50272-101

| REPORT DOCUMENTATION PAGE | 1. REPORT NO. | 2. | 3 PB89-186662 |
|---|---|---|---|
| 4. Title and Subtitle Industrial Hygiene Survey Report of Pan American Tannery, Gloverville, New York, Report No. IWS-076-13 | | | 5. Report Date 89/01/00 |
| | | | 6. |
| 7. Author(s) Fajen, J. M., and G. Calvert | | | 8. Performing Organization Rept. No. IWS-076-13 |
| 9. Performing Organization Name and Address Industrywide Studies Branch, NIOSH, U.S. Department of Health and Human Services, Cincinnati, Ohio | | | 10. Project/Task/Work Unit No. |
| | | | 11. Contract (C) or Grant(G) No. (C) (G) |
| 12. Sponsoring Organization Name and Address | | | 13. Type of Report & Period Covered |
| | | | 14. |

15. Supplementary Notes

16. Abstract (Limit: 200 words) As part of a larger study concerning the clustering of testicular cancer among finish department employees in tanneries, a visit was made to the Pan American Tannery (SIC-3111), Gloverville, New York. Area air samples were taken for dimethylformamide (68122), glycol ethers, and substances in the general air. Bulk samples were also obtained to determine the potential for exposure to heavy metals. Major components in the air samples were identified as butyl-cellosolve (111762), diisobutylketone (108838), limonene (5989275), and 2-ethylhexyl-acetate (103093). Dimethylformamide was not found in the air, and was no longer used in the facility. Lead (7439921) was found in concentrations as high as 22,400 parts per million (ppm) in a bulk scraping from a ventilation duct. The high concentrations of lead result from lead based pigments. There were three cases of testicular cancer in finishing department employees, representing a crude standardized incidence ratio of 40.5. Area air samples indicate that exposure to glycol ethers did not exceed the Federal recommended limits. The authors recommend that an ongoing testicular cancer surveillance program be provided for past and present male employees in the finishing department. Improvements should be made in the personal protective equipment offered to the workers. Strict controls should be instituted regarding lead exposures.

17. Document Analysis a. Descriptors

b. Identifiers/Open-Ended Terms NIOSH-Publication, NIOSH-Author, NIOSH-Survey, Field-Study, IWS-076-13, Region-2, Tanning-industry, Cancer-rates, Risk-analysis, Epidemiology, Carcinogens, Reproductive-system-disorders

c. COSATI Field/Group



| 18. Availability Statement | 19. Security Class (This Report) | 21. No. of Pages 37 |
|---|---|---|
| | 20. Security Class (This Page) | 22. Price |

# Industrial Hygiene Survey Report
# of
# Pan American Tannery
# Gloverville, New York

Survey Conducted by:
John M. Fajen
Geoff Calvert, M.D.
William Halperin, M.D.
Dan Middleton, M.D.

Dates of Survey:
February 17, 1988

Report Written by:
John M. Fajen, M.S.
Geoff Calvert, M.D.

Date of Report:
January, 1989

Report Number:
76.13

Industrial Hygiene Section
Industrywide Studies Branch
Division of Surveillance, Hazard Evaluations and Field Studies
National Institute for Occupational Safety and Health
Centers for Disease Control
Cincinnati, Ohio

DISCLAIMER

Mention of company names or products in this report does not constitute endorsement by the National Institute for Occupational Safety and Health (NIOSH).

| | |
|---|---|
| Purpose of Survey: | To perform a walk-through industrial hygiene survey and epidemiologic evaluation of the Pan American Tannery as part of an investigation into a cluster of testicular cancer among their finish department employees. |
| Employer Representatives Contacted: | Mr. Tom Romaine, Plant Manager<br>Mr. Ron Sonbert, Technical Director<br>Mr. Scott N. Fein, Company Attorney |
| Employee Representatives Contacted: | Mr. William Towne, Manager, Glove City Joint Board, ACTWU<br><br>Mr. Richard Handy<br>President - Union Local 1712<br><br>Mr. William Lampher<br>Chairman, Health & Safety Committee<br><br>Mr. Michell Braithwaite<br>Industrial Hygienist, ACTWU |
| New York State Health Department: | Mr. Matt London<br>Industrial Hygienist<br><br>Ms. Betsy Marshall<br>Epidemiologist |
| NIOSH Representatives: | Mr. John Fajen<br>Industrial Hygienist<br><br>Dr. William J. Halperin<br>Physician<br><br>Dr. Geoff Calvert<br>Physician<br><br>Dr. Dan Middleton<br>Physician |
| Standard Industrial Classification of Plant: | SIC 3111 Leather Tanning and Finishing |

## ABSTRACT

An evaluation was conducted at the Pan American Tanneries following a report published by Levin et al in Lancet documenting a cluster of three men with testicular cancer who worked in that tannery, on the same shift, in the same department and during the same time period. NIOSH conducted a standardized incidence ratio study (SIR) of testicular cancer among finishing department workers at the Pan American Tannery. The three cases of testicular cancer in the finishing department represents a crude SIR of 40.5 (95% CI 8.15, 118.45). An industrial hygiene survey was also conducted in the finishing department. Area air samples were taken for dimethylformamide, glycol ethers, and substances in the general air. Bulk samples were also obtained to determine the potential for exposure to heavy metals. The major components in the air samples were identified as butyl cellusolve, diisobutylketone, limonene, and 2-ethylhexyl acetate. Dimethylformamide, no longer used at the tannery, was not detected in any of the air or bulk samples. Lead was found as high as 22,400 ppm in a bulk scraping from a ventilation duct.

We propose a plan to screen former and current male employees in the finishing department at the Pan American Tannery for testicular cancer. In support of the testicular screening an indepth industrial hygiene evaluation of the finishing department is also proposed.

## Introduction

In December 1987, NIOSH received a request from the Amalgamated Clothing and Textile Workers Union (ACTWU) to conduct an investigation of an outbreak of cancer in leather tannery workers in Gloversville, New York. This request came soon after a report published by Levin et al[1] in Lancet documenting a cluster of three men with testicular cancer who worked at the same tannery, on the same shift, in the same department and during the same time period (Table 1). In response to this request, NIOSH in February 1988, conducted a walk-through industrial hygiene survey and a standardized incidence ratio study of finishing department workers at the Pan American Tannery, the site of the reported cluster.

Soon after Levin et al[1] reported the cluster of testicular cancer at the Pan American Tannery, the New York Department of Health conducted a case-referent study to determine the risk of testicular cancer in Fulton County, New York.[2] Gloversville is located in Fulton County. Using New York State Cancer Registry Data, occupation was determined for all male residents aged 20-54 residing in Fulton County who developed testicular cancer between 1974 and March, 1987. Occupation was also determined for a control group consisting of men of similar age living in Fulton County who developed any other type of cancer between 1977 and March, 1987. Ten testicular cancer were identified and matched with 115 controls. Five of the 10 cases and 17 of the 115 controls were found to have been employed in leather related occupations. This represents an odds ratio of 5.76 (95% CI 1.50-22.05). Three of the five cases employed in leather related occupations were the men who worked in the finishing department of the Pan American Tannery. One of the two remaining men with tannery-associated testicular cancer had testicular problems as a child, which can be a risk factor for developing testicular cancer. Although this individual never worked at the Pan American Tannery, 11 years before his diagnosis he had worked for one year in the finishing department of another tannery. The other individual with tannery employment and testicular cancer never worked at the Pan American Tannery; however, he worked for 21 years in tanneries, although never in a finishing department.

This cluster of cases of testicular cancer is cause for concern because these workers were exposed to glycol ethers, a known testicular toxin, and to DMF, which has been cited in some studies as the possible agent responsible for the observed elevations in testicular cancer.

In a cross-sectional study by Ducatman et al, an elevation of testicular cancer among workers at two of three Navy aircraft maintenance sites was reported.[3] The authors proposed that dimethylformamide (DMF) may be responsible for testicular cancer. This study was undertaken when investigators were informed that at one Navy F-4 aircraft maintenance site three workers had testicular cancer. The investigators next surveyed another Navy F-4 aircraft maintenance site with exposures similar to the first facility. Four cases of testicular cancer were detected. Finally, the investigators surveyed an F-15 aircraft maintenance facility having similar exposures as the first two facilities, except that DMF had never been used.

No testicular cancer was detected at this facility. Although the investigators speculated that DMF may have been responsible for the elevated risk of testicular cancer at the first two facilities, workers at all three facilities were exposed to numerous chemicals. It is possible that chemical exposures other than DMF may also have been unique to the first two facilities and that the true exposure responsible for the elevation in testicular cancer was not identified by the investigators.

Citing the study by Ducatman et al[3], Levin et al[1] proposed that DMF may have been responsible for the three cases of testicular cancer at the Pan American Tannery. However, like the workers at the aircraft maintenance sites investigated by Ducatman, workers at the Pan American Tannery were exposed to a large number of chemicals including DMF. Because of the large number of exposures and small number of employees at the tannery, determination of the agent responsible for the cluster will be difficult if not impossible.

One month before the study by Ducatman et al[3] was published, a standardized incidence ratio study was completed by DuPont on 2430 current or pensioned DMF-exposed employees. At this plant, DMF was used as a spinning solvent in the production of acrylic fiber. No elevation of testicular cancer was found.[4,27] Limitations of the study included a limited exposure assessment, no reference to latency or length of exposure in their analysis of testicular cancer, and the use of the cancer registry which had limitations for epidemiologic research.

DuPont also conducted an unpublished case-control study for cancer among DMF-exposed workers at four plants.[5] Because of the study by Ducatman et al[3], testicular cancer was chosen as one of the outcomes to be investigated. Exposure estimates, based on DMF air measurements and monomethylformamide (MMF) urinary metabolite sampling, were made for each job category. Sixty-four percent of the workers had no DMF exposure, 20% had DMF exposures below 10 ppm, the Occupational Safety and Health Administration's Permissible Exposure Limit (OSHA PEL), and 16% had exposures greater than 10 ppm. No worker had exposure greater than 50 ppm. Only three of the 11 individuals with testicular cancer had DMF exposure. Latency ranged from 3 to 16 years for these three cases. Odds ratios were calculated for all plants combined and for each individual plant. The summary odds ratio for all plants was 0.99 (90% CI 0.22,4.44). Workers with DMF exposures greater than 10 ppm had a statistically non-significant elevation in risk for testicular cancer (logistic adjusted O.R.=11.6, 90% CI= 0.47,286). In only one plant were DMF exposed workers found to have an elevated risk for testicular cancer, although the risk was not statistically significant (cases - 1 exposed, 3 unexposed; controls - 0 exposed, 8 unexposed; O.R. 15.0, 90% C.I. 0.37,608). The major limitations of the study are low DMF exposure among employees, a statistical power too low to detect a statistically significant excess of testicular cancer, and possible overmatching of cases and controls on DMF exposure.

## Exposure Evaluation Criteria

As a guide to the evaluation of the hazards posed by workplace exposures, NIOSH field staff employed several environmental evaluation criteria for assessment of a number of chemical and physical agents. These criteria are intended to suggest levels of exposure to which most workers may be exposed up to 10 hours per day, 40 hours per week for a working lifetime without experiencing adverse health effects. It is, however, important to note that not all workers will be protected from adverse health effects if their exposures are maintained below these levels. A small percentage may experience adverse health effects because of individual susceptibility, a pre-existing medical condition, and/or a hypersensitivity (allergy).

In addition, some hazardous substances may act in combination with other workplace exposures, the general environment, or with medications or personal habits of the worker to produce health effects even if the occupational exposures are controlled at the level set by the evaluation criteria. Also, some substances are absorbed by direct contact with the skin and mucous membranes, and thus potentially increase the overall exposure. Finally, evaluation criteria may change over the years as new information on the toxic effects of any agent become available.

The primary sources of environmental evaluation criteria for the workplace are 1) NIOSH Criteria Documents and recommendations, 2) The American Conference of Governmental Industrial Hygienists' (ACGIH) Threshold Limit Values (TLV's), and 3) The U.S. Department of Labor (OSHA) occupational health standards (PEL). Often, the NIOSH recommendations and ACGIH TLV's are lower than the corresponding OSHA standards. The OSHA standards also may be required to take into account the feasibility of controlling exposures in various industries where the agents are used; the NIOSH recommended standards, by contrast, are based primarily on concerns relating to the prevention of occupational disease. In reviewing the exposure levels and the recommendations for reducing those levels found in this report, it should be noted that industry is required by the Occupational Safety and Health Administration (OSHA) Act of 1970 to meet those levels specified by OSHA standards.

A time weighted average (TWA) exposure refers to the average airborne concentration of a substance during a normal 8- to 10-hour workday. Some substances have recommended short-term exposure limits or ceiling values which are intended to supplement the TWA where there are recognized toxic effects from high short-term exposures.

Evaluation Criteria used in this report are present in Table 2 and in the following Toxicity Discussion.

### Dimethylformamide

DMF as a liquid is readily absorbed through the skin, or *via* inhalation or oral exposure.[6] It is rapidly metabolized and excreted in the urine, in the form of *N*-hydroxymethyl-*N*-methylformamide and, to a small extent,

N-methylformamide, N-hydroxymethylformamide and unmetabolized dimethylformamide.[7]

Liver toxicity has been observed in persons occupationally exposed to DMF.[7] DMF is not a mutagen in animals.[8] Only one animal species (rat) has developed cancer after exposure to DMF.[9] This finding was made in a study undertaken to assess the carcinogenic effects of aflatoxins. DMF was used as the solvent vehicle for the aflatoxin. Eighteen male rats were given 0.1 ml intraperitoneal injections of gas chromatography grade DMF weekly for 10 weeks. One rat developed a testicular tumor (embryoral cell carcinoma). Two of the remaining 17 rats developed malignant tumors (one developed stomach cancer and one developed a sarcoma of the colon.)

Using different methods of administration and different doses, other investigators have not found DMF to be tumorogenic. No increase in tumors was observed in rats fed daily oral doses of 75 or 150 mg/kg of DMF for 250 to 500 days and observed for 750 days.[10] Another study found no tumors in rats fed a single dose of 0.1 ml of DMF and observed for 13 to 34 months. No tumors were observed in rats, with or without partial hepatectomy, given a single i.p. dose of 0.5 mg/kg/DMF[26]. No tumors were detected in hamsters given weekly intraperitoneal injections of 0.1 ml of a 50% solution of DMF.[11]

Occupational exposure to DMF followed by consumption of alcohol has resulted in dermal flushing (especially of the face), severe headache, dizziness, anxiety, and blurred vision, indicating alcohol intolerance [12,13].

Lead

Inhalation (breathing) of lead dust and fume is the major route of lead exposure in industry. A secondary source of exposure may be from ingestion (swallowing) of lead dust deposited on food, cigarettes, or other objects. Once absorbed, lead is excreted from the body very slowly. Absorbed lead can have effects on the kidneys, peripheral and central nervous systems, and blood forming organs (bone marrow). These effects are weakness, tiredness, irritability, digestive disturbances, high blood pressure, kidney damage, mental deficiency, or slowed reaction times. Chronic lead exposure is associated with infertility and with fetal damage in pregnant women. There is some evidence that lead can also impair fertility in occupationally exposed men.[14]

The blood lead test is one measure of the amount of lead in the body and is the best available measure of recent lead absorption. Adults not exposed to lead at work usually have a blood lead concentration less than 30 ug/dl; the average is less than 15 ug/dl.[15,16] In 1985, the Centers for Disease Control (CDC) recommended 25 ug/dl as the highest acceptable blood level for young children.[17] Since the blood lead concentration of a fetus is similar to that of its mother, and since the fetus's brain is presumed to be at least as sensitive to the effect of lead as a child's, the CDC advised that a pregnant woman's blood be kept below 25 ug/dl.[17] Recent evidence suggests that the fetus may be adversely affected at blood lead concentrations well

below 25 ug/dl.[18] Furthermore, there is evidence to suggest that levels as low as 10.4 ug/dl affect the performance of children on educational attainment tests, and that there is a dose-response relationship with no evidence of a threshold or safe level.[19] Lead levels between 40-60 ug/dl in lead exposed workers indicate excessive absorption of lead and may result in some adverse health effects. Levels of 60-100 ug/dl represent unacceptable elevations which may cause serious adverse health effects. Levels over 100 ug/dl are considered dangerous and often require hospitalization and medical treatment.

Zinc protoporphyrin (ZPP) levels measure the effect of lead on ferrochelatase, the rate-limiting factor for heme synthesis. ZPP levels increase abruptly when blood lead levels reach about 40 ug/dl, and they to tend to stay elevated for several months. A normal ZPP level is less than 100 ug/dl.[20]

Glycol Ethers

2-Ethoxyethanol (2EE) caused a significant increase in diverse reproductive effects in experimental animals of both sexes. In females 2EE was teratogenic and embryotoxic when administered to pregnant rats and rabbits.[21,22] In non-pregnant female rats, exposure to 2EE did not affect fertility.[22] In males, 2EE produced testicular atrophy in mice and microscopic testicular changes in mice, rats, and dogs.[23] In animals 2EE has caused liver, kidney, and lung damage and anemia as well as eye irritation.

The limited information that is available on the toxic effect of the individual compounds that are structurally relative to 2EE (e.g. 2-ethyoxyethylacetate and 2-butoxyethanol) is consistent with the reproductive effects caused by 2EE.[23]

## Background

A tannery has existed at the site of the Pan American Tannery since the late 1800's. The tannery initially processed sheep skins but switched to cow hides in 1973 when the company was purchased by the Fuer Group. Currently, 97% of the stock is crust from domestic and international sources with the remaining 3% being wet blue stock from domestic sources.

The crust is a completely tanned hide before it arrives at Pan American unlike the wet blue stock which has to go through retan, coloring, and fat-liquoring prior to applying the finish top coats. Therefore the major process area at Pan American is the finishing department.

The finishing process at Pan American has been modified over time as to the equipment and the finish materials used. The tannery installed automated finish lines which increased production and the consumption of finish materials. The finish process begins when the feeder places a crust on the conveyor line (bolster). The hides then pass under a trough that drips the finish material onto the hides. The finish is spread by passing under a rotating brush. The hides then pass by two men (swabbers) on each side of the conveyor who use hand held felt applicators to smooth the coating materials

onto the surface of the hides. The hides are manually transferred from the bolster to the finish line (transfer) which conveys the hide under a gas fired drier. Additional finishes are applied to the hide by automated rotary sprayers in two ventilated spray booths. The hides once again pass under a gas fired drier. Finally, the hides are transferred (take off) to drying sticks and pass through a drying room.

The following is a description of the jobs in the finishing department and their potential for exposure.

Job Descriptions in the Finishing Department

Feeder: Transfers the "crust" to the bolster. The worker is approximately 3 feet from the trough which applies the finish. Exposure under the present working conditions appears to be minimal. However, past exposures could have been higher because the finishing material was sprayed on the hides. The spraying process resulted in a mist being generated and the canopy hood used to ventilate the area was approximately six feet from the worker's breathing zone.

Swabber: The four swabbers smooth and evenly distribute the finish material on the hides with a hand held felt applicator. The potential for exposure to the pigments and solvents is highest with the swabber because he smooths the material with his right hand and uses his left hand to even out the hide and because of the workers' proximity to the operation. Prior to the recent installation of the trough and drip system, a spraying process was used to apply the finish materials. Because the spraying process generated a mist of the finish material and the ventilation system was approximately 3 feet above the table, the swabbers described a high potential for exposure. The workers had to lean over the table to complete the swabbing process resulting in an increased potential for exposure. The workers did not wear gloves and the hands come in direct dermal contact with the finish material.

Transfer: Two employees pick up the wet hides with their hands and transfer the hides to the finish conveyor line. The employee's hands are coated with a thin film of petroleum jelly because the hands must be cleaned between each color change. The potential for respiratory exposure to finish materials among transfer workers was less than for the swabbers. They had the same dermal contact with the finish material but are stationed at the end of the swabbing table. The further the worker was from the sprayers the lower the potential for exposure.

Lineman: Responsible for the amount and quality of the finish material being applied to the hides. The potential for exposure is reduced because the worker is not stationed at the swabbing table.

Set-up: Prepares the finish material for the next color run. Potential for exposure is less than the swabbers and transfer jobs. The worker does wear gloves because he works with the concentrated chemicals prior to diluting them for application.

Take-off: Transfers the hides from the finish line to the drying sticks or from the drying sticks to the horse after the hides have gone through the dryer. The relative risk for exposure is lower for this job description. Dermal exposure is minimal.

## Analytical Methods

### Dimethylformamide

Airborne concentrations of DMF were evaluated by drawing air at a rate of 100 cc/minute through a series (150 mg/75 mg) of silica gel tubes. Section A and B were separated and analyzed by gas chromatography according to NIOSH Method 2004.[28] The calculated limit of detection for DMF was 0.01 mg/sample.

### Glycol Ethers

Airborne concentrations of cellosolve (2EE) were evaluated by drawing air at a rate of 50 cc/minute through SKC charcoal tubes. The samples were analyzed according to NIOSH Method 1403.[29] They were extracted with 1 ml of 5% methanol/methylene chloride and analyzed by gas chromatography using an HP 5890A gas chromatograph equipped with a 30-meter DB-1 fused silica capillary column and flame ionization detector (FID).

### Qualitative Analysis of Charcoal Tubes and Bulk Material for Organic Compounds

Nine bulk materials and seven charcoal tubes were submitted for qualitative analysis of organic compounds by gas chromatography-mass spectroscopy (GC-MS). The bulk samples consisted of various scrapings from the floor, pieces of wood from work areas, leather aprons, vent dust, and paints.

The charcoal tube samples were desorbed with 1 ml carbon disulfide and screened by gas chromatography. Portions of each of the bulk materials were extracted separately with methanol and carbon disulfide, filtered if necessary, and screened by gas chromatography. All extract solutions from the charcoal and bulk samples were analyzed on a 30-meter DB-1 fused silica capillary column (splitless mode). Based on a comparison of chromatograms from these analyses, selected samples were chosen for further analysis by GC-MS.

### Trace Metals

Eight bulk samples were submitted for trace metal analysis. Three replicate aliquots of each sample were weighed and then wet-ashed using nitric and perchloric acids. The residues were dissolved in a diluted solution of the

same acids and analyzed for trace metal content by inductively coupled plasma-atomic absorption spectroscopy. The limit of quantitation for this sample set was 15 micrograms per gram of sample.

## Results

### Epidemiology - Standardized Incidence Ratio Study

NIOSH conducted a standardized incidence ratio study (SIR) of finishing department workers at the Pan American Tannery.[24] An SIR is a ratio in which the rate of disease of interest in an exposed population is in the numerator, and the rate of a disease of interest in an unexposed population is in the denominator. Eighty individuals identified from yearly seniority lists for 1975-1988 had worked in the finishing department of the tannery. No records exist to identify workers employed in the finishing department before 1975. Data on year of first employment in the finishing department and age were used to calculate person-years at risk. Expected numbers of cases of testicular cancer were determined by applying age specific incidence rates for all males from upstate New York to the person-years at risk. Although all cases at Pan American were white, race-specific incidence rates are not available for upstate New York. In addition to a crude SIR, separate SIR calculations were made examining risk by years of latency and by years of exposure in the Pan American finishing department. A latency period of three years was chosen. This agrees with the latency period used in two other reports that examined the association between testicular cancer and occupation.[2,25]

The results of the analysis are summarized in Table 3. Three cases of testicular cancer among Pan American finishing department workers represents a crude SIR of 40.5 (95% CI 8.15, 118.45). A statistically significant SIR was found for those finishing department workers with 1 to 5 years of exposure (SIR=55.5, 95% CI 6.24, 200.6), with greater than 5 years of exposure (SIR=76.9, 95% CI 1.01, 427.99), and with greater than 5 years of latency (SIR=76.9, 95% CI 15.5, 224.76).

### Industrial Hygiene

During the week of February 15, 1988, NIOSH conducted a preliminary industrial hygiene survey of the finishing department at the Pan American Tannery. Area air samples were taken for DMF, glycol ethers, and the general process air. Bulk samples were also obtained to determine the potential for exposure to heavy metals. The process air samples were qualitatively analyzed by gas chromatography/mass spectroscopy. The major components of the air samples were identified as butyl cellosolve, diisobutylketone, limonene, and 2-ethylhexyl acetate. Other peaks identified were cellosolve, toluene, xylene, cellosolve acetate, n-butyl acetate, diacetone alcohol, and n-propylbenzene. DMF, no longer used at Pan American, was non-detectable in all of the air and bulk samples. The company estimates it had used DMF based materials from 1975 to 1987 but does not have any records to support the dates. The company discontinued the use of DMF in 1987 because of the possible association with adverse health effects.

Area air levels of glycol ethers (see Table 4) ranged from 0.3-0.47 ppm with an average of 0.39 ppm for cellosolve, 0.17-1.46 ppm with an average of 0.62 ppm for cellosolve acetate, and 0.46-10.9 ppm with an average of 4.5 ppm for butyl cellosolve. Diisobutylketone levels (see Table 4) ranged from non-detectable to 21.7 ppm with an average of 6.1 ppm.

Samples PA-50 and PA-8 were qualitatively analyzed by GC-MSD. The major components of sample PA-50 were identified as butyl cellosolve, diisobutylketone, limonene, and 2-ethylhexyl acetate, molecular weight (MW) 120 aromatic hydrocarbons such as trimethylbenzenes, and MW 134 aromatic hydrocarbons such as propyltoluene. The major components of sample PA-8 were diisobutylketone, butyl cellosolve, and 2-ethylhexyl acetate. Minor components identified were n-butanol, cellosolve, toluene, n-butyl acetate, diacetone alcohol, methyl isoamyl ketone (MIAK), xylene, cellosolve acetate, n-propylbenzene, and MW 120 and MW 134 aromatic hydrocarbons. A copy of the reconstructed total ion chromatograms of the mass spectral analyses of samples PA-50 and PA-8 are in Appendix 1 with all identified peaks labeled.

Eight bulk samples were collected in the finishing department and were submitted for trace metal analysis. The bulk samples represent scrapings from different locations or products in the finishing department and the results can be found in Table 5. The results are reported as average (N=3) micrograms per gram of each element. The quantitative lead results range from <15 - 22400 ppm with an average of 7100 ppm.

The American Conference of Governmental Industrial Hygienists (ACGIH) recommends a Threshold Limit Value (TLV) of 5 ppm, 5 ppm, 25 ppm, and 25 ppm respectively for cellosolve, cellosolve acetate, butyl cellosolve, and diisobutylketone.

The results of the qualitative analysis of the charcoal tubes and the bulk samples can be found in Table 6. Copies of the reconstructed total ion chromatographs for all of the GC-MS analyses are found in Appendix 2. Only the area air sample taken near the feeder on the number 1 finish line, and the area air sample taken near the spray booth in the number 2 finish line were analyzed by GC-MS.

The area air levels of glycol ethers were highest in the area of the spray booths. The pumps were located directly above the drums containing the finish material. The glycol ethers are volatile and the drums are not ventilated. The sample is not representative of occupational exposure in the area. However, the potential for exposure to the set-up and lineman jobs are greatest when the employee is working directly in the area of the drums.

## Conclusions

The purpose of the survey at the Pan American Tannery was to obtain information on the process, review the employment records, and to obtain information on the possible association between employment at the tannery and the cluster of testicular cancer in the finishing department. Three cases of

testicular cancer were found in this group whereas only 0.074 cases were expected. This represents a forty fold increase in risk, and it is statistically significant. Since the cluster of three cases were identified prior to any study of the workers, it is possible that this observation was a chance occurrence.

One must bear in mind the nature of a cluster. A cluster is an epidemiologic term used to describe an aggregation of relatively uncommon events or diseases. Although a cluster can arise as a result of a particular hazardous exposure, a cluster can arise by chance. Therefore, although a disease cluster may cause one to suspect a particular hazardous exposure, extensive study of other exposed cohorts is needed before one can conclude that the disease is associated with a particular exposure. Therefore, we are searching for another DMF-exposed cohort in which to study the possible association with testicular cancer. In addition, NIOSH has proposed that a testicular cancer screening program be provided to past and present male employees in the finishing department at the Pan American Tannery. The screening program will attempt to uncover any undetected cases of testicular cancer. As part of the screening program a thorough historical exposure evaluation should be conducted to ascertain what exposures were experienced in the finishing department.

It is also recommended that an ongoing testicular cancer surveillance program be provided to past and present male employees in the finishing department at the Pan American Tannery. Details on the composition and frequency of the ongoing surveillance program need to be developed. The data collected can be analyzed to determine if an elevated risk for testicular cancer persists.

The area air sampling results obtained from the initial visit to the plant in February 1988 indicated that occupational exposure to glycol ethers did not exceed the Federal recommended limits. These are current levels and may not reflect levels in the past. The analytical results also support the fact that DMF is no longer used in the finishing department. However, of concern was the high level of lead found (22,400 ppm) in the scraping from the ventilation duct. The high concentrations of lead are due to the lead chromate based pigments. Although this is a bulk sample it indicates there may be exposure, especially to the swabbers.

Although the February, 1988 survey by NIOSH was only an initial industrial hygiene evaluation, a number of health and safety issues were observed. The indepth industrial hygiene survey that is proposed would evaluate the health and safety program at the plant as well as the housekeeping. However, the initial recommendations or observations are the following:

1. Limited personal protective equipment were made available to the employees. The eye goggles and face shields available in the wet department were old and worn. The gloves used by the set-up man in the finishing department showed excessive wear.

2. The feeder on line one in the finishing department did not wear a shirt. The survey was conducted in the winter. There is concern also regarding the dress of the men during the heat of the summer months. Failure to protect the skin from contact with hazardous chemicals could lead to increased absorption of these chemicals.

3. At the time of the survey a new ventilation system was being installed in the finishing department. The effectiveness of the new system could not be evaluated at the time of the survey. An indepth industrial hygiene survey by NIOSH would evaluate the new system.

4. Lead should be strictly controlled according to all provisions of the OSHA lead standard.

References


1. Levin, SM, Baker DB, Landrigan PJ et al. Testicular cancer in leather tanners exposed to dimethylformamide (letter). Lancet: 2:1153, 1987.

2. New York State Department of Health. Testicular cancer in Fulton County. 1988. Unpublished

3 Ducatman AM, Conwill DE, Crawl J. Germ cell tumors of the testicle among aircraft repairmen. J Urol: 136:834-836, 1986.

4. Chen JL, Kennedy GL. Dimethylformamide and testicular cancer (letter). Lancet: 1:55;1988.

5. Walrath J, Fayerweather WE, Gilby PG. A case-control study of cancer among DuPont employees with potential for exposure to dimethylformamide. May 10, 1988. Unpublished.

6. Maxfield, ME, Barnes, JR, Azar, A. Trochimowiez, HT. Urinary excretion of metabolite following experimental human exposure to dimethylformamide or to dimethylacetamide. J Occup Med: 506-511, 1975.

7. Vsil'eva, VN & Sukharevskaya, TM. Hepatotropic action of N-methylformamide. Gig Tr prof Zabol: 10: 53, 1966.

8. Kennedy GL. Biological effects of acetamide, formamide and their monomethyl and dimethyl derivatives. CRC Critical Reviews in Toxicology; 17:129-182, 1986.

9. Kommeneni C. Pathological studies on aflatoxin fractions and dimethyl formamide in MRC rats. Diss Abstr Intr B Sci Eng 1973.

10. Druckrey H, Preussman R, Ivankovic S, Schmahl D. Organotrophic carcinogenic effects of 65 different N-nitroso compounds in BD rats. Z Krebsforsh: 69:103, 1967.

11. Herrold KM. Aflatoxin induced lesions in Syrian hamsters. Br J Cancer: 23:655, 1969.

12. Reinl, W. & Urban HJ Erkrankungen durch Dimethylformamide. Int Arch Gewerbepathol Gewerbehyg: 21: 333-346, 1965.

13. Lyle, WH, Spence, TWM, McKinneley WM & Duckers, K. Dimethylformamide and alcohol intolerance. Br J Ind Med: 36: 63-66, 1979.

14. Lancranjan I, Popecu HI, Gavanescu O, et al. Reproductive ability of workmen occupationally exposed to lead. Arch Environ Health: 30: 396-401, 1975.

15. Muhaffey K, Annest J, Roberts J, Murphy R. National estimates of blood lead levels. United States, 1976-1980. N Engl J Med: 307: 573-9, 1982.

16. Annest J, Dirkle J, Makuc C, Nesse J, Bayse D, Kovar M. Chronological trends in blood lead levels between 1976 and 1980. N Engl J Med: 308: 1373-7, 1983.

17. Centers for Disease Control. Preventing Lead Poisoning in Young Children: Centers for Disease Control, 1985.

18. Bellinger D, Leviton A, Waternaux C, Needleman H, Rabinowitz M. Longitudinal analysis of prenatal and postnatal lead exposure and early cognitive development. N Eng J Med: 316: 1037-43, 1987.

19. Fulton M, Hepburn, W, Hunter R, Laxen D, Raab D, Thomson G. Influence of blood lead on the ability of and attainment of children in Edinburgh. Lancet: 1221-25, 1987.

20. Cullen MR, and Rosenstock L. Clinical Occupational Medicine. W.B. Saunders Company; Philadelphia, PA 1986.

21. Stenger EC, Aeppli L, Muller D, Peheim E, and Thomann P.: The toxicology of ethylene elycol monoethylether. Arzneim Forsch: 21: 880-885, 1971.

22. Andrew, FD. Buschbom, RL, Cannon, WC, Miller, RA, Montgomery, LF, Phelps, DW, and Sikov MR: Teratologic assessment of ethylbenzene and 2-ethoxyethanol. Submitted to NIOSH under contract No. 210-79-0037. Battette Pacific Northwest Laboratory, Richland, WA, 99 pp, 1981.

23. Nagano K, Nakayama E, Koyano M. Oobayaski H, Adachi H, and Yamada T.: Mouse testicular atrophy induced by ethylene glycol monoalkyl ethers. Jap J Ind Health: 21: 29-35, 1979.

24. Rothman, KJ Modern epidemiology. Little, Brown, Boston, MA: pp 45-49, 1986

25. Rose LI, Weiss W, Gilby CW, Borowski G, Levy RA. Carcinoma of the testes in podiatrists. Annals Int Med: 99: 636-637, 1983.

26. Craddock VW. Liver carcinomas induced in rats by a single administration of dimethyl nitrosamine after partial hepatectomy. J Nat Cancer Inst: 47: 899, 1971.

27. Chen SL, Fayerweather WE, Pell S. Cancer incidence of workers exposed to dimethylformamide and/or acrylonitrile. J Occup Med: 30: 813-818, 1988.

28. Eller P. Dimethylformamide (Method 2004). NIOSH Manual of Analytical Methods, 3rd ed. U.S. Department of Health and Human Services, National Institute for Occupational Safety and Health Publ. No. 84-10, Cincinnati, Ohio, 1986.

29. Eller P. Alcohols IV (Method 1403). NIOSH Manual of Analytical Methods, 3rd ed. U.S. Department of Health and Human Services, National Institute for Occupational Safety and Health Publ. No. 84-10, Cincinnati, Ohio, 1986.

Table 1
Dates of Interest for the
Testicular Cancer Cases at Pan American
Finishing Department Workers

| | Year first worked in Pan American finishing dept. | Year last worked in Pan American finishing dept. | Date of Diagnosis | Age at Diagnosis | Race |
|---|---|---|---|---|---|
| Case 1 | 1976 | 1980 | Aug, 1982 | 31 | White |
| Case 2 | 1973 | present | Apr, 1984 | 36 | White |
| Case 3 | 1978 | 1979 | Apr, 1984 | 25 | White |

Table 2
Evaluation Criteria and Health Effects Summary
Pan American Tannery
Gloversville, New York

| Contaminant | Recommended Exposure Limit[1] | Source | Health Effects | |
|---|---|---|---|---|
| | | | Symptom or Specific Effects | Target Organ |
| Dimethylformamide | 30 mg/m$^3$<br>10 ppm | NIOSH[2] | Nausea, vomiting, liver damage, hepatomegaly; high blood pressure, face flush, dermatitis | Liver, Kidneys cardiovascular system, skin |
| | 10 ppm (skin) | ACGIH[3] | | |
| | 10 ppm | OSHA[4] | | |
| Lead | <0.1 mg/m$^3$<br>10-hr TWA | NIOSH | Lassitude, insomnia; pallor, anorexia, weight loss, malnutrition; constipation, abdominal pain, colic; anemia, gingival lead line; tremors, paresis | Gastrointestinal tract, Central nervous system kidneys, blood, gingival tissue, reproductive system |
| | 0.15 mg/m$^3$ | ACGIH | | |
| | 0.05 mg/m$^3$ | OSHA | | |
| Glycol Ethers | | | | |
| 2-ethoxyethanol | Lowest feasible limit | NIOSH | In animals: Hematologic effects; liver damage, kidney damage, liver damage, eye irritant | In animals: lungs, eyes, blood, liver, kidneys |
| | 19 mg/m$^3$<br>5 ppm | ACGIH | | |
| | 740 mg/m$^3$<br>200 ppm | OSHA | | |
| 2-ethoxyethyl-acetate | 540 mg/m$^3$<br>100 ppm | OSHA | Eye & nose irritant, vomitting, kidney damage, paralysis | Respiratory system, eyes, gastrointestinal tract |
| | 27 mg/m$^3$<br>5 ppm | ACGIH | | |

| | | | | |
|---|---|---|---|---|
| 2-butoxyethanol (skin) | 240 mg/m$^3$<br>50 ppm | OSHA | Eyes, nose, throat irritant; hemolysis, hemoglobinuria | Liver, kidneys, lymphoid system, skin, blood, eyes, respiratory system |
| | 120 mg/m$^3$<br>25 ppm | ACGIH | | |
| Diisobutylketone | 290 mg/m$^3$<br>50 ppm | OSHA | Eyes, nose, throat irritant, dizziness, dermatitis, loss of consciousness | Respiratory system, skin, and eyes |
| | 25 ppm<br>10 hr TWA | NIOSH | | |
| | 25 ppm | ACGIH | | |

1. Exposure limits are given in milligrams per cubic meter (mg/m$^3$) and parts per million (ppm) where applicable
2. National Institute for Occupational Safety and Health
3. American Conference of Governmental Industrial Hygienists
4. Occupational Safety and Health Administration

**Table 3**
**Summary Table**
**Testicular Cancer in Leather Workers**
**Pan American Tannery**
**Gloversville, New York**

| | Person-Years | OBS/EXP | SIR | 95% C.I. |
|---|---|---|---|---|
| Total | 826 | 3/0.074 | 40.5 | 8.15, 118.45 |
| **Exposure** | | | | |
| 1 yr | 257.4 | 0/0.025 | - | |
| 1-5 | 379.25 | 2/0.036 | 55.5 | 6.24, 200.60 |
| >5 yr | 189.32 | 1/0.013 | 76.9 | 1.01, 427.99 |
| **Latency** | | | | |
| <5 yr | 369.64 | 0/0.034 | - | |
| >5 yr | 456.31 | 3/0.039 | 76.9 | 15.5, 224.76 |

Exposure = Number of years of exposure in the Pan American finishing department

Latency = Latency period between first year of employment in the Pan American finishing department and the date of diagnosis of testicular cancer.

Table 4
Glycol Ethers and Diisobutylketone
Pan American Tannery
Gloversville, New York
February 17, 1988

| Sample No. | Sample Area | Sampling Time (min) | Concentration (ppm)* | | | |
|---|---|---|---|---|---|---|
| | | | cellusolve | cellusolve acetate | butyl cellusolve | diisobutylketone |
| PA-6 | Spray booth #2 line #2 | 356 | N.D.** | 0.17 | 3.2 | 1.32 |
| PA-8 | Spray booth #2 line #2 | 352 | 0.47 | 1.46 | 10.9 | 21.7 |
| PA-9 | Swabbing table-next to take-off man | 359 | N.D. | N.D. | 0.5 | 0.44 |
| PA-16 | Control | | N.D. | N.D. | N.D. | N.D. |
| PA-20 | Spray booth #3 line #2 | 340 | 0.30 | 0.22 | 7.21 | 6.5 |
| PA-50 | Above swabbing by roller | 298 | N.D. | N.D. | 0.46 | 0.40 |

* ppm = Parts per million
** N.D. Non-detectable

Table 5
Quantitative Results of Trace Metal
Analysis of Bulk Samples at the
Pan American Tannery
Gloversville, New York
February 17, 1988

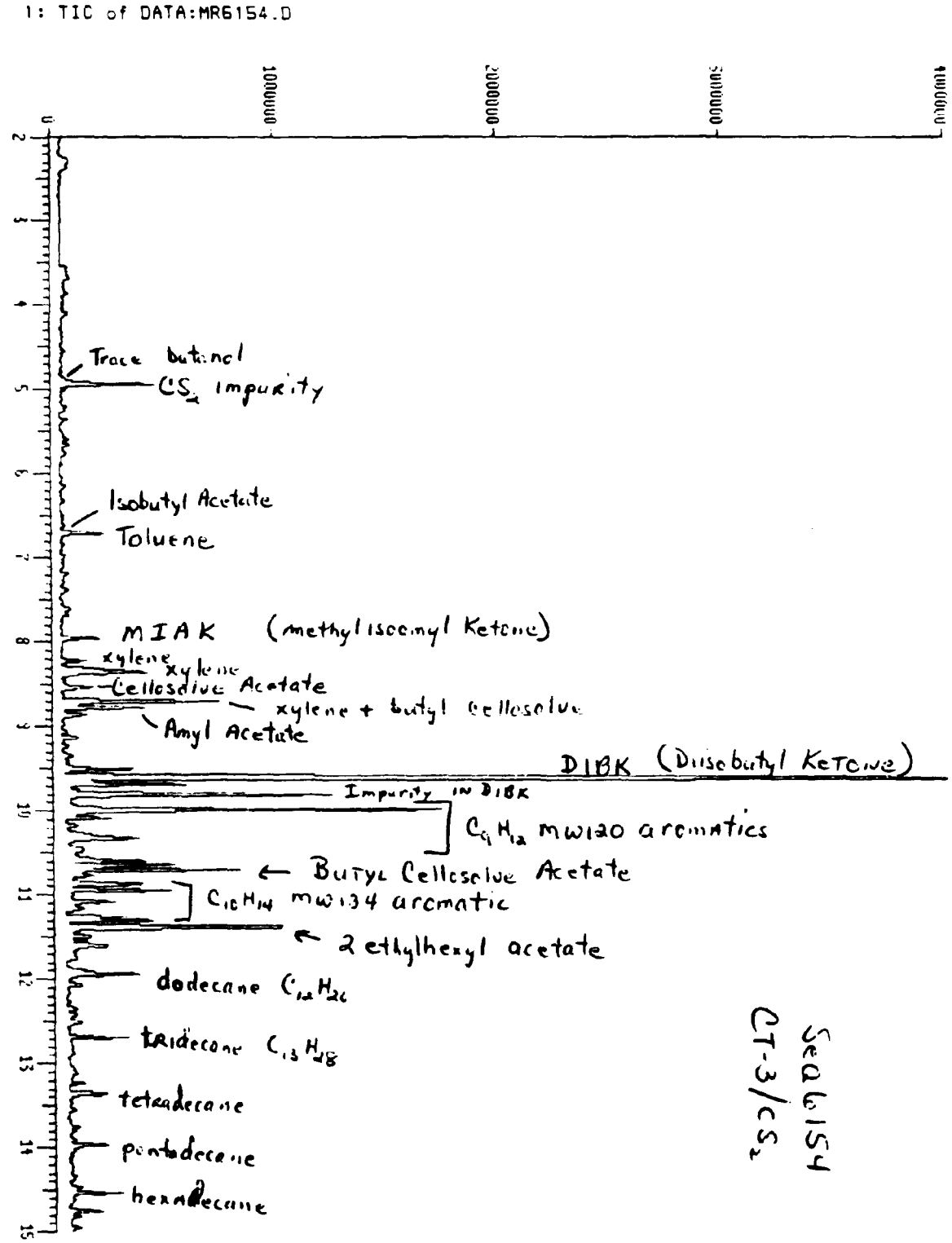
| Metal | Bulk Sample ug/gram | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| Silver | <15 | <15 | <15 | <15 | <15 | <15 | <15 | <15 |
| Aluminum | 1850 | <15 | 3980 | 6730 | 5110 | 1910 | 1240 | 1450 |
| Arsenic | <15 | <15 | <15 | <15 | <15 | <15 | <15 | <15 |
| Barium | 55 | <15 | 32 | 86 | 18 | <15 | <15 | 42 |
| Berilleum | <15 | <15 | <15 | <15 | <15 | <15 | <15 | <15 |
| Calcium | 11610 | <15 | 1500 | 3030 | 187 | 23 | 69 | 6920 |
| Cadmium | <15 | <15 | <15 | <15 | <15 | <15 | <15 | <15 |
| Cobalt | <15 | <15 | <15 | <15 | <15 | <15 | <15 | <15 |
| Chromium | 419 | <15 | 9430 | 3020 | 5170 | 347 | 2780 | 443 |
| Copper | 22 | <15 | 68 | 157 | 54 | <15 | <15 | <15 |
| Iron | 4200 | <15 | 5170 | 31430 | 62670 | 4710 | 41460 | 1152 |
| Lanthanum | <15 | <15 | <15 | <15 | <15 | <15 | <15 | <15 |
| Lithium | <15 | <15 | <15 | <15 | <15 | <15 | <15 | <15 |
| Magnesium | 1840 | <15 | 336 | 781 | 135 | <15 | 101 | 1100 |
| Manganese | 31 | <15 | 16 | 63 | <15 | <15 | <15 | 21 |
| Molybdenum | <15 | <15 | 79 | 249 | 574 | 43 | 224 | <15 |
| Sodium | 4910 | 21 | 4110 | 5170 | 2540 | 335 | 914 | 5480 |
| Nickel | <15 | <15 | <15 | 20 | <15 | <15 | <15 | <15 |
| Phosphorus | 106 | <15 | 34 | 355 | 329 | 34 | 122 | 46 |
| Lead | 4760 | <15 | 2170 | 11570 | 22400 | 1590 | 11870 | 2460 |
| Platinum | <15 | <15 | <15 | <15 | <15 | <15 | <15 | <15 |
| Antimony | <15 | <15 | <15 | <15 | <15 | <15 | <15 | <15 |
| Selenium | <15 | <15 | <15 | <15 | <15 | <15 | <15 | <15 |
| Strontium | 95 | <15 | <15 | <15 | <15 | <15 | <15 | 40 |
| Tellurium | <15 | <15 | <15 | <15 | <15 | <15 | <15 | <15 |
| Titanium | 111 | 38 | 89 | 370 | 168 | 204 | 37 | 113 |
| Thallium | <15 | <15 | <15 | <15 | <15 | <15 | <15 | <15 |
| Vanadium | <15 | <15 | <15 | <15 | <15 | <15 | <15 | <15 |
| Yttrium | <15 | <15 | <15 | <15 | <15 | <15 | <15 | <15 |
| Zinc | 393 | <15 | 247 | 654 | 964 | <15 | <15 | 189 |
| Zirconium | <15 | <15 | 5980 | 36 | <15 | <15 | <15 | <15 |

* Bulk Sample
1 Wood sample from platform by swabbing table
2 Bulk sample Boothcoat
3 A leather apron worn daily by swabber for fifteen years
4 Scraping from floor by takeoff
5 Scraping from flanged exhaust vent hood that was used over the swabbing table. It was removed and stored in the finishing department.
6 #1 line #1 spray booth pigment
7 Bulk material being swabbed
8 Wood sample from platform of swabbing table

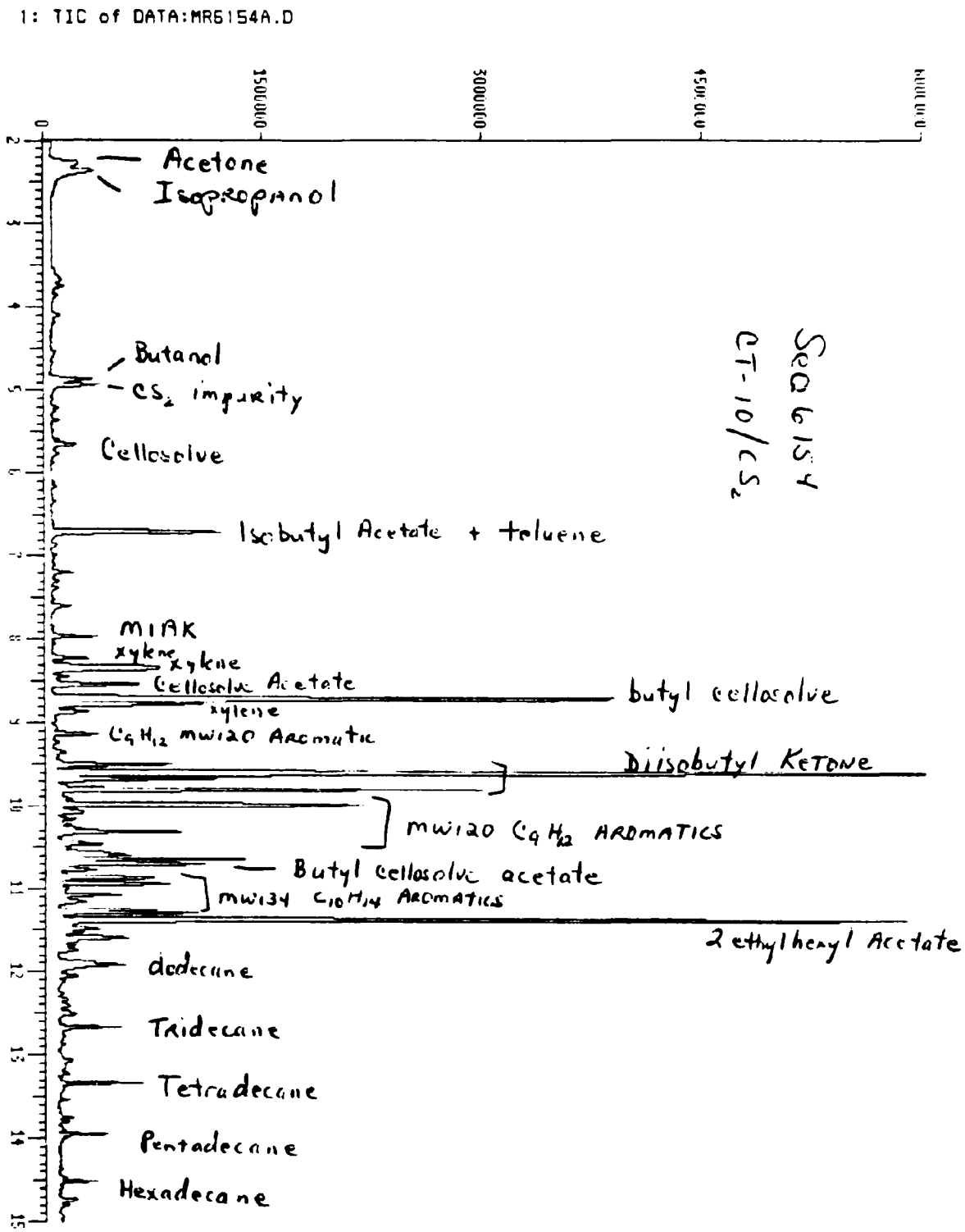
Table 6
Results of the Qualitative Analysis
Charcoal Tubes and Bulk Samples

| Field Sample | Compounds Identified By GC-MS |
|---|---|
| Charcoal Tubes | Diisobutyl ketone (DIBK), 2-ethylhexyl acetate, butyl cellosolve, $C_9H_{12}$ MW 120 aromatics, isobutyl acetate, acetone, isopropanol, butanol, cellosolve, cellosolve acetate, xylenes, methyl isoamyl ketone (MIAK), toluene |
| Scraping from floor by takeoff ($CS_2$ extract) | $C_{20}$-$C_{30}$ paraffins, butyl cellosolve, phthalate, 2-ethylhexyl acetate, terpineol, dodecanol, a butoxyethanol phosphate (tentative ID), o-phenylphenol, triethylamine, diacetone alcohol, DIBK, propoxyethanol |
| #1 Line #1 spray booth pigment ($CS_2$ extract) | Acetone, 2-propoxyethanol, diacetone alcohol, butyl cellosolve, triethylamine, butanol, MW120 and 134 aromatics, mesityl oxide, xylenes, a methyl pyrrolidinone (tentative ID) |
| Material being swabbed ($CS_2$ extract) | Butyl cellosolve, terpene derivatives, butanol, triethylamine, o-phenol |
| Wood sample from platform of swabbing table ($CS_2$ extract) | $C_{20}$-$C_{30}$ paraffins, triethylamine, phthalate o-phenylphenol |
| Boothcoat ($CS_2$ extract) | $C_{20}$-$C_{30}$ paraffins, toluene |
| Ventilation hood ($CS_2$ extract) | Triethylamine, $C_{20}$-$C_{30}$ paraffins |
| Leather apron | $C_{20}$-$C_{30}$ paraffins, butyl cellosolve, phthalate, 2-ethylhexyl acetate, terpineol, dodecanol, a butoxyethanol phosphate (tentative ID), o-phenylphenol, triethylamine, diacetone alcohol, DIBK, propoxyethanol |
| Wood sample from platform of swabbing table | $C_{20}$-$C_{30}$ paraffins, butyl cellosolve, phthalate, 2-ethylhexyl acetate, terpineol, dodecanol, a butoxyethanol phosphate (tentative ID), o-phenylphenol, triethylamine, diacetone alcohol, DIBK, propoxyethanol |
| Floor scraping-#1 spray line | $C_{20}$-$C_{30}$ paraffins, butyl cellosolve, phthalate, 2-ethylhexyl acetate, terpineol, dodecanol, a butoxyethanol phosphate (tentative ID), o-phenylphenol, triethylamine, diacetone alcohol, DIBK, propoxyethanol |

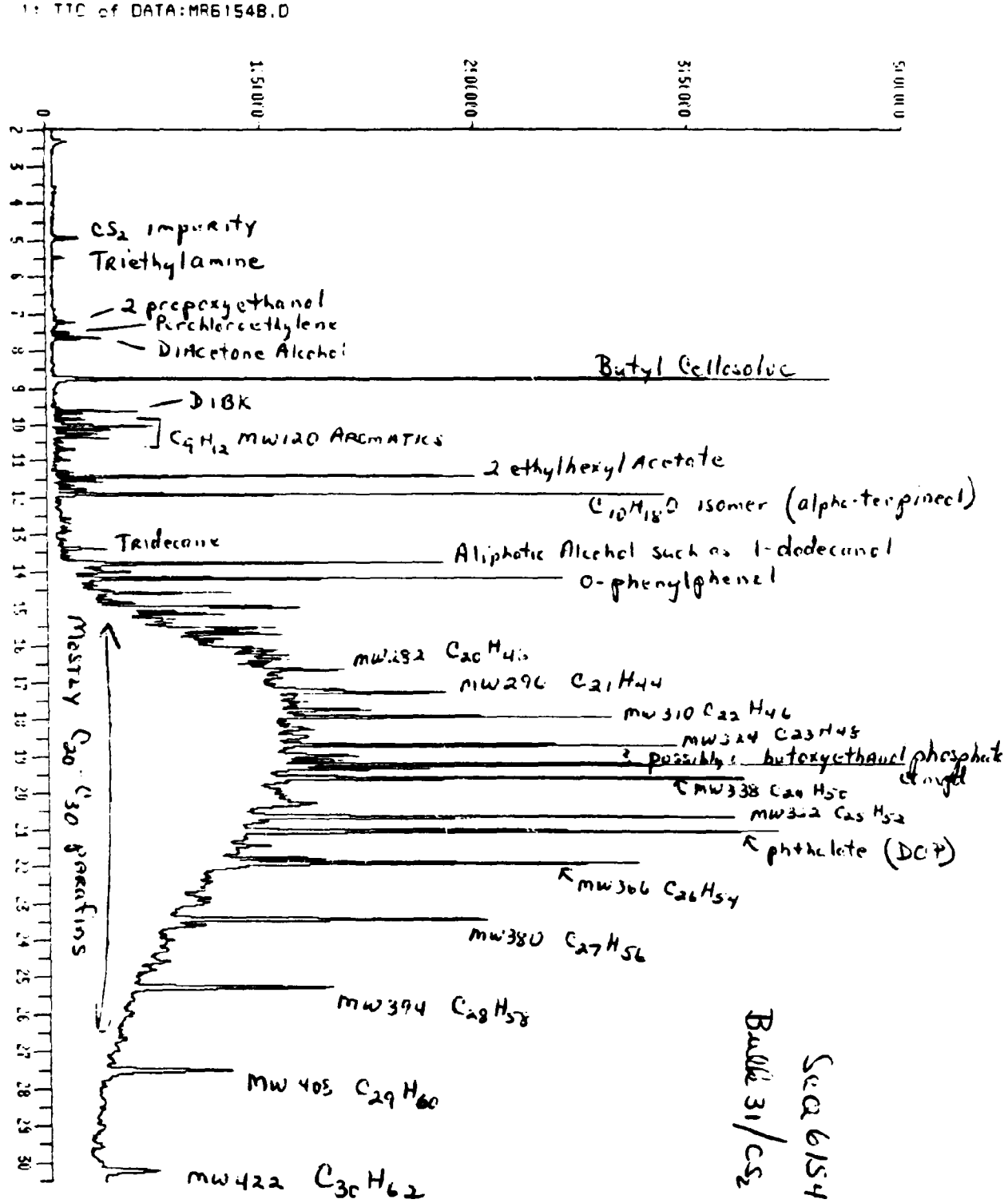
**Appendix 1**
**Qualitative Analysis**
**by GC-MS of Charcoal Tubes**



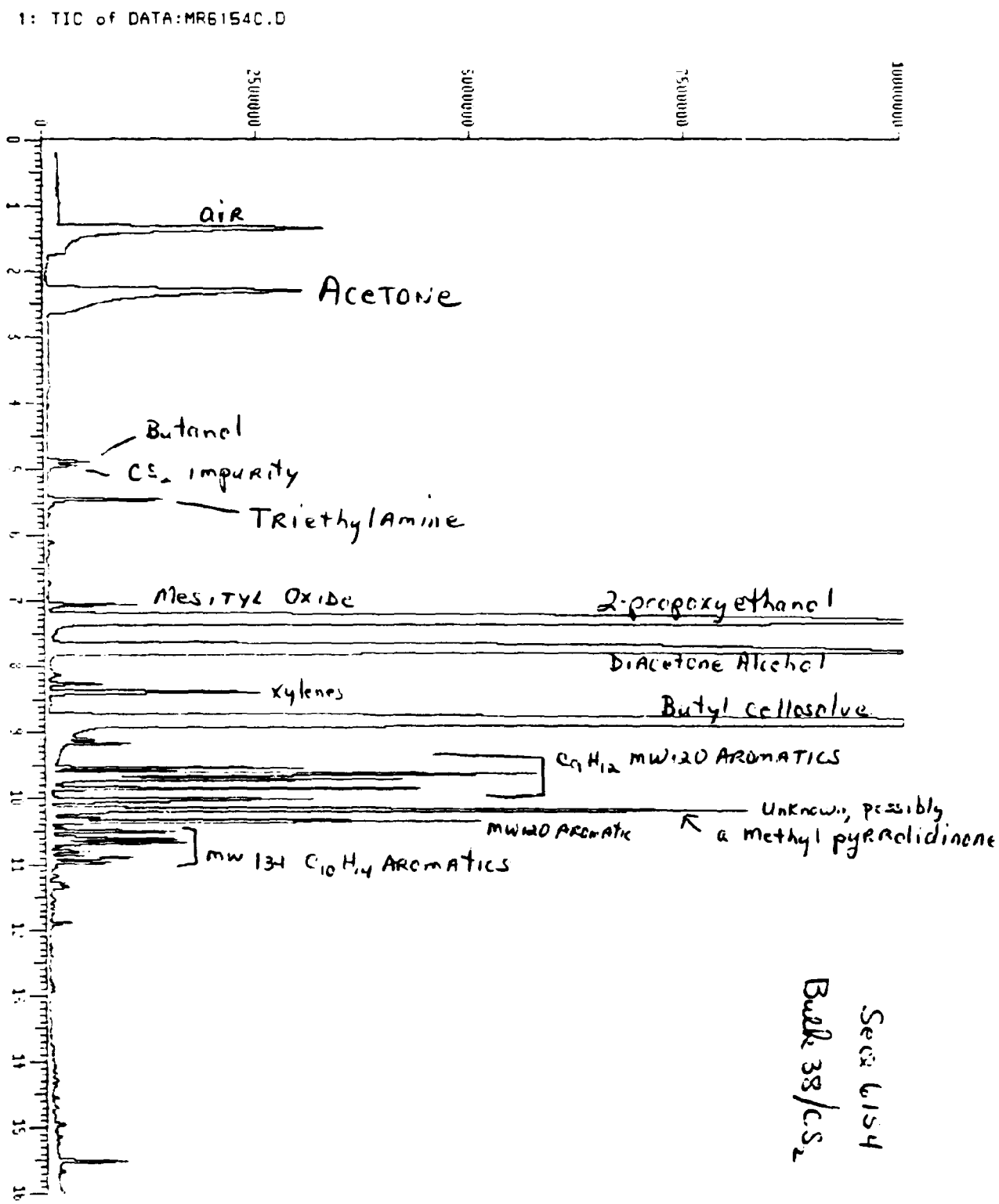

End of plot. Time = 2.00 to 15.00 minutes Chart speed = 1.53 cm/min



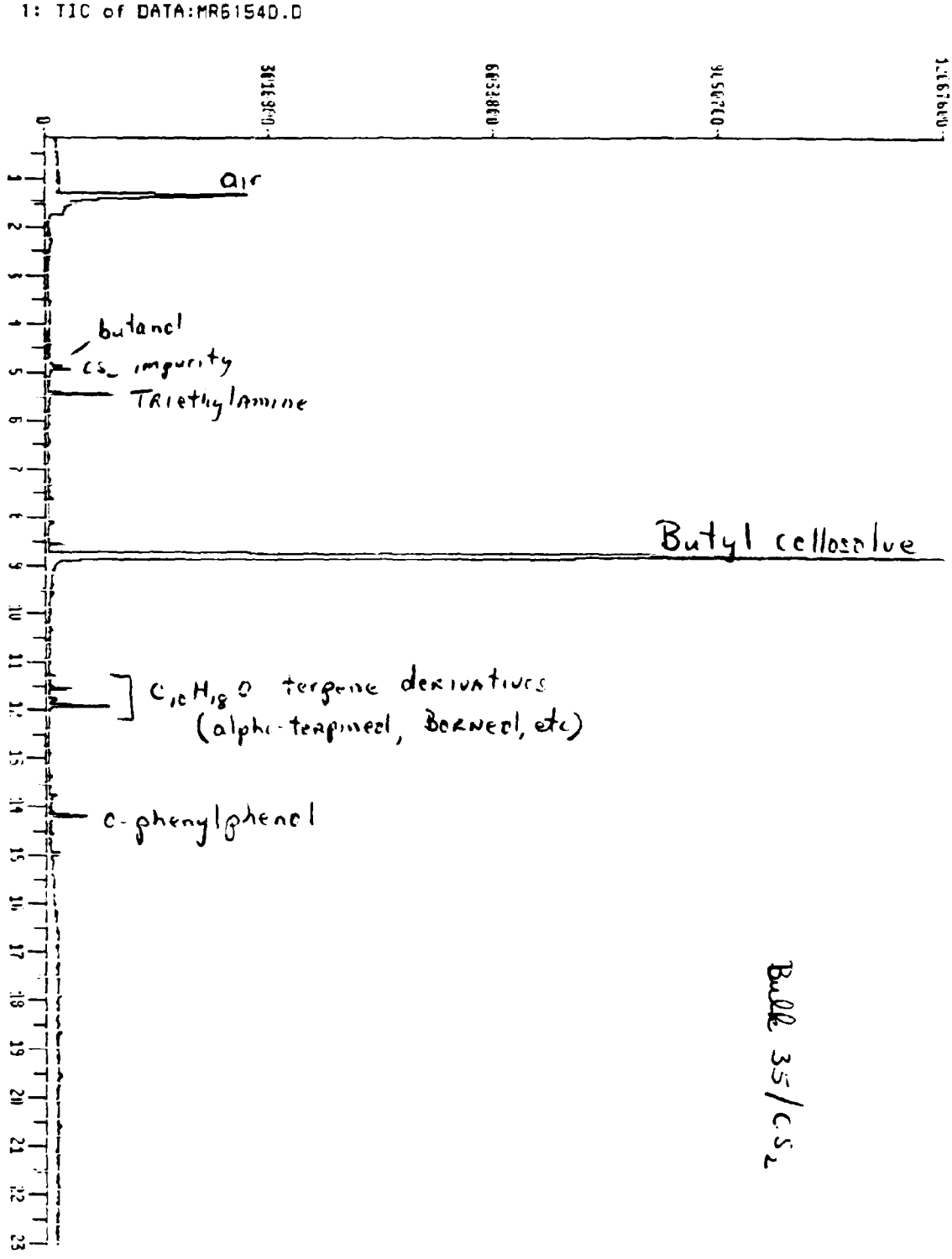

End of plot. Time = 2.00 to 15.00 minutes Chart speed = 1.53 cm/min




End of plot. Time = 2.00 to 30.50 minutes Chart speed = 0.70 cm/min

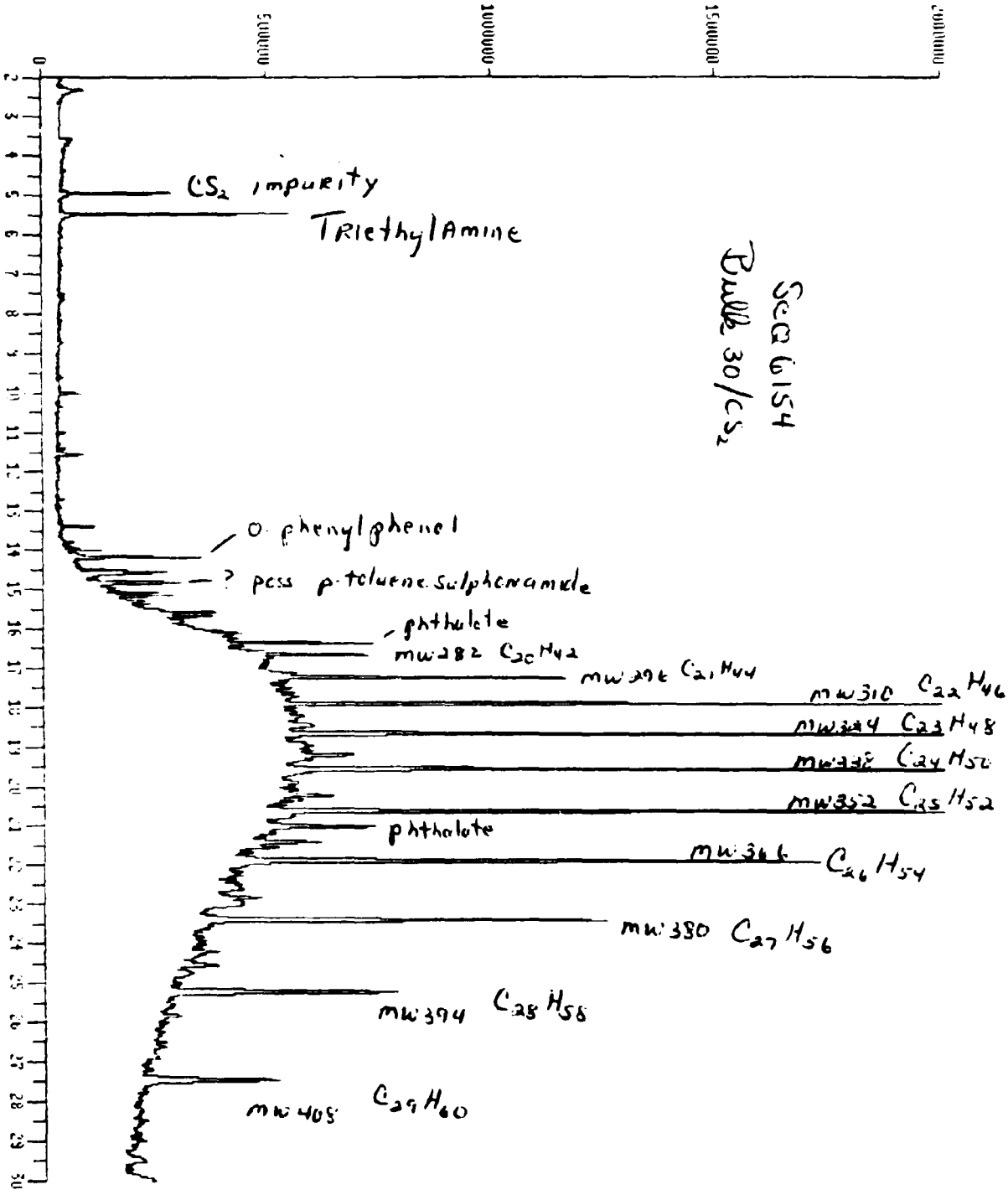



End of plot. Time = 0.00 to 16.00 minutes Chart speed = 1.25 cm/min

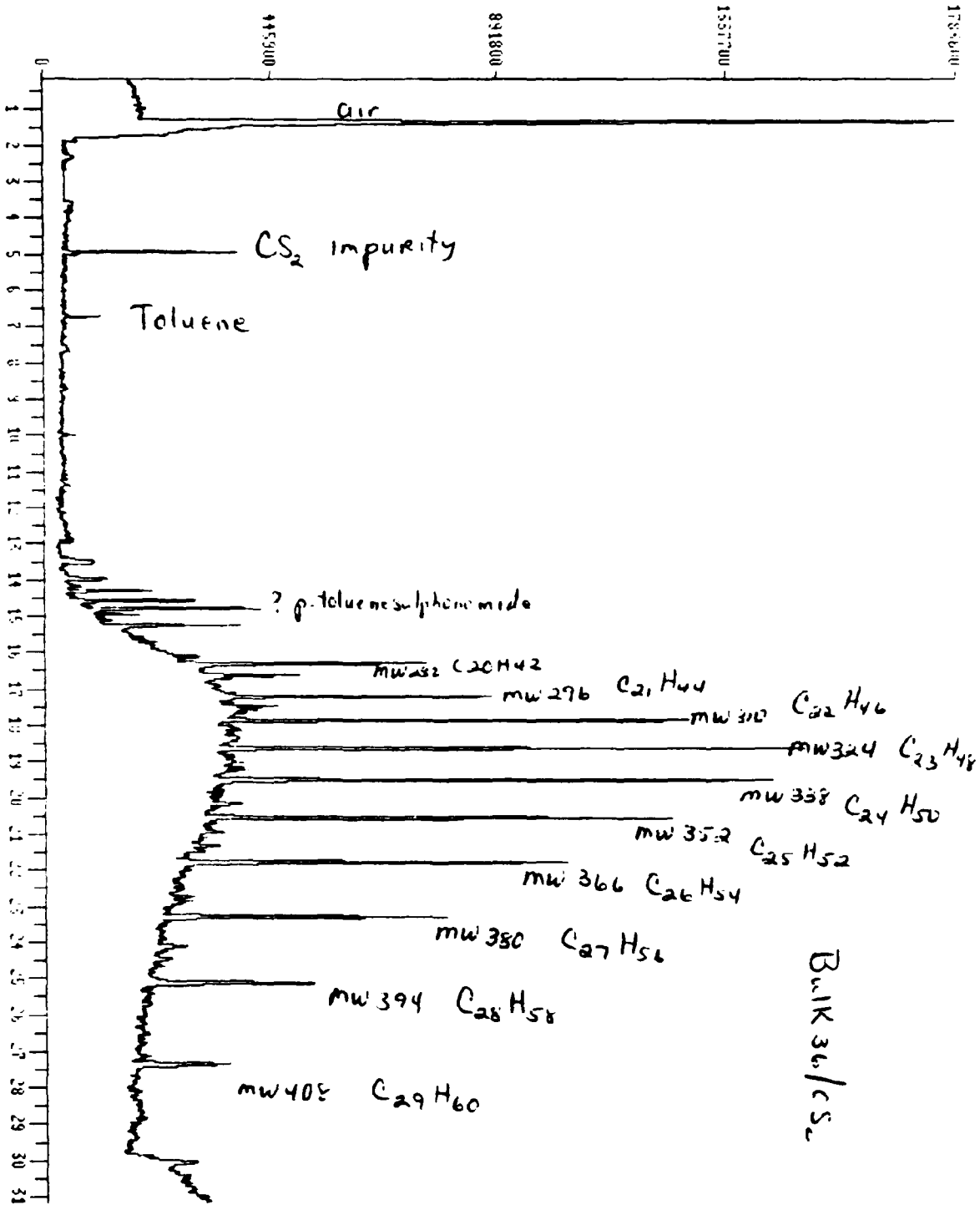



End of plot. Time = 0.18 to 23.02 minutes Chart speed = 0.87 cm/min

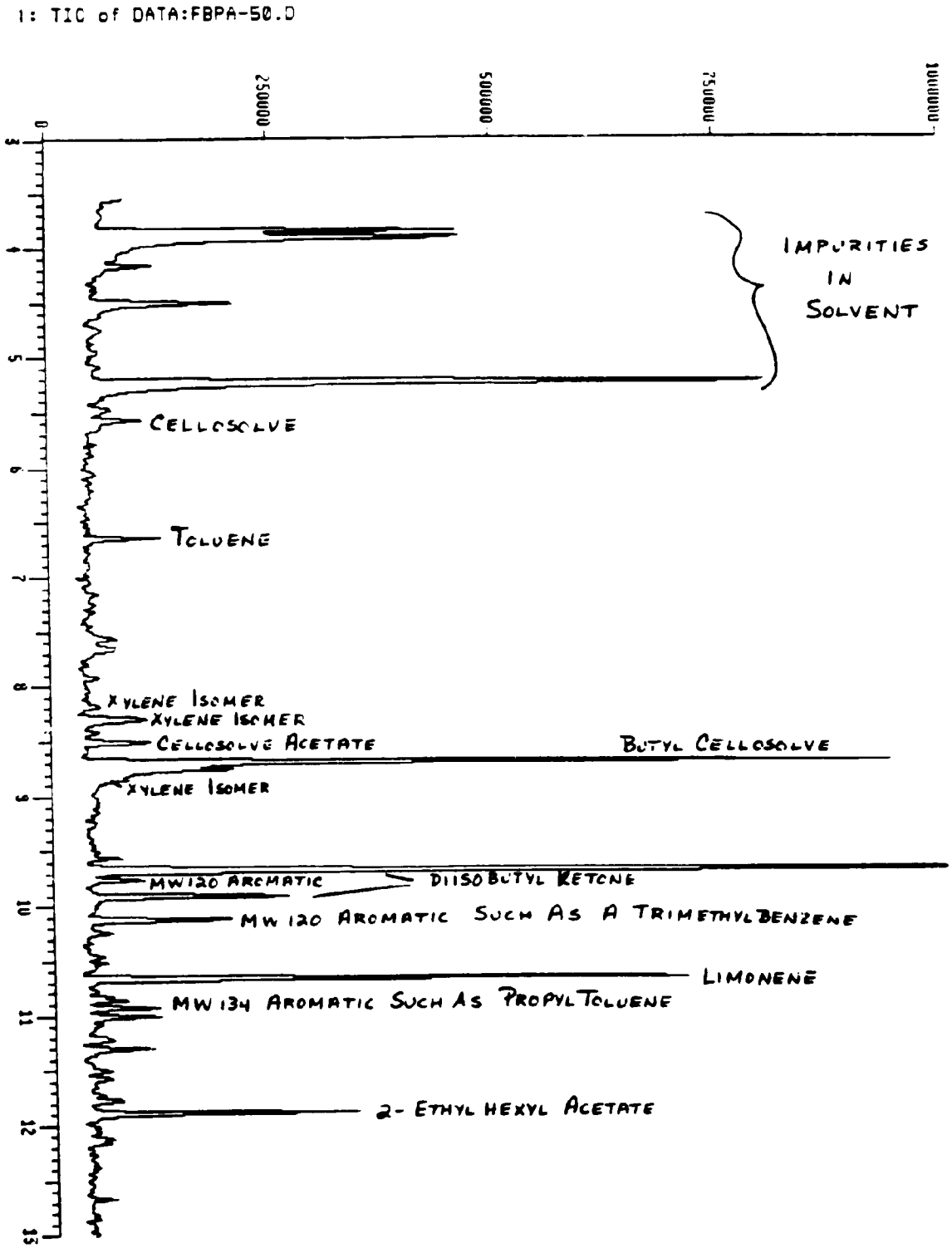
1: TIC of DATA:MR6154E.D




End of plot. Time = 2.00 to 30.00 minutes Chart speed = 0.71 cm/min


1: TIC of DATA:MR6154F.D
air
$CS_2$ impurity
Toluene
? p-toluenesulphonamide
mw 282 $C_{20}H_{42}$
mw 296 $C_{21}H_{44}$
mw 310 $C_{22}H_{46}$
mw 324 $C_{23}H_{48}$
mw 338 $C_{24}H_{50}$
mw 352 $C_{25}H_{52}$
mw 366 $C_{26}H_{54}$
mw 380 $C_{27}H_{56}$
mw 394 $C_{28}H_{58}$
mw 408 $C_{29}H_{60}$
Bulk 36/cs2
End of plot. Time = 0.18 to 31.14 minutes
Chart speed = 0.64 cm/min

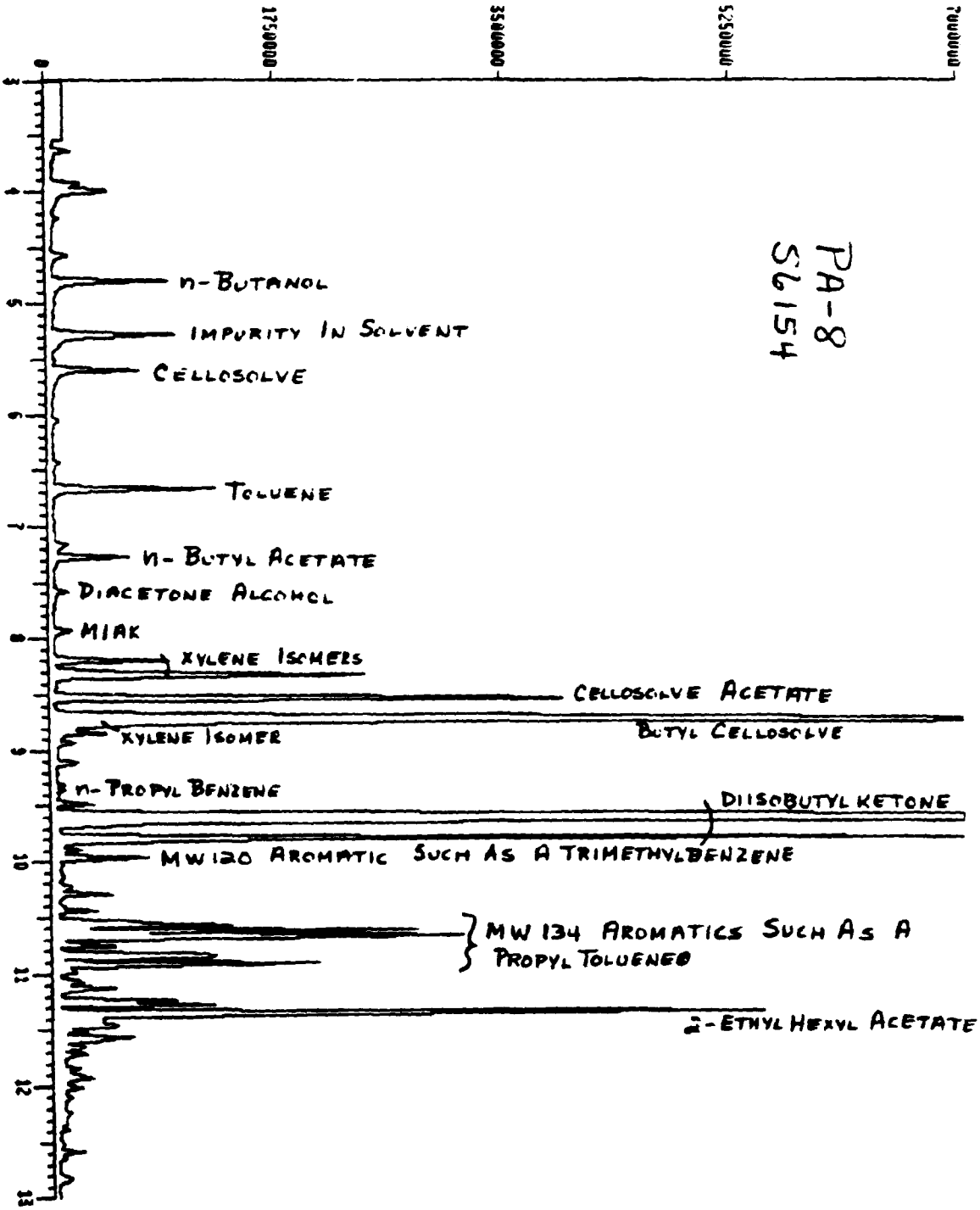
**Appendix 2**
**Qualitative Analysis**
**by GC-MS of Bulk Samples**




PA-50
56154

End of plot. Time = 3.00 to 13.00 minutes Chart speed = 1.99 cm/min

1: TIC of DATA:FBPA-8.D




PA-8
S6154

End of plot. Time = 3.00 to 13.00 minutes Chart speed = 1.99 cm/min