

5. POTENTIAL FOR HUMAN EXPOSURE

5.1 OVERVIEW

NDMA is not an industrially or commercially important chemical; nevertheless, it can be released into the environment from a wide variety of manmade sources. This is due to the inadvertent formation of NDMA in industrial situations when alkylamines, mainly dimethylamine and trimethylamine, come in contact and react with nitrogen oxides, nitrous acid, or nitrite salts, or when trans-nitrosation via nitro or nitroso compounds occurs. Thus, potential exists for release into the environment from industries such as tanneries, pesticide manufacturing plants, rubber and tire manufacturers, alkylamine manufacture/use sites, fish processing industries, foundries and dye manufacturers. At this time, NDMA has been found in at least 1 out of 1177 hazardous waste sites on the National Priorities List (NPL) in the United States (VIEW Database 1989). Nitrosation reaction may also result in the formation of NDMA in the environment. In air, NDMA may form as a product of the nighttime reaction of dimethylamine with NO_x. In water and soil, NDMA forms by the reaction of widely-occurring primary, secondary or tertiary amines in the presence of nitrite.

In the ambient atmosphere, NDMA should be rapidly degraded upon exposure to sunlight. The half-life for direct photolysis of NDMA vapor is on the order of 5 to 30 minutes. In surface water exposed to sunlight, NDMA would also be subject to photolysis. On soil surfaces, NDMA would be subject to removal by photolysis and volatilization. The volatilization half-life of NDMA from soil surfaces under field conditions has been found to be 1 to 2 hours. In subsurface soil and in water beyond the penetration of sunlight, NDMA would be susceptible to slow microbial decomposition under both aerobic and anaerobic conditions. In aerobic subsurface soil, the half-life of NDMA has been found to be about 50 to 55 days. Degradation has been found to proceed slightly faster under aerobic conditions than under anaerobic conditions.

NDMA has been detected in ambient air, water and soil; however, monitoring data are rather scant. Low levels of NDMA (measurable in terms of ppb) are commonly found in the air of car interiors, food, malt beverages (beer, whiskey), toiletry and cosmetic products, rubber baby bottle nipples and pacifiers, tobacco products and tobacco smoke, pesticides used in agriculture, hospitals, and homes, and sewage sludge.

The general population is exposed to NDMA from a variety of different sources. Primary sources of exposure include: chewing tobacco, tobacco smoke, foods [beer, liquor, cured meats (particularly bacon), fish, cheeses, and other food items], cosmetics and toiletry articles, interior air of cars, various household commodities such as detergents and home-and-garden pesticides, and formation in the upper gastrointestinal tract during digestion of secondary amine-containing foods. Infants may also be exposed

5. POTENTIAL FOR HUMAN EXPOSURE

to NDMA from the use of rubber baby bottle nipples and pacifiers which may contain very low amounts of NDMA, from ingestion of contaminated infant formula, and from breast milk from some nursing mothers. Very low levels of NDMA have been found in breast milk. Occupational settings in which there is potential for exposure to NDMA include, but are not limited to: leather tanneries, rubber and tire industries, rocket fuel industries, dye manufacturers, soap, detergent and surfactant industries, foundries (coremaking), fish-processing industries (fish-meal production), pesticide manufacturers, warehouse and sale rooms (especially for rubber products), and research laboratories where NDMA is synthesized/studied.

5.2 RELEASES TO THE ENVIRONMENT

5.2.1 Air

NDMA may occasionally be emitted into the atmosphere from sites of manufacture/use of dimethylamine and other sites at which NDMA is inadvertently formed, i.e. tanneries, pesticide manufacturing plants, rubber and tire industries, etc. NDMA may also form in nighttime air as the result of the atmospheric reaction of dimethylamine with NO_x (Cohen and Bachman 1978, Fine et al. 1976a, Fine et al. 1976b, Hanst et al. 1977).

5.2.2 Water

NDMA may be released in waste streams from facilities at which NDMA was inadvertently formed during manufacturing processes. This would include such facilities as amine manufacturing plants, tanneries, rubber and tire industries, fish processing industries, foundries, rocket fuel industries, dye manufacturers, soap, detergent, and surfactant industries, and pesticide manufacturers (Cohen and Bachman 1978). In addition to industrial sources, NDMA may form in aqueous systems, sewage and soil as the result of either biological, chemical or photochemical processes. Biological formation occurs via the reaction of a secondary or tertiary amine with nitrite. The nitrite can arise in the environment from the microbial transformation of ammonia or nitrate or through manmade production. Chemical formation of nitrosamines occurs optimally under acidic conditions and may occur from the reaction of primary, secondary or tertiary amines with nitrite (Ayanaba and Alexander 1974; Mills and Alexander 1976). Formation of NDMA by photochemical transformation of dimethylamine in the presence of nitrite has been found to occur more readily under alkaline conditions than under acidic or neutral conditions (Ohta et al. 1982). Nitrosamine precursors are widespread throughout the environment, occurring in plants, fish, algae, urine, and feces and are formed in the environment as pesticide degradation products (Ayanaba and Alexander 1974, Greene et al. 1981, Neurath et al. 1977, Windholz 1983). The Contract Laboratory Program statistical data base reports that NDMA has been detected in groundwater samples at one out of 1177 hazardous waste site on the National Priorities List (NPL). This site is Martin Marietta (Denver Aerospace) in Waterton, CO (VIEW Database 1989):

5. POTENTIAL FOR HUMAN EXPOSURE

No data are available regarding contamination of drinking water, irrigation water, sewers, or storm drains in the vicinity of NPL sites.

5.2.3 Soil

NDMA may be released into the environment as the result of land application of sewage sludge containing this compound or as the result of land application of certain pesticides contaminated with this compound. NDMA may also form in soils under conditions which favor nitrosation of nitrosamine precursors (Mills and Alexander 1976, Pancholy 1978). There is no data pertaining to the detection of NDMA in soil samples collected at or in the vicinity of NPL sites.

5.3 ENVIRONMENTAL FATE

5.3.1 Transport and Partitioning

Organic compounds in the atmosphere having vapor pressures greater than 10^{-4} mm Hg are expected to exist almost entirely in the vapor phase (Eisenreich et al. 1981). The estimated vapor pressure of NDMA [2.7 mm Hg at 20°C (see Table 3-2)] indicates that this compound should not partition from the vapor phase to particulates in the atmosphere.

Using linear regression equations based on log Kow data [$\log Kow = -0.57$ (see Table 3-2)], a bioconcentration factor of 0.2 and a soil adsorption coefficient (Koc) of 12 have been estimated for NDMA (Bysshe 1982, Hansch and Leo 1985, Lyman 1982). These values, as well as the complete water solubility of NDMA, indicate that bioaccumulation in aquatic organisms and adsorption to suspended solids and sediments in water would not be important environmental fate processes. The low value of the Henry's Law Constant for NDMA [2.63×10^{-7} atm-m³/mol at 20°C (see Table 3-2)] suggests that volatilization would be a relatively insignificant fate process in water (Thomas 1982).

NDMA is expected to be highly mobile in soil and it has the potential to leach into groundwater supplies (Dean-Raymond and Alexander 1976, Greene et al. 1981, Swann et al. 1983). If NDMA were released to soil surfaces, as might be the case during application of contaminated pesticides, a substantial proportion of the nitrosamine would volatilize. The volatilization half-life from soil surfaces under field conditions is estimated to be on the order of 1-2 hours (Oliver 1979). If NDMA were incorporated into subsurface soil, far less of the nitrosamine would enter the atmosphere by volatilization and the rate of volatilization would be greatly reduced. Under these circumstances volatilization would be of minor importance (Oliver 1979).

5. POTENTIAL FOR HUMAN EXPOSURE

5.3.2 Transformation and Degradation

5.3.2.1 Air

In the atmosphere, NDMA vapor would rapidly degrade by direct photolysis to form dimethylnitramine. Based on experimental data, the photolytic half-life of NDMA vapor exposed to sunlight has been determined to be about 5 to 30 minutes (Hanst et al. 1977, Tuazon et al. 1984). Reaction of NDMA with photochemically-generated hydroxyl radicals or ozone molecules in the atmosphere would be too slow to be environmentally significant (Atkinson and Carter 1984, Tuazon et al. 1984).

5.3.2.2 Water

Limited available data suggest that NDMA would be subject to slow photolysis in natural waters exposed to sunlight (Polo and Chow 1976; Callahan et al. 1979). In unlit waters, it appears that NDMA would be rather persistent, eventually degrading as the result of microbial transformation (Kaplan and Kaplan 1985, Kobayashi and Tchan 1978, Tate and Alexander 1975). There is evidence which suggests that formaldehyde and methylamine may form as biodegradation products of NDMA (Kaplan and Kaplan 1985). Insufficient data are available to predict the rate at which NDMA would degrade in water. NDMA is not expected to chemically react under the conditions found in natural waters (Callahan et al. 1979, O.liver et al. 1979).

5.3.2.3 Soil

It appears that microbial degradation would be an important removal process for NDMA in subsurface soil. Oliver et al. (1979) amended Metapeake loam with 10 ppm NDMA at 23°C and observed a half-life of 50 days (Oliver et al. 1979). Loss of NDMA was attributed to volatilization and biodegradation. Tate and Alexander (1975) amended silt loam with 22.5 ppm NDMA at 30°C and observed a lag of approximately 30 days before slow disappearance from soil commenced; 50% loss occurred after about 55 days incubation and 60% loss occurred after about 70 days incubation. As part of the same study, 40% loss was observed in 2 days in soil amended with 50 ppm NDMA and 44% loss was observed in 5 days in soil amended with 250 ppm NDMA. These initial losses were followed by very little or no loss over the next 3 weeks. Initial, rapid loss of NDMA was attributed to volatilization and slow, gradual loss of NDMA was attributed to biodegradation. Mallik and Tesfai (1981) incubated NDMA at 4, 25 and 37°C and found that at all three temperatures, about 20-30% of added NDMA disappeared in the first 20 days of incubation, but little loss was noted thereafter; even after 30 days of incubation, over 50% of the NDMA was retained. The rate of disappearance of NDMA was found to be slightly higher in sandy loam soil than in either clay or silt loam soil. The rate of loss was also found to be slightly higher in aerobic soil at field capacity compared to super saturated (anaerobic) soil. After a 30-day incubation period, 60% of added NDMA remained in soil at

5. POTENTIAL FOR HUMAN EXPOSURE

field capacity and 70% of added NDMA remained in super saturated soil. Available data on the degradation of NDMA in water and air indicate that photolysis may be an important removal process on soil surfaces.

5.4 LEVELS MONITORED OR ESTIMATED IN THE ENVIRONMENT

5.4.1 Air

When it was used as a rocket fuel intermediate, NDMA was identified in ambient air on-site and in the vicinity of factories which were manufacturing rocket fuel (Fine et al. 1977b; Gordon 1978). At a plant in Baltimore, MD, which was manufacturing unsymmetrical dimethylh drazine rocket fuel, the average concentration on-site was 11,600 ng/m³, and in neighboring residential communities it was 1,070 ng/m³, with levels ranging between 30 to 100 ng/m³ in the downtown area (Fine et al. 1977b). As a result of these findings, the use of NDMA was discontinued at this plant (Shapley 1976). During December 1975, NDMA was found in air samples collected in Belle, WV near a factory which was manufacturing dimethylamine. The highest level found (980 ng/m³) was collected during a temporary weather inversion (Fine et al. 1976b). NDMA has also been measured in ambient air in urban areas with no known point sources of nitrosamines: Baltimore, MD several miles upwind of the rocket fuel plant (0.02-0.1 µg/m³); the Cross Bronx Expressway in New York City (0.8 µg/m³); and Philadelphia, PA (0.025 ppb) (Fine et al. 1976b, Shapley 1976).

Occurrence of volatile nitrosamines in air has been associated with tire and rubber products, leather tanneries, and automotive upholstery, and, as a result, measurable levels of the nitrosamines have been found in certain confined areas, e.g. automobile interiors. Concentrations of NDMA in interior air of automobiles have been found to vary widely due to differences in age of the car, design and decor. Levels of NDMA in interior air of new cars were found to range from <0.02 to 0.83 µg/m³ (Dropkin 1985, Rounbehler et al. 1980).

5.4.2 Water

Data from the EPA STORET Water Quality data base indicate that NDMA is not a common contaminant of surface waters in the United States (EPA 1988b). During the time when NDMA was being used as a chemical intermediate at a rocket fuel manufacturing plant in Baltimore, MD, concentrations up to 940 ng/L were found in adjacent surface waters. Mud puddles adjacent to the facility contained 0.20-9.0 mg/kg (moist basis) of NDMA (Fine et al. 1977b). Information found in STORET also reveals that NDMA is infrequently found in groundwater samples. STORET gross analysis data input from 1980 to 1988 indicate that NDMA was positively identified in 0.9% of 2308 groundwater samples collected in the United States. The average concentration of positive samples was 12.4 µg/L (EPA, 1988b). NDMA also has been detected at a concentration of 10 µg/L in groundwater samples at one of 1177 hazardous waste sites on the National Priorities List (NPL). This site is Martin

5. POTENTIAL FOR HUMAN EXPOSURE

Marietta (Denver Aerospace) in Waterton, Co (VIEW 1989, VIAR 1987). NDMA was reportedly found in tap water from Philadelphia, PA at levels of 0.003-0.006 µg/L (Kimoto et al. 1981). The authors of this study concluded that NDMA did not form in the resin used to accumulate the nitrosamines, but that it may have formed from the reaction of low concentrations of nitrite, an oxidizing agent (possibly chlorine) and secondary amines present in the water sample. NDMA has been found in deionized laboratory water at levels ranging from 0.03-0.34 µg/L (Fiddler et al. 1977, Gough et al. 1977). Anion exchanger resins were identified as the source of NDMA found in the water samples. There have been reports of NDMA occurring infrequently in wastewater samples collected from various locations situated throughout the United States. When present, levels of NDMA are generally in the low µg/L range (maximum reported concentration 2.7 µg/L) (Cohen and Bachman 1978, Ellis et al. 1982, EPA 1988b, Fine et al. 1977b).

5.4.3 Soil

NDMA has been found in soil at 1-8 µg/kg (dry basis) in Belle and Charleston, WV, New Jersey and New York City (Fine et al. 1977c). It is speculated that occurrence of NDMA in soil may have arisen from (a) absorption of NDMA in air, (b) absorption of dimethylamine from air and its subsequent N-nitrosation, or (c) from pesticide application.

5.4.4 Other Media

N-Nitrosamines are formed in foods by the reaction of secondary and tertiary amines with a nitrosating agent, usually nitrous anhydride, which forms from nitrite in acidic, aqueous solution. NDMA is the most common volatile amine found in food. Food constituents and the physical make-up of the food can affect the extent of nitrosamine formation. Ascorbic acid and sulfur dioxide have been used to inhibit the formation of nitrosamines. NDMA has been found in some processed foods as a result of direct-fire drying; it forms from the nitrosation of amines in drying food by oxides of nitrogen in drying air (Scanlan 1983). Trace levels (usually less than 1 ppb) of NDMA have been found in a variety of foods; however, not all samples of a particular type of food contain detectable levels of NDMA. Table 5-1 lists the levels of NDMA which have been found in food. NDMA may also occur in human breast milk. In a study of 51 samples of breast milk collected from 13 nursing women, NDMA concentrations greater than 0.2 ppb were found in 23.5% of the samples, and the maximum concentration detected was 1.1 ppb (Lakritz and Pensabene 1984). During this study, it was determined that eating a meal containing bacon did not result in increased NDMA levels in milk, although eating a meal containing bacon and a vegetable high in nitrate occasionally resulted in higher levels of NDMA in breast milk. NDMA has been found to occur in a variety of toiletry and cosmetic products, including shampoos, hair conditioners, color toners, shower gels, bath cremes and oils, children's shampoos, children's bath and health care products, and face tonics, cleansers, and masks. In a study of 145

5. POTENTIAL FOR HUMAN EXPOSURE

TABLE 5-1. Detection of N-Nitrosodimethylamine in Food^a

Food Item	Concentration ($\mu\text{g}/\text{kg}$)
Vegetable oils and margarines	0.22-1.01
Apple cider distillates	1-10 ^b
Dried cheeses (parmesan, romano, and American)	0.2-0.3
Soy-containing foods	0.1-0.6
Non-fat dry milk	0.17-4.47
Milk	0.05-0.60
Infant formula	1
Dried legumes	0.2-0.8
Malt vinegar	0.4
Cereal products	0.3-4.2
Cooked fish	0.1-4.2
Chinese seafood	0.1-131.5
Meat	0.1-7.4
Fried bacon	1-44

^aSources: Canas et al. 1986, Fazio and Havery 1982, Fiddler et al. 1981, Goff and Fine 1979, Huang et al. 1981, Lakritz and Pensabene 1981, Lawrence and Weber 1984, Sen and Seaman 1981b, Sen et al. 1984, Sen et al. 1985a, Song and Hu 1988, Weston 1984

^b $\mu\text{g}/\text{L}$

5. POTENTIAL FOR HUMAN EXPOSURE

products, 50 samples (34.5%) contained NDMA, with a maximum concentration of 24 µg/kg occurring in a sample of shampoo (Spiegelhalder and Preussman 1984).

The U.S. Food and Drug Administration (FDA) established an action level, effective January 1, 1984, of 60 ppb total N-nitrosamines in rubber nipples as measured by a dichloromethane extraction procedure (Thompson et al. 1986). This means that the Consumer Product Safety Commission can take action against any company which introduces baby bottle or pacifier nipples into interstate commerce containing greater than 60 ppb total N-nitrosamines. Compliance testing of infant pacifiers entered into commerce after January 1, 1984 and sold in the U.S. revealed that total N-nitrosamine levels ranged from not detectable to 36.9 ppb, and that NDMA levels ranged from not detectable to 3.55 ppb, with infrequent occurrence of NDMA (Billedeau et al. 1986). This compares well with levels found in pacifiers entered into commerce prior to January 1, 1984, when total N-nitrosamine levels as high as 332 ppb and NDMA levels as high as 6.78 ppb were detected using the same analytical procedure (Billedeau et al. 1986). It should be noted that several companies have discontinued supplying rubber nipples since January 1984, because they could not meet the compliance level.

Most malt beverages, regardless of origin, contain NDMA. This includes many domestic and foreign beers and most brands of whiskey (Havery et al. 1981, Hotchkiss et al. 1981, Scanlan et al. 1980, Sen and Seaman 1981C). It is generally accepted that the nitrosamine is formed in malt during the direct-drying phase of its processing (Fazio and Havery 1982). At one time, it was estimated that 64% by weight, of the dietary intake of NDMA of the West German male population could be attributed to the consumption of beer (Hotchkiss et al. 1981, Spiegelhalder et al. 1979). As a result of these findings, the U.S. Food and Drug Administration established an action level of 5 ppb for NDMA in malt beverages sold in the United States (Hotchkiss et al. 1981). Compliance testing of domestic (United States) and imported beers by the FDA showed that domestic beers (180 samples) contained NDMA levels ranging from not detectable to 9 ppb, with the average level being less than 1 ppb (1% contained greater than 5 ppb), and that imported beers (80 samples) contained levels ranging from not detectable to 13 ppb, with an average level of 1 ppb (5% contained greater than 5 ppb) (Havery et al. 1981). These results compared favorably with levels found during a market survey carried out prior to establishment of the action level, when 81% of domestic beers contained greater than or equal to 1 ppb and 17% contained greater than 5 ppb (Hotchkiss et al. 1981). Compliance survey data indicate that levels of NDMA in scotch whiskey (44 samples) ranged from not detectable to 2 ppb, with an average of less than 1 ppb (Havery et al. 1981).

NDMA is commonly found in commercially-available tobacco products in the United States. Results of one study showed that chewing tobaccos purchased in the United States contained NDMA at levels ranging from <0.2 to

5. POTENTIAL FOR HUMAN EXPOSURE

85.1 ppb (Brunnemann et al. 1985). NDMA also occurs in mainstream and sidestream smoke from cigarettes and other tobacco products, with higher levels occurring in sidestream smoke than in mainstream smoke (Brunnemann et al. 1983, Chamberlain and Arrendale 1982, McCormick et al. 1973). Sidestream smoke from commercially-available tobacco products purchased in the United States were found to contain NDMA at the following levels: nonfiltered cigarette, 680 rig/cigarette; filtered cigarette, 736 rig/cigarette; and small cigar, 1700 rig/cigarette. The ratio of NDMA in sidestream smoke to NDMA in mainstream smoke in the non-filtered cigarette, filtered cigarette and small cigar was found to be 52:1, 139:1, and 41:1, respectively (Hoffman et al. 1987).

NDMA has been found to occur in various technical and commercial pesticides used in agriculture, hospitals and homes as the result of (a) formation during the manufacturing process, (b) formation during storage, and (c) contamination of amines used in the manufacturing process (Bontoyan et al. 1979). Herbicides in which NDMA has been found include the amine salt formulations of 2,4-D, dicamba, MCPA, MCPP, and 2,3,6-trichlorobenzoic acid. Levels ranging from 0.05 to 640 ppm have been detected in these herbicides (Bontoyan et al. 1979, Cohen et al. 1978, Hindle et al. 1987, Ross et al. 1977).

NDMA is a common constituent of municipal sewage sludge (Brewer et al. 1980, Mumma et al. 1984). NDMA was detected in dried sludges from 14 out of 15 cities geographically located throughout the U.S. at levels ranging from 0.6-45 ppb (Mumma et al. 1984). Occurrence of NDMA in sewage sludge appears to be the result of biological and chemical transformation of alkylamines in the presence of nitrite (Ayanaba and Alexander 1974, Mills and Alexander 1976, Pancholy 1978).

5.5 GENERAL POPULATION AND OCCUPATIONAL EXPOSURE

N-Nitrosamine precursors can be found in a large variety of man-made and natural products. Such products include agricultural chemicals, tobacco, detergents, rust inhibitors, rubber additives, solvents, drugs, plastics, leather tanning, textiles, and cosmetics. Considering the widespread occurrence of these products and the common occurrence of nitrogen oxides in industry, there is a fairly high likelihood that N-nitrosamines are found in these products or in industrial setting in which these products are used and/or produced (Fajen 1980). Occupational settings in which there is potential for exposure to NDMA include, but are not limited to: leather tanneries, rubber and tire industries, rocket fuel industries, dye manufacturers, soap, detergent and surfactant industries, foundries (core-making), fish-processing industries (fish-meal production), pesticide manufacturers, and warehouse and sale rooms (especially for rubber products) (Spiegelhalder 1984). When present in workroom air, NDMA levels are typically less than 1 ppb (Fajen et al. 1982). Exposure may result from inhalation or dermal contact. Results of a NIOSH survey carried out between

5. POTENTIAL FOR HUMAN EXPOSURE

1981 and 1983 indicate that 747 workers are potentially exposed to NDMA in occupational settings (NIOSH 1988).

Laboratory workers handling NDMA could potentially be exposed to the nitrosamine as a result of diffusion through rubber gloves. Walker et al. (1978) showed that rubber gloves worn in research laboratories do not provide complete protection from dermal exposure to NDMA, because 11.8% of the NDMA contained in a dichloromethane solution was found to diffuse through latex surgical gloves into saline solution, over a period of 20 minutes. Dichloromethane is a common solvent for NDMA.

General population exposure to NDMA results from a number of different sources, primarily chewing tobacco, tobacco smoke, foods (beer, cured meats, fish, cheeses, and other food items), cosmetic products, interior air of cars, and various household commodities. Exposure to NDMA may also result from its in vivo formation during digestion in the upper gastrointestinal tract of secondary amine-containing foods or drugs, especially those containing dimethylamine (Groenen et al. 1980, Magee et al. 1976, Sakai et al. 1984). Infants may be exposed to NDMA from baby bottle nipples and pacifiers which may contain small amounts of NDMA, from ingestion of contaminated infant formulas, and from breast milk from some nursing mothers. Very low levels of NDMA have been found in breast milk. Based on older estimates of dietary intake in Germany, the Netherlands, and England and on recent data pertaining to occurrence of NDMA in various foods in the U.S., it appears that the average adult dietary intake of NDMA in the U.S. is less than 1 µg per day (Preussmann 1984). Insufficient data are available to predict the average daily intake of NDMA from other sources of exposure.

5.6 POPULATIONS WITH POTENTIALLY HIGH EXPOSURE

It appears that those segments of the general population with potentially high exposure to NDMA from exogenous sources would include tobacco smokers and nonsmokers who come in contact with tobacco smoke for extended periods of time, snuff dippers, people who are occupationally exposed, and people who consume large quantities of food known to contain NDMA, beer or whiskey. .

5.7 ADEQUACY OF THE DATABASE

Section 104 (i) (5) of CERCLA, directs the Administrator of ATSDR (in consultation with the Administrator of EPA and agencies and programs of the Public Health Service) to assess whether adequate information on the health effects of NDMA is available. Where adequate information is not available, ATSDR, in cooperation with the National Toxicology Program (NTP), is required to assure the initiation of a program of research designed to determine these health effects (and techniques for developing methods to determine such health effects). The following discussion highlights the availability, or absence, of exposure and toxicity information applicable to

5. POTENTIAL FOR HUMAN EXPOSURE

human health assessment. A statement of the relevance of identified data needs is also included. In a separate effort, ATSDR, in collaboration with NTP and EPA, will prioritize data needs across chemicals that have been profiled.

5.7.1 Data Needs

Physical and Chemical Properties. Physical and chemical properties are essential for estimating the partitioning of a chemical among environmental media. Many physical and chemical properties are available for NDMA; however, measured values for Koc and Henry's Law Constant at ambient temperature are not available. Methods for estimating these properties appear to provide relatively close estimates of Koc and Henry's Law Constant. Nevertheless, measured values at environmentally significant temperatures would assist in accurately predicting the fate of this compound in the environment.

Environmental Fate. Sufficient data are available to develop a general understanding of the environmental fate of NDMA. Kinetic data regarding photolysis in water and on soil surfaces, biodegradation in water under aerobic and anaerobic conditions, and biodegradation in soil under anaerobic conditions are lacking. Natural water grab sample biodegradation studies and soil metabolism studies carried out in the dark under aerobic and anaerobic conditions would be useful in establishing the persistence of NDMA in the environment. Photolysis studies carried out under simulated environmental conditions in water and soil would be useful in establishing the rate of photolytic degradation, the significance of this process as a removal mechanism, and the products of this reaction in these media.

Exposure Levels in Environmental Media. Limited data suggest that NDMA may be found in urban air, but recent comprehensive monitoring data pertaining to the detection of NDMA in ambient air are needed to establish this fact. Occurrence of NDMA in air has been associated with rubber products, leather products, and cigarette smoke and measurable levels of NDMA have been found in car interiors. This information, combined with the fact that NDMA has been found in ambient air at various urban locations, suggests that detectable levels of NDMA exist in the interior air of homes, offices, etc. Studies pertaining to the monitoring of NDMA in indoor air are needed to confirm this supposition.

Exposure Levels in Humans. Although numerous studies are available concerning the detection of NDMA in various foods, a market basket study is needed to provide a reliable estimate of the average daily dietary intake of NDMA. Available monitoring data on NDMA need to be evaluated, and estimates of the amount of exposure from each source need to be developed. These data would be useful in establishing the relative importance of each source of intake to overall human exposure and for predicting typical levels of exposure to NDMA.

5. POTENTIAL FOR HUMAN EXPOSURE

Exposure Registries. Since NDMA occurs most commonly in occupational settings as a result of its inadvertent formation, it would be difficult to develop a reliable estimate of occupational exposure to this compound. Nevertheless, NIOSH has established a registry for occupational exposure to NDMA. It would be difficult to develop a registry for environmental exposure to NDMA since such exposure can occur from a wide variety of sources and level of exposure can vary markedly depending upon an individual's lifestyle. There is no registry available for environmental exposure to this compound.

5.7.2 On-going Studies

There is no indication that there are any studies currently in progress which are related to the level of NDMA in environmental media, environmental fate of NDMA, or general population or occupational exposure to NDMA.