44 | 7M | 1 | 30 | 0.405 | 0.405 |
| (REPRODUCTIVE SYSTEM) | 2M | 41 | 48 | 7M | 29 | 30 | 0.110 | 0.248 |
| (MISCELLANEOUS TUMORS) | 2M | 6 | 48 | 7M | 6 | 31 | 0.302 | 1.000 |

TBA = Tumor-bearing animal; M = Male

TABLE XI

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

FISHER'S ANALYSIS OF TUMOR-BEARING ANIMALS - ACID BLACK 52

RATS - INTRATRACHEAL

| ORGAN SYSTEM | TREATED GROUP & SEX | TREATED TBA | TREATED AT RISK | CONTROL GROUP & SEX | CONTROL TBA | CONTROL AT RISK | PROBABILITY 1-TAIL | PROBABILITY 2-TAIL |
|---|---|---|---|---|---|---|---|---|
| (ALL TISSUES) | 2F | 35 | 47 | 7F | 26 | 33 | 0.432 | 1.000 |
| (SKIN/MAMMARY GLAND) | 2F | 11 | 43 | 7F | 14 | 30 | 0.053 | 0.081 |
| (LUNG) | 2F | 5 | 43 | 7F | 1 | 30 | 0.205 | 0.390 |
| (RESPIRATORY SYSTEM) | 2F | 5 | 43 | 7F | 1 | 30 | 0.205 | 0.390 |
| (CARDIOVASCULAR SYSTEM) | 2F | 0 | 36 | 7F | 1 | 26 | 0.419 | 0.419 |
| (LIVER) | 2F | 9 | 44 | 7F | 6 | 30 | 0.601 | 1.000 |
| (SPLEEN) | 2F | 7 | 44 | 7F | 7 | 30 | 0.306 | 1.000 |
| (HEMATOPOIETIC/LYMPHATIC SYSTEM) | 2F | 7 | 44 | 7F | 7 | 30 | 0.306 | 1.000 |
| (PANCREAS) | 2F | 1 | 47 | 7F | 4 | 33 | 0.090 | 0.154 |
| (ENDOCRINE SYSTEM) | 2F | 25 | 47 | 7F | 18 | 33 | 0.544 | 1.000 |
| (DIGESTIVE SYSTEM) | 2F | 9 | 44 | 7F | 6 | 30 | 0.601 | 1.000 |
| (STOMACH) | 2F | 1 | 36 | 7F | 0 | 24 | 0.600 | 1.000 |
| (KIDNEY) | 2F | 1 | 36 | 7F | 0 | 24 | 0.600 | 1.000 |
| (URINARY SYSTEM) | 2F | 1 | 36 | 7F | 0 | 24 | 0.600 | 1.000 |
| (BRAIN) | 2F | 1 | 47 | 7F | 1 | 33 | 0.658 | 1.000 |
| (NERVOUS SYSTEM) | 2F | 1 | 47 | 7F | 1 | 33 | 0.658 | 1.000 |
| (REPRODUCTIVE SYSTEM) | 2F | 8 | 36 | 7F | 4 | 24 | 0.427 | 1.000 |

TBA = Tumor-bearing animal; F = Female

TABLE XI

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

FISHER'S ANALYSIS OF TUMOR-BEARING ANIMALS - ACID BLACK 52

RATS - DIETARY

| ORGAN SYSTEM | TREATED GROUP & SEX | TREATED TBA | TREATED AT RISK | CONTROL GROUP & SEX | CONTROL TBA | CONTROL AT RISK | PROBABILITY 1-TAIL | PROBABILITY 2-TAIL | |
|---|---|---|---|---|---|---|---|---|---|
| (ALL TISSUES) | 10M | 38 | 47 | 15M | 35 | 35 | 0.005 | 0.009 | S* |
| (SKIN/MAMMARY GLAND) | 10M | 1 | 43 | 15M | 5 | 34 | 0.056 | 0.082 | |
| (MUSCLE/SKELETAL SYSTEM) | 10M | 0 | 17 | 15M | 1 | 28 | 0.622 | 1.000 | |
| (LUNG) | 10M | 5 | 41 | 15M | 8 | 33 | 0.148 | 0.362 | |
| (RESPIRATORY SYSTEM) | 10M | 5 | 41 | 15M | 8 | 33 | 0.148 | 0.362 | |
| (CARDIOVASCULAR SYSTEM) | 10M | 0 | 17 | 15M | 1 | 28 | 0.622 | 1.000 | |
| (LIVER) | 10M | 1 | 21 | 15M | 13 | 29 | 0.002 | 0.003 | S* |
| (SPLEEN) | 10M | 2 | 28 | 15M | 11 | 31 | 0.009 | 0.012 | S* |
| (HEMATOPOIETIC/LYMPHATIC SYSTEM) | 10M | 2 | 28 | 15M | 11 | 31 | 0.009 | 0.012 | S* |
| (PANCREAS) | 10M | 3 | 14 | 15M | 7 | 27 | 0.535 | 1.000 | |
| (ENDOCRINE SYSTEM) | 10M | 6 | 18 | 15M | 17 | 28 | 0.065 | 0.082 | |
| (DIGESTIVE SYSTEM) | 10M | 1 | 35 | 15M | 15 | 33 | 0.00003 | 0.00003 | S* |
| (KIDNEY) | 10M | 0 | 17 | 15M | 1 | 28 | 0.622 | 1.000 | |
| (URINARY SYSTEM) | 10M | 0 | 26 | 15M | 2 | 31 | 0.291 | 0.495 | |
| (BRAIN) | 10M | 1 | 11 | 15M | 2 | 27 | 0.653 | 1.000 | |
| (NERVOUS SYSTEM) | 10M | 1 | 11 | 15M | 2 | 27 | 0.653 | 1.000 | |
| (REPRODUCTIVE SYSTEM) | 10M | 36 | 47 | 15M | 32 | 34 | 0.031 | 0.063 | |
| (MISCELLANEOUS TUMORS) | 10M | 1 | 47 | 15M | 1 | 35 | 0.675 | 1.000 | |

TBA = Tumor-bearing animal; M = Male

*A significantly higher incidence of tumor-bearing animals was present in the control group as compared to the treated group.

TABLE XI

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

FISHER'S ANALYSIS OF TUMOR-BEARING ANIMALS - ACID BLACK 52

RATS - DIETARY

| ORGAN SYSTEM | TREATED GROUP & SEX | TREATED TBA | TREATED AT RISK | CONTROL GROUP & SEX | CONTROL TBA | CONTROL AT RISK | PROBABILITY 1-TAIL | PROBABILITY 2-TAIL |
|---|---|---|---|---|---|---|---|---|
| (ALL TISSUES) | 10F | 43 | 49 | 15F | 32 | 34 | 0.284 | 0.711 |
| (SKIN/MAMMARY GLAND) | 10F | 14 | 49 | 15F | 15 | 34 | 0.110 | 0.243 |
| (LUNG) | 10F | 3 | 49 | 15F | 4 | 34 | 0.302 | 0.695 |
| (RESPIRATORY SYSTEM) | 10F | 3 | 49 | 15F | 4 | 34 | 0.302 | 0.695 |
| (LIVER) | 10F | 7 | 46 | 15F | 15 | 33 | 0.003 | 0.005S* |
| (SPLEEN) | 10F | 6 | 46 | 15F | 9 | 33 | 0.098 | 0.148 |
| (HEMATOPOIETIC/LYMPHATIC SYSTEM) | 10F | 7 | 49 | 15F | 10 | 34 | 0.081 | 0.166 |
| (PANCREAS) | 10F | 2 | 28 | 15F | 0 | 21 | 0.321 | 0.500 |
| (ENDOCRINE SYSTEM) | 10F | 30 | 48 | 15F | 16 | 34 | 0.123 | 0.375 |
| (DIGESTIVE SYSTEM) | 10F | 8 | 46 | 15F | 15 | 33 | 0.007 | 0.011S* |
| (STOMACH) | 10F | 1 | 28 | 15F | 0 | 21 | 0.571 | 1.000 |
| (KIDNEY) | 10F | 2 | 35 | 15F | 1 | 25 | 0.626 | 1.000 |
| (URINARY SYSTEM) | 10F | 3 | 35 | 15F | 1 | 25 | 0.443 | 1.000 |
| (REPRODUCTIVE SYSTEM) | 10F | 6 | 41 | 15F | 6 | 28 | 0.338 | 1.000 |
| (MISCELLANEOUS TUMORS) | 10F | 3 | 45 | 15F | 3 | 32 | 0.489 | 1.000 |

TBA = Tumor-bearing animal; F = Female

*A significantly higher incidence of tumor-bearing animals was present in the control group as compared to the treated group.

CARCINOGENICITY OF AZO DYES:ACID BLACK 52 AND YELLOW 3
IN HAMSTERS AND RATS

TABLE XII

SUMMARY OF HISTOPATHOLOGY FINDINGS* - ACID BLACK 52

*Expressed as the number of animals with the lesion, followed by the range of severity (1=minimal, 2=slight, 3=moderate, 4=severe). The number of animals examined [#], equals the number of animals in that group.

KEY

| | | |
|---|---|---|
| DYE: | ACID BLACK 52 | SPECIES: HAMSTER |
| ROUTE: | INTRATRACHEAL | DIETARY |
| GROUPS: | 1 (Treated) | 9 (Treated) |
| | 5 (Control) | 13 (Control) |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( MALES )

| | GROUP 1 | GROUP 5 | GROUP 9 | GROUP 13 |
|---|---|---|---|---|
| SKIN | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 33 | 24 | 26 | 29 |
| MISSING. | 1 | 0 | 0 | 0 |
| MUSCULAR DYSTROPHY, SUBCUTANEOUS. | 1 2+ | 1 3+ | 1 1+ | 0 |
| ACARIASIS. | 7 | 1 | 16 1+ - 4+ | 0 |
| EDEMA, SUBCUTANEOUS. | 5 3+ - 4+ | 7 3+ - 4+ | 10 2+ - 4+ | 3 2+ - 4+ |
| ACARIASIS, DERMATITIS, CHRONIC. | 1 4+ | 0 | 0 | 0 |
| ACARIASIS, EDEMA, SUBCUTANEOUS. | 1 3+ | 0 | 0 | 0 |
| DERMATITIS, PERACUTE. | 1 4+ | 0 | 0 | 0 |
| DERMATITIS, ACUTE. | 1 4+ | 0 | 0 | 0 |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 0 | 1 | 1 | 0 |
| HYPERKERATOSIS. | 0 | 1 3+ | 1 4+ | 0 |
| CELLULITIS, ACUTE, PURULENT. | 0 | 1 4+ | 0 | 0 |
| (MASS), SARCOMA, UNDIFFERENTIATED. | 0 | 1 | 0 | 0 |
| AUTOLYZED. | 0 | 0 | 1 | 2 |
| EPIDERMIS, NECROSIS. | 0 | 0 | 1 4+ | 0 |
| DERMATITIS, CHRONIC. | 0 | 0 | 0 | 1 2+ |
| MAMMARY GLAND | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 1 | 1 | 2 | 0 |
| NOT PRESENT IN SECTION. | 49 | 34 | 46 | 33 |
| AUTOLYZED. | 0 | 0 | 2 | 2 |
| MUSCLE | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 44 | 30 | 45 | 30 |
| MUSCULAR DYSTROPHY. | 6 1+ - 4+ | 4 3+ - 4+ | 2 2+ | 3 3+ |
| MYOSITIS, ACUTE, PURULENT. | 0 | 1 3+ | 0 | 0 |
| NOT PRESENT IN SECTION. | 0 | 0 | 1 | 0 |
| AUTOLYZED. | 0 | 0 | 2 | 2 |
| SALIVARY GLAND | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 49 | 32 | 47 | 32 |
| NEOPLASM, UNDIFFERENTIATED. | 1 | 0 | 0 | 0 |
| MISSING. | 0 | 2 | 0 | 1 |
| MALIGNANT LYMPHOMA. | 0 | 1 | 0 | 0 |
| AUTOLYZED. | 0 | 0 | 3 | 2 |
| MANDIBULAR LYMPH NODE | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 32 | 12 | 25 | 15 |
| AUTOLYZED. | 1 | 2 | 2 | 2 |
| MISSING. | 4 | 8 | 5 | 2 |
| PLASMACYTOSIS. | 11 3+ - 4+ | 11 3+ - 4+ | 9 3+ - 4+ | 12 2+ - 3+ |
| ERYTHROPHAGOCYTOSIS. | 1 4+ | 0 | 0 | 1 1+ |
| PLASMACYTOMA. | 1 | 1 | 0 | 1 |
| EXTRAMEDULLARY HEMATOPOIESIS. | 0 | 1 2+ | 1 2+ | 0 |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( MALES )

| | GROUP 1 | | GROUP 5 | | GROUP 9 | | GROUP 13 | |
|---|---|---|---|---|---|---|---|---|
| MANDIBULAR LYMPH NODE (continued) | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| RETICULOENDOTHELIAL CELL HYPERPLASIA. | 0 | | 1 | 3+ | 0 | | 0 | |
| PIGMENTATION, INTRACELLULAR. | 0 | | 0 | | 3 | 1+ - 3+ | 0 | |
| AMYLOIDOSIS. | 0 | | 0 | | 1 | 1+ | 0 | |
| CONGESTION. | 0 | | 0 | | 2 | 3+ | 0 | |
| HEMORRHAGE. | 0 | | 0 | | 1 | 4+ | 0 | |
| (SUBCAPSULAR SINUSES), | | | | | | | | |
| PIGMENTATION, INTRACELLULAR. | 0 | | 0 | | 1 | 3+ | 0 | |
| RETICULUM CELL HYPERPLASIA. | 0 | | 0 | | 2 | 3+ | 0 | |
| SIDEROCYTOSIS. | 0 | | 0 | | 0 | | 1 | 2+ |
| MALIGNANT LYMPHOMA. | 0 | | 0 | | 0 | | 2 | |
| EDEMA, MEDULLARY. | 0 | | 0 | | 0 | | 1 | 3+ |
| CYST(S). | 0 | | 0 | | 0 | | 1 | |
| SCIATIC NERVE | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 43 | | 31 | | 44 | | 25 | |
| MISSING. | 5 | | 2 | | 0 | | 6 | |
| INSUFFICIENT TISSUE | | | | | | | | |
| PRESENT IN SECTION. | 2 | | 2 | | 3 | | 2 | |
| NOT PRESENT IN SECTION. | 0 | | 0 | | 1 | | 0 | |
| AUTOLYZED. | 0 | | 0 | | 2 | | 2 | |
| THYMUS | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 30 | | 11 | | 23 | | 15 | |
| NOT PRESENT IN SECTION. | 12 | | 13 | | 13 | | 10 | |
| ATROPHY. | 1 | | 0 | | 1 | | 0 | |
| INVOLUTION. | 2 | | 2 | | 9 | 2+ | 0 | |
| CYST(S). | 4 | | 5 | | 1 | | 3 | |
| MASTOCYTOSIS. | 2 | 3+ | 2 | 3+ | 1 | 2+ | 2 | 2+ |
| MISSING. | 0 | | 1 | | 0 | | 1 | |
| INSUFFICIENT TISSUE | | | | | | | | |
| PRESENT IN SECTION. | 0 | | 1 | | 1 | | 0 | |
| AUTOLYZED. | 0 | | 0 | | 2 | | 2 | |
| PLASMACYTOSIS. | 0 | | 0 | | 0 | | 1 | 3+ |
| MALIGNANT LYMPHOMA. | 0 | | 0 | | 0 | | 1 | |
| LARYNX | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 49 | | 33 | | 46 | | 32 | |
| LARYNGITIS, ACUTE, CHRONIC. | 1 | 4+ | 0 | | 0 | | 0 | |
| AMYLOIDOSIS. | 0 | | 1 | 4+ | 0 | | 0 | |
| CYSTIC ECTATIC SUBMUCOSAL GLAND. | 0 | | 1 | | 0 | | 0 | |
| NOT PRESENT IN SECTION. | 0 | | 0 | | 1 | | 0 | |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( MALES )

| | GROUP 1 | | GROUP 5 | | GROUP 9 | | GROUP 13 | |
|---|---|---|---|---|---|---|---|---|
| LARYNX (continued) | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| AUTOLYZED. | 0 | | 0 | | 2 | | 2 | |
| LUMENAL PURULENT EXUDATE. | 0 | | 0 | | 1 | | 0 | |
| MISSING. | 0 | | 0 | | 0 | | 1 | |
| THYROID | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 28 | | 21 | | 30 | | 20 | |
| NOT PRESENT IN SECTION. | 2 | | 3 | | 11 | | 3 | |
| AMYLOIDOSIS. | 1 | 3+ | 7 | 2+ - 4+ | 3 | 2+ - 4+ | 5 | 2+ - 4+ |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 5 | | 1 | | 0 | | 2 | |
| FOLLICULAR CYST(S). | 1 | | 2 | | 2 | | 0 | |
| PSAMMOMA BODY(S), INTERFOLLICULAR. | 0 | | 1 | 3+ | 0 | | 0 | |
| FATTY INFILTRATION, INTRAFOLLICULAR. | 0 | | 1 | 3+ | 0 | | 0 | |
| AUTOLYZED. | 0 | | 0 | | 2 | | 2 | |
| MISSING. | 0 | | 0 | | 1 | | 3 | |
| (LACK OF COLLOID). | 0 | | 0 | | 1 | 4+ | 0 | |
| FOLLICULAR CELL ADENOMA. | 0 | | 0 | | 1 | | 0 | |
| PARATHYROID | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 23 | | 20 | | 25 | | 17 | |
| NOT PRESENT IN SECTION. | 25 | | 13 | | 21 | | 12 | |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 2 | | 0 | | 0 | | 0 | |
| HYPERPLASIA. | 0 | | 1 | 3+ | 0 | | 0 | |
| NODULAR HYPERPLASIA. | 0 | | 1 | 1+ | 0 | | 0 | |
| AUTOLYZED. | 0 | | 0 | | 2 | | 2 | |
| MISSING. | 0 | | 0 | | 1 | | 3 | |
| CYST(S), MULTILOCULATED. | 0 | | 0 | | 1 | | 0 | |
| ADENOMA. | 0 | | 0 | | 0 | | 1 | |
| TRACHEA | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 49 | | 35 | | 46 | | 32 | |
| TRACHEITIS, ACUTE, CHRONIC. | 1 | 3+ | 0 | | 0 | | 0 | |
| AUTOLYZED. | 0 | | 0 | | 2 | | 2 | |
| (TRACHEAL GLANDS-LAMINA PROPRIA), ADENITIS. | 0 | | 0 | | 1 | 3+ | 0 | |
| LUMENAL PURULENT EXUDATE. | 0 | | 0 | | 1 | | 0 | |
| MISSING. | 0 | | 0 | | 0 | | 1 | |
| BRONCHUS | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 46 | | 33 | | 47 | | 25 | |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 4 | | 1 | | 1 | | 7 | |
| MISSING. | 0 | | 1 | | 0 | | 1 | |
| AUTOLYZED. | 0 | | 0 | | 2 | | 2 | |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( MALES )

| | GROUP 1 | | GROUP 5 | | GROUP 9 | | GROUP 13 | |
|---|---|---|---|---|---|---|---|---|
| ESOPHAGUS | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 47 | | 35 | | 48 | | 32 | |
| MISSING. | 1 | | 0 | | 0 | | 1 | |
| MEDIASTINITIS, ACUTE, PURULENT. | 1 | 3+ | 0 | | 0 | | 0 | |
| (MUCOUS GLANDS), HYPERPLASIA, SUBMUCOSA. | 1 | 3+ | 0 | | 0 | | 0 | |
| AUTOLYZED. | 0 | | 0 | | 2 | | 2 | |
| ADRENAL | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 8 | | 13 | | 11 | | 9 | |
| CORTICAL NODULAR HYPERPLASIA. | 21 | | 13 | | 15 | | 14 | |
| MISSING. | 1 | | 0 | | 0 | | 1 | |
| AMYLOIDOSIS. | 11 | 2+ - 4+ | 11 | 3+ - 4+ | 4 | 2+ - 3+ | 4 | 3+ |
| HEMATOCYST(S). | 1 | | 0 | | 0 | | 0 | |
| PIGMENTATION, INTRACELLULAR. | 2 | 3+ | 0 | | 23 | 1+ - 4+ | 2 | 1+ - 4+ |
| CORTICAL CELL ADENOMA. | 16 | | 9 | | 6 | | 5 | |
| CYST(S). | 1 | | 0 | | 0 | | 0 | |
| HEMORRHAGE. | 1 | 3+ | 0 | | 0 | | 0 | |
| NECROSIS. | 1 | 3+ | 0 | | 0 | | 0 | |
| (SECOND ADRENAL MISSING). | 2 | | 1 | | 0 | | 0 | |
| PHEOCHROMOCYTOMA. | 1 | | 1 | | 0 | | 0 | |
| PIGMENTATION, INTERCELLULAR. | 1 | 1+ | 1 | 2+ | 0 | | 0 | |
| CORTICAL CELL HYPERPLASIA. | 1 | | 1 | | 0 | | 0 | |
| CONGESTION. | 0 | | 2 | 4+ | 0 | | 0 | |
| AUTOLYZED. | 0 | | 0 | | 2 | | 2 | |
| LYMPHOCYTOSIS, MEDULLARY. | 0 | | 0 | | 0 | | 1 | 3+ |
| MALIGNANT LYMPHOMA. | 0 | | 0 | | 0 | | 1 | |
| HYPERPLASIA, EXTRA-CORTICAL. | 0 | | 0 | | 0 | | 1 | |
| STOMACH | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 43 | | 30 | | 42 | | 24 | |
| AUTOLYZED. | 5 | | 3 | | 6 | | 6 | |
| GASTRITIS. | 1 | 2+ | 0 | | 0 | | 0 | |
| (NONGLANDULAR MUCOSA), PIGMENTATION, (BLACK). | 1 | 2+ | 0 | | 0 | | 0 | |
| (GLANDULAR), PIGMENTATION, (BLACK). | 0 | | 1 | | 0 | | 0 | |
| (GLANDULAR), AUTOLYSIS. | 0 | | 1 | | 0 | | 0 | |
| (FORESTOMACH), GASTRITIS, CHRONIC. | 0 | | 1 | 3+ | 0 | | 0 | |
| (GLANDULAR), PIGMENTATION, (YELLOW-BROWN). | 0 | | 1 | | 0 | | 0 | |
| (FORESTOMACH), GASTRITIS. | 0 | | 0 | | 1 | 4+ | 0 | |
| PAPILLOMA. | 0 | | 0 | | 1 | | 0 | |
| MISSING. | 0 | | 0 | | 0 | | 1 | |
| MALIGNANT LYMPHOMA. | 0 | | 0 | | 0 | | 1 | |
| PIGMENTATION, HEPATOCELLULAR. | 0 | | 0 | | 0 | | 1 | 2+ |
| (FORESTOMACH), HYPERPLASIA. | 0 | | 0 | | 0 | | 1 | 3+ |
| BILIARY CELL HYPERPLASIA. | 0 | | 0 | | 0 | | 1 | 2+ |
| (GLANDULAR), MELANOSIS. | 0 | | 0 | | 0 | | 1 | 3+ |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( MALES )

| | GROUP 1 | | GROUP 5 | | GROUP 9 | | GROUP 13 | |
|---|---|---|---|---|---|---|---|---|
| DUODENUM | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 45 | | 31 | | 42 | | 27 | |
| AUTOLYZED. | 5 | | 3 | | 7 | | 6 | |
| ENTERITIS, MUSCULARIS, ACUTE. | 0 | | 1 | 3+ | 0 | | 0 | |
| ENTERITIS AND PERITONITIS, ACTIVE, CHRONIC. | 0 | | 0 | | 1 | 4+ | 0 | |
| MISSING. | 0 | | 0 | | 0 | | 1 | |
| MALIGNANT LYMPHOMA. | 0 | | 0 | | 0 | | 1 | |
| JEJUNUM | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 44 | | 32 | | 42 | | 27 | |
| AUTOLYZED. | 4 | | 3 | | 7 | | 6 | |
| MISSING. | 2 | | 0 | | 0 | | 1 | |
| ENTERITIS AND PERITONITIS, ACTIVE, CHRONIC. | 0 | | 0 | | 1 | 4+ | 0 | |
| MALIGNANT LYMPHOMA. | 0 | | 0 | | 0 | | 1 | |
| ILEUM | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 38 | | 29 | | 40 | | 22 | |
| ILEITIS, PROLIFERATIVE. | 4 | 3+ | 2 | 3+ - 4+ | 2 | 3+ | 4 | 3+ - 4+ |
| AUTOLYZED. | 7 | | 4 | | 7 | | 6 | |
| MISSING. | 1 | | 0 | | 0 | | 1 | |
| ENTERITIS AND PERITONITIS, ACTIVE, CHRONIC. | 0 | | 0 | | 1 | 4+ | 0 | |
| MALIGNANT LYMPHOMA. | 0 | | 0 | | 0 | | 1 | |
| ILEITIS, CHRONIC. | 0 | | 0 | | 0 | | 1 | 4+ |
| CECUM | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 45 | | 28 | | 39 | | 25 | |
| AUTOLYZED. | 4 | | 3 | | 7 | | 6 | |
| ENTERITIS, PROLIFERATIVE. | 1 | 3+ | 3 | 3+ - 4+ | 2 | 4+ | 2 | 4+ |
| CRYPT ECTASIA. | 0 | | 1 | 3+ | 0 | | 0 | |
| ENTERITIS AND PERITONITIS, ACTIVE, CHRONIC. | 0 | | 0 | | 1 | 4+ | 0 | |
| CECITIS, PROLIFERATIVE. | 0 | | 0 | | 1 | 4+ | 0 | |
| MISSING. | 0 | | 0 | | 0 | | 1 | |
| MALIGNANT LYMPHOMA. | 0 | | 0 | | 0 | | 1 | |
| COLON | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 46 | | 32 | | 41 | | 27 | |
| AUTOLYZED. | 4 | | 3 | | 7 | | 6 | |
| ENTERITIS AND PERITONITIS, ACTIVE, CHRONIC. | 0 | | 0 | | 1 | 4+ | 0 | |
| PLASMACYTOSIS, LAMINA PROPRIA. | 0 | | 0 | | 1 | 4+ | 0 | |
| MISSING. | 0 | | 0 | | 0 | | 1 | |
| MALIGNANT LYMPHOMA. | 0 | | 0 | | 0 | | 1 | |
| RECTUM | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( MALES )

| | GROUP 1 | GROUP 5 | GROUP 9 | GROUP 13 |
|---|---|---|---|---|
| RECTUM (continued) | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 45 | 32 | 42 | 27 |
| AUTOLYZED. | 4 | 3 | 7 | 6 |
| INTUSSUSCEPTION. | 1 | 0 | 0 | 0 |
| ENTERITIS AND PERITONITIS, ACTIVE, CHRONIC. | 0 | 0 | 1 4+ | 0 |
| MISSING. | 0 | 0 | 0 | 1 |
| MALIGNANT LYMPHOMA. | 0 | 0 | 0 | 1 |
| MESENTERIC LYMPH NODE | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 36 | 22 | 20 | 20 |
| RETICULOENDOTHELIAL CELL HYPERPLASIA. | 2 3+ | 2 3+ | 2 3+ | 0 |
| AUTOLYZED. | 4 | 1 | 7 | 4 |
| MISSING. | 3 | 3 | 6 | 6 |
| PLASMACYTOSIS. | 1 2+ | 3 3+ | 5 2+ - 3+ | 2 3+ |
| LYMPHADENITIS, CHRONIC. | 1 4+ | 0 | 0 | 0 |
| LYMPHOID HYPERPLASIA. | 2 3+ - 4+ | 1 3+ | 1 3+ | 0 |
| FOLLICULAR HYPERPLASIA. | 1 3+ | 0 | 0 | 0 |
| NOT PRESENT IN SECTION. | 0 | 1 | 0 | 0 |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 0 | 1 | 1 | 0 |
| LYMPHADENITIS, ACUTE, PURULENT. | 0 | 1 4+ | 0 | 0 |
| PIGMENTATION, INTRACELLULAR. | 0 | 0 | 3 3+ - 4+ | 0 |
| HISTIOCYTOSIS. | 0 | 0 | 1 3+ | 0 |
| AMYLOIDOSIS. | 0 | 0 | 1 2+ | 0 |
| CONGESTION. | 0 | 0 | 1 3+ | 0 |
| FIBROSIS. | 0 | 0 | 1 2+ | 0 |
| LYMPHADENITIS, SUBACUTE, PURULENT. | 0 | 0 | 1 3+ | 0 |
| HEMOSIDEROSIS. | 0 | 0 | 1 1+ | 0 |
| HYPERPLASIA. | 0 | 0 | 1 3+ | 0 |
| MALIGNANT LYMPHOMA. | 0 | 0 | 1 | 1 |
| EPITHELIAL CELL PROLIFERATION. | 0 | 0 | 1 3+ | 0 |
| ERYTHROPHAGOCYTOSIS. | 0 | 0 | 1 2+ | 0 |
| RETICULUM CELL HYPERPLASIA. | 0 | 0 | 1 2+ | 0 |
| MINERALIZATION. | 0 | 0 | 0 | 1 2+ |
| CYSTIC. | 0 | 0 | 0 | 1 |
| LUNG | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 4 | 18 | 21 | 21 |
| PNEUMONOPATHY. | 40 1+ - 4+ | 1 1+ | 0 | 0 |
| PNEUMONITIS, INTERSTITIAL. | 3 3+ - 4+ | 1 4+ | 1 2+ | 1 2+ |
| EOSINOPHILIC MASS(ES). | 2 1+ - 3+ | 0 | 0 | 0 |
| ALVEOLAR/BRONCHIOLAR CELL HYPERPLASIA. | 2 2+ - 3+ | 3 1+ - 2+ | 5 1+ - 3+ | 3 1+ - 2+ |
| EOSINOPHILIC MASS(ES), INTRA-ALVEOLAR. | 1 3+ | 0 | 0 | 0 |
| HISTIOCYTOSIS. | 1 3+ | 4 2+ - 3+ | 8 2+ - 4+ | 6 1+ - 4+ |
| (PULMONARY ARTERY), RECANALIZED THROMBUS. | 1 | 0 | 0 | 0 |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( MALES )

| | GROUP 1 | | GROUP 5 | | GROUP 9 | | GROUP 13 | |
|---|---|---|---|---|---|---|---|---|
| LUNG (continued) | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| PLEURITIS. | 0 | | 1 | 4+ | 0 | | 0 | |
| ALVEOLAR/BRONCHIOLAR CELL ADENOMA. | 1 | | 0 | | 0 | | 0 | |
| PNEUMONITIS. | 2 | 4+ | 0 | | 1 | 4+ | 0 | |
| PIGMENT LADEN HISTIOCYTES. | 1 | 1+ | 0 | | 0 | | 0 | |
| AMYLOIDOSIS. | 0 | | 1 | 2+ | 0 | | 0 | |
| AUTOLYZED. | 0 | | 1 | | 3 | | 2 | |
| BRONCHOPNEUMONIA. | 0 | | 3 | 3+ - 4+ | 2 | 2+ - 3+ | 2 | 2+ - 4+ |
| CONGESTION. | 0 | | 1 | 3+ | 1 | | 1 | 3+ |
| BRONCHOPNEUMONIA, ACUTE. | 0 | | 1 | 4+ | 0 | | 0 | |
| PNEUMOLITHIASIS. | 0 | | 1 | 1+ | 1 | 2+ | 0 | |
| PNEUMONITIS, INTERSTITIAL, SUBACUTE. | 0 | | 1 | 3+ | 0 | | 0 | |
| ALVEOLAR/BRONCHIOLAR CELL PROLIFERATION. | 0 | | 1 | 3+ | 0 | | 0 | |
| PLASMACYTOMA. | 0 | | 1 | 3+ | 0 | | 0 | |
| ATELECTASIS. | 0 | | 0 | | 5 | 2+ - 3+ | 1 | 3+ |
| SIDEROCYTOSIS. | 0 | | 0 | | 5 | 1+ - 3+ | 0 | |
| HEMORRHAGE. | 0 | | 0 | | 2 | 3+ - 4+ | 1 | 3+ |
| PNEUMONITIS, INTERSTITIAL, CHRONIC. | 0 | | 0 | | 1 | 4+ | 0 | |
| LEUKEMIA. | 0 | | 0 | | 1 | | 1 | |
| ALVEOLAR/BRONCHIOLAR CELL ADENOMATOUS HYPERPLASIA. | 0 | | 0 | | 1 | 1+ | 0 | |
| BRONCHOPNEUMONIA, ACTIVE, CHRONIC, PURULENT. | 0 | | 0 | | 1 | 4+ | 0 | |
| PNEUMONITIS, GRANULOMATOUS. | 0 | | 0 | | 1 | 4+ | 0 | |
| BRONCHIOLAR PNEUMONIA. | 0 | | 0 | | 1 | 4+ | 0 | |
| BRONCHOPNEUMONIA, ACUTE, PURULENT. | 0 | | 0 | | 1 | 4+ | 0 | |
| (SINGLE LOBE), ATELECTASIS. | 0 | | 0 | | 0 | | 1 | 4+ |
| SQUAMOUS METAPLASIA. | 0 | | 0 | | 0 | | 1 | 1+ |
| LIVER | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 12 | | 11 | | 13 | | 14 | |
| BILIARY CYST(S). | 5 | | 1 | | 0 | | 6 | |
| AMYLOIDOSIS. | 10 | 1+ - 4+ | 8 | 2+ - 4+ | 2 | 3+ | 4 | 2+ - 3+ |
| SIDEROPHAGOCYTOSIS. | 12 | 1+ - 3+ | 6 | 1+ - 3+ | 17 | 1+ - 3+ | 4 | 1+ - 3+ |
| CONGESTION. | 10 | 3+ - 4+ | 7 | 2+ - 4+ | 4 | 2+ - 4+ | 4 | 3+ - 4+ |
| HEPATOCELLULAR ATYPIA. | 1 | 4+ | 0 | | 0 | | 0 | |
| PIGMENTATION, HEPATOCELLULAR. | 5 | 1+ - 3+ | 0 | | 26 | 1+ - 4+ | 2 | 2+ - 3+ |
| HEPATOCELLULAR VACUOLATION. | 2 | 2+ - 3+ | 1 | 3+ | 0 | | 0 | |
| CYST(S). | 3 | | 1 | | 1 | | 0 | |
| NECROSIS. | 1 | 3+ | 0 | | 0 | | 0 | |
| BILE DUCT HYPERPLASIA. | 1 | 3+ | 0 | | 0 | | 0 | |
| TRABECULAR CHOLANGIOMA. | 1 | | 0 | | 0 | | 0 | |
| CIRRHOSIS. | 1 | | 0 | | 0 | | 0 | |
| CLEAR CELL FOCUS/FOCI. | 2 | | 1 | | 0 | | 0 | |
| TRIADITIS, LYMPHOCYTIC. | 1 | 2+ | 0 | | 0 | | 0 | |
| HEPATITIS, ACTIVE, ACUTE AND CHRONIC, DISSEMINATED. | 1 | 4+ | 0 | | 0 | | 0 | |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( MALES )

| | GROUP 1 | | GROUP 5 | | GROUP 9 | | GROUP 13 | |
|---|---|---|---|---|---|---|---|---|
| LIVER (continued) | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| CHOLANGITIS, ACUTE. | 1 | 3+ | 0 | | 0 | | 0 | |
| TELANGIECTASIS. | 1 | 4+ | 0 | | 0 | | 0 | |
| AUTOLYZED. | 0 | | 3 | | 3 | | 3 | |
| NECROSIS, CENTRILOBULAR. | 0 | | 1 | | 0 | | 0 | |
| HEPATOCELLULAR VACUOLATION, PERIPORTAL. | 0 | | 1 | 3+ | 0 | | 1 | 3+ |
| BILIARY HYPERPLASIA. | 0 | | 1 | 4+ | 0 | | 1 | 2+ |
| EXTRAMEDULLARY HEMATOPOIESIS. | 0 | | 2 | 2+ | 2 | 2+ - 3+ | 0 | |
| HEPATITIS, PERIPORTAL, CHRONIC. | 0 | | 1 | 3+ | 0 | | 0 | |
| CONGESTION, PASSIVE, CHRONIC. | 0 | | 1 | 3+ | 3 | 4+ | 1 | 3+ |
| HEPATOCELLULAR VACUOLATION, PERILOBULAR. | 0 | | 1 | 2+ | 0 | | 0 | |
| BILE DUCT PROLIFERATION. | 0 | | 1 | 3+ | 0 | | 0 | |
| TRIADITIS. | 0 | | 1 | 1+ | 0 | | 0 | |
| PLASMACYTOMA. | 0 | | 2 | 4+ | 0 | | 0 | |
| BILIARY CYST(S), MULTILOBULAR. | 0 | | 1 | | 0 | | 0 | |
| CONGESTION, PASSIVE. | 0 | | 0 | | 1 | 4+ | 0 | |
| SIDEROCYTOSIS. | 0 | | 0 | | 1 | 4+ | 0 | |
| CONGESTION, CENTRILOBULAR. | 0 | | 0 | | 1 | 4+ | 0 | |
| MALIGNANT LYMPHOMA. | 0 | | 0 | | 1 | | 2 | |
| HEPATITIS, PERIPORTAL, SUBACUTE, CHRONIC. | 0 | | 0 | | 1 | 3+ | 0 | |
| HEMOSIDEROSIS, INTRACELLULAR. | 0 | | 0 | | 1 | 3+ | 0 | |
| HEPATITIS, SUBACUTE. | 0 | | 0 | | 2 | 1+ - 2+ | 0 | |
| LEUKEMIA. | 0 | | 0 | | 1 | | 0 | |
| ISCHEMIC NECROSIS. | 0 | | 0 | | 1 | 3+ | 0 | |
| SINUSOIDAL DILATATION. | 0 | | 0 | | 1 | 4+ | 0 | |
| HEPATOCELLULAR INDIVIDUALIZATION. | 0 | | 0 | | 1 | 3+ | 0 | |
| BILIARY EPITHELIAL CELL PROLIFERATION. | 0 | | 0 | | 0 | | 1 | 2+ |
| GALLBLADDER | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 27 | | 20 | | 31 | | 24 | |
| AUTOLYZED. | 21 | | 15 | | 17 | | 10 | |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 1 | | 0 | | 0 | | 0 | |
| EDEMA. | 1 | | 0 | | 0 | | 0 | |
| NOT PRESENT IN SECTION. | 0 | | 0 | | 1 | | 1 | |
| MISSING. | 0 | | 0 | | 1 | | 0 | |
| SPLEEN | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 28 | | 19 | | 21 | | 25 | |
| AUTOLYZED. | 3 | | 4 | | 3 | | 3 | |
| MISSING. | 3 | | 1 | | 0 | | 1 | |
| AMYLOIDOSIS. | 13 | 2+ - 4+ | 6 | 3+ - 4+ | 3 | 2+ - 3+ | 2 | 3+ |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 1 | | 0 | | 0 | | 0 | |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( MALES )

| | GROUP 1 | GROUP 5 | GROUP 9 | GROUP 13 |
|---|---|---|---|---|
| SPLEEN (continued) | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| EXTRAMEDULLARY HEMATOPOIESIS. | 4 2+ - 4+ | 2 3+ | 13 2+ - 4+ | 1 4+ |
| FIBROSIS. | 1 4+ | 0 | 0 | 0 |
| PIGMENTATION, CELLULAR & EXTRACELLULAR. | 1 4+ | 0 | 0 | 0 |
| (WHITE PULP), HEMOSIDEROSIS. | 0 | 1 3+ | 0 | 0 |
| HYPERPLASIA. | 0 | 1 4+ | 5 4+ | 0 |
| PLASMACYTOMA. | 0 | 2 | 0 | 0 |
| PIGMENTATION, INTRACELLULAR. | 0 | 0 | 2 1+ - 3+ | 0 |
| (WHITE PULP), SIDEROCYTOSIS. | 0 | 0 | 1 2+ | 0 |
| HEMOSIDEROSIS. | 0 | 0 | 3 1+ - 3+ | 0 |
| PIGMENTATION, INTRACELLULAR, (BLACK). | 0 | 0 | 1 | 0 |
| MALIGNANT LYMPHOMA. | 0 | 0 | 1 | 2 3+ |
| HEMANGIOMA, CAVERNOUS. | 0 | 0 | 1 | 0 |
| SIDEROCYTOSIS. | 0 | 0 | 0 | 1 3+ |
| PANCREAS | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 34 | 26 | 39 | 28 |
| AUTOLYZED. | 4 | 6 | 4 | 3 |
| MISSING. | 5 | 2 | 0 | 1 |
| PANCREATITIS, ACUTE, NECROTIZING. | 1 4+ | 0 | 0 | 0 |
| DUCTAL ECTASIA. | 3 2+ - 3+ | 0 | 4 1+ - 2+ | 0 |
| ACINAR CELL HYPERTROPHY. | 1 2+ | 0 | 0 | 1 3+ |
| ISLET CELL HYPERPLASIA. | 1 | 0 | 0 | 0 |
| ISLET CELL ADENOMA. | 1 | 0 | 0 | 0 |
| PLASMACYTOMA, INTRALOBULAR. | 0 | 1 3+ | 0 | 0 |
| FIBROSIS. | 0 | 0 | 2 1+ - 2+ | 0 |
| ACINAR CELL ATROPHY. | 0 | 0 | 1 | 0 |
| DUCTAL HYPERPLASIA. | 0 | 0 | 1 2+ | 0 |
| STEATITIS, SUBACUTE. | 0 | 0 | 1 3+ | 0 |
| AMYLOIDOSIS. | 0 | 0 | 0 | 1 4+ |
| ACINAR CELL HYPERPLASIA. | 0 | 0 | 0 | 1 |
| EOSINOPHILIA. | 0 | 0 | 0 | 1 4+ |
| ADENOMATOUS HYPERPLASIA, INTRADUCTAL, HEPATOID. | 0 | 0 | 0 | 1 |
| KIDNEY | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 8 | 7 | 15 | 8 |
| AUTOLYZED. | 1 | 1 | 3 | 3 |
| AMYLOIDOSIS. | 21 1+ - 4+ | 10 3+ - 4+ | 3 2+ - 3+ | 6 2+ - 4+ |
| SIDEROPHAGOCYTOSIS. | 1 3+ | 0 | 0 | 0 |
| NEPHROLITHIASIS. | 4 2+ - 4+ | 7 2+ - 3+ | 2 1+ - 2+ | 10 2+ - 3+ |
| GLOMERULAR NEPHROSIS. | 15 2+ - 4+ | 5 1+ - 4+ | 14 1+ - 3+ | 18 2+ - 4+ |
| MINERALIZATION. | 3 2+ | 1 4+ | 0 | 1 2+ |
| NECROSIS. | 1 4+ | 0 | 0 | 0 |
| GLOMERULOSCLEROSIS. | 2 3+ | 7 2+ - 4+ | 1 2+ | 0 |
| NEPHROSIS. | 2 2+ - 3+ | 1 3+ | 2 1+ - 3+ | 0 |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( MALES )

| | GROUP 1 | | GROUP 5 | | GROUP 9 | | GROUP 13 | |
|---|---|---|---|---|---|---|---|---|
| KIDNEY (continued) | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| TUBULAR DILATATION. | 1 | 3+ | 0 | | 0 | | 0 | |
| PELVIS, MINERALIZATION. | 0 | | 1 | 1+ | 0 | | 0 | |
| (CORTEX), TOXIC TUBULAR NECROSIS. | 0 | | 1 | 4+ | 0 | | 0 | |
| RENAL VESSELS, THROMBOSIS. | 0 | | 1 | 4+ | 0 | | 0 | |
| NEPHROSIS, SENILE. | 0 | | 2 | 1+ - 4+ | 0 | | 0 | |
| MINERALIZATION, MEDULLA. | 0 | | 1 | 2+ | 0 | | 0 | |
| PIGMENTATION, INTRACELLULAR. | 0 | | 0 | | 20 | 1+ - 4+ | 0 | |
| CORTICAL CYST(S). | 0 | | 0 | | 1 | | 0 | |
| TUBULAR CELL HYPERPLASIA. | 0 | | 0 | | 1 | 2+ | 0 | |
| GLOMERULAR AMYLOIDOSIS. | 0 | | 0 | | 2 | 2+ - 3+ | 0 | |
| HYALINE DROPLET DEGENERATION. | 0 | | 0 | | 1 | 4+ | 0 | |
| PYELONEPHRITIS. | 0 | | 0 | | 1 | 4+ | 0 | |
| PIGMENTATION. | 0 | | 0 | | 2 | 3+ | 0 | |
| NEPHRITIS. | 0 | | 0 | | 1 | 4+ | 0 | |
| PIGMENTATION, INTRACELLLAR. | 0 | | 0 | | 1 | 2+ | 0 | |
| (MASS), MISSING. | 0 | | 0 | | 0 | | 1 | |
| HEART | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 34 | | 29 | | 36 | | 24 | |
| AUTOLYZED. | 1 | | 1 | | 3 | | 2 | |
| MISSING. | 2 | | 0 | | 0 | | 0 | |
| MUSCULAR DYSTROPHY. | 1 | 3+ | 0 | | 0 | | 0 | |
| ATRIAL THROMBOSIS. | 11 | | 3 | | 8 | | 6 | |
| THROMBOSIS, VENTRICULAR. | 1 | | 0 | | 0 | | 0 | |
| MYOCARDIOPATHY. | 1 | 2+ | 0 | | 0 | | 1 | 3+ |
| MURAL THROMBUS. | 0 | | 2 | | 0 | | 0 | |
| FIBROSIS. | 0 | | 0 | | 2 | 3+ | 0 | |
| MYOCARDIAL FIBROSIS. | 0 | | 0 | | 2 | 2+ - 3+ | 0 | |
| MINERALIZATION, MYOCARDIAL. | 0 | | 0 | | 0 | | 2 | 2+ |
| URINARY BLADDER | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 38 | | 28 | | 44 | | 29 | |
| AUTOLYZED. | 7 | | 5 | | 4 | | 5 | |
| MISSING. | 2 | | 0 | | 0 | | 0 | |
| AMYLOIDOSIS. | 1 | 4+ | 0 | | 0 | | 0 | |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 1 | | 1 | | 0 | | 1 | |
| NECROSIS. | 1 | 4+ | 0 | | 0 | | 0 | |
| EPITHELIOMATOUS HYPERPLASIA. | 1 | | 0 | | 0 | | 0 | |
| CYSTITIS, ACUTE. | 0 | | 1 | 3+ | 0 | | 0 | |
| CYSTITIS, CHRONIC. | 0 | | 0 | | 1 | 2+ | 0 | |
| LUMEN, BLACK PARTICULATE MATTER. | 0 | | 0 | | 1 | | 0 | |
| SEMINAL VESICLE | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 46 | | 31 | | 45 | | 31 | |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( MALES )

| | GROUP 1 | | GROUP 5 | | GROUP 9 | | GROUP 13 | |
|---|---|---|---|---|---|---|---|---|
| SEMINAL VESICLE (continued) | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| AUTOLYZED. | 4 | | 2 | | 3 | | 3 | |
| MISSING. | 0 | | 2 | | 1 | | 0 | |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 0 | | 0 | | 1 | | 0 | |
| VESICULITIS, ACUTE, PURULENT. | 0 | | 0 | | 0 | | 1 | 4+ |
| PROSTATE | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 40 | | 25 | | 34 | | 28 | |
| AUTOLYZED. | 4 | | 3 | | 3 | | 3 | |
| MISSING. | 5 | | 3 | | 9 | | 0 | |
| PROSTATITIS, ACUTE, PURULENT. | 1 | 4+ | 2 | 4+ | 0 | | 2 | 4+ |
| LITHIASIS. | 0 | | 1 | 2+ | 0 | | 0 | |
| PROSTATITIS, NECROTIZING. | 0 | | 1 | 4+ | 0 | | 0 | |
| NOT PRESENT IN SECTION. | 0 | | 0 | | 1 | | 0 | |
| GIANT CELL(S). | 0 | | 0 | | 1 | | 0 | |
| PROSTATITIS. | 0 | | 0 | | 1 | 4+ | 0 | |
| PROSTATITIS, ACTIVE, CHRONIC. | 0 | | 0 | | 1 | 4+ | 0 | |
| MALIGNANT LYMPHOMA. | 0 | | 0 | | 0 | | 1 | |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 0 | | 0 | | 0 | | 1 | |
| TESTIS | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 34 | | 24 | | 26 | | 22 | |
| AUTOLYZED. | 4 | | 2 | | 3 | | 2 | |
| ATROPHY. | 3 | | 1 | | 0 | | 1 | |
| OLIGOSPERMIA. | 9 | | 9 | 4+ | 16 | 2+ | 8 | |
| (SEMINIFEROUS TUBULES), PIGMENTATION, INTRACELLULAR. | 1 | 3+ | 0 | | 1 | 2+ | 0 | |
| (SEMINIFEROUS TUBULES), MINERALIZATION. | 1 | 2+ | 0 | | 0 | | 1 | 3+ |
| PERIARTERITIS, CHRONIC, (HEALED). | 1 | 3+ | 0 | | 0 | | 0 | |
| MULTINUCLEATED GIANT CELL(S), OCCASIONAL. | 1 | | 0 | | 0 | | 0 | |
| (SEMINIFEROUS TUBULES), PIGMENTATION, INTERCELLULAR. | 1 | 3+ | 0 | | 0 | | 0 | |
| ARTERIOSCLEROSIS. | 1 | 2+ | 0 | | 0 | | 0 | |
| PIGMENTATION, INTRACELLULAR. | 0 | | 0 | | 11 | 2+ - 4+ | 0 | |
| INFARCTION. | 0 | | 0 | | 1 | 4+ | 0 | |
| (SEMINIFEROUS TUBULES), NECROSIS. | 0 | | 0 | | 0 | | 1 | |
| NECROSIS. | 0 | | 0 | | 0 | | 2 | 4+ |
| CEREBRUM | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 48 | | 31 | | 46 | | 32 | |
| AUTOLYZED. | 1 | | 1 | | 3 | | 3 | |
| MINERALIZATION. | 1 | 1+ | 2 | 1+ - 2+ | 0 | | 0 | |
| MINERALIZATION, VASCULAR. | 0 | | 1 | 2+ | 0 | | 0 | |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( MALES )

| | GROUP 1 | GROUP 5 | GROUP 9 | GROUP 13 |
|---|---|---|---|---|
| CEREBRUM (continued) | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| ENCEPHALITIS, GRANULAMATOUS, NECROTIZING. | 0 | 0 | 1 4+ | 0 |
| CEREBELLUM | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 49 | 34 | 46 | 31 |
| AUTOLYZED. | 1 | 1 | 3 | 3 |
| MISSING. | 0 | 0 | 1 | 1 |
| PITUITARY | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 20 | 18 | 14 | 22 |
| NOT PRESENT IN SECTION. | 2 | 0 | 0 | 0 |
| AUTOLYZED. | 1 | 1 | 3 | 2 |
| MISSING. | 26 | 16 | 32 | 11 |
| CYST(S). | 1 | 0 | 0 | 0 |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 0 | 0 | 1 | 0 |
| STERNABRAE | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 48 | 33 | 48 | 33 |
| MUSCULAR DYSTROPHY, INTERCOSTAL MUSCLES. | 2 3+ - 4+ | 0 | 0 | 0 |
| MISSING. | 0 | 2 | 0 | 0 |
| AUTOLYZED. | 0 | 0 | 2 | 2 |
| FEMUR | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 50 | 33 | 48 | 33 |
| MISSING. | 0 | 2 | 0 | 0 |
| AUTOLYZED. | 0 | 0 | 2 | 2 |
| (MASS), MISSING. | 0 | 1 | 0 | 0 |
| BONE MARROW | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 47 | 26 | 43 | 27 |
| AUTOLYZED. | 2 | 2 | 3 | 3 |
| HEMORRHAGE. | 1 3+ | 0 | 0 | 0 |
| MISSING. | 0 | 2 | 0 | 0 |
| HYPERPLASIA. | 0 | 1 3+ | 0 | 0 |
| RETICULUM CELL HYPERPLASIA. | 0 | 1 3+ | 0 | 0 |
| HYPOPLASIA. | 0 | 1 3+ | 2 | 2 3+ |
| MALIGNANT LYMPHOMA. | 0 | 1 | 0 | 3 |
| MONONUCLEAR CELL HYPERPLASIA. | 0 | 1 3+ | 0 | 0 |
| MONONUCLEOCYTOSIS. | 0 | 0 | 1 3+ | 0 |
| MYELOID HYPERPLASIA. | 0 | 0 | 1 3+ | 0 |
| NASAL CAVITY | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 48 | 31 | 46 | 31 |
| (TISSUE MASS), AMYLOID TUMOR. | 1 | 0 | 0 | 0 |
| RHINITIS, CHRONIC. | 1 3+ | 0 | 0 | 0 |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( MALES )

| | GROUP 1 | | GROUP 5 | | GROUP 9 | | GROUP 13 | |
|---|---|---|---|---|---|---|---|---|
| NASAL CAVITY (continued) | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| MISSING. | 0 | | 2 | | 1 | | 0 | |
| RHINITIS, ACUTE, PURULENT. | 0 | | 2 | 4+ | 0 | | 2 | 4+ |
| AUTOLYZED. | 0 | | 0 | | 3 | | 2 | |
| OTHER | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NOT REQUIRED. | 46 | | 31 | | 44 | | 28 | |
| (ALL TISSUES MODERATELY AUTOLYZED). | 2 | | 0 | | 2 | | 3 | |
| (MASS-AXILLARY LYMPH NODE), MISSING. | 0 | | 0 | | 0 | | 1 | |
| (BRONCHIAL LYMPH NODE), PLASMACYTOMA. | 0 | | 1 | | 0 | | 0 | |
| (EYES), CATARACT(S). | 1 | 4+ | 0 | | 0 | | 0 | |
| (SPINAL CORD), WHITE MATTER AND NEURONAL VACUOLATION. | 1 | 3+ | 0 | | 0 | | 0 | |
| (MASS-ABDOMINAL CAVITY), SARCOMA, UNDIFFERENTIATED. | 1 | | 0 | | 0 | | 0 | |
| (MASS-PENIS), DERMATITIS, CHRONIC, NECROTIZING. | 0 | | 1 | 4+ | 0 | | 0 | |
| (ALL TISSUES SEVERELY AUTOLYZED). | 0 | | 1 | | 2 | | 1 | |
| (ALL TISSUES MODERATE TO SEVERELY AUTOLYZED). | 0 | | 0 | | 1 | | 3 | |
| (PERITONEUM), PERITONITIS, GRANULOMATOUS. | 0 | | 0 | | 1 | 4+ | 0 | |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( FEMALES )

| | GROUP 1 | GROUP 5 | GROUP 9 | GROUP 13 |
|---|---|---|---|---|
| **SKIN** | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 35 | 24 | 42 | 25 |
| EDEMA, SUBCUTANEOUS. | 6 3+ - 4+ | 8 2+ - 4+ | 6 3+ - 4+ | 4 4+ |
| HYPERKERATOSIS. | 2 3+ - 4+ | 0 | 0 | 0 |
| MUSCULAR DYSTROPHY. | 1 3+ | 0 | 0 | 0 |
| MUSCULAR DYSTROPHY, SUBCUTANEOUS. | 2 3+ | 0 | 2 2+ - 4+ | 3 2+ - 4+ |
| AMYLOIDOSIS, (CUTANEOUS BLOOD VESSELS). | 1 3+ | 0 | 0 | 0 |
| DERMATITIS, CHRONIC. | 1 1+ | 0 | 0 | 0 |
| MINERALIZATION. | 1 1+ | 0 | 0 | 0 |
| LEUKEMIA. | 1 | 0 | 0 | 0 |
| EDEMA. | 2 4+ | 0 | 0 | 2 4+ |
| (SUBCUTANEOUS MUSCLE), PERIARTERITIS. | 1 3+ | 0 | 0 | 0 |
| (MASS), NEUROFIBROMA. | 0 | 1 | 0 | 0 |
| ACARIASIS. | 0 | 2 2+ | 1 | 2 |
| MELANOSIS, PERIFOLLICULAR. | 0 | 1 3+ | 0 | 0 |
| (MASS-JAW), CARCINOMA, UNDIFFERENTIATED, ORIGIN UNDETERMINED. | 0 | 1 | 0 | 0 |
| KERATOTIC INCLUSION CYST(S). | 0 | 0 | 0 | 1 |
| (MASS-FORELEG), CHONDROMA. | 0 | 0 | 0 | 1 |
| (MASS), NO SIGNIFICANT LESION RECOGNIZED. | 0 | 0 | 0 | 1 |
| **MAMMARY GLAND** | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 8 | 4 | 5 | 4 |
| NOT PRESENT IN SECTION. | 41 | 30 | 45 | 31 |
| AUTOLYZED. | 1 | 0 | 0 | 0 |
| FIBROSIS, INTRALOBULAR. | 0 | 1 3+ | 0 | 0 |
| (MASS-AXILLA), FIBROMA. | 0 | 0 | 0 | 1 |
| **MUSCLE** | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 42 | 29 | 43 | 30 |
| MUSCULAR DYSTROPHY. | 3 1+ - 3+ | 3 3+ | 7 1+ - 4+ | 5 2+ - 4+ |
| (SMALL ARTERIES), MEDIAL HYPERTROPHY. | 1 | 0 | 0 | 0 |
| ARTERIAL THROMBOSIS. | 1 | 0 | 0 | 0 |
| PERIARTERITIS, CHRONIC. | 2 1+ - 3+ | 0 | 0 | 0 |
| MYOPATHY. | 1 4+ | 0 | 0 | 0 |
| PERIARTERITIS. | 1 3+ | 0 | 0 | 0 |
| PANARTERITIS. | 0 | 1 1+ | 0 | 0 |
| MINERALIZATION. | 0 | 1 2+ | 0 | 0 |
| PERIARTERITIS, PYOGRANULOMATOUS. | 0 | 1 3+ | 0 | 0 |
| **SALIVARY GLAND** | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 50 | 35 | 48 | 35 |
| MISSING. | 0 | 0 | 1 | 0 |
| LYMPHOCYTOSIS, PERIDUCTAL. | 0 | 0 | 1 2+ | 0 |
| **MANDIBULAR LYMPH NODE** | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 32 | 18 | 19 | 8 |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( FEMALES )

| | GROUP 1 | | GROUP 5 | | GROUP 9 | | GROUP 13 | |
|---|---|---|---|---|---|---|---|---|
| MANDIBULAR LYMPH NODE (continued) | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| MISSING. | 4 | | 3 | | 5 | | 3 | |
| CONGESTION. | 1 | 4+ | 1 | 3+ | 2 | 3+ - 4+ | 1 | 3+ |
| PLASMA CELL HYPERPLASIA, MEDULLA. | 1 | 3+ | 0 | | 0 | | 0 | |
| PLASMACYTOSIS. | 11 | 3+ - 4+ | 11 | 3+ - 4+ | 18 | 2+ - 3+ | 16 | 3+ - 4+ |
| MALIGNANT LYMPHOMA. | 1 | | 0 | | 1 | | 0 | |
| RETICULOENDOTHELIAL CELL HYPERPLASIA. | 1 | | 1 | 3+ | 0 | | 1 | 3+ |
| PLASMACYTOMA. | 1 | | 0 | | 0 | | 1 | |
| AUTOLYZED. | 0 | | 1 | | 0 | | 0 | |
| LYMPHOID HYPERPLASIA. | 0 | | 1 | 3+ | 4 | 3+ - 4+ | 3 | 3+ - 4+ |
| AMYLOIDOSIS. | 0 | | 0 | | 3 | 2+ - 3+ | 0 | |
| PIGMENTATION, INTRACELLULAR. | 0 | | 0 | | 8 | 1+ - 3+ | 3 | 3+ |
| HYPERPLASIA. | 0 | | 0 | | 1 | 3+ | 0 | |
| MOTT CELL(S), OCCASIONAL. | 0 | | 0 | | 1 | | 0 | |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 0 | | 0 | | 1 | | 0 | |
| LYMPHOCYTOSIS. | 0 | | 0 | | 0 | | 1 | 3+ |
| EDEMA. | 0 | | 0 | | 0 | | 1 | 3+ |
| PLASMA CELL HYPERPLASIA. | 0 | | 0 | | 0 | | 1 | 3+ |
| SCIATIC NERVE | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 37 | | 31 | | 45 | | 31 | |
| NOT PRESENT IN SECTION. | 1 | | 1 | | 2 | | 0 | |
| MISSING. | 8 | | 2 | | 1 | | 2 | |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 3 | | 1 | | 2 | | 2 | |
| NEURITIS, CHRONIC. | 1 | 3+ | 0 | | 0 | | 0 | |
| THYMUS | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 25 | | 6 | | 22 | | 11 | |
| NOT PRESENT IN SECTION. | 15 | | 19 | | 19 | | 10 | |
| AMYLOIDOSIS. | 1 | 1+ | 1 | 3+ | 1 | 2+ | 0 | |
| MISSING. | 6 | | 0 | | 2 | | 0 | |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 1 | | 1 | | 0 | | 3 | |
| CYST(S). | 1 | | 0 | | 0 | | 2 | |
| FOLLICULAR CYST(S), MULTIPLE. | 1 | | 0 | | 0 | | 0 | |
| MASTOCYTOSIS. | 0 | | 2 | 3+ | 0 | | 5 | 2+ - 3+ |
| ATROPHY. | 0 | | 2 | | 1 | | 0 | |
| INVOLUTED. | 0 | | 3 | | 3 | | 4 | |
| AMYLOIDOSIS, INTRAFOLLICULAR. | 0 | | 1 | 2+ | 0 | | 0 | |
| CYST(S), MULTILOCULATED. | 0 | | 1 | | 1 | | 0 | |
| RETICULUM CELL HYPERPLASIA. | 0 | | 0 | | 1 | 3+ | 0 | |
| EOSINOPHILIC MASS(ES). | 0 | | 0 | | 0 | | 2 | |
| HEMORRHAGE. | 0 | | 0 | | 0 | | 1 | 4+ |
| LARYNX | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |

( FEMALES )

| | GROUP 1 | GROUP 5 | GROUP 9 | GROUP 13 |
|---|---|---|---|---|
| LARYNX (continued) | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 50 | 34 | 50 | 34 |
| MISSING. | 0 | 1 | 0 | 0 |
| AMYLOIDOSIS. | 0 | 0 | 0 | 1 4+ |
| THYROID | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 18 | 15 | 22 | 12 |
| AMYLOIDOSIS. | 28 1+ - 4+ | 16 2+ - 4+ | 17 2+ - 4+ | 19 2+ - 4+ |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 3 | 0 | 4 | 0 |
| CYST(S). | 1 | 0 | 1 | 0 |
| PAPILLARY HYPERPLASIA. | 1 1+ | 0 | 0 | 0 |
| FOLLICULAR CYST(S). | 1 | 1 3+ | 5 2+ - 3+ | 2 |
| THYROIDITIS, CHRONIC. | 1 1+ | 0 | 0 | 0 |
| NOT PRESENT IN SECTION. | 0 | 4 | 2 | 1 |
| SIDEROPHAGOCYTOSIS. | 0 | 0 | 0 | 2 2+ - 3+ |
| PARATHYROID | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 24 | 19 | 23 | 22 |
| NOT PRESENT IN SECTION. | 24 | 15 | 25 | 12 |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 1 | 1 | 2 | 0 |
| ADENOMA. | 1 | 0 | 0 | 0 |
| NODULAR HYPERPLASIA. | 0 | 0 | 0 | 1 |
| TRACHEA | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 48 | 34 | 50 | 35 |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 1 | 0 | 0 | 0 |
| GLANDULAR ECTASIA, SUBMUCOSAL. | 1 | 0 | 0 | 0 |
| ADENITIS, ACUTE, PURULENT. | 1 1+ | 0 | 0 | 0 |
| TRACHEITIS, ACUTE, CHRONIC. | 0 | 1 3+ | 0 | 0 |
| BRONCHUS | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 41 | 33 | 47 | 32 |
| MISSING. | 1 | 1 | 0 | 0 |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 8 | 1 | 2 | 3 |
| HISTIOCYTOSIS, PIGMENTED, INTRALUMINAL. | 0 | 0 | 1 2+ | 0 |
| ESOPHAGUS | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 49 | 35 | 50 | 35 |
| MISSING. | 1 | 0 | 0 | 0 |
| ADRENAL | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 16 | 4 | 19 | 3 |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( FEMALES )

| | GROUP 1 | | GROUP 5 | | GROUP 9 | | GROUP 13 | |
|---|---|---|---|---|---|---|---|---|
| ADRENAL (continued) | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| AUTOLYZED. | 1 | | 1 | | 0 | | 0 | |
| AMYLOIDOSIS. | 24 | 1+ - 4+ | 22 | 2+ - 4+ | 27 | 1+ - 4+ | 24 | 2+ - 4+ |
| CORTICAL NODULAR HYPERPLASIA. | 11 | | 4 | 3+ | 4 | | 5 | 2+ |
| PIGMENTATION, INTRACELLULAR. | 2 | 2+ | 0 | | 19 | 1+ - 3+ | 1 | 3+ |
| EXTRACORTICAL NODULAR HYPERPLASIA. | 3 | | 0 | | 0 | | 0 | |
| HEMATOCYST(S). | 2 | 3+ | 0 | | 1 | | 1 | |
| CORTICAL CYST(S). | 1 | | 0 | | 0 | | 0 | |
| CORTICAL CELL ADENOMA. | 0 | | 5 | | 0 | | 4 | |
| CONGESTION. | 0 | | 1 | 3+ | 0 | | 0 | |
| PHEOCHROMACYTOSIS. | 0 | | 1 | | 0 | | 0 | |
| (MASS), CARCINOMA, ENDOCRINE PATTERN. | 0 | | 1 | | 0 | | 0 | |
| (SECOND ADRENAL MISSING). | 0 | | 1 | | 0 | | 0 | |
| PIGMENTATION. | 0 | | 0 | | 2 | 2+ | 0 | |
| MEDULLARY CYST(S). | 0 | | 0 | | 0 | | 1 | |
| STOMACH | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 38 | | 25 | | 46 | | 24 | |
| AUTOLYZED. | 8 | | 5 | | 2 | | 7 | |
| MISSING. | 1 | | 1 | | 0 | | 1 | |
| MINERALIZATION. | 1 | 3+ | 0 | | 0 | | 0 | |
| (FORESTOMACH), HYPERKERATOSIS. | 1 | | 0 | | 1 | 3+ | 0 | |
| (GLANDULAR), AMYLOIDOSIS. | 1 | 3+ | 0 | | 0 | | 1 | 3+ |
| (GLANDULAR), MINERALIZATION. | 1 | 2+ | 0 | | 0 | | 0 | |
| GASTRITIS, EOSINOPHILIC, ACUTE. | 0 | | 1 | 3+ | 0 | | 0 | |
| (FORESTOMACH), MINERALIZATION, MUSCULARIS. | 0 | | 1 | | 1 | | 0 | |
| (FORESTOMACH), PAPILLARY HYPERPLASIA. | 0 | | 1 | | 0 | | 0 | |
| MULTIPLE BLACK FOCI. | 0 | | 1 | | 0 | | 0 | |
| (FORESTOMACH-LAMINA PROPRIA), PLASMACYTOSIS. | 0 | | 0 | | 1 | | 0 | |
| AMYLOIDOSIS. | 0 | | 0 | | 0 | | 1 | 2+ |
| PAPILLARY HYPERPLASIA. | 0 | | 0 | | 0 | | 1 | 3+ |
| (GLANDULAR), MELANOSIS. | 0 | | 0 | | 0 | | 1 | 1+ |
| HYPERKERATOSIS, FORESTOMACH. | 0 | | 0 | | 0 | | 1 | 3+ |
| DUODENUM | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 42 | | 29 | | 48 | | 29 | |
| AUTOLYZED. | 8 | | 5 | | 2 | | 6 | |
| AMYLOIDOSIS. | 0 | | 1 | 3+ | 0 | | 0 | |
| JEJUNUM | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 42 | | 30 | | 48 | | 29 | |
| AUTOLYZED. | 8 | | 5 | | 2 | | 6 | |
| ILEUM | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 31 | | 28 | | 41 | | 27 | |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( FEMALES )

| | GROUP 1 | GROUP 5 | GROUP 9 | GROUP 13 |
|---|---|---|---|---|
| ILEUM (continued) | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| AUTOLYZED. | 8 | 4 | 2 | 6 |
| ILEITIS, PROLIFERATIVE. | 10 1+ - 4+ | 3 4+ | 7 3+ | 0 |
| ILEITIS, NECROTIZING. | 1 3+ | 0 | 0 | 0 |
| ENTERITIS, PROLIFERATIVE. | 0 | 0 | 0 | 1 3+ |
| ILEITIS. | 0 | 0 | 0 | 1 4+ |
| CECUM | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 39 | 28 | 42 | 26 |
| AUTOLYZED. | 8 | 5 | 4 | 6 |
| MISSING. | 1 | 0 | 0 | 0 |
| CECITIS, PROLIFERATIVE. | 1 3+ | 0 | 0 | 0 |
| ENTERITIS, PROLIFERATIVE. | 1 4+ | 2 3+ - 4+ | 2 3+ - 4+ | 1 3+ |
| PIGMENTATION, INTRACELLULAR, LAMINA PROPIC. | 0 | 0 | 1 4+ | 0 |
| HYPERPLASIA, EPITHELIAL. | 0 | 0 | 1 3+ | 0 |
| HEMORRHAGE, MUCOSA. | 0 | 0 | 1 3+ | 0 |
| AMYLOIDOSIS. | 0 | 0 | 0 | 1 3+ |
| ENTERITIS, SUBACUTE. | 0 | 0 | 0 | 1 3+ |
| COLON | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 39 | 30 | 47 | 25 |
| AUTOLYZED. | 8 | 5 | 2 | 6 |
| MISSING. | 1 | 0 | 0 | 0 |
| NEMATODIASIS. | 1 | 0 | 0 | 0 |
| COLITIS, PROTOZOAN. | 1 | 0 | 0 | 0 |
| HEMORRHAGE, MUCOSA. | 0 | 0 | 1 3+ | 0 |
| AMYLOIDOSIS. | 0 | 0 | 0 | 2 3+ |
| ENTERITIS, PROLIFERATIVE. | 0 | 0 | 0 | 2 2+ - 4+ |
| RECTUM | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 41 | 30 | 48 | 29 |
| AUTOLYZED. | 7 | 5 | 2 | 6 |
| MISSING. | 1 | 0 | 0 | 0 |
| INTUSSUSCEPTION. | 1 | 0 | 0 | 0 |
| MESENTERIC LYMPH NODE | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 32 | 23 | 22 | 12 |
| CALCIFICATION, DYSTROPHIC. | 2 3+ | 0 | 0 | 0 |
| AUTOLYZED. | 5 | 4 | 2 | 4 |
| MISSING. | 1 | 3 | 1 | 1 |
| LYMPHOID HYPERPLASIA. | 2 4+ | 1 3+ | 6 3+ - 4+ | 4 3+ - 4+ |
| CONGESTION. | 1 4+ | 0 | 0 | 0 |
| ERYTHROPHAGOCYTOSIS. | 1 3+ | 0 | 0 | 0 |
| PLASMACYTOSIS. | 3 2+ - 3+ | 1 3+ | 10 2+ - 3+ | 7 3+ - 4+ |
| PIGMENTATION, INTRACELLULAR. | 1 3+ | 0 | 9 2+ - 4+ | 3 2+ - 4+ |
| RETICULUM CELL HYPERPLASIA. | 2 3+ | 0 | 2 3+ | 0 |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( FEMALES )

| | GROUP 1 | GROUP 5 | GROUP 9 | GROUP 13 |
|---|---|---|---|---|
| MESENTERIC LYMPH NODE (continued) | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| (MASS), MALIGNANT LYMPHOMA. | 1 | 0 | 0 | 0 |
| AMYLOIDOSIS. | 0 | 2 3+ | 1 2+ | 1 2+ |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 0 | 1 | 1 | 0 |
| HISTIOCYTOSIS, PIGMENTED. | 0 | 0 | 1 | 0 |
| MOTT CELL(S), OCCASIONAL. | 0 | 0 | 2 | 1 |
| MALIGNANT LYMPHOMA. | 0 | 0 | 1 | 0 |
| RETICULOENDOTHELIAL CELL HYPERPLASIA. | 0 | 0 | 0 | 2 3+ |
| PLASMACYTOMA. | 0 | 0 | 0 | 1 |
| EXTRAMEDULLARY HEMATOPOIESIS. | 0 | 0 | 0 | 1 1+ |
| HEMOSIDEROSIS. | 0 | 0 | 0 | 1 3+ |
| LYMPHADENITIS, ACUTE, PURULENT. | 0 | 0 | 0 | 1 3+ |
| PIGMENTATION. | 0 | 0 | 0 | 1 1+ |
| TELANGIECTASIS. | 0 | 0 | 0 | 1 3+ |
| LUNG | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 3 | 14 | 21 | 6 |
| PNEUMONOPATHY. | 46 1+ - 4+ | 1 | 0 | 0 |
| HEMORRHAGE. | 1 3+ | 1 2+ | 2 1+ - 3+ | 1 2+ |
| PNEUMONITIS, INTERSTITIAL. | 3 3+ - 4+ | 1 3+ | 2 2+ - 3+ | 5 2+ - 4+ |
| ATELECTASIS. | 1 3+ | 1 1+ | 3 2+ - 3+ | 3 3+ |
| BRONCHOPNEUMONIA. | 1 4+ | 5 3+ - 4+ | 3 3+ - 4+ | 2 3+ - 4+ |
| BRONCHOPNEUMONIA, ACUTE, PURULENT. | 2 4+ | 0 | 0 | 1 4+ |
| PNEUMONITIS. | 1 3+ | 0 | 0 | 0 |
| HISTIOCYTOSIS. | 0 | 7 1+ - 4+ | 12 1+ - 4+ | 16 3+ - 4+ |
| ALVEOLAR/BRONCHIOLAR CELL HYPERPLASIA. | 0 | 3 1+ - 2+ | 5 1+ - 2+ | 4 2+ |
| SQUAMOUS METAPLASIA. | 0 | 3 1+ - 2+ | 0 | 0 |
| ADENOMATOSIS. | 0 | 3 1+ - 2+ | 2 2+ | 2 1+ - 2+ |
| PNEUMOLITHIASIS. | 0 | 1 1+ | 0 | 1 1+ |
| BRONCHOPNEUMONIA, ACUTE AND CHRONIC. | 0 | 1 4+ | 0 | 0 |
| BRONCHOPNEUMONIA, SUBACUTE, PURULENT. | 0 | 1 4+ | 0 | 0 |
| BRONCHOPNEUMONIA, SUBACUTE. | 0 | 1 4+ | 3 4+ | 0 |
| FIBROSIS, SUBPLEURAL. | 0 | 1 1+ | 0 | 0 |
| CARCINOMA, UNDIFFERENTIATED, METASTATIC. | 0 | 1 | 0 | 0 |
| EOSINOPHILIC MASS(ES). | 0 | 1 3+ | 1 | 0 |
| PNEUMONITIS, ACUTE AND SUBACUTE, PURULENT. | 0 | 1 4+ | 0 | 0 |
| NECROSIS. | 0 | 0 | 1 3+ | 0 |
| LEUKOCYTOSIS. | 0 | 0 | 2 4+ | 0 |
| (PULMONARY ARTERY), THROMBOSIS. | 0 | 0 | 1 4+ | 0 |
| OSSEOUS METAPLASIA. | 0 | 0 | 1 2+ | 0 |
| BRONCHOPNEUMONIA, CHRONIC. | 0 | 0 | 1 4+ | 0 |
| PNEUMONITIS, INTERSTITIAL, SUBACUTE. | 0 | 0 | 1 4+ | 0 |
| PIGMENTED LATENT MACROPHAGES. | 0 | 0 | 1 | 0 |
| ALVEOLAR/BRONCHIOLAR CELL PROLIFERATION. | 0 | 0 | 2 2+ | 2 1+ - 3+ |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( FEMALES )

| | GROUP 1 | GROUP 5 | GROUP 9 | GROUP 13 |
|---|---|---|---|---|
| LUNG (continued) | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| LEUKOCYTOSTASIS. | 0 | 0 | 1 3+ | 0 |
| PERIVASCULAR MONONUCLEAR CELL AGGREGATE(S). | 0 | 0 | 0 | 2 3+ |
| SQUAMOUS CELL METAPLASIA. | 0 | 0 | 0 | 1 |
| LEUKEMIA. | 0 | 0 | 0 | 2 |
| FIBROSIS. | 0 | 0 | 0 | 1 1+ |
| INTRABRONCHIAL PURULENT EXUDATE. | 0 | 0 | 0 | 2 1+ |
| LIVER | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 8 | 2 | 13 | 3 |
| AUTOLYZED. | 1 | 1 | 1 | 0 |
| CAVERNOUS HEMANGIOMA. | 1 | 0 | 0 | 0 |
| NECROSIS. | 6 3+ - 4+ | 3 4+ | 2 3+ - 4+ | 2 4+ |
| AMYLOIDOSIS. | 27 1+ - 4+ | 29 1+ - 4+ | 18 1+ - 4+ | 23 2+ - 4+ |
| CONGESTION. | 7 3+ - 4+ | 6 3+ - 4+ | 4 3+ - 4+ | 7 3+ - 4+ |
| HEMORRHAGE. | 1 4+ | 0 | 0 | 0 |
| SIDEROPHAGOCYTOSIS. | 18 1+ - 3+ | 8 1+ - 2+ | 29 1+ - 4+ | 9 1+ - 2+ |
| HEPATOCELLULAR VACUOLATION, (INDIVIDUAL). | 1 2+ | 0 | 0 | 0 |
| BILIARY CYST(S). | 16 3+ | 8 | 0 | 7 |
| FATTY METAMORPHOSIS. | 2 2+ - 3+ | 0 | 0 | 0 |
| HEPATITIS, ACUTE, CHRONIC. | 1 3+ | 0 | 0 | 0 |
| HEPATOCELLULAR VACUOLATION. | 4 1+ - 3+ | 3 2+ - 3+ | 14 1+ - 3+ | 3 2+ - 3+ |
| CONGESTION, PASSIVE, CHRONIC. | 2 3+ | 2 3+ - 4+ | 4 3+ - 4+ | 5 3+ - 4+ |
| BILE DUCT ECTASIA. | 1 2+ | 0 | 1 1+ | 1 3+ |
| BILIARY CYST(S), MULTILOCULAR. | 2 3+ | 0 | 0 | 0 |
| MALIGNANT LYMPHOMA. | 1 | 0 | 0 | 0 |
| BILIARY CYSTIC HYPERPLASIA. | 1 3+ | 0 | 0 | 0 |
| TRIADITIS. | 1 1+ | 0 | 0 | 0 |
| BILIARY HYPERPLASIA. | 2 2+ - 3+ | 1 4+ | 0 | 0 |
| HEPATOCELLULAR VACUOLATION, PERILOBULAR. | 1 3+ | 0 | 1 3+ | 3 3+ - 4+ |
| TELANGIECTASIS. | 1 3+ | 0 | 0 | 0 |
| TRABECULAR CHOLANGIOMA. | 1 | 0 | 0 | 0 |
| TRIADITIS, MONONUCLEAR CELL(S). | 1 3+ | 0 | 0 | 0 |
| BILIARY CYSTIC HYPERPLASIA, PROLIFERATIVE. | 1 4+ | 0 | 0 | 0 |
| NECROSIS, HEMORRHAGIC. | 1 4+ | 2 3+ - 4+ | 1 3+ | 0 |
| CHOLANGIOMA. | 2 | 1 | 0 | 0 |
| HEPATITIS, GRANULOMATOUS. | 0 | 1 1+ | 0 | 0 |
| MISSING. | 0 | 1 | 0 | 0 |
| BILIARY STASIS. | 0 | 1 | 0 | 0 |
| NECROSIS, COAGULATIVE. | 0 | 1 2+ | 0 | 0 |
| BILE DUCT PROLIFERATION. | 0 | 1 2+ | 0 | 0 |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( FEMALES )

| | GROUP 1 | | GROUP 5 | | GROUP 9 | | GROUP 13 | |
|---|---|---|---|---|---|---|---|---|
| LIVER (continued) | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| PATCHY CONGESTION, CHRONIC. | 0 | | 1 | 4+ | 0 | | 0 | |
| (MIDZONAL), HEPATOCELLULAR FATTY METAMORPHOSIS. | 0 | | 1 | 4+ | 0 | | 0 | |
| (PERIPHERAL LOBULAR), HEPATOCELLULAR FATTY METAMORPHOSIS. | 0 | | 1 | 4+ | 0 | | 0 | |
| SIDEROCYTOSIS. | 0 | | 1 | 1+ | 0 | | 0 | |
| HISTIOCYTOSIS, PIGMENTED. | 0 | | 0 | | 1 | 2+ | 0 | |
| PIGMENTATION, HEPATOCELLULAR. | 0 | | 0 | | 8 | 1+ - 3+ | 0 | |
| CONGESTION, PASSIVE, CHRONIC, ACUTE. | 0 | | 0 | | 1 | 4+ | 0 | |
| HEPATITIS, MONONUCLEAR CELL. | 0 | | 0 | | 1 | 1+ | 0 | |
| HEPATOCELLULAR VACUOLATION, CENTRILOBULAR. | 0 | | 0 | | 1 | 4+ | 0 | |
| SIDEROPHAGOCYTOSIS, CENTRILOBULAR. | 0 | | 0 | | 1 | 3+ | 0 | |
| KARYOMEGALY WITH INCLUSION BODY(S). | 0 | | 0 | | 0 | | 1 | 1+ |
| CLEAR CELL FOCUS/FOCI. | 3 | | 9 | | 2 | | 2 | |
| CYST(S). | 0 | | 0 | | 0 | | 1 | |
| GALLBLADDER | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 32 | | 16 | | 40 | | 21 | |
| AUTOLYZED. | 15 | | 18 | | 8 | | 12 | |
| MISSING. | 3 | | 1 | | 1 | | 1 | |
| AMYLOIDOSIS. | 0 | | 0 | | 1 | 2+ | 0 | |
| PAPILLARY HYPERPLASIA. | 0 | | 0 | | 0 | | 1 | |
| SPLEEN | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 14 | | 6 | | 22 | | 6 | |
| AUTOLYZED. | 1 | | 1 | | 0 | | 0 | |
| AMYLOIDOSIS. | 29 | 2+ - 4+ | 28 | 2+ - 4+ | 21 | 3+ - 4+ | 25 | 2+ - 4+ |
| MISSING. | 1 | | 0 | | 0 | | 0 | |
| LYMPHOID HYPERPLASIA. | 1 | 4+ | 0 | | 0 | | 0 | |
| (MASS), CONGESTION. | 1 | 3+ | 0 | | 0 | | 0 | |
| CONGESTION. | 1 | 3+ | 0 | | 0 | | 1 | 4+ |
| HYPERPLASIA. | 3 | 3+ | 0 | | 5 | 3+ - 4+ | 0 | |
| MYELOID HYPERPLASIA. | 1 | 3+ | 0 | | 0 | | 1 | 2+ |
| EXTRAMEDULLARY HEMATOPOIESIS. | 1 | 2+ | 2 | 3+ | 3 | 3+ - 4+ | 7 | 2+ - 4+ |
| PIGMENTATION, INTRACELLULAR. | 0 | | 0 | | 1 | 3+ | 0 | |
| MALIGNANT LYMPHOMA. | 0 | | 0 | | 3 | | 0 | |
| RETICULOENDOTHELIAL CELL HYPERPLASIA. | 0 | | 0 | | 0 | | 1 | 3+ |
| HEMOSIDEROSIS. | 0 | | 0 | | 0 | | 1 | 1+ |
| PANCREAS | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 36 | | 30 | | 44 | | 26 | |
| AUTOLYZED. | 8 | | 2 | | 3 | | 4 | |
| AMYLOIDOSIS. | 2 | 2+ - 3+ | 0 | | 0 | | 0 | |
| MISSING. | 1 | | 1 | | 0 | | 0 | |
| ACINAR CYST(S). | 1 | | 0 | | 0 | | 0 | |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( FEMALES )

| | GROUP 1 | GROUP 5 | GROUP 9 | GROUP 13 |
|---|---|---|---|---|
| PANCREAS (continued) | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| ISLET CELL ADENOMA. | 1 | 0 | 0 | 1 |
| ACINAR CELL ADENOMA. | 1 | 0 | 0 | 0 |
| NOT PRESENT IN SECTION. | 0 | 1 | 0 | 0 |
| FIBROSIS. | 0 | 1 1+ | 0 | 0 |
| DUCTAL PROLIFERATION. | 0 | 1 1+ | 0 | 0 |
| PIGMENTATION, INTRACELLULAR. | 0 | 0 | 1 3+ | 0 |
| DUCTAL ECTASIA. | 0 | 0 | 1 2+ | 0 |
| ISLET CELL HYPERPLASIA. | 0 | 0 | 1 3+ | 1 |
| AMYLOIDOSIS, PERIACINAR. | 0 | 0 | 0 | 1 3+ |
| ACINAR CELL HYPERTROPHY. | 0 | 0 | 0 | 2 3+ |
| PLASMACYTOSIS, INTERACINAR. | 0 | 0 | 0 | 1 3+ |
| KIDNEY | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 10 | 5 | 10 | 2 |
| AMYLOIDOSIS. | 36 2+ - 4+ | 28 2+ - 4+ | 29 1+ - 4+ | 27 3+ - 4+ |
| NEPHRITIS, ACUTE, PURULENT. | 1 2+ | 0 | 1 4+ | 0 |
| GRANULAR ATROPHY. | 1 3+ | 0 | 0 | 0 |
| MINERALIZATION. | 4 1+ - 3+ | 0 | 2 1+ - 2+ | 3 1+ - 3+ |
| CORTICAL CYST(S). | 1 | 1 | 0 | 0 |
| NEPHROLITHIASIS. | 3 2+ - 3+ | 0 | 5 1+ - 3+ | 6 2+ - 3+ |
| GLOMERULAR NEPHROSIS. | 3 2+ - 4+ | 1 4+ | 1 1+ | 4 2+ - 4+ |
| TUBULAR DILATATION. | 0 | 1 | 0 | 0 |
| EOSINOPHILIC CYST(S). | 0 | 1 | 0 | 0 |
| SENILE NEPHROSIS. | 0 | 4 3+ - 4+ | 0 | 0 |
| (RENAL ARTERY), THROMBOSIS. | 0 | 1 | 0 | 0 |
| MINERALIZATION, MEDULLA. | 0 | 1 3+ | 0 | 0 |
| NEPHRITIS, INTERSTITIAL, CHRONIC. | 0 | 1 1+ | 0 | 3 2+ - 3+ |
| INFARCT, CORTICAL. | 0 | 1 | 0 | 0 |
| PIGMENTATION, INTRACELLULAR. | 0 | 0 | 16 1+ - 4+ | 0 |
| MISSING. | 0 | 0 | 1 | 0 |
| (PROXIMAL TUBULES), PIGMENTATION, INTRACELLULAR. | 0 | 0 | 2 2+ - 3+ | 0 |
| (PROXIMAL TUBULES), PIGMENTATION. | 0 | 0 | 3 1+ - 3+ | 0 |
| PIGMENTATION. | 0 | 0 | 2 1+ - 2+ | 0 |
| VACUOLATION. | 0 | 0 | 1 3+ | 0 |
| CORTICAL TUBULAR NEPHROSIS. | 0 | 0 | 0 | 2 3+ - 4+ |
| PYELONEPHRITIS, ACUTE, PURULENT. | 0 | 0 | 0 | 1 3+ |
| PYELITIS, ACUTE, PURULENT. | 0 | 0 | 0 | 1 4+ |
| HEART | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 25 | 25 | 38 | 20 |
| ATRIAL THROMBOSIS. | 18 | 10 | 10 | 14 |
| MUSCULAR DYSTROPHY. | 3 2+ - 3+ | 0 | 1 4+ | 2 3+ |
| (CORONARY VESSELS), AMYLOIDOSIS. | 1 3+ | 0 | 0 | 0 |
| MURAL THROMBUS. | 3 | 0 | 1 | 0 |
| (VENTRICLE), MURAL THROMBUS. | 1 | 0 | 0 | 0 |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( FEMALES )

| | GROUP 1 | | GROUP 5 | | GROUP 9 | | GROUP 13 | |
|---|---|---|---|---|---|---|---|---|
| HEART (continued) | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| (CORONARY ARTERIES), PERIARTERITIS. | 1 | 3+ | 0 | | 0 | | 0 | |
| (CORONARY ARTERIES), MEDIAL HYPERTROPHY. | 1 | 3+ | 0 | | 0 | | 0 | |
| MINERALIZATION, MYOCARDIAL. | 1 | 3+ | 0 | | 0 | | 0 | |
| MUSCULAR DYSTROPHY, MYOCARDIUM. | 0 | | 0 | | 1 | 3+ | 0 | |
| CHONDROPLASIA. | 0 | | 0 | | 1 | 2+ | 0 | |
| (CORONARY ARTERY), THROMBOSIS. | 0 | | 0 | | 0 | | 1 | |
| URINARY BLADDER | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 44 | | 29 | | 47 | | 33 | |
| AUTOLYZED. | 6 | | 5 | | 0 | | 1 | |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 0 | | 1 | | 0 | | 0 | |
| VACUOLATION, UROTHELIUM. | 0 | | 0 | | 1 | 4+ | 0 | |
| HEMORRHAGE, INTRALUMINAL. | 0 | | 0 | | 1 | | 0 | |
| CYSTITIS, SUBACUTE, PURULENT. | 0 | | 0 | | 1 | 3+ | 0 | |
| AMYLOIDOSIS. | 0 | | 0 | | 0 | | 1 | 3+ |
| OVARY | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 44 | | 28 | | 33 | | 31 | |
| MISSING. | 1 | | 0 | | 0 | | 0 | |
| CYST(S). | 1 | | 2 | | 4 | | 3 | |
| PIGMENTATION, INTRACELLULAR. | 1 | 3+ | 0 | | 2 | 3+ | 0 | |
| GRANULOSA CELL TUMOR(S). | 1 | | 1 | | 1 | | 0 | |
| PAROVARIAN CYST(S). | 2 | | 1 | | 5 | | 0 | |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 0 | | 1 | | 0 | | 0 | |
| AUTOLYZED. | 0 | | 2 | | 0 | | 0 | |
| FIBROMA. | 0 | | 1 | | 0 | | 0 | |
| NOT PRESENT IN SECTION. | 0 | | 0 | | 1 | | 0 | |
| CYSTIC HYPERPLASIA. | 0 | | 0 | | 1 | 2+ | 0 | |
| CYST(S), HEMORRHAGIC. | 0 | | 0 | | 3 | 4+ | 0 | |
| NODULAR STROMAL HYPERPLASIA. | 0 | | 0 | | 0 | | 1 | |
| UTERUS | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 47 | | 30 | | 45 | | 32 | |
| AUTOLYZED. | 1 | | 2 | | 0 | | 1 | |
| PERIARTERITIS, CHRONIC. | 1 | | 0 | | 0 | | 0 | |
| (ARTERIES-VASCULAR PLEXUS), FIBRINOID DEGENERATION. | 1 | | 0 | | 0 | | 0 | |
| (ARTERIES), FIBRINOID DEGENERATION. | 1 | 3+ | 0 | | 0 | | 0 | |
| LEIOMYOMA, CERVIX. | 0 | | 1 | | 1 | | 0 | |
| ENDOMETRIAL PAPILLARY HYPERPLASIA. | 0 | | 1 | 3+ | 0 | | 1 | 2+ |
| METRITIS, ACUTE, PURULENT. | 0 | | 1 | 3+ | 0 | | 0 | |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( FEMALES )

| | GROUP 1 | | GROUP 5 | | GROUP 9 | | GROUP 13 | |
|---|---|---|---|---|---|---|---|---|
| UTERUS (continued) | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| LEIOMYOMA. | 0 | | 0 | | 2 | | 0 | |
| PERITONITIS, SUBACUTE. | 0 | | 0 | | 1 | 4+ | 0 | |
| (UTERINE ARTERIES), HYALINIZATION. | 0 | | 0 | | 1 | 4+ | 0 | |
| ADENOCARCINOMA. | 0 | | 0 | | 0 | | 1 | |
| CEREBRUM | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 46 | | 33 | | 49 | | 32 | |
| MISSING. | 1 | | 0 | | 0 | | 0 | |
| MINERALIZATION. | 2 | 2+ | 2 | 1+ - 3+ | 0 | | 1 | 1+ |
| (CEREBRUM & OLFACTORY LOBE), MINERALIZATION. | 1 | | 0 | | 0 | | 0 | |
| MYELINOLYSIS. | 0 | | 0 | | 1 | 3+ | 0 | |
| AUTOLYZED. | 0 | | 0 | | 0 | | 1 | |
| (CAPILLARIES), AMYLOIDOSIS. | 0 | | 0 | | 0 | | 1 | 3+ |
| CEREBELLUM | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 49 | | 35 | | 48 | | 34 | |
| (WHITE MATTER), VACUOLATION, MEDULLA. | 1 | | 0 | | 0 | | 0 | |
| MYELINOLYSIS. | 0 | | 0 | | 1 | 3+ | 0 | |
| (WHITE MATTER), VACUOLATION. | 0 | | 0 | | 1 | 3+ | 0 | |
| AUTOLYZED. | 0 | | 0 | | 0 | | 1 | |
| PITUITARY | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 5 | | 11 | | 15 | | 3 | |
| MISSING. | 44 | | 24 | | 35 | | 29 | |
| CHROMOPHOBE ADENOMA. | 1 | | 0 | | 0 | | 0 | |
| ADENOMA. | 0 | | 0 | | 0 | | 1 | |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 0 | | 0 | | 0 | | 2 | |
| STERNABRAE | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 48 | | 34 | | 49 | | 34 | |
| (INTERCOSTAL MUSCLES), MUSCULAR DYSTROPHY. | 2 | 3+ - 4+ | 1 | 1+ | 1 | | 1 | 4+ |
| FEMUR | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 49 | | 35 | | 50 | | 35 | |
| MISSING. | 1 | | 0 | | 0 | | 0 | |
| BONE MARROW | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 50 | | 32 | | 49 | | 31 | |
| AUTOLYZED. | 0 | | 1 | | 0 | | 0 | |
| ERYTHROID HYPERPLASIA. | 0 | | 1 | | 0 | | 0 | |
| MONOCYTIC HYPERPLASIA. | 0 | | 1 | 3+ | 0 | | 0 | |
| HYPERPLASIA. | 0 | | 0 | | 1 | 3+ | 1 | |
| MYELOID HYPERPLASIA. | 0 | | 0 | | 0 | | 2 | 2+ - 4+ |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( FEMALES )

| | GROUP 1 | | GROUP 5 | | GROUP 9 | | GROUP 13 | |
|---|---|---|---|---|---|---|---|---|
| BONE MARROW (continued) | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| HYPOPLASIA. | 0 | | 0 | | 0 | | 1 | |
| NASAL CAVITY | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 50 | | 32 | | 49 | | 32 | |
| MISSING. | 0 | | 1 | | 0 | | 0 | |
| PLASMACYTOSIS. | 0 | | 1 | 3+ | 0 | | 0 | |
| RHINITIS, ACUTE, PURULENT. | 0 | | 1 | 4+ | 1 | 4+ | 2 | 4+ |
| HYPERPLASIA, MUCOSAL. | 0 | | 1 | 3+ | 0 | | 0 | |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 0 | | 0 | | 0 | | 1 | |
| OTHER | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NOT REQUIRED. | 44 | | 34 | | 32 | | 30 | |
| (ALL TISSUES MODERATE TO SEVERELY AUTOLYZED). | 3 | | 0 | | 5 | | 0 | |
| (MASS-AXILLARY LYMPH NODE), HYPERPLASIA. | 1 | 3+ | 0 | | 0 | | 0 | |
| (RENAL LYMPH NODE), PLASMACYTOSIS. | 1 | 4+ | 0 | | 0 | | 0 | |
| (MASS-LUMBAR MUSCLE), PERITONITIS, PURULENT. | 1 | 4+ | 0 | | 0 | | 0 | |
| (ABDOMINAL WALL), INFLAMMATION, CHRONIC. | 1 | | 0 | | 0 | | 0 | |
| (ALL TISSUES SEVERELY AUTOLYZED). | 1 | | 0 | | 2 | | 0 | |
| (MASS-INTESTINE), INTUSSUSCEPTION, (MASS), BLOOD CLOT(S). | 0 | | 0 | | 1 | | 0 | |
| (ALL TISSUES MODERATELY AUTOLYZED). | 0 | | 0 | | 6 | | 0 | |
| (MESENTERY & ADIPOSE TISSUE), STEATITIS. | 0 | | 0 | | 1 | | 0 | |
| (ALL TISSUES SLIGHTLY AUTOLYZED). | 0 | | 0 | | 2 | | 0 | |
| (EYES), NO SIGNIFICANT LESIONS RECOGNIZED. | 0 | | 0 | | 1 | | 0 | |
| (MASS-MESENTERIC), SARCOMA, UNDIFFERENTIATED. | 0 | | 0 | | 0 | | 1 | |
| (SPINAL CORD), NO SIGNIFICANT LESION RECOGNIZED. | 0 | | 0 | | 0 | | 1 | |
| (MASS-INTESTINE), NECROSIS, (INCARCERATED). | 0 | | 0 | | 0 | | 1 | 4+ |

KEY

| | | |
|---|---|---|
| DYE: | ACID BLACK 52 | SPECIES: RAT |
| ROUTE: | INTRATRACHEAL | DIETARY |
| GROUPS: | 2 (Treated) | 10 (Treated) |
| | 7 (Control) | 15 (Control) |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( MALES )

| | GROUP 2 | | GROUP 7 | | GROUP 10 | | GROUP 15 | |
|---|---|---|---|---|---|---|---|---|
| SKIN | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 44 | | 32 | | 44 | | 31 | |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 1 | | 0 | | 1 | | 1 | |
| MISSING. | 3 | | 0 | | 2 | | 2 | |
| (MASS-NOSE), PAPILLOMA. | 1 | | 0 | | 0 | | 0 | |
| (MASS-FACE), SARCOMA, UNDIFFERENTIATED. | 1 | | 0 | | 0 | | 0 | |
| (MASS-STERNUM), FIBROMA. | 1 | | 0 | | 0 | | 0 | |
| (MASS), BASAL CELL TUMOR. | 1 | | 0 | | 0 | | 0 | |
| AUTOLYZED. | 2 | | 0 | | 2 | | 0 | |
| (MASS-BACK), FIBROMA. | 1 | | 0 | | 0 | | 0 | |
| (MASS-EAR), FIBROSARCOMA. | 1 | | 0 | | 0 | | 0 | |
| (MASS), TRICHOEPITHELIOMA. | 1 | | 0 | | 0 | | 0 | |
| (MASS-CERVICAL), TRICHOEPITHELIOMA. | 1 | | 0 | | 0 | | 0 | |
| LEUKEMIA. | 0 | | 1 | | 0 | | 0 | |
| MALIGNANT LYMPHOMA. | 0 | | 1 | | 0 | | 1 | |
| (MASS), FIBROADENOMA. | 0 | | 2 | | 0 | | 0 | |
| (MASS-SHOULDER), TRICHOEPITHELIOMA. | 0 | | 1 | | 0 | | 0 | |
| EDEMA, SUBCUTANEOUS. | 0 | | 1 | 4+ | 0 | | 0 | |
| (MASS-LIP), PAPILLOMA. | 0 | | 1 | | 0 | | 0 | |
| (MASS), MISSING. | 0 | | 0 | | 1 | | 0 | |
| TRICHOEPITHELIOMA. | 0 | | 0 | | 1 | | 0 | |
| (MASS-FACE), PAPILLOMA. | 0 | | 0 | | 0 | | 1 | |
| (MASS), KERATOTIC HORN. | 0 | | 0 | | 0 | | 1 | |
| (MASS-FACE), SARCOMA, UNDIFFERENTIATED. | 0 | | 0 | | 1 | | 0 | |
| (MASS-FORE LIMB), FIBROMA. | 0 | | 0 | | 0 | | 1 | |
| (ABDOMEN), CELLULITIS, ACTIVE, CHRONIC. | 0 | | 0 | | 0 | | 1 | 4+ |
| (MASS-SIDE), MISSING. | 0 | | 0 | | 0 | | 1 | |
| MAMMARY | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 4 | | 1 | | 3 | | 1 | |
| NOT PRESENT IN SECTION. | 28 | | 26 | | 44 | | 28 | |
| ACTIVE. | 13 | | 8 | | 1 | | 5 | |
| MISSING. | 3 | | 0 | | 0 | | 0 | |
| (MASS), NOT PRESENT IN SECTION. | 1 | | 0 | | 1 | | 0 | |
| AUTOLYZED. | 2 | | 0 | | 2 | | 0 | |
| (MASS-INGUINAL), ADENOFIBROMA. | 1 | | 2 | | 0 | | 0 | |
| (MASS-AXILLA), FIBROADENOMA. | 1 | | 0 | | 0 | | 0 | |
| (MASS-AXILLA), FIBROSARCOMA. | 0 | | 0 | | 0 | | 1 | |
| (MASS-INGUINAL), FIBROMA. | 0 | | 0 | | 0 | | 1 | |
| (MASS-AXILLA), FIBROMA. | 0 | | 0 | | 0 | | 1 | |
| FIBROSIS, PERIDUCTAL. | 0 | | 1 | 3+ | 0 | | 0 | |
| (MASS-ABDOMEN), FIBROADENOMA. | 0 | | 1 | | 0 | | 0 | |
| DUCTAL ECTASIA. | 0 | | 0 | | 0 | | 1 | |
| LACTATION. | 0 | | 0 | | 0 | | 1 | |
| THIGH MUSCLE | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 46 | | 33 | | 45 | | 34 | |
| NECROSIS. | 1 | 4+ | 0 | | 0 | | 0 | |
| AUTOLYZED. | 2 | | 0 | | 2 | | 0 | |
| MYOPATHY. | 1 | 2+ | 0 | | 3 | 3+ - 4+ | 1 | 4+ |
| PERIARTERITIS. | 0 | | 1 | 3+ | 0 | | 0 | |
| SARCOMA, UNDIFFERENTIATED. | 0 | | 1 | | 0 | | 0 | |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( MALES )

| | GROUP 2 | GROUP 7 | GROUP 10 | GROUP 15 |
|---|---|---|---|---|
| SALIVARY GLAND | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 44 | 33 | 40 | 32 |
| MISSING. | 4 | 0 | 7 | 1 |
| AUTOLYZED. | 2 | 0 | 2 | 0 |
| MALIGNANT LYMPHOMA. | 0 | 1 | 0 | 0 |
| CYST(S). | 0 | 1 | 0 | 0 |
| NOT PRESENT IN SECTION. | 0 | 0 | 1 | 0 |
| SARCOMA, UNDIFFERENTIATED. | 0 | 0 | 0 | 1 |
| SIALADENITIS, ACTIVE, CHRONIC. | 0 | 0 | 0 | 1 4+ |
| BRONCHI | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 43 | 35 | 47 | 35 |
| MISSING. | 1 | 0 | 1 | 0 |
| BRONCHITIS, CHRONIC. | 4 3+ - 4+ | 0 | 0 | 0 |
| AUTOLYZED. | 2 | 0 | 2 | 0 |
| (MASS-MAINSTEM BRONCHUS), SCIRRHOUS CARCINOMA. | 0 | 1 | 0 | 0 |
| TRACHEA | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 41 | 35 | 47 | 35 |
| MISSING. | 1 | 0 | 1 | 0 |
| TRACHEITIS, CHRONIC. | 6 3+ - 4+ | 0 | 0 | 0 |
| AUTOLYZED. | 2 | 0 | 2 | 0 |
| LARYNX | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 40 | 35 | 45 | 34 |
| C-CELL CARCINOMA. | 1 | 0 | 0 | 0 |
| (ARTERIES), MEDIAL CALCIFICATION. | 1 4+ | 0 | 0 | 0 |
| LARYNGITIS, CHRONIC. | 6 3+ - 4+ | 0 | 0 | 0 |
| AUTOLYZED. | 2 | 0 | 2 | 0 |
| MISSING. | 0 | 0 | 2 | 1 |
| LARYNGITIS, ACUTE, PURULENT. | 0 | 0 | 1 4+ | 0 |
| THYROID | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 30 | 17 | 30 | 21 |
| NOT PRESENT IN SECTION. | 5 | 3 | 3 | 2 |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 1 | 0 | 2 | 1 |
| C-CELL CARCINOMA. | 1 | 1 | 0 | 0 |
| C-CELL HYPERPLASIA. | 4 3+ | 4 2+ - 3+ | 1 2+ | 6 2+ - 3+ |
| C-CELL ADENOMA. | 6 | 8 | 0 | 5 |
| AUTOLYZED. | 2 | 0 | 9 | 0 |
| FOLLICULAR CELL CARCINOMA. | 1 | 0 | 1 | 0 |
| FOLLICULAR CYST(S). | 0 | 1 | 0 | 0 |
| FOLLICULAR CELL ADENOMA. | 0 | 2 | 1 | 0 |
| MISSING. | 0 | 0 | 3 | 1 |
| PARATHYROID | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 28 | 22 | 11 | 22 |
| NOT PRESENT IN SECTION. | 16 | 11 | 12 | 9 |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( MALES )

| | GROUP 2 | | GROUP 7 | | GROUP 10 | | GROUP 15 | |
|---|---|---|---|---|---|---|---|---|
| PARATHYROID (continued) | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| INSUFFICIENT TISSUE | | | | | | | | |
| PRESENT IN SECTION. | 1 | | 0 | | 0 | | 0 | |
| HYPERPLASIA. | 3 | 2+ - 3+ | 2 | 2+ - 3+ | 22 | 2+ - 4+ | 3 | 2+ - 3+ |
| AUTOLYZED. | 2 | | 0 | | 2 | | 0 | |
| MISSING. | 0 | | 0 | | 3 | | 1 | |
| ESOPHAGUS | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 46 | | 33 | | 47 | | 34 | |
| MISSING. | 2 | | 2 | | 1 | | 1 | |
| AUTOLYZED. | 2 | | 0 | | 2 | | 0 | |
| MANDIBULAR LYMPH NODE | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 30 | | 18 | | 30 | | 24 | |
| NOT PRESENT IN SECTION. | 1 | | 0 | | 2 | | 0 | |
| LYMPHOID HYPERPLASIA. | 6 | 3+ - 4+ | 4 | 3+ | 0 | | 3 | 3+ |
| MISSING. | 7 | | 5 | | 13 | | 5 | |
| RETICULOENDOTHELIAL CELL HYPERPLASIA. | 1 | 3+ | 0 | | 0 | | 0 | |
| MALIGNANT LYMPHOMA. | 1 | | 2 | | 0 | | 1 | |
| PLASMACYTOSIS. | 1 | 3+ | 2 | 3+ | 0 | | 0 | |
| MASTOCYTOSIS. | 1 | 3+ | 0 | | 0 | | 0 | |
| CONGESTION. | 1 | 4+ | 0 | | 0 | | 0 | |
| AUTOLYZED. | 2 | | 0 | | 3 | | 0 | |
| LEUKEMIA. | 0 | | 2 | | 0 | | 0 | |
| FOLLICULAR HYPERPLASIA. | 0 | | 1 | 3+ | 0 | | 1 | 3+ |
| HEMANGIOECTASIA. | 0 | | 1 | 4+ | 0 | | 0 | |
| HISTIOCYTOSIS. | 0 | | 0 | | 2 | 3+ | 0 | |
| LYMPHOCYTIC HYPERPLASIA. | 0 | | 0 | | 0 | | 1 | 3+ |
| ADRENALS | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 22 | | 18 | | 40 | | 20 | |
| MISSING. | 2 | | 0 | | 0 | | 1 | |
| EXTRACORTICAL NODULAR HYPERPLASIA. | 2 | 1+ | 1 | | 0 | | 0 | |
| CORTICAL NODULAR HYPERPLASIA. | 10 | 1+ - 3+ | 3 | 2+ | 1 | | 6 | |
| LIPIDOSIS. | 5 | 1+ - 3+ | 7 | 1+ - 3+ | 5 | 1+ - 3+ | 6 | 1+ - 3+ |
| PHEOCHROMOCYTOMA. | 8 | | 3 | | 0 | | 1 | |
| MEDULLARY CELL HYPERPLASIA. | 2 | 3+ | 2 | 2+ - 3+ | 1 | 2+ | 1 | 1+ |
| CYST(S). | 2 | | 1 | | 0 | | 0 | |
| AUTOLYZED. | 2 | | 0 | | 2 | | 0 | |
| LEUKEMIA. | 0 | | 2 | | 0 | | 1 | |
| MALIGNANT LYMPHOMA. | 0 | | 1 | | 0 | | 1 | |
| HEMATOCYST(S). | 0 | | 3 | | 0 | | 0 | |
| CORTICAL CELL CARCINOMA. | 0 | | 0 | | 1 | | 0 | |
| THYMUS | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 23 | | 19 | | 11 | | 19 | |
| NOT PRESENT IN SECTION. | 13 | | 3 | | 17 | | 9 | |

| | GROUP 2 | | GROUP 7 | | GROUP 10 | | GROUP 15 | |
|---|---|---|---|---|---|---|---|---|
| THYMUS (continued) | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| INSUFFICIENT TISSUE | | | | | | | | |
| PRESENT IN SECTION. | 3 | | 1 | | 1 | | 4 | |
| MISSING. | 5 | | 1 | | 4 | | 0 | |
| INVOLUTED. | 1 | | 2 | | 15 | | 1 | |
| CYST(S). | 1 | | 0 | | 0 | | 0 | |
| AUTOLYZED. | 2 | | 0 | | 2 | | 0 | |
| EPITHELIAL HYPERPLASIA. | 2 | 3+ | 1 | 3+ | 0 | | 0 | |
| LEUKEMIA. | 0 | | 1 | | 0 | | 0 | |
| MALIGNANT LYMPHOMA. | 0 | | 1 | | 0 | | 1 | |
| EXTRAMEDULLARY HEMATOPOIESIS. | 0 | | 6 | 3+ | 0 | | 1 | 2+ |
| SCIATIC NERVE | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 45 | | 32 | | 41 | | 29 | |
| INSUFFICIENT TISSUE | | | | | | | | |
| PRESENT IN SECTION. | 1 | | 0 | | 3 | | 3 | |
| MISSING. | 2 | | 3 | | 2 | | 2 | |
| AUTOLYZED. | 2 | | 0 | | 4 | | 1 | |
| STOMACH | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 39 | | 23 | | 20 | | 30 | |
| (FORESTOMACH), ACANTHOSIS. | 1 | 3+ | 0 | | 0 | | 0 | |
| (GLANDULAR), MINERALIZATION. | 2 | 3+ - 4+ | 0 | | 0 | | 0 | |
| AUTOLYZED. | 2 | | 0 | | 11 | | 2 | |
| (FORESTOMACH), GASTRITIS, ACUTE, NECROTIZING, PURULENT. | 2 | 4+ | 2 | 4+ | 0 | | 0 | |
| (FORESTOMACH), GASTRITIS, SUBACUTE. | 1 | 4+ | 0 | | 0 | | 0 | |
| GASTRITIS, SUBACUTE. | 1 | 4+ | 0 | | 0 | | 0 | |
| (FORESTOMACH), GASTRITIS, ACUTE, NECROTIZING. | 1 | 4+ | 2 | 4+ | 0 | | 0 | |
| (FORESTOMACH-LAMINA PROPRIA), EDEMA. | 1 | 4+ | 0 | | 0 | | 0 | |
| (GLANDULAR-LAMINA PROPRIA), GASTRITIS, CHRONIC. | 0 | | 1 | 4+ | 0 | | 0 | |
| MALIGNANT LYMPHOMA. | 0 | | 1 | | 0 | | 0 | |
| PIGMENTED FOCUS. | 0 | | 1 | | 0 | | 0 | |
| (LAMINA PROPRIA), EDEMA. | 0 | | 2 | 4+ | 0 | | 0 | |
| GASTRITIS, ACUTE, NECROTIZING, PURULENT. | 0 | | 1 | 4+ | 0 | | 0 | |
| (FORESTOMACH-LAMINA PROPRIA), FIBROSIS. | 0 | | 1 | 3+ | 0 | | 0 | |
| (GLANDULAR), GASTRITIS, ACUTE, NECROTIZING. | 0 | | 1 | 4+ | 0 | | 0 | |
| MINERALIZATION. | 0 | | 0 | | 18 | 2+ - 4+ | 0 | |
| (FORESTOMACH), MISSING. | 0 | | 0 | | 1 | | 1 | |
| MINERALIZATION, MUCOSA. | 0 | | 0 | | 1 | 4+ | 0 | |
| AMYLOIDOSIS, MUSCULARIS. | 0 | | 0 | | 2 | 3+ | 0 | |
| AMYLOIDOSIS. | 0 | | 0 | | 1 | | 0 | |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( MALES )

| | GROUP 2 | | GROUP 7 | | GROUP 10 | | GROUP 15 | |
|---|---|---|---|---|---|---|---|---|
| STOMACH (continued) | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| (FORESTOMACH), GASTRITIS, ULCERATIVE. | 0 | | 0 | | 0 | | 1 | 4+ |
| (LAMINA PROPRIA), HISTIOCYTOSIS. | 0 | | 0 | | 0 | | 1 | |
| DUODENUM | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 48 | | 35 | | 33 | | 32 | |
| AUTOLYZED. | 2 | | 0 | | 17 | | 2 | |
| CARCINOMA. | 0 | | 0 | | 0 | | 1 | |
| JEJUNUM | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 47 | | 35 | | 33 | | 33 | |
| MISSING. | 1 | | 0 | | 0 | | 0 | |
| AUTOLYZED. | 2 | | 0 | | 17 | | 2 | |
| ILEUM | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 47 | | 35 | | 33 | | 33 | |
| MISSING. | 1 | | 0 | | 0 | | 0 | |
| AUTOLYZED. | 2 | | 0 | | 17 | | 2 | |
| CECUM | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 46 | | 35 | | 33 | | 33 | |
| MISSING. | 1 | | 0 | | 0 | | 0 | |
| AUTOLYZED. | 2 | | 0 | | 17 | | 2 | |
| ENTERITIS, CHRONIC. | 1 | 3+ | 0 | | 0 | | 0 | |
| COLON | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 46 | | 33 | | 33 | | 32 | |
| MISSING. | 1 | | 0 | | 0 | | 0 | |
| AUTOLYZED. | 2 | | 0 | | 17 | | 2 | |
| ENTERITIS, CHRONIC. | 1 | 3+ | 0 | | 0 | | 0 | |
| MALIGNANT LYMPHOMA. | 0 | | 1 | | 0 | | 0 | |
| NEMATODIASIS. | 0 | | 1 | | 0 | | 1 | |
| RECTUM | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 46 | | 35 | | 33 | | 32 | |
| MISSING. | 1 | | 0 | | 0 | | 0 | |
| AUTOLYZED. | 2 | | 0 | | 17 | | 2 | |
| ENTERITIS, CHRONIC. | 1 | 3+ | 0 | | 0 | | 0 | |
| NEMATODIASIS. | 0 | | 0 | | 0 | | 1 | |
| MESENTERIC LYMPH NODES | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 34 | | 15 | | 12 | | 14 | |
| INSUFFICIENT TISSUE | | | | | | | | |
| PRESENT IN SECTION. | 1 | | 0 | | 0 | | 0 | |
| MISSING. | 5 | | 5 | | 20 | | 5 | |
| HISTIOCYTOSIS. | 8 | 3+ | 8 | 2+ - 3+ | 5 | 3+ - 4+ | 11 | 2+ - 3+ |
| (MASS), NOT PRESENT IN SECTION. | 1 | | 0 | | 0 | | 0 | |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( MALES )

| | GROUP 2 | | GROUP 7 | | GROUP 10 | | GROUP 15 | |
|---|---|---|---|---|---|---|---|---|
| MESENTERIC LYMPH NODES (continued) | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| CONGESTION. | 1 | 3+ | 0 | | 0 | | 1 | 4+ |
| AUTOLYZED. | 2 | | 0 | | 10 | | 0 | |
| RETICULUM CELL HYPERPLASIA. | 1 | 3+ | 0 | | 0 | | 0 | |
| ANGIOECTASIA. | 0 | | 1 | 4+ | 0 | | 0 | |
| LYMPHOID HYPERPLASIA. | 0 | | 4 | 3+ - 4+ | 0 | | 1 | 3+ |
| MALIGNANT LYMPHOMA. | 0 | | 2 | | 0 | | 1 | |
| MASTOCYTOSIS. | 0 | | 1 | 3+ | 0 | | 3 | 3+ |
| MALIGNANT LYMPHOMA, (HISTIOCYTIC TYPE). | 0 | | 1 | | 0 | | 0 | |
| NOT PRESENT IN SECTION. | 0 | | 0 | | 3 | | 0 | |
| LEUKEMIA. | 0 | | 0 | | 0 | | 1 | |
| LUNGS (ALL LOBES) | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 6 | | 13 | | 31 | | 19 | |
| HISTIOCYTOSIS, PIGMENTED. | 24 | 1+ - 3+ | 1 | 2+ | 0 | | 1 | 2+ |
| EMPHYSEMA. | 2 | 3+ | 0 | | 0 | | 0 | |
| HISTIOCYTOSIS. | 3 | 2+ - 3+ | 0 | | 1 | 2+ | 1 | 2+ |
| LEUKEMIA. | 3 | | 8 | | 2 | | 7 | |
| PNEUMONITIS, INTERSTITIAL. | 3 | 2+ - 3+ | 0 | | 1 | 1+ | 0 | |
| CARCINOMA, METASTATIC. | 1 | | 0 | | 1 | | 0 | |
| CHRONIC MURINE PNEUMONIA. | 14 | 2+ - 4+ | 1 | 3+ | 2 | 2+ | 3 | 1+ - 2+ |
| ALVEOLAR/BRONCHIOLAR CELL ADENOMA. | 3 | | 1 | | 1 | | 1 | |
| HISTIOCYTOSIS, INTRA-ALVEOLAR. | 1 | 2+ | 1 | 3+ | 1 | 1+ | 0 | |
| CONGESTION. | 1 | 3+ | 0 | | 0 | | 0 | |
| AUTOLYZED. | 2 | | 0 | | 4 | | 0 | |
| ADENOMATOSIS. | 2 | 2+ - 3+ | 0 | | 0 | | 0 | |
| ATELECTASIS. | 1 | 3+ | 7 | 3+ - 4+ | 1 | 3+ | 3 | 3+ - 4+ |
| PNEUMONITIS, GRANULOMATOUS. | 1 | 1+ | 2 | 1+ - 3+ | 0 | | 0 | |
| FIBROSARCOMA, METASTATIC. | 1 | | 0 | | 0 | | 0 | |
| PULMONARY EDEMA. | 1 | 4+ | 0 | | 1 | 3+ | 0 | |
| (PLEURAL SURFACE), ADENOCARCINOMA, ORIGIN UNDETERMINED. | 1 | | 0 | | 0 | | 0 | |
| BRONCHOPNEUMONIA, ACUTE, PURULENT. | 1 | 4+ | 0 | | 0 | | 0 | |
| MALIGNANT LYMPHOMA. | 0 | | 1 | | 0 | | 0 | |
| SCLEROSING CARCINOMA. | 0 | | 1 | | 0 | | 0 | |
| ALVEOLAR/BRONCHIOLAR CELL HYPERPLASIA. | 0 | | 0 | | 2 | 2+ - 3+ | 1 | |
| PNEUMONITIS, CHRONIC. | 0 | | 0 | | 1 | | 0 | |
| FOREIGN BODY(S). | 0 | | 0 | | 1 | 3+ | 0 | |
| HEMORRHAGE. | 0 | | 0 | | 1 | 3+ | 1 | 1+ |
| (GLANDULAR NEOPLASM), ALVEOLAR/BRONCHIOLAR CELL ADENOMA. | 0 | | 0 | | 1 | | 0 | |
| PNEUMOLITHIASIS. | 0 | | 0 | | 1 | 2+ | 0 | |
| (ALVEOLAR WALLS), MINERALIZATION. | 0 | | 0 | | 1 | 3+ | 0 | |
| PIGMENTATION, INTRACELLULAR. | 0 | | 0 | | 0 | | 1 | 4+ |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( MALES )

| | GROUP 2 | GROUP 7 | GROUP 10 | GROUP 15 |
|---|---|---|---|---|
| LIVER | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 23 | 10 | 29 | 5 |
| BILE DUCT HYPERPLASIA. | 6 2+ - 4+ | 13 2+ - 3+ | 5 1+ - 2+ | 10 2+ - 3+ |
| FIBROSIS, PORTAL. | 4 2+ - 3+ | 4 2+ - 3+ | 1 2+ | 0 |
| LEUKEMIA. | 8 | 7 | 1 | 10 |
| HEPATOCELLULAR VACUOLATION. | 1 4+ | 1 3+ | 0 | 1 3+ |
| MALIGNANT LYMPHOMA. | 1 | 2 | 0 | 0 |
| NEOPLASTIC NODULE(S). | 4 | 4 | 0 | 4 |
| EOSINOPHILIC FOCUS/FOCI. | 8 | 5 | 3 | 7 |
| CLEAR CELL FOCUS/FOCI. | 3 | 3 | 10 | 8 |
| HEPATITIS, NECROTIZING. | 1 3+ | 0 | 0 | 0 |
| AUTOLYZED. | 2 | 0 | 2 | 0 |
| NECROSIS, CENTRILOBULAR. | 1 4+ | 0 | 0 | 0 |
| EOSINOPHILIC NODULE(S). | 1 | 0 | 1 2+ | 0 |
| (PORTAL AREA), SQUAMOUS METAPLASIA. | 0 | 1 1+ | 0 | 0 |
| HEPATITIS, ACTIVE, CHRONIC. | 0 | 1 3+ | 0 | 0 |
| CONGESTION, PASSIVE, CHRONIC. | 0 | 1 4+ | 0 | 0 |
| HEPATOCELLULAR CARCINOMA. | 0 | 1 | 0 | 0 |
| HEPATITIS, CHRONIC. | 0 | 0 | 1 2+ | 0 |
| HEPATOCELLULAR ATYPIA. | 0 | 0 | 1 1+ | 0 |
| HEPATOCELLULAR PLEOMORPHISM. | 0 | 0 | 1 2+ | 0 |
| GRANULOMA. | 0 | 0 | 0 | 1 1+ |
| SCATTERED CLEAR CELLS. | 0 | 0 | 0 | 1 |
| NECROSIS. | 0 | 0 | 0 | 1 4+ |
| BILE DUCT PROLIFERATION. | 0 | 0 | 0 | 4 2+ - 3+ |
| HEPATOCELLULAR VACUOLATION, PERILOBULAR. | 0 | 0 | 0 | 1 3+ |
| (CLEAR CELL DIFFERENTIATION), EOSINOPHILIC FOCUS. | 0 | 0 | 0 | 1 |
| HEPATITIS, GRANULOMATOUS. | 0 | 0 | 0 | 2 1+ - 3+ |
| SPLEEN | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 31 | 21 | 35 | 23 |
| EXTRAMEDULLARY HEMATOPOIESIS. | 6 3+ | 2 2+ - 3+ | 1 3+ | 1 2+ |
| LEUKEMIA. | 8 | 5 | 2 | 10 |
| MALIGNANT LYMPHOMA. | 1 | 4 | 0 | 1 |
| HEMOSIDEROSIS. | 1 4+ | 0 | 0 | 0 |
| AUTOLYZED. | 2 | 0 | 3 | 0 |
| FIBROSIS. | 2 3+ | 1 3+ | 0 | 0 |
| RETICULOENDOTHELIAL CELL HYPERPLASIA. | 0 | 2 2+ - 4+ | 0 | 0 |
| PIGMENTATION. | 0 | 0 | 8 3+ - 4+ | 0 |
| MISSING. | 0 | 0 | 1 | 0 |
| PANCREAS | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 36 | 23 | 32 | 24 |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( MALES )

| | GROUP 2 | GROUP 7 | GROUP 10 | GROUP 15 |
|---|---|---|---|---|
| PANCREAS (continued) | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| MISSING. | 1 | 0 | 1 | 0 |
| ACINAR CELL ATROPHY. | 7 2+ - 4+ | 4 1+ - 4+ | 1 2+ | 0 |
| LOBULAR ATROPHY. | 3 3+ - 4+ | 3 2+ - 3+ | 9 2+ - 3+ | 3 3+ - 4+ |
| AUTOLYZED. | 2 | 0 | 5 | 0 |
| FAT NECROSIS. | 1 1+ | 0 | 0 | 0 |
| ISLET CELL ADENOMA. | 2 | 1 | 3 | 5 |
| LEUKEMIA. | 0 | 1 | 0 | 0 |
| MALIGNANT LYMPHOMA. | 0 | 1 | 0 | 0 |
| ACINAR CELL HEPATOCELLULAR DIFFERENTIATION. | 0 | 2 2+ - 3+ | 0 | 0 |
| ACINAR CELL ADENOMA. | 0 | 1 | 0 | 1 |
| ISLET CELL HYPERPLASIA. | 0 | 3 1+ - 3+ | 0 | 1 2+ |
| DUCTAL HYPERPLASIA. | 0 | 0 | 0 | 1 2+ |
| PANCREATITIS, PERIDUCTAL. | 0 | 0 | 0 | 1 3+ |
| ACINAR CELL CARCINOMA. | 0 | 0 | 0 | 1 |
| KIDNEYS | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 13 | 16 | 4 | 13 |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 1 | 0 | 0 | 0 |
| NEPHRITIS. | 1 3+ | 0 | 0 | 0 |
| NEPHROLITHIASIS. | 2 3+ | 0 | 0 | 0 |
| NEPHROPATHY, CHRONIC. | 31 2+ - 4+ | 23 1+ - 4+ | 43 4+ | 30 1+ - 4+ |
| AUTOLYZED. | 2 | 0 | 2 | 0 |
| NEPHRITIS, INTERSTITIAL, CHRONIC. | 1 3+ | 0 | 0 | 0 |
| (CONVOLUTED TUBULES), NECROSIS. | 1 4+ | 0 | 0 | 0 |
| MALIGNANT LYMPHOMA. | 0 | 2 | 0 | 0 |
| TUBULAR CELL ADENOMA. | 0 | 1 | 0 | 0 |
| PYELONEPHRITIS. | 0 | 1 3+ | 0 | 0 |
| NEPHROSIS, CHRONIC. | 0 | 0 | 1 4+ | 0 |
| LEUKEMIA. | 0 | 0 | 0 | 1 |
| INFARCT, CORTICAL. | 0 | 0 | 0 | 1 |
| TUBULAR CELL HYPERPLASIA. | 0 | 0 | 0 | 1 1+ |
| (PROXIMAL TUBULES), NECROSIS. | 0 | 0 | 0 | 1 4+ |
| NEPHRITIS, GRANULOMATOUS. | 0 | 0 | 0 | 1 1+ |
| HEART | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 32 | 20 | 23 | 32 |
| MYOCARDIOPATHY. | 14 1+ - 4+ | 18 1+ - 4+ | 21 2+ - 4+ | 9 2+ - 4+ |
| AUTOLYZED. | 2 | 0 | 2 | 0 |
| FIBROSIS. | 1 4+ | 0 | 0 | 0 |
| FIBROMA. | 1 | 0 | 0 | 0 |
| ATRIAL SEPTIC THROMBOSIS. | 1 4+ | 0 | 0 | 0 |
| LEUKEMIA. | 0 | 2 | 0 | 1 |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( MALES )

| | GROUP 2 | | GROUP 7 | | GROUP 10 | | GROUP 15 | |
|---|---|---|---|---|---|---|---|---|
| HEART (continued) | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| MALIGNANT LYMPHOMA. | 0 | | 1 | | 0 | | 0 | |
| THROMBOSIS. | 0 | | 1 | | 0 | | 0 | |
| ATRIAL THROMBOSIS. | 0 | | 1 | | 0 | | 0 | |
| (CORONARY ARTERY), MEDIAL CALCIFICATION. | 0 | | 0 | | 2 | 3+ | 0 | |
| (CORONARY ARTERY), PERIARTERITIS. | 0 | | 0 | | 1 | 2+ | 0 | |
| (CORONARY VESSELS), MINERALIZATION. | 0 | | 0 | | 1 | 4+ | 0 | |
| MYOCARDITIS, ACUTE. | 0 | | 0 | | 1 | 1+ | 0 | |
| (CORONARY VESSELS), MEDIAL CALCIFICATION. | 0 | | 0 | | 1 | 3+ | 0 | |
| NEPHROPATHY, CHRONIC. | 0 | | 0 | | 0 | | 1 | 4+ |
| (AORTA), MINERALIZATION. | 0 | | 0 | | 1 | 4+ | 0 | |
| (AORTA), MEDIAL CALCIFICATION. | 0 | | 0 | | 1 | 4+ | 0 | |
| URINARY BLADDER | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 41 | | 27 | | 38 | | 25 | |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 1 | | 2 | | 4 | | 1 | |
| MISSING. | 5 | | 5 | | 1 | | 6 | |
| AUTOLYZED. | 2 | | 0 | | 6 | | 0 | |
| UROTHELIUM HYPERPLASIA. | 1 | 3+ | 0 | | 0 | | 0 | |
| MALIGNANT LYMPHOMA. | 0 | | 1 | | 0 | | 0 | |
| CYSTITIS, CHRONIC. | 0 | | 0 | | 1 | 4+ | 0 | |
| PAPILLARY HYPERPLASIA. | 0 | | 0 | | 0 | | 1 | 4+ |
| CYSTITIS, FOLLICULAR. | 0 | | 0 | | 0 | | 1 | 2+ |
| TRANSITIONAL CELL CARCINOMA. | 0 | | 0 | | 0 | | 1 | |
| SEMINAL VESICLE | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 42 | | 28 | | 37 | | 33 | |
| MISSING. | 4 | | 4 | | 7 | | 1 | |
| AUTOLYZED. | 2 | | 0 | | 2 | | 0 | |
| VESICULITIS, ACTIVE, CHRONIC. | 2 | 4+ | 2 | 4+ | 0 | | 0 | |
| MALIGNANT LYMPHOMA. | 0 | | 1 | | 0 | | 0 | |
| ATROPHY. | 0 | | 0 | | 2 | | 0 | |
| VESICULITIS, ACUTE, PURULENT. | 0 | | 0 | | 1 | 4+ | 0 | |
| VESICULITIS, CHRONIC. | 0 | | 0 | | 1 | 4+ | 0 | |
| LEUKEMIA. | 0 | | 0 | | 0 | | 1 | |
| PROSTATE | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 26 | | 17 | | 32 | | 24 | |
| MISSING. | 7 | | 4 | | 4 | | 5 | |
| (MASS), PROSTATIC CARCINOMA. | 1 | | 0 | | 0 | | 0 | |
| ACINAR STRUCTURE(S). | 1 | | 0 | | 0 | | 0 | |
| PROSTATITIS, ACTIVE, CHRONIC. | 14 | 3+ - 4+ | 8 | 2+ - 4+ | 5 | 3+ - 4+ | 3 | 4+ |
| AUTOLYZED. | 2 | | 0 | | 2 | | 0 | |
| ACINAR CELL HYPERPLASIA. | 1 | 3+ | 2 | 1+ - 2+ | 0 | | 0 | |
| MALIGNANT LYMPHOMA. | 0 | | 1 | | 0 | | 0 | |
| HYPERPLASIA, ADENOMATOUS. | 0 | | 1 | 3+ | 0 | | 0 | |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( MALES )

| | GROUP 2 | GROUP 7 | GROUP 10 | GROUP 15 |
|---|---|---|---|---|
| PROSTATE (continued) | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| PAPILLARY HYPERPLASIA. | 0 | 1 2+ | 0 | 0 |
| PROSTATITIS, CHRONIC. | 0 | 1 3+ | 0 | 0 |
| MINERALIZATION. | 0 | 0 | 1 1+ | 0 |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 0 | 0 | 1 | 0 |
| PROSTATITIS, ACUTE, PURULENT. | 0 | 0 | 4 1+ - 4+ | 0 |
| PROSTATITIS, ACUTE. | 0 | 0 | 2 1+ | 2 2+ - 3+ |
| LEUKEMIA. | 0 | 0 | 0 | 1 |
| HYPERPLASIA. | 0 | 0 | 0 | 2 1+ |
| TESTES | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 5 | 5 | 8 | 0 |
| MISSING. | 1 | 0 | 0 | 0 |
| INTERSTITIAL CELL TUMOR(S). | 41 | 29 | 37 | 32 |
| INTERSTITIAL CELL HYPERPLASIA. | 4 2+ - 3+ | 0 | 2 2+ - 3+ | 1 3+ |
| OLIGOSPERMIA. | 1 | 0 | 5 | 0 |
| (SEMINIFEROUS TUBULES), MULTINUCLEATED GIANT CELL(S). | 1 4+ | 0 | 0 | 0 |
| ATROPHY. | 2 | 3 | 4 | 7 4+ |
| AUTOLYZED. | 2 | 0 | 3 | 0 |
| MINERALIZATION. | 0 | 1 4+ | 0 | 0 |
| TUNIC MESOTHELIAL PAPILLARY HYPERPLASIA. | 0 | 1 3+ | 0 | 0 |
| HEMORRHAGE. | 0 | 1 4+ | 0 | 0 |
| (SEMINIFEROUS TUBULES), MINERALIZATION. | 0 | 1 4+ | 0 | 0 |
| ORCHITIS, ACTIVE, CHRONIC. | 0 | 1 4+ | 0 | 0 |
| PERIARTERITIS. | 0 | 0 | 2 2+ - 3+ | 0 |
| BRAIN | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 47 | 33 | 45 | 32 |
| MISSING. | 1 | 0 | 0 | 0 |
| AUTOLYZED. | 2 | 0 | 3 | 0 |
| LEUKEMIA. | 0 | 1 | 1 | 1 |
| MINERALIZATION. | 0 | 1 3+ | 0 | 0 |
| MENINGIOENCEPHALITIS, PYOGRANULOMATOUS. | 0 | 0 | 1 4+ | 0 |
| PHYCOMYCOSIS. | 0 | 0 | 1 | 0 |
| NECROSIS. | 0 | 0 | 0 | 1 |
| ASTROCYTOMA. | 0 | 0 | 0 | 1 |
| PITUITARY | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 27 | 24 | 28 | 17 |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 3 | 1 | 3 | 1 |
| MISSING. | 10 | 5 | 14 | 8 |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( MALES )

| | GROUP 2 | GROUP 7 | GROUP 10 | GROUP 15 |
|---|---|---|---|---|
| PITUITARY (continued) | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| ADENOMA. | 8 | 4 | 0 | 8 |
| AUTOLYZED. | 2 | 0 | 4 | 0 |
| MALIGNANT LYMPHOMA. | 0 | 1 | 0 | 0 |
| CYST(S). | 0 | 0 | 1 | 1 |
| STERNUM/RIB & RIB JUNCTION | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 46 | 35 | 34 | 33 |
| FIBROUS OSTEODYSTROPHY. | 2 2+ - 3+ | 0 | 14 1+ - 4+ | 0 |
| AUTOLYZED. | 2 | 0 | 2 | 0 |
| MISSING. | 0 | 0 | 0 | 1 |
| LEUKEMIA. | 0 | 0 | 0 | 1 |
| FEMUR | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 45 | 35 | 25 | 32 |
| (BONE MARROW), MALIGNANT LYMPHOMA. | 1 | 2 | 0 | 0 |
| (BONE MARROW), HYPOPLASIA. | 0 | 0 | 1 4+ | 0 |
| (BONE MARROW), FIBROSIS. | 0 | 0 | 1 4+ | 0 |
| (BONE MARROW), AUTOLYZED. | 0 | 0 | 2 | 0 |
| FIBROUS OSTEODYSTROPHY. | 2 3+ - 4+ | 0 | 23 2+ - 4+ | 0 |
| AUTOLYZED. | 2 | 0 | 2 | 0 |
| ENDOSTOSIS. | 1 3+ | 0 | 0 | 1 |
| MISSING. | 0 | 0 | 0 | 1 |
| LEUKEMIA. | 0 | 0 | 0 | 1 |
| NASAL CAVITY | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 46 | 34 | 33 | 31 |
| FIBROUS OSTEODYSTROPHY. | 2 3+ - 4+ | 0 | 13 1+ - 4+ | 0 |
| AUTOLYZED. | 2 | 0 | 2 | 0 |
| RHINITIS, CHRONIC. | 0 | 1 1+ | 0 | 0 |
| MISSING. | 0 | 0 | 1 | 1 |
| OSTEOPLASIA. | 0 | 0 | 1 2+ | 0 |
| RHINITIS, ACUTE, PURULENT. | 0 | 0 | 1 4+ | 2 4+ |
| RHINITIS, ACTIVE, CHRONIC. | 0 | 0 | 0 | 1 4+ |
| OTHER | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| (ALL TISSUES MODERATE TO SEVERELY AUTOLYZED). | 12 | 2 | 3 | 1 |
| (ZYMBAL'S GLAND), CARCINOMA. | 1 | 0 | 0 | 0 |
| (ALL TISSUES MODERATELY AUTOLYZED). | 2 | 0 | 3 | 1 |
| NOT REQUIRED. | 20 | 20 | 19 | 22 |
| (ALL TISSUES SLIGHTLY AUTOLYZED). | 2 | 0 | 0 | 0 |
| (MASS-PREPUTIAL GLAND), HYPERPLASIA. | 1 4+ | 0 | 0 | 0 |
| (ALL TISSUES SEVERELY AUTOLYZED). | 7 | 10 | 13 | 3 |
| (MASS-ABDOMINAL CAVITY), FIBROSARCOMA. | 2 | 0 | 0 | 0 |
| (EYES), CATARACT(S). | 2 | 0 | 1 | 0 |
| (MASS-ABDOMINAL CAVITY), SARCOMA, UNDIFFERENTIATED. | 1 | 0 | 0 | 0 |
| (MASS-RENAL LYMPH NODE), INSUFFICIENT TISSUE PRESENT IN SECTION. | 1 | 0 | 0 | 0 |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( MALES )

| | GROUP 2 | | GROUP 7 | | GROUP 10 | | GROUP 15 | |
|---|---|---|---|---|---|---|---|---|
| OTHER (continued) | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| (MASS), LIPOMA. | 1 | | 0 | | 0 | | 0 | |
| (SPERMATIC CORD), FAT NECROSIS. | 1 | | 0 | | 0 | | 0 | |
| (RENAL LYMPH NODES), MALIGNANT LYMPHOMA. | 1 | | 0 | | 0 | | 0 | |
| (BRONCHIAL LYMPH NODES), ERYTHROPHAGOCYTOSIS. | 1 | 2+ | 0 | | 0 | | 0 | |
| (MANDIBULE), SQUAMOUS CELL CARCINOMA. | 1 | | 0 | | 0 | | 0 | |
| (BRONCHIAL LYMPH NODES), LEUKEMIA. | 0 | | 1 | | 0 | | 0 | |
| (CERVICAL REGION-ZYMBAL'S GLAND), SQUAMOUS CELL CARCINOMA. | 0 | | 1 | | 0 | | 0 | |
| GENERALIZED LYMPHOMA. | 0 | | 2 | | 0 | | 0 | |
| GENERALIZED MALIGNANT LYMPHOMA. | 0 | | 1 | | 0 | | 0 | |
| (ABDOMINAL CAVITY), SARCOMA, INVASIVE, UNDIFFERENTIATED. | 0 | | 1 | | 0 | | 0 | |
| (PREPUTIAL GLAND), ADENOMA. | 0 | | 1 | | 0 | | 0 | |
| (BRONCHIAL LYMPH NODES), MALIGNANT LYMPHOMA. | 0 | | 1 | | 0 | | 0 | |
| (EYES), RETINAL GENERATION. | 0 | | 0 | | 1 | 4+ | 0 | |
| (MESENTERIC ARTERY), PERIARTERITIS. | 0 | | 0 | | 10 | 4+ | 2 | 4+ |
| (MESENTERIC VESSELS), PERIARTERITIS. | 0 | | 0 | | 3 | 4+ | 0 | |
| (TISSUE MASS), MISSING. | 0 | | 0 | | 1 | | 0 | |
| (ABDOMINAL CAVITY), HEMANGIOMA. | 0 | | 0 | | 0 | | 1 | |
| (BRONCHIAL LYMPH NODES), LYMPHADENITIS, ACUTE. | 0 | | 0 | | 0 | | 1 | 4+ |
| (ABDOMEN-SUBCUTANEOUS TISSUE), LIPOMA. | 0 | | 0 | | 0 | | 1 | |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( FEMALES )

| | GROUP 2 | GROUP 7 | GROUP 10 | GROUP 15 |
|---|---|---|---|---|
| SKIN | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 46 | 31 | 48 | 34 |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 1 | 0 | 0 | 0 |
| AUTOLYZED. | 3 | 2 | 1 | 0 |
| (MASS), CUTANEOUS HORN. | 0 | 1 | 0 | 0 |
| FOLLICULITIS, CHRONIC. | 0 | 1 3+ | 0 | 0 |
| (MASS-EAR), PAPILLOMA. | 0 | 1 | 0 | 0 |
| CALCINOSIS CIRCUMSCRIPTA, SUBCUTANEOUS. | 0 | 1 4+ | 0 | 0 |
| CUTANEOUS HORN. | 0 | 0 | 1 | 0 |
| (MASS-FORELEG), FIBROMA. | 0 | 0 | 0 | 1 |
| (MASS-ABDOMEN), FIBROMA. | 0 | 0 | 0 | 1 |
| (MASS-FACE), ZYMBAL'S GLAND TUMOR(S). | 0 | 0 | 0 | 1 |
| DERMATITIS, NECROTIZING. | 0 | 0 | 0 | 1 4+ |
| (MASS-FOOT), MISSING. | 0 | 1 | 0 | 0 |
| (HEAD-SIDE), ZYMBAL'S GLAND SQUAMOUS CELL CARCINOMA. | 0 | 0 | 1 | 0 |
| MAMMARY | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 10 | 1 | 5 | 4 |
| NOT PRESENT IN SECTION. | 22 | 15 | 23 | 12 |
| ACTIVE. | 13 | 16 | 9 | 10 |
| AUTOLYZED. | 3 | 2 | 1 | 0 |
| ADENOFIBROMA. | 0 | 0 | 4 | 4 |
| ADENOCARCINOMA. | 0 | 0 | 1 | 1 |
| FIBROADENOMA. | 0 | 0 | 6 | 3 |
| MINERALIZATION. | 0 | 0 | 1 1+ | 0 |
| (MASS-AXILLA), FIBROMA. | 0 | 0 | 1 | 0 |
| (MASS-INGUINAL), FIBROADENOMA. | 3 | 3 | 0 | 0 |
| (MASS-INGUINAL), FIBROSARCOMA. | 1 | 0 | 0 | 0 |
| (MASS-AXILLA), FIBROADENOMA. | 4 | 5 | 0 | 0 |
| (MASS-THORAX), LACTATING. | 1 | 0 | 0 | 0 |
| (MASS-AXILLA), ADENOFIBROMA. | 2 | 1 | 0 | 0 |
| (MASS-INGUINAL), CYSTIC ADENOFIBROMA. | 1 | 0 | 0 | 0 |
| (MASS-AXILLA), CYSTIC FIBROADENOMA. | 1 | 0 | 0 | 0 |
| (MASS-ABDOMEN), FIBROADENOMA. | 1 | 1 | 0 | 0 |
| (MASS-AXILLA), ADENOMA. | 1 | 1 | 0 | 0 |
| (MASS-INGUINAL), ADENOFIBROMA. | 0 | 5 | 0 | 0 |
| (MASS-CERVICAL), FIBROADENOMA. | 0 | 1 | 0 | 0 |
| (MASS-ABDOMEN), CYSTIC FIBROADENOMA. | 0 | 1 | 0 | 0 |
| (MASS-SIDE), FIBROADENOMA. | 0 | 1 | 0 | 0 |
| (MASS-THORAX), FIBROADENOMA. | 0 | 1 | 0 | 0 |
| (MASS-INGUINAL), CYSTADENOFIBROMA. | 0 | 1 | 0 | 0 |
| (MASS-AXILLA), CYSTADENOFIBROMA. | 0 | 1 | 0 | 0 |
| (MASS), ADENOFIBROMA. | 0 | 0 | 1 | 1 |
| (MASS), FIBROADENOMA. | 0 | 0 | 2 | 1 |
| (MASS), ADENOCARCINOMA. | 0 | 0 | 1 | 0 |
| (MASS-AXILLA), LACTATING. | 0 | 0 | 0 | 1 |
| (MASS), ADENOMA. | 0 | 0 | 0 | 1 |
| (MASS-AXILLARY), MISSING. | 0 | 0 | 0 | 1 |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( FEMALES )

| | GROUP 2 | GROUP 7 | GROUP 10 | GROUP 15 |
|---|---|---|---|---|
| MAMMARY (continued) | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| (MASS), LIPOMATOUS, LACTATING. | 0 | 0 | 0 | 1 |
| THIGH MUSCLE | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 47 | 32 | 47 | 32 |
| AUTOLYZED. | 3 | 2 | 1 | 1 |
| NECROSIS. | 0 | 1 | 0 | 0 |
| MYOPATHY, (ZENKER'S TYPE), NECROSIS. | 0 | 0 | 1 4+ | 0 |
| MYOPATHY. | 0 | 0 | 1 2+ | 1 3+ |
| MISSING. | 0 | 0 | 0 | 1 |
| SALIVARY GLAND | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 46 | 32 | 48 | 34 |
| AUTOLYZED. | 3 | 2 | 1 | 1 |
| ADENOCARCINOMA. | 1 | 0 | 0 | 0 |
| MISSING. | 0 | 1 | 1 | 0 |
| BRONCHI | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 37 | 32 | 46 | 34 |
| MISSING. | 3 | 1 | 2 | 0 |
| BRONCHITIS, CHRONIC. | 7 3+ - 4+ | 0 | 0 | 0 |
| AUTOLYZED. | 3 | 2 | 1 | 1 |
| NOT PRESENT IN SECTION. | 0 | 0 | 1 | 0 |
| TRACHEA | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 40 | 32 | 48 | 34 |
| MISSING. | 2 | 1 | 1 | 0 |
| TRACHEITIS, CHRONIC. | 5 3+ - 4+ | 0 | 0 | 0 |
| AUTOLYZED. | 3 | 2 | 1 | 1 |
| LARYNX | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 37 | 31 | 45 | 33 |
| MISSING. | 2 | 1 | 0 | 1 |
| LARYNGITIS, CHRONIC. | 8 3+ - 4+ | 0 | 0 | 0 |
| AUTOLYZED. | 3 | 2 | 1 | 1 |
| HEMORRHAGE. | 0 | 1 3+ | 0 | 0 |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 0 | 0 | 2 | 0 |
| LARYNGITIS, ACUTE, PURULENT. | 0 | 0 | 2 2+ - 3+ | 0 |
| THYROID | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 27 | 22 | 27 | 21 |
| NOT PRESENT IN SECTION. | 7 | 0 | 7 | 1 |
| MISSING. | 2 | 1 | 0 | 1 |
| C-CELL ADENOMA. | 10 | 4 | 5 | 4 |
| AUTOLYZED. | 3 | 2 | 2 | 1 |
| C-CELL HYPERPLASIA. | 1 3+ | 5 1+ - 3+ | 7 2+ - 4+ | 6 2+ - 3+ |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( FEMALES )

| | GROUP 2 | | GROUP 7 | | GROUP 10 | | GROUP 15 | |
|---|---|---|---|---|---|---|---|---|
| THYROID (continued) | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| FOLLICULAR CYST(S). | 0 | | 1 | | 0 | | 0 | |
| FOLLICULAR CELL ADENOMA. | 0 | | 1 | | 1 | | 0 | |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 0 | | 1 | | 1 | | 0 | |
| FOLLICULAR CELL CARCINOMA. | 0 | | 0 | | 1 | | 0 | |
| C-CELL CARCINOMA. | 0 | | 0 | | 2 | | 0 | |
| (POSSIBLE NEOPLASM), AUTOLYSIS. | 0 | | 0 | | 0 | | 1 | 4+ |
| PARATHYROID | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 29 | | 23 | | 27 | | 20 | |
| NOT PRESENT IN SECTION. | 14 | | 8 | | 17 | | 11 | |
| MISSING. | 2 | | 1 | | 0 | | 1 | |
| AUTOLYZED. | 3 | | 2 | | 1 | | 1 | |
| HYPERPLASIA. | 2 | 3+ | 1 | 3+ | 5 | 2+ - 4+ | 1 | 3+ |
| ADENOMA. | 0 | | 0 | | 0 | | 1 | |
| ESOPHAGUS | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 45 | | 32 | | 46 | | 34 | |
| MISSING. | 2 | | 1 | | 2 | | 0 | |
| AUTOLYZED. | 3 | | 2 | | 1 | | 1 | |
| NOT PRESENT IN SECTION. | 0 | | 0 | | 1 | | 0 | |
| MANDIBULAR LYMPH NODE | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 28 | | 20 | | 33 | | 21 | |
| NOT PRESENT IN SECTION. | 4 | | 0 | | 1 | | 0 | |
| MISSING. | 14 | | 5 | | 10 | | 8 | |
| AUTOLYZED. | 3 | | 2 | | 1 | | 0 | |
| MALIGNANT LYMPHOMA. | 1 | | 0 | | 1 | | 0 | |
| PLASMACYTOSIS. | 0 | | 1 | 3+ | 0 | | 0 | |
| LYMPHOID HYPERPLASIA. | 0 | | 7 | 3+ - 4+ | 1 | 3+ | 4 | 3+ |
| HISTIOCYTOSIS. | 0 | | 0 | | 1 | 3+ | 0 | |
| RETICULOENDOTHELIAL CELL HYPERPLASIA. | 0 | | 0 | | 2 | 3+ | 0 | |
| PIGMENTATION. | 0 | | 0 | | 0 | | 1 | 3+ |
| FOLLICULAR HYPERPLASIA. | 0 | | 0 | | 0 | | 1 | 3+ |
| ADRENALS | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 34 | | 16 | | 25 | | 12 | |
| LIPIDOSIS. | 5 | 2+ | 14 | 1+ - 3+ | 21 | 1+ - 4+ | 11 | 1+ - 3+ |
| CORTICAL CELL ADENOMA. | 1 | | 0 | | 2 | | 0 | |
| PHEOCHROMOCYTOMA. | 2 | | 1 | | 1 | | 1 | |
| AUTOLYZED. | 3 | | 2 | | 1 | | 0 | |
| CORTICAL NODULAR HYPERPLASIA. | 2 | 2+ | 5 | | 0 | | 10 | |
| EXTRACORTICAL NODULAR HYPERPLASIA. | 2 | | 0 | | 0 | | 0 | |
| MEDULLARY CELL HYPERPLASIA. | 1 | 3+ | 0 | | 0 | | 0 | |
| HEMATOCYST(S). | 1 | | 2 | 3+ | 2 | | 5 | |
| LEUKEMIA. | 0 | | 1 | | 0 | | 0 | |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( FEMALES )

| | GROUP 2 | | GROUP 7 | | GROUP 10 | | GROUP 15 | |
|---|---|---|---|---|---|---|---|---|
| ADRENALS (continued) | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| MISSING. | 0 | | 0 | | 0 | | 1 | |
| MINERALIZATION, MEDULLA. | 0 | | 0 | | 0 | | 1 | |
| THYMUS | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 23 | | 19 | | 25 | | 15 | |
| NOT PRESENT IN SECTION. | 11 | | 6 | | 14 | | 13 | |
| MISSING. | 7 | | 2 | | 1 | | 1 | |
| INVOLUTED. | 1 | | 0 | | 1 | | 0 | |
| EPITHELIAL HYPERPLASIA. | 3 | 3+ | 4 | 3+ - 4+ | 6 | 2+ | 4 | 2+ - 3+ |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 1 | | 0 | | 2 | | 1 | |
| AUTOLYZED. | 3 | | 2 | | 1 | | 1 | |
| MALIGNANT LYMPHOMA. | 1 | | 0 | | 0 | | 0 | |
| LEUKEMIA. | 0 | | 1 | | 0 | | 0 | |
| HEMOSIDEROSIS. | 0 | | 1 | 3+ | 0 | | 0 | |
| MASTOCYTOSIS. | 0 | | 1 | 3+ | 0 | | 0 | |
| SCIATIC NERVE | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 43 | | 32 | | 45 | | 33 | |
| MISSING. | 4 | | 1 | | 2 | | 0 | |
| AUTOLYZED. | 3 | | 2 | | 1 | | 1 | |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 0 | | 0 | | 2 | | 0 | |
| NEURITIS, ACUTE, PURULENT. | 0 | | 0 | | 0 | | 1 | 2+ |
| STOMACH | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 38 | | 25 | | 43 | | 28 | |
| (FORESTOMACH-LAMINA PROPRIA), EDEMA. | 1 | 3+ | 1 | 4+ | 0 | | 0 | |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 2 | | 1 | | 0 | | 0 | |
| (FORESTOMACH), GASTRITIS, CHRONIC. | 2 | 3+ | 0 | | 0 | | 0 | |
| AUTOLYZED. | 3 | | 2 | | 2 | | 1 | |
| (FORESTOMACH), GASTRITIS, ACUTE. | 2 | 3+ - 4+ | 0 | | 0 | | 0 | |
| (FORESTOMACH), GASTRITIS, ACUTE, NECROTIZING. | 1 | 4+ | 0 | | 0 | | 0 | |
| MALIGNANT LYMPHOMA. | 1 | | 0 | | 0 | | 0 | |
| (FORESTOMACH), PAPILLARY HYPERPLASIA. | 0 | | 1 | 3+ | 0 | | 0 | |
| GLANDULAR CYST(S). | 0 | | 1 | 1+ | 0 | | 0 | |
| (FORESTOMACH), GASTRITIS, NECROTIZING, PURULENT. | 0 | | 1 | 4+ | 0 | | 0 | |
| (FORESTOMACH), NECROSIS. | 0 | | 1 | | 0 | | 0 | |
| (FORESTOMACH-LAMINA PROPRIA), GASTRITIS, ACUTE. | 0 | | 2 | 4+ | 0 | | 0 | |
| GASTRITIS, ACUTE, NECROTIZING. | 0 | | 0 | | 1 | 4+ | 0 | |
| (SEROSAL-NEOPLASM), ADENOCARCINOMA. | 0 | | 0 | | 1 | | 0 | |
| MINERALIZATION. | 0 | | 0 | | 1 | 3+ | 0 | |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( FEMALES )

| | GROUP 2 | GROUP 7 | GROUP 10 | GROUP 15 |
|---|---|---|---|---|
| STOMACH (continued) | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| MINERALIZATION, MUCOSA. | 0 | 0 | 1 4+ | 0 |
| (FORESTOMACH), MINERALIZATION, MUCOSA. | 0 | 0 | 1 1+ | 0 |
| NOT PRESENT IN SECTION. | 0 | 0 | 0 | 1 |
| (FORESTOMACH), MINERALIZATION. | 0 | 0 | 0 | 1 2+ |
| (FORESTOMACH), HYPERKERATOSIS. | 0 | 0 | 0 | 1 2+ |
| ACANTHOSIS. | 0 | 0 | 0 | 1 2+ |
| (FORESTOMACH-LAMINA PROPRIA), PERIARTERITIS. | 0 | 0 | 0 | 1 3+ |
| (FORESTOMACH-LAMINA PROPRIA). | 0 | 0 | 0 | 1 4+ |
| DUODENUM | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 47 | 33 | 46 | 34 |
| AUTOLYZED. | 3 | 2 | 4 | 1 |
| JEJUNUM | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 47 | 32 | 46 | 34 |
| AUTOLYZED. | 3 | 2 | 4 | 1 |
| CESTODIASIS. | 0 | 1 | 0 | 0 |
| ILEUM | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 47 | 32 | 45 | 33 |
| AUTOLYZED. | 3 | 2 | 4 | 1 |
| CESTODIASIS. | 0 | 1 | 0 | 0 |
| (LARGE INTESTINE), ENTERITIS, NECROTIZING. | 0 | 0 | 1 4+ | 0 |
| NEMATODIASIS. | 0 | 0 | 0 | 1 |
| CECUM | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 45 | 33 | 45 | 34 |
| NEMATODIASIS. | 2 | 0 | 0 | 0 |
| AUTOLYZED. | 3 | 2 | 4 | 1 |
| (LARGE INTESTINE), ENTERITIS, NECROTIZING. | 0 | 0 | 1 4+ | 0 |
| COLON | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 46 | 32 | 45 | 29 |
| NEMATODIASIS. | 1 | 1 | 0 | 3 |
| AUTOLYZED. | 3 | 2 | 4 | 1 |
| (LARGE INTESTINE), ENTERITIS, NECROTIZING. | 0 | 0 | 1 4+ | 0 |
| PERIARTERITIS. | 0 | 0 | 0 | 2 3+ - 4+ |
| RECTUM | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 47 | 33 | 45 | 34 |
| AUTOLYZED. | 3 | 2 | 4 | 1 |
| (MASS), NO SIGNIFICANT LESIONS RECOGNIZED. | 1 | 0 | 0 | 0 |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( FEMALES )

| | GROUP 2 | | GROUP 7 | | GROUP 10 | | GROUP 15 | |
|---|---|---|---|---|---|---|---|---|
| RECTUM (continued) | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| (LARGE INTESTINE), ENTERITIS, NECROTIZING. | 0 | | 0 | | 1 | 4+ | 0 | |
| MESENTERIC LYMPH NODES | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 28 | | 17 | | 26 | | 16 | |
| NOT PRESENT IN SECTION. | 1 | | 0 | | 0 | | 0 | |
| MISSING. | 1 | | 3 | | 10 | | 3 | |
| HISTIOCYTOSIS. | 11 | 2+ - 3+ | 9 | 2+ - 3+ | 13 | 2+ - 4+ | 11 | 2+ - 4+ |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 2 | | 0 | | 0 | | 0 | |
| AUTOLYZED. | 3 | | 2 | | 1 | | 1 | |
| MASTOCYTOSIS. | 3 | 3+ | 1 | 3+ | 1 | 3+ | 2 | 3+ |
| MALIGNANT LYMPHOMA. | 1 | | 0 | | 0 | | 1 | |
| RETICULOENDOTHELIAL CELL HYPERPLASIA. | 1 | 3+ | 0 | | 0 | | 0 | |
| LYMPHANGIECTASIS. | 1 | 3+ | 0 | | 0 | | 0 | |
| LEUKEMIA. | 0 | | 1 | | 0 | | 1 | |
| CONGESTION. | 0 | | 1 | 4+ | 0 | | 0 | |
| LYMPHOID HYPERPLASIA. | 0 | | 2 | 3+ | 0 | | 0 | |
| LYMPHADENITIS. | 0 | | 0 | | 0 | | 1 | 3+ |
| (GUT), SARCOMA, UNDIFFERENTIATED. | 0 | | 0 | | 1 | | 0 | |
| LUNGS (ALL LOBES) | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 3 | | 25 | | 39 | | 28 | |
| CHRONIC MURINE PNEUMONIA. | 11 | 2+ - 4+ | 1 | 3+ | 0 | | 0 | |
| HISTIOCYTOSIS, PIGMENTED. | 38 | 1+ - 3+ | 1 | 1+ | 2 | 2+ | 0 | |
| ATELECTASIS. | 1 | 3+ | 3 | 2+ - 4+ | 2 | 2+ - 3+ | 0 | |
| PNEUMONITIS, INTERSTITIAL. | 2 | 2+ | 0 | | 0 | | 1 | 3+ |
| HISTIOCYTOSIS. | 4 | 1+ - 3+ | 0 | | 2 | 2+ | 0 | |
| LEUKEMIA. | 3 | | 1 | | 1 | | 4 | |
| ALVEOLAR/BRONCHIOLAR CELL ADENOMA. | 1 | | 0 | | 1 | | 1 | |
| AUTOLYZED. | 3 | | 2 | | 1 | | 0 | |
| PNEUMONITIS, GRANULOMATOUS. | 1 | | 1 | 3+ | 0 | | 0 | |
| ALVEOLAR/BRONCHIOLAR CELL HYPERPLASIA. | 2 | 2+ | 1 | 2+ | 0 | | 0 | |
| BRONCHOPNEUMONIA, ACUTE. | 1 | 4+ | 0 | | 0 | | 0 | |
| ADENOMATOSIS. | 1 | 4+ | 0 | | 0 | | 0 | |
| MALIGNANT LYMPHOMA. | 1 | | 0 | | 0 | | 0 | |
| MINERALIZATION, INTRALOBULAR. | 0 | | 0 | | 1 | 2+ | 0 | |
| SQUAMOUS CELL CARCINOMA, METASTATIC. | 0 | | 0 | | 1 | | 0 | |
| BRONCHIOLITIS. | 0 | | 0 | | 1 | | 0 | |
| INTRALUMENAL SUPPURATIVE EXUDATE. | 0 | | 0 | | 1 | | 0 | |
| PNEUMONITIS, INTERSTITIAL, CHRONIC. | 0 | | 0 | | 0 | | 1 | 2+ |
| PNEUMONITIS, GRANULAMATOUS. | 0 | | 0 | | 0 | | 1 | 2+ |
| LIVER | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 23 | | 16 | | 19 | | 9 | |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( FEMALES )

| | GROUP 2 | GROUP 7 | GROUP 10 | GROUP 15 |
|---|---|---|---|---|
| LIVER (continued) | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| EOSINOPHILIC FOCUS/FOCI. | 9 | 4 | 11 | 6 |
| BILE DUCT HYPERPLASIA. | 3 2+ - 4+ | 2 3+ | 0 | 0 |
| HEPATITIS, GRANULOMATOUS. | 3 1+ - 3+ | 1 3+ | 3 2+ | 2 3+ - 4+ |
| LEUKEMIA. | 5 | 5 | 4 | 9 |
| CLEAR CELL FOCUS/FOCI. | 3 | 0 | 7 | 4 |
| HEPATOCELLULAR VACUOLATION. | 2 3+ | 2 2+ - 3+ | 0 | 0 |
| AUTOLYZED. | 3 | 2 | 1 | 0 |
| NEOPLASTIC NODULE(S). | 3 | 1 | 3 | 5 |
| CONGESTION. | 1 3+ | 0 | 0 | 0 |
| MALIGNANT LYMPHOMA. | 2 | 0 | 0 | 0 |
| BASOPHILIC FOCUS/FOCI. | 2 | 0 | 3 | 4 |
| HEMANGIOECTASIS. | 1 2+ | 0 | 0 | 0 |
| NECROSIS, CENTRILOBULAR. | 0 | 1 4+ | 0 | 2 4+ |
| NECROSIS. | 0 | 1 2+ | 3 2+ - 4+ | 1 2+ |
| FIBROSIS, PORTAL. | 0 | 1 3+ | 1 3+ | 1 3+ |
| HEPATITIS, ACTIVE, CHRONIC. | 0 | 1 2+ | 0 | 0 |
| HEPATOCELLULAR ALTERATION, MIXED. | 0 | 1 | 0 | 0 |
| HEPATITIS, MONONUCLEAR CELL. | 0 | 0 | 1 2+ | 0 |
| EOSINOPHILIC NODULE(S). | 0 | 0 | 1 | 0 |
| HEPATITIS, CHRONIC, NONSUPPURATIVE. | 0 | 0 | 1 1+ | 0 |
| BILE DUCT PROLIFERATION. | 0 | 0 | 2 2+ | 0 |
| MICROGRANULOMATOSIS. | 0 | 0 | 1 2+ | 1 2+ |
| HEPATITIS, PORTAL, MONONUCLEAR CELL. | 0 | 0 | 2 2+ | 0 |
| CHOLANGIECTASIS. | 0 | 0 | 1 3+ | 0 |
| HEPATOCELLULAR VACUOLATION, PERILOBULAR. | 0 | 0 | 1 4+ | 0 |
| HEPATITIS, NECROTIZING. | 0 | 0 | 0 | 2 4+ |
| BASOPHILIC NODULE(S). | 0 | 0 | 0 | 1 |
| CHOLANGIOFIBROSIS. | 0 | 0 | 0 | 1 |
| HEPATITIS, TOXIC, NECROTIZING. | 0 | 0 | 0 | 1 4+ |
| HEMANGIOMA. | 0 | 0 | 0 | 1 |
| HEPATITIS, SUBACUTE. | 0 | 0 | 0 | 1 2+ |
| MACROPHAGES, PIGMENTED. | 0 | 0 | 0 | 1 2+ |
| HEPATOCELLULAR VACUOLATION, PERIPHEROLOBULAR. | 0 | 0 | 0 | 1 3+ |
| SPLEEN | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 37 | 23 | 35 | 17 |
| LEUKEMIA. | 5 | 7 | 4 | 9 |
| EXTRAMEDULLARY HEMATOPOIESIS. | 3 2+ - 4+ | 2 3+ | 8 2+ - 4+ | 6 3+ - 4+ |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( FEMALES )

| | GROUP 2 | | GROUP 7 | | GROUP 10 | | GROUP 15 | |
|---|---|---|---|---|---|---|---|---|
| SPLEEN (continued) | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| FOLLICULAR HYPERPLASIA. | 1 | 3+ | 0 | | 0 | | 0 | |
| RETICULUM CELL HYPERPLASIA. | 1 | 3+ | 0 | | 0 | | 0 | |
| AUTOLYZED. | 3 | | 2 | | 1 | | 2 | |
| MALIGNANT LYMPHOMA. | 3 | | 0 | | 2 | | 0 | |
| HEMOSIDEROSIS. | 0 | | 1 | 4+ | 0 | | 0 | |
| HEMANGIOMA. | 0 | | 1 | | 0 | | 0 | |
| LYMPHOID HYPERPLASIA. | 0 | | 0 | | 1 | 4+ | 0 | |
| PIGMENTATION. | 0 | | 0 | | 0 | | 1 | 3+ |
| PANCREAS | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 40 | | 24 | | 35 | | 29 | |
| ACINAR CELL ATROPHY. | 2 | 2+ - 3+ | 2 | 2+ - 3+ | 2 | 3+ | 2 | 2+ |
| AUTOLYZED. | 3 | | 2 | | 2 | | 1 | |
| LOBULAR ATROPHY. | 2 | 2+ | 2 | 3+ - 4+ | 7 | 2+ - 4+ | 0 | |
| MALIGNANT LYMPHOMA. | 1 | | 0 | | 0 | | 0 | |
| ISLET CELL HYPERPLASIA. | 1 | 3+ | 1 | 2+ | 0 | | 1 | 2+ |
| LEUKEMIA. | 0 | | 1 | | 0 | | 0 | |
| ISLET CELL ADENOMA. | 0 | | 2 | | 2 | | 0 | |
| DUCTAL ECTASIA. | 0 | | 1 | 1+ | 0 | | 0 | |
| ACINAR CELL ADENOMA. | 0 | | 1 | | 0 | | 0 | |
| MISSING. | 0 | | 0 | | 1 | | 0 | |
| PERIARTERITIS. | 0 | | 0 | | 1 | 4+ | 1 | 4+ |
| NOT PRESENT IN SECTION. | 0 | | 0 | | 0 | | 1 | |
| KIDNEYS | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 28 | | 20 | | 8 | | 18 | |
| NEPHROPATHY, CHRONIC. | 18 | 1+ - 4+ | 10 | 1+ - 4+ | 39 | 2+ - 4+ | 13 | 1+ - 4+ |
| AUTOLYZED. | 3 | | 2 | | 1 | | 0 | |
| MALIGNANT LYMPHOMA. | 1 | | 0 | | 0 | | 0 | |
| NEPHROLITHIASIS. | 0 | | 2 | 3+ - 4+ | 0 | | 1 | 2+ |
| (CORTICAL TUBULES), NECROSIS. | 0 | | 1 | 4+ | 0 | | 0 | |
| TRANSITIONAL CELL CARCINOMA. | 0 | | 0 | | 1 | | 0 | |
| SARCOMA, UNDIFFERENTIATED. | 0 | | 0 | | 1 | | 0 | |
| NEPHROPATHY. | 0 | | 0 | | 1 | 2+ | 0 | |
| NEPHROSIS. | 0 | | 0 | | 0 | | 1 | 4+ |
| LIPOMA. | 0 | | 0 | | 0 | | 1 | |
| NEPHRITIS, ACUTE, PURULENT. | 0 | | 0 | | 0 | | 1 | 4+ |
| (CORTEX), PIGMENTATION, INTRACELLULAR. | 0 | | 0 | | 0 | | 1 | 4+ |
| HEART | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 43 | | 24 | | 38 | | 26 | |
| AUTOLYZED. | 3 | | 2 | | 1 | | 0 | |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( FEMALES )

| | GROUP 2 | | GROUP 7 | | GROUP 10 | | GROUP 15 | |
|---|---|---|---|---|---|---|---|---|
| HEART (continued) | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| MYOCARDIOPATHY. | 4 | 2+ - 3+ | 7 | 1+ - 4+ | 10 | 2+ - 4+ | 7 | 2+ - 3+ |
| LEUKEMIA. | 0 | | 1 | | 0 | | 0 | |
| ATRIAL THROMBOSIS. | 0 | | 1 | | 0 | | 0 | |
| (CORONARY VESSELS), PERIARTERITIS. | 0 | | 0 | | 1 | 1+ | 0 | |
| (CORONARY VESSELS & AORTA), MEDIAL MINERALIZATION. | 0 | | 0 | | 0 | | 1 | |
| MINERALIZATION. | 0 | | 0 | | 0 | | 1 | |
| (CORTEX), PIGMENT DEPOSITION. | 0 | | 0 | | 0 | | 1 | 4+ |
| MYOCARDITIS, ACUTE, PURULENT. | 0 | | 0 | | 0 | | 1 | 4+ |
| URINARY BLADDER | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 45 | | 31 | | 39 | | 29 | |
| MISSING. | 2 | | 2 | | 2 | | 4 | |
| AUTOLYZED. | 3 | | 2 | | 1 | | 1 | |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 0 | | 0 | | 6 | | 1 | |
| PAPILLARY HYPERPLASIA. | 0 | | 0 | | 1 | 3+ | 0 | |
| TRANSITIONAL CELL CARCINOMA. | 0 | | 0 | | 1 | | 0 | |
| OVARIES | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 34 | | 29 | | 47 | | 29 | |
| MISSING. | 2 | | 1 | | 0 | | 1 | |
| ADENOMATOUS HYPERPLASIA. | 1 | 2+ | 0 | | 0 | | 0 | |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 1 | | 0 | | 0 | | 0 | |
| CYST(S). | 2 | | 1 | | 2 | | 4 | |
| (CONTIGUOUS TISSUE), FAT NECROSIS. | 1 | | 0 | | 0 | | 0 | |
| AUTOLYZED. | 3 | | 2 | | 1 | | 0 | |
| FIBROSIS. | 1 | | 0 | | 0 | | 0 | |
| OOPHORITIS, ACTIVE, CHRONIC, PURULENT. | 1 | 4+ | 0 | | 0 | | 0 | |
| MALIGNANT LYMPHOMA. | 1 | | 0 | | 0 | | 0 | |
| OOPHORITIS, ACUTE. | 2 | 4+ | 0 | | 0 | | 0 | |
| OOPHORITIS, CHRONIC. | 1 | 4+ | 0 | | 0 | | 0 | |
| OOPHORITIS, ACTIVE, CHRONIC. | 1 | 4+ | 0 | | 0 | | 0 | |
| GRANULOSA CELL TUMOR(S). | 0 | | 1 | | 0 | | 1 | |
| PAROVARIAN CYST(S). | 0 | | 1 | | 0 | | 0 | |
| UTERUS | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 34 | | 29 | | 40 | | 27 | |
| MISSING. | 1 | | 0 | | 0 | | 1 | |
| STROMAL POLYP(S). | 1 | | 3 | | 2 | | 3 | |
| ENDOMETRIAL ADENOMA. | 2 | | 0 | | 0 | | 0 | |
| METRITIS, ACTIVE, CHRONIC. | 1 | 4+ | 0 | | 0 | | 0 | |
| CYSTIC HYPERPLASIA. | 2 | 3+ | 0 | | 0 | | 1 | 2+ |
| FIBROMA. | 2 | | 0 | | 1 | | 0 | |
| AUTOLYZED. | 3 | | 2 | | 1 | | 1 | |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( FEMALES )

| | GROUP 2 | | GROUP 7 | | GROUP 10 | | GROUP 15 | |
|---|---|---|---|---|---|---|---|---|
| UTERUS (continued) | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| (MASS-UTERUS), AUTOLYZED. | 0 | | 0 | | 0 | | 1 | |
| METRITIS, ACUTE, PURULENT. | 1 | 4+ | 0 | | 1 | 3+ | 1 | 3+ |
| ENDOMETRIAL CARCINOMA. | 1 | | 0 | | 0 | | 0 | |
| MALIGNANT LYMPHOMA. | 1 | | 0 | | 0 | | 0 | |
| FIBROUS POLYP(S). | 1 | | 0 | | 0 | | 0 | |
| ENDOMETRITIS, ACUTE. | 1 | 4+ | 0 | | 0 | | 0 | |
| METRITIS, ACUTE. | 1 | 4+ | 0 | | 0 | | 0 | |
| LEIOMYOMA. | 0 | | 1 | | 0 | | 0 | |
| ADENOFIBROMA. | 0 | | 0 | | 1 | | 0 | |
| POLYP(S). | 0 | | 0 | | 1 | | 0 | |
| FIBROADENOMA. | 0 | | 0 | | 1 | | 0 | |
| HEMATOCYST(S). | 0 | | 0 | | 1 | | 0 | |
| ENDOMETRIAL HYPERPLASIA. | 0 | | 0 | | 1 | 3+ | 0 | |
| (MASS), FIBROMA. | 0 | | 0 | | 0 | | 1 | |
| LEIOMYOSARCOMA. | 0 | | 0 | | 0 | | 1 | |
| BRAIN | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 44 | | 28 | | 49 | | 34 | |
| MISSING. | 1 | | 0 | | 0 | | 0 | |
| (CEREBRUM), ASTROCYTOMA. | 1 | | 0 | | 0 | | 0 | |
| AUTOLYZED. | 3 | | 2 | | 1 | | 1 | |
| HEMORRHAGIC NECROSIS. | 1 | 3+ | 0 | | 0 | | 0 | |
| LEUKEMIA. | 0 | | 1 | | 0 | | 0 | |
| (WHITE MATTER), CEREBELLAR VACUOLATION. | 0 | | 2 | 2+ - 3+ | 0 | | 0 | |
| CEREBELLAR VACUOLATION. | 0 | | 1 | 2+ | 0 | | 0 | |
| VACUOLATION. | 0 | | 1 | 4+ | 0 | | 0 | |
| PITUITARY | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 19 | | 14 | | 12 | | 11 | |
| MISSING. | 6 | | 2 | | 8 | | 6 | |
| ADENOMA. | 18 | | 11 | | 25 | | 13 | |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 1 | | 0 | | 3 | | 0 | |
| CYST(S). | 2 | | 6 | | 1 | | 1 | |
| AUTOLYZED. | 3 | | 2 | | 1 | | 0 | |
| MALIGNANT LYMPHOMA. | 1 | | 0 | | 0 | | 0 | |
| LEUKEMIA. | 0 | | 1 | | 0 | | 1 | |
| MULTILOCULAR CYST(S). | 0 | | 1 | | 0 | | 0 | |
| HEMATOCYST(S). | 0 | | 0 | | 0 | | 1 | |
| EOSINOPHILIC CYST(S). | 0 | | 0 | | 0 | | 2 | |
| STERNUM/RIB & RIB JUNCTION | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 44 | | 28 | | 48 | | 35 | |
| AUTOLYZED. | 3 | | 2 | | 1 | | 0 | |
| FIBROUS OSTEODYSTROPHY. | 0 | | 1 | 2+ | 1 | 4+ | 0 | |
| ENDOSTOSIS. | 0 | | 4 | 2+ | 0 | | 0 | |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( FEMALES )

| | GROUP 2 | | GROUP 7 | | GROUP 10 | | GROUP 15 | |
|---|---|---|---|---|---|---|---|---|
| FEMUR | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 44 | | 28 | | 44 | | 34 | |
| AUTOLYZED. | 3 | | 2 | | 1 | | 0 | |
| MISSING. | 0 | | 1 | | 0 | | 0 | |
| ENDOSTOSIS. | 0 | | 4 | 2+ | 3 | 4+ | 1 | |
| (BONE MARROW), MALIGNANT LYMPHOMA. | 0 | | 1 | | 0 | | 0 | |
| FIBROUS OSTEODYSTROPHY. | 0 | | 0 | | 2 | 4+ | 0 | |
| NASAL CAVITY | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 44 | | 33 | | 46 | | 34 | |
| AUTOLYZED. | 3 | | 2 | | 1 | | 0 | |
| RHINITIS, ACUTE, PURULENT. | 0 | | 0 | | 2 | 4+ | 1 | 2+ |
| FIBROUS OSTEODYSTROPHY. | 0 | | 0 | | 1 | 4+ | 0 | |
| OTHER | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| (EYES), CATARACT(S). | 5 | | 0 | | 0 | | 0 | |
| NOT REQUIRED. | 29 | | 19 | | 30 | | 19 | |
| (ALL TISSUES MODERATE TO SEVERELY AUTOLYZED). | 5 | | 5 | | 0 | | 4 | |
| (ALL TISSUES SEVERELY AUTOLYZED). | 5 | | 6 | | 9 | | 6 | |
| (ALL TISSUES MODERATELY AUTOLYZED). | 1 | | 1 | | 4 | | 1 | |
| (CLITORAL GLAND), CYSTIC HYPERPLASIA. | 1 | 3+ | 0 | | 0 | | 0 | |
| (CLITORAL GLAND), ADENITIS, CHRONIC. | 1 | 4+ | 0 | | 0 | | 0 | |
| (CLITORAL GLAND), HYPERPLASIA. | 1 | | 0 | | 0 | | 0 | |
| (MESENTERY), FAT NECROSIS. | 0 | | 2 | | 0 | | 0 | |
| (MASS-ABDOMEN), FIBROMA. | 0 | | 1 | | 0 | | 0 | |
| (MASS-PANCREATIC LYMPH NODE), NO SIGNIFICANT LESIONS RECOGNIZED. | 0 | | 1 | | 0 | | 0 | |
| (PANCREATIC LYMPH NODES), MALIGNANT LYMPHOMA. | 1 | | 0 | | 0 | | 0 | |
| (PANCREATIC LYMPH NODES), RETICULOENDOTHELIAL CELL HYPERPLASIA. | 0 | | 0 | | 1 | | 0 | |
| (CLITORAL GLAND), KERATOTIC CYST(S). | 0 | | 0 | | 1 | | 0 | |
| (MASS), ENDOMETRIAL POLYP(S). | 0 | | 0 | | 1 | | 0 | |
| (MESENTERIC ARTERY), PERIARTERITIS. | 0 | | 0 | | 2 | 4+ | 0 | |
| (EYES), AUTOLYZED. | 0 | | 0 | | 1 | | 0 | |
| (MESENTERIC VESSEL), PERIARTERITIS. | 0 | | 0 | | 1 | 4+ | 0 | |
| (MASS-ABDOMINAL CAVITY), AUTOLYZED. | 0 | | 0 | | 1 | | 0 | |
| (ZYMBAL'S GLAND), SQUAMOUS CELL CARCINOMA. | 0 | | 0 | | 1 | | 0 | |
| (ZYMBAL'S GLAND), KERATOACANTHOMA. | 0 | | 0 | | 1 | | 0 | |
| (PANCREATIC LYMPH NODES), LYMPHADENITIS, GRANULOMATOUS. | 0 | | 0 | | 1 | 4+ | 0 | |
| (CLITORAL GLAND), ADENOCARCINOMA. | 0 | | 0 | | 1 | | 1 | |
| (MASS), MESENTERIC FAT NECROSIS. | 0 | | 0 | | 0 | | 1 | |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( FEMALES )

| | GROUP 2 | GROUP 7 | GROUP 10 | GROUP 15 |
|---|---|---|---|---|
| OTHER (continued) | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| (HEMORRHAGIC MASS-MONONUCLEAR CELLS), AUTOLYZED. | 0 | 0 | 0 | 1 |
| (CLITORAL GLAND), ADENOMA. | 0 | 0 | 0 | 1 |
| (MASS), AUTOLYZED. | 0 | 0 | 0 | 1 |
| (ABDOMINAL CAVITY), MESOTHELIOMA. | 0 | 0 | 0 | 1 |

TABLE XIII

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

SURVIVAL[a] - YELLOW 3

| | INTRATRACHEAL | | | | | | | | DIETARY | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | MALE | | | | FEMALE | | | | MALE | | | | FEMALE | | | |
| GROUP | 3 | 6 | 4 | 8 | 3 | 6 | 4 | 8 | 11 | 13 | 12 | 16 | 11 | 13 | 12 | 16 |
| SPECIES (TREATMENT)[b] | H(T) | H(C) | R(T) | R(C) | H(T) | H(C) | R(T) | H(C) | H(T) | H(C) | R(T) | R(C) | H(T) | H(C) | R(T) | R(C) |
| DOSE LEVEL[c] | 15.0 | 0 | 15.0 | 0 | 15.0 | 0 | 15.0 | 0 | 0.8 | 0 | 0.8 | 0 | 0.8 | 0 | 0.8 | 0 |
| Week | | | | | | | | | | | | | | | | |
| 1 | 50 | 35 | 50 | 35 | 50 | 35 | 50 | 35 | 50 | 35 | 50 | 35 | 50 | 35 | 50 | 35 |
| 2 | 50 | 35 | 50 | 35 | 50 | 35 | 50 | 35 | 48 | 35 | 50 | 35 | 50 | 35 | 50 | 35 |
| 3 | 50 | 35 | 50 | 35 | 50 | 35 | 50 | 35 | 48 | 35 | 50 | 35 | 50 | 35 | 50 | 35 |
| 4 | 50 | 35 | 50 | 35 | 50 | 35 | 50 | 35 | 48 | 35 | 50 | 35 | 50 | 35 | 50 | 35 |
| 5 | 50 | 35 | 50 | 35 | 50 | 35 | 50 | 35 | 48 | 35 | 50 | 35 | 50 | 35 | 50 | 35 |
| 6 | 50 | 34 | 50 | 35 | 50 | 35 | 50 | 35 | 48 | 35 | 50 | 35 | 50 | 35 | 50 | 35 |
| 7 | 50 | 34 | 50 | 35 | 50 | 35 | 50 | 35 | 48 | 35 | 50 | 35 | 50 | 35 | 50 | 35 |
| 8 | 50 | 34 | 50 | 35 | 50 | 35 | 50 | 35 | 48 | 35 | 50 | 35 | 50 | 35 | 50 | 35 |
| 9 | 50 | 34 | 50 | 35 | 49 | 35 | 50 | 35 | 48 | 35 | 50 | 35 | 50 | 35 | 50 | 35 |
| 10 | 50 | 34 | 50 | 35 | 49 | 35 | 50 | 35 | 48 | 35 | 50 | 35 | 50 | 35 | 50 | 35 |
| 11 | 50 | 34 | 50 | 35 | 49 | 35 | 50 | 35 | 48 | 35 | 50 | 35 | 50 | 35 | 50 | 35 |
| 12 | 50 | 34 | 50 | 35 | 48 | 35 | 50 | 34 | 48 | 35 | 50 | 35 | 50 | 35 | 50 | 35 |
| 13 | 50 | 34 | 50 | 35 | 48 | 35 | 50 | 34 | 48 | 35 | 50 | 35 | 50 | 35 | 50 | 35 |
| 14 | 48 | 34 | 50 | 35 | 48 | 35 | 50 | 34 | 48 | 35 | 50 | 35 | 50 | 35 | 50 | 35 |
| 15 | 47 | 34 | 50 | 35 | 48 | 35 | 50 | 34 | 48 | 35 | 50 | 35 | 50 | 35 | 50 | 35 |
| 16 | 47 | 34 | 50 | 35 | 48 | 35 | 50 | 34 | 48 | 35 | 50 | 35 | 50 | 35 | 50 | 35 |
| 17 | 47 | 34 | 50 | 35 | 48 | 35 | 50 | 34 | 48 | 35 | 50 | 35 | 50 | 35 | 50 | 35 |
| 18 | 47 | 34 | 50 | 35 | 48 | 35 | 50 | 34 | 48 | 35 | 50 | 35 | 50 | 35 | 50 | 35 |
| 19 | 47 | 34 | 50 | 35 | 48 | 35 | 50 | 34 | 48 | 35 | 50 | 35 | 50 | 35 | 50 | 35 |
| 20 | 47 | 34 | 50 | 35 | 48 | 35 | 50 | 34 | 48 | 35 | 50 | 35 | 50 | 35 | 50 | 35 |
| 21 | 47 | 34 | 50 | 35 | 48 | 35 | 50 | 34 | 48 | 35 | 50 | 35 | 50 | 35 | 50 | 35 |
| 22 | 47 | 34 | 49 | 35 | 48 | 35 | 50 | 34 | 48 | 35 | 50 | 35 | 50 | 35 | 50 | 35 |
| 23 | 47 | 34 | 49 | 35 | 48 | 35 | 50 | 34 | 48 | 35 | 50 | 35 | 50 | 35 | 50 | 35 |
| 24 | 47 | 34 | 49 | 35 | 48 | 35 | 50 | 34 | 48 | 35 | 50 | 35 | 50 | 35 | 50 | 35 |
| 25 | 47 | 33 | 49 | 35 | 47 | 35 | 50 | 33 | 48 | 35 | 50 | 35 | 50 | 35 | 50 | 35 |
| 26 | 47 | 33 | 49 | 35 | 47 | 35 | 50 | 33 | 48 | 35 | 50 | 35 | 50 | 34 | 50 | 35 |
| 27 | 47 | 33 | 49 | 35 | 47 | 35 | 50 | 33 | 48 | 35 | 50 | 35 | 50 | 34 | 50 | 35 |
| 28 | 47 | 33 | 49 | 35 | 47 | 35 | 50 | 33 | 48 | 34 | 50 | 35 | 50 | 33 | 50 | 35 |
| 29 | 47 | 33 | 49 | 35 | 47 | 35 | 50 | 33 | 48 | 34 | 50 | 35 | 50 | 33 | 50 | 35 |
| 30 | 47 | 33 | 49 | 35 | 47 | 35 | 50 | 33 | 48 | 34 | 50 | 35 | 50 | 33 | 50 | 35 |
| 31 | 47 | 33 | 49 | 35 | 47 | 35 | 50 | 33 | 48 | 34 | 50 | 35 | 50 | 33 | 50 | 35 |
| 32 | 47 | 33 | 49 | 35 | 47 | 35 | 50 | 33 | 48 | 34 | 50 | 35 | 50 | 33 | 50 | 35 |
| 33 | 47 | 33 | 49 | 35 | 47 | 35 | 50 | 33 | 48 | 34 | 50 | 35 | 50 | 33 | 50 | 35 |

[a] Number of animals alive on the last day of each week.

[b] Species: Hamster = H, Rat = R; (Treatment): Treated = (T), Control = (C).

[c] Intratracheal doses administered as mg/0.2 ml saline; control animals received 0.2 ml saline without dye. Dietary doses administered as % of total diet; all diets were prepared with 1.3% w/w Mazola® corn oil and control diets consisted of meal plus corn oil (1.3%).

TABLE XIII

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

SURVIVAL[a] - YELLOW 3

| | INTRATRACHEAL | | | | | | | | DIETARY | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | MALE | | | | FEMALE | | | | MALE | | | | FEMALE | | | |
| GROUP | 3 | 6 | 4 | 8 | 3 | 6 | 4 | 8 | 11 | 14 | 12 | 16 | 11 | 14 | 12 | 16 |
| SPECIES (TREATMENT)[b] | H(T) | H(C) | R(T) | R(C) | H(T) | H(C) | R(T) | R(C) | H(T) | H(C) | R(T) | R(C) | H(T) | H(C) | R(T) | R(C) |
| DOSE LEVEL[c] | 15.0 | 0 | 15.0 | 0 | 15.0 | 0 | 15.0 | 0 | 0.8 | 0 | 0.8 | 0 | 0.8 | 0 | 0.8 | 0 |
| Week | | | | | | | | | | | | | | | | |
| 34 | 47 | 33 | 49 | 35 | 47 | 35 | 50 | 33 | 48 | 34 | 50 | 35 | 50 | 33 | 50 | 35 |
| 35 | 47 | 33 | 49 | 35 | 47 | 35 | 50 | 33 | 48 | 34 | 50 | 35 | 50 | 33 | 50 | 35 |
| 36 | 47 | 33 | 49 | 35 | 47 | 35 | 50 | 33 | 48 | 34 | 50 | 35 | 50 | 33 | 50 | 35 |
| 37 | 47 | 32 | 49 | 35 | 47 | 35 | 50 | 33 | 48 | 34 | 50 | 35 | 50 | 33 | 50 | 35 |
| 38 | 47 | 32 | 49 | 35 | 47 | 34 | 50 | 33 | 48 | 33 | 50 | 35 | 50 | 32 | 50 | 35 |
| 39 | 46 | 32 | 49 | 35 | 47 | 34 | 50 | 33 | 48 | 33 | 50 | 35 | 50 | 32 | 50 | 35 |
| 40 | 46 | 31 | 49 | 35 | 47 | 34 | 50 | 33 | 48 | 33 | 50 | 35 | 49 | 31 | 50 | 35 |
| 41 | 46 | 31 | 49 | 35 | 47 | 34 | 50 | 33 | 48 | 33 | 50 | 35 | 49 | 31 | 50 | 35 |
| 42 | 46 | 31 | 49 | 35 | 47 | 33 | 50 | 33 | 48 | 33 | 50 | 35 | 49 | 31 | 50 | 35 |
| 43 | 46 | 31 | 49 | 35 | 47 | 33 | 50 | 33 | 48 | 33 | 50 | 35 | 49 | 31 | 50 | 35 |
| 44 | 46 | 31 | 49 | 35 | 47 | 32 | 50 | 33 | 48 | 33 | 50 | 35 | 49 | 31 | 50 | 35 |
| 45 | 46 | 31 | 49 | 35 | 47 | 32 | 50 | 33 | 48 | 33 | 50 | 35 | 49 | 31 | 50 | 35 |
| 46 | 45 | 31 | 49 | 34 | 47 | 32 | 50 | 33 | 48 | 33 | 50 | 35 | 49 | 31 | 50 | 35 |
| 47 | 45 | 31 | 49 | 34 | 47 | 32 | 50 | 33 | 48 | 33 | 50 | 35 | 49 | 31 | 50 | 35 |
| 48 | 45 | 28 | 49 | 34 | 47 | 32 | 50 | 33 | 48 | 33 | 50 | 35 | 49 | 31 | 50 | 35 |
| 49 | 45 | 28 | 49 | 34 | 47 | 32 | 50 | 33 | 48 | 33 | 50 | 35 | 49 | 31 | 50 | 35 |
| 50 | 45 | 28 | 49 | 34 | 46 | 32 | 50 | 33 | 47 | 33 | 50 | 35 | 49 | 31 | 50 | 35 |
| 51 | 44 | 28 | 49 | 34 | 45 | 32 | 50 | 33 | 47 | 33 | 49 | 35 | 49 | 31 | 50 | 35 |
| 52 | 44 | 28 | 49 | 34 | 44 | 32 | 49 | 33 | 47 | 33 | 49 | 35 | 49 | 30 | 50 | 35 |
| 53 | 44 | 27 | 49 | 34 | 44 | 32 | 49 | 33 | 47 | 33 | 49 | 35 | 49 | 30 | 49 | 35 |
| 54 | 44 | 27 | 49 | 34 | 44 | 31 | 49 | 33 | 47 | 33 | 49 | 35 | 49 | 30 | 49 | 34 |
| 55 | 44 | 27 | 49 | 34 | 43 | 31 | 49 | 33 | 47 | 33 | 49 | 35 | 49 | 30 | 49 | 34 |
| 56 | 44 | 27 | 49 | 34 | 43 | 31 | 49 | 33 | 47 | 33 | 49 | 35 | 49 | 30 | 49 | 34 |
| 57 | 44 | 27 | 49 | 34 | 43 | 31 | 49 | 33 | 47 | 33 | 49 | 35 | 49 | 30 | 49 | 34 |
| 58 | 44 | 26 | 49 | 34 | 43 | 31 | 49 | 33 | 47 | 33 | 49 | 35 | 49 | 30 | 48 | 34 |
| 59 | 44 | 26 | 49 | 34 | 43 | 31 | 49 | 33 | 46 | 32 | 49 | 35 | 48 | 30 | 48 | 34 |
| 60 | 43 | 26 | 49 | 34 | 42 | 31 | 49 | 33 | 46 | 31 | 49 | 35 | 47 | 30 | 48 | 34 |
| 61 | 43 | 26 | 48 | 34 | 42 | 31 | 49 | 33 | 46 | 31 | 48 | 35 | 47 | 28 | 48 | 34 |
| 62 | 43 | 26 | 48 | 34 | 42 | 31 | 49 | 33 | 46 | 31 | 48 | 35 | 47 | 28 | 48 | 34 |
| 63 | 42 | 26 | 48 | 34 | 40 | 30 | 49 | 33 | 45 | 30 | 40 | 35 | 46 | 28 | 48 | 34 |
| 64 | 42 | 26 | 48 | 34 | 40 | 30 | 49 | 33 | 44 | 30 | 48 | 35 | 46 | 28 | 48 | 33 |
| 65 | 42 | 26 | 48 | 34 | 38 | 30 | 49 | 33 | 43 | 30 | 48 | 35 | 46 | 28 | 48 | 33 |
| 66 | 41 | 25 | 48 | 34 | 37 | 30 | 49 | 33 | 43 | 30 | 47 | 35 | 46 | 27 | 48 | 32 |

[a] Number of animals alive on the last day of each week.

[b] Species: Hamster = H, Rat = R; (Treatment): Treated = (T), Control = (C).

[c] Intratracheal doses administered as mg/0.2 ml saline; control animals received 0.2 ml saline without dye. Dietary doses administered as % of total diet; all diets were prepared with 1.3% w/w Mazola® corn oil and control diets consisted of meal plus corn oil (1.3%).

TABLE XIII

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

SURVIVAL[a] - YELLOW 3

| | INTRATRACHEAL | | | | | | | | DIETARY | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | MALE | | | | FEMALE | | | | MALE | | | | FEMALE | | | |
| GROUP | 3 | 6 | 4 | 8 | 3 | 6 | 4 | 8 | 11 | 14 | 12 | 16 | 11 | 14 | 12 | 16 |
| SPECIES (TREATMENT)[b] | H(T) | H(C) | R(T) | R(C) | H(T) | H(C) | R(T) | R(C) | H(T) | H(C) | R(T) | R(C) | H(T) | H(C) | R(T) | R(C) |
| DOSE LEVEL[c] | 15.0 | 0 | 15.0 | 0 | 15.0 | 0 | 15.0 | 0 | 0.8 | 0 | 0.8 | 0 | 0.8 | 0 | 0.8 | 0 |
| Week | | | | | | | | | | | | | | | | |
| 67 | 41 | 25 | 48 | 34 | 37 | 29 | 49 | 33 | 42 | 29 | 47 | 35 | 46 | 27 | 48 | 32 |
| 68 | 41 | 25 | 48 | 34 | 37 | 29 | 49 | 33 | 42 | 29 | 47 | 35 | 44 | 26 | 48 | 32 |
| 69 | 40 | 24 | 48 | 34 | 36 | 28 | 49 | 33 | 41 | 28 | 47 | 35 | 44 | 25 | 48 | 32 |
| 70 | 40 | 24 | 47 | 34 | 35 | 27 | 49 | 33 | 41 | 28 | 47 | 35 | 41 | 23 | 48 | 32 |
| 71 | 40 | 24 | 47 | 34 | 35 | 27 | 49 | 33 | 41 | 28 | 47 | 35 | 41 | 23 | 48 | 32 |
| 72 | 39 | 24 | 47 | 34 | 34 | 27 | 49 | 33 | 41 | 28 | 47 | 35 | 40 | 23 | 48 | 32 |
| 73 | 39 | 24 | 47 | 34 | 34 | 27 | 49 | 33 | 41 | 28 | 47 | 35 | 39 | 23 | 48 | 32 |
| 74 | 39 | 23 | 47 | 34 | 32 | 27 | 49 | 33 | 41 | 28 | 47 | 35 | 38 | 22 | 47 | 32 |
| 75 | 39 | 22 | 47 | 34 | 30 | 27 | 49 | 33 | 41 | 28 | 47 | 35 | 38 | 22 | 47 | 32 |
| 76 | 39 | 22 | 47 | 34 | 29 | 25 | 49 | 33 | 41 | 28 | 47 | 35 | 38 | 21 | 47 | 32 |
| 77 | 37 | 22 | 47 | 34 | 28 | 24 | 49 | 33 | 41 | 28 | 47 | 35 | 37 | 20 | 47 | 31 |
| 78 | 37 | 21 | 47 | 34 | 27 | 24 | 48 | 33 | 41 | 28 | 47 | 35 | 36 | 19 | 47 | 31 |
| 79 | 37 | 21 | 47 | 34 | 27 | 20 | 48 | 33 | 39 | 28 | 47 | 35 | 35 | 19 | 47 | 31 |
| 80 | 35 | 20 | 47 | 34 | 25 | 15 | 48 | 33 | 39 | 28 | 47 | 35 | 34 | 19 | 47 | 31 |
| 81 | 35 | 20 | 47 | 34 | 25 | 14 | 48 | 33 | 39 | 28 | 47 | 35 | 30 | 19 | 47 | 31 |
| 82 | 35 | 20 | 47 | 34 | 25 | 13 | 48 | 32 | 39 | 26 | 47 | 35 | 30 | 16 | 47 | 31 |
| 83 | 35 | 20 | 47 | 34 | 23 | 13 | 47 | 31 | 37 | 26 | 47 | 35 | 27 | 15 | 47 | 31 |
| 84 | 35 | 18 | 46 | 34 | 23 | 11 | 47 | 31 | 36 | 25 | 47 | 35 | 26 | 15 | 47 | 31 |
| 85 | 35 | 17 | 46 | 34 | 22 | 10 | 47 | 31 | 35 | 25 | 47 | 35 | 23 | 14 | 47 | 31 |
| 86 | 34 | 17 | 46 | 34 | 20 | 10 | 47 | 31 | 34 | 24 | 47 | 35 | 21 | 14 | 47 | 31 |
| 87 | 34 | 17 | 46 | 34 | 20 | 9 | 47 | 31 | 33 | 24 | 47 | 35 | 19 | 13 | 47 | 31 |
| 88 | 34 | 16 | 46 | 34 | 19 | 9 | 47 | 31 | 33 | 24 | 47 | 35 | 17 | 13 | 47 | 31 |
| 89 | 34 | 15 | 46 | 34 | 18 | 8 | 47 | 31 | 33 | 24 | 47 | 35 | 17 | 13 | 47 | 31 |
| 90 | 32 | 15 | 45 | 34 | 16 | 8 | 45 | 31 | 33 | 22 | 47 | 35 | 16 | 11 | 46 | 31 |
| 91 | 32 | 15 | 45 | 34 | 13 | 7 | 45 | 30 | 33 | 22 | 47 | 35 | 15 | 10 | 46 | 30 |
| 92 | 32 | 14 | 44 | 34 | 12 | 6 | 45 | 30 | 33 | 22 | 47 | 35 | 14 | 9 | 46 | 30 |
| 93 | 28 | 14 | 43 | 34 | 11 | 6 | 45 | 30 | 32 | 21 | 47 | 35 | 14 | 9 | 46 | 30 |
| 94 | 27 | 13 | 42 | 34 | 9 | 6 | 44 | 30 | 31 | 21 | 47 | 35 | 11 | 9 | 46 | 29 |
| 95 | 27 | 13 | 42 | 34 | 8 | 6 | 44 | 30 | 30 | 20 | 46 | 35 | 11 | 9 | 46 | 29 |
| 96 | 27 | 13 | 41 | 34 | 8 | 6 | 44 | 30 | 29 | 20 | 46 | 35 | 0[d] | 0[d] | 45 | 28 |
| 97 | 26 | 13 | 41 | 33 | 7 | 6 | 44 | 30 | 28 | 19 | 45 | 35 | | | 45 | 28 |
| 98 | 26 | 13 | 40 | 33 | 7 | 4 | 44 | 30 | 27 | 19 | 45 | 35 | | | 44 | 26 |
| 99 | 26 | 13 | 40 | 32 | 7 | 4 | 44 | 29 | 27 | 18 | 45 | 35 | | | 44 | 25 |

[a] Number of animals alive on the last day of each week.

[b] Species: Hamster = H, Rat = R; (Treatment): Treated = (T), Control = (C).

[c] Intratracheal doses administered as mg/0.2 ml saline; control animals received 0.2 ml saline without dye. Dietary doses administered as % of total diet; all diets were prepared with 1.3% w/w Mazola® corn oil and control diets consisted of meal plus corn oil (1.3%).

[d] "0" indicates week of terminal sacrifice for the indicated group, sex and species.

TABLE XIII

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

SURVIVAL[a] - YELLOW 3

| | INTRATRACHEAL | | | | | | | | DIETARY | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | MALE | | | | FEMALE | | | | MALE | | | | FEMALE | | | |
| GROUP : | 3 | 6 | 4 | 8 | 3 | 6 | 4 | 8 | 11 | 14 | 12 | 16 | 11 | 14 | 12 | 16 |
| SPECIES (TREATMENT)[b] : | H(T) | H(C) | R(T) | R(C) | H(T) | H(C) | R(T) | R(C) | H(T) | H(C) | R(T) | R(C) | H(T) | H(C) | R(T) | R(C) |
| DOSE LEVEL[c] : | 15.0 | 0 | 15.0 | 0 | 15.0 | 0 | 15.0 | 0 | 0.8 | 0 | 0.8 | 0 | 0.8 | 0 | 0.8 | 0 |
| Week | | | | | | | | | | | | | | | | |
| 100 | 26 | 13 | 40 | 32 | 6 | 3 | 43 | 29 | 27 | 17 | 45 | 34 | - | - | 43 | 23 |
| 101 | 25 | 13 | 40 | 32 | 4 | 3 | 43 | 28 | 25 | 15 | 43 | 33 | - | - | 42 | 22 |
| 102 | 25 | 12 | 40 | 32 | 3 | 3 | 42 | 28 | 25 | 14 | 43 | 33 | - | - | 42 | 22 |
| 103 | 25 | 12 | 40 | 32 | 0[d] | 0[d] | 42 | 28 | 25 | 14 | 43 | 33 | - | - | 42 | 22 |
| 104 | 25 | 11 | 40 | 32 | | | 41 | 28 | 24 | 13 | 43 | 33 | - | - | 42 | 22 |
| 105 | 23 | 9 | 39 | 31 | | | 41 | 28 | 23 | 12 | 43 | 32 | - | - | 42 | 21 |
| 106 | 21 | 9 | 38 | 31 | | | 40 | 27 | 21 | 11 | 41 | 31 | - | - | 41 | 21 |
| 107 | 18 | 8 | 38 | 31 | | | 40 | 27 | 19 | 8 | 41 | 31 | - | - | 41 | 21 |
| 108 | 18 | 7 | 38 | 31 | | | 40 | 26 | 19 | 6 | 41 | 31 | - | - | 40 | 19 |
| 109 | 17 | 7 | 38 | 31 | | | 40 | 22 | 19 | 6 | 0[d] | 0[d] | - | - | 40 | 17 |
| 110 | 17 | 7 | 37 | 30 | | | 39 | 21 | 0[d] | 0[d] | | | | | 40 | 16 |
| 111 | 15 | 7 | 37 | 30 | | | 38 | 20 | | | | | | | 40 | 16 |
| 112 | 14 | 7 | 34 | 29 | | | 36 | 20 | | | | | | | 39 | 16 |
| 113 | 13 | 7 | 33 | 29 | | | 35 | 19 | | | | | | | 38 | 16 |
| 114 | 12 | 6 | 33 | 29 | | | 35 | 19 | | | | | | | 38 | 15 |
| 115 | 12 | 6 | 33 | 29 | | | 34 | 19 | | | | | | | 38 | 15 |
| 116 | 12 | 6 | 33 | 29 | | | 33 | 19 | | | | | | | 38 | 15 |
| 117 | 0[d] | 0[d] | 0[d] | 0[d] | | | 0[d] | 0[d] | | | | | | | 0[d] | 0[d] |

[a] Number of animals alive on the last day of each week.

[b] Species: Hamster = H, Rat = R; (Treatment): Treated = (T), Control = (C).

[c] Intratracheal doses administered as mg/0.2 ml saline; control animals received 0.2 ml saline without dye. Dietary doses administered as % of total diet; all diets were prepared with 1.3% w/w Mazola® corn oil and control diets consisted of meal plus corn oil (1.3%).

[d] "0" indicates week of terminal sacrifice for the indicated group, sex and species.

FIGURE 8

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTER AND RATS

YELLOW 3 - HAMSTERS

MALES

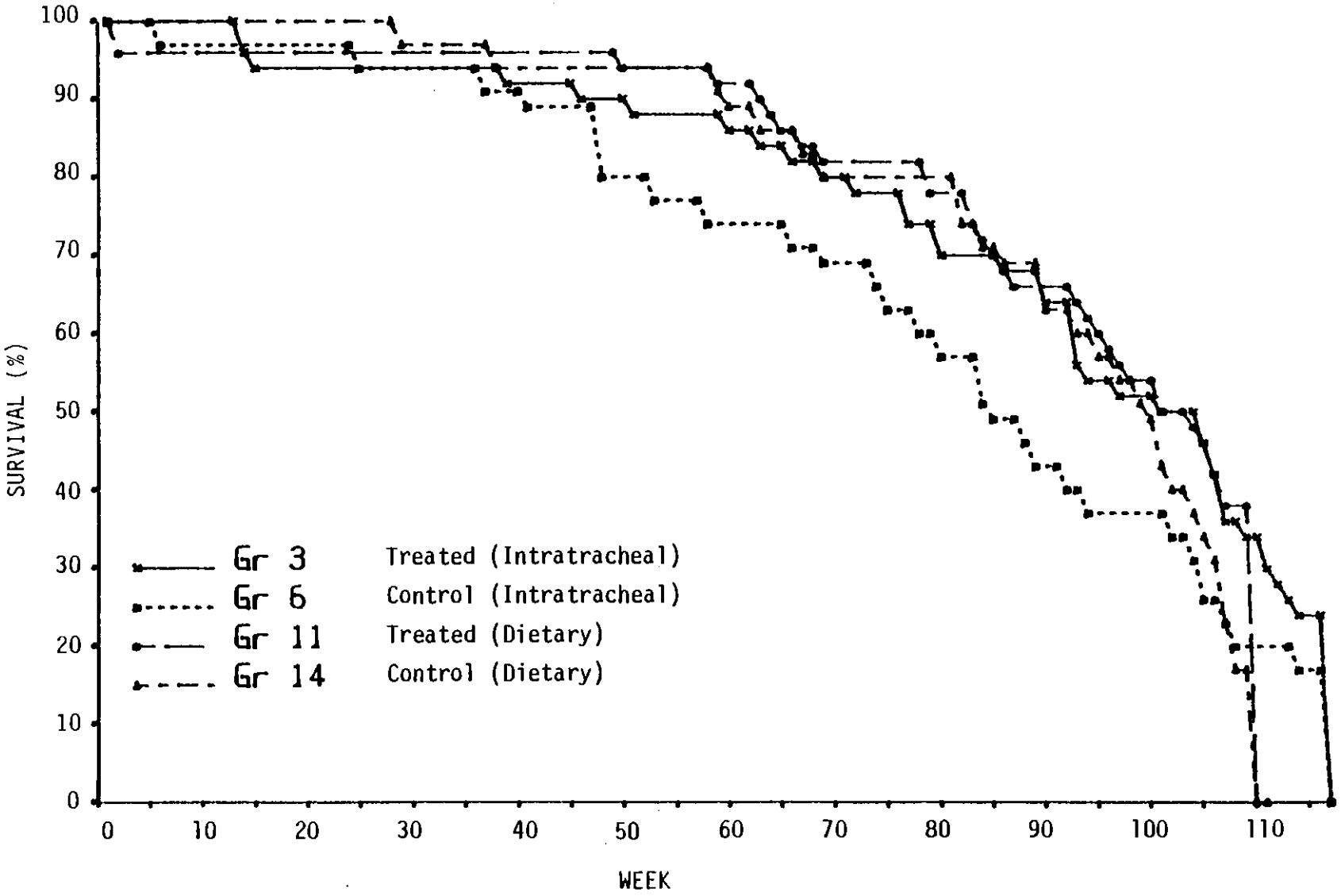

FIGURE 8

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTER AND RATS

YELLOW 3 - HAMSTERS

FEMALES

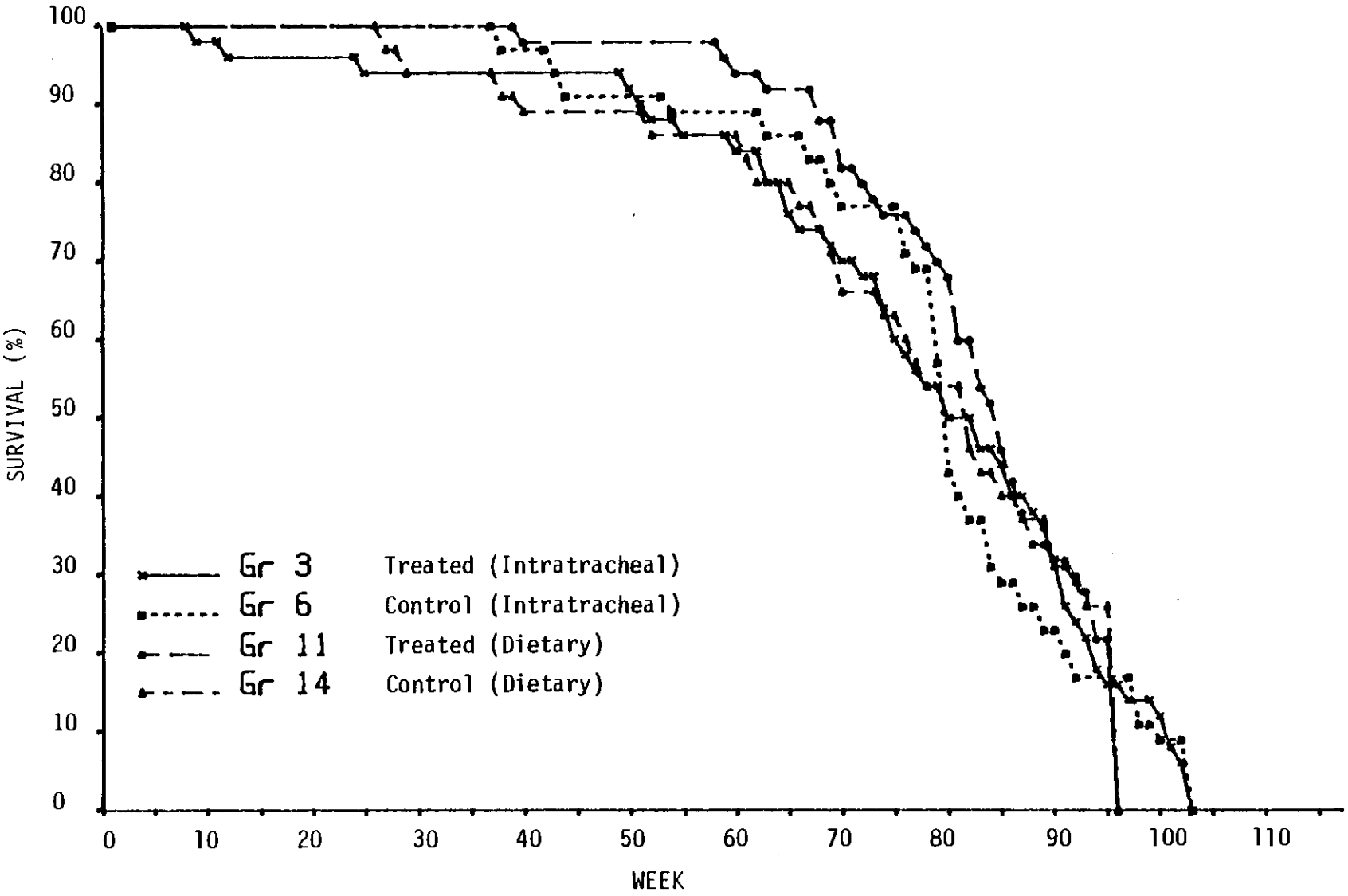

FIGURE 8

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTER AND RATS

YELLOW 3 - RATS

MALES

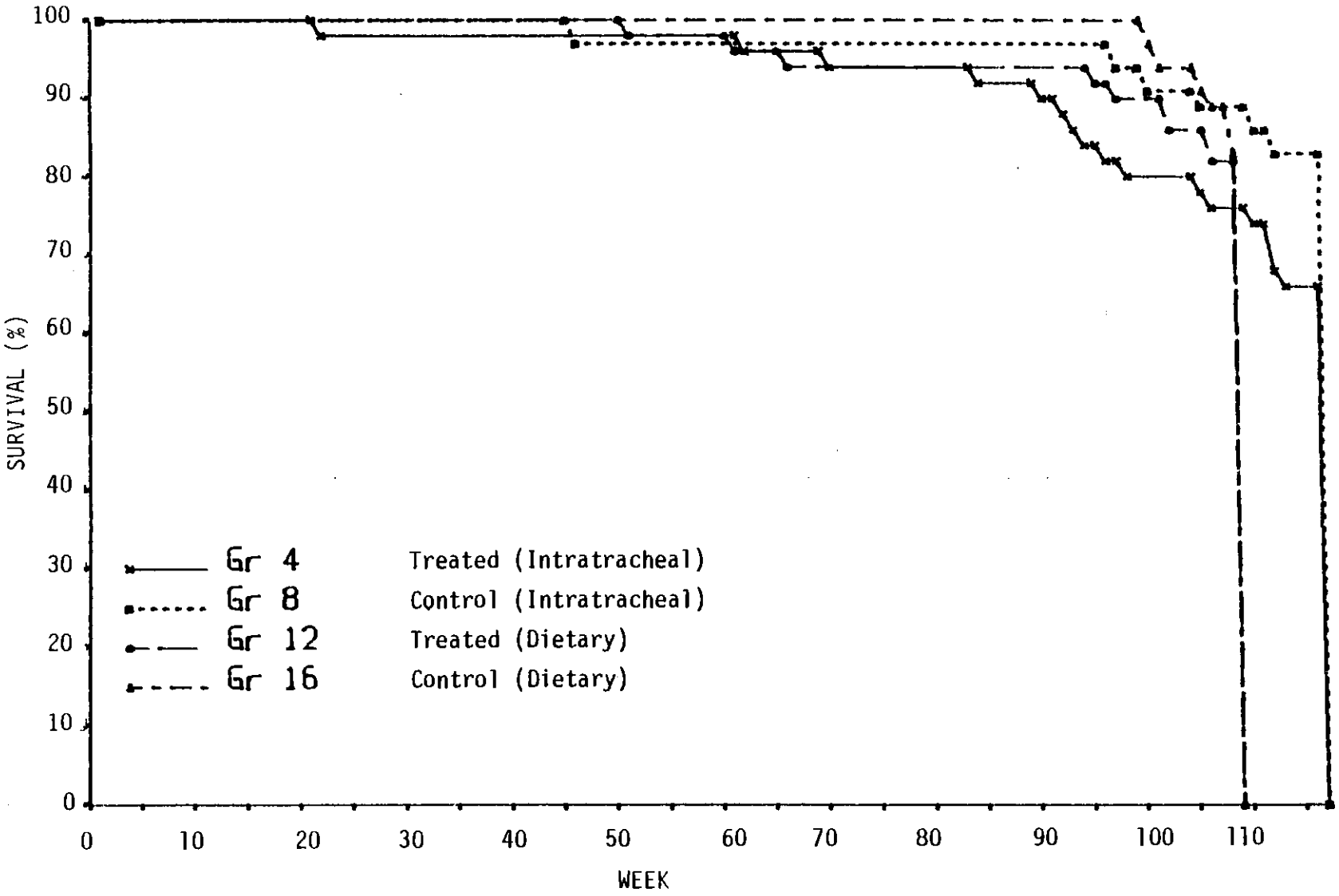

FIGURE 8

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTER AND RATS

YELLOW 3 - RATS

FEMALES

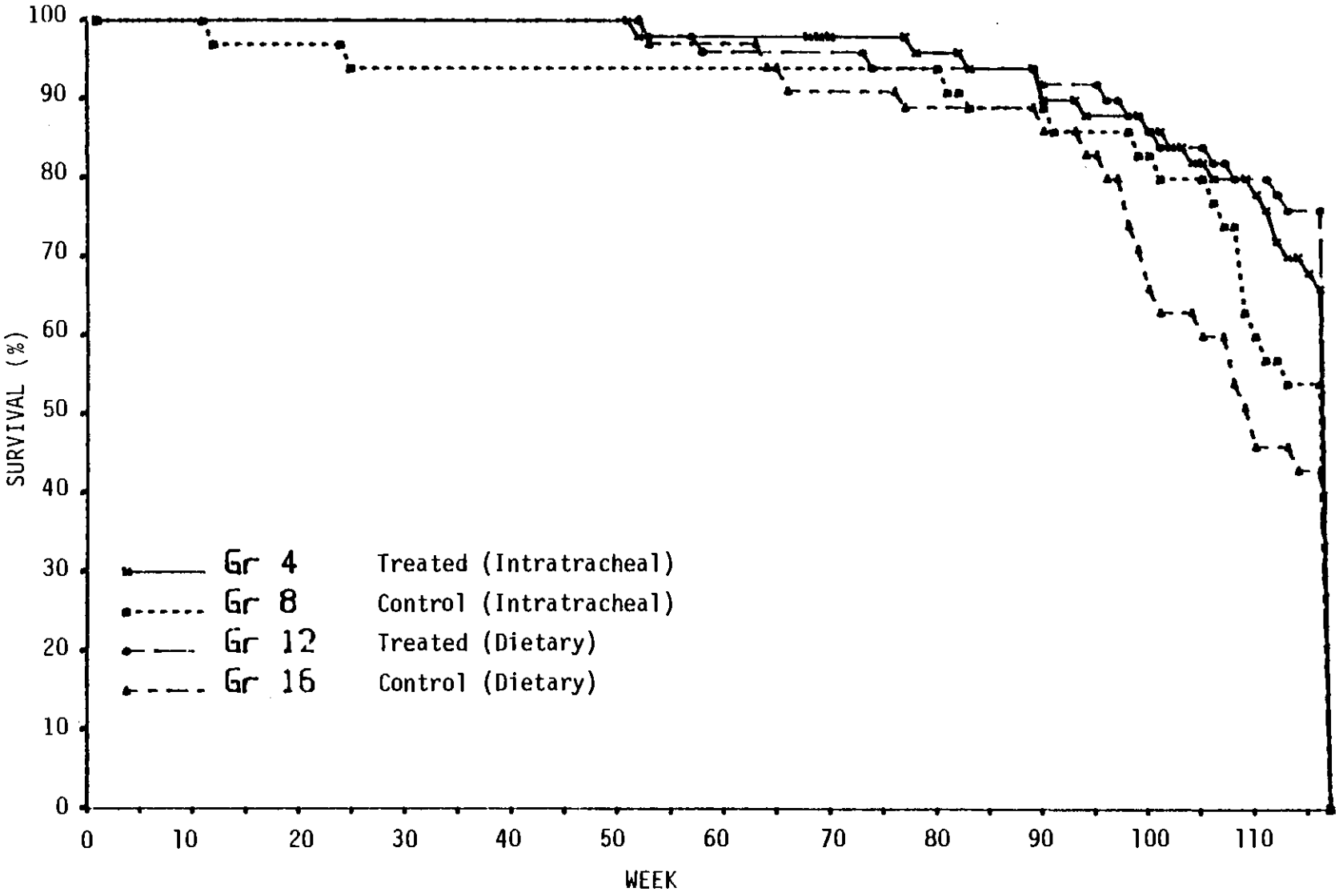

TABLE XIV

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

MEAN BODY WEIGHT DATA WITH STANDARD DEVIATIONS[a]

YELLOW 3 - INTRATRACHEAL INSTILLATION

| | MALES | | | | FEMALES | | | |
|---|---|---|---|---|---|---|---|---|
| GROUP | 3 | 6 | 4 | 8 | 3 | 6 | 4 | 8 |
| SPECIES (TREATMENT)[b] | H(T) | H(C) | R(T) | R(C) | H(T) | H(C) | R(T) | R(C) |
| DOSE LEVEL (mg)[c] | 15.0 | 0 | 15.0 | 0 | 15.0 | 0 | 15.0 | 0 |
| Week | | | | | | | | |
| 1 | 82(7) | 80(8) | 118(10) | 115(11) | 83(8) | 78(8) | 97(6) | 99(6) |
| 5 | 92(11) | 93(10) | 239(16) | 244(13) | 101(14) | 99(11) | 154(8) | 156(8) |
| 9 | 99(12) | 101(11) | 283(18) | 288(16) | 108(17) | 109(13) | 173(15) | 177(9) |
| 13 | 110(15) | 111(16) | 299(21) | 306(19) | 119(18) | 122(18) | 181(11) | 185(12) |
| 18 | 119(16) | 118(16) | 323(24) | 330(30) | 126(18) | 127(18) | 195(14) | 200(11) |
| 22 | 121(17) | 119(16) | 343(27) | 349(24) | 126(18) | 125(17) | 206(14) | 207(13) |
| 27 | 123(17) | 117(15) | 357(26) | 364(26) | 129(21) | 125(18) | 217(15) | 219(13) |
| 31 | 120(16) | 115(18) | 379(26) | 381(26) | 124(19) | 121(19) | 225(16) | 228(14) |
| 36 | 124(17) | 120(17) | 398(27) | 398(27) | 126(18) | 122(18) | 235(16) | 240(15) |
| 37 | - | - | - | - | - | - | - | - |
| 40 | 128(16) | 125(16) | 404(29) | 402(29) | 126(19) | 121(17) | 242(17) | 242(16) |
| 44 | 131(16) | 128(15) | - | - | 131(19) | 125(18) | - | - |
| 45 | - | - | 413(33) | 406(30) | - | - | 248(19) | 248(18) |
| 49 | 134(16) | 130(16) | 418(31) | 411(29) | 133(19) | 124(20) | 251(24) | 251(18) |
| 53 | 135(17) | 128(21) | 423(30) | 413(29) | 134(22) | 129(19) | 262(26) | 262(21) |
| 57 | 134(16) | 131(18) | - | - | 133(19) | 131(18) | - | - |
| 59 | - | - | 422(33) | 419(31) | - | - | 274(27) | 268(30) |
| 62 | 133(16) | 130(16) | 422(36) | 416(32) | 128(18) | 128(21) | 277(25) | 270(26) |
| 66 | 127(18) | 125(16) | - | - | 129(18) | 127(20) | - | - |
| 67 | - | - | 417(38) | 411(32) | - | - | 274(31) | 268(24) |
| 70 | 121(15) | 121(18) | - | - | 126(16) | 126(18) | - | - |
| 71 | - | - | 422(39) | 413(34) | - | - | 278(27) | 270(28) |
| 75 | 121(15) | 118(20) | 428(39) | 425(37) | 126(18) | 122(19) | 288(30) | 285(27) |
| 79 | 126(14) | 123(15) | 433(37) | 428(37) | 124(19) | 115(19) | 296(30) | 280(32) |
| 83 | 129(14) | 123(17) | - | - | 124(18) | 116(22) | - | - |
| 84 | - | - | 438(42) | 434(36) | - | - | 305(30) | 299(29) |
| 87 | 132(13) | 126(15) | - | - | 124(18) | 115(24) | - | - |
| 88 | - | - | 435(38) | 423(38) | - | - | 304(34) | 303(31) |
| 92 | 133(15) | 131(17) | - | - | 121(22) | 111(23) | - | - |
| 93 | - | - | 437(39) | 425(38) | - | - | 316(35) | 310(34) |
| 96 | 136(13) | 136(16) | - | - | 118(19) | 119(15) | - | - |

[a] Data are presented as mean (S.D.); data are in grams.

[b] Species: Hamster = H, Rat = R; (Treatment): Treated = (T), Control = (C).

[c] All doses administered in 0.2 ml saline suspensions; control animals received 0.2 ml saline without dye.

"-" Body weight not required at this week for the indicated group and species.

TABLE XIV

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

MEAN BODY WEIGHT DATA WITH STANDARD DEVIATIONS[a]

YELLOW 3 - INTRATRACHEAL INSTILLATION

| | MALES | | | | FEMALES | | | |
|---|---|---|---|---|---|---|---|---|
| GROUP | 3 | 6 | 4 | 8 | 3 | 6 | 4 | 8 |
| SPECIES (TREATMENT)[b] | H(T) | H(C) | R(T) | R(C) | H(T) | H(C) | R(T) | R(C) |
| DOSE LEVEL (mg)[c] | 15.0 | 0 | 15.0 | 0 | 15.0 | 0 | 15.0 | 0 |
| Week | | | | | | | | |
| 97 | - | - | 438(25) | 426(41) | - | - | 323(33) | 313(40) |
| 101 | 137(11) | 131(14) | 431(35) | 420(41) | 113(19)[d] | 119(19)[d] | 323(33) | 313(38) |
| 104 | 137(14) | 142(50) | - | - | | | - | - |
| 106 | 132(14) | 124(23) | 418(35) | 409(29) | | | 308(62) | 307(34) |
| 109 | - | - | - | - | | | - | - |
| 111 | - | - | 401(38) | 368(39) | | | 305(47) | 299(42) |
| 114 | 116(19) | 120(12) | - | - | | | - | - |
| 117 | 121(14)[d] | 116(14)[d] | 361(51)[d] | 355(45)[d] | | | 283(37)[d] | 282(37)[d] |

[a] Data are presented as mean (S.D.); data are in grams.

[b] Species: Hamster = H, Rat = R; (Treatment): Treated = (T), Control = (C).

[c] All doses administered in 0.2 ml saline suspensions; control animals received 0.2 ml saline without dye.

"-" Body weight not required at this week for the indicated group and species.

[d] Represents last body weight interval prior to terminal sacrifice.

TABLE XIV

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

MEAN BODY WEIGHT DATA WITH STANDARD DEVIATIONS[a]

YELLOW 3 - DIETARY ADMINISTRATION

| | MALES | | | | FEMALES | | | |
|---|---|---|---|---|---|---|---|---|
| GROUP | 11 | 14 | 12 | 16 | 11 | 14 | 12 | 16 |
| SPECIES (TREATMENT)[b] | H(T) | H(C) | R(T) | R(C) | H(T) | H(C) | R(T) | R(C) |
| DOSE LEVEL (%)[c] | 0.8 | 0 | 0.8 | 0 | 0.8 | 0 | 0.8 | 0 |
| Week | | | | | | | | |
| 1 | 65(5) | 64(6) | 113(10) | 113(11) | 64(6) | 63(7) | 87(6) | 87(5) |
| 5 | 84(8) | 91(10) | 208(12) | 232(18) | 91(10) | 94(10) | 131(8) | 144(9) |
| 9 | 99(12) | 105(10) | 259(17) | 291(22) | 110(13) | 115(16) | 152(8) | 169(11) |
| 13 | 106(13) | 112(12) | 291(20) | 324(25) | 116(18) | 121(18) | 163(10) | 184(15) |
| 18 | 112(13) | 116(12) | 313(19) | 347(25) | 120(18) | 126(21) | 170(11) | 195(18) |
| 23 | 110(14) | 114(15) | 330(21) | 361(32) | 113(24) | 121(34) | 179(8) | 203(16) |
| 27 | 114(14) | 115(16) | 344(20) | 378(35) | 122(19) | 119(21) | 185(10) | 210(17) |
| 31 | 118(14) | 120(15) | 356(22) | 395(32) | 125(18) | 123(21) | 187(10) | 218(23) |
| 36 | 121(13) | 123(13) | 366(19) | 403(34) | 126(18) | 125(20) | 191(10) | 222(10) |
| 40 | 124(14) | 126(13) | 377(23) | 416(38) | 135(22) | 128(18) | 196(15) | 230(21) |
| 44 | 125(14) | 128(12) | 385(25) | 425(40) | 136(28) | 127(23) | 201(11) | 234(26) |
| 48 | 124(14) | 127(14) | 388(28) | 432(39) | 133(20) | 130(18) | 204(11) | 245(27) |
| 52 | 124(14) | 127(12) | 393(25) | 436(40) | 129(19) | 131(18) | 210(13) | 249(27) |
| 56 | 124(14) | 128(12) | - | - | 129(18) | 126(15) | - | - |
| 57 | - | - | 397(27) | 435(42) | - | - | 213(14) | 258(30) |
| 61 | 121(15) | 124(13) | 399(33) | 443(43) | 130(17) | 126(14) | 217(18) | 262(32) |
| 66 | 118(17) | 121(14) | 397(26) | 435(41) | 126(17) | 126(16) | 216(23) | 268(29) |
| 69 | 123(16) | 125(15) | - | - | 126(16) | 128(17) | - | - |
| 70 | - | - | 390(28) | 447(43) | - | - | 223(21) | 274(31) |
| 74 | 122(15) | 127(14) | 401(26) | 454(42) | 126(14) | 126(17) | 231(17) | 280(29) |
| 79 | 121(16) | 126(14) | - | - | 126(20) | 124(16) | - | - |
| 83 | 125(16) | 130(15) | 401(25) | 455(41) | 121(16) | 122(15) | 238(19) | 290(26) |
| 87 | 127(13) | 131(15) | 399(24) | 457(40) | 128(27) | 118(18) | 238(31) | 367(36) |
| 91 | 129(14) | 133(14) | - | - | 124(23) | 120(22) | - | - |
| 93 | - | - | 400(27) | 452(38) | - | - | 250(17) | 310(41) |
| 96 | 128(15) | 133(14) | - | - | 125(27)[d] | 112(18)[d] | - | - |
| 97 | - | - | 386(31) | 440(37) | | | 242(25) | 293(48) |
| 100 | 129(15) | 129(19) | - | - | | | - | - |
| 101 | - | - | 378(33) | 434(34) | | | 246(26) | 293(34) |
| 104 | 129(15) | 129(15) | - | - | | | - | - |
| 106 | - | - | 363(29) | 427(40) | | | 244(20) | 277(54) |
| 110 | 128(18)[d] | 124(15)[d] | 365(35)[d] | 433(41)[d] | | | 244(22) | 283(49) |
| 113 | | | | | | | 237(24) | 273(46) |
| 117 | | | | | | | 175(36)[d] | 220(43)[d] |

[a] Data are presented as mean (S.D.); data are in grams.

[b] Species: Hamster = H, Rat = R; (Treatment): Treated = (T), Control = (C).

[c] All doses administered as % of total diet; all diets were prepared with 1.3% w/w Mazola® corn oil and control diets consisted of meal plus corn oil (1.3%).

"-" Body weight not required at this week for the indicated groups and species.

[d] Represents the last body weight interval prior to terminal sacrifice.

TABLE XV

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

MEAN FOOD CONSUMPTION DATA WITH STANDARD DEVIATIONS[a]
YELLOW 3 - DIETARY ADMINISTRATION

| GROUP | MALES | | | | FEMALES | | | |
|---|---|---|---|---|---|---|---|---|
| SPECIES (TREATMENT)[b] | 11 H(T) | 14 H(C) | 12 R(T) | 16 R(C) | 11 H(T) | 14 H(C) | 12 R(T) | 16 R(C) |
| DOSE LEVEL (%)[c] | 0.8 | 0 | 0.8 | 0 | 0.8 | 0 | 0.8 | 0 |
| Week | | | | | | | | |
| 1 | 94(43) | 107(47) | 99(11) | 117(9) | 106(44) | 103(54) | 74(12) | 93(7) |
| 2 | 60(8) | 88(37) | 106(8) | 123(14) | 81(38) | 89(37) | 126(6) | 87(9) |
| 3 | 61(8) | 51(12) | 112(8) | 122(10) | 69(16) | 45(11) | 78(7) | 83(8) |
| 4 | 59(15) | 72(22) | 120(8) | 125(18) | 69(20) | 71(23) | 70(11) | 85(11) |
| 5 | 62(10) | 62(14) | 112(10) | 134(10) | 69(12) | 67(17) | 76(12) | 92(14) |
| 6 | 53(13) | 60(11) | 115(10) | 116(13) | 54(12) | 59(10) | 80(7) | 80(7) |
| 7 | 63(10) | 55(9) | 116(16) | 125(21) | 67(16) | 54(14) | 80(8) | 81(13) |
| 8 | 61(12) | 58(14) | 115(13) | 127(21) | 68(12) | 55(15) | 81(7) | 91(10) |
| 9 | 62(10) | 63(15) | 119(7) | 132(14) | 65(15) | 64(12) | 82(6) | 85(11) |
| 10 | 54(9) | 59(15) | 117(8) | 118(15) | 61(14) | 59(15) | 78(16) | 84(8) |
| 11 | 62(9) | 66(18) | 115(7) | 124(17) | 69(18) | 65(10) | 78(11) | 81(7) |
| 12 | 58(9) | 55(13) | 117(23) | 124(16) | 64(13) | 56(13) | 86(19) | 91(7) |
| 13 | 61(10) | 63(11) | 122(13) | 131(11) | 60(11) | 61(9) | 91(15) | 87(8) |
| 14 | 62(8) | 57(13) | 129(7) | 116(22) | 62(10) | 58(9) | 86(19) | 79(10) |
| 15 | 62(8) | 55(12) | 123(14) | 131(19) | 64(10) | 54(11) | 90(16) | 95(9) |
| 16 | 61(9) | 62(12) | 125(8) | 113(10) | 59(9) | 61(12) | 85(20) | 80(8) |
| 17 | 58(10) | 51(14) | 132(8) | 115(10) | 59(9) | 51(9) | 91(18) | 81(7) |
| 18 | 64(8) | 49(12) | 133(14) | 127(14) | 63(8) | 47(11) | 88(15) | 85(16) |
| 19 | 58(8) | 49(11) | 129(8) | 123(10) | 60(9) | 51(9) | 93(14) | 84(12) |
| 20 | 55(14) | 43(14) | 134(8) | 117(15) | 57(11) | 37(12) | 92(15) | 84(7) |
| 21 | 59(11) | 48(13) | 128(9) | 126(10) | 62(10) | 48(11) | 90(9) | 87(7) |
| 22 | 58(9) | 51(12) | 127(10) | 127(10) | 60(12) | 51(10) | 93(6) | 93(6) |
| 23 | 66(15) | 58(13) | 129(8) | 132(14) | 59(12) | 58(13) | 89(8) | 95(7) |
| 24 | 69(11) | 57(16) | 136(9) | 123(18) | 73(18) | 52(15) | 93(13) | 85(9) |
| 25 | 73(12) | 59(17) | 127(9) | 127(19) | 80(20) | 62(14) | 87(14) | 93(8) |
| 26 | 68(11) | 56(14) | 126(8) | 122(10) | 76(21) | 53(14) | 90(12) | 85(9) |
| 27 | 56(11) | 55(23) | 118(9) | 117(10) | 77(39) | 65(19) | 80(16) | 83(7) |
| 28 | 62(11) | 51(13) | 123(9) | 126(10) | 74(23) | 56(16) | 91(27) | 90(9) |
| 29 | 56(11) | 55(13) | 131(8) | 118(9) | 64(18) | 59(16) | 92(14) | 81(7) |
| 30 | 70(12) | 55(13) | 132(9) | 126(10) | 72(20) | 60(14) | 88(19) | 88(8) |
| 31 | 68(10) | 50(11) | 133(14) | 126(8) | 74(17) | 50(10) | 90(17) | 90(7) |
| 32 | 72(10) | 58(11) | 131(8) | 133(9) | 79(16) | 60(11) | 88(9) | 101(8) |

[a] Data are presented as mean (S.D.); data are in grams.

[b] Species: Hamster = H, Rat = R; (Treatment): Treated = (T), Control = (C).

[c] All doses administered as % of total diet; all diets were prepared with 1.3% w/w Mazola® corn oil and control diets consisted of meal plus corn oil (1.3%).

TABLE XV
CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

MEAN FOOD CONSUMPTION DATA WITH STANDARD DEVIATIONS[a]
YELLOW 3 - DIETARY ADMINISTRATION

| | MALES | | | | FEMALES | | | |
|---|---|---|---|---|---|---|---|---|
| GROUP | 11 | 14 | 12 | 16 | 11 | 14 | 12 | 16 |
| SPECIES (TREATMENT)[b] | H(T) | H(C) | R(T) | R(C) | H(T) | H(C) | R(T) | R(C) |
| DOSE LEVEL (%)[c] | 0.8 | 0 | 0.8 | 0 | 0.8 | 0 | 0.8 | 0 |
| Week | | | | | | | | |
| 33 | 90(35) | 64(11) | 131(9) | 122(11) | 90(35) | 65(11) | 89(7) | 99(9) |
| 34 | 72(11) | 58(11) | 132(8) | 136(10) | 77(18) | 61(11) | 86(8) | 100(9) |
| 35 | 62(13) | 61(10) | 137(9) | 138(10) | 71(26) | 66(15) | 90(12) | 100(9) |
| 36 | 79(10) | 63(9) | 138(11) | 146(11) | 84(20) | 70(13) | 91(9) | 108(14) |
| 37 | 73(11) | 62(10) | 130(14) | 136(12) | 82(15) | 66(12) | 85(18) | 99(11) |
| 38 | 74(11) | 60(10) | 130(10) | 127(13) | 87(22) | 66(15) | 83(17) | 88(9) |
| 39 | 71(15) | 55(11) | 130(9) | 130(17) | 93(27) | 61(18) | 82(5) | 92(8) |
| 40 | 69(18) | 59(12) | 133(10) | 129(12) | 87(26) | 64(16) | 90(18) | 95(9) |
| 41 | 72(10) | 60(12) | 120(10) | 128(20) | 87(25) | 64(17) | 86(18) | 93(9) |
| 42 | 76(14) | 58(12) | 132(10) | 133(10) | 89(26) | 61(18) | 89(7) | 93(14) |
| 43 | 71(11) | 65(11) | 139(10) | 134(11) | 87(28) | 71(28) | 91(12) | 96(9) |
| 44 | 69(16) | 66(16) | 133(10) | 131(11) | 95(30) | 83(37) | 96(14) | 96(15) |
| 45 | 79(13) | 74(28) | 129(15) | 126(27) | 96(39) | 88(35) | 85(13) | 102(10) |
| 46 | 74(10) | 70(19) | 138(11) | 140(9) | 88(29) | 76(26) | 91(6) | 104(12) |
| 47 | 74(11) | 69(18) | 134(11) | 133(10) | 87(34) | 77(26) | 90(6) | 101(10) |
| 48 | 82(11) | 75(17) | 139(10) | 140(14) | 92(29) | 77(27) | 97(12) | 102(19) |
| 49 | 85(14) | 71(17) | 134(18) | 134(16) | 95(30) | 87(39) | 94(15) | 104(9) |
| 50 | 87(14) | 68(15) | 135(11) | 140(11) | 90(28) | 75(26) | 96(6) | 102(10) |
| 51 | 76(14) | 72(19) | 132(19) | 137(10) | 86(28) | 81(30) | 93(12) | 97(16) |
| 52 | 81(12) | 76(13) | 126(10) | 136(15) | 86(21) | 80(25) | 91(13) | 103(10) |
| 53 | 76(10) | 62(12) | 131(8) | 133(12) | 81(23) | 62(19) | 93(8) | 99(12) |
| 54 | 77(14) | 67(18) | 133(9) | 130(19) | 83(22) | 64(20) | 93(8) | 91(8) |
| 55 | 83(14) | 67(19) | 128(12) | 131(11) | 89(19) | 67(18) | 93(10) | 99(9) |
| 56 | 79(13) | 65(14) | 133(16) | 129(13) | 84(17) | 69(24) | 99(13) | 102(14) |
| 57 | 74(15) | 67(18) | 131(9) | 140(17) | 79(19) | 66(18) | 89(9) | 110(11) |
| 58 | 74(16) | 71(15) | 139(9) | 134(17) | 81(19) | 73(20) | 98(10) | 104(12) |
| 59 | 80(15) | 67(22) | 137(10) | 126(21) | 91(25) | 67(22) | 94(12) | 92(10) |
| 60 | 82(28) | 69(19) | 133(12) | 128(16) | 92(33) | 66(24) | 98(11) | 94(13) |
| 61 | 74(29) | 66(23) | 115(13) | 117(14) | 80(20) | 67(36) | 90(9) | 86(14) |
| 62 | 68(17) | NA | 127(13) | 123(20) | 68(20) | NA | 85(13) | 90(12) |
| 63 | 72(18) | 57(20) | 135(19) | 135(13) | 78(19) | 59(26) | 96(7) | 98(12) |

[a] Data are presented as mean (S.D.); data are in grams.

[b] Species: Hamster = H, Rat = R; (Treatment): Treated = (T), Control = (C).

[c] All doses administered as % of total diet; all diets were prepared with 1.3% w/w Mazola® corn oil and control diets consisted of meal plus corn oil (1.3%).

NA = Not available due to error.

TABLE XV

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

MEAN FOOD CONSUMPTION DATA WITH STANDARD DEVIATIONS[a]

YELLOW 3 - DIETARY ADMINISTRATION

| GROUP | MALES | | | | FEMALES | | | |
|---|---|---|---|---|---|---|---|---|
| SPECIES (TREATMENT)[b] | 11 H(T) | 14 H(C) | 12 R(T) | 16 R(C) | 11 H(T) | 14 H(C) | 12 R(T) | 16 R(C) |
| DOSE LEVEL (%)[c] | 0.8 | 0 | 0.8 | 0 | 0.8 | 0 | 0.8 | 0 |
| Week | | | | | | | | |
| 64 | 68(12) | 61(26) | 134(22) | 138(30) | 78(21) | 54(21) | 97(18) | 98(24) |
| 65 | 69(11) | 65(14) | 129(22) | 132(21) | 75(24) | 61(16) | 94(17) | 95(15) |
| 66 | 72(14) | 65(21) | 127(18) | 133(23) | 77(23) | 78(88) | 92(16) | 104(10) |
| 67 | 71(11) | 59(29) | 129(10) | 138(21) | 73(19) | 54(18) | 86(15) | 110(14) |
| 68 | 72(20) | 75(29) | 121(21) | 121(33) | 69(22) | 68(19) | 103(12) | 93(17) |
| 69 | 70(26) | 59(16) | 125(19) | 149(17) | 64(23) | 62(30) | 99(21) | 109(22) |
| 70 | 68(23) | 70(15) | 130(25) | 147(13) | 74(31) | 73(25) | 91(15) | 107(29) |
| 71 | 60(17) | 64(15) | 130(20) | 137(20) | 70(31) | 64(20) | 92(12) | 107(28) |
| 72 | 62(34) | 64(16) | 133(22) | 133(19) | 77(35) | 66(23) | 94(11) | 99(13) |
| 73 | 61(17) | 70(29) | 133(19) | 132(12) | 77(26) | 61(17) | 89(12) | 105(31) |
| 74 | 67(15) | 59(13) | 132(15) | 136(14) | 72(22) | 58(17) | 91(8) | 103(22) |
| 75 | 69(14) | 69(37) | 131(23) | 135(21) | 78(26) | 68(28) | 92(14) | 104(29) |
| 76 | 85(19) | 70(34) | 123(27) | 143(18) | 92(37) | 75(28) | 88(16) | 110(19) |
| 77 | 79(19) | 84(24) | 127(17) | 131(12) | 80(33) | 84(27) | 88(18) | 104(10) |
| 78 | 70(17) | 75(18) | 133(21) | 131(10) | 72(25) | 82(36) | 92(21) | 102(16) |
| 79 | 77(14) | 67(16) | 133(12) | 133(11) | 81(31) | 76(32) | 91(10) | 99(12) |
| 80 | 79(24) | 63(24) | 124(29) | 137(29) | 75(30) | 62(30) | 92(21) | 111(17) |
| 81 | 76(15) | 65(27) | 126(30) | 136(36) | 80(27) | 68(39) | 94(19) | 116(13) |
| 82 | 71(18) | 70(20) | 130(22) | 131(31) | 72(22) | 69(26) | 89(21) | 99(17) |
| 83 | 77(19) | 69(24) | 125(17) | 132(14) | 74(32) | 71(34) | 81(8) | 106(16) |
| 84 | 76(21) | 75(25) | 125(15) | 138(14) | 75(23) | 79(32) | 81(19) | 106(14) |
| 85 | 73(20) | 60(19) | 127(12) | 133(21) | 80(33) | 67(22) | 90(15) | 98(26) |
| 86 | 75(24) | 70(22) | 128(11) | 128(24) | 77(26) | 67(23) | 97(22) | 103(25) |
| 87 | 79(42) | 78(30) | 140(13) | 143(12) | 92(28) | 66(20) | 107(16) | 110(22) |
| 88 | 91(33) | 91(39) | 136(11) | 134(14) | 98(43) | 64(21) | 104(16) | 107(13) |
| 89 | 81(25) | 78(31) | 134(14) | 135(23) | 94(31) | 62(29) | 96(27) | 107(16) |
| 90 | 77(18) | 74(32) | 133(13) | 136(21) | 92(40) | 74(31) | 94(13) | 100(15) |
| 91 | 68(26) | 82(44) | 134(29) | 131(13) | 81(35) | 62(19) | 103(13) | 89(31) |
| 92 | 89(25) | 105(47) | 131(22) | 137(14) | 95(46) | 83(34) | 107(11) | 106(36) |
| 93 | 80(24) | 76(24) | 145(19) | 148(12) | 84(30) | 69(26) | 110(19) | 119(25) |

[a] Data are presented as mean (S.D.); data are in grams.

[b] Species: Hamster = H, Rat = R; (Treatment): Treated = (T), Control = (C).

[c] All doses administered as % of total diet; all diets were prepared with 1.3% w/w Mazola® corn oil and control diets consisted of meal plus corn oil (1.3%).

TABLE XV

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

MEAN FOOD CONSUMPTION DATA WITH STANDARD DEVIATIONS[a]

YELLOW 3 - DIETARY ADMINISTRATION

| | MALES | | | | FEMALES | | | |
|---|---|---|---|---|---|---|---|---|
| GROUP | 11 | 14 | 12 | 16 | 11 | 14 | 12 | 16 |
| SPECIES (TREATMENT)[b] | H(T) | H(C) | R(T) | R(C) | H(T) | H(C) | R(T) | R(C) |
| DOSE LEVEL (%)[c] | 0.8 | 0 | 0.8 | 0 | 0.8 | 0 | 0.8 | 0 |
| Week | | | | | | | | |
| 94 | 78(26) | 80(25) | 111(16) | 121(21) | 94(34) | 68(17) | 79(15) | 85(32) |
| 95 | 87(27) | 82(18) | 137(16) | 140(13) | 108(51)[d] | 76(26)[d] | 98(25) | 102(33) |
| 96 | 85(22) | 80(24) | 125(23) | 136(16) | | | 103(21) | 106(37) |
| 97 | 76(20) | 68(20) | 136(14) | 131(32) | | | 89(32) | 106(33) |
| 98 | 90(25) | 90(32) | 139(10) | 135(33) | | | 89(37) | 113(19) |
| 99 | 95(24) | 94(23) | 135(19) | 144(25) | | | 104(26) | 122(28) |
| 100 | 97(29) | 93(28) | 132(12) | 127(20) | | | 102(17) | 102(29) |
| 101 | 93(31) | 94(29) | 133(23) | 145(16) | | | 121(28) | 128(23) |
| 102 | 101(32) | 60(29) | 93(16) | 150(29) | | | 79(17) | 120(25) |
| 103 | 76(23) | 85(27) | 140(13) | 130(26) | | | 109(16) | 102(14) |
| 104 | 64(21) | 76(26) | 132(15) | 127(35) | | | 100(15) | 112(34) |
| 105 | 72(25) | 82(16) | 127(35) | 131(21) | | | 111(11) | 92(22) |
| 106 | 72(17) | 85(22) | 122(24) | 131(17) | | | 102(15) | 106(21) |
| 107 | 73(37) | 63(17) | 137(12)[d] | 132(24)[d] | | | 109(9) | 102(22) |
| 108 | 75(19)[d] | 82(19)[d] | NA | NA | | | NA | NA |
| 109 | NA | NA | NA | NA | | | NA | NA |
| 110 | NA | NA | | | | | NA | NA |
| 111 | | | | | | | NA | NA |
| 112 | | | | | | | 99(13) | 88(13) |
| 113 | | | | | | | 97(15) | 102(21) |
| 114 | | | | | | | 108(16) | 111(20) |
| 115 | | | | | | | 80(15) | 84(12) |
| 116 | | | | | | | 109(21)[d] | 120(19)[d] |
| 117 | | | | | | | 98(18) | 103(30) |

[a] Data are presented as mean (S.D.); data are in grams.

[b] Species: Hamster = H, Rat = R; (Treatment): Treated = (T), Control = (C).

[c] All doses administered as % of total diet; all diets were prepared with 1.3% w/w Mazola® corn oil and control diets consisted of meal plus corn oil (1.3%).

NA = Not available due to error.

[d] Represents the last available food consumption interval prior to terminal sacrifice.

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

TOTAL TUMOR INCIDENCE OF MAJOR ORGANS - YELLOW 3

HAMSTERS - INTRATRACHEAL

GROUP 3 MALE (TREATED)

| | |
|---|---|
| SKIN | 0 TUMORS |
| MAMMARY GLAND | 0 TUMORS |
| MUSCLE | 0 TUMORS |
| SALIVARY GLAND | 0 TUMORS |
| MANDIBULAR LYMPH NODE | 0 TUMORS |
| SCIATIC NERVE | 0 TUMORS |
| THYMUS | 0 TUMORS |
| LARYNX | 0 TUMORS |
| THYROID | 2 TUMORS |
| PARATHYROID | 0 TUMORS |
| TRACHEA | 0 TUMORS |
| BRONCHUS | 0 TUMORS |
| ESOPHAGUS | 0 TUMORS |
| ADRENAL | 14 TUMORS |
| STOMACH | 0 TUMORS |
| DUODENUM | 0 TUMORS |
| JEJUNUM | 0 TUMORS |
| ILEUM | 0 TUMORS |
| CECUM | 0 TUMORS |
| COLON | 0 TUMORS |
| RECTUM | 0 TUMORS |
| MESENTERIC LYMPH NODE | 0 TUMORS |
| LUNG | 0 TUMORS |
| LIVER | 0 TUMORS |
| GALLBLADDER | 0 TUMORS |
| SPLEEN | 0 TUMORS |
| PANCREAS | 0 TUMORS |
| KIDNEY | 0 TUMORS |
| HEART | 0 TUMORS |
| URINARY BLADDER | 0 TUMORS |
| SEMINAL VESICLE | 0 TUMORS |
| PROSTATE | 0 TUMORS |
| TESTIS | 0 TUMORS |
| CEREBRUM | 0 TUMORS |
| CEREBELLUM | 0 TUMORS |
| PITUITARY | 0 TUMORS |
| STERNABRAE | 0 TUMORS |
| FEMUR | 0 TUMORS |
| BONE MARROW | 0 TUMORS |
| NASAL CAVITY | 0 TUMORS |
| OTHER | 0 TUMORS |

THERE WERE 15 TUMOR-BEARING ANIMALS; 16 TUMORS AVG.= 1.1

GROUP 6 MALE (CONTROL)

| | |
|---|---|
| SKIN | 0 TUMORS |
| MAMMARY GLAND | 0 TUMORS |
| MUSCLE | 0 TUMORS |
| SALIVARY GLAND | 0 TUMORS |
| MANDIBULAR LYMPH NODE | 2 TUMORS |
| SCIATIC NERVE | 0 TUMORS |
| THYMUS | 1 TUMORS |
| LARYNX | 0 TUMORS |
| THYROID | 1 TUMORS |
| PARATHYROID | 1 TUMORS |
| TRACHEA | 0 TUMORS |
| BRONCHUS | 0 TUMORS |
| ESOPHAGUS | 0 TUMORS |
| ADRENAL | 6 TUMORS |
| STOMACH | 0 TUMORS |
| DUODENUM | 0 TUMORS |
| JEJUNUM | 0 TUMORS |
| ILEUM | 0 TUMORS |
| CECUM | 0 TUMORS |
| COLON | 0 TUMORS |
| RECTUM | 0 TUMORS |
| MESENTERIC LYMPH NODE | 2 TUMORS |
| LUNG | 3 TUMORS |
| LIVER | 2 TUMORS |
| GALLBLADDER | 0 TUMORS |
| SPLEEN | 3 TUMORS |
| PANCREAS | 0 TUMORS |
| KIDNEY | 0 TUMORS |
| HEART | 0 TUMORS |
| URINARY BLADDER | 0 TUMORS |
| SEMINAL VESICLE | 0 TUMORS |
| PROSTATE | 1 TUMORS |
| TESTIS | 0 TUMORS |
| CEREBRUM | 0 TUMORS |
| CEREBELLUM | 0 TUMORS |
| PITUITARY | 0 TUMORS |
| STERNABRAE | 0 TUMORS |
| FEMUR | 0 TUMORS |
| BONE MARROW | 1 TUMORS |
| NASAL CAVITY | 0 TUMORS |
| OTHER | 2 TUMORS |

THERE WERE 14 TUMOR-BEARING ANIMALS; 22 TUMORS AVG.= 1.6

TOTAL TUMOR INCIDENCE OF MAJOR ORGANS - YELLOW 3

HAMSTERS - INTRATRACHEAL

GROUP 3 FEMALE (TREATED)

| | |
|---|---|
| SKIN | 0 TUMORS |
| MAMMARY GLAND | 0 TUMORS |
| MUSCLE | 0 TUMORS |
| SALIVARY GLAND | 0 TUMORS |
| MANDIBULAR LYMPH NODE | 1 TUMORS |
| SCIATIC NERVE | 0 TUMORS |
| THYMUS | 1 TUMORS |
| LARYNX | 0 TUMORS |
| THYROID | 1 TUMORS |
| PARATHYROID | 0 TUMORS |
| TRACHEA | 0 TUMORS |
| BRONCHUS | 0 TUMORS |
| ESOPHAGUS | 0 TUMORS |
| ADRENAL | 6 TUMORS |
| STOMACH | 1 TUMORS |
| DUODENUM | 0 TUMORS |
| JEJUNUM | 0 TUMORS |
| ILEUM | 0 TUMORS |
| CECUM | 0 TUMORS |
| COLON | 0 TUMORS |
| RECTUM | 0 TUMORS |
| MESENTERIC LYMPH NODE | 2 TUMORS |
| LUNG | 4 TUMORS |
| LIVER | 3 TUMORS |
| GALLBLADDER | 0 TUMORS |
| SPLEEN | 2 TUMORS |
| PANCREAS | 1 TUMORS |
| KIDNEY | 1 TUMORS |
| HEART | 0 TUMORS |
| URINARY BLADDER | 0 TUMORS |
| OVARY | 1 TUMORS |
| UTERUS | 0 TUMORS |
| CEREBRUM | 0 TUMORS |
| CEREBELLUM | 0 TUMORS |
| PITUITARY | 0 TUMORS |
| STERNABRAE | 0 TUMORS |
| FEMUR | 1 TUMORS |
| BONE MARROW | 1 TUMORS |
| NASAL CAVITY | 0 TUMORS |
| OTHER | 1 TUMORS |

THERE WERE 15 TUMOR-BEARING ANIMALS; 30 TUMORS AVG.= 2.0

GROUP 6 FEMALE (CONTROL)

| | |
|---|---|
| SKIN | 0 TUMORS |
| MAMMARY GLAND | 1 TUMORS |
| MUSCLE | 0 TUMORS |
| SALIVARY GLAND | 0 TUMORS |
| MANDIBULAR LYMPH NODE | 1 TUMORS |
| SCIATIC NERVE | 0 TUMORS |
| THYMUS | 1 TUMORS |
| LARYNX | 1 TUMORS |
| THYROID | 0 TUMORS |
| PARATHYROID | 0 TUMORS |
| TRACHEA | 0 TUMORS |
| BRONCHUS | 0 TUMORS |
| ESOPHAGUS | 0 TUMORS |
| ADRENAL | 4 TUMORS |
| STOMACH | 0 TUMORS |
| DUODENUM | 0 TUMORS |
| JEJUNUM | 0 TUMORS |
| ILEUM | 1 TUMORS |
| CECUM | 0 TUMORS |
| COLON | 0 TUMORS |
| RECTUM | 0 TUMORS |
| MESENTERIC LYMPH NODE | 1 TUMORS |
| LUNG | 2 TUMORS |
| LIVER | 1 TUMORS |
| GALLBLADDER | 0 TUMORS |
| SPLEEN | 0 TUMORS |
| PANCREAS | 1 TUMORS |
| KIDNEY | 0 TUMORS |
| HEART | 0 TUMORS |
| URINARY BLADDER | 0 TUMORS |
| OVARY | 1 TUMORS |
| UTERUS | 0 TUMORS |
| CEREBRUM | 0 TUMORS |
| CEREBELLUM | 0 TUMORS |
| PITUITARY | 0 TUMORS |
| STERNABRAE | 0 TUMORS |
| FEMUR | 0 TUMORS |
| BONE MARROW | 1 TUMORS |
| NASAL CAVITY | 0 TUMORS |
| OTHER | 1 TUMORS |

THERE WERE 10 TUMOR-BEARING ANIMALS; 11 TUMORS AVG.= 1.1

TABLE XVI

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

TOTAL TUMOR INCIDENCE OF MAJOR ORGANS - YELLOW 3

HAMSTERS - DIETARY

GROUP 11 MALE (TREATED)

| | |
|---|---|
| SKIN | 0 TUMORS |
| MAMMARY GLAND | 0 TUMORS |
| MUSCLE | 0 TUMORS |
| SALIVARY GLAND | 0 TUMORS |
| MANDIBULAR LYMPH NODE | 0 TUMORS |
| SCIATIC NERVE | 0 TUMORS |
| THYMUS | 0 TUMORS |
| LARYNX | 0 TUMORS |
| THYROID | 1 TUMORS |
| PARATHYROID | 0 TUMORS |
| TRACHEA | 0 TUMORS |
| BRONCHUS | 0 TUMORS |
| ESOPHAGUS | 0 TUMORS |
| ADRENAL | 15 TUMORS |
| STOMACH | 0 TUMORS |
| DUODENUM | 0 TUMORS |
| JEJUNUM | 0 TUMORS |
| ILEUM | 0 TUMORS |
| CECUM | 0 TUMORS |
| COLON | 0 TUMORS |
| RECTUM | 0 TUMORS |
| MESENTERIC LYMPH NODE | 0 TUMORS |
| LUNG | 0 TUMORS |
| LIVER | 0 TUMORS |
| GALLBLADDER | 0 TUMORS |
| SPLEEN | 0 TUMORS |
| PANCREAS | 0 TUMORS |
| KIDNEY | 0 TUMORS |
| HEART | 0 TUMORS |
| URINARY BLADDER | 0 TUMORS |
| SEMINAL VESICLE | 0 TUMORS |
| PROSTATE | 0 TUMORS |
| TESTIS | 0 TUMORS |
| CEREBRUM | 0 TUMORS |
| CEREBELLUM | 0 TUMORS |
| PITUITARY | 0 TUMORS |
| STERNABRAE | 0 TUMORS |
| FEMUR | 0 TUMORS |
| BONE MARROW | 0 TUMORS |
| NASAL CAVITY | 0 TUMORS |
| OTHER | 0 TUMORS |

THERE WERE 17 TUMOR-BEARING ANIMALS; 17 TUMORS AVG.= 1.0

GROUP 14 MALE (CONTROL)

| | |
|---|---|
| SKIN | 1 TUMORS |
| MAMMARY GLAND | 0 TUMORS |
| MUSCLE | 0 TUMORS |
| SALIVARY GLAND | 0 TUMORS |
| MANDIBULAR LYMPH NODE | 3 TUMORS |
| SCIATIC NERVE | 0 TUMORS |
| THYMUS | 0 TUMORS |
| LARYNX | 0 TUMORS |
| THYROID | 1 TUMORS |
| PARATHYROID | 0 TUMORS |
| TRACHEA | 0 TUMORS |
| BRONCHUS | 0 TUMORS |
| ESOPHAGUS | 0 TUMORS |
| ADRENAL | 18 TUMORS |
| STOMACH | 1 TUMORS |
| DUODENUM | 0 TUMORS |
| JEJUNUM | 0 TUMORS |
| ILEUM | 0 TUMORS |
| CECUM | 0 TUMORS |
| COLON | 0 TUMORS |
| RECTUM | 0 TUMORS |
| MESENTERIC LYMPH NODE | 1 TUMORS |
| LUNG | 5 TUMORS |
| LIVER | 5 TUMORS |
| GALLBLADDER | 0 TUMORS |
| SPLEEN | 5 TUMORS |
| PANCREAS | 1 TUMORS |
| KIDNEY | 1 TUMORS |
| HEART | 1 TUMORS |
| URINARY BLADDER | 0 TUMORS |
| SEMINAL VESICLE | 0 TUMORS |
| PROSTATE | 0 TUMORS |
| TESTIS | 0 TUMORS |
| CEREBRUM | 0 TUMORS |
| CEREBELLUM | 0 TUMORS |
| PITUITARY | 0 TUMORS |
| STERNABRAE | 0 TUMORS |
| FEMUR | 0 TUMORS |
| BONE MARROW | 5 TUMORS |
| NASAL CAVITY | 0 TUMORS |
| OTHER | 1 TUMORS |

THERE WERE 22 TUMOR-BEARING ANIMALS; 44 TUMORS AVG.= 2.0

TABLE XVI

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

TOTAL TUMOR INCIDENCE OF MAJOR ORGANS - YELLOW 3

HAMSTERS - DIETARY

GROUP 11 FEMALE (TREATED)

| | |
|---|---|
| SKIN | 1 TUMORS |
| MAMMARY GLAND | 0 TUMORS |
| MUSCLE | 0 TUMORS |
| SALIVARY GLAND | 0 TUMORS |
| MANDIBULAR LYMPH NODE | 1 TUMORS |
| SCIATIC NERVE | 0 TUMORS |
| THYMUS | 0 TUMORS |
| LARYNX | 0 TUMORS |
| THYROID | 1 TUMORS |
| PARATHYROID | 0 TUMORS |
| TRACHEA | 0 TUMORS |
| BRONCHUS | 0 TUMORS |
| ESOPHAGUS | 0 TUMORS |
| ADRENAL | 10 TUMORS |
| STOMACH | 0 TUMORS |
| DUODENUM | 0 TUMORS |
| JEJUNUM | 0 TUMORS |
| ILEUM | 0 TUMORS |
| CECUM | 0 TUMORS |
| COLON | 0 TUMORS |
| RECTUM | 0 TUMORS |
| MESENTERIC LYMPH NODE | 2 TUMORS |
| LUNG | 4 TUMORS |
| LIVER | 3 TUMORS |
| GALLBLADDER | 0 TUMORS |
| SPLEEN | 0 TUMORS |
| PANCREAS | 0 TUMORS |
| KIDNEY | 1 TUMORS |
| HEART | 0 TUMORS |
| URINARY BLADDER | 0 TUMORS |
| OVARY | 1 TUMORS |
| UTERUS | 2 TUMORS |
| CEREBRUM | 0 TUMORS |
| CEREBELLUM | 0 TUMORS |
| PITUITARY | 0 TUMORS |
| STERNABRAE | 0 TUMORS |
| FEMUR | 0 TUMORS |
| BONE MARROW | 2 TUMORS |
| NASAL CAVITY | 0 TUMORS |
| OTHER | 4 TUMORS |

THERE WERE 16 TUMOR-BEARING ANIMALS; 32 TUMORS AVG.= 2.0

GROUP 14 FEMALE (CONTROL)

| | |
|---|---|
| SKIN | 0 TUMORS |
| MAMMARY GLAND | 0 TUMORS |
| MUSCLE | 0 TUMORS |
| SALIVARY GLAND | 0 TUMORS |
| MANDIBULAR LYMPH NODE | 1 TUMORS |
| SCIATIC NERVE | 0 TUMORS |
| THYMUS | 0 TUMORS |
| LARYNX | 0 TUMORS |
| THYROID | 1 TUMORS |
| PARATHYROID | 0 TUMORS |
| TRACHEA | 0 TUMORS |
| BRONCHUS | 0 TUMORS |
| ESOPHAGUS | 0 TUMORS |
| ADRENAL | 4 TUMORS |
| STOMACH | 0 TUMORS |
| DUODENUM | 0 TUMORS |
| JEJUNUM | 0 TUMORS |
| ILEUM | 0 TUMORS |
| CECUM | 0 TUMORS |
| COLON | 0 TUMORS |
| RECTUM | 0 TUMORS |
| MESENTERIC LYMPH NODE | 1 TUMORS |
| LUNG | 0 TUMORS |
| LIVER | 1 TUMORS |
| GALLBLADDER | 0 TUMORS |
| SPLEEN | 1 TUMORS |
| PANCREAS | 0 TUMORS |
| KIDNEY | 0 TUMORS |
| HEART | 0 TUMORS |
| URINARY BLADDER | 0 TUMORS |
| OVARY | 0 TUMORS |
| UTERUS | 3 TUMORS |
| CEREBRUM | 0 TUMORS |
| CEREBELLUM | 0 TUMORS |
| PITUITARY | 0 TUMORS |
| STERNABRAE | 0 TUMORS |
| FEMUR | 0 TUMORS |
| BONE MARROW | 1 TUMORS |
| NASAL CAVITY | 0 TUMORS |
| OTHER | 0 TUMORS |

THERE WERE 6 TUMOR-BEARING ANIMALS; 13 TUMORS AVG.= 1.1

TABLE XVI

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

TOTAL TUMOR INCIDENCE OF MAJOR ORGANS - YELLOW 3

RATS - INTRATRACHEAL

GROUP 4 MALE (TREATED)

| | |
|---|---|
| SKIN | 10 TUMORS |
| MAMMARY | 2 TUMORS |
| THIGH MUSCLE | 0 TUMORS |
| SALIVARY GLAND | 0 TUMORS |
| BRONCHI | 0 TUMORS |
| TRACHEA | 0 TUMORS |
| LARYNX | 0 TUMORS |
| THYROID | 9 TUMORS |
| PARATHYROID | 0 TUMORS |
| ESOPHAGUS | 0 TUMORS |
| MANDIBULAR LYMPH NODE | 2 TUMORS |
| ADRENALS | 8 TUMORS |
| THYMUS | 1 TUMORS |
| SCIATIC NERVE | 0 TUMORS |
| STOMACH | 2 TUMORS |
| DUODENUM | 0 TUMORS |
| JEJUNUM | 0 TUMORS |
| ILEUM | 0 TUMORS |
| CECUM | 0 TUMORS |
| COLON | 0 TUMORS |
| RECTUM | 0 TUMORS |
| MESENTERIC LYMPH NODES | 0 TUMORS |
| LUNGS (ALL LOBES) | 12 TUMORS |
| LIVER | 18 TUMORS |
| SPLEEN | 13 TUMORS |
| PANCREAS | 9 TUMORS |
| KIDNEYS | 4 TUMORS |
| HEART | 2 TUMORS |
| URINARY BLADDER | 2 TUMORS |
| SEMINAL VESICLE | 0 TUMORS |
| PROSTATE | 1 TUMORS |
| TESTES | 48 TUMORS |
| BRAIN | 2 TUMORS |
| PITUITARY | 12 TUMORS |
| STERNUM/RIB & RIB JUNCTIO | 0 TUMORS |
| FEMUR | 3 TUMORS |
| NASAL CAVITY | 0 TUMORS |
| OTHER | 8 TUMORS |

THERE WERE 49 TUMOR-BEARING ANIMALS; 168 TUMORS AVG.= 3.4

GROUP 8 MALE (CONTROL)

| | |
|---|---|
| SKIN | 1 TUMORS |
| MAMMARY | 1 TUMORS |
| THIGH MUSCLE | 0 TUMORS |
| SALIVARY GLAND | 0 TUMORS |
| BRONCHI | 0 TUMORS |
| TRACHEA | 0 TUMORS |
| LARYNX | 0 TUMORS |
| THYROID | 9 TUMORS |
| PARATHYROID | 0 TUMORS |
| ESOPHAGUS | 0 TUMORS |
| MANDIBULAR LYMPH NODE | 2 TUMORS |
| ADRENALS | 10 TUMORS |
| THYMUS | 0 TUMORS |
| SCIATIC NERVE | 0 TUMORS |
| STOMACH | 0 TUMORS |
| DUODENUM | 0 TUMORS |
| JEJUNUM | 0 TUMORS |
| ILEUM | 0 TUMORS |
| CECUM | 0 TUMORS |
| COLON | 0 TUMORS |
| RECTUM | 0 TUMORS |
| MESENTERIC LYMPH NODES | 0 TUMORS |
| LUNGS (ALL LOBES) | 6 TUMORS |
| LIVER | 13 TUMORS |
| SPLEEN | 10 TUMORS |
| PANCREAS | 3 TUMORS |
| KIDNEYS | 0 TUMORS |
| HEART | 1 TUMORS |
| URINARY BLADDER | 1 TUMORS |
| SEMINAL VESICLE | 0 TUMORS |
| PROSTATE | 9 TUMORS |
| TESTES | 32 TUMORS |
| BRAIN | 1 TUMORS |
| PITUITARY | 16 TUMORS |
| STERNUM/RIB & RIB JUNCTIO | 0 TUMORS |
| FEMUR | 0 TUMORS |
| NASAL CAVITY | 0 TUMORS |
| OTHER | 4 TUMORS |

THERE WERE 33 TUMOR-BEARING ANIMALS; 119 TUMORS AVG.= 3.6

TABLE XVI

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

TOTAL TUMOR INCIDENCE OF MAJOR ORGANS - YELLOW 3

RATS - INTRATRACHEAL

GROUP 4 FEMALE (TREATED)

| | |
|---|---|
| SKIN | 3 TUMORS |
| MAMMARY | 22 TUMORS |
| THIGH MUSCLE | 1 TUMORS |
| SALIVARY GLAND | 0 TUMORS |
| BRONCHI | 0 TUMORS |
| TRACHEA | 0 TUMORS |
| LARYNX | 0 TUMORS |
| THYROID | 4 TUMORS |
| PARATHYROID | 0 TUMORS |
| ESOPHAGUS | 0 TUMORS |
| MANDIBULAR LYMPH NODE | 2 TUMORS |
| ADRENALS | 3 TUMORS |
| THYMUS | 2 TUMORS |
| SCIATIC NERVE | 0 TUMORS |
| STOMACH | 1 TUMORS |
| DUODENUM | 2 TUMORS |
| JEJUNUM | 0 TUMORS |
| ILEUM | 1 TUMORS |
| CECUM | 0 TUMORS |
| COLON | 0 TUMORS |
| RECTUM | 0 TUMORS |
| MESENTERIC LYMPH NODES | 3 TUMORS |
| LUNGS (ALL LOBES) | 10 TUMORS |
| LIVER | 13 TUMORS |
| SPLEEN | 12 TUMORS |
| PANCREAS | 4 TUMORS |
| KIDNEYS | 2 TUMORS |
| HEART | 4 TUMORS |
| URINARY BLADDER | 1 TUMORS |
| OVARIES | 3 TUMORS |
| UTERUS | 5 TUMORS |
| BRAIN | 3 TUMORS |
| PITUITARY | 26 TUMORS |
| STERNUM/RIB & RIB JUNCTIO | 1 TUMORS |
| FEMUR | 2 TUMORS |
| NASAL CAVITY | 1 TUMORS |
| OTHER | 6 TUMORS |

THERE WERE 43 TUMOR-BEARING ANIMALS; 136 TUMORS AVG.= 3.2

GROUP 3 FEMALE (CONTROL)

| | |
|---|---|
| SKIN | 3 TUMORS |
| MAMMARY | 14 TUMORS |
| THIGH MUSCLE | 0 TUMORS |
| SALIVARY GLAND | 1 TUMORS |
| BRONCHI | 0 TUMORS |
| TRACHEA | 0 TUMORS |
| LARYNX | 0 TUMORS |
| THYROID | 8 TUMORS |
| PARATHYROID | 0 TUMORS |
| ESOPHAGUS | 0 TUMORS |
| MANDIBULAR LYMPH NODE | 1 TUMORS |
| ADRENALS | 4 TUMORS |
| THYMUS | 1 TUMORS |
| SCIATIC NERVE | 0 TUMORS |
| STOMACH | 1 TUMORS |
| DUODENUM | 0 TUMORS |
| JEJUNUM | 0 TUMORS |
| ILEUM | 1 TUMORS |
| CECUM | 0 TUMORS |
| COLON | 0 TUMORS |
| RECTUM | 0 TUMORS |
| MESENTERIC LYMPH NODES | 0 TUMORS |
| LUNGS (ALL LOBES) | 6 TUMORS |
| LIVER | 6 TUMORS |
| SPLEEN | 8 TUMORS |
| PANCREAS | 2 TUMORS |
| KIDNEYS | 0 TUMORS |
| HEART | 1 TUMORS |
| URINARY BLADDER | 0 TUMORS |
| OVARIES | 0 TUMORS |
| UTERUS | 3 TUMORS |
| BRAIN | 0 TUMORS |
| PITUITARY | 11 TUMORS |
| STERNUM/RIB & RIB JUNCTIO | 0 TUMORS |
| FEMUR | 1 TUMORS |
| NASAL CAVITY | 0 TUMORS |
| OTHER | 4 TUMORS |

THERE WERE 29 TUMOR-BEARING ANIMALS; 75 TUMORS AVG.= 2.6

TABLE XVI

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

TOTAL TUMOR INCIDENCE OF MAJOR ORGANS - YELLOW 3

RATS - DIETARY

GROUP 12 MALE (TREATED)

| | | |
|---|---|---|
| SKIN | 2 | TUMORS |
| MAMMARY | 3 | TUMORS |
| THIGH MUSCLE | 0 | TUMORS |
| SALIVARY GLAND | 0 | TUMORS |
| BRONCHI | 0 | TUMORS |
| TRACHEA | 0 | TUMORS |
| LARYNX | 0 | TUMORS |
| THYROID | 7 | TUMORS |
| PARATHYROID | 1 | TUMORS |
| ESOPHAGUS | 0 | TUMORS |
| MANDIBULAR LYMPH NODE | 0 | TUMORS |
| ADRENALS | 7 | TUMORS |
| THYMUS | 0 | TUMORS |
| SCIATIC NERVE | 0 | TUMORS |
| STOMACH | 1 | TUMORS |
| DUODENUM | 0 | TUMORS |
| JEJUNUM | 0 | TUMORS |
| ILEUM | 0 | TUMORS |
| CECUM | 0 | TUMORS |
| COLON | 0 | TUMORS |
| RECTUM | 0 | TUMORS |
| MESENTERIC LYMPH NODES | 0 | TUMORS |
| LUNGS (ALL LOBES) | 2 | TUMORS |
| LIVER | 28 | TUMORS |
| SPLEEN | 1 | TUMORS |
| PANCREAS | 2 | TUMORS |
| KIDNEYS | 7 | TUMORS |
| HEART | 0 | TUMORS |
| URINARY BLADDER | 2 | TUMORS |
| SEMINAL VESICLE | 0 | TUMORS |
| PROSTATE | 2 | TUMORS |
| TESTES | 45 | TUMORS |
| BRAIN | 0 | TUMORS |
| PITUITARY | 6 | TUMORS |
| STERNUM/RIB & RIB JUNCTIO | 0 | TUMORS |
| FEMUR | 0 | TUMORS |
| NASAL CAVITY | 0 | TUMORS |
| OTHER | 4 | TUMORS |

THERE WERE 48 TUMOR-BEARING ANIMALS; 120 TUMORS AVG.= 2.5

GROUP 16 MALE (CONTROL)

| | | |
|---|---|---|
| SKIN | 1 | TUMORS |
| MAMMARY | 4 | TUMORS |
| THIGH MUSCLE | 0 | TUMORS |
| SALIVARY GLAND | 0 | TUMORS |
| BRONCHI | 0 | TUMORS |
| TRACHEA | 0 | TUMORS |
| LARYNX | 0 | TUMORS |
| THYROID | 8 | TUMORS |
| PARATHYROID | 0 | TUMORS |
| ESOPHAGUS | 0 | TUMORS |
| MANDIBULAR LYMPH NODE | 0 | TUMORS |
| ADRENALS | 2 | TUMORS |
| THYMUS | 0 | TUMORS |
| SCIATIC NERVE | 0 | TUMORS |
| STOMACH | 1 | TUMORS |
| DUODENUM | 0 | TUMORS |
| JEJUNUM | 1 | TUMORS |
| ILEUM | 0 | TUMORS |
| CECUM | 0 | TUMORS |
| COLON | 0 | TUMORS |
| RECTUM | 0 | TUMORS |
| MESENTERIC LYMPH NODES | 0 | TUMORS |
| LUNGS (ALL LOBES) | 4 | TUMORS |
| LIVER | 7 | TUMORS |
| SPLEEN | 5 | TUMORS |
| PANCREAS | 4 | TUMORS |
| KIDNEYS | 0 | TUMORS |
| HEART | 1 | TUMORS |
| URINARY BLADDER | 1 | TUMORS |
| SEMINAL VESICLE | 0 | TUMORS |
| PROSTATE | 1 | TUMORS |
| TESTES | 35 | TUMORS |
| BRAIN | 0 | TUMORS |
| PITUITARY | 6 | TUMORS |
| STERNUM/RIB & RIB JUNCTIO | 0 | TUMORS |
| FEMUR | 0 | TUMORS |
| NASAL CAVITY | 0 | TUMORS |
| OTHER | 0 | TUMORS |

THERE WERE 31 TUMOR-BEARING ANIMALS; 81 TUMORS AVG.= 2.4

TABLE XVI

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

TOTAL TUMOR INCIDENCE OF MAJOR ORGANS - YELLOW 3

RATS - DIETARY

GROUP 12 FEMALE (TREATED)

| | |
|---|---|
| SKIN | 4 TUMORS |
| MAMMARY | 13 TUMORS |
| THIGH MUSCLE | 0 TUMORS |
| SALIVARY GLAND | 0 TUMORS |
| BRONCHI | 0 TUMORS |
| TRACHEA | 0 TUMORS |
| LARYNX | 0 TUMORS |
| THYROID | 7 TUMORS |
| PARATHYROID | 0 TUMORS |
| ESOPHAGUS | 0 TUMORS |
| MANDIBULAR LYMPH NODE | 0 TUMORS |
| ADRENALS | 2 TUMORS |
| THYMUS | 0 TUMORS |
| SCIATIC NERVE | 0 TUMORS |
| STOMACH | 0 TUMORS |
| DUODENUM | 0 TUMORS |
| JEJUNUM | 0 TUMORS |
| ILEUM | 0 TUMORS |
| CECUM | 0 TUMORS |
| COLON | 1 TUMORS |
| RECTUM | 0 TUMORS |
| MESENTERIC LYMPH NODES | 1 TUMORS |
| LUNGS (ALL LOBES) | 1 TUMORS |
| LIVER | 4 TUMORS |
| SPLEEN | 0 TUMORS |
| PANCREAS | 0 TUMORS |
| KIDNEYS | 0 TUMORS |
| HEART | 0 TUMORS |
| URINARY BLADDER | 0 TUMORS |
| OVARIES | 2 TUMORS |
| UTERUS | 4 TUMORS |
| BRAIN | 1 TUMORS |
| PITUITARY | 24 TUMORS |
| STERNUM/RIB & RIB JUNCTIO | 0 TUMORS |
| FEMUR | 0 TUMORS |
| NASAL CAVITY | 0 TUMORS |
| OTHER | 5 TUMORS |

THERE WERE 36 TUMOR-BEARING ANIMALS; 69 TUMORS AVG.= 1.9

GROUP 16 FEMALE (CONTROL)

| | |
|---|---|
| SKIN | 0 TUMORS |
| MAMMARY | 16 TUMORS |
| THIGH MUSCLE | 0 TUMORS |
| SALIVARY GLAND | 0 TUMORS |
| BRONCHI | 0 TUMORS |
| TRACHEA | 0 TUMORS |
| LARYNX | 0 TUMORS |
| THYROID | 1 TUMORS |
| PARATHYROID | 0 TUMORS |
| ESOPHAGUS | 0 TUMORS |
| MANDIBULAR LYMPH NODE | 1 TUMORS |
| ADRENALS | 4 TUMORS |
| THYMUS | 1 TUMORS |
| SCIATIC NERVE | 0 TUMORS |
| STOMACH | 0 TUMORS |
| DUODENUM | 0 TUMORS |
| JEJUNUM | 0 TUMORS |
| ILEUM | 1 TUMORS |
| CECUM | 0 TUMORS |
| COLON | 0 TUMORS |
| RECTUM | 0 TUMORS |
| MESENTERIC LYMPH NODES | 2 TUMORS |
| LUNGS (ALL LOBES) | 5 TUMORS |
| LIVER | 8 TUMORS |
| SPLEEN | 8 TUMORS |
| PANCREAS | 2 TUMORS |
| KIDNEYS | 1 TUMORS |
| HEART | 1 TUMORS |
| URINARY BLADDER | 2 TUMORS |
| OVARIES | 1 TUMORS |
| UTERUS | 1 TUMORS |
| BRAIN | 2 TUMORS |
| PITUITARY | 13 TUMORS |
| STERNUM/RIB & RIB JUNCTIO | 0 TUMORS |
| FEMUR | 0 TUMORS |
| NASAL CAVITY | 0 TUMORS |
| OTHER | 1 TUMORS |

THERE WERE 23 TUMOR-BEARING ANIMALS; 71 TUMORS AVG.= 2.5

TABLE XVII

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

FISHER'S ANALYSIS OF TUMOR-BEARING ANIMALS - YELLOW 3

HAMSTERS - INTRATRACHEAL

| ORGAN SYSTEM | TREATED GROUP & SEX | TREATED TBA | TREATED AT RISK | CONTROL GROUP & SEX | CONTROL TBA | CONTROL AT RISK | PROBABILITY 1-TAIL | PROBABILITY 2-TAIL |
|---|---|---|---|---|---|---|---|---|
| (ALL TISSUES) | 3M | 15 | 45 | 6M | 14 | 31 | 0.211 | 1.000 |
| (REPRODUCTIVE SYSTEM) | 3M | 0 | 37 | 6M | 1 | 22 | 0.373 | 0.373 |
| (RESPIRATORY SYSTEM) | 3M | 0 | 44 | 6M | 3 | 27 | 0.051 | 0.051 |
| (LUNG) | 3M | 0 | 44 | 6M | 3 | 27 | 0.051 | 0.051 |
| (DIGESTIVE SYSTEM) | 3M | 0 | 44 | 6M | 2 | 27 | 0.141 | 0.141 |
| (LIVER) | 3M | 0 | 44 | 6M | 2 | 27 | 0.141 | 0.141 |
| (HEMATOPOIETIC/LYMPHATIC SYSTEM) | 3M | 0 | 44 | 6M | 4 | 27 | 0.018 | 0.018 S* |
| (ENDOCRINE SYSTEM) | 3M | 15 | 45 | 6M | 8 | 31 | 0.329 | 0.527 |
| (SPLEEN) | 3M | 0 | 44 | 6M | 3 | 27 | 0.051 | 0.051 |
| (MISCELLANEOUS TUMORS) | 3M | 0 | 31 | 6M | 2 | 15 | 0.101 | 0.101 |

TBA = Tumor-bearing animal; M = Male

*A significantly higher incidence of tumor-bearing animals was present in the control group as compared to the treated group.

TABLE XVII

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

FISHER'S ANALYSIS OF TUMOR-BEARING ANIMALS - YELLOW 3

HAMSTERS - INTRATRACHEAL

| ORGAN SYSTEM | TREATED GROUP & SEX | TREATED TBA | TREATED AT RISK | CONTROL GROUP & SEX | CONTROL TBA | CONTROL AT RISK | PROBABILITY 1-TAIL | PROBABILITY 2-TAIL |
|---|---|---|---|---|---|---|---|---|
| (ALL TISSUES) | 3F | 15 | 39 | 6F | 10 | 30 | 0.427 | 0.998 |
| (MUSCLE/SKELETAL SYSTEM) | 3F | 1 | 4 | 6F | 0 | 3 | 0.571 | 0.571 |
| (REPRODUCTIVE SYSTEM) | 3F | 1 | 7 | 6F | 2 | 6 | 0.437 | 0.577 |
| (RESPIRATORY SYSTEM) | 3F | 4 | 37 | 6F | 2 | 30 | 0.442 | 1.000 |
| (LUNG) | 3F | 4 | 37 | 6F | 2 | 30 | 0.442 | 1.000 |
| (DIGESTIVE SYSTEM) | 3F | 7 | 37 | 6F | 2 | 30 | 0.135 | 0.135 |
| (STOMACH) | 3F | 1 | 37 | 6F | 0 | 30 | 0.552 | 1.000 |
| (LIVER) | 3F | 6 | 34 | 6F | 1 | 27 | 0.096 | 0.121 |
| (HEMATOPOIETIC/LYMPHATIC SYSTEM) | 3F | 4 | 37 | 6F | 2 | 30 | 0.442 | 1.000 |
| (URINARY SYSTEM) | 3F | 1 | 4 | 6F | 0 | 3 | 0.571 | 0.571 |
| (KIDNEY) | 3F | 1 | 4 | 6F | 0 | 3 | 0.571 | 0.571 |
| (PANCREAS) | 3F | 1 | 32 | 6F | 1 | 27 | 0.710 | 1.000 |
| (ENDOCRINE SYSTEM) | 3F | 7 | 39 | 6F | 5 | 30 | 0.575 | 1.000 |
| (SPLEEN) | 3F | 2 | 37 | 6F | 0 | 30 | 0.301 | 0.498 |
| (MISCELLANEOUS TUMORS) | 3F | 1 | 4 | 6F | 0 | 3 | 0.571 | 0.571 |

TBA = Tumor-bearing animal; F = Female

TABLE XVII

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

FISHER'S ANALYSIS OF TUMOR-BEARING ANIMALS - YELLOW 3

HAMSTERS - DIETARY

| ORGAN SYSTEM | TREATED GROUP & SEX | TBA | AT RISK | CONTROL GROUP & SEX | TBA | AT RISK | PROBABILITY 1-TAIL | 2-TAIL | |
|---|---|---|---|---|---|---|---|---|---|
| (ALL TISSUES) | 11M | 17 | 48 | 14M | 22 | 34 | 0.008 | 0.013 | S* |
| (RESPIRATORY SYSTEM) | 11M | 0 | 48 | 14M | 5 | 34 | 0.010 | 0.010 | S* |
| (LUNG) | 11M | 0 | 48 | 14M | 5 | 34 | 0.010 | 0.010 | S* |
| (DIGESTIVE SYSTEM) | 11M | 0 | 33 | 14M | 5 | 22 | 0.008 | 0.008 | S* |
| (STOMACH) | 11M | 0 | 25 | 14M | 1 | 14 | 0.359 | 0.359 | |
| (LIVER) | 11M | 0 | 33 | 14M | 5 | 22 | 0.008 | 0.008 | S* |
| (HEMATOPOIETIC/LYMPHATIC SYSTEM) | 11M | 0 | 48 | 14M | 7 | 34 | 0.001 | 0.001 | S* |
| (URINARY SYSTEM) | 11M | 0 | 25 | 14M | 1 | 14 | 0.359 | 0.359 | |
| (KIDNEY) | 11M | 0 | 25 | 14M | 1 | 14 | 0.359 | 0.359 | |
| (PANCREAS) | 11M | 0 | 25 | 14M | 1 | 14 | 0.359 | 0.359 | |
| (ENDOCRINE SYSTEM) | 11M | 17 | 43 | 14M | 17 | 30 | 0.114 | 0.233 | |
| (SPLEEN) | 11M | 0 | 29 | 14M | 5 | 20 | 0.008 | 0.008 | S* |
| (CARDIOVASCULAR SYSTEM) | 11M | 0 | 25 | 14M | 1 | 14 | 0.359 | 0.359 | |

TBA = Tumor-bearing animal; M = Male

*A significantly higher incidence of tumor-bearing animals was present in the control group as compared to the treated group.

TABLE XVII

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

FISHER'S ANALYSIS OF TUMOR-BEARING ANIMALS - YELLOW 3

HAMSTERS - DIETARY

| ORGAN SYSTEM | TREATED GROUP & SEX | TREATED TBA | TREATED AT RISK | CONTROL GROUP & SEX | CONTROL TBA | CONTROL AT RISK | PROBABILITY 1-TAIL | PROBABILITY 2-TAIL |
|---|---|---|---|---|---|---|---|---|
| (ALL TISSUES) | 11F | 16 | 48 | 14F | 6 | 30 | 0.155 | 0.449 |
| (REPRODUCTIVE SYSTEM) | 11F | 3 | 36 | 14F | 3 | 19 | 0.338 | 0.653 |
| (RESPIRATORY SYSTEM) | 11F | 4 | 48 | 14F | 0 | 30 | 0.136 | 0.156 |
| (LUNG) | 11F | 4 | 48 | 14F | 0 | 30 | 0.136 | 0.156 |
| (DIGESTIVE SYSTEM) | 11F | 3 | 23 | 14F | 1 | 14 | 0.509 | 1.000 |
| (LIVER) | 11F | 3 | 23 | 14F | 1 | 14 | 0.509 | 1.000 |
| (HEMATOPOIETIC/LYMPHATIC SYSTEM) | 11F | 2 | 48 | 14F | 1 | 30 | 0.672 | 1.000 |
| (URINARY SYSTEM) | 11F | 1 | 34 | 14F | 0 | 19 | 0.642 | 1.000 |
| (KIDNEY) | 11F | 1 | 34 | 14F | 0 | 19 | 0.642 | 1.000 |
| (ENDOCRINE SYSTEM) | 11F | 10 | 44 | 14F | 4 | 25 | 0.367 | 1.000 |
| (SPLEEN) | 11F | 0 | 11 | 14F | 1 | 9 | 0.450 | 0.450 |

TBA = Tumor-bearing animal; F = Female

TABLE XVII

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

FISHER'S ANALYSIS OF TUMOR-BEARING ANIMALS - YELLOW 3

RATS - INTRATRACHEAL

| ORGAN SYSTEM | TREATED GROUP & SEX | TREATED TBA | TREATED AT RISK | CONTROL GROUP & SEX | CONTROL TBA | CONTROL AT RISK | PROBABILITY 1-TAIL | PROBABILITY 2-TAIL |
|---|---|---|---|---|---|---|---|---|
| (ALL TISSUES) | 4M | 49 | 49 | 8M | 33 | 34 | 0.410 | 0.410 |
| (SKIN/MAMMARY GLAND) | 4M | 9 | 40 | 8M | 2 | 32 | 0.055 | 0.055 |
| (LUNG) | 4M | 11 | 47 | 8M | 5 | 34 | 0.248 | 1.000 |
| (RESPIRATORY SYSTEM) | 4M | 11 | 47 | 8M | 5 | 34 | 0.248 | 1.000 |
| (CARDIOVASCULAR SYSTEM) | 4M | 2 | 45 | 8M | 1 | 34 | 0.605 | 1.000 |
| (LIVER) | 4M | 14 | 47 | 8M | 12 | 34 | 0.387 | 1.000 |
| (SPLEEN) | 4M | 12 | 47 | 8M | 9 | 34 | 0.562 | 1.000 |
| (HEMATOPOIETIC/LYMPHATIC SYSTEM) | 4M | 12 | 47 | 8M | 9 | 34 | 0.562 | 1.000 |
| (PANCREAS) | 4M | 8 | 41 | 8M | 3 | 34 | 0.165 | 0.165 |
| (ENDOCRINE SYSTEM) | 4M | 27 | 45 | 8M | 22 | 34 | 0.425 | 1.000 |
| (DIGESTIVE SYSTEM) | 4M | 15 | 47 | 8M | 12 | 34 | 0.467 | 1.000 |
| (STOMACH) | 4M | 2 | 47 | 8M | 0 | 34 | 0.334 | 0.507 |
| (KIDNEY) | 4M | 4 | 45 | 8M | 0 | 34 | 0.099 | 0.130 |
| (URINARY SYSTEM) | 4M | 5 | 45 | 8M | 1 | 34 | 0.179 | 0.394 |
| (BRAIN) | 4M | 2 | 47 | 8M | 1 | 34 | 0.621 | 1.000 |
| (NERVOUS SYSTEM) | 4M | 2 | 47 | 8M | 1 | 34 | 0.621 | 1.000 |
| (REPRODUCTIVE SYSTEM) | 4M | 45 | 49 | 8M | 32 | 34 | 0.524 | 1.000 |
| (MISCELLANEOUS TUMORS) | 4M | 6 | 49 | 8M | 4 | 34 | 0.614 | 1.000 |

TBA = Tumor-bearing animal; M = Male

TABLE XVII

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

FISHER'S ANALYSIS OF TUMOR-BEARING ANIMALS - YELLOW 3

RATS - INTRATRACHEAL

| ORGAN SYSTEM | TREATED GROUP & SEX | TREATED TBA | TREATED AT RISK | CONTROL GROUP & SEX | CONTROL TBA | CONTROL AT RISK | PROBABILITY 1-TAIL | PROBABILITY 2-TAIL |
|---|---|---|---|---|---|---|---|---|
| (ALL TISSUES) | 4F | 43 | 50 | 8F | 29 | 34 | 0.584 | 1.000 |
| (SKIN/MAMMARY GLAND) | 4F | 19 | 50 | 8F | 14 | 34 | 0.473 | 1.000 |
| (MUSCLE/SKELETAL SYSTEM) | 4F | 2 | 41 | 8F | 0 | 28 | 0.350 | 0.511 |
| (LUNG) | 4F | 10 | 49 | 8F | 6 | 33 | 0.518 | 1.000 |
| (RESPIRATORY SYSTEM) | 4F | 11 | 49 | 8F | 6 | 33 | 0.429 | 1.000 |
| (CARDIOVASCULAR SYSTEM) | 4F | 4 | 47 | 8F | 1 | 31 | 0.335 | 0.643 |
| (LIVER) | 4F | 12 | 49 | 8F | 6 | 33 | 0.347 | 1.000 |
| (SPLEEN) | 4F | 12 | 49 | 8F | 8 | 33 | 0.597 | 1.000 |
| (HEMATOPOIETIC/LYMPHATIC SYSTEM) | 4F | 13 | 49 | 8F | 8 | 33 | 0.513 | 1.000 |
| (PANCREAS) | 4F | 4 | 42 | 8F | 2 | 28 | 0.544 | 1.000 |
| (ENDOCRINE SYSTEM) | 4F | 31 | 48 | 8F | 19 | 32 | 0.406 | 1.000 |
| (DIGESTIVE SYSTEM) | 4F | 14 | 49 | 8F | 8 | 33 | 0.432 | 1.000 |
| (STOMACH) | 4F | 1 | 44 | 8F | 1 | 30 | 0.650 | 1.000 |
| (KIDNEY) | 4F | 2 | 42 | 8F | 0 | 28 | 0.357 | 0.513 |
| (URINARY SYSTEM) | 4F | 2 | 42 | 8F | 0 | 28 | 0.357 | 0.513 |
| (BRAIN) | 4F | 3 | 49 | 8F | 0 | 33 | 0.208 | 0.270 |
| (NERVOUS SYSTEM) | 4F | 3 | 49 | 8F | 0 | 33 | 0.208 | 0.270 |
| (REPRODUCTIVE SYSTEM) | 4F | 7 | 45 | 8F | 3 | 31 | 0.351 | 1.000 |
| (MISCELLANEOUS TUMORS) | 4F | 6 | 40 | 8F | 4 | 22 | 0.504 | 1.000 |

TBA = Tumor-bearing animal; F = Female

TABLE XVII

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

FISHER'S ANALYSIS OF TUMOR-BEARING ANIMALS - YELLOW 3

RATS - DIETARY

| ORGAN SYSTEM | TREATED GROUP & SEX | TREATED TBA | TREATED AT RISK | CONTROL GROUP & SEX | CONTROL TBA | CONTROL AT RISK | PROBABILITY 1-TAIL | PROBABILITY 2-TAIL |
|---|---|---|---|---|---|---|---|---|
| (ALL TISSUES) | 12M | 48 | 50 | 16M | 34 | 35 | 0.633 | 1.000 |
| (SKIN/MAMMARY GLAND) | 12M | 4 | 41 | 16M | 4 | 31 | 0.478 | 1.000 |
| (LUNG) | 12M | 2 | 45 | 16M | 4 | 35 | 0.227 | 0.396 |
| (RESPIRATORY SYSTEM) | 12M | 2 | 45 | 16M | 4 | 35 | 0.227 | 0.396 |
| (CARDIOVASCULAR SYSTEM) | 12M | 0 | 41 | 16M | 1 | 31 | 0.431 | 0.431 |
| (LIVER) | 12M | 27 | 50 | 16M | 7 | 35 | 0.001 | 0.001 S† |
| (SPLEEN) | 12M | 1 | 45 | 16M | 5 | 35 | 0.054 | 0.081 |
| (HEMATOPOIETIC/LYMPHATIC SYSTEM) | 12M | 1 | 45 | 16M | 5 | 35 | 0.054 | 0.081 |
| (PANCREAS) | 12M | 2 | 41 | 16M | 4 | 31 | 0.214 | 0.392 |
| (ENDOCRINE SYSTEM) | 12M | 18 | 50 | 16M | 15 | 35 | 0.339 | 1.000 |
| (DIGESTIVE SYSTEM) | 12M | 27 | 50 | 16M | 9 | 35 | 0.008 | 0.014S† |
| (STOMACH) | 12M | 1 | 43 | 16M | 1 | 32 | 0.675 | 1.000 |
| (KIDNEY) | 12M | 7 | 41 | 16M | 0 | 31 | 0.015 | 0.017S† |
| (URINARY SYSTEM) | 12M | 9 | 41 | 16M | 1 | 31 | 0.022 | 0.036S† |
| (REPRODUCTIVE SYSTEM) | 12M | 46 | 50 | 16M | 34 | 35 | 0.310 | 0.645 |
| (MISCELLANEOUS TUMORS) | 12M | 3 | 48 | 16M | 0 | 35 | 0.188 | 0.260 |

TBA = Tumor-bearing animal; M = Male

†A significantly higher incidence of tumor-bearing animals was present in the treated group as compared to the control group.

TABLE XVII

CARCINOGENICITY OF AZO DYES: ACID BLACK 52 AND YELLOW 3 IN HAMSTERS AND RATS

FISHER'S ANALYSIS OF TUMOR-BEARING ANIMALS - YELLOW 3

RATS - DIETARY

| ORGAN SYSTEM | TREATED GROUP & SEX | TBA | AT RISK | CONTROL GROUP & SEX | TBA | AT RISK | PROBABILITY 1-TAIL | 2-TAIL | |
|---|---|---|---|---|---|---|---|---|---|
| (ALL TISSUES) | 12F | 36 | 47 | 16F | 28 | 34 | 0.366 | 1.000 | |
| (SKIN/MAMMARY GLAND) | 12F | 17 | 47 | 16F | 13 | 34 | 0.516 | 1.000 | |
| (LUNG) | 12F | 1 | 46 | 16F | 5 | 30 | 0.033 | 0.033 | S* |
| (RESPIRATORY SYSTEM) | 12F | 1 | 46 | 16F | 5 | 30 | 0.033 | 0.033 | S* |
| (CARDIOVASCULAR SYSTEM) | 12F | 0 | 46 | 16F | 1 | 30 | 0.395 | 0.395 | |
| (LIVER) | 12F | 4 | 46 | 16F | 8 | 30 | 0.039 | 0.053 | |
| (SPLEEN) | 12F | 0 | 46 | 16F | 8 | 30 | 0.0003 | 0.0003 | S* |
| (HEMATOPOIETIC/LYMPHATIC SYSTEM) | 12F | 1 | 46 | 16F | 8 | 30 | 0.002 | 0.002 | S* |
| (PANCREAS) | 12F | 0 | 46 | 16F | 2 | 30 | 0.153 | 0.153 | |
| (ENDOCRINE SYSTEM) | 12F | 29 | 46 | 16F | 16 | 30 | 0.273 | 1.000 | |
| (DIGESTIVE SYSTEM) | 12F | 4 | 46 | 16F | 8 | 30 | 0.039 | 0.053 | |
| (KIDNEY) | 12F | 0 | 34 | 16F | 1 | 15 | 0.306 | 0.306 | |
| (URINARY SYSTEM) | 12F | 0 | 46 | 16F | 3 | 30 | 0.058 | 0.058 | |
| (BRAIN) | 12F | 1 | 46 | 16F | 2 | 30 | 0.342 | 0.558 | |
| (NERVOUS SYSTEM) | 12F | 1 | 46 | 16F | 2 | 30 | 0.342 | 0.558 | |
| (REPRODUCTIVE SYSTEM) | 12F | 6 | 46 | 16F | 2 | 30 | 0.315 | 1.000 | |
| (MISCELLANEOUS TUMORS) | 12F | 5 | 42 | 16F | 1 | 22 | 0.320 | 0.655 | |

TBA = Tumor-bearing animal; F = Female

*A significantly higher incidence of tumor-bearing animals was present in the control group as compared to the treated group.

CARCINOGENICITY OF AZO DYES:ACID BLACK 52 AND YELLOW 3
IN HAMSTERS AND RATS

TABLE XVIII

SUMMARY OF HISTOPATHOLOGY FINDINGS* - YELLOW 3

*Expressed as the number of animals with the lesion, followed by the range of severity (1=minimal, 2=slight, 3=moderate, 4=severe). The number of animals examined [#], equals the number of animals in that group.

KEY

| | | |
|---|---|---|
| DYE: | YELLOW 3 | SPECIES: HAMSTER |
| ROUTE: | INTRATRACHEAL | DIETARY |
| GROUPS: | 3 (Treated) | 11 (Treated) |
| | 6 (Control) | 14 (Control) |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( MALES )

| | GROUP 3 | GROUP 6 | GROUP 11 | GROUP 14 |
|---|---|---|---|---|
| SKIN | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 39 | 24 | 26 | 22 |
| ACARIASIS. | 3 3+ | 3 | 15 1+ | 6 |
| HYPERKERATOSIS. | 4 3+ - 4+ | 0 | 0 | 0 |
| AUTOLYZED. | 2 | 1 | 0 | 0 |
| DERMATITIS, SUBACUTE, PURULENT. | 1 4+ | 0 | 0 | 0 |
| EDEMA, SUBCUTANEOUS. | 3 3+ - 4+ | 4 3+ - 4+ | 6 2+ - 4+ | 5 3+ - 4+ |
| MUSCULAR DYSTROPHY, SUBCUTANEOUS. | 1 3+ | 0 | 0 | 0 |
| DERMATITIS. | 1 4+ | 0 | 0 | 0 |
| AMYLOIDOSIS. | 0 | 1 1+ | 0 | 0 |
| DERMATITIS, NECROTIZING, CHRONIC. | 0 | 1 4+ | 0 | 0 |
| DERMATITIS, NECROTIZING. | 0 | 1 4+ | 0 | 0 |
| MELANOSIS. | 0 | 1 2+ | 0 | 0 |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 0 | 0 | 2 | 0 |
| EDEMA, SUBCUTANEOUS, SUBACUTE. | 0 | 0 | 1 4+ | 0 |
| NECROSIS. | 0 | 0 | 1 2+ | 0 |
| DERMATITIS, ACTIVE, CHRONIC. | 0 | 0 | 1 4+ | 0 |
| FOLLICULITIS, ACUTE, NECROPURULENT. | 0 | 0 | 0 | 1 4+ |
| DERMATITIS, CHRONIC. | 0 | 0 | 0 | 2 3+ - 4+ |
| DERMATITIS, ACUTE, NECROTIZING. | 0 | 0 | 0 | 1 3+ |
| (SUBCUTANEOUS TISSUE), MALIGNANT LYMPHOMA. | 0 | 0 | 0 | 1 |
| MAMMARY GLAND | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NOT PRESENT IN SECTION. | 48 | 34 | 48 | 35 |
| AUTOLYZED. | 2 | 1 | 0 | 0 |
| NO SIGNIFICANT LESION RECOGNIZED. | 0 | 0 | 2 | 0 |
| MUSCLE | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 47 | 31 | 49 | 33 |
| AUTOLYZED. | 2 | 1 | 0 | 0 |
| MINERALIZATION. | 1 4+ | 0 | 0 | 0 |
| MUSCULAR DYSTROPHY. | 0 | 3 2+ - 4+ | 0 | 2 1+ - 4+ |
| NOT PRESENT IN SECTION. | 0 | 0 | 1 | 0 |
| SALIVARY GLAND | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 48 | 33 | 50 | 35 |
| AUTOLYZED. | 2 | 1 | 0 | 0 |
| MISSING. | 0 | 1 | 0 | 0 |
| MANDIBULAR LYMPH NODE | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 25 | 17 | 24 | 15 |
| PLASMACYTOSIS. | 11 2+ - 3+ | 4 3+ | 20 3+ - 4+ | 11 3+ |
| AUTOLYZED. | 2 | 2 | 0 | 0 |
| MISSING. | 6 | 3 | 2 | 3 |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( MALES )

| | GROUP 3 | GROUP 6 | GROUP 11 | GROUP 14 |
|---|---|---|---|---|
| MANDIBULAR LYMPH NODE (continued) | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| LYMPHOID HYPERPLASIA. | 1 4+ | 4 3+ | 1 3+ | 2 3+ |
| CONGESTION. | 4 3+ - 4+ | 3 3+ - 4+ | 3 3+ - 4+ | 0 |
| HEMOSIDEROSIS. | 1 1+ | 0 | 0 | 0 |
| LARYNGITIS, SUBACUTE. | 1 3+ | 0 | 0 | 0 |
| RETICULOENDOTHELIAL CELL HYPERPLASIA. | 0 | 1 3+ | 0 | 0 |
| MALIGNANT LYMPHOMA. | 0 | 2 | 0 | 2 |
| LYMPHOCYTOSIS. | 0 | 1 3+ | 0 | 0 |
| EXTRAMEDULLARY HEMATOPOIESIS. | 0 | 0 | 1 1+ | 0 |
| PIGMENTATION, INTRACELLULAR. | 0 | 0 | 1 2+ | 0 |
| MOTT CELL(S), OCCASIONAL. | 1 | 0 | 1 | 0 |
| RETICULUM CELL HYPERPLASIA. | 0 | 0 | 2 3+ | 0 |
| LYMPHADENITIS, ACUTE, PURULENT. | 0 | 0 | 1 4+ | 0 |
| INSUFFICIENT TISSUE | | | | |
| PRESENT IN SECTION. | 0 | 0 | 0 | 1 |
| NECROSIS. | 0 | 0 | 0 | 1 2+ |
| PLASMACYTOMA. | 0 | 0 | 0 | 1 |
| SCIATIC NERVE | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 42 | 28 | 46 | 28 |
| NOT PRESENT IN SECTION. | 1 | 0 | 2 | 0 |
| INSUFFICIENT TISSUE | | | | |
| PRESENT IN SECTION. | 2 | 1 | 1 | 2 |
| AUTOLYZED. | 2 | 2 | 0 | 0 |
| MISSING. | 2 | 3 | 1 | 5 |
| CYST(S), MASTOCYTOSIS. | 1 2+ | 0 | 0 | 0 |
| PERINEURITIS, CHRONIC. | 0 | 1 3+ | 0 | 0 |
| THYMUS | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 16 | 16 | 20 | 21 |
| NOT PRESENT IN SECTION. | 23 | 12 | 21 | 11 |
| INSUFFICIENT TISSUE | | | | |
| PRESENT IN SECTION. | 2 | 0 | 0 | 1 |
| AUTOLYZED. | 2 | 2 | 0 | 0 |
| MISSING. | 1 | 0 | 0 | 0 |
| CYST(S). | 5 | 3 | 1 | 2 |
| ATROPHY. | 1 | 0 | 0 | 0 |
| MALIGNANT LYMPHOMA. | 0 | 1 | 0 | 0 |
| INVOLUTED. | 0 | 1 | 4 | 0 |
| EOSINOPHILIC MASS(ES). | 0 | 1 | 0 | 0 |
| PLASMACYTOSIS. | 0 | 0 | 2 3+ | 0 |
| MINERALIZATION. | 0 | 0 | 1 2+ | 0 |
| INVOLUTED MASTOCYTOSIS. | 0 | 0 | 1 3+ | 0 |
| LARYNX | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 46 | 34 | 50 | 34 |

( MALES )

| | GROUP 3 | GROUP 6 | GROUP 11 | GROUP 14 |
|---|---|---|---|---|
| LARYNX (continued) | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NOT PRESENT IN SECTION. | 1 | 0 | 0 | 1 |
| AUTOLYZED. | 2 | 1 | 0 | 0 |
| PAPILLARY HYPERPLASIA. | 1 2+ | 0 | 0 | 0 |
| THYROID | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 26 | 24 | 33 | 23 |
| NOT PRESENT IN SECTION. | 8 | 4 | 2 | 1 |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 2 | 1 | 1 | 2 |
| AUTOLYZED. | 2 | 2 | 0 | 0 |
| AMYLOIDOSIS. | 8 1+ - 4+ | 1 2+ | 11 2+ - 4+ | 6 3+ - 4+ |
| FOLLICULAR CYST(S). | 2 3+ | 2 3+ | 3 | 1 |
| C-CELL CARCINOMA. | 1 | 0 | 0 | 0 |
| C-CELL ADENOMA. | 1 | 0 | 0 | 1 |
| FOLLICULAR CELL ADENOMA. | 0 | 1 | 2 | 0 |
| FOLLICULAR CELL PAPILLARY HYPERPLASIA. | 0 | 0 | 1 2+ | 0 |
| MISSING. | 0 | 0 | 0 | 1 |
| PARATHYROID | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 21 | 16 | 21 | 20 |
| NOT PRESENT IN SECTION. | 24 | 17 | 29 | 13 |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 1 | 0 | 0 | 1 |
| AUTOLYZED. | 2 | 1 | 0 | 0 |
| FOLLICULAR CYST(S). | 1 | 0 | 0 | 0 |
| HYPERPLASIA. | 1 4+ | 0 | 0 | 0 |
| ADENOMA. | 0 | 1 | 0 | 0 |
| MISSING. | 0 | 0 | 0 | 1 |
| TRACHEA | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 48 | 33 | 49 | 34 |
| AUTOLYZED. | 2 | 2 | 0 | 0 |
| INTRALUMINAL EXUDATE. | 0 | 0 | 1 | 0 |
| (TRACHEAL GLANDS-LAMINA PROPRIA), ADENITIS, ACUTE. | 0 | 0 | 0 | 1 4+ |
| BRONCHUS | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 45 | 30 | 50 | 35 |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 3 | 3 | 0 | 0 |
| AUTOLYZED. | 2 | 2 | 0 | 0 |
| ESOPHAGUS | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 48 | 33 | 50 | 35 |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( MALES )

| | GROUP 3 | | GROUP 6 | | GROUP 11 | | GROUP 14 | |
|---|---|---|---|---|---|---|---|---|
| ESOPHAGUS (continued) | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| AUTOLYZED. | 2 | | 2 | | 0 | | 0 | |
| ADRENAL | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 9 | | 13 | | 5 | | 7 | |
| CORTICAL NODULAR HYPERPLASIA. | 21 | 2+ | 14 | | 20 | | 8 | |
| PIGMENTATION, INTRACELLULAR. | 8 | 1+ - 3+ | 1 | 1+ | 4 | 1+ - 3+ | 3 | 2+ |
| AUTOLYZED. | 2 | | 2 | | 0 | | 0 | |
| AMYLOIDOSIS. | 8 | 2+ - 4+ | 3 | 2+ - 3+ | 12 | 2+ - 4+ | 4 | 2+ - 4+ |
| CORTICAL CELL ADENOMA. | 12 | | 6 | | 15 | | 16 | |
| CORTICAL CELL CARCINOMA. | 2 | | 0 | | 0 | | 1 | |
| HEMATOCYST(S). | 1 | | 0 | | 0 | | 0 | |
| MINERALIZATION, CORTICAL. | 1 | 3+ | 0 | | 0 | | 0 | |
| (SECOND ADRENAL MISSING). | 1 | | 0 | | 1 | | 0 | |
| CORTICAL NODULAR HYPERPLASIA, AMYLOID. | 0 | | 1 | 3+ | 0 | | 0 | |
| CORTICAL CELL HYPERPLASIA. | 0 | | 1 | | 0 | | 0 | |
| NODULAR HYPERPLASIA. | 0 | | 0 | | 1 | | 1 | |
| PIGMENTATION, INTRACELLULAR RETICULARIS. | 0 | | 0 | | 4 | 1+ | 0 | |
| CORTICAL HYPERPLASIA. | 0 | | 0 | | 1 | | 0 | |
| PHEOCHROMOCYTOMA. | 0 | | 0 | | 0 | | 1 | |
| STOMACH | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 38 | | 27 | | 41 | | 26 | |
| AUTOLYZED. | 9 | | 8 | | 5 | | 6 | |
| (GLANDULAR), MINERALIZATION. | 1 | 1+ | 0 | | 0 | | 0 | |
| (FORESTOMACH), PAPILLARY HYPERPLASIA. | 1 | | 0 | | 1 | | 1 | |
| (FORESTOMACH), ACANTHOSIS. | 1 | 3+ | 0 | | 0 | | 0 | |
| (FORESTOMACH), GASTRITIS, CHRONIC. | 1 | 3+ | 0 | | 0 | | 1 | 2+ |
| MISSING. | 0 | | 0 | | 1 | | 0 | |
| GASTRITIS, SUBACUTE. | 0 | | 0 | | 1 | 3+ | 0 | |
| (GLANDULAR), PIGMENTATION, (BLACK). | 0 | | 0 | | 1 | 3+ | 0 | |
| MALIGNANT LYMPHOMA. | 0 | | 0 | | 0 | | 1 | |
| (FORESTOMACH), HYPERPLASIA. | 0 | | 0 | | 0 | | 1 | 3+ |
| DUODENUM | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 39 | | 26 | | 45 | | 27 | |
| AUTOLYZED. | 11 | | 8 | | 5 | | 8 | |
| (SMALL INTESTINE), ENTERITIS, PROLIFERATIVE. | 0 | | 1 | 4+ | 0 | | 0 | |
| JEJUNUM | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 39 | | 26 | | 45 | | 27 | |
| AUTOLYZED. | 11 | | 9 | | 5 | | 8 | |
| ILEUM | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 36 | | 25 | | 45 | | 21 | |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( MALES )

| | GROUP 3 | | GROUP 6 | | GROUP 11 | | GROUP 14 | |
|---|---|---|---|---|---|---|---|---|
| ILEUM (continued) | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| AUTOLYZED. | 11 | | 8 | | 5 | | 8 | |
| ENTERITIS, PROLIFERATIVE. | 1 | 4+ | 1 | 4+ | 0 | | 0 | |
| ILEITIS, PROLIFERATIVE. | 2 | 4+ | 1 | 4+ | 0 | | 2 | 4+ |
| ILEITIS. | 0 | | 0 | | 0 | | 3 | 4+ |
| ENTERITIS. | 0 | | 0 | | 0 | | 1 | 3+ |
| CECUM | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 31 | | 20 | | 42 | | 26 | |
| AUTOLYZED. | 11 | | 8 | | 5 | | 8 | |
| ENTERITIS, PROLIFERATIVE. | 8 | 3+ - 4+ | 6 | 2+ - 4+ | 0 | | 0 | |
| ENTERITIS. | 0 | | 1 | 2+ | 0 | | 0 | |
| CECITIS, CHRONIC. | 0 | | 0 | | 1 | 4+ | 0 | |
| CECITIS. | 0 | | 0 | | 2 | 4+ | 0 | |
| ENTERITIS, HEMORRHAGIC. | 0 | | 0 | | 0 | | 1 | 3+ |
| INTRALUMINAL AUTOLYZED BOLLE. | 0 | | 0 | | 0 | | 1 | |
| COLON | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 38 | | 27 | | 44 | | 26 | |
| AUTOLYZED. | 11 | | 8 | | 5 | | 8 | |
| ADENOMATOUS HYPERPLASIA. | 1 | 3+ | 0 | | 0 | | 0 | |
| ENTERITIS, PROTOZOAN. | 0 | | 0 | | 1 | 4+ | 0 | |
| COLITIS, PROLIFERATIVE. | 0 | | 0 | | 0 | | 1 | 4+ |
| RECTUM | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 39 | | 26 | | 45 | | 26 | |
| AUTOLYZED. | 11 | | 8 | | 5 | | 9 | |
| INTUSSUSCEPTION, CONGESTED, ACUTE. | 0 | | 1 | | 0 | | 0 | |
| MESENTERIC LYMPH NODE | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 21 | | 13 | | 29 | | 18 | |
| NOT PRESENT IN SECTION. | 1 | | 0 | | 0 | | 0 | |
| PLASMACYTOSIS. | 3 | 3+ | 1 | 3+ | 9 | 3+ - 4+ | 5 | 3+ - 4+ |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 1 | | 0 | | 0 | | 0 | |
| AUTOLYZED. | 5 | | 7 | | 7 | | 5 | |
| MISSING. | 16 | | 3 | | 1 | | 3 | |
| LYMPHOID HYPERPLASIA. | 1 | 3+ | 2 | 3+ | 2 | 4+ | 1 | 3+ |
| CONGESTION. | 1 | 4+ | 0 | | 0 | | 0 | |
| (PANCREATIC LYMPH NODE), PLASMACYTOSIS. | 1 | 3+ | 0 | | 0 | | 0 | |
| INTERSTITIAL EPITHELIAL PROLIFERATION. | 0 | | 2 | 3+ - 4+ | 0 | | 0 | |
| RETICULOENDOTHELIAL CELL HYPERPLASIA. | 0 | | 3 | 3+ | 1 | 3+ | 0 | |
| MALIGNANT LYMPHOMA. | 0 | | 2 | | 0 | | 1 | |
| LYMPHADENITIS, SUBACUTE. | 0 | | 1 | 2+ | 0 | | 0 | |
| LYMPHADENITIS. | 0 | | 1 | 1+ | 0 | | 0 | |
| MACROPHAGES, VACUOLATED, (ALL SINUSES). | 0 | | 0 | | 1 | | 0 | |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( MALES )

| | GROUP 3 | GROUP 6 | GROUP 11 | GROUP 14 |
|---|---|---|---|---|
| MESENTERIC LYMPH NODE (continued) | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| PIGMENTATION, INTRACELLULAR. | 0 | 0 | 0 | 1 2+ |
| ERYTHROPHAGOCYTOSIS. | 0 | 0 | 0 | 1 3+ |
| PIGMENTATION. | 0 | 0 | 0 | 1 2+ |
| HEMORRHAGE. | 0 | 0 | 0 | 1 3+ |
| LUNG | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 21 | 16 | 29 | 14 |
| AUTOLYZED. | 3 | 2 | 0 | 0 |
| ATELECTASIS. | 4 3+ | 1 1+ | 3 3+ - 4+ | 4 2+ - 4+ |
| ALVEOLAR/BRONCHIOLAR CELL PROLIFERATION. | 1 1+ | 0 | 1 1+ | 0 |
| HISTIOCYTOSIS, PIGMENTED. | 1 4+ | 0 | 0 | 0 |
| BRONCHOPNEUMONIA. | 4 2+ - 4+ | 3 2+ - 4+ | 3 2+ - 4+ | 2 3+ |
| HISTIOCYTOSIS. | 9 2+ - 4+ | 2 2+ - 3+ | 15 2+ - 4+ | 6 3+ - 4+ |
| ALVEOLAR/BRONCHIOLAR CELL HYPERPLASIA. | 5 1+ - 2+ | 0 | 5 2+ - 3+ | 2 2+ |
| PNEUMONOPATHY. | 7 1+ - 4+ | 6 1+ - 3+ | 0 | 1 3+ |
| MINERALIZATION. | 1 2+ | 0 | 0 | 0 |
| PNEUMONITIS, INTERSTITIAL. | 1 2+ | 1 2+ | 1 4+ | 4 2+ - 3+ |
| SIDEROCYTOSIS. | 1 1+ | 0 | 1 1+ | 0 |
| HEMORRHAGE. | 3 2+ - 3+ | 0 | 2 2+ - 3+ | 1 3+ |
| CALCAREOUS BODY(S). | 1 1+ | 0 | 0 | 0 |
| PNEUMOLITH(S). | 1 2+ | 0 | 0 | 0 |
| EOSINOPHILIC MASS(ES). | 1 1+ | 0 | 0 | 0 |
| FIBROSIS, SUBPLEURAL. | 1 1+ | 0 | 0 | 0 |
| CONGESTION. | 0 | 1 4+ | 1 4+ | 1 3+ |
| MISSING. | 0 | 1 | 0 | 0 |
| PNEUMONITIS, SUBACUTE, PURULENT. | 0 | 1 3+ | 0 | 0 |
| ADENOMATOSIS. | 0 | 3 1+ - 3+ | 1 1+ | 0 |
| LEUKEMIA. | 0 | 2 | 0 | 4 |
| MESENCHYMAL NEOPLASM, UNDIFFERENTIATED. | 0 | 1 3+ | 0 | 0 |
| PIGMENTATION, INTRACELLULAR. | 0 | 0 | 1 1+ | 0 |
| PNEUMONITIS, SUBACUTE. | 0 | 0 | 1 2+ | 0 |
| HEMORRHAGE, ACUTE. | 0 | 0 | 1 3+ | 0 |
| PLASMACYTOSIS. | 0 | 0 | 0 | 1 3+ |
| CARCINOMA, METASTATIC. | 0 | 0 | 0 | 1 |
| THROMBOSIS. | 0 | 0 | 0 | 2 |
| LIVER | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 22 | 15 | 7 | 14 |
| SIDEROPHAGOCYTOSIS. | 12 2+ - 3+ | 5 1+ - 4+ | 16 2+ - 4+ | 6 2+ - 3+ |
| AUTOLYZED. | 6 | 3 | 0 | 0 |
| AMYLOIDOSIS. | 6 1+ - 3+ | 2 2+ - 3+ | 8 1+ - 3+ | 5 2+ - 3+ |
| BILIARY CYST(S). | 3 2+ | 6 | 4 | 3 |
| PIGMENTATION, HEPATOCELLULAR. | 3 1+ - 3+ | 0 | 31 1+ - 3+ | 4 1+ - 2+ |
| SIDEROPHAGOCYTOSIS, CENTRILOBULAR. | 1 2+ | 0 | 0 | 0 |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( MALES )

| | GROUP 3 | GROUP 6 | GROUP 11 | GROUP 14 |
|---|---|---|---|---|
| LIVER (continued) | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| CONGESTION. | 6 2+ - 4+ | 2 3+ - 4+ | 7 3+ - 4+ | 3 3+ - 4+ |
| EXTRAMEDULLARY HEMATOPOIESIS. | 1 1+ | 0 | 2 2+ | 0 |
| CONGESTION, PASSIVE, ACUTE. | 3 3+ - 4+ | 0 | 0 | 0 |
| HEPATOCELLULAR VACUOLATION, PERILOBULAR. | 2 2+ - 3+ | 1 3+ | 1 3+ | 0 |
| HEPATITIS, CHRONIC, MONONUCLEAR, DISSEMINATED. | 1 4+ | 0 | 0 | 0 |
| NECROSIS. | 1 3+ | 1 1+ | 0 | 0 |
| HEPATITIS, SUBACUTE, NECROTIZING. | 1 4+ | 0 | 0 | 0 |
| CONGESTION, PASSIVE, CHRONIC. | 1 4+ | 1 4+ | 1 4+ | 1 3+ |
| TELANGIECTASIS. | 1 4+ | 1 2+ | 0 | 0 |
| HEPATOCELLULAR CLEAR CELL ATYPIA. | 1 2+ | 0 | 0 | 1 3+ |
| AMYLOIDOSIS, LOBULAR. | 0 | 1 3+ | 0 | 0 |
| BILE DUCT REDUPLICATION. | 0 | 1 3+ | 0 | 0 |
| MALIGNANT LYMPHOMA. | 0 | 1 | 0 | 2 |
| LEUKEMIA. | 0 | 1 | 0 | 2 |
| HEPATITIS, MONONUCLEAR, PERILOBULAR. | 0 | 1 3+ | 0 | 0 |
| HEPATITIS, PORTAL, ACTIVE, CHRONIC. | 0 | 1 3+ | 0 | 0 |
| HEPATOCELLULAR VACUOLATION, CENTRILOBULAR. | 0 | 1 4+ | 0 | 0 |
| HEPATITIS, LYMPHOCYTIC, SUBACUTE, PERILOBULAR. | 0 | 0 | 1 3+ | 0 |
| PIGMENTATION, INTRACELLULAR. | 0 | 0 | 2 2+ - 3+ | 1 1+ |
| CYST(S). | 0 | 0 | 1 | 0 |
| HEPATITIS, SUBACUTE, PERILOBULAR. | 0 | 0 | 2 3+ | 0 |
| AMYLOIDOSIS, PORTAL. | 0 | 0 | 2 3+ | 0 |
| KARYOMEGALY. | 0 | 0 | 1 2+ | 0 |
| INTRANUCLEAR INCLUSION BODY(S). | 0 | 0 | 1 | 0 |
| CLEAR CELL FOCUS. | 0 | 0 | 1 | 0 |
| HEPATOCELLULAR VACUOLATION. | 0 | 0 | 2 2+ - 3+ | 3 1+ - 3+ |
| SIDEROCYTOSIS, PORTAL. | 0 | 0 | 1 3+ | 0 |
| EXTRAMEDULLARY HEMATOPOIESIS, PORTAL. | 0 | 0 | 0 | 1 3+ |
| MICROGRANULOMATOSIS. | 0 | 0 | 0 | 1 3+ |
| CARCINOMA, METASTATIC. | 0 | 0 | 0 | 1 |
| HEPATOCELLULAR EOSINOPHILIC NODULE(S). | 0 | 0 | 0 | 1 |
| HEPATOCYTOMEGALY. | 0 | 0 | 0 | 1 1+ |
| (PORTAL AREA), VASCULAR ECTASIA. | 0 | 0 | 0 | 1 3+ |
| HEPATITIS, CHRONIC, MONONUCLEAR, PERILOBULAR. | 0 | 0 | 0 | 1 3+ |
| HEPATOCELLULAR ATYPIA. | 0 | 0 | 0 | 1 |
| INTRANUCLEAR INCLUSION(S), OCCASIONAL. | 0 | 0 | 0 | 1 |
| HEPATITIS, LYMPHOCYTIC, PORTAL. | 0 | 0 | 0 | 1 3+ |
| GALLBLADDER | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 30 | 20 | 34 | 17 |
| AUTOLYZED. | 19 | 15 | 15 | 16 |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( MALES )

| | GROUP 3 | | GROUP 6 | | GROUP 11 | | GROUP 14 | |
|---|---|---|---|---|---|---|---|---|
| GALLBLADDER (continued) | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| CHOLECYSTITIS, ACUTE, PURULENT. | 1 | 4+ | 0 | | 0 | | 0 | |
| MISSING. | 0 | | 0 | | 1 | | 1 | |
| NOT PRESENT IN SECTION. | 0 | | 0 | | 0 | | 1 | |
| SPLEEN | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 24 | | 20 | | 27 | | 18 | |
| PIGMENTATION, INTRACELLULAR. | 1 | 3+ | 0 | | 0 | | 0 | |
| FIBROSIS. | 2 | 3+ - 4+ | 0 | | 1 | 4+ | 0 | |
| AUTOLYZED. | 6 | | 3 | | 2 | | 1 | |
| AMYLOIDOSIS. | 6 | 2+ - 4+ | 4 | 3+ | 10 | 3+ - 4+ | 6 | 2+ - 4+ |
| MISSING. | 3 | | 1 | | 6 | | 1 | |
| CONGESTION. | 1 | 4+ | 0 | | 0 | | 1 | 4+ |
| EXTRAMEDULLARY HEMATOPOIESIS. | 6 | 2+ - 4+ | 2 | 4+ | 4 | 2+ - 3+ | 4 | 2+ - 4+ |
| (WHITE PULP), HEMOSIDEROSIS. | 1 | 3+ | 0 | | 0 | | 0 | |
| RETICULOENDOTHELIAL CELL HYPERPLASIA. | 1 | 3+ | 0 | | 0 | | 0 | |
| CAVERNOUS HEMANGIOMA. | 0 | | 1 | | 0 | | 0 | |
| HYPERPLASIA. | 0 | | 1 | 3+ | 2 | 3+ | 1 | 3+ |
| (WHITE PULP), SIDEROCYTOSIS. | 0 | | 1 | 3+ | 0 | | 1 | 2+ |
| MALIGNANT LYMPHOMA. | 0 | | 2 | | 0 | | 4 | |
| LYMPHOID HYPOPLASIA. | 0 | | 0 | | 1 | 4+ | 0 | |
| LEUKEMIA. | 0 | | 0 | | 0 | | 1 | |
| PANCREAS | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 39 | | 27 | | 37 | | 27 | |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 1 | | 0 | | 0 | | 0 | |
| DUCTAL ECTASIA. | 1 | 2+ | 1 | 3+ | 1 | 2+ | 1 | 4+ |
| AUTOLYZED. | 4 | | 7 | | 7 | | 3 | |
| MISSING. | 2 | | 0 | | 2 | | 1 | |
| ISLET CELL HYPERPLASIA. | 1 | 2+ | 0 | | 0 | | 1 | |
| HEPATOCELLULAR DIFFERENTIATION. | 1 | | 0 | | 0 | | 1 | 2+ |
| ACINAR CELL ATROPHY. | 1 | 2+ | 0 | | 0 | | 0 | |
| DUCTAL HYPERPLASIA. | 0 | | 1 | 3+ | 0 | | 1 | 2+ |
| FIBROSIS. | 0 | | 0 | | 1 | 3+ | 0 | |
| ACINAR CELL HYPERTROPHY. | 0 | | 0 | | 3 | 2+ | 1 | 2+ |
| EOSINOPHILIA. | 0 | | 0 | | 2 | 3+ - 4+ | 0 | |
| MALIGNANT LYMPHOMA. | 0 | | 0 | | 0 | | 1 | |
| KIDNEY | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 10 | | 11 | | 17 | | 4 | |
| GLOMERULAR NEPHROSIS. | 23 | 1+ - 4+ | 13 | 2+ - 4+ | 16 | 1+ - 4+ | 17 | 2+ - 4+ |
| AMYLOIDOSIS. | 14 | 3+ - 4+ | 6 | 2+ - 4+ | 15 | 3+ - 4+ | 10 | 1+ - 4+ |
| NEPHROLITHIASIS. | 12 | 1+ - 3+ | 6 | 2+ | 7 | 2+ - 3+ | 10 | 1+ - 2+ |
| MINERALIZATION. | 2 | 2+ - 3+ | 0 | | 2 | 2+ | 2 | 2+ |
| NEPHROSIS. | 3 | 2+ | 0 | | 0 | | 2 | 2+ - 4+ |
| (PROXIMAL TUBULES), TUBULAR NEPHROSIS. | 1 | 3+ | 0 | | 0 | | 0 | |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( MALES )

| | GROUP 3 | GROUP 6 | GROUP 11 | GROUP 14 |
|---|---|---|---|---|
| KIDNEY (continued) | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NEPHRITIS, ACUTE, PURULENT. | 2 2+ - 4+ | 0 | 1 4+ | 0 |
| (CORTEX), PIGMENTATION, INTRATUBULAR. | 1 2+ | 0 | 0 | 0 |
| AUTOLYZED. | 0 | 3 | 0 | 1 |
| NEPHRITIS, CHRONIC, INTERSTITIAL. | 0 | 1 1+ | 0 | 0 |
| NEPHROCALCINOSIS. | 0 | 1 2+ | 0 | 0 |
| ATROPHY. | 0 | 2 2+ - 4+ | 0 | 0 |
| HYDRONEPHROSIS. | 0 | 1 | 0 | 0 |
| MINERALIZATION, MEDULLA. | 0 | 1 4+ | 0 | 0 |
| CORTICAL CYST(S). | 0 | 0 | 1 | 0 |
| (PELVIC EPITHELIUM), BALOON DEGENERATION. | 0 | 0 | 1 3+ | 0 |
| MALIGNANT LYMPHOMA. | 0 | 0 | 0 | 1 |
| NEPHRITIS, INTERSTITIAL, CHRONIC. | 0 | 0 | 0 | 1 3+ |
| (PROXIMAL TUBULES), NECROSIS. | 0 | 0 | 0 | 2 3+ |
| HEART | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 35 | 29 | 36 | 23 |
| FIBROSIS. | 2 3+ | 1 3+ | 0 | 0 |
| AUTOLYZED. | 2 | 2 | 0 | 1 |
| MURAL THROMBUS. | 1 | 0 | 1 | 1 |
| ATRIAL THROMBOSIS. | 9 | 3 | 12 | 4 |
| MINERALIZATION. | 1 2+ | 0 | 0 | 0 |
| MYOCARDIAL MINERALIZATION. | 1 4+ | 0 | 0 | 1 3+ |
| MYOCARDIAL FIBROSIS. | 0 | 0 | 2 2+ | 0 |
| MALIGNANT LYMPHOMA. | 0 | 0 | 0 | 1 |
| ATRIAL SEPTIC THROMBOSIS. | 0 | 0 | 0 | 1 |
| MUSCULAR DYSTROPHY. | 0 | 0 | 0 | 2 3+ - 4+ |
| (CORONARY ARTERY), MEDIAL CALCIFICATION. | 0 | 0 | 0 | 1 |
| (CORONARY VESSEL), PERIARTERITIS, CHRONIC. | 0 | 0 | 0 | 1 |
| (CORONARY ARTERIES AND AORTA), MEDIAL CALCIFICATION. | 0 | 0 | 0 | 1 |
| URINARY BLADDER | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 36 | 27 | 47 | 26 |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 3 | 0 | 0 | 3 |
| AUTOLYZED. | 9 | 4 | 3 | 5 |
| MISSING. | 1 | 1 | 0 | 1 |
| CYSTITIS, ACUTE, PURULENT. | 1 4+ | 0 | 0 | 0 |
| MINERALIZATION, INTRAMURAL. | 0 | 1 3+ | 0 | 0 |
| CYSTITIS, CHRONIC. | 0 | 1 4+ | 0 | 0 |
| MINERALIZATION. | 0 | 1 3+ | 0 | 0 |
| MINERALIZATION, LAMINA PROPRIA. | 0 | 1 | 0 | 0 |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( MALES )

| | GROUP 3 | | GROUP 6 | | GROUP 11 | | GROUP 14 | |
|---|---|---|---|---|---|---|---|---|
| SEMINAL VESICLE | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 42 | | 31 | | 47 | | 31 | |
| AUTOLYZED. | 7 | | 4 | | 3 | | 4 | |
| VESICULITIS, ACUTE, PURULENT. | 1 | 4+ | 0 | | 0 | | 0 | |
| PROSTATE | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 37 | | 25 | | 43 | | 28 | |
| NOT PRESENT IN SECTION. | 4 | | 0 | | 0 | | 2 | |
| AUTOLYZED. | 5 | | 4 | | 3 | | 3 | |
| PROSTATITIS, ACUTE, PURULENT. | 1 | 4+ | 1 | 4+ | 0 | | 1 | 4+ |
| MISSING. | 2 | | 2 | | 4 | | 1 | |
| MICROLITHIASIS. | 1 | 1+ | 0 | | 0 | | 0 | |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 0 | | 1 | | 0 | | 0 | |
| MALIGNANT LYMPHOMA. | 0 | | 1 | | 0 | | 0 | |
| ADENOMATOUS HYPERPLASIA. | 0 | | 1 | 3+ | 0 | | 0 | |
| FIBROSIS. | 0 | | 1 | 4+ | 0 | | 0 | |
| TESTIS | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 31 | | 26 | | 37 | | 26 | |
| FIBROSIS. | 1 | 2+ | 0 | | 0 | | 0 | |
| AUTOLYZED. | 7 | | 2 | | 3 | | 2 | |
| MISSING. | 1 | | 0 | | 0 | | 0 | |
| OLIGOSPERMIA. | 10 | | 5 | 3+ | 7 | | 6 | |
| MINERALIZATION, INTRATUBULAR. | 0 | | 1 | 1+ | 0 | | 0 | |
| GIANT CELL(S), (SEMINIFEROUS TUBULES), | 1 | | 1 | | 0 | | 0 | |
| PAPILLARY HYPERPLASIA. | 0 | | 0 | | 1 | 1+ | 0 | |
| (SEMINIFEROUS TUBULES), GIANT CELL(S). | 0 | | 0 | | 3 | 3+ - 4+ | 0 | |
| ATROPHY. | 0 | | 0 | | 0 | | 1 | |
| GIANT CELL(S), MULTINUCLEATED, OCCASIONAL. | 0 | | 0 | | 0 | | 1 | |
| CEREBRUM | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 47 | | 31 | | 48 | | 33 | |
| AUTOLYZED. | 3 | | 3 | | 1 | | 2 | |
| (CEREBRAL CAPILLARIES), MINERALIZATION. | 0 | | 1 | 3+ | 0 | | 0 | |
| MINERALIZATION. | 0 | | 0 | | 1 | 2+ | 0 | |
| CEREBELLUM | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 47 | | 32 | | 49 | | 33 | |
| AUTOLYZED. | 3 | | 3 | | 1 | | 2 | |
| PITUITARY | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 17 | | 12 | | 13 | | 16 | |
| AUTOLYZED. | 2 | | 2 | | 0 | | 0 | |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( MALES )

| | GROUP 3 | GROUP 6 | GROUP 11 | GROUP 14 |
|---|---|---|---|---|
| PITUITARY (continued) | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| MISSING. | 30 | 19 | 33 | 19 |
| CYST(S). | 1 | 0 | 0 | 0 |
| NOT PRESENT IN SECTION. | 0 | 1 | 0 | 0 |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 0 | 1 | 4 | 0 |
| STERNABRAE | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 48 | 32 | 50 | 34 |
| AUTOLYZED. | 2 | 2 | 0 | 1 |
| (INTERCOSTAL MUSCLES), MUSCULAR DYSTROPHY. | 0 | 1 4+ | 0 | 0 |
| FEMUR | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 47 | 33 | 50 | 34 |
| AUTOLYZED. | 3 | 2 | 0 | 1 |
| BONE MARROW | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 46 | 31 | 45 | 29 |
| AUTOLYZED. | 3 | 2 | 2 | 0 |
| HYPERPLASIA. | 1 | 1 3+ | 0 | 0 |
| MALIGNANT LYMPHOMA. | 0 | 1 | 0 | 5 |
| HYPOPLASIA. | 0 | 0 | 3 3+ - 4+ | 0 |
| MYELOID HYPERPLASIA. | 0 | 0 | 0 | 1 3+ |
| NASAL CAVITY | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 47 | 33 | 50 | 34 |
| AUTOLYZED. | 2 | 2 | 0 | 0 |
| RHINITIS, ACUTE, PURULENT. | 1 4+ | 0 | 0 | 0 |
| MISSING. | 0 | 0 | 0 | 1 |
| OTHER | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NOT REQUIRED. | 40 | 30 | 46 | 26 |
| (ALL TISSUES SEVERELY AUTOLYZED). | 2 | 3 | 0 | 1 |
| (ALL TISSUES MODERATELY AUTOLYZED). | 7 | 0 | 0 | 5 |
| (ALL TISSUES MODERATE TO SEVERELY AUTOLYZED). | 1 | 0 | 3 | 1 |
| (ABDOMINAL CAVITY), MESOTHELIOMA. | 0 | 1 | 0 | 0 |
| (MASS-LEG), MESENCHYMAL TUMOR, UNDIFFERENTIATED. | 0 | 1 | 0 | 0 |
| (MASS-EXTREMITIES), MALIGNANT LYMPHOMA. | 0 | 1 | 0 | 0 |
| (MASS-GENITAL FAT PAD), NO SIGNIFICANT LESIONS RECOGNIZED. | 0 | 0 | 1 | 0 |
| (MASS-ABDOMEN), ABCESS(ES), LARGE. | 0 | 0 | 0 | 1 |
| (ALL TISSUES SLIGHTLY AUTOLYZED). | 0 | 0 | 0 | 1 |
| (AXILLARY LYMPH NODE), MALIGNANT LYMPHOMA. | 0 | 0 | 0 | 1 |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( FEMALES )

| | GROUP 3 | GROUP 6 | GROUP 11 | GROUP 14 |
|---|---|---|---|---|
| SKIN | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| ACARIASIS. | 1 3+ | 0 | 1 | 0 |
| EDEMA, SUBCUTANEOUS. | 16 3+ - 4+ | 7 3+ - 4+ | 9 3+ - 4+ | 2 4+ |
| NO SIGNIFICANT LESION RECOGNIZED. | 31 | 24 | 35 | 29 |
| AMYLOIDOSIS. | 1 4+ | 0 | 0 | 0 |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 1 | 0 | 0 | 0 |
| AUTOLYZED. | 0 | 2 | 0 | 0 |
| MISSING. | 0 | 1 | 0 | 0 |
| (SUBCUTANEOUS MUSCLE), MUSCULAR DYSTROPHY. | 2 3+ | 1 3+ | 3 2+ - 3+ | 1 3+ |
| DERMATITIS, CHRONIC, NONSUPPURATIVE. | 0 | 0 | 1 2+ | 0 |
| PLASMA CELL SARCOMA. | 0 | 0 | 1 | 0 |
| NOT PRESENT IN SECTION. | 0 | 0 | 0 | 1 |
| (SUBCUTANEOUS MUSCLE), MYOSITIS, CHRONIC, NONSUPPURATIVE. | 0 | 0 | 0 | 1 |
| MASTOCYTOSIS. | 0 | 0 | 0 | 1 |
| (FOOT), DERMATITIS, CHRONIC. | 0 | 0 | 0 | 1 4+ |
| MAMMARY GLAND | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NOT PRESENT IN SECTION. | 41 | 31 | 49 | 31 |
| NO SIGNIFICANT LESION RECOGNIZED. | 8 | 2 | 1 | 3 |
| AUTOLYZED. | 1 | 0 | 0 | 0 |
| MISSING. | 0 | 1 | 0 | 0 |
| FIBROSIS, INTERALVEOLAR. | 0 | 1 3+ | 0 | 0 |
| ACTIVE. | 0 | 0 | 0 | 1 |
| MUSCLE | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 42 | 25 | 47 | 32 |
| AUTOLYZED. | 1 | 0 | 0 | 0 |
| MUSCULAR DYSTROPHY. | 6 1+ - 3+ | 4 2+ - 3+ | 3 1+ - 2+ | 2 1+ - 3+ |
| PERIARTERITIS. | 1 3+ | 6 1+ - 4+ | 0 | 0 |
| PERIARTERITIS, CHRONIC. | 0 | 0 | 0 | 1 1+ |
| SALIVARY GLAND | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 47 | 34 | 50 | 33 |
| AUTOLYZED. | 1 | 0 | 0 | 1 |
| MISSING. | 1 | 1 | 0 | 0 |
| MONONUCLEAR CELL INFILTRATE, PERIDUCTAL. | 1 4+ | 0 | 0 | 0 |
| ADENOMATOUS HYPERPLASIA. | 0 | 0 | 0 | 1 3+ |
| MANDIBULAR LYMPH NODE | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 34 | 24 | 12 | 8 |
| AMYLOIDOSIS. | 2 2+ - 3+ | 1 1+ | 0 | 0 |
| AUTOLYZED. | 2 | 1 | 0 | 2 |
| MISSING. | 4 | 3 | 4 | 1 |

| | GROUP 3 | GROUP 6 | GROUP 11 | GROUP 14 |
|---|---|---|---|---|
| MANDIBULAR LYMPH NODE (continued) | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| CONGESTION. | 1 4+ | 0 | 0 | 1 3+ |
| EXTRAMEDULLARY HEMATOPOIESIS. | 1 1+ | 0 | 0 | 0 |
| MALIGNANT LYMPHOMA. | 1 | 1 | 0 | 1 |
| PLASMACYTOSIS. | 7 2+ - 4+ | 4 2+ - 3+ | 31 2+ - 4+ | 17 2+ - 4+ |
| HISTIOCYTOSIS, PIGMENTED. | 1 2+ | 0 | 0 | 0 |
| PLASMA CELL HYPERPLASIA. | 1 3+ | 0 | 1 4+ | 0 |
| MOTT CELL(S), NUMEROUS. | 1 | 0 | 0 | 0 |
| LYMPHOID HYPERPLASIA. | 0 | 1 4+ | 3 3+ | 0 |
| ERYTHROPHAGOCYTOSIS. | 0 | 2 3+ | 0 | 0 |
| PIGMENTATION, INTRACELLULAR. | 0 | 0 | 1 3+ | 0 |
| HYPERPLASIA. | 0 | 0 | 1 3+ | 0 |
| HEMOSIDEROSIS. | 0 | 0 | 1 2+ | 1 3+ |
| MOTT CELL(S), OCCASIONAL. | 0 | 0 | 1 | 0 |
| PLASMA CELL SARCOMA. | 0 | 0 | 1 | 0 |
| PLASMACYTOSIS, (WITH MULTINUCLEATED FORMS). | 0 | 0 | 0 | 1 3+ |
| SIDEROCYTOSIS. | 0 | 0 | 0 | 1 2+ |
| RETICULOENDOTHELIAL CELL HYPERPLASIA. | 0 | 0 | 0 | 1 3+ |
| NECROSIS. | 0 | 0 | 0 | 1 4+ |
| AMYLOIDOSIS, INTRACELLULAR. | 0 | 0 | 0 | 2 2+ - 3+ |
| LYMPHOID NODULAR HYPERPLASIA. | 0 | 0 | 0 | 1 3+ |
| SCIATIC NERVE | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NOT PRESENT IN SECTION. | 1 | 0 | 0 | 0 |
| NO SIGNIFICANT LESION RECOGNIZED. | 36 | 32 | 45 | 33 |
| AUTOLYZED. | 1 | 0 | 0 | 0 |
| MISSING. | 11 | 2 | 2 | 0 |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 1 | 1 | 3 | 1 |
| PERINEURITIS, PLASMACYTIC. | 0 | 0 | 0 | 1 1+ |
| THYMUS | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NOT PRESENT IN SECTION. | 17 | 8 | 23 | 15 |
| NO SIGNIFICANT LESION RECOGNIZED. | 23 | 16 | 18 | 10 |
| AMYLOIDOSIS. | 2 3+ - 4+ | 2 1+ - 3+ | 0 | 0 |
| AUTOLYZED. | 1 | 1 | 0 | 0 |
| MISSING. | 3 | 1 | 2 | 0 |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 1 | 3 | 1 | 1 |
| (THYROID ORIGIN), CYST(S), MULTINUCLEATED. | 1 | 0 | 0 | 0 |
| MALIGNANT LYMPHOMA. | 1 | 1 | 0 | 0 |
| ATROPHY. | 1 | 0 | 0 | 3 4+ |
| CYST(S). | 0 | 1 | 0 | 0 |
| MASTOCYTOSIS. | 0 | 2 3+ | 4 2+ - 3+ | 4 2+ - 3+ |
| INVOLUTION. | 0 | 0 | 3 | 2 |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( FEMALES )

| | GROUP 3 | GROUP 6 | GROUP 11 | GROUP 14 |
|---|---|---|---|---|
| THYMUS (continued) | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| RETICULOENDOTHELIAL CELL HYPERPLASIA. | 0 | 0 | 0 | 1 3+ |
| CYST(S), MULTILOCULATED. | 0 | 0 | 0 | 2 |
| RUSSELL BODY(S). | 0 | 0 | 0 | 2 1+ - 3+ |
| LARYNX | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 49 | 33 | 49 | 35 |
| AUTOLYZED. | 1 | 0 | 0 | 0 |
| MALIGNANT LYMPHOMA. | 0 | 1 | 0 | 0 |
| EPITHELIAL CYST(S), SUBMUCOSA. | 0 | 1 | 0 | 0 |
| MISSING. | 0 | 0 | 1 | 0 |
| THYROID | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 17 | 11 | 11 | 10 |
| AMYLOIDOSIS. | 29 2+ - 4+ | 18 1+ - 4+ | 30 2+ - 4+ | 22 2+ - 4+ |
| AUTOLYZED. | 2 | 1 | 0 | 0 |
| INSUFFICIENT TISSUE | | | | |
| PRESENT IN SECTION. | 1 | 0 | 2 | 1 |
| FOLLICULAR CELL ADENOMA. | 1 | 0 | 0 | 0 |
| FOLLICULAR CYST(S). | 1 3+ | 0 | 7 2+ - 3+ | 2 2+ - 3+ |
| NOT PRESENT IN SECTION. | 0 | 3 | 3 | 0 |
| FOLLICULAR CELL HYPERPLASIA. | 0 | 1 2+ | 0 | 0 |
| THYROIDITIS, ACTIVE, CHRONIC. | 0 | 1 3+ | 0 | 0 |
| THYROIDITIS. | 0 | 1 2+ | 0 | 0 |
| FOLLICULAR CELL PAPILLARY ADENOMA. | 0 | 0 | 1 | 0 |
| C-CELL ADENOMA. | 0 | 0 | 0 | 1 |
| PARATHYROID | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NOT PRESENT IN SECTION. | 16 | 15 | 25 | 19 |
| NO SIGNIFICANT LESION RECOGNIZED. | 28 | 15 | 22 | 15 |
| AUTOLYZED. | 4 | 1 | 0 | 0 |
| INSUFFICIENT TISSUE | | | | |
| PRESENT IN SECTION. | 2 | 3 | 2 | 0 |
| AMYLOIDOSIS. | 0 | 1 2+ | 0 | 0 |
| CYST(S). | 0 | 0 | 1 | 0 |
| HYPERPLASIA. | 0 | 0 | 0 | 1 |
| TRACHEA | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 47 | 34 | 50 | 35 |
| AUTOLYZED. | 2 | 0 | 0 | 0 |
| INTRALUMENAL PURULENT EXUDATE. | 1 | 0 | 0 | 0 |
| INSUFFICIENT TISSUE | | | | |
| PRESENT IN SECTION. | 0 | 1 | 0 | 0 |
| BRONCHUS | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NOT PRESENT IN SECTION. | 1 | 0 | 0 | 0 |
| NO SIGNIFICANT LESION RECOGNIZED. | 43 | 30 | 48 | 32 |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( FEMALES )

| | GROUP 3 | | GROUP 6 | | GROUP 11 | | GROUP 14 | |
|---|---|---|---|---|---|---|---|---|
| BRONCHUS (continued) | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| AUTOLYZED. | 2 | | 0 | | 0 | | 0 | |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 4 | | 5 | | 2 | | 3 | |
| ESOPHAGUS | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 48 | | 35 | | 50 | | 33 | |
| AUTOLYZED. | 2 | | 0 | | 0 | | 0 | |
| AMYLOIDOSIS. | 0 | | 0 | | 0 | | 2 | 3+ |
| ADRENAL | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 8 | | 10 | | 6 | | 10 | |
| AMYLOIDOSIS. | 31 | 2+ - 4+ | 20 | 2+ - 4+ | 32 | 2+ - 4+ | 19 | 2+ - 4+ |
| SIDEROPHAGOCYTOSIS. | 1 | | 0 | | 0 | | 0 | |
| AUTOLYZED. | 2 | | 1 | | 1 | | 0 | |
| MISSING. | 2 | | 0 | | 1 | | 1 | |
| CORTICAL NODULAR HYPERPLASIA. | 6 | | 2 | | 11 | | 8 | |
| MALIGNANT LYMPHOMA. | 1 | | 0 | | 0 | | 0 | |
| CORTICAL CELL ADENOMA. | 5 | | 4 | | 6 | | 4 | |
| HEMATOCYST(S). | 3 | | 1 | | 2 | | 0 | |
| CYST(S). | 0 | | 1 | | 3 | | 0 | |
| (MASS), ADRENAL CORTICAL ADENOCARCINOMA. | 0 | | 0 | | 1 | | 0 | |
| PIGMENTATION, INTRACELLULAR. | 0 | | 0 | | 5 | 2+ - 3+ | 2 | 1+ - 2+ |
| HEMORRHAGE. | 0 | | 0 | | 1 | 3+ | 1 | 3+ |
| CORTICAL CYST(S). | 0 | | 0 | | 1 | | 0 | |
| CARCINOMA. | 0 | | 0 | | 1 | | 0 | |
| CORTICAL CELL CARCINOMA. | 0 | | 0 | | 1 | | 0 | |
| HEMATOCYST(S), CORTICAL. | 0 | | 0 | | 1 | | 0 | |
| PHEOCHROMOCYTOMA. | 0 | | 0 | | 1 | | 0 | |
| CHROMATOCYST(S). | 0 | | 0 | | 1 | | 0 | |
| B-CELL PROLIFERATION. | 0 | | 0 | | 0 | | 1 | |
| CONGESTION. | 0 | | 0 | | 0 | | 1 | 4+ |
| EXTRACORTICAL NODULAR HYPERPLASIA. | 0 | | 0 | | 0 | | 1 | |
| (GLANDULAR), PIGMENTATION, (BLACK). | 0 | | 0 | | 0 | | 1 | |
| STOMACH | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 26 | | 22 | | 35 | | 24 | |
| AUTOLYZED. | 19 | | 11 | | 13 | | 10 | |
| (FORESTOMACH), PAPILLOMA. | 1 | | 0 | | 0 | | 0 | |
| HYPERKERATOSIS. | 2 | 3+ | 0 | | 0 | | 0 | |
| (FORESTOMACH), GASTRITIS, SUBACUTE. | 1 | 3+ | 0 | | 0 | | 0 | |
| GASTRITIS. | 1 | | 1 | 1+ | 0 | | 0 | |
| PAPILLARY HYPERPLASIA. | 1 | 3+ | 0 | | 0 | | 0 | |
| (GLANDULAR STOMACH), PIGMENTATION, (BLACK). | 1 | | 0 | | 0 | | 0 | |
| AMYLOIDOSIS. | 0 | | 1 | 1+ | 0 | | 0 | |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( FEMALES )

| | GROUP 3 | | GROUP 6 | | GROUP 11 | | GROUP 14 | |
|---|---|---|---|---|---|---|---|---|
| STOMACH (continued) | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NECROSIS. | 0 | | 1 | 3+ | 0 | | 0 | |
| (FORESTOMACH), GASTRITIS, NECROTIZING. | 0 | | 0 | | 1 | 4+ | 0 | |
| GASTRITIS, SUBACUTE. | 0 | | 0 | | 1 | 3+ | 0 | |
| (FORESTOMACH), HYPERPLASIA. | 0 | | 0 | | 1 | 3+ | 0 | |
| (FORESTOMACH), HYPERKERATOSIS. | 0 | | 0 | | 1 | 3+ | 0 | |
| (FORESTOMACH), MINERALIZATION. | 0 | | 0 | | 0 | | 1 | 1+ |
| DUODENUM | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 27 | | 23 | | 38 | | 24 | |
| AUTOLYZED. | 22 | | 12 | | 12 | | 10 | |
| ENTERITIS, PURULENT. | 1 | 3+ | 0 | | 0 | | 0 | |
| AMYLOIDOSIS. | 0 | | 0 | | 0 | | 1 | 2+ |
| JEJUNUM | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 28 | | 23 | | 38 | | 24 | |
| AUTOLYZED. | 22 | | 12 | | 12 | | 10 | |
| AMYLOIDOSIS. | 0 | | 0 | | 0 | | 1 | 2+ |
| ILEUM | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 27 | | 22 | | 29 | | 21 | |
| AUTOLYZED. | 22 | | 12 | | 12 | | 10 | |
| ILEITIS, PROLIFERATIVE. | 1 | 2+ | 0 | | 5 | 3+ - 4+ | 3 | 3+ - 4+ |
| POLYP(S). | 0 | | 1 | | 0 | | 0 | |
| ILEITIS. | 0 | | 0 | | 2 | 2+ - 4+ | 0 | |
| ENTERITIS. | 0 | | 0 | | 1 | 1+ | 0 | |
| ENTERITIS, PROLIFERATIVE. | 0 | | 0 | | 1 | 3+ | 0 | |
| AMYLOIDOSIS. | 0 | | 0 | | 0 | | 1 | 2+ |
| CECUM | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 21 | | 20 | | 35 | | 23 | |
| AUTOLYZED. | 24 | | 12 | | 12 | | 11 | |
| ENTERITIS, PROLIFERATIVE. | 3 | 2+ - 4+ | 3 | 3+ - 4+ | 1 | 3+ | 0 | |
| CECITIS. | 1 | 3+ | 0 | | 0 | | 0 | |
| CECITIS, PROLIFERATIVE. | 1 | 4+ | 0 | | 0 | | 0 | |
| ENTERITIS. | 0 | | 0 | | 2 | 1+ - 4+ | 0 | |
| (LUMEN), AUTOLYZED BLOOD. | 0 | | 0 | | 0 | | 1 | |
| COLON | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 27 | | 22 | | 37 | | 23 | |
| AUTOLYZED. | 23 | | 12 | | 12 | | 11 | |
| ADENOMATOUS HYPERPLASIA. | 0 | | 1 | 3+ | 0 | | 0 | |
| (LUMEN), PROTOZOA. | 0 | | 0 | | 1 | | 0 | |
| ENTERITIS, PROLIFERATIVE. | 0 | | 0 | | 0 | | 1 | 4+ |
| RECTUM | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 27 | | 23 | | 38 | | 23 | |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( FEMALES )

| | GROUP 3 | | GROUP 6 | | GROUP 11 | | GROUP 14 | |
|---|---|---|---|---|---|---|---|---|
| RECTUM (continued) | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| AUTOLYZED. | 23 | | 12 | | 12 | | 11 | |
| INTUSSCEPTION. | 0 | | 0 | | 0 | | 1 | |
| PROCTITIS, ACUTE, NECROPURULENT. | 0 | | 0 | | 0 | | 1 | 4+ |
| MESENTERIC LYMPH NODE | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NOT PRESENT IN SECTION. | 1 | | 0 | | 0 | | 0 | |
| NO SIGNIFICANT LESION RECOGNIZED. | 21 | | 21 | | 16 | | 14 | |
| AUTOLYZED. | 14 | | 8 | | 8 | | 8 | |
| MISSING. | 8 | | 3 | | 3 | | 4 | |
| MALIGNANT LYMPHOMA. | 1 | | 1 | | 1 | | 1 | |
| PLASMACYTOSIS. | 2 | 3+ | 0 | | 14 | 2+ - 3+ | 6 | 3+ |
| MOTT CELL(S) CONTAINING RUSSELL'S BODIES, OCCASIONAL. | 1 | | 0 | | 0 | | 0 | |
| LYMPHOID HYPERPLASIA. | 2 | 3+ | 0 | | 4 | 3+ - 4+ | 0 | |
| MOTT CELL(S), OCCASIONAL. | 1 | | 0 | | 1 | | 0 | |
| PLASMACYTOMA. | 1 | | 0 | | 0 | | 0 | |
| RETICULOENDOTHELIAL CELL HYPERPLASIA. | 0 | | 2 | 2+ - 3+ | 0 | | 0 | |
| AMYLOIDOSIS. | 0 | | 0 | | 1 | 2+ | 0 | |
| CONGESTION. | 0 | | 0 | | 1 | 3+ | 0 | |
| PIGMENTATION, INTRACELLULAR. | 0 | | 0 | | 3 | 2+ - 3+ | 1 | 3+ |
| HYPERPLASIA. | 0 | | 0 | | 2 | 3+ - 4+ | 0 | |
| LYMPHADENITIS, PURULENT. | 0 | | 0 | | 1 | 4+ | 0 | |
| PLASMA CELL SARCOMA. | 0 | | 0 | | 1 | | 0 | |
| HISTIOCYTOSIS. | 0 | | 0 | | 0 | | 1 | 3+ |
| AMYLOIDOSIS, INTRACELLULAR. | 0 | | 0 | | 0 | | 1 | 3+ |
| ADENOMATOSIS, INTESTINAL EPITHELIUM. | 0 | | 0 | | 0 | | 1 | |
| LUNG | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 9 | | 11 | | 13 | | 12 | |
| HISTIOCYTOSIS. | 6 | 3+ - 4+ | 4 | 3+ - 4+ | 19 | 2+ - 4+ | 16 | 2+ - 4+ |
| AUTOLYZED. | 4 | | 0 | | 1 | | 0 | |
| PNEUMONOPATHY. | 19 | 1+ - 4+ | 4 | 2+ - 3+ | 0 | | 0 | |
| PNEUMONITIS, INTERSTITIAL. | 4 | 1+ - 4+ | 2 | 2+ - 4+ | 5 | 2+ - 4+ | 2 | 3+ - 4+ |
| LEUKEMIA. | 3 | | 0 | | 1 | | 0 | |
| HEMORRHAGE. | 2 | 2+ - 3+ | 1 | 1+ | 3 | 2+ - 4+ | 1 | 1+ |
| HISTIOCYTOSIS, PIGMENTED. | 1 | 2+ | 0 | | 0 | | 0 | |
| ALVEOLAR/BRONCHIOLAR CELL HYPERPLASIA. | 2 | 2+ | 0 | | 3 | 1+ - 3+ | 2 | 2+ - 3+ |
| ATELECTASIS. | 2 | 2+ - 3+ | 0 | | 4 | 2+ - 4+ | 3 | 2+ - 3+ |
| BRONCHIOLAR PNEUMONIA. | 1 | 4+ | 0 | | 0 | | 0 | |
| BRONCHOPNEUMONIA, ACUTE. | 1 | 4+ | 0 | | 0 | | 0 | |
| PNEUMOLITHIASIS. | 2 | 2+ | 0 | | 0 | | 1 | 2+ |
| ADENOCARCINOMA, METASTATIC. | 1 | | 0 | | 1 | 4+ | 0 | |
| AMYLOIDOSIS. | 0 | | 6 | 1+ - 4+ | 0 | | 0 | |
| MALIGNANT LYMPHOMA. | 0 | | 1 | | 0 | | 0 | |
| MUCINOUS ADENOCARCINOMA, PRIMARY UNDETERMINED. | 0 | | 1 | | 0 | | 0 | |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( FEMALES )

| | GROUP 3 | GROUP 6 | GROUP 11 | GROUP 14 |
|---|---|---|---|---|
| LUNG (continued) | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| BRONCHOPNEUMONIA. | 0 | 7 3+ - 4+ | 4 2+ - 4+ | 2 3+ - 4+ |
| SIDEROCYTOSIS. | 0 | 1 3+ | 0 | 0 |
| PNEUMONITIS. | 0 | 2 3+ - 4+ | 0 | 1 |
| SIDEROCYTOSIS, PERIBRONCHIOLAR. | 0 | 1 2+ | 0 | 0 |
| CONGESTION. | 0 | 0 | 1 4+ | 1 1+ |
| BRONCHOPNEUMONIA, SUBACUTE. | 0 | 0 | 1 3+ | 0 |
| FIBROSIS. | 0 | 0 | 1 3+ | 0 |
| CARCINOMA, METASTATIC. | 0 | 0 | 1 3+ | 0 |
| BRONCHOPNEUMONIA, CHRONIC. | 0 | 0 | 1 2+ | 1 4+ |
| PLASMA CELL SARCOMA. | 0 | 0 | 1 | 0 |
| OSSEOUS METAPLASIA. | 0 | 0 | 1 1+ | 0 |
| ALVEOLAR/BRONCHIOLAR CELL PROLIFERATION. | 0 | 0 | 1 3+ | 2 2+ |
| ADENOMATOSIS. | 0 | 0 | 1 2+ | 1 2+ |
| BRONCHOPNEUMONIA, ACTIVE, CHRONIC. | 0 | 0 | 1 4+ | 0 |
| BRONCHITIS, ACUTE, PURULENT. | 0 | 0 | 1 3+ | 1 3+ |
| PNEUMONITIS, ACUTE, PURULENT. | 0 | 0 | 0 | 2 3+ - 4+ |
| SQUAMOUS CELL METAPLASIA. | 0 | 0 | 0 | 1 2+ |
| ERYTHROPHAGOCYTOSIS. | 0 | 0 | 0 | 1 1+ |
| EMBOLISM(S). | 0 | 0 | 0 | 1 |
| LIVER | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 4 | 2 | 1 | 3 |
| AMYLOIDOSIS. | 35 1+ - 4+ | 17 1+ - 4+ | 36 1+ - 4+ | 24 2+ - 4+ |
| SIDEROPHAGOCYTOSIS. | 9 1+ - 3+ | 6 2+ - 3+ | 34 1+ - 3+ | 15 1+ - 3+ |
| BILIARY CYST(S). | 9 | 3 | 16 | 7 |
| AUTOLYZED. | 5 | 4 | 2 | 3 |
| HEPATOCELLULAR VACUOLATION, PERILOBULAR. | 7 3+ | 0 | 1 2+ | 1 2+ |
| CONGESTION. | 5 2+ - 4+ | 9 3+ - 4+ | 13 3+ - 4+ | 3 3+ - 4+ |
| CYST(S). | 1 | 6 | 0 | 0 |
| MALIGNANT LYMPHOMA. | 1 | 0 | 0 | 1 |
| SIDEROCYTOSIS. | 1 3+ | 0 | 0 | 0 |
| HEMOSIDEROSIS, KUPFFER'S CELLS. | 1 4+ | 0 | 0 | 0 |
| HEPATOCELLULAR VACUOLATION. | 3 2+ - 3+ | 3 3+ | 11 2+ - 3+ | 5 2+ - 4+ |
| BILE DUCT ECTASIA. | 1 | 0 | 2 2+ - 3+ | 0 |
| CONGESTION, PASSIVE, CHRONIC. | 3 3+ - 4+ | 0 | 1 3+ | 2 4+ |
| NECROSIS. | 1 4+ | 3 2+ - 4+ | 1 4+ | 2 4+ |
| CHOLANGIOMA. | 3 | 1 | 1 | 0 |
| CHOLANGIECTASIS. | 1 3+ | 0 | 0 | 0 |
| PAPILLARY CYSTIC CHOLANGIOMA. | 1 | 0 | 0 | 0 |
| PLASMACYTOMA, PORTAL. | 1 | 0 | 0 | 0 |
| HEPATOCELLULAR VACUOLATION, PERIPORTAL. | 1 2+ | 0 | 0 | 1 3+ |
| NECROSIS, CENTRILOBULAR. | 0 | 1 4+ | 0 | 0 |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( FEMALES )

| | GROUP 3 | GROUP 6 | GROUP 11 | GROUP 14 |
|---|---|---|---|---|
| LIVER (continued) | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| PIGMENTATION, PORTAL. | 0 | 1 3+ | 0 | 0 |
| PIGMENTATION, INTRACELLULAR. | 0 | 0 | 1 1+ | 0 |
| PIGMENTATION, HEPATOCELLULAR. | 0 | 0 | 4 1+ - 2+ | 0 |
| HEPATOCELLULAR ADENOMA. | 0 | 0 | 1 | 0 |
| EXTRAMEDULLARY HEMATOPOIESIS. | 0 | 0 | 1 2+ | 0 |
| NECROSIS, HEMORRHAGIC. | 0 | 0 | 3 3+ - 4+ | 0 |
| CONGESTION, PASSIVE. | 0 | 0 | 1 | 0 |
| ADENOCARCINOMA, INVASIVE, METASTATIC. | 0 | 0 | 1 4+ | 0 |
| TRIADITIS. | 0 | 0 | 1 4+ | 0 |
| HEPATOCELLULAR CLEAR CELL ATYPIA. | 0 | 0 | 0 | 1 2+ |
| BILE DUCT REDUPLICATION. | 0 | 0 | 0 | 1 3+ |
| HEPATOCELLULAR ALTERATION. | 0 | 0 | 0 | 1 |
| CLEAR CELL FOCUS/FOCI. | 3 | 0 | 0 | 1 |
| GALLBLADDER | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NOT PRESENT IN SECTION. | 1 | 0 | 0 | 0 |
| NO SIGNIFICANT LESION RECOGNIZED. | 19 | 16 | 33 | 21 |
| AUTOLYZED. | 29 | 17 | 17 | 14 |
| PAPILLARY PROLIFERATION. | 1 4+ | 0 | 0 | 0 |
| MISSING. | 0 | 1 | 0 | 0 |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 0 | 1 | 0 | 0 |
| SPLEEN | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 10 | 3 | 4 | 8 |
| AMYLOIDOSIS. | 31 2+ - 4+ | 27 2+ - 4+ | 36 2+ - 4+ | 21 1+ - 4+ |
| AUTOLYZED. | 4 | 4 | 1 | 4 |
| MISSING. | 2 | 0 | 4 | 0 |
| EXTRAMEDULLARY HEMATOPOIESIS. | 3 3+ - 4+ | 3 3+ - 4+ | 11 2+ - 4+ | 2 4+ |
| MALIGNANT LYMPHOMA. | 2 | 0 | 0 | 1 |
| HYPERPLASIA. | 1 3+ | 2 3+ | 1 3+ | 0 |
| TELANGIECTASIS. | 0 | 0 | 0 | 1 3+ |
| PANCREAS | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 33 | 25 | 41 | 29 |
| AMYLOIDOSIS. | 2 1+ - 2+ | 0 | 0 | 0 |
| AUTOLYZED. | 12 | 8 | 3 | 5 |
| MISSING. | 2 | 1 | 2 | 0 |
| PLASMACYTOMA, INTRALOBULAR. | 1 3+ | 0 | 0 | 0 |
| MALIGNANT LYMPHOMA. | 0 | 1 | 0 | 0 |
| AMYLOIDOSIS, INTERLOBULAR. | 0 | 0 | 1 3+ | 0 |
| AMYLOIDOSIS, PERIACINAR. | 0 | 0 | 1 3+ | 0 |
| DUCTAL ECTASIA. | 0 | 0 | 3 1+ - 2+ | 1 3+ |
| KIDNEY | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 7 | 2 | 4 | 2 |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( FEMALES )

| | GROUP 3 | GROUP 6 | GROUP 11 | GROUP 14 |
|---|---|---|---|---|
| KIDNEY (continued) | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| AMYLOIDOSIS. | 42 2+ - 4+ | 30 2+ - 4+ | 41 2+ - 4+ | 28 2+ - 4+ |
| NEPHROLITHIASIS. | 3 2+ - 3+ | 7 2+ - 3+ | 3 2+ - 3+ | 0 |
| MINERALIZATION. | 1 4+ | 0 | 2 3+ | 4 1+ - 3+ |
| TUBULAR DILATATION. | 1 3+ | 0 | 0 | 0 |
| TUBULAR CYST(S). | 1 | 0 | 0 | 0 |
| GLOMERULOSCLEROSIS. | 1 1+ | 0 | 0 | 0 |
| (PELVIS), MINERALIZATION. | 1 4+ | 0 | 0 | 0 |
| (PERIRENAL TISSUE), PLASMACYTOMA. | 1 | 0 | 0 | 0 |
| AUTOLYZED. | 0 | 1 | 1 | 2 |
| NECROSIS, TUBULAR CELL. | 0 | 1 3+ | 0 | 0 |
| NEPHRITIS, INTERSTITIAL, CHRONIC. | 0 | 1 2+ | 1 3+ | 0 |
| PYELONEPHRITIS, ACUTE, PURULENT. | 0 | 1 4+ | 0 | 0 |
| GLOMERULAR NEPHROSIS. | 0 | 1 3+ | 2 1+ - 2+ | 4 3+ - 4+ |
| INFARCT. | 0 | 0 | 1 | 0 |
| HYDRONEPHROSIS. | 0 | 0 | 1 2+ | 0 |
| ADRENAL CARCINOMA, INVASIVE. | 0 | 0 | 1 | 0 |
| NEPHRITIS, PURULENT. | 0 | 0 | 1 2+ | 0 |
| (PROXIMAL TUBULES), PIGMENTATION, INTRACELLULAR. | 0 | 0 | 1 | 0 |
| NEPHRITIS, ACUTE, PURULENT. | 0 | 0 | 0 | 2 1+ - 2+ |
| HEART | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 27 | 18 | 34 | 22 |
| AUTOLYZED. | 1 | 1 | 0 | 1 |
| ATRIAL THROMBOSIS. | 22 | 16 | 16 | 13 |
| MURAL THROMBUS. | 4 | 2 | 2 | 0 |
| MINERALIZATION. | 0 | 0 | 1 3+ | 0 |
| (A/V VALVE), CHONDROPLASIA. | 0 | 0 | 1 | 0 |
| URINARY BLADDER | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 43 | 25 | 43 | 31 |
| AUTOLYZED. | 6 | 6 | 5 | 2 |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 1 | 2 | 2 | 0 |
| MISSING. | 0 | 1 | 0 | 1 |
| (LAMINA PROPRIA), PERIARTERITIS, CHRONIC. | 0 | 1 3+ | 0 | 0 |
| CAST(S), MINERALIZED, INTRALUMINAL. | 0 | 0 | 0 | 1 |
| OVARY | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 39 | 29 | 37 | 32 |
| AUTOLYZED. | 3 | 2 | 4 | 2 |
| PAROVARIAN CYST(S). | 3 | 0 | 3 | 0 |
| CYST(S). | 1 | 1 | 3 | 0 |
| STROMA CELL HYPERPLASIA. | 2 3+ | 0 | 0 | 0 |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( FEMALES )

| | GROUP 3 | | GROUP 6 | | GROUP 11 | | GROUP 14 | |
|---|---|---|---|---|---|---|---|---|
| OVARY (continued) | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| THECA CELL HYPERPLASIA. | 1 | 2+ | 0 | | 0 | | 0 | |
| PAPILLARY CYST ADENOCARCINOMA. | 1 | | 0 | | 0 | | 0 | |
| PERIARTERITIS. | 0 | | 1 | 3+ | 0 | | 0 | |
| GRANULOSA CELL TUMOR(S). | 0 | | 2 | | 1 | | 0 | |
| INSUFFICIENT TISSUE | | | | | | | | |
| PRESENT IN SECTION. | 0 | | 0 | | 1 | | 0 | |
| OOPHORITIS, CYSTIC, PURULENT. | 0 | | 0 | | 1 | 4+ | 0 | |
| FIBROMA. | 0 | | 0 | | 0 | | 1 | |
| UTERUS | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 41 | | 31 | | 43 | | 27 | |
| AUTOLYZED. | 5 | | 3 | | 5 | | 3 | |
| CYSTIC HYPERPLASIA. | 2 | 2+ - 3+ | 0 | | 0 | | 0 | |
| ENDOMETRIAL PAPILLARY HYPERPLASIA. | 1 | 4+ | 1 | 3+ | 0 | | 1 | 4+ |
| PERIARTERITIS, SEROSA, CHRONIC. | 1 | 4+ | 0 | | 0 | | 0 | |
| LEIOMYOMA. | 0 | | 0 | | 1 | | 1 | |
| ENDOMETRIAL ADENOCARCINOMA. | 0 | | 0 | | 1 | | 0 | |
| INSUFFICIENT TISSUE | | | | | | | | |
| PRESENT IN SECTION. | 0 | | 0 | | 0 | | 1 | |
| METRITIS, ACUTE, PURULENT. | 0 | | 0 | | 0 | | 1 | 4+ |
| PAPILLARY ADENOCARCINOMA. | 0 | | 0 | | 0 | | 1 | |
| NEUROLEMMOMA. | 0 | | 0 | | 0 | | 1 | |
| CEREBRUM | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 45 | | 30 | | 46 | | 33 | |
| AUTOLYZED. | 3 | | 4 | | 1 | | 1 | |
| MINERALIZATION. | 1 | 1+ | 0 | | 0 | | 1 | 2+ |
| (MEDIAL SMALL ARTERIES), CALCIFICATION. | 1 | 4+ | 0 | | 0 | | 0 | |
| (CHOROID PLEXUS), MELANOSIS. | 0 | | 1 | 2+ | 0 | | 0 | |
| ARTERIOLAR MEDIAL CALCIFICATION. | 0 | | 0 | | 1 | 3+ | 0 | |
| PERIVASCULAR CUFFING, MONONUCLEAR. | 0 | | 0 | | 1 | 2+ | 0 | |
| (WHITE MATTER), VACUOLATION. | 0 | | 0 | | 1 | 3+ | 0 | |
| CEREBELLUM | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 46 | | 31 | | 48 | | 32 | |
| AUTOLYZED. | 3 | | 4 | | 1 | | 1 | |
| (WHITE MATTER), VACUOLATION, MEDULLA. | 1 | 3+ | 0 | | 0 | | 0 | |
| (WHITE MATTER), VACUOLATION. | 0 | | 0 | | 1 | 3+ | 0 | |
| MISSING. | 0 | | 0 | | 0 | | 1 | |
| VACUOLATION, MEDULLA. | 0 | | 0 | | 0 | | 1 | 2+ |
| PITUITARY | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 31 | | 3 | | 7 | | 10 | |
| AUTOLYZED. | 3 | | 1 | | 0 | | 0 | |
| MISSING. | 16 | | 31 | | 39 | | 24 | |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( FEMALES )

| | GROUP 3 | | GROUP 6 | | GROUP 11 | | GROUP 14 | |
|---|---|---|---|---|---|---|---|---|
| PITUITARY (continued) | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NOT PRESENT IN SECTION. | 0 | | 0 | | 4 | | 0 | |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 0 | | 0 | | 0 | | 1 | |
| STERNABRAE | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 46 | | 34 | | 49 | | 35 | |
| AUTOLYZED. | 3 | | 0 | | 1 | | 0 | |
| MISSING. | 1 | | 0 | | 0 | | 0 | |
| (INTERCOSTAL MUSCLES), MUSCULAR DYSTROPHY. | 0 | | 1 | 2+ | 0 | | 0 | |
| FEMUR | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 46 | | 34 | | 50 | | 35 | |
| AUTOLYZED. | 2 | | 0 | | 0 | | 0 | |
| MISSING. | 1 | | 0 | | 0 | | 0 | |
| PLASMACYTOMA. | 1 | | 0 | | 0 | | 0 | |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 0 | | 1 | | 0 | | 0 | |
| BONE MARROW | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 41 | | 34 | | 44 | | 30 | |
| AUTOLYZED. | 4 | | 0 | | 3 | | 4 | |
| MISSING. | 1 | | 0 | | 0 | | 0 | |
| MALIGNANT LYMPHOMA. | 1 | | 1 | | 1 | | 1 | |
| MONONUCLEAR CELL HYPERPLASIA. | 2 | 3+ | 0 | | 0 | | 0 | |
| HYPERPLASIA. | 1 | 3+ | 0 | | 1 | 4+ | 0 | |
| PLASMA CELL SARCOMA. | 0 | | 0 | | 1 | | 0 | |
| NASAL CAVITY | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 47 | | 35 | | 50 | | 35 | |
| AUTOLYZED. | 2 | | 0 | | 0 | | 0 | |
| MISSING. | 1 | | 0 | | 0 | | 0 | |
| OTHER | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [50] | | [35] | |
| NOT REQUIRED. | 47 | | 26 | | 39 | | 24 | |
| PERITONITIS, ACTIVE, CHRONIC. | 1 | 4+ | 0 | | 0 | | 0 | |
| (RENAL LYMPH NODE), PLASMACYTOSIS. | 1 | 4+ | 0 | | 0 | | 0 | |
| (MASS-ABDOMINAL CAVITY), SCLEROSING PAPILLARY CYSTADENOMCARCINOMA. | 1 | | 0 | | 0 | | 0 | |
| (ALL TISSUES MODERATELY AUTOLYZED). | 0 | | 4 | | 1 | | 3 | |
| (SUBLUMBAR LYMPH NODE), MALIGNANT LYMPHOMA. | 0 | | 1 | | 0 | | 0 | |
| (ALL TISSUES SEVERELY AUTOLYZED). | 0 | | 3 | | 3 | | 4 | |
| (MASS-INGUINAL), LIPOMA. | 0 | | 1 | | 0 | | 0 | |

| | GROUP 3 | GROUP 6 | GROUP 11 | GROUP 14 |
|---|---|---|---|---|
| OTHER (continued) | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [50] | [35] |
| (ALL TISSUES MODERATE TO SEVERELY AUTOLYZED). | 1 | 0 | 4 | 4 |
| (MASS-RENAL LYMPH NODE), LYMPHOID HYPERPLASIA. | 0 | 0 | 1 3+ | 0 |
| (MASS-RENAL LYMPH NODE), PLASMA CELL HYPERPLASIA. | 0 | 0 | 1 3+ | 0 |
| (MASS-BRONCHIAL LYMPH NODE), PLASMA CELL SARCOMA. | 0 | 0 | 1 | 0 |
| (MASS-SUBLUMBAR LYMPH NODE), PLASMA CELL SARCOMA. | 0 | 0 | 1 | 0 |
| (MASS-PERIRENAL LYMPH NODE), PLASMA CELL SARCOMA. | 0 | 0 | 1 | 0 |
| MESENCHYMAL TUMOR, GENERALIZED. | 0 | 0 | 1 | 0 |
| (PERIPHERAL LYMPH NODE), MALIGNANT LYMPHOMA. | 0 | 0 | 1 | 0 |

KEY

| | | |
|---|---|---|
| DYE: | YELLOW 3 | SPECIES: RAT |
| ROUTE: | INTRATRACHEAL | DIETARY |
| GROUPS: | 4 (Treated) | 12 (Treated) |
| | 8 (Control) | 16 (Control) |

( MALES )

| | GROUP 4 | | GROUP 8 | | GROUP 12 | | GROUP 16 | |
|---|---|---|---|---|---|---|---|---|
| SKIN | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [51] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 41 | | 33 | | 48 | | 30 | |
| MISSING. | 3 | | 0 | | 1 | | 4 | |
| FIBROUS HISTIOCYTOMA. | 1 | | 0 | | 0 | | 0 | |
| (MASS-TAIL), FIBROMA. | 1 | | 0 | | 0 | | 0 | |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 3 | | 0 | | 0 | | 0 | |
| (MASS-ABDOMEN), FIBROSARCOMA. | 1 | | 0 | | 0 | | 0 | |
| STEATITIS, ACTIVE, CHRONIC. | 1 | 3+ | 0 | | 0 | | 0 | |
| (MASS), FIBROMA. | 1 | | 0 | | 0 | | 0 | |
| SARCOMA, UNDIFFERENTIATED. | 1 | | 0 | | 0 | | 0 | |
| AUTOLYZED. | 0 | | 2 | | 1 | | 1 | |
| (MASS-SIDE), TRICHOEPITHELIOMA. | 0 | | 1 | | 0 | | 0 | |
| (MASS), DERMATITIS, CHRONIC. | 0 | | 0 | | 1 | | 0 | |
| (MASS-NOSE), PAPILLOMA. | 0 | | 0 | | 1 | | 0 | |
| (MASS-LIP), NOT PRESENT IN SECTION. | 0 | | 0 | | 0 | | 1 | |
| (MASS-ABDOMEN), EPITHELIOMATOUS HYPERPLASIA. | 1 | | 0 | | 0 | | 0 | |
| (MASS-ABDOMEN), FIBROMA. | 1 | | 0 | | 0 | | 0 | |
| (PRESCAPULAR), ADNEXAL ADENOFIBROMA. | 1 | | 0 | | 0 | | 0 | |
| (MASS-SIDE), LIPOMA. | 1 | | 0 | | 0 | | 0 | |
| (MASS-SIDE), SARCOMA, UNDIFFERENTIATED. | 1 | | 0 | | 0 | | 0 | |
| (MASS-HIP), SARCOMA, UNDIFFERENTIATED. | 1 | | 0 | | 0 | | 0 | |
| (FOOT), DERMATITIS, CHRONIC. | 0 | | 1 | 3+ | 0 | | 0 | |
| (MASS-REAR LEG), FIBROMA. | 0 | | 1 | | 0 | | 0 | |
| (ABDOMEN), KERATOTIC INCLUSION CYST(S). | 0 | | 1 | | 0 | | 0 | |
| (MASS-ABDOMEN), KERATOTIC HORN. | 0 | | 0 | | 1 | | 0 | |
| (MASS-LUMBAR), FIBROMA. | 0 | | 0 | | 1 | | 0 | |
| (MASS-LUMBAR), MINERALIZATION. | 0 | | 0 | | 0 | | 1 | 3+ |
| (MASS-LEG), FIBROSARCOMA. | 0 | | 0 | | 0 | | 1 | |
| (MANDIBLE), NO SIGNIFICANT LESION RECOGNIZED. | 0 | | 0 | | 0 | | 1 | |
| MAMMARY | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [51] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 13 | | 6 | | 10 | | 9 | |
| NOT PRESENT IN SECTION. | 25 | | 19 | | 28 | | 11 | |
| MISSING. | 4 | | 0 | | 0 | | 4 | |
| ACTIVE. | 8 | | 8 | | 11 | | 10 | |
| CYST(S), HEMORRHAGIC. | 1 | | 0 | | 0 | | 0 | |
| AUTOLYZED. | 0 | | 2 | | 1 | | 1 | |
| (MASS-AXILLA), FIBROADENOMA. | 1 | | 1 | | 1 | | 0 | |
| (MASS-CERVICAL), FIBROADENOMA. | 0 | | 0 | | 1 | | 0 | |
| (MASS-CERVICAL), ADENOFIBROMA. | 0 | | 0 | | 1 | | 0 | |
| (MASS-INGUINAL), FIBROADENOMA. | 1 | | 0 | | 0 | | 2 | |
| (MASS-AXILLA), FIBROMA. | 0 | | 1 | | 0 | | 1 | |
| (MASS-INGUINAL), AUTOLYZED. | 0 | | 0 | | 0 | | 1 | |
| (MASS-INGUINAL), NO SIGNIFICANT LESION RECOGNIZED. | 0 | | 0 | | 0 | | 1 | |
| (MASS-VENTRAL THORAX), FIBROADENOMA. | 0 | | 0 | | 0 | | 1 | |
| (MASS-AXILLA), NO SIGNIFICANT LESION RECOGNIZED. | 0 | | 0 | | 0 | | 1 | |
| THIGH MUSCLE | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [51] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 45 | | 31 | | 47 | | 33 | |
| NOT PRESENT IN SECTION. | 2 | | 1 | | 0 | | 0 | |
| MYOPATHY. | 1 | 3+ | 0 | | 0 | | 0 | |
| MINERALIZATION. | 2 | 3+ | 0 | | 0 | | 0 | |
| AUTOLYZED. | 0 | | 3 | | 2 | | 1 | |
| MISSING. | 0 | | 0 | | 1 | | 0 | |
| NECROSIS. | 0 | | 0 | | 0 | | 1 | 4+ |
| SALIVARY GLAND | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [51] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 46 | | 29 | | 42 | | 33 | |
| NOT PRESENT IN SECTION. | 2 | | 0 | | 0 | | 0 | |
| MISSING. | 1 | | 0 | | 6 | | 1 | |
| AUTOLYZED. | 1 | | 4 | | 2 | | 1 | |
| BASOPHILIC FOCUS/FOCI. | 0 | | 2 | | 0 | | 0 | |
| BRONCHI | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [51] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 46 | | 19 | | 47 | | 33 | |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( MALES )

| | GROUP 4 | GROUP 8 | GROUP 12 | GROUP 16 |
|---|---|---|---|---|
| BRONCHI (continued) | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [51] | [35] |
| NOT PRESENT IN SECTION. | 2 | 0 | 0 | 0 |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 1 | 0 | 0 | 0 |
| BRONCHITIS, CHRONIC. | 1 4+ | 2 3+ - 4+ | 0 | 0 |
| AUTOLYZED. | 0 | 3 | 2 | 1 |
| BRONCHITIS, ACTIVE, CHRONIC. | 0 | 11 3+ - 4+ | 0 | 1 4+ |
| MISSING. | 0 | 0 | 1 | 0 |
| TRACHEA | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [51] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 45 | 16 | 48 | 34 |
| NOT PRESENT IN SECTION. | 2 | 0 | 0 | 0 |
| MISSING. | 1 | 0 | 0 | 0 |
| TRACHEITIS, CHRONIC. | 2 3+ - 4+ | 2 4+ | 0 | 0 |
| AUTOLYZED. | 0 | 3 | 2 | 1 |
| TRACHEITIS, ACTIVE, CHRONIC. | 0 | 14 2+ - 4+ | 0 | 0 |
| LARYNX | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [51] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 44 | 16 | 48 | 34 |
| NOT PRESENT IN SECTION. | 2 | 0 | 0 | 0 |
| MISSING. | 2 | 0 | 0 | 0 |
| LARYNGITIS, CHRONIC. | 2 4+ | 1 4+ | 0 | 0 |
| LARYNGITIS, ACTIVE, CHRONIC. | 0 | 14 2+ - 4+ | 0 | 0 |
| AUTOLYZED. | 0 | 3 | 2 | 1 |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 0 | 1 | 0 | 0 |
| EPITHELIAL PAPILLARY HYPERPLASIA. | 0 | 1 1+ | 0 | 0 |
| THYROID | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [51] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 23 | 13 | 15 | 17 |
| NOT PRESENT IN SECTION. | 4 | 5 | 3 | 3 |
| MISSING. | 3 | 0 | 0 | 1 |
| C-CELL HYPERPLASIA. | 7 2+ - 3+ | 3 2+ - 3+ | 4 3+ | 3 2+ - 3+ |
| C-CELL ADENOMA. | 8 | 6 | 5 | 8 |
| AUTOLYZED. | 4 | 6 | 4 | 3 |
| C-CELL CARCINOMA. | 1 | 1 | 0 | 0 |
| FOLLICULAR CELL ADENOMA. | 0 | 1 | 1 | 0 |
| FOLLICULAR CELL CARCINOMA. | 0 | 1 | 1 | 0 |
| FOLLICULAR CELL HYPERPLASIA. | 0 | 0 | 15 3+ - 4+ | 1 2+ |
| ACINAR CELL HYPERPLASIA. | 0 | 0 | 1 3+ | 0 |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 0 | 0 | 2 | 2 |
| PARATHYROID | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [51] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 26 | 13 | 32 | 26 |
| NOT PRESENT IN SECTION. | 16 | 18 | 7 | 7 |
| MISSING. | 2 | 0 | 0 | 1 |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( MALES )

| | GROUP 4 | GROUP 8 | GROUP 12 | GROUP 16 |
|---|---|---|---|---|
| PARATHYROID (continued) | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [51] | [35] |
| HYPERPLASIA. | 3 2+ - 3+ | 1 3+ | 5 2+ - 3+ | 0 |
| AUTOLYZED. | 3 | 3 | 5 | 1 |
| CYSTADENOMA. | 0 | 0 | 1 | 0 |
| ESOPHAGUS | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [51] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 46 | 31 | 47 | 33 |
| NOT PRESENT IN SECTION. | 2 | 1 | 0 | 0 |
| AUTOLYZED. | 2 | 3 | 3 | 1 |
| MISSING. | 0 | 0 | 0 | 1 |
| MANDIBULAR LYMPH NODE | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [51] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 23 | 13 | 30 | 17 |
| NOT PRESENT IN SECTION. | 1 | 0 | 0 | 0 |
| HISTIOCYTOSIS. | 1 2+ | 0 | 0 | 0 |
| HISTIOCYTOSIS, PIGMENTED. | 1 3+ | 0 | 0 | 0 |
| MISSING. | 10 | 4 | 11 | 7 |
| PIGMENTATION, INTRACELLULAR. | 2 3+ | 0 | 0 | 0 |
| LYMPHOID HYPERPLASIA. | 6 3+ | 10 3+ - 4+ | 4 3+ - 4+ | 6 4+ |
| PLASMACYTOSIS. | 3 3+ | 2 4+ | 0 | 1 3+ |
| AUTOLYZED. | 1 | 4 | 2 | 3 |
| CYST(S). | 1 | 0 | 0 | 0 |
| MALIGNANT LYMPHOMA. | 2 | 2 | 0 | 0 |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 0 | 0 | 1 | 0 |
| RETICULOENDOTHELIAL CELL HYPERPLASIA. | 0 | 0 | 1 3+ | 0 |
| PLASMA CELL HYPERPLASIA. | 0 | 0 | 1 3+ | 0 |
| MULTIPLE CYST(S). | 0 | 0 | 0 | 1 |
| ADRENALS | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [51] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 26 | 13 | 35 | 25 |
| NOT PRESENT IN SECTION. | 1 | 0 | 0 | 0 |
| ADENOCARCINOMA, METASTATIC. | 1 | 0 | 0 | 0 |
| MISSING. | 1 | 0 | 0 | 0 |
| CORTICAL CELL ADENOMA. | 5 | 0 | 3 | 0 |
| LIPIDOSIS. | 11 2+ - 3+ | 3 1+ - 2+ | 2 1+ - 2+ | 3 1+ - 2+ |
| CONGESTION. | 1 3+ | 0 | 0 | 0 |
| AUTOLYZED. | 1 | 3 | 2 | 2 |
| CORTICAL NODULAR HYPERPLASIA. | 2 2+ - 3+ | 0 | 2 2+ - 3+ | 0 |
| CYST(S). | 1 | 1 | 0 | 0 |
| PHEOCHROMOCYTOMA. | 1 | 9 | 4 | 1 |
| MEDULLARY CELL HYPERPLASIA. | 3 2+ | 5 1+ - 3+ | 6 2+ - 3+ | 3 1+ - 2+ |
| MALIGNANT LYMPHOMA. | 1 | 0 | 0 | 0 |
| CORTICAL CELL HYPERPLASIA. | 1 2+ | 1 2+ | 0 | 0 |
| LEUKEMIA. | 0 | 1 | 0 | 0 |
| HEMATOCYST(S). | 0 | 0 | 1 | 0 |
| GANGLIONEUROMA. | 0 | 0 | 0 | 1 |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( MALES )

| | GROUP 4 | | GROUP 8 | | GROUP 12 | | GROUP 16 | |
|---|---|---|---|---|---|---|---|---|
| ADRENALS (continued) | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [51] | | [35] | |
| LIPIDOSIS, CORTICAL. | 0 | | 0 | | 0 | | 1 | 4+ |
| THYMUS | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [51] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 16 | | 20 | | 44 | | 27 | |
| NOT PRESENT IN SECTION. | 18 | | 8 | | 2 | | 4 | |
| MISSING. | 5 | | 0 | | 0 | | 0 | |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 2 | | 0 | | 0 | | 0 | |
| EPITHELIAL HYPERPLASIA. | 7 | 3+ | 3 | 3+ | 0 | | 2 | 3+ |
| AUTOLYZED. | 1 | | 4 | | 4 | | 1 | |
| MALIGNANT LYMPHOMA. | 1 | | 0 | | 0 | | 0 | |
| ADENOMATOUS HYPERPLASIA. | 0 | | 0 | | 0 | | 1 | |
| (MASS-THYMUS), CYST(S). | 1 | | 0 | | 0 | | 0 | |
| SCIATIC NERVE | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [51] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 42 | | 30 | | 47 | | 33 | |
| NOT PRESENT IN SECTION. | 2 | | 0 | | 0 | | 0 | |
| MISSING. | 3 | | 0 | | 1 | | 1 | |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 2 | | 0 | | 0 | | 0 | |
| AUTOLYZED. | 1 | | 5 | | 2 | | 1 | |
| STOMACH | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [51] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 28 | | 28 | | 45 | | 30 | |
| GASTRITIS, ACUTE, NECROTIZING. | 1 | 4+ | 0 | | 0 | | 0 | |
| SEROSA, MESOTHELIOMA. | 1 | | 0 | | 0 | | 0 | |
| (FORESTOMACH), LEUKEMIA. | 1 | | 0 | | 0 | | 0 | |
| AUTOLYZED. | 9 | | 4 | | 3 | | 2 | |
| (FORESTOMACH), GASTRITIS, SUBACUTE, NECROTIZING. | 2 | 4+ | 0 | | 0 | | 0 | |
| (FORESTOMACH), GASTRITIS, SUBACUTE. | 4 | 3+ | 0 | | 0 | | 1 | 3+ |
| (GLANDULAR), MULTIPLE CYST(S). | 4 | 3+ | 0 | | 0 | | 0 | |
| (FORESTOMACH), GASTRITIS, NECROTIZING. | 0 | | 2 | 2+ - 3+ | 1 | 4+ | 1 | 3+ |
| (FORESTOMACH), CYST(S). | 0 | | 1 | | 0 | | 0 | |
| NOT PRESENT IN SECTION. | 0 | | 0 | | 1 | | 0 | |
| MESOTHELIOMA. | 0 | | 0 | | 0 | | 1 | |
| DUODENUM | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [51] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 40 | | 28 | | 45 | | 32 | |
| NOT PRESENT IN SECTION. | 1 | | 0 | | 0 | | 0 | |
| AUTOLYZED. | 9 | | 7 | | 5 | | 3 | |
| JEJUNUM | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [51] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 40 | | 28 | | 45 | | 30 | |
| NOT PRESENT IN SECTION. | 1 | | 0 | | 0 | | 0 | |
| AUTOLYZED. | 9 | | 7 | | 5 | | 3 | |
| CYSTIC HYPERPLASIA. | 0 | | 0 | | 0 | | 1 | 3+ |

( MALES )

| | GROUP 4 | GROUP 8 | GROUP 12 | GROUP 16 |
|---|---|---|---|---|
| JEJUNUM (continued) | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [51] | [35] |
| LEIOMYOMA. | 0 | 0 | 0 | 1 |
| ILEUM | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [51] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 40 | 28 | 42 | 32 |
| NOT PRESENT IN SECTION. | 1 | 0 | 0 | 0 |
| AUTOLYZED. | 9 | 7 | 5 | 3 |
| FOLLICULAR CELL HYPERPLASIA. | 0 | 0 | 2 3+ - 4+ | 0 |
| HYPERPLASIA, ADENOMATOUS. | 0 | 0 | 1 4+ | 0 |
| CECUM | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [51] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 40 | 27 | 45 | 31 |
| NOT PRESENT IN SECTION. | 1 | 0 | 0 | 0 |
| AUTOLYZED. | 9 | 7 | 5 | 3 |
| ENTEROPATHY. | 0 | 1 1+ | 0 | 1 2+ |
| COLON | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [51] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 40 | 27 | 44 | 32 |
| NOT PRESENT IN SECTION. | 1 | 0 | 0 | 0 |
| AUTOLYZED. | 9 | 7 | 5 | 3 |
| NEMATODIASIS. | 0 | 1 | 0 | 0 |
| INTUSSUSCEPTION, POSTMORTEM. | 0 | 0 | 1 | 0 |
| RECTUM | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [51] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 40 | 28 | 45 | 32 |
| NOT PRESENT IN SECTION. | 1 | 0 | 0 | 0 |
| AUTOLYZED. | 9 | 7 | 5 | 3 |
| MESENTERIC LYMPH NODES | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [51] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 11 | 12 | 34 | 19 |
| HISTIOCYTOSIS. | 23 1+ - 3+ | 11 2+ - 3+ | 5 2+ - 3+ | 10 2+ - 3+ |
| HISTIOCYTOSIS, PIGMENTED. | 1 2+ | 0 | 0 | 0 |
| MISSING. | 6 | 4 | 5 | 2 |
| CONGESTION. | 2 3+ - 4+ | 1 3+ | 1 3+ | 0 |
| CHRONIC MURINE PNEUMONIA. | 1 2+ | 0 | 0 | 0 |
| AUTOLYZED. | 5 | 7 | 4 | 3 |
| CYST(S). | 1 | 0 | 0 | 0 |
| RETICULOENDOTHELIAL CELL HYPERPLASIA. | 1 3+ | 1 3+ | 0 | 1 3+ |
| MASTOCYTOSIS. | 2 2+ - 3+ | 0 | 0 | 0 |
| RETICULUM CELL HYPERPLASIA. | 0 | 1 3+ | 0 | 0 |
| MULTILOCULATED CYST(S). | 0 | 1 | 0 | 0 |
| LYMPHOID HYPERPLASIA. | 0 | 0 | 1 3+ | 0 |
| NOT PRESENT IN SECTION. | 0 | 0 | 1 | 0 |
| LUNGS (ALL LOBES) | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [51] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 3 | 4 | 31 | 22 |
| ADENOCARCINOMA, METASTATIC. | 1 | 0 | 0 | 0 |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( MALES )

| | GROUP 4 | | GROUP 8 | | GROUP 12 | | GROUP 16 | |
|---|---|---|---|---|---|---|---|---|
| LUNGS (ALL LOBES) (continued) | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [51] | | [35] | |
| HISTIOCYTOSIS. | 3 | 2+ | 0 | | 0 | | 0 | |
| HISTIOCYTOSIS, PIGMENTED. | 40 | 1+ - 4+ | 0 | | 1 | 1+ | 0 | |
| NECROSIS, CENTRILOBULAR. | 1 | 4+ | 0 | | 0 | | 0 | |
| PIGMENTATION, INTRACELLULAR. | 3 | 1+ - 3+ | 0 | | 0 | | 0 | |
| MESOTHELIOMA, METASTATIC. | 1 | | 0 | | 0 | | 0 | |
| LEUKEMIA. | 7 | | 4 | | 0 | | 3 | |
| CONGESTION. | 3 | 4+ | 0 | | 0 | | 0 | |
| CHRONIC MURINE PNEUMONIA. | 6 | 1+ - 3+ | 22 | 1+ - 4+ | 10 | 1+ - 3+ | 0 | |
| ALVEOLAR/BRONCHIOLAR CELL ADENOMA. | 1 | | 1 | | 1 | | 0 | |
| ALVEOLAR/BRONCHIOLAR CELL HYPERPLASIA. | 2 | 1+ - 2+ | 2 | 2+ - 4+ | 1 | 1+ | 4 | 1+ - 2+ |
| HEMORRHAGE. | 1 | 2+ | 0 | | 2 | 2+ | 0 | |
| PNEUMONITIS, ACTIVE, CHRONIC. | 1 | 3+ | 0 | | 0 | | 0 | |
| ADENOMATOSIS. | 3 | 2+ - 3+ | 0 | | 1 | 2+ | 0 | |
| ATELECTASIS. | 1 | 1+ | 1 | 2+ | 3 | 2+ - 3+ | 5 | 2+ |
| MALIGNANT LYMPHOMA. | 1 | | 0 | | 0 | | 0 | |
| SARCOMA, METASTATIC, UNDIFFERENTIATED. | 1 | | 0 | | 0 | | 0 | |
| AUTOLYZED. | 0 | | 3 | | 2 | | 1 | |
| PNEUMONITIS, INTERSTITIAL. | 0 | | 2 | 1+ - 2+ | 0 | | 1 | 1+ |
| ADENOCARCINOMA. | 0 | | 1 | | 0 | | 0 | |
| PNEUMONITIS, GRANULOMATOUS. | 0 | | 0 | | 1 | 4+ | 0 | |
| ALVEOLAR/BRONCHIOLAR CELL CARCINOMA. | 0 | | 0 | | 1 | | 0 | |
| RETICULOENDOTHELIAL CELL HYPERPLASIA. | 0 | | 0 | | 0 | | 1 | 1+ |
| FIBROSARCOMA, METASTATIC. | 0 | | 0 | | 0 | | 1 | |
| LIVER | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [51] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 12 | | 12 | | 3 | | 9 | |
| HISTIOCYTOSIS, PIGMENTED. | 1 | 2+ | 0 | | 0 | | 0 | |
| (BILE DUCT), CARCINOMA, MULTICENTRIC. | 1 | | 0 | | 0 | | 0 | |
| NECROSIS, CENTRILOBULAR. | 4 | 2+ - 4+ | 0 | | 0 | | 0 | |
| NEOPLASTIC NODULE(S). | 7 | | 4 | | 23 | | 2 | |
| LEUKEMIA. | 9 | | 9 | | 0 | | 5 | |
| FIBROSIS, PORTAL. | 4 | 2+ - 4+ | 1 | 2+ | 0 | | 0 | |
| BILE DUCT HYPERPLASIA. | 7 | 2+ - 3+ | 5 | 2+ - 4+ | 1 | 3+ | 0 | |
| HEPATOCELLULAR VACUOLATION, CENTRILOBULAR. | 1 | 3+ | 0 | | 0 | | 0 | |
| CONGESTION. | 2 | 3+ | 0 | | 0 | | 0 | |
| BASOPHILIC FOCUS/FOCI. | 1 | | 0 | | 0 | | 0 | |
| AUTOLYZED. | 2 | | 4 | | 3 | | 1 | |
| EOSINOPHILIC FOCUS/FOCI. | 6 | | 6 | | 23 | | 16 | |
| CLEAR CELL FOCUS/FOCI. | 4 | | 1 | | 33 | | 2 | |
| HEPATOCELLULAR VACUOLATION. | 4 | 3+ | 0 | | 1 | 3+ | 2 | 1+ - 2+ |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( MALES )

| | GROUP 4 | | GROUP 8 | | GROUP 12 | | GROUP 16 | |
|---|---|---|---|---|---|---|---|---|
| LIVER (continued) | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [51] | | [35] | |
| MALIGNANT LYMPHOMA. | 1 | | 0 | | 0 | | 0 | |
| (MIXED FOCUS OF CELLULAR ALTERATION). | 0 | | 1 | | 0 | | 0 | |
| HEPATITIS, GRANULOMATOUS. | 0 | | 2 | 3+ | 4 | 2+ - 3+ | 0 | |
| HEPATOCELLULAR CYSTIC DEGENERATION. | 0 | | 1 | 2+ | 11 | 2+ - 4+ | 0 | |
| MULTIPLE NEOPLASTIC NODULE(S). | 0 | | 0 | | 2 | | 0 | |
| HEPATOCELLULAR CARCINOMA. | 0 | | 0 | | 2 | | 0 | |
| CYST(S). | 0 | | 0 | | 1 | | 0 | |
| SARCOMA, INVASIVE. | 0 | | 0 | | 1 | | 0 | |
| NECROSIS. | 0 | | 0 | | 0 | | 1 | 2+ |
| SPLEEN | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [51] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 30 | | 21 | | 44 | | 24 | |
| ADENOCARCINOMA, METASTATIC. | 1 | | 0 | | 0 | | 0 | |
| HISTIOCYTOSIS, PIGMENTED. | 1 | 2+ | 0 | | 0 | | 0 | |
| LEUKEMIA. | 10 | | 9 | | 0 | | 5 | |
| SPLENITIS, GRANULOMATOUS. | 1 | 3+ | 0 | | 0 | | 0 | |
| AUTOLYZED. | 2 | | 4 | | 3 | | 1 | |
| HEMOSIDEROSIS. | 1 | 4+ | 1 | 3+ | 0 | | 0 | |
| (CAPSULE), FIBROUS PROLIFERATION. | 1 | 3+ | 0 | | 0 | | 0 | |
| MALIGNANT LYMPHOMA. | 1 | | 0 | | 0 | | 0 | |
| EXTRAMEDULLARY HEMATOPOIESIS. | 1 | 3+ | 0 | | 0 | | 2 | 2+ |
| HEMATOPOIESIS. | 1 | 4+ | 0 | | 0 | | 0 | |
| SARCOMA, METASTATIC, UNDIFFERENTIATED. | 1 | | 0 | | 0 | | 0 | |
| (MASS), MESENCHYMAL NEOPLASM(S), UNDIFFERENTIATED. | 0 | | 1 | | 0 | | 0 | |
| FIBROSIS, (WITH VACUOLATION). | 0 | | 1 | 2+ | 0 | | 0 | |
| ACINAR CELL HYPERPLASIA. | 0 | | 0 | | 1 | 2+ | 0 | |
| MULTIPLE CLEAR CELL FOCI. | 0 | | 0 | | 1 | | 0 | |
| HEPATOCELLULAR CYSTIC DEGENERATION. | 0 | | 0 | | 1 | 1+ | 0 | |
| EOSINOPHILIC FOCUS. | 0 | | 0 | | 1 | | 0 | |
| FIBROMA. | 0 | | 0 | | 1 | | 0 | |
| FIBROSIS. | 0 | | 0 | | 0 | | 3 | 1+ |
| PANCREAS | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [51] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 24 | | 20 | | 34 | | 16 | |
| HISTIOCYTOSIS, PIGMENTED. | 1 | 2+ | 0 | | 0 | | 0 | |
| MISSING. | 2 | | 0 | | 0 | | 0 | |
| PIGMENTATION, INTRACELLULAR. | 1 | 4+ | 0 | | 0 | | 0 | |
| ISLET CELL CARCINOMA. | 1 | | 0 | | 0 | | 0 | |
| MESOTHELIOMA, INVASIVE. | 1 | | 0 | | 0 | | 0 | |
| ACINAR CELL ADENOMA. | 3 | | 0 | | 1 | | 1 | |
| ISLET CELL HYPERPLASIA. | 2 | 2+ | 1 | 2+ | 3 | 1+ - 2+ | 1 | 3+ |
| LOBULAR ATROPHY. | 9 | 2+ - 4+ | 2 | 3+ - 4+ | 4 | 1+ - 3+ | 7 | 1+ - 4+ |
| ACINAR CELL ATROPHY. | 2 | 2+ | 5 | 1+ - 2+ | 2 | 1+ - 2+ | 4 | 2+ - 4+ |
| AUTOLYZED. | 4 | | 5 | | 3 | | 1 | |
| ISLET CELL ADENOMA. | 3 | | 1 | | 1 | | 2 | |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( MALES )

| | GROUP 4 | GROUP 8 | GROUP 12 | GROUP 16 |
|---|---|---|---|---|
| PANCREAS (continued) | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [51] | [35] |
| MALIGNANT LYMPHOMA. | 1 | 1 | 0 | 0 |
| LEUKEMIA. | 0 | 1 | 0 | 0 |
| NOT PRESENT IN SECTION. | 0 | 0 | 1 | 0 |
| MULTIPLE EOSINOPHILIC ACINAR FOCI. | 0 | 0 | 1 | 0 |
| CELLULAR CHANGE. | 0 | 0 | 1 | 0 |
| DUCTAL ECTASIA. | 0 | 0 | 1 1+ | 1 1+ |
| BASOPHILIC FOCUS/FOCI. | 0 | 0 | 0 | 1 |
| LOBULAR EOSINOPHILIA. | 0 | 0 | 0 | 1 3+ |
| MESOTHELIOMA. | 0 | 0 | 0 | 1 |
| PERIARTERITIS. | 0 | 0 | 0 | 1 4+ |
| KIDNEYS | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [51] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 4 | 2 | 3 | 3 |
| ADENOCARCINOMA, METASTATIC. | 1 | 0 | 0 | 0 |
| MISSING. | 1 | 0 | 2 | 0 |
| NEPHROPATHY, CHRONIC. | 40 2+ - 4+ | 28 2+ - 4+ | 36 2+ - 4+ | 31 1+ - 4+ |
| TRANSITIONAL CELL CARCINOMA. | 1 | 0 | 0 | 0 |
| AUTOLYZED. | 2 | 5 | 2 | 1 |
| MALIGNANT LYMPHOMA. | 1 | 0 | 0 | 0 |
| SARCOMA, METASTATIC, UNDIFFERENTIATED. | 1 | 0 | 0 | 0 |
| RENAL CELL HYPERTROPHY. | 0 | 1 2+ | 0 | 0 |
| RENAL CELL ADENOMA. | 0 | 0 | 1 | 0 |
| TUBULAR CELL ADENOMA. | 0 | 0 | 6 | 0 |
| CYST(S). | 0 | 0 | 2 | 0 |
| NEPHROCALCINOSIS, MEDULLA. | 0 | 0 | 2 2+ | 0 |
| TUBULAR CELL HYPERPLASIA. | 0 | 0 | 3 1+ - 2+ | 1 1+ |
| PIGMENTATION, INTRACELLULAR. | 0 | 0 | 1 4+ | 0 |
| HEART | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [51] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 30 | 17 | 30 | 21 |
| ADENOCARCINOMA, METASTATIC. | 1 | 0 | 0 | 1 |
| MISSING. | 1 | 0 | 2 | 0 |
| MYOCARDIOPATHY. | 15 2+ - 3+ | 13 1+ - 4+ | 15 1+ - 3+ | 11 1+ - 3+ |
| MYOCARDITIS, CHRONIC. | 1 1+ | 0 | 0 | 0 |
| AUTOLYZED. | 1 | 4 | 3 | 1 |
| MALIGNANT LYMPHOMA. | 1 | 0 | 0 | 0 |
| LEUKEMIA. | 0 | 1 | 0 | 0 |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 0 | 0 | 0 | 1 |
| URINARY BLADDER | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [51] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 38 | 25 | 39 | 31 |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( MALES )

| | GROUP 4 | | GROUP 8 | | GROUP 12 | | GROUP 16 | |
|---|---|---|---|---|---|---|---|---|
| URINARY BLADDER (continued) | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [51] | | [35] | |
| MISSING. | 5 | | 0 | | 2 | | 1 | |
| MESOTHELIOMA. | 1 | | 0 | | 0 | | 1 | |
| INSUFFICIENT TISSUE | | | | | | | | |
| PRESENT IN SECTION. | 2 | | 0 | | 2 | | 0 | |
| AUTOLYZED. | 2 | | 7 | | 4 | | 2 | |
| MALIGNANT LYMPHOMA. | 1 | | 0 | | 0 | | 0 | |
| CYSTITIS, CHRONIC. | 1 | 3+ | 1 | 3+ | 0 | | 0 | |
| EPITHELIAL HYPERPLASIA. | 0 | | 1 | 3+ | 0 | | 0 | |
| CYSTITIS, ACTIVE, CHRONIC. | 0 | | 1 | 4+ | 0 | | 0 | |
| UROTHELIAL HYPERPLASIA. | 0 | | 1 | 4+ | 0 | | 0 | |
| TRANSITIONAL CELL ADENOMA. | 0 | | 1 | | 0 | | 0 | |
| EPITHELIAL CELL ATYPIA. | 0 | | 0 | | 1 | 1+ | 0 | |
| TRANSITIONAL CELL CARCINOMA. | 0 | | 0 | | 2 | | 0 | |
| SEMINAL VESICLE | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [51] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 42 | | 29 | | 46 | | 33 | |
| MISSING. | 6 | | 0 | | 1 | | 0 | |
| AUTOLYZED. | 2 | | 6 | | 3 | | 2 | |
| PROSTATE | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [51] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 27 | | 6 | | 33 | | 22 | |
| MISSING. | 6 | | 2 | | 1 | | 0 | |
| HYPERPLASIA. | 2 | | 6 | 1+ - 3+ | 0 | | 3 | 2+ |
| ADENOMA. | 1 | | 8 | | 0 | | 1 | |
| PROSTATITIS, ACTIVE, CHRONIC. | 11 | 2+ - 4+ | 10 | 1+ - 4+ | 7 | 2+ - 4+ | 6 | 1+ - 4+ |
| AUTOLYZED. | 1 | | 3 | | 3 | | 1 | |
| PROSTATITIS, ACUTE, CHRONIC. | 1 | 2+ | 0 | | 0 | | 0 | |
| PROSTATITIS, ACUTE, PURULENT. | 1 | 4+ | 0 | | 0 | | 0 | |
| PAPILLARY HYPERPLASIA. | 0 | | 2 | 1+ | 0 | | 2 | 1+ |
| ADENOCARCINOMA. | 0 | | 1 | | 0 | | 0 | |
| PROSTATITIS, CHRONIC. | 0 | | 1 | 3+ | 0 | | 1 | 2+ |
| ACINAR CELL HYPERPLASIA. | 0 | | 0 | | 1 | 1+ | 0 | |
| INTERSTITIAL CELL TUMOR(S). | 0 | | 0 | | 1 | | 0 | |
| INSUFFICIENT TISSUE | | | | | | | | |
| PRESENT IN SECTION. | 0 | | 0 | | 1 | | 0 | |
| ACINAR CELL ADENOMA. | 0 | | 0 | | 1 | | 0 | |
| PAPILLARY ADENOMATOUS HYPERPLASIA. | 0 | | 0 | | 1 | 3+ | 0 | |
| ACINAR CELL ADENOMATOUS HYPERPLASIA. | 0 | | 0 | | 1 | 2+ | 0 | |
| TESTES | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [51] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 2 | | 0 | | 2 | | 0 | |
| HISTIOCYTOSIS, INTERSTITIAL CELL. | 1 | 2+ | 0 | | 0 | | 0 | |
| MESOTHELIOMA. | 3 | | 0 | | 0 | | 1 | |
| INTERSTITIAL CELL TUMOR(S). | 44 | | 32 | | 45 | | 34 | |
| INTERSTITIAL CELL HYPERPLASIA. | 1 | | 1 | 2+ | 2 | 2+ | 1 | 1+ |
| ATROPHY. | 1 | 4+ | 9 | | 1 | | 0 | |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( MALES )

| | GROUP 4 | GROUP 8 | GROUP 12 | GROUP 16 |
|---|---|---|---|---|
| TESTES (continued) | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [51] | [35] |
| (SEMINIFEROUS TUBULES), MINERALIZATION. | 4 3+ - 4+ | 6 4+ | 1 3+ | 0 |
| MALIGNANT LYMPHOMA. | 1 | 0 | 0 | 0 |
| AUTOLYZED. | 0 | 3 | 2 | 1 |
| BRAIN | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [51] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 46 | 26 | 45 | 33 |
| LEUKEMIA. | 1 | 0 | 0 | 0 |
| AUTOLYZED. | 1 | 4 | 5 | 2 |
| HEMORRHAGE. | 1 3+ | 0 | 0 | 0 |
| NECROSIS. | 2 3+ - 4+ | 0 | 0 | 0 |
| ASTROCYTOMA. | 1 | 0 | 0 | 0 |
| INTERSTITIAL CELL TUMOR(S). | 0 | 1 | 0 | 0 |
| (WHITE MATTER), VACUOLATION. | 0 | 2 1+ - 2+ | 0 | 0 |
| VACUOLATION. | 0 | 1 3+ | 0 | 0 |
| (WHITE MATTER), CEREBELLAR VACUOLATION. | 0 | 1 3+ | 0 | 0 |
| PITUITARY | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [51] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 29 | 13 | 32 | 23 |
| MISSING. | 6 | 1 | 4 | 1 |
| ADENOMA. | 12 | 16 | 6 | 6 |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 1 | 1 | 4 | 2 |
| AUTOLYZED. | 2 | 3 | 3 | 1 |
| CYST(S). | 1 | 1 | 0 | 1 |
| HYPERPLASIA. | 0 | 0 | 1 1+ | 1 1+ |
| STERNUM/RIB & RIB JUNCTION | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [51] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 50 | 33 | 48 | 34 |
| AUTOLYZED. | 0 | 2 | 1 | 1 |
| FIBROUS OSTEODYSTROPHY. | 0 | 0 | 1 4+ | 0 |
| FEMUR | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [51] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 50 | 33 | 48 | 33 |
| (BONE MARROW), LEUKEMIA. | 1 | 0 | 0 | 0 |
| (BONE MARROW), MALIGNANT LYMPHOMA. | 1 | 0 | 0 | 0 |
| (BONE MARROW), HYPOPLASIA. | 1 3+ | 0 | 0 | 0 |
| (BONE MARROW), HYPERPLASIA. | 1 3+ | 0 | 0 | 0 |
| (BONE MARROW), SARCOMA, METASTATIC, UNDIFFERENTIATED. | 1 | 0 | 0 | 0 |
| AUTOLYZED. | 0 | 2 | 1 | 1 |
| FIBROUS OSTEODYSTROPHY. | 0 | 0 | 1 3+ | 1 3+ |
| NASAL CAVITY | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [51] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 44 | 28 | 48 | 33 |
| RHINITIS, ACUTE, PURULENT. | 4 3+ - 4+ | 0 | 0 | 0 |
| RHINITIS, ACTIVE, CHRONIC. | 2 3+ - 4+ | 4 4+ | 0 | 1 4+ |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( MALES )

| | GROUP 4 | | GROUP 8 | | GROUP 12 | | GROUP 16 | |
|---|---|---|---|---|---|---|---|---|
| NASAL CAVITY (continued) | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [51] | | [35] | |
| AUTOLYZED. | 0 | | 2 | | 1 | | 1 | |
| RHINITIS, CHRONIC. | 0 | | 1 | 3+ | 0 | | 0 | |
| FIBROUS OSTEODYSTROPHY. | 0 | | 0 | | 1 | 2+ | 0 | |
| OTHER | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [51] | | [35] | |
| (ALL TISSUES SLIGHT TO MODERATELY AUTOLYZED). | 1 | | 0 | | 0 | | 0 | |
| (MASS-ABDOMINAL CAVITY), MESOTHELIOMA. | 1 | | 0 | | 0 | | 0 | |
| NOT REQUIRED. | 29 | | 22 | | 37 | | 24 | |
| (BRONCHIAL LYMPH NODES), PIGMENTATION, INTRACELLULAR. | 2 | 3+ | 0 | | 0 | | 0 | |
| (BRONCHIAL LYMPH NODES), PLASMACYTOSIS. | 1 | 3+ | 1 | 4+ | 0 | | 0 | |
| (MASS-MEDIASTINUM), ABSCESS(ES). | 0 | | 1 | | 0 | | 0 | |
| (PANCREATIC LYMPH NODES), HISTIOCYTOSIS, PIGMENTED. | 1 | 3+ | 0 | | 0 | | 0 | |
| (MASS-RENAL LYMPH NODE), NOT PRESENT IN SECTION. | 1 | | 0 | | 0 | | 0 | |
| (ALL TISSUES MODERATELY AUTOLYZED). | 4 | | 0 | | 2 | | 1 | |
| (EYES), KERATITIS, ACTIVE, CHRONIC. | 1 | 4+ | 0 | | 0 | | 0 | |
| (EYES), CATARACT(S). | 1 | | 6 | | 2 | | 0 | |
| (PERITONEUM), FAT NECROSIS. | 1 | 4+ | 0 | | 0 | | 0 | |
| (MASS-CERVICAL REGION), FIBROMA. | 1 | | 0 | | 0 | | 0 | |
| (MASS-VISCERAL PERITONEUM), MESOTHELIOMA. | 1 | | 0 | | 0 | | 0 | |
| (ALL TISSUES MODERATE TO SEVERELY AUTOLYZED). | 2 | | 0 | | 2 | | 1 | |
| (BRONCHIAL LYMPH NODES), MALIGNANT LYMPHOMA. | 1 | | 0 | | 0 | | 0 | |
| (PANCREATIC LYMPH NODES), MALIGNANT LYMPHOMA. | 1 | | 0 | | 0 | | 0 | |
| (ABDOMINAL CAVITY), MESOTHELIOMA. | 1 | | 0 | | 0 | | 0 | |
| (PERITONIUM), MESOTHELIOMA. | 1 | | 0 | | 0 | | 0 | |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( MALES )

| | GROUP 4 | GROUP 8 | GROUP 12 | GROUP 16 |
|---|---|---|---|---|
| OTHER (continued) | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [51] | [35] |
| (VISCERAL PERITONEUM), MESOTHELIOMA. | 1 | 0 | 0 | 0 |
| (PREPUTIAL GLAND), ADENOMA. | 0 | 2 | 1 | 0 |
| (MESENTERY), PERITONITIS, CHRONIC. | 0 | 1 1+ | 0 | 0 |
| (ALL TISSUES SEVERELY AUTOLYZED). | 0 | 2 | 0 | 0 |
| (EYES), RETINAL DEGENERATION. | 0 | 5 4+ | 0 | 0 |
| (EYES), KERATITIS, CHRONIC. | 0 | 1 3+ | 1 4+ | 0 |
| (MASS-MESENTERY), FAT NECROSIS. | 0 | 1 1+ | 0 | 0 |
| (PANCREATIC LYMPH NODES), HEMOSIDEROSIS. | 0 | 0 | 1 4+ | 0 |
| (MASS-LYMPH NODE), NO SIGNIFICANT LESIONS RECOGNIZED. | 0 | 0 | 1 | 0 |
| (EYES), RETINAL ATROPHY. | 0 | 0 | 1 | 0 |
| (PREPUTIAL GLAND), DUCTAL ECTASIA. | 0 | 0 | 1 4+ | 0 |
| (MASS-STOMACH), FIBROMA. | 0 | 0 | 1 | 0 |
| (MASS-ABDOMINAL CAVITY), SARCOMA, UNDIFFERENTIATED. | 0 | 0 | 1 4+ | 0 |
| (MASS-THORACIC CAVITY), SARCOMA, UNDIFFERENTIATED. | 0 | 0 | 1 4+ | 0 |
| (MASS-CERVICAL AREA), SARCOMA, UNDIFFERENTIATED. | 0 | 0 | 1 | 0 |
| (MASS-PINEAL GLAND), NO SIGNIFICANT LESION RECOGNIZED. | 0 | 0 | 1 | 0 |
| (PREPUTIAL GLAND), ADENITIS, ACTIVE, CHRONIC. | 0 | 0 | 1 | 0 |
| (TONGUE), NO SIGNIFICANT LESION RECOGNIZED. | 0 | 0 | 0 | 1 |
| (BRONCHIAL LYMPH NODES), LYMPHOID HYPERPLASIA. | 0 | 0 | 0 | 1 4+ |
| (MASS-RENAL LYMPH NODE), NOT PRESENT IN SECTION. | 0 | 0 | 0 | 1 |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( FEMALES )

| | GROUP 4 | | GROUP 8 | | GROUP 12 | GROUP 16 |
|---|---|---|---|---|---|---|
| SKIN | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [49] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 47 | | 33 | | 45 | 33 |
| MISSING. | 1 | | 1 | | 0 | 1 |
| LEUKEMIA. | 1 | | 0 | | 0 | 0 |
| NECROSIS. | 1 | 1+ | 0 | | 0 | 0 |
| AUTOLYZED. | 0 | | 1 | | 1 | 0 |
| (MASS-THORAX), FIBROMA. | 0 | | 1 | | 0 | 0 |
| EPIDERMAL INCLUSION CYST(S). | 0 | | 0 | | 1 | 0 |
| (MASS-MUZZLE), PAPILLOMA. | 0 | | 0 | | 1 | 0 |
| NOT PRESENT IN SECTION. | 0 | | 0 | | 1 | 0 |
| (MASS-GENITAL AREA), SARCOMA, UNDIFFERENTIATED. | 0 | | 0 | | 1 | 0 |
| (MASS-PRESCAPULAR), SEBACEOUS ADENOMA. | 0 | | 0 | | 1 | 0 |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 0 | | 0 | | 0 | 1 |
| (MASS-HIND FOOT), DERMATITIS, ACTIVE, CHRONIC. | 1 | 4+ | 0 | | 0 | 0 |
| (MASS-FORELIMB), FIBROADENOMA. | 1 | | 0 | | 0 | 0 |
| (PAW-SORE), MISSING. | 2 | | 0 | | 0 | 0 |
| (FRONT LEG), EPIDERMAL INCLUSION CYST(S). | 1 | | 0 | | 0 | 0 |
| (MASS-REAR FOOT), PAPILLARY ADENOFIBROMA. | 1 | | 0 | | 0 | 0 |
| (HIND LEG), DERMATITIS, ACTIVE, CHRONIC. | 0 | | 1 | 3+ | 0 | 0 |
| (MASS-PAW), MISSING. | 0 | | 1 | | 0 | 0 |
| (MASS-HIND LEG), SARCOMA. | 0 | | 1 | | 0 | 0 |
| (MASS-FOOT), ADNEXAL ADENOMA. | 0 | | 1 | | 0 | 0 |
| MAMMARY | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [49] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 4 | | 5 | | 0 | 1 |
| NOT PRESENT IN SECTION. | 22 | | 11 | | 24 | 19 |
| MISSING. | 1 | | 1 | | 0 | 1 |
| AUTOLYZED. | 2 | | 1 | | 1 | 2 |
| ACTIVE. | 18 | | 13 | | 23 | 10 |
| FIBROADENOMA. | 1 | | 0 | | 0 | 0 |
| (MASS-INGUINAL), ADENOFIBROMA. | 6 | | 3 | | 1 | 4 |
| (MASS), ACTIVE. | 1 | | 0 | | 0 | 0 |
| ADENOFIBROMA. | 2 | | 0 | | 1 | 0 |
| (MASS-AXILLA), ADENOFIBROMA. | 3 | | 1 | | 1 | 1 |
| (MASS-ABDOMEN), ADENOFIBROMA. | 1 | | 1 | | 0 | 0 |
| (MASS-INGUINAL), ADENOCARCINOMA. | 1 | | 0 | | 0 | 0 |
| (MASS-AXILLA), FIBROADENOMA. | 1 | | 2 | | 1 | 2 |
| (MASS-INGUINAL), FIBROADENOMA. | 1 | | 2 | | 3 | 3 |
| (MASS-INGUINAL), CYSTIC ADENOFIBROMA. | 0 | | 1 | | 0 | 0 |
| (MASS-INGUINAL), PAPILLARY ADENOCARCINOMA. | 0 | | 1 | | 0 | 0 |
| (MASS), FIBROADENOMA. | 0 | | 1 | | 0 | 0 |
| (MASS-AXILLA), ADENOMA. | 0 | | 1 | | 2 | 1 |
| [illegible], ADENOFIBROMA. | 0 | | 1 | | 0 | 0 |
| [illegible], LACTATING. | 0 | | 1 | | 0 | 0 |
| [illegible]. | 0 | | 1 | 3+ | 0 | 0 |
| [illegible], ADENOMA. | 0 | | 0 | | 1 | 1 |
| [illegible], FIBROADENOMA. | 4 | | 0 | | 1 | 0 |
| [illegible], FIBROADENOMA. | 0 | | 0 | | 0 | 1 |
| [illegible], ADENOMA. | 0 | | 0 | | 0 | 1 |
| [illegible], ADENOFIBROMA. | 0 | | 0 | | 0 | 1 |
| [illegible], FIBROADENOMA. | 0 | | 0 | | 0 | 1 |
| [illegible], LIPOMA. | 2 | | 0 | | 0 | 0 |
| [illegible], FIBROMA. | 0 | | 0 | | 2 | 0 |
| [illegible], MISSING. | 0 | | 0 | | 0 | 1 |
| THIGH MUSCLE | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [49] | [35] |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( FEMALES )

| | GROUP 4 | | GROUP 8 | | GROUP 12 | | GROUP 16 | |
|---|---|---|---|---|---|---|---|---|
| THIGH MUSCLE (continued) | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [49] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 44 | | 31 | | 45 | | 29 | |
| AUTOLYZED. | 2 | | 2 | | 3 | | 4 | |
| LEUKEMIA. | 1 | | 0 | | 0 | | 0 | |
| NECROSIS. | 1 | 4+ | 0 | | 1 | 4+ | 1 | 4+ |
| MYOPATHY. | 2 | 3+ | 1 | 4+ | 0 | | 1 | 3+ |
| MISSING. | 0 | | 1 | | 0 | | 0 | |
| SALIVARY GLAND | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [49] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 43 | | 29 | | 43 | | 29 | |
| MISSING. | 3 | | 2 | | 3 | | 0 | |
| AUTOLYZED. | 4 | | 3 | | 3 | | 6 | |
| MALIGNANT LYMPHOMA. | 0 | | 1 | | 0 | | 0 | |
| BRONCHI | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [49] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 46 | | 31 | | 44 | | 28 | |
| AUTOLYZED. | 3 | | 2 | | 3 | | 6 | |
| BRONCHITIS, CHRONIC. | 1 | 4+ | 0 | | 0 | | 0 | |
| MISSING. | 0 | | 1 | | 1 | | 1 | |
| BRONCHITIS, ACTIVE, CHRONIC. | 0 | | 1 | 3+ | 1 | 4+ | 0 | |
| TRACHEA | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [49] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 46 | | 27 | | 45 | | 29 | |
| AUTOLYZED. | 3 | | 2 | | 3 | | 6 | |
| TRACHEITIS, CHRONIC. | 1 | 4+ | 0 | | 0 | | 0 | |
| TRACHEITIS, ACTIVE, CHRONIC. | 0 | | 6 | 3+ | 1 | 4+ | 0 | |
| LARYNX | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [49] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 46 | | 28 | | 44 | | 29 | |
| AUTOLYZED. | 3 | | 2 | | 3 | | 6 | |
| LARYNGITIS, CHRONIC. | 1 | 4+ | 0 | | 0 | | 0 | |
| LARYNGITIS, ACTIVE, CHRONIC. | 0 | | 5 | 2+ - 3+ | 1 | 4+ | 0 | |
| MISSING. | 0 | | 0 | | 1 | | 0 | |
| THYROID | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [49] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 32 | | 12 | | 24 | | 14 | |
| NOT PRESENT IN SECTION. | 6 | | 0 | | 4 | | 0 | |
| AUTOLYZED. | 7 | | 11 | | 9 | | 17 | |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 1 | | 2 | | 0 | | 0 | |
| C-CELL ADENOMA. | 3 | | 2 | | 6 | | 1 | |
| FOLLICULAR CELL ADENOMA. | 1 | | 2 | | 1 | | 0 | |
| C-CELL HYPERPLASIA. | 0 | | 2 | 2+ - 3+ | 2 | 2+ | 3 | 2+ |
| FOLLICULAR CYST(S). | 0 | | 1 | | 3 | | 0 | |
| C-CELL CARCINOMA. | 0 | | 4 | | 0 | | 0 | |
| MISSING. | 0 | | 0 | | 1 | | 0 | |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( FEMALES )

| | GROUP 4 | | GROUP 8 | | GROUP 12 | | GROUP 16 | |
|---|---|---|---|---|---|---|---|---|
| PARATHYROID | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [49] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 25 | | 16 | | 34 | | 21 | |
| NOT PRESENT IN SECTION. | 18 | | 12 | | 11 | | 6 | |
| AUTOLYZED. | 5 | | 6 | | 2 | | 7 | |
| HYPERPLASIA. | 2 | 2+ - 4+ | 1 | 3+ | 0 | | 0 | |
| LIPIDOSIS. | 0 | | 0 | | 1 | 2+ | 0 | |
| MISSING. | 0 | | 0 | | 1 | | 0 | |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 0 | | 0 | | 0 | | 1 | |
| ESOPHAGUS | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [49] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 46 | | 33 | | 45 | | 29 | |
| AUTOLYZED. | 4 | | 2 | | 3 | | 6 | |
| NOT PRESENT IN SECTION. | 0 | | 0 | | 1 | | 0 | |
| MANDIBULAR LYMPH NODE | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [49] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 25 | | 14 | | 13 | | 12 | |
| MISSING. | 13 | | 9 | | 27 | | 13 | |
| AUTOLYZED. | 2 | | 5 | | 4 | | 6 | |
| MALIGNANT LYMPHOMA. | 1 | | 0 | | 0 | | 1 | |
| LEUKEMIA. | 1 | | 1 | | 0 | | 0 | |
| LYMPHOID HYPERPLASIA. | 4 | 3+ - 4+ | 6 | 3+ - 4+ | 0 | | 2 | 3+ |
| RETICULOENDOTHELIAL CELL HYPERPLASIA. | 1 | 3+ | 0 | | 0 | | 0 | |
| CONGESTION. | 1 | 3+ | 0 | | 0 | | 0 | |
| HISTIOCYTOSIS. | 1 | 3+ | 0 | | 0 | | 0 | |
| PLASMACYTOSIS. | 1 | 4+ | 0 | | 1 | 3+ | 1 | 3+ |
| NOT PRESENT IN SECTION. | 0 | | 0 | | 3 | | 0 | |
| HISTIOCYTOSIS, PIGMENTED. | 0 | | 0 | | 1 | 3+ | 0 | |
| ADRENALS | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [49] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 30 | | 18 | | 30 | | 19 | |
| AUTOLYZED. | 2 | | 5 | | 3 | | 6 | |
| LEUKEMIA. | 1 | | 0 | | 0 | | 2 | |
| LIPIDOSIS. | 9 | 2+ - 3+ | 9 | 1+ - 4+ | 10 | 1+ - 4+ | 4 | 1+ - 3+ |
| CORTICAL NODULAR HYPERPLASIA. | 4 | 2+ | 0 | | 0 | | 0 | |
| HEMATOCYST(S). | 3 | | 0 | | 2 | | 1 | |
| GANGLIONEUROMA. | 1 | | 0 | | 0 | | 0 | |
| MEDULLARY CELL HYPERPLASIA. | 1 | 2+ | 1 | 1+ | 3 | 1+ - 2+ | 1 | 2+ |
| PHEOCHROMOCYTOMA. | 1 | | 3 | | 2 | | 1 | |
| CORTICAL CELL HYPERPLASIA. | 0 | | 1 | 2+ | 1 | 2+ | 0 | |
| CORTICAL CELL ADENOMA. | 0 | | 1 | | 0 | | 1 | |
| NOT PRESENT IN SECTION. | 0 | | 0 | | 1 | | 0 | |
| LYMPHOCYTOSIS, MEDULLA. | 0 | | 0 | | 1 | 2+ | 0 | |
| EDEMA. | 0 | | 0 | | 0 | | 1 | 4+ |
| THYMUS | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [49] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 28 | | 18 | | 6 | | 13 | |
| NOT PRESENT IN SECTION. | 13 | | 7 | | 35 | | 11 | |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( FEMALES )

| | GROUP 4 | | GROUP 8 | | GROUP 12 | | GROUP 16 | |
|---|---|---|---|---|---|---|---|---|
| THYMUS (continued) | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [49] | | [35] | |
| MISSING. | 1 | | 0 | | 1 | | 0 | |
| AUTOLYZED. | 3 | | 8 | | 5 | | 10 | |
| MALIGNANT LYMPHOMA. | 2 | | 1 | | 0 | | 0 | |
| CYST(S). | 1 | | 1 | | 0 | | 0 | |
| INSUFFICIENT TISSUE | | | | | | | | |
| PRESENT IN SECTION. | 1 | | 0 | | 0 | | 0 | |
| EPITHELIAL HYPERPLASIA. | 1 | 3+ | 0 | | 2 | 3+ | 0 | |
| LEUKEMIA. | 0 | | 0 | | 0 | | 1 | |
| SCIATIC NERVE | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [49] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 45 | | 27 | | 43 | | 28 | |
| MISSING. | 3 | | 2 | | 1 | | 0 | |
| AUTOLYZED. | 2 | | 4 | | 3 | | 7 | |
| NOT PRESENT IN SECTION. | 0 | | 1 | | 1 | | 0 | |
| INSUFFICIENT TISSUE | | | | | | | | |
| PRESENT IN SECTION. | 0 | | 1 | | 1 | | 0 | |
| STOMACH | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [49] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 35 | | 22 | | 26 | | 7 | |
| MISSING. | 1 | | 0 | | 0 | | 0 | |
| AUTOLYZED. | 6 | | 11 | | 13 | | 16 | |
| MALIGNANT LYMPHOMA. | 1 | | 0 | | 0 | | 0 | |
| (GLANDULAR), MINERALIZATION. | 1 | 4+ | 0 | | 0 | | 1 | 4+ |
| (GLANDULAR), MULTIPLE CYST(S). | 1 | | 0 | | 2 | | 0 | |
| (FORESTOMACH), GASTRITIS, NECROTIZING, SUBACUTE. | 1 | 4+ | 0 | | 0 | | 0 | |
| (FORESTOMACH), GASTRITIS, ACUTE, NECROTIZING. | 2 | 4+ | 0 | | 0 | | 0 | |
| (FORESTOMACH), GASTRITIS, GRANULOMATOUS. | 1 | 2+ | 0 | | 0 | | 0 | |
| (FORESTOMACH), GASTRITIS, NECROTIZING. | 1 | 4+ | 0 | | 3 | 4+ | 1 | 4+ |
| NOT PRESENT IN SECTION. | 0 | | 1 | | 0 | | 0 | |
| (FORESTOMACH), MALIGNANT LYMPHOMA. | 0 | | 1 | | 0 | | 0 | |
| (FORESTOMACH), GASTRITIS, SUBACUTE. | 0 | | 0 | | 4 | 2+ - 4+ | 6 | 2+ - 3+ |
| GASTROPATHY. | 0 | | 0 | | 1 | 3+ | 0 | |
| GASTRITIS, NECROTIZING. | 0 | | 0 | | 1 | 4+ | 0 | |
| INSUFFICIENT TISSUE | | | | | | | | |
| PRESENT IN SECTION. | 0 | | 0 | | 0 | | 1 | |
| (FORESTOMACH), EDEMA. | 0 | | 0 | | 0 | | 1 | 3+ |
| (FORESTOMACH), GASTRITIS, CHRONIC. | 0 | | 0 | | 0 | | 4 | 3+ - 4+ |
| (FORESTOMACH), GASTRITIS, SUBACUTE, NECROTIZING. | 0 | | 0 | | 0 | | 1 | 4+ |
| DUODENUM | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [49] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 37 | | 24 | | 35 | | 18 | |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( FEMALES )

| | GROUP 4 | | GROUP 8 | | GROUP 12 | | GROUP 16 | |
|---|---|---|---|---|---|---|---|---|
| DUODENUM (continued) | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [49] | | [35] | |
| AUTOLYZED. | 11 | | 10 | | 14 | | 17 | |
| LEIOMYOMA. | 1 | | 0 | | 0 | | 0 | |
| SARCOMA, UNDIFFERENTIATED. | 1 | | 0 | | 0 | | 0 | |
| ENTERITIS, ACUTE. | 0 | | 1 | 4+ | 0 | | 0 | |
| JEJUNUM | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [49] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 39 | | 25 | | 35 | | 17 | |
| AUTOLYZED. | 11 | | 10 | | 14 | | 18 | |
| ILEUM | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [49] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 39 | | 24 | | 35 | | 16 | |
| AUTOLYZED. | 11 | | 10 | | 14 | | 18 | |
| POLYP(S). | 0 | | 1 | | 0 | | 0 | |
| LEUKEMIA. | 0 | | 0 | | 0 | | 1 | |
| CECUM | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [49] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 39 | | 24 | | 15 | | 16 | |
| AUTOLYZED. | 10 | | 10 | | 14 | | 18 | |
| NECROSIS. | 1 | 4+ | 0 | | 0 | | 0 | |
| ENTEROPATHY. | 0 | | 1 | 2+ | 20 | 2+ - 4+ | 1 | 2+ |
| COLON | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [49] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 38 | | 25 | | 33 | | 17 | |
| AUTOLYZED. | 9 | | 10 | | 14 | | 17 | |
| NEMATODIASIS. | 1 | | 0 | | 0 | | 1 | |
| ENTERITIS, NECROTIZING. | 2 | 4+ | 0 | | 0 | | 0 | |
| MULTIPLE CYST(S). | 0 | | 0 | | 1 | | 0 | |
| MALIGNANT LYMPHOMA. | 0 | | 0 | | 1 | | 0 | |
| RECTUM | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [49] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 40 | | 25 | | 35 | | 17 | |
| AUTOLYZED. | 10 | | 10 | | 14 | | 18 | |
| MESENTERIC LYMPH NODES | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [49] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 13 | | 10 | | 17 | | 8 | |
| MISSING. | 4 | | 8 | | 6 | | 2 | |
| AUTOLYZED. | 6 | | 6 | | 9 | | 15 | |
| MALIGNANT LYMPHOMA. | 2 | | 0 | | 1 | | 1 | |
| LEUKEMIA. | 1 | | 0 | | 0 | | 1 | |
| RETICULOENDOTHELIAL CELL HYPERPLASIA. | 5 | 3+ | 0 | | 0 | | 0 | |
| HISTIOCYTOSIS. | 21 | 2+ - 3+ | 11 | 1+ - 3+ | 12 | 3+ - 4+ | 7 | 1+ - 3+ |
| MASTOCYTOSIS. | 1 | 3+ | 1 | 3+ | 0 | | 1 | 3+ |
| LYMPHOID HYPOPLASIA. | 1 | 4+ | 0 | | 0 | | 0 | |
| LYMPHOID HYPERPLASIA. | 0 | | 1 | 2+ | 1 | 3+ | 0 | |
| RETICULUM CELL HYPERPLASIA. | 0 | | 2 | 3+ | 0 | | 1 | 3+ |
| MULTIPLE CYST(S). | 0 | | 0 | | 1 | | 0 | |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( FEMALES )

| | GROUP 4 | GROUP 8 | GROUP 12 | GROUP 16 |
|---|---|---|---|---|
| MESENTERIC LYMPH NODES (continued) | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [49] | [35] |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 0 | 0 | 2 | 0 |
| LUNGS (ALL LOBES) | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [49] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 2 | 12 | 33 | 21 |
| HISTIOCYTOSIS, PIGMENTED. | 42 1+ - 3+ | 2 1+ | 5 1+ | 0 |
| AUTOLYZED. | 1 | 1 | 4 | 7 |
| LEUKEMIA. | 7 | 3 2+ | 0 | 5 |
| CHRONIC MURINE PNEUMONIA. | 8 1+ - 3+ | 15 1+ - 4+ | 2 3+ - 4+ | 0 |
| HISTIOCYTOSIS. | 1 | 0 | 0 | 0 |
| PNEUMONITIS, INTERSTITIAL. | 1 2+ | 0 | 0 | 0 |
| ADENOMATOSIS. | 2 2+ | 0 | 0 | 0 |
| MINERALIZATION, ALVEOLAR. | 1 4+ | 0 | 0 | 0 |
| ALVEOLAR/BRONCHIOLAR CELL ADENOMA. | 3 | 0 | 1 | 0 |
| ALVEOLAR/BRONCHIOLAR CELL HYPERPLASIA. | 4 2+ | 1 1+ | 0 | 1 3+ |
| ALVEOLAR PROTEINOSIS. | 1 3+ | 0 | 0 | 0 |
| FIBROSIS. | 0 | 1 2+ | 0 | 0 |
| ATELECTASIS. | 0 | 2 3+ - 4+ | 0 | 0 |
| C-CELL CARCINOMA, METASTATIC. | 0 | 2 | 0 | 0 |
| SARCOMA, METASTATIC, UNDIFFERENTIATED. | 0 | 1 | 0 | 0 |
| BRONCHOPNEUMONIA, ACUTE, PURULENT. | 0 | 1 4+ | 0 | 0 |
| PNEUMONITIS, GRANULOMATOUS. | 0 | 1 4+ | 3 1+ - 2+ | 1 1+ |
| BRONCHOPNEUMONIA, ACTIVE, CHRONIC. | 0 | 0 | 1 4+ | 0 |
| CONGESTION. | 0 | 0 | 1 4+ | 0 |
| HEMORRHAGE. | 0 | 0 | 0 | 1 2+ |
| LIVER | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [49] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 19 | 13 | 19 | 11 |
| AUTOLYZED. | 2 | 1 | 4 | 5 |
| LEUKEMIA. | 9 | 6 | 0 | 7 |
| HEPATITIS, GRANULOMATOUS. | 3 1+ - 2+ | 4 1+ - 2+ | 12 1+ - 3+ | 5 1+ - 2+ |
| EOSINOPHILIC FOCUS/FOCI. | 11 | 9 | 10 | 3 |
| NEOPLASTIC NODULE(S). | 3 | 0 | 3 | 1 |
| HEPATOCELLULAR VACUOLATION, CENTRILOBULAR. | 1 4+ | 1 4+ | 2 2+ - 3+ | 1 3+ |
| HISTIOCYTOSIS, PIGMENTED, PORTAL. | 2 2+ | 0 | 0 | 0 |
| NECROSIS, CENTRILOBULAR. | 1 4+ | 0 | 1 1+ | 1 4+ |
| HEPATITIS, MONONUCLEAR CELL, PORTAL. | 1 2+ | 0 | 0 | 0 |
| FIBROUS HISTIOCYTOMA. | 1 | 0 | 0 | 0 |
| HEPATOCELLULAR VACUOLATION. | 1 3+ | 3 2+ - 4+ | 7 2+ - 4+ | 6 2+ - 3+ |
| BASOPHILIC FOCUS/FOCI. | 1 | 2 | 1 | 1 |
| HEPATITIS, NECROTIZING. | 0 | 1 1+ | 0 | 0 |
| HEPATITIS, PORTAL, MONONUCLEAR CELL. | 0 | 0 | 1 3+ | 0 |
| HISTIOCYTOSIS, PIGMENTED. | 0 | 0 | 4 1+ - 2+ | 0 |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( FEMALES )

| | GROUP 4 | | GROUP 8 | | GROUP 12 | | GROUP 16 | |
|---|---|---|---|---|---|---|---|---|
| LIVER (continued) | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [49] | | [35] | |
| HEPATOCELLULAR NUCLEAR ATYPIA. | 0 | | 0 | | 1 | 1+ | 0 | |
| HEPATITIS, ACTIVE, CHRONIC, NECROTIZING. | 0 | | 0 | | 1 | 3+ | 0 | |
| CONGESTION, CENTRILOBULAR. | 0 | | 0 | | 2 | 3+ | 0 | |
| HEPATITIS, ACUTE, PURULENT. | 0 | | 0 | | 1 | 4+ | 0 | |
| CLEAR CELL FOCUS/FOCI. | 0 | | 0 | | 2 | | 1 | |
| MALIGNANT LYMPHOMA. | 0 | | 0 | | 1 | | 0 | |
| TELANGIECTASIS. | 0 | | 0 | | 1 | 3+ | 0 | |
| BILE DUCT HYPERPLASIA. | 0 | | 0 | | 0 | | 1 | 4+ |
| EXTRAMEDULLARY HEMATOPOIESIS. | 0 | | 0 | | 0 | | 1 | 2+ |
| SPLEEN | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [49] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 32 | | 19 | | 32 | | 13 | |
| AUTOLYZED. | 3 | | 3 | | 8 | | 10 | |
| LEUKEMIA. | 10 | | 6 | | 0 | | 7 | |
| CONGESTION. | 1 | 4+ | 1 | 4+ | 0 | | 1 | 4+ |
| EXTRAMEDULLARY HEMATOPOIESIS. | 2 | 4+ | 2 | 3+ - 4+ | 1 | 3+ | 3 | 2+ - 4+ |
| FIBROMA. | 1 | | 0 | | 0 | | 0 | |
| FIBROUS HISTIOCYTOMA. | 1 | | 0 | | 0 | | 0 | |
| HEMOSIDEROSIS. | 1 | 4+ | 1 | 3+ | 6 | 3+ - 4+ | 0 | |
| FIBROSIS. | 0 | | 1 | 1+ | 0 | | 0 | |
| MALIGNANT LYMPHOMA. | 0 | | 1 | | 0 | | 0 | |
| SIDEROPHAGOCYTOSIS. | 0 | | 1 | 3+ | 0 | | 0 | |
| SARCOMA, METASTATIC, UNDIFFERENTIATED. | 0 | | 1 | | 0 | | 0 | |
| NECROSIS. | 0 | | 0 | | 1 | 4+ | 0 | |
| MONONUCLEAR CELL HYPERPLASIA. | 0 | | 0 | | 1 | 3+ | 0 | |
| SPLENOMA. | 0 | | 0 | | 0 | | 1 | |
| PANCREAS | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [49] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 38 | | 19 | | 34 | | 17 | |
| AUTOLYZED. | 5 | | 8 | | 8 | | 11 | |
| LEUKEMIA. | 1 | | 0 | | 0 | | 1 | |
| ISLET CELL CARCINOMA. | 1 | | 0 | | 0 | | 0 | |
| ACINAR CELL ATROPHY. | 2 | 2+ | 2 | 1+ | 4 | 1+ - 3+ | 3 | 1+ - 4+ |
| DUCTAL ECTASIA. | 1 | 2+ | 0 | | 0 | | 0 | |
| ISLET CELL ADENOMA. | 2 | | 1 | | 0 | | 1 | |
| LOBULAR ATROPHY. | 1 | 2+ | 1 | | 1 | 4+ | 0 | |
| MISSING. | 0 | | 1 | | 0 | | 2 | |
| MALIGNANT LYMPHOMA. | 0 | | 1 | | 0 | | 0 | |
| ACINAR CELL BASOPHILLIA. | 0 | | 1 | 2+ | 0 | | 0 | |
| BASOPHILIC FOCUS. | 0 | | 1 | | 0 | | 0 | |
| MULTIPLE EOSINOPHILIC ACINAR FOCI. | 0 | | 0 | | 2 | | 0 | |
| ISLET CELL HYPERPLASIA. | 0 | | 0 | | 0 | | 1 | |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( FEMALES )

| | GROUP 4 | | GROUP 8 | | GROUP 12 | | GROUP 16 | |
|---|---|---|---|---|---|---|---|---|
| KIDNEYS | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [49] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 27 | | 17 | | 12 | | 12 | |
| NEPHROPATHY, CHRONIC. | 13 | 1+ - 4+ | 10 | 1+ - 4+ | 30 | 2+ - 4+ | 12 | 1+ - 4+ |
| NEPHROCALCINOSIS, MEDULLA. | 3 | 3+ | 0 | | 3 | 2+ - 3+ | 0 | |
| AUTOLYZED. | 5 | | 8 | | 4 | | 10 | |
| LEUKEMIA. | 2 | | 0 | | 0 | | 0 | |
| (CORTICAL TUBULES), MINERALIZATION. | 1 | 4+ | 0 | | 0 | | 0 | |
| NEPHRITIS, GRANULOMATOUS. | 1 | 1+ | 0 | | 0 | | 0 | |
| NEPHROLITHIASIS, MEDULLA. | 1 | 3+ | 0 | | 0 | | 0 | |
| NEPHROCALCINOSIS. | 0 | | 1 | 1+ | 0 | | 1 | 2+ |
| NEPHRITIS, ACUTE, PURULENT. | 0 | | 0 | | 1 | 4+ | 0 | |
| HYPERPLASIA, PELVIC EPITHELIUM. | 0 | | 0 | | 1 | 2+ | 0 | |
| TUBULAR CELL HYPERPLASIA. | 0 | | 0 | | 1 | 2+ | 0 | |
| NEPHRITIS, SUBACUTE, PURULENT. | 0 | | 0 | | 0 | | 1 | 4+ |
| TUBULAR CELL ADENOMA. | 0 | | 0 | | 0 | | 1 | |
| HEART | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [49] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 30 | | 26 | | 29 | | 20 | |
| AUTOLYZED. | 3 | | 5 | | 5 | | 8 | |
| LEUKEMIA. | 3 | | 1 | | 0 | | 1 | |
| MYOCARDIOPATHY. | 11 | 1+ - 4+ | 2 | 1+ - 2+ | 14 | 1+ - 3+ | 6 | 1+ - 2+ |
| MINERALIZATION. | 1 | 3+ | 0 | | 0 | | 0 | |
| (PERICARDIUM), LEUKEMIA. | 1 | | 0 | | 0 | | 0 | |
| ATRIAL THROMBOSIS. | 1 | | 1 | | 0 | | 0 | |
| MYOCARDITIS, SUBACUTE. | 2 | 1+ - 4+ | 0 | | 0 | | 0 | |
| (CORONARY ARTERY), PERIARTERITIS. | 0 | | 0 | | 1 | 4+ | 0 | |
| PERIARTERITIS, CHRONIC. | 0 | | 0 | | 0 | | 1 | 3+ |
| URINARY BLADDER | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [49] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 41 | | 24 | | 38 | | 21 | |
| MISSING. | 2 | | 2 | | 2 | | 1 | |
| AUTOLYZED. | 4 | | 9 | | 6 | | 11 | |
| LEUKEMIA. | 1 | | 0 | | 0 | | 1 | |
| PAPILLARY HYPERPLASIA. | 1 | 2+ | 0 | | 1 | 3+ | 0 | |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 1 | | 0 | | 2 | | 0 | |
| (MASS), LEIOMYOMA. | 0 | | 0 | | 0 | | 1 | |
| EPITHELIAL HYPERPLASIA. | 0 | | 0 | | 0 | | 1 | 3+ |
| OVARIES | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [49] | | [35] | |
| NO SIGNIFICANT LESION RECOGNIZED. | 41 | | 26 | | 39 | | 21 | |
| AUTOLYZED. | 4 | | 4 | | 4 | | 8 | |
| LEUKEMIA. | 2 | | 0 | | 0 | | 1 | |
| CYST(S). | 1 | | 1 | | 2 | | 4 | |
| PAROVARIAN CYST(S). | 1 | | 1 | | 3 | | 0 | |
| GRANULOSA CELL TUMOR(S). | 1 | | 0 | | 2 | | 0 | |
| OOPHORITIS, CHRONIC, PURULENT. | 0 | | 3 | 4+ | 0 | | 0 | |
| MISSING. | 0 | | 0 | | 0 | | 1 | |
| (LESION), MISSING. | 0 | | 0 | | 1 | | 0 | |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( FEMALES )

| | GROUP 4 | GROUP 8 | GROUP 12 | GROUP 16 |
|---|---|---|---|---|
| UTERUS | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [49] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 40 | 23 | 37 | 26 |
| MISSING. | 1 | 0 | 0 | 1 |
| AUTOLYZED. | 3 | 4 | 4 | 6 |
| LEUKEMIA. | 1 | 0 | 0 | 0 |
| ENDOMETRITIS, ACUTE, PURULENT. | 1 4+ | 0 | 0 | 0 |
| MULTILOBULAR CYST(S). | 1 | 0 | 0 | 0 |
| FIBROMA. | 1 | 0 | 0 | 0 |
| STROMAL POLYP(S). | 2 | 2 | 3 | 1 |
| CYSTIC HYPERPLASIA. | 0 | 5 2+ - 3+ | 3 2+ - 3+ | 1 2+ |
| SARCOMA, UNDIFFERENTIATED. | 0 | 1 | 0 | 0 |
| POLYP(S). | 0 | 0 | 1 | 0 |
| ENDOMETRIAL HYPERPLASIA. | 0 | 0 | 1 3+ | 0 |
| ENDOMETRITIS. | 0 | 0 | 1 4+ | 0 |
| (CERVIX), FIBROMA. | 1 | 0 | 1 | 0 |
| BRAIN | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [49] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 41 | 29 | 42 | 23 |
| AUTOLYZED. | 4 | 6 | 6 | 7 |
| LEUKEMIA. | 3 | 0 | 0 | 0 |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 1 | 0 | 0 | 1 |
| HEMORRHAGE. | 1 1+ | 0 | 0 | 0 |
| PITUITARY ADENOMA, INVASIVE. | 0 | 0 | 1 | 0 |
| NECROSIS. | 0 | 0 | 0 | 1 4+ |
| ASTROCYTOMA, UNDIFFERENTIATED. | 0 | 0 | 0 | 1 |
| (WHITE MATTER), CEREBELLAR VACUOLATION. | 0 | 0 | 0 | 1 3+ |
| (CEREBRUM), PITUITARY ADENOMA, INVASIVE. | 0 | 0 | 0 | 1 |
| PITUITARY | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [49] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 10 | 10 | 8 | 8 |
| MISSING. | 7 | 8 | 6 | 8 |
| AUTOLYZED. | 1 | 3 | 2 | 3 |
| LEUKEMIA. | 1 | 0 | 0 | 0 |
| CYST(S). | 3 | 1 | 5 | 2 |
| ADENOMA. | 25 | 11 | 24 | 13 |
| INSUFFICIENT TISSUE PRESENT IN SECTION. | 4 | 2 | 4 | 1 |
| STERNUM/RIB & RIB JUNCTION | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [49] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 44 | 34 | 48 | 31 |
| AUTOLYZED. | 1 | 1 | 1 | 1 |
| ADENOMA. | 1 | 0 | 0 | 0 |
| FIBROUS OSTEODYSTROPHY. | 1 4+ | 0 | 0 | 0 |
| ENDOSTOSIS. | 3 3+ - 4+ | 0 | 0 | 2 4+ |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( FEMALES )

| | GROUP 4 | GROUP 8 | GROUP 12 | GROUP 16 |
|---|---|---|---|---|
| FEMUR | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [49] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 43 | 33 | 48 | 28 |
| AUTOLYZED. | 1 | 1 | 1 | 1 |
| ADENOMA. | 1 | 0 | 0 | 0 |
| FIBROUS OSTEODYSTROPHY. | 1 4+ | 0 | 0 | 0 |
| ENDOSTOSIS. | 4 3+ - 4+ | 1 3+ | 0 | 5 3+ - 4+ |
| (BONE MARROW), FIBROUS HISTIOCYTOMA. | 1 | 0 | 0 | 0 |
| (BONE MARROW), LEUKEMIA. | 0 | 1 | 0 | 0 |
| NASAL CAVITY | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [49] | [35] |
| NO SIGNIFICANT LESION RECOGNIZED. | 46 | 34 | 47 | 32 |
| MISSING. | 1 | 0 | 0 | 0 |
| AUTOLYZED. | 1 | 1 | 1 | 1 |
| ADENOMA. | 1 | 0 | 0 | 0 |
| FIBROUS OSTEODYSTROPHY. | 1 4+ | 0 | 0 | 0 |
| RHINITIS, ACUTE, PURULENT. | 0 | 0 | 1 4+ | 0 |
| OTHER | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | [35] | [49] | [35] |
| (MUZZLE), CUTANEOUS HORN. | 1 | 0 | 0 | 0 |
| NOT REQUIRED. | 27 | 20 | 32 | 25 |
| (ALL TISSUES SEVERELY AUTOLYZED). | 2 | 1 | 1 | 1 |
| (MASS-RENAL LYMPH NODE), NOT PRESENT IN SECTION. | 1 | 0 | 0 | 0 |
| MASTOCYTOSIS. | 1 3+ | 0 | 0 | 0 |
| (ALL TISSUES MODERATE TO SEVERELY AUTOLYZED). | 3 | 0 | 3 | 3 |
| (CLITORAL GLAND), ADENOMA. | 4 | 0 | 1 | 1 |
| (MASS-THORACIC CAVITY), MISSING. | 1 | 0 | 0 | 0 |
| (BRONCHIAL LYMPH NODES), HISTIOCYTOSIS, PIGMENTED. | 1 4+ | 0 | 0 | 0 |
| (EYES), CATARACT(S). | 3 | 4 | 0 | 0 |
| (EYES), RETINAL ATROPHY. | 2 4+ | 0 | 0 | 0 |
| (ALL TISSUES MODERATELY AUTOLYZED). | 1 | 4 | 1 | 2 |
| (MASS-UMBILICUS), ADNEXAL ADENOMA. | 1 | 0 | 0 | 0 |
| (MASS-CLITORAL GLAND), SQUAMOUS CELL CARCINOMA. | 1 | 1 | 0 | 0 |
| (EYES), RETINAL DEGENERATION. | 0 | 4 | 0 | 0 |

CARCINOGENICITY OF AZO DYES:
ACID BLACK 52 AND YELLOW 3

( FEMALES )

| | GROUP 4 | | GROUP 8 | | GROUP 12 | | GROUP 16 | |
|---|---|---|---|---|---|---|---|---|
| OTHER (continued) | | | | | | | | |
| NUMBER OF ANIMALS EXAMINED | [50] | | [35] | | [49] | | [35] | |
| (MESENTERY), FAT NECROSIS. | 0 | | 1 | 4+ | 0 | | 2 | 4+ |
| (MESENTERY), MALIGNANT LYMPHOMA. | 0 | | 1 | | 0 | | 0 | |
| (MASS-CLITORAL GLAND), ADENOMA. | 0 | | 1 | | 0 | | 0 | |
| (VAGINA), STROMAL POLYP(S). | 0 | | 1 | | 0 | | 0 | |
| (MASS-CERVICAL), ADENOCARCINOMA. | 0 | | 0 | | 1 | | 0 | |
| (CLITORAL GLAND), DUCTAL ECTASIA. | 0 | | 0 | | 1 | 3+ | 0 | |
| (VAGINA), POLYP(S). | 0 | | 0 | | 1 | | 0 | |
| (OMENTUM), FAT NECROSIS. | 0 | | 0 | | 1 | 3+ | 0 | |
| (EYES-CILIARY BODY), HEMORRHAGE. | 0 | | 0 | | 1 | 3+ | 0 | |
| (ZYMBAL'S GLAND), CARCINOMA. | 0 | | 0 | | 1 | | 0 | |
| (EYES), KERATITIS. | 0 | | 0 | | 1 | 4+ | 0 | |
| (ORBITAL GLAND), ADENOMA. | 0 | | 0 | | 1 | | 0 | |
| (MASS), AUTOLYZED. | 0 | | 0 | | 1 | | 0 | |
| (MASS-ABDOMINAL CAVITY), AUTOLYZED. | 0 | | 0 | | 0 | | 1 | |
| (CLITORAL GLAND), HYPERPLASIA. | 0 | | 0 | | 0 | | 1 | 3+ |