Industrial Hygiene Study of Workers Exposed to Nitrosamines

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ABSTRACT

Under the NIOSH-sponsored contract, a total of 45 plant surveys were conducted at 37 separate manufacturing plants. The industries surveyed were the azo dyes, fish processing, fish meal, cutting fluid manufacturers and users, rubber and tanning. Airborne concentrations of Thermal Energy Analyzer (TEA) responsive compounds were found in all the industries except fish processing. The dye industry had airborne TEA responsive material as high as 40 ug/cu m, but they were not identified. Air levels of N-nitrosodiethanolamine were detected at 0.08 ng/cu m in a plant which uses cutting fluids. A fish meal factory was found to contain N-nitrosodimethylamine (NDMA) at 0.06 ug/cu m. In a chrome tannery NDMA was identified at 47 ug/cu m. The rubber industry has airborn levels of N-nitrosomorpholine as high as 250 ug/cu m.

This study has resulted in an increased understanding of mans' exposure to performed N-nitrosamines. It is conceivable, from the information that has been generated in this study, that nitrosamine exposure as large as that in the tire and rubber industry exist in other industry not yet surveyed.

INTRODUCTION

The National Institute for Occupational Safety and Health (NIOSH) has conducted, under contract, environmental monitoring in a wide variety of industrial facilities to determine workers' exposure to N-nitrosamines. These compounds have been demonstrated to be highly toxic and potent carcinogens in laboratory animals (Druckrey et al., 1967). N-nitrosamines consist of a large family of compounds of which more than 100 of the 130 different N-nitroso compounds tested have been shown to be carcinogenic in a wide variety of animal species (Druckrey et al., 1969; Magee & Barnes, 1967; Magee & Schoental, 1964; Magee et al., 1976). Some of these compounds have been shown to be carcinogenic in rats with doses as low as 1 to 5 ppm of N-nitrosodimethylamine (NDMA) and N-nitrosodiethylamine (NDEA) in the diet.

N-nitrosamines are the N-nitroso derivatives of secondary amines with the general formula $\begin{matrix}R_1\\R_2\end{matrix}\!\!>$N-NO, R_1 and R_2 being virtually any organic group. One of the simplest members of this family of compounds is N-nitrosodimethylamine $\begin{matrix}CH_3\\CH_3\end{matrix}\!\!>$N-NO. This compound is also a regulated carcinogen under part 1910.1016 of the United States Occupational Safety and Health Standards. N-nitrosamines may be formed by the reaction of secondary amines (Mirvish, 1975; Scanlan, 1975) and nitrogen oxides, however, under appropriate conditions primary and tertiary amines (Smith, 1967; Ohshima & Kawabata, 1977) can also be nitrosated to produce these compounds. The NO, or nitrosyl part of the compound, can be derived from nitrogen oxides such as NO, NO_2, N_2O_4, or N_2O_3 (Challis et al., 1977) or from nitrous acid or nitrite salts (Mirvish, 1975; Scanlan, 1975). N-nitrosamines can also be formed by transnitrosation whereby other nitro or nitroso compounds serve as the nitrosating agent (Singer et al., 1977; Buglass et al., 1974). N-nitrosamines are commonly made by the reaction of a secondary amine with sodium nitrite at acidic pH, however, depending on the reactant and catalysts that are used, N-nitrosation can also occur at neutral or alkaline pH (Fine, 1979). Compounds known to catalyze N-nitrosation include formaldehyde (Keefer & Roller, 1973), chloral (Keefer & Roller, 1973), ozone (Fine, 1977a), and some metal ions (Keefer, 1976).

The amine fragment of the N-nitroso compounds can be found in a large variety of both man-made and natural products. Secondary amines such as dimethylamine, diethylamine and morpholine are produced in large quantities and are used in both consumer and industrial products. These products are, for example, used in agricultural chemicals, detergents, rust inhibitors, rubber additives, solvents, drugs, plastics, leather tanning, textiles, cosmetics and synthetic cutting and grinding fluids. Given the widespread use of secondary amines and the ever present nitrogen oxides of an industrial society, the likelihood of N-nitrosamines being found in these products or in an industrial situation where these compounds may occur together, is high.

Recent advances in detection have made it possible to examine consumer and industrial products and the environment for N-nitrosamines. It has been found that substantial numbers of people are indeed exposed. Levels which have been determined in commercial products and environmental samples range from parts per billion to percent amounts. Six human populations have been identified as having a potential exposure to significantly higher than background levels of carcinogenic N-nitrosamines. They are, chemical workers at a rocket fuel factory making unsymmetrical dimethylhydrazine (UDMH) from NDMA (Fine et al., 1976a), agricultural workers handling pesticides contaminated with nitrosamines (Fine, et al., 1977b), machinists using synthetic cutting and grinding fluids contaminated with N-nitrosodiethanolamine (NDELA) (Fan et al., 1977b), persons using facial cosmetics contaminated with N-nitrosodiethanolamine (Fan et al., 1977a), rubber chemical workers exposed to N-nitrosomorpholine (NMOR) (Fajen et al., 1979), and leather tanners exposed to N-nitrosodimethylamine in tannery air (Rounbehler et al., 1979). The probability that certain other occupations may involve exposure to N-nitrosamines is the basis of this NIOSH-sponsored study. While direct evidence for the carcinogenicity of N-nitroso compounds in man is presently lacking, it is unlikely that man alone will be uniquely resistant to their carcinogenic action.

STUDY DESIGN

During the study, a total of 51 on-site plant visits were conducted at 37 separate manufacturing plants. These plants represented 5 different industries. The study was intended to determine if there was worker exposure to N-nitrosamines. The basis for selecting the plants that were surveyed included:

- Known or suspected use of N-nitroso compounds
- Known use of products likely to contain N-nitroso compounds as impurities
- Use of chemicals that could give rise to N-nitroso compounds
- Epidemiological data which, along with the possibility of worker exposure to N-nitroso compounds, suggested a higher than usual risk of worker exposure to an environmental carcinogen
- Results of the study as it proceeded

In order to illustrate the level of N-nitrosamines found in the factory environment, the data from the rubber and leather tanning industries will be discussed. Nineteen factories were visited, nine associated with the manufacture of rubber and tire products, and ten associated with the leather trade. The rubber and tire industry was chosen because a variety of amines, nitrosamines, nitroso and nitro compounds are used in various aspects of the manufacturing process, including N-nitrosodiphenylamine (NDPhA), diethanolamine, and morpholine based accelerators (Rubber World, N.Y., 1975). In addition, rubber industry workers have been identified in several epidemiological studies as suffering from excess mortality from cancer of a variety of organs including lung, bladder, stomach, and prostate (McMichael et al., 1976). The leather industry was chosen because the tanning process includes a dimethylamine salt used in the dehairing processes (Walker et al., 1976). What little data is available on leather workers show an increased tumor incidence of nasopharyngeal and bladder cancers among shoe and bootmakers (Cole, et al., 1972). Another group stated that the increased buccal, larynx, nasopharyngeal and bladder cancer incidence they observed among "leather industry operatives" (job sites not specified) might be related to the tanning process (Viadana, et al., 1976). In both cases the specific agents responsible for the excess cancer deaths have not been clearly identified.

DATA COLLECTION

The laboratory apparatus, including a Shimadzu programmable gas chromatograph, a high pressure liquid chromatograph, fume hood, and two Thermal Energy Analysers (TEA™) are located inside a fully equipped, self-contained mobile laboratory (Krull, et al., 1978), which was parked nearby each site.

The majority of the air samples were collected by two methods. The first method pulled air at a flow rate of between 1 and 2 ℓ/min through a glass impinger containing 45 ml of 1N KOH. The second method used a Thermosorb/N® tube which consisted of 15 mm ID x 20 mm length tubes containing a mixture of magnesium silicate and an amine trapping (complexing) agent and a nitrosating inhibitor. The air samples were collected by drawing air through the traps at a constant rate of from 1.5 to 6 ℓ/min for 5 to 200 minutes using a Bendix C115 pump or a 10 ℓ/min metal bellows air pump. The Thermosorb/N® tubes were used to absorb N-nitroso compounds and to assess the presence of nitrosating agents in the sampled air (Rounbehler, et al., 1979). The nitrosating capacity of the sampled air was estimated by measuring the amount of N-nitrosomorpholine formed from the reaction of morpholine, which was spiked on the Thermosorb/N[R] adsorbant, and whatever nitrosating agent may have been present in the air. The other trapping methods used in collecting samples were dry cellulose fiber traps, alkaline cellulose fiber and Tenax GC cartridges.

Analytical techniques for the quantitative analysis of NDMA in air at levels down to 0.001 $\mu g/m^3$ are available in the literature (Fine, et al., 1976b; Fine, et al., 1977c). Analysis of nitrosamines has been greatly simplified by the availability of the TEA (Fine, et al., 1975b) designed to be nitroso specific. The TEA is used as a detector for both gas chromatography (GC-TEA) (Fine, et al., 1976a) and high pressure liquid chromatography (HPLC-TEA) (Fine, et al., 1976c). The TEA simplifies the analysis because virtually no cleanup of the air sample is required.

RESULTS

The industries surveyed by the NIOSH sponsored study were the azo dyes, fish processing, fish meal, cutting fluid manufacturers and users, rubber and tanning. Airborne concentrations of TEA responsive compounds were found in all the industries except fish processing. The dye industry had airborne TEA responsive material as high as 40 $\mu g/m^3$, but they were not identified. Air levels of NDELA were detected at 0.08 ng/m^3 in a plant that used cutting fluids. A fish meal factory was found to contain

0.06 $\mu g/m^3$ of NDMA. The data generated on the leather and rubber industries will be discussed in further detail.

In an aircraft tire factory, NMOR was found to be present at levels between 0.6 and 27 $\mu g/m^3$. All 16 air samples which were collected inside the factory were positive for NMOR, with the average NMOR level being 4.85 $\mu g/m^3$. The highest NMOR levels were found where rubber was being cured and extruded. Further evidence as to the identity of NMOR was obtained by combining the samples and identifying the NMOR by GC-high resolution mass spectrometry (GC-MS).

In a chemical plant which was manufacturing rubber chemicals three N-nitrosamines were found: NMOR, NDMA and NDPhA. The NMOR levels varied from 0.07 $\mu g/m^3$ in the lunchroom to 4.6 $\mu g/m^3$ near the NDPhA reactor. The highest level of NDMA detected was 0.3 $\mu g/m^3$. NDPhA, which was being produced in the factory, was found to be present at most of the sites sampled. The highest NDPhA level found was 47 $\mu g/m^3$. A dirt sample, scraped from a staircase in the factory, contained 731 µg/g of NMOR and 15,000 µg/g of NDPhA. The presence of NMOR in the dirt sample was confirmed by GC-MS.

Further investigations were made at five tire manufacturing plants to determine if the levels in the aircraft tire plant were unique or if indeed nitrosamines were ubiquitous in the rubber industry. Each plant had NMOR levels similar to the aircraft tire plant (0.6 to 27 $\mu g/m^3$), however, one plant had 248 $\mu g/m^3$ of NMOR. Table I summarizes the N-nitroso compounds found in the rubber industry survey.

At the leather tannery, NDMA was found to be present in all the air samples which were taken inside the factory. The NDMA level varied from 0.1 $\mu g/m^3$ in the lunchroom, to 47 $\mu g/m^3$ inside the tannery, adjacent to the coloring and fat liquoring process. The average NDMA level in the 19 air samples which were collected was 17 $\mu g/m^3$. Further evidence as to the identity of the NDMA was obtained by combining the samples and identifying the NDMA by GC-MS. Air samples taken at the doping area were also found to contain NMOR at the 2 $\mu g/m^3$ level, plus smaller amounts of two unidentified TEA responsive compounds.

Further investigation of the leather industry was also made to determine if N-nitrosodimethylamine was unique to this plant. Nine other tanneries were surveyed for N-nitrosamines. Four tanneries had levels ranging from 0.03 - 10.8 $\mu g/m^3$; N-nitrosamines were not detected in the other five plants. Table II summarizes the levels of nitrosamines found in the first tannery which was surveyed.

DISCUSSION

The question arises as to the source of the airborne N-nitrosamines in these two industries.

N-nitrosomorpholine was found in both the chemical factory and the factory where tires were being produced. In the chemical factory, N-nitrosomorpholine was found as an impurity in the morpholine (0.8 $\mu g/g$) and in the product, bismorpholinecarbamylsulfonamide (.4 to .7 $\mu g/g$), which is used as an accelerator. Also, the steam condensate contained 0.002 µg/g, possibly from the use of morpholine as a corrosion inhibitor in the steam process equipment.

We believe this to be the first report of N-nitrosomorpholine as an air pollutant. While the effects of NMOR by the inhalation route have not been tested, and its actions in humans are unknown, studies in animals by both oral and parenteral dosing have shown it to be carcinogenic to a variety of species. Shank and Newberne (1976) have reported increased incidence of liver angiosarcomas (15%), and lung angiosarcomas (9%) in rats fed a diet containing 5 µg/g (5ppm) NMOR.

In the leather tannery, NDMA was found at 0.5 µg/kg in an aqueous solution of dimethylamine sulfate which is a depilatory agent in the unhairing step. However, the NDMA impurity in the dimethylamine sulfate is insufficient, in this plant, to account for the level of NDMA in the plant environment. The causitive agent or agents responsible for the total environmental load of NDMA in the tannery has not been found; however, it can be speculated that the source of the airborne NDMA may be due to gas phase nitrosation of airborne amines by nitrogen oxides. It can be further speculated that the source of the airborne amines in these plants may be the dimethylamine sulfate and the dimethylamine produced or released during the unhairing process.

The significance of the tannery findings may be inferred from the results of a recent study by Moiseev and Benemansky (1975). They reported that 30 male Wistar rats breathing air containing 220 $\mu g/m^3$ NDMA 24 hours/day for 25 months showed an incidence of malignant tumors of 83% in the exposed as compared to 13% in the control animals. These tumors were mainly of the liver and kidney. However, it is not possible to extrapolate the animal data on NMOR or NDMA, as these compounds have not been identified as human carcinogens.

SUMMARY

Under the NIOSH-sponsored contract, a total of 51 plant surveys were conducted at 37 separate manufacturing plants. The industries investigated were the fish processing, fish meal, manufacturers and users of cutting fluids, azo dye, leather and rubber.

NDELA, NMOR, NDMA, NDPhA were found in the environmental air of several factories. In a chrome tannery, NDMA was identified as high as 47 $\mu g/m^3$ and NMOR at 248 $\mu g/m^3$ in a rubber tire plant.

This study has resulted in an increased understanding of mans' exposure to preformed N-nitrosamines. It is conceivable, from the information that has been generated in this study, that nitrosamine exposure as large as that in the tire and rubber industry exists in other industries not yet surveyed.

NIOSH is continuing its research on nitrosamines in the industrial environment.

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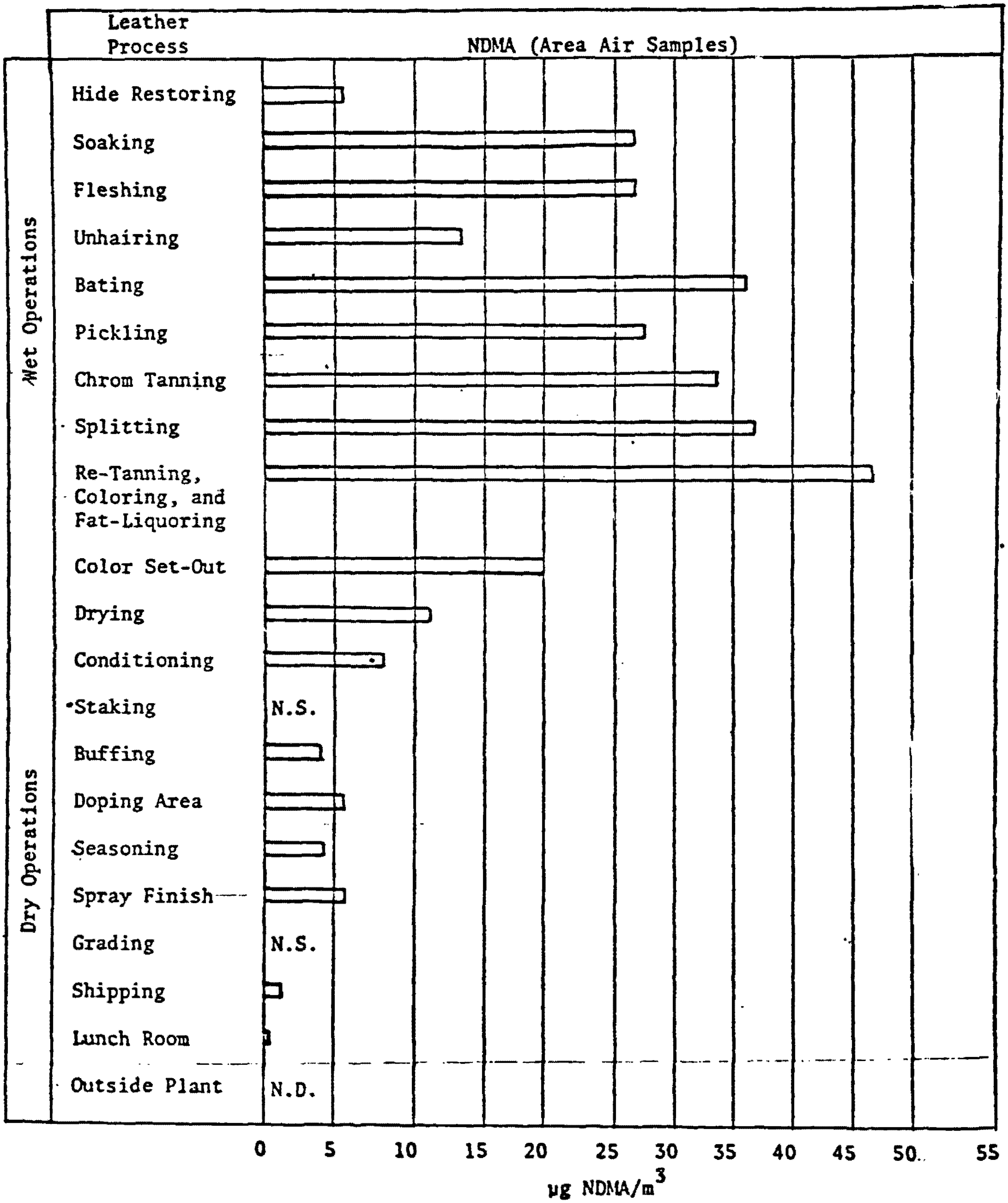
Table I
Nitrosamines in Air Samples Collected at Four Rubber Industry Plants

Location	NMOR $\mu g/m^3$	NDMA $\mu g/m^3$	NDPhA $\mu g/m^3$	NYPR* $\mu g/m^3$
1. Tire Chemical Factory				
DMA tank	0.9, 4.6		0.8, 0.6	
Chemical storage	1.5	0.08	17	
BMCS centrifuge	3.4	0.3	0.2	
BMCS reactor	3.0	0.3	0.9	
BMCS drier	0.7	0	0.3	
BMCS discharge	1.6	0.1	0	
NDPhA reactor	4.1, 5.1	0.2, 0.1	47, 0	
NDPhA decantor	4.6, 3.9	0.05, 0.07	12, 25	
Lunch room	0.07	0	0.7	
Outdoors	0	0	0	
2. Industrial Rubber Products Factory				
Solution area	0	0.14	0	
Banbury machining	0	0.14	0	
Batch off mill area	0	0.09	0	
Office	0	0.07	0	
3. Aircraft Tire Factory				
Curing press	2.2, 4.9	0	0	
Extruder	1.7, 2.4	0	0	
Extruder	27, 12	0	0	
Warm-up and mixing	2.2, 1.3	0	0	
Cooling pool	3.3	0	0	
Cutting area	2.2	0	0	
Large tire curing	7.1, 2.6	0	0	
Small tire curing	4.6	0	0	
Batchstock storage	2.5	0	0	
Finishing and inspection	0.6	0	0	
Office	1.0	0	0	
Outdoors	0	0	0	
4. Synthetic Rubber and Latex Factory				
Four areas	0	0	0	
5. Other Tire Plants				
Curing	1.5, 1.3, .03	.24	0	
Extruder	22.0, 9.2, 8.5	2.0, .03	0	
Warm-up mill	2.8, .73		0	
Calendar	248	2.9	12.4	2.6
Warehouse	3.7	.38		
Outdoors	0	0	0	

*N-nitrosopyrrolidine

Table 2
N-Nitrosodimethylamine in Air Samples
Collected in a Chrome Tannery



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The papers included in these Proceedings were printed as they were submitted to this office.

Appropriate portions of the discussions, working groups and plenary session were sent to the participants for editing. The style of editing varied, as could be expected. To the extent possible, we have attempted to arrive at a consistent format.

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