

**INITIAL HUMAN HEALTH AND  
ENVIRONMENTAL SCREENING ASSESSMENT  
FOR  
DIMETHYL ETHER (DME)  
TECHNICAL SUMMARY**

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*Revised*  
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## LIST OF ACRONYMS

|                    |  |
|--------------------|--|
| AEL                | Acceptable Exposure Limit                                |
| atm                | atmosphere   |
| CFC                | chlorofluorocarbon                                       |
| cm <sup>3</sup>    | cubic centimeters  |
| DME                | dimethyl ether   |
| EEAA               | expanded exposure assessment addendum                    |
| EPA                | Environmental Protection Agency                          |
| g/l                | grams per liter  |
| GLP                | Good Laboratory Practices                                |
| HPV                | High Production Volume                                   |
| LOAEC              | Lowest Observed Adverse Effect Concentration             |
| m <sup>3</sup> /hr | cubic meters per hour                                    |
| mg/kg/day          | milligrams per kilogram per day                          |
| mg/l               | milligrams per liter                                     |
| mm Hg              | millimeters of mercury                                   |
| NOAEC              | No Observed Adverse Effect Concentration                 |
| NOAEL              | No Observed Adverse Effect Level                         |
| OECD               | Organization for Economic Cooperation and Development    |
| ppm                | parts per million  |
| scfm               | standard cubic feet per minute                           |
| SGPT               | serum glutamic pyruvic transaminase                      |
| SIAR               | Screening Information Data Set Initial Assessment Report |
| SIDS               | Screening Information Data Set                           |

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Note: This document has been structured to provide varying levels of detail to audiences with varying information needs. Section 1 provides a three-page summary of DME, including brief information and discussion regarding hazard and exposure information, results and conclusions, and recommendations. Section 2 provides the next layer of detail with a summary of the screening evaluation, offering a synopsis of the relevant hazard and exposure information. Section 3 follows the OECD SIAR format, where an emphasis on the hazard information and an abbreviated review of exposure data leads to a conclusion about the priority of the chemical for further action. Section 4 provides another layer of reporting that includes expanded descriptions and documentation of the exposure assessment efforts. Section 5 is the final section which provides exposure equations and calculations used to determine individual exposure of workers and consumers to DME.

## **SECTION 1**

### **CHEMICAL PROFILE SUMMARY**

#### **CHEMICAL NAME**

Dimethyl Ether (DME)

#### **CAS NO.**

115-10-6

#### **STRUCTURAL FORMULA**

CH<sub>3</sub>-O-CH<sub>3</sub>

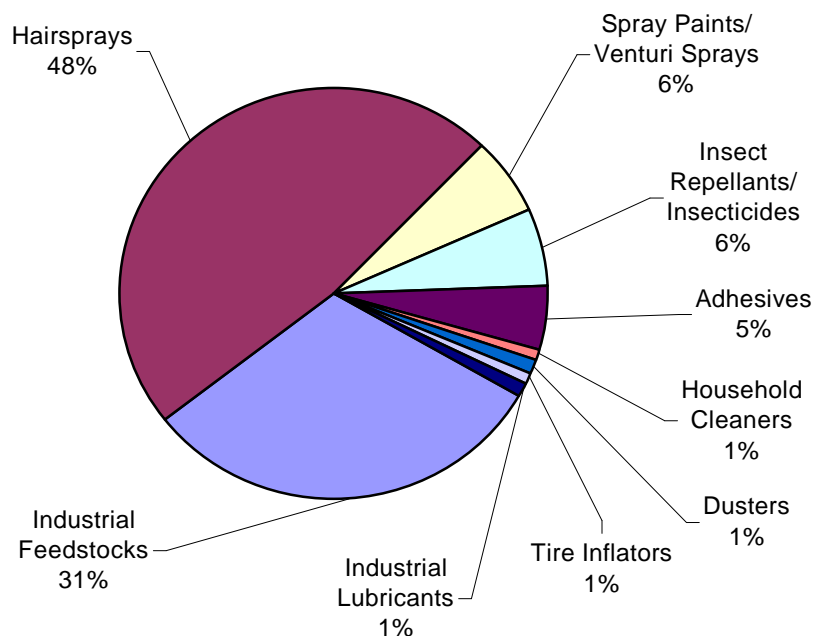
#### **INTRODUCTION**

This report presents the results of a screening level human health exposure assessment for DME. DME is a volatile gas used as a chemical intermediate and propellant/co-solvent in a variety of industrial and household aerosol products (e.g., hairsprays, pesticides, cleaning products). Based on DuPont knowledge, national production of DME is 15 to 20 million kilograms in the United States. This production is distributed across the following primary uses: industrial feedstock for the product of other chemical substances (31%), hairsprays (48%), spray paints/venturi sprays (6%), insect repellents/insecticides (6%), adhesives (5%), household cleaners (1%), dusters (1%), tire inflators (1%), industrial lubricants (1%; see Figure 1). DME is used at concentrations between 15 and 50% in formulation of its different aerosol products. It should be noted that DME is a replacement for chemicals that contribute to surface ozone formation and chlorofluorocarbons (CFCs), which are being phased out as tropospheric ozone depleters.

This screening level assessment combines existing information on chemical hazard (i.e., toxicity) with an assessment of potential exposures to evaluate the risk/safety of the current use(s) of DME in commerce. As such, it is intended to improve the public's understanding of the hazards of DME in the context of how the chemical is used and potential exposure to it so that its risks can be understood and managed more effectively.

#### **HAZARD DATA**

The hazard data used in this study were derived from a compilation of publicly available information compiled under the voluntary U.S. High Production Volume (HPV) Chemicals Challenge program, summarized in Section 2. A detailed summary of the toxicity studies used in this analysis is publicly available. These studies evaluated acute and subchronic toxicity, carcinogenicity and mutagenicity, and developmental toxicity. Results from these studies showed a Lowest Observed Adverse Effect Concentration (LOAEC) of approximately 20,000 parts per million (ppm). (This LOAEC was derived from concentrations in air, in repeated dose rat toxicity, and development toxicity studies.) For the purposes of comparison to predicted exposures, a No Observed Adverse Effect Concentration (NOAEC) of 10,000 ppm (concentration in air) was chosen as the critical threshold value.



**Figure 1. DME Applications**  
**(Source: DuPont business and market information)**

## EXPOSURE ASSESSMENT

The exposure assessment component of this analysis encompasses the manufacture, processing, transport, and major uses of DME in commerce. As a screening level evaluation, the exposure assessment is not a comprehensive assessment of every possible use of this material, but captures currently known uses. Based on the high volatility of DME, attention was focused on exposure via the most likely route of inhalation, not dermal contact or ingestion. Key routes of exposure studied were the production and use of DME as a chemical intermediate, in commercial products (resulting in occupational exposures), and as a household product ingredient in aerosol sprays (especially hairsprays, pesticides, and household spray cleaners) that are used frequently by the general public. All product categories other than those listed above are used much more intermittently or under carefully controlled conditions that limit exposure relative to these products. Estimated commercial exposures were calculated using extreme use practices and human inhalation rates. The analysis of consumer exposure involved three basic models and predicted aggregate exposure as a result of the typical use of all of the products combined. One model predicted airborne levels in the vicinity of the user. The two other models evaluated actual inhalation, assuming 100% uptake in the lungs and systemic distribution of the material. Sensitive subpopulations (e.g., children, pregnant women, the elderly) also were accounted for by applying an additional safety factor of 10 to reduce the effective Acceptable Exposure Limit (AEL)/NOAEC for commercial workers and consumers, respectively.

## RESULTS AND CONCLUSIONS

Based on studies to date, DME has a comparatively low acute and chronic inhalation toxicity and is not a teratogen, mutagen, or carcinogen. Based on an overall review of the available toxicity data and on results from the repeated dose rat toxicity and development toxicity studies, a

conservative NOAEC of 10,000 ppm (concentration in air) was used for the human risk characterization.

Risk of personal injury or adverse health effects during DME manufacture or processing is low when the chemical is handled in accordance with appropriate industrial hygiene and safety measures. These measures typically include fume hoods and other air collection, circulation, and containment systems and respirators for specific tasks (e.g., system cleanouts). Under extreme conditions, there are flammability, explosion, and narcosis hazards associated with virtually all propellant gases, including DME.

The predicted exposure during the commercial use of key products (i.e., hairsprays) is 247-fold less than the 1,000 ppm toxicity safety threshold for workers, factoring a significant degree of conservatism into the analysis. The predicted aggregate exposure of the general public while using key products (i.e., hairsprays, pesticides, and cleaning sprays) is between 700- and 4,100-fold less than the 10,000 ppm toxicity threshold depending on the model used.

It is also important to recognize that these exposure assessments are based on conservative default assumptions and probably represent exaggerated exposure conditions. Based on these screening assessments, the intended use of consumer and commercial products containing DME appears to present no meaningful safety risk (recognizing that intentional misuse via deliberate concentration and inhalation of vapors can be potentially life-threatening and that misuse presents flammability and explosion hazards typical of many aerosol products). Even using an additional safety factor of 10 to reduce the NOAEC for sensitive subpopulations, the estimated exposure levels are 25- and 70-fold less than the toxicity threshold for potentially more sensitive commercial workers and consumers, respectively.

This screening analysis included limited ecotoxicity elements because ecotoxicity was not considered to be significant due to the nature of the product. DME has relatively low toxicity, high volatility, and photochemical reactivity that suggests it is not likely to be persistent or present in the ecosystem at concentrations approaching concern.

## RECOMMENDATION

Based on its comparatively low order of toxicity with respect to estimated exposures, DME is recommended to be a **low priority for further work**. However, normal surveillance practices by both DME producers and users should be used to continue to monitor the development of any new information on the chemical, and reevaluations may be conducted as appropriate.

It is also recommended that warnings continue to be provided concerning the potential physical hazards of DME (e.g., flammability) and potential for acute toxicity if products containing it are misused or abused.

NOTE: The results of this assessment are not intended to rescind or modify any existing regulatory obligations with respect to DME (e.g., labeling requirements). In the event that significant new hazards, exposure data, or new applications for DME arise, this assessment should be revisited.

## SECTION 2

### HAZARD AND EXPOSURE DATA SUMMARY

#### CHEMICAL NAME

DME

#### CAS NO.

115-10-6

#### PHYSICAL AND CHEMICAL ELEMENTS

| Elements                           | Results | Units               |
|------------------------------------|---------|---------------------|
| Melting Point <sup>1</sup>         | -141.5  | °C                  |
| Boiling Point <sup>1</sup>         | -24.8   | °C                  |
| Vapor Pressure <sup>2</sup>        | 4450    | mm Hg @ 25°F        |
| Partition Coefficient <sup>3</sup> | 0.1     | Log K <sub>ow</sub> |
| Water Solubility <sup>2</sup>      | 35.3    | g/l in water @ 25°F |

Notes:

mm Hg = millimeters of mercury

g/l = grams per liter

<sup>1</sup> Lide, D.R. (ed.) 1995-1996. *CRC Handbook of Chemistry and Physics*, 76<sup>th</sup> Edition. CRC Press, Inc., Boca Raton, FL. pp. 3-207.

<sup>2</sup> Riddick, J.A., et al. 1985. *Techniques of Chemistry*, 4<sup>th</sup> Edition, Volume II, *Organic Solvents*. John Wiley & Sons, New York, NY. pp. 1325.

<sup>3</sup> Hansch, C., et al. 1995. *Exploring QSAR—Hydrophobic, Electronic, and Steric Constants*. American Chemical Society, Washington, DC. pp. 5.

## ENVIRONMENTAL FATE AND PATHWAY ELEMENTS

| Elements                               | Results                      | Units  |
|--|------------------------------|--|
| Photochemical Degradation <sup>1</sup> | 5.4                          | In air T <sub>1/2</sub> = days<br>(@ 5 x 10 <sup>5</sup> hydroxyl radicals/cm <sup>3</sup> ) |
| Stability in Water <sup>2</sup>        | 2.1 (rivers)<br>64.8 (lakes) | T <sub>1/2</sub> = hrs   |
| Transport (Fugacity) <sup>3</sup>      | 98.2                         | In air (%)   |
|  | 1.67                         | In water (%)   |
|  | 0.108                        | In sediment (%)  |
|  | 0.003                        | In soil (%)  |
| Biodegradation <sup>4</sup>            | 5% degraded<br>in 28 days    | 2 mg/l in water  |

Notes:

cm<sup>3</sup> = cubic centimeters

mg/l = milligrams per liter

<sup>1</sup> Atkinson, R. 1994. *J. Phys. Chem. Ref. Data*, Monograph 2, pp. 132 (HSDB/354).

<sup>2</sup> Lyman, W.J., et al. 1990. *Handbook of Chemical Property Estimation Methods*. American Chemical Society, Washington, DC. pp. 15-1—15-29.

<sup>3</sup> Syracuse Research Corporation EPIWIN version 3.05 contains a Level III fugacity model. The methodology and programming approach was developed by Dr. Donald Mackay and co-workers, which is detailed in the following publications:

(a) Mackay, D. 1991. *Multimedia Environmental Models: The Fugacity Approach*. Lewis Publishers, CRC Press. pp. 67-183.

(b) Mackay, D., et al. 1996. *Environ. Toxicol. Chem.*, 15(9):1618-1637.

<sup>4</sup> Akzo-sponsored study, March 1988 (cited in IUCLID 1995). IUCLID data sheet for DME (October 23, 1995).



## ECOTOXICITY ELEMENTS

| Type   | Species                     | Value (mg/l) | Method                            | GLP | Test Substance            | Results   | Reliability   |
|--|-----------------------------|--------------|-----------------------------------|-----|---------------------------|---|---|
| <b>Acute Toxicity to Fish<sup>1</sup></b>          |                             |              |                                   |     |                           |   |   |
| NOAEC  | Poecilia reticulata (Guppy) | > 4,000      | NEN 6504; Semistatic <sup>2</sup> | Yes | DME, purity not specified | All fishes survived the dosages studied (nominal concentrations of 1,900 and 3,200 mg/l; maximum DME concentration of 4,100 mg/l).  | Not assignable because limited study information was available. |
| <b>Acute Toxicity to Invertebrates<sup>1</sup></b> |                             |              |                                   |     |                           |   |   |
| NOAEC  | Daphnia magna               | > 4,000      | NEN 6501 <sup>3</sup>             | Yes | DME                       | All animals survived the dosages studied (nominal concentrations of 1,000 and 3,200 mg/l; maximum DME concentration of 4,400 mg/l). | Not assignable because limited study information was available. |

Notes:

NA = not applicable

GLP = Good Laboratory Practices

<sup>1</sup> Akzo-sponsored study, March 1988 (cited in IUCLID 1995). IUCLID data sheet for DME (October 23, 1995). No additional references found.

<sup>2</sup> With respect to rapid DME volatilization, sealed flasks were used for testing. Renewal of test solutions occurred after 48 hours.

<sup>3</sup> With respect to rapid DME volatilization, sealed flasks were used for testing.

## HEALTH ELEMENTS

| Health Elements  | Species | Protocol  | Results  |
|--|---------|---|--|
| Acute Toxicity <sup>1</sup>                            | Rat     | Inhalation toxicity, 4-hour exposure  | LD <sub>50</sub> = 164,000 ppm   |
|  | Mice    | Inhalation toxicity, 15 and 30 minutes  | LD <sub>50</sub> = 490,000 ppm and 380,000 ppm, respectively. Sedation and narcosis effects only.  |
| Repeat Dose Toxicity <sup>2</sup>                      | Rat     | Subchronic inhalation; 6 hours/day for 90 days  | No gross clinical or pathological evidence associated with exposure ≤20,000 ppm.   |
|  | Rat     | Subchronic inhalation; 200,000 ppm 6 hours/day for 13 weeks   | Slight changes in blood chemistry [increase in serum glutamic pyruvic transaminase (SGPT), reduction in total serum protein and a slight decrease in lymphocyte]. Changes were considered not biologically significant |
|  | Rat     | Lifetime inhalation toxicity and carcinogenicity (2,000; 10,000; and 25,000 ppm)  | No carcinogenic effects and no gross clinical or pathological evidence of adverse effects was associated with any exposure level.  |
| Acute Stress Simulation <sup>2, 3</sup>                | Dog     | High dose inhalation and adrenaline injection   | Cardiac sensitization reported at 20,000 ppm.  |
| Genetic Toxicity <sup>2</sup>                          | Various | Ames assay, Drosophila test, Mouse Lymphoma assay, Sister Chromatid exchange assay, and DNA repair test   | No mutagenic or genotoxic potential observed with or without metabolic activation.   |
| Reproductive Toxicity <sup>2</sup>                     | Rat     | Lifetime inhalation toxicity and carcinogenicity (2,000; 10,000; and 25,000 ppm)  | No compound-related effects on the reproductive organs of male or female rats were observed.   |
| Developmental Toxicity/<br>Teratogenicity <sup>2</sup> | Rats    | Pregnant rats exposed to five levels via inhalation: 0, 1; 250; 5,000; 20,000; and 40,000 ppm in air. Second strain exposed to 28,000 ppm for full gestation. | Reduced fetal weights and increased skeletal variations seen at 20,000 ppm. No resorption or teratogenic effects were observed.  |

Notes:

<sup>1</sup> Davidson, B. 1925. *J. Pharmacol. Exp. Ther.*, 26:43-48.

<sup>2</sup> All references are unpublished data based on studies performed by the DuPont Haskell Laboratory. GLP were performed for each study.

<sup>3</sup> Reinhardt, C.F., et al. 1971. *Arch. Environ. Health*, 22:265-279.

## HUMAN EXPOSURE EVALUATION

| DME Product             | Weekly Exposure<br>(ppm.minutes) |
|-------------------------|----------------------------------|
| Hairspray               | 9,450                            |
| Insecticide             | 7,700                            |
| Household Cleaner Spray | 7,700                            |
| <b>TOTAL</b>            | <b>24,850</b>                    |

### Notes:

Values are derived from L.J.M. Bohnenn (Aerofako), presented at the Annual Meeting of the Western Aerosol Information Bureau, Las Vegas, NV, October 16 and 17, 1980.

Selected product categories have been omitted from this aggregate example either because exposure is more intermittent (e.g., adhesives, paint) or contained (e.g., tire inflators).

Selected product categories studied in the original reference for these measurements are not included in this example because DME is no longer used as a propellant for these product types (i.e., body deodorant spray, air fresheners).

## ECOLOGICAL EXPOSURE EVALUATION

This study included an ecological exposure evaluation. Although data were limited, data were sufficient to assess the potential for ecological risk. The nature of the product (i.e., relatively low toxicity, high volatility, and photochemical reactivity) suggests that DME is not likely to be persistent or present in the ecosystem at concentrations approaching concern.

## SECTION 3

### SUMMARY OF HAZARD DATA AND KEY USE AND EXPOSURE INFORMATION<sup>1</sup>

#### 1.0 IDENTITY

##### General Information/Physical Properties

DME is a colorless liquefied gas, having a slight odor. Its physical/chemical properties are listed in the table below.

| Properties               | Result                     |
|--------------------------|----------------------------|
| Molecular weight         | 46.07                      |
| Boiling point            | -24.8°C                    |
| Density/specific gravity | 1.918 g/l @ 25°C and 1 atm |
| Vapor pressure           | 4450 mm Hg @ 25°C          |
| Flash point/flammability | -5.5°C (Tag open cup)      |
| Explosive limits         | 3.4 to 26.7%               |
| Solubility               | 35.3 g/l in water @ 25°C   |

Notes:

atm = atmospheres

#### 2.0 GENERAL INFORMATION ON EXPOSURE

##### Function

DME is used as an industrial chemical intermediate and as a propellant/co-solvent in industrial and consumer aerosol products, respectively.

##### Applications

Based on DuPont knowledge, national production of DME is 15 to 20 million kilograms in the United States. This production is distributed among the following primary uses: industrial feedstock for the product of other chemical substances (31%), hairsprays (48%), spray paints/venturi sprays (6%), insect repellents/insecticides (6%), adhesives (5%), household cleaners (1%), dusters (1%), tire inflators (1%), industrial lubricants (1%; see Figure 1 of the Chemical Profile Summary).

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<sup>1</sup> This document follows the format of the Organization for Economic Cooperation and Development (OECD) Screening Information Data Set (SIDS) Initial Assessment Report (SIAR).

## Uses in Representative Products where Human Exposure or Environmental Releases May Occur

DME is used between 15 and 50% in formulation of aerosol products as listed below.

| Product Type                   | Weight % in Product |
|--------------------------------|---------------------|
| Hairsprays                     | 15 to 35            |
| Spray Paints/Venturi Spray     | 30 to 50            |
| Insect Repellents/Insecticides | 20 to 45            |
| Adhesives                      | 20 to 40            |
| Household Cleaners             | 20 to 30            |
| Dusters                        | 25 to 30            |
| Tire Inflators                 | 15 to 20            |
| Industrial Lubricants          | 20 to 30            |

### 2.1 Environmental Exposure and Fate

This study did not include environmental data or exposure analysis; however, DME is relatively nontoxic, highly volatile, and photochemically reactive. Thus, it likely will not be detected in the ecosystem at concentrations approaching concern.

### 2.2 Human Exposure

#### Human Exposure Assessment

Due to the volatility and applications of DME, the major route of exposure is via inhalation, not dermal exposure or ingestion. Based on a review of DME flow through commerce, potentially meaningful exposures to DME may occur in the following areas:

- DME manufacture or processing as a chemical intermediate, resulting in occupational exposures.
- DME commercial use for personal care aerosol products, resulting in occupational exposures.
- DME use in personal care and household aerosol products, resulting in consumer exposures.

#### Occupational Exposure

Occupational exposure to DME during its manufacture or use as a chemical intermediate by U.S. industry is typically well controlled to minimize potential exposures. Exposures are generally viewed as negligible in the context of the toxicity of DME because of the following:

- The use of closed systems for manufacturing and processing
- Implementation and maintenance of strict industrial hygiene measures (e.g., hoods and other air collection, containment, and circulation systems and use of personal protective equipment) that are intended to ensure minimal exposure during handling and use

Both standard work practices and emergency procedures used by DME producers and processors typically result in low to zero airborne levels of DME in industrial settings. Where necessary, engineering controls (e.g., ventilation or equipment isolation) are used to ensure that recommended exposure levels (AELs) are not exceeded. AELs are an eight-hour, time-weighted average

concentration to which nearly all workers can be repeatedly exposed for five days/week without adverse health effects. For DME, the AEL for occupational exposure is 1,000 ppm in air. DME levels in working environments typically are less than 10 ppm based on industry practices, work area monitoring, and personnel monitoring studies conducted by DuPont.

### **Commercial Worker Exposure**

Commercial worker exposure to DME may occur immediately after using aerosol products containing this material as a propellant. In particular, attention is focused on hairspray (48% of use) because it is used on a more regular basis (i.e., daily) relative to other DME applications. Exposure estimates for beauticians using these products are calculated (detailed in Sections 4 and 5) based on estimated airborne levels and time of product use for an average body weight and breathing rate.

### **Consumer Exposure**

Consumer exposure to DME may occur immediately after using aerosol products containing this material as a propellant. In particular, attention is focused on hairsprays, pesticides and household cleaning products because they are used on a more regular basis (often daily) relative to other DME applications. Estimates of exposures via three different screening level approaches for the general public while using these products are described in Section 4. The basis for these calculations is provided in Section 5. The approaches are as follows:

1. Estimate exposure based on measurements of airborne DME concentrations from use of representative aerosol products in an experimental environment and habits and practices data for the length of time that they are typically used by household consumers. The results provides an estimate for “aggregate consumer exposure.”
2. Calculate an inhaled dose of DME based on measured airborne levels and time of product use for an average body weight and breathing rate.
3. Calculate an inhaled dose of DME based on estimated airborne levels and time of product use for an average body weight and breathing rate. This theoretical calculation was used to validate the calculations made in No. 2 above.

### **Indirect Exposure**

Indirect exposure via contact with DME from indoor air, ambient levels from environmental emissions, and other sources was not assessed quantitatively in this study. However, such exposure is expected to be much lower than either occupational or consumer product exposures based on the removed proximity for exposure compared to concentrated sources of DME.

### 3.0 HUMAN HEALTH HAZARDS

This section provides a summary of human health hazards. The complete “Robust Summary” for DME is provided in the Environmental Protection Agency’s (EPA’s) voluntary HPV program database, which can be found at the following web site:

<<http://www.epa.gov/opptintr/chemrtk/viewsrch.htm>>.

#### 3.1 Effects on Human Health

The following table summarizes the available mammalian toxicity, mutagenicity, and genotoxicity data for DME.

| Test Type   | Results  |
|---|--|
| Acute inhalation toxicity test in rats (4-hour exposure)  | LC <sub>50</sub> = 164,000 ppm   |
| Acute inhalation toxicity test in mice (15 and 30 minutes)  | LC <sub>50</sub> = 490,000 ppm and 380,000 ppm, respectively<br>Sedation and narcosis were the only effects observed.  |
| Stress simulation in dogs (acute high-dose inhalation and adrenaline injection)   | Cardiac sensitization reported at 20,000 ppm.  |
| Subchronic inhalation (6 hrs/day for 90 days) in rats   | No gross clinical or pathological evidence associated with exposure $\leq$ 20,000 ppm.   |
| Subchronic inhalation (200,000 ppm 6 hrs/day for 13 weeks) in rats  | Slight changes in blood chemistry (increase in SGPT, reduction in total serum protein, and a slight decrease in lymphocyte). Changes were not considered biologically significant. |
| Developmental and teratology studies (pregnant rats were exposed via inhalation to six levels: 0; 1; 250; 5,000; 20,000; and 40,000 ppm). Another strain was exposed to 28,000 ppm for full gestation period. | Reduced fetal weights and increased skeletal variations seen at 20,000 ppm. No resorption or teratogenic effects were observed.  |
| Mutagenicity and genotoxicity testing in Ames assay, Drosophila test, Mouse Lymphoma assay, Sister Chromatid exchange assay, and DNA repair test  | DME did not show any mutagenic or genotoxic potential with or without metabolic activation.  |
| Lifetime inhalation toxicity and carcinogenicity (2,000; 10,000; and 25,000 ppm)  | DME did not show any carcinogenic effects, and no gross clinical or pathological evidence of adverse effects was associated with any exposure level.                               |

Note:

On the basis of these data and results from the repeat dose rat toxicity and development toxicity studies, a conservative NOAEC of 10,000 ppm (in air) was used as the basis for comparison to exposures.

### 4.0 HAZARDS TO THE ENVIRONMENT

This study included an ecological hazard assessment. Although data were limited, data were sufficient to determine potential ecological risk (see following page). The nature of the product (i.e., relatively low toxicity, high volatility, and photochemical reactivity) suggests that DME is not likely to be persistent or present in the ecosystem at concentrations approaching concern.

#### 4.1 Effects on the Environment

The following table summarizes the available environmental toxicity data for DME.

| Type   | Species                     | Value (mg/l) | Method                            | GLP | Test Substance            | Results   | Reliability   |
|--|-----------------------------|--------------|-----------------------------------|-----|---------------------------|---|---|
| <b>Acute Toxicity to Fish<sup>1</sup></b>          |                             |              |                                   |     |                           |   |   |
| NOAEC  | Poecilia reticulata (Guppy) | > 4,000      | NEN 6504; Semistatic <sup>2</sup> | Yes | DME, purity not specified | All fishes survived the dosages studied (nominal concentrations of 1,900 and 3,200 mg/l; maximum DME concentration of 4,100 mg/l).  | Not assignable because limited study information was available. |
| <b>Acute Toxicity to Invertebrates<sup>1</sup></b> |                             |              |                                   |     |                           |   |   |
| NOAEC  | Daphnia magna               | > 4,000      | NEN 6501 <sup>3</sup>             | Yes | DME                       | All animals survived the dosages studied (nominal concentrations of 1,000 and 3,200 mg/l; maximum DME concentration of 4,400 mg/l). | Not assignable because limited study information was available. |

Notes:

NA = not applicable

<sup>1</sup> Akzo-sponsored study, March 1988 (cited in IUCLID 1995). IUCLID data sheet for DME (October 23, 1995). No additional references found.

<sup>2</sup> With respect to rapid DME volatilization, sealed flasks were used for testing. Renewal of test solutions occurred after 48 hours.

<sup>3</sup> With respect to rapid DME volatilization, sealed flasks were used for testing.

#### 5.0 CONCLUSIONS

DME has a comparatively low acute and chronic inhalation toxicity and is not a teratogen, mutagen, or carcinogen. Based on an overall review of the available toxicity data and results from the repeat dose rat toxicity and developmental toxicity studies, a conservative NOAEC of 10,000 ppm was used for the human risk characterization. Risk of personal injury or adverse health effects during DME manufacture or processing is low when the chemical used in accordance with appropriate industrial hygiene and safety measures (noting flammability, explosion, and narcosis hazards associated with propellant gases under extreme conditions). Further, based on this screening evaluation, the intended use of commercial or consumer products containing DME appears to present no meaningful safety risk. (The intentional misuse via deliberate concentration and inhalation of vapors can be potentially life threatening and also presents flammability/explosion hazards typical of many aerosol products.) The estimated exposures for key commercial uses of this product (e.g., hairsprays by beauticians) are approximately 247-fold below the worker AEL or 1,000 mg/l. The predicted aggregate consumer exposure during product use is approximately 700 times lower than the NOAEC when determined using the “ppm.min” approach and approximately 4,100 lower when determined using the “milligrams per kilogram per day (mg/kg/day) inhaled dose” approach. It is also important to recognize that these exposure assessments are based on conservative default assumptions and probably represent exaggerated exposure conditions. Furthermore, by applying an additional safety factor of 10 times for sensitive subpopulations (e.g., children, pregnant women, the elderly), exposure levels still are approximately 25- to 70-fold below the threshold risk levels for DME.



## 6.0 RECOMMENDATIONS

Based on its comparatively low order of toxicity with respect to estimated exposures, DME is recommended to be a **low priority for further work**. However, normal surveillance practices by both DME producers and users should be used to continue to monitor the development of any new information on the chemical and reevaluations may be conducted as appropriate.

## 7.0 REFERENCES

- Akzo-sponsored study. March 1988 (cited in IUCLID 1995). IUCLID data sheet for DME (October 23, 1995).
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## **SECTION 4**

### **EXPANDED EXPOSURE ASSESSMENT ADDENDUM (EEAA)**

### **FOR DME**

#### **INTRODUCTION**

The purpose of this expanded exposure assessment addendum (EEAA) is to provide a more detailed discussion of exposure analyses that are available beyond the basic information required in the OECD SIAR.

Based on DuPont knowledge, national production of DME is 15 to 20 kilograms in the United States. This production is distributed across the following primary uses: industrial feedstock for the product of other chemical substances (31%), hairsprays (48%), spray paints/venturi sprays (6%), insect repellents/insecticides (6%), adhesives (5%), household cleaners (1%), dusters (1%), tire inflators (1%), industrial lubricants (1%). DME is used between 15 and 50% in formulation of aerosol products as listed below.

| <b>Product Type</b>            | <b>Weight % in Product</b> |
|--------------------------------|----------------------------|
| Hairsprays                     | 15 to 35                   |
| Spray Paints/Venturi Spray     | 30 to 50                   |
| Insect Repellents/Insecticides | 20 to 45                   |
| Adhesives                      | 20 to 40                   |
| Household Cleaners             | 20 to 30                   |
| Dusters                        | 25 to 30                   |
| Tire Inflators                 | 15 to 20                   |
| Industrial Lubricants          | 20 to 30                   |

#### **HUMAN EXPOSURE ASSESSMENT**

Based on the high volatility and uses of DME, exposure is primarily via inhalation, not dermal adsorption or ingestion. Assessing inhalation exposure to DME requires an understanding of DME use, the environment in which it is used, and the amount of time a person spends in that environment. Based on this understanding, scenarios can be defined to quantify DME exposure by either measurement (e.g., monitoring studies) or calculation. Then, the level of measured or calculated DME exposure can be compared against an appropriate benchmark to assess the safety of its particular use.

When assessing DME exposure, three different scenarios were evaluated which represent the key exposure to DME based on the best understanding of practices and circumstances related to its manufacture and use today. The following scenarios are believed to represent the maximum potential exposure that could be achieved based on how DME is manufactured and used:

- **DME Manufacture and Use as a Chemical Intermediate**  
These scenarios can result in occupational exposures during DME production, transport, or handling, especially in bulk quantities.
- **DME Commercial Use for Personal Care Aerosol Products**  
In particular, attention is focused on beauticians as they use hairsprays regularly in enclosed but ventilated areas.
- **DME Use in Personal Care and Household Aerosol Products**  
In particular, attention is focused on hairsprays, pesticides, and household cleaning sprays because they are used on a more regular basis than other DME applications and in situations where inhalation contact is likely.

These scenarios are discussed in the subsections below.

### **Exposures Related to the Production, Handling, or Formulation of DME in Industrial Facilities**

The following exposures are related to the production, handling, or formulation of DME in industrial facilities:

- **Occupational Exposures**  
In industrial environments where DME is used as a chemical intermediate, industrial safety and hygiene practices minimize potential exposures to DME. The following factors limit exposure to negligible levels:
  - The use of closed systems for manufacturing and processing
  - Implementation and maintenance of strict industrial hygiene measures to ensure minimal exposure during handling and use

Both standard work practices and emergency procedures provide guidance that results in low to zero airborne levels of DME. Where necessary, engineering controls (i.e., ventilation, equipment isolation, and/or personal protective equipment) are used to ensure that recommended exposure levels are not exceeded. The recommended exposure level, called an AEL, is an eight-hour, time weighted average concentration to which nearly all workers can be exposed repeatedly for five days/week without adverse health effects. For DME, the AEL is 1,000 ppm in air. DME levels in working environments are typically less than 10 ppm (as measured periodically by DuPont in the workplace) or 100 times lower than the AEL.

- **Community Exposures**  
This study did not evaluate this area quantitatively. However, the magnitude of such exposures to humans is likely to be significantly lower than the occupational and aerosol product uses given normal regulatory and voluntary emissions control systems for such volatile gases.
- **Exposures Related to the Handling of Chemicals and Products During Transport**  
This study did not evaluate this area quantitatively. However, DME must be transported in fully contained vessels. Thus, releases would only occur during an accident, where potential exposure is unpredictable.

## Exposures Related to the Handling and Use of End Products Containing DME

The following exposures are related to the handling and use of end products containing DME:

- **Industrial**  
Based on the known applications of DME, its only industrial application is as a lubricant, representing approximately 1% of its volume. Given the properties of DME and the likelihood of exposure controls during normal use, exposure is considered to be minimal relative to consumer/household applications. Therefore, industrial exposure to DME was not studied further.
- **Institutional/Commercial**  
The primary use of DME in commercial products is as a propellant/solvent in hairspray (48% of production). In the absence of measured data, the human exposure to DME for commercial use of a hairspray product (i.e., beautician) was estimated using a theoretical approach based on a given setting and use pattern. Thus, an airborne DME concentration was estimated for a small hair care salon, a conservative number of hairspray uses per day, and an exponential decay (as a function of a standard room ventilation rate) in air level following each use. The resulting exposure level (in ppm.minute) was translated to a DME dose level (in mg/kg/day) for a typical worker and compared to the AEL. Method 1 in Section 5 shows the calculations. A conservative estimate of DME exposure to a beautician is 2.69 mg/kg/day versus a worker AEL of 664 mg/kg/day.

*Commercial exposure estimate:*

2.69 mg/kg/day

When compared to the AEL-equivalent dose of 664 mg/kg/day, this estimate for commercial exposure is 247-fold less than the AEL.

- **Consumer Exposure**  
Consumer exposure to DME is one of the primary areas of interest for this report since it may occur immediately after using aerosol products containing this material as a propellant. The analysis focused on hairspray, household pesticides, and household cleaner sprays as used by the general public. Other listed consumer product applications for the chemical were omitted either because they are more intermittent in nature or do not result in direct consumer exposure. Consumer exposures were assessed using the following three different methods (Section 5):
  1. **Method 2—Consumer Aggregate Exposure Estimate (concentration.time)**  
This method involves estimating exposure based on measurements of airborne DME concentrations from representative aerosol product use in an experimental environment and publishing habits and practices data for the length of time that aerosol products typically are used. This number provides one estimate for aggregate consumer exposure and is expressed in ppm.minute units. This value defines a maximum amount of DME to which a consumer would be exposed, but does not estimate what may actually be inhaled.  
  
More specifically, this estimate of exposure (Section 5, Method 2) presents an indication of the length of time consumers may spend in an atmosphere containing DME after using consumer products. The exposure is estimated by multiplying the length of time spent conducting a product use task by the airborne concentration of DME during that task.

This information is used to quantify weekly exposure in ppm.minutes. The result of this analysis is as follows:

*Consumer aggregate exposure estimate:* 24,850 ppm.min

As noted above, a NOAEC of 10,000 ppm in air was chosen as a conservative toxicity threshold based on available hazards data. This level, converted in the same fashion as the aggregate exposure, is 18,000,000 ppm.min, which yields aggregate consumer exposures 720-fold less than the No Observable Adverse Effect Level (NOAEL).

2. Method 3—Consumer Aggregate Exposure Estimate (inhaled dose)

This method involves calculating an inhaled dose of DME based on measured airborne levels and time of product use for an average body weight and breathing rate, assuming that 100% of that which is inhaled is also absorbed by the body (Section 5, Method 3).

In reality, it is unlikely that all inhaled DME is truly retained and delivered to potential target organs; much will be expired with exhaled air before it has the chance to be absorbed. As a result, the following calculation is conservative.

*Consumer aggregate exposure estimate of inhaled dose:* 1.62 mg/kg/day

For reference, the dose (i.e., NOAEL) delivered in a representative animal study at the NOAEC, calculated in the same fashion, is 6,638 mg/kg/day, which yields aggregate consumer exposures 4,098-fold less than the NOAEL.

3. Method 3—Theoretical Estimate for Use of a Hairspray Product

This method involves calculating an inhaled dose of DME based on estimated airborne levels and time of product use for an average body weight and breathing rate. In the absence of measured data, airborne levels can be estimated by knowing the amounts of DME discharged during aerosol use and the size of the room in which use occurs (Section 5, Method 3). This value is compared to the estimate for hairspray use derived in Method 2, to help calibrate and verify the integrity of the second aggregate assessment. With complete habits and practices data for all product types formulated with DME (not available for preparation of this example), a total aggregate assessment could be made in this fashion. This calibration exercise serves to demonstrate another way of calculating exposure and supporting the integrity of Method 3.

*Exposure (ppm.min method):* 0.61 mg/kg/day

*Exposure (habits/practices method):* 0.21 mg/kg/day

As can be seen, these values compare favorably despite the fact that the approaches used to calculate the estimates differed significantly. When compared to a NOAEL of 6,500 mg/kg/day, estimated consumer exposure levels are 10,600- to 31,000-fold less than this NOAEL.

### **Other Exposures**

Based on DME uses and its high volatility, indirect exposure human via contact with DME from indoor air, ambient environmental levels, and other sources are expected to be negligible in comparison to exposures occurring during execution of the actual “tasks” associated with use of these consumer products. Therefore, other exposure sources were not considered in these calculations.

### **Sensitive Populations**

In some instances, specific chemicals may present the potential for sensitive populations (e.g., children, pregnant women, the elderly) to be disproportionately impacted by a chemical. In the absence of measured data relative to DME, an additional safety factor of 10 was applied to the AEL/NOAEL. Therefore, although the previously discussed exposure estimates move closer to the appropriate AEL/NOAEL, exposure still remains 25- to 72-fold less than these levels.

## **ECOLOGICAL EXPOSURE ASSESSMENT**

This study included an ecological exposure assessment. Although data were limited, data were sufficient to determine a potential ecological risk. The nature of the product (i.e., relatively low toxicity, high volatility, and photochemical reactivity) suggests that DME is not likely to be persistent or present in the ecosystem at concentrations approaching concern.

## **HAZARD/EXPOSURE-BASED HUMAN SAFETY ASSESSMENT**

DME has a low order of acute and chronic inhalation toxicity, and it is not a teratogen, mutagen, or carcinogen. Risk of personal injury or adverse health effects during DME manufacture or processing is acceptably low when used in accordance with appropriate industrial hygiene and safety measures (noting flammability, explosion and narcosis hazards associated with propellant gases under extreme conditions). Likewise, based on this screening estimate, the intended use of commercial or consumer products containing DME appears to present no meaningful safety risk. (Intentional misuse via deliberate concentration and inhalation of vapors can be potentially life threatening and also presents flammability/explosion hazards typical of aerosol products.) The estimated exposure during commercial use of DME (e.g., hairsprays) is 247-fold less than the 1,000 ppm worker safety threshold. The predicted aggregate consumer exposure is approximately 700 times lower than the NOAEL when determined using the ppm.min approach and approximately 4,100 lower when determined using the mg/kg/day inhaled dose approach. Using an additional safety factor of 10 times for sensitive subpopulations still allows for ample margins of safety below the NOAEL. It is also important to recognize that these exposure assessments are highly conservative and most likely represent exaggerated exposures. As a consequence of this screening level analysis, DME is recommended to be a low priority for future work.

## SECTION 5

### SUMMARIZING INDIVIDUAL EXPOSURE EVALUATIONS FOR PRODUCT USE OF DME

#### METHOD 1: THEORETICAL EXPOSURE ESTIMATE FOR USE OF HAIRSPRAY PRODUCT BY COMMERCIAL WORKER

##### Objective

The objective of this study was to estimate commercial worker (i.e., beauticians) exposure conservatively using theoretical calculations under simulated exposure conditions. Simulated conditions were based on the amount of DME in the product and extreme (i.e., well beyond typical) product use habits and practices.

##### Description of Method

Human exposure to DME for commercial use of a hairspray product (i.e., beauticians) was estimated using a theoretical approach based on a given setting and use pattern. In this example, the airborne DME concentration was estimated for a small hair care salon (i.e., two person) and a conservative number of hairspray uses per day (i.e., every 15 minutes throughout an eight-hour work day). Average daily DME air concentrations were calculated using an exponential decay in level following each use. The decay rate is a function of the room ventilation rate. The resulting exposure (in ppm.minute) was translated to a DME dose level (in mg/kg/day) using the following assumptions:

- 35% = Maximum DME concentration used as a hairspray propellant
- 1.5 grams (g) = Amount of product dispensed and/or used
- 51 cubic meters (m<sup>3</sup>) or 12 by 15 by 10 feet = Salon size
- 32 uses/day = Number of 15 minute uses throughout an eight-hour work day
- 58 kg = Nominal (female) adult body weight
- 0.83 m<sup>3</sup>/hr = Nominal human ventilation rate
- 41.67 m<sup>3</sup>/hr or 25 standard cubic feet per minute (scfm) per person = Recommended ventilation rate for beauty salon according to the American Society of Heating, Refrigeration, and Air-Conditioning Engineers (ASHRAE) standard on *Ventilation for Acceptable Indoor Air Quality* (ANSI/ASHRAE 62-1989).

##### Exposure Equation and Results

The following exposure equation is based on a value of 5,890 ppm.minutes from exponential decay calculation for 32 uses/day throughout an eight-hour work day in the small salon:

$$\left( \frac{5890 \text{ ppm} \cdot \text{min}}{\text{day}} \right) \left( \frac{1.92 \text{ mg/m}^3}{1 \text{ ppm}} \right) \left( \frac{0.83 \text{ m}^3}{\text{hour}} \right) \left( \frac{1 \text{ hour}}{60 \text{ min}} \right) \left( \frac{1}{58 \text{ kg}} \right) = 2.69 \text{ mg/kg/day}$$

**Comparison to AEL**

This value compares to the AEL of 1,000 ppm converted to a dose of 664 mg/kg/day so that the exposure is calculated by dividing 664 by 2.69. The AEL is an allowable time-weighted average for a worker exposed eight hours per day, five days per week over a work lifetime without adverse health effects. The result is 247-fold below the worker AEL.

For sensitive supopulations (e.g., children, pregnant women, the elderly), an additional safety factor of 10 results in an equivalent AEL of 65 mg/kg/day. Thus, conservative commercial worker exposure estimates remain 25-fold below this AEL.

**Data Reliability**

Data reliability is not applicable as this is a theoretical calculation.

**References**

References are not applicable as this is a theoretical calculation.



## METHOD 2: CONSUMER AGGREGATE EXPOSURE ESTIMATE (PPM.MINUTE METHOD)

### Objective

The objective of this study was to provide a conservative estimate of potential exposure to DME in aerosol consumer products (i.e., hairsprays, spray insecticides, spray cleaners) based on airborne measurements during simulated uses of these products in controlled laboratory conditions.

### Scenario Monitored

Use of a hairspray, spray insecticides, and household spray cleaners was examined under laboratory conditions. The product was used in a typical manner by a consumer, and airborne levels of DME were measured in the area of the head for the duration of the task. Additional details are provided in the reference cited below.

### Results

Aggregate exposure to DME in a given product was estimated by multiplying the length of time spent conducting a product use “task” by the airborne concentration of DME during that task. This value was multiplied by the number of uses of the product per week. This result was used to quantify weekly exposure in ppm.minutes based on actual measurement of DME airborne concentrations during simulated use of consumer aerosol products, as shown in the table below:

| DME Product             | Weekly Exposure<br>(ppm.minutes) |
|-------------------------|----------------------------------|
| Hairspray               | 9,450                            |
| Insecticide             | 7,700                            |
| Household Cleaner Spray | 7,700                            |
| <b>TOTAL</b>            | <b>24,850</b>                    |

Notes:

- (1) Selected product categories have been omitted from this aggregate example either because exposure is more intermittent (e.g., adhesives, paint) or contained (e.g., tire inflators).
- (2) Selected product categories studied in the original reference for these measurements are not included in this example because DME is no longer used as a propellant for these product types (i.e., body deodorant spray, air fresheners).
- (3) Total exposure assumes use of all products on a daily basis. Thus, the total exposure estimate is conservative.

### Comparison to NOAEL

The 10,000 ppm NOAEC determined from toxicity testing (Section 3) is converted from a ppm exposure concentration to a NOAEL in weekly ppm.minutes as follows:

$$\begin{aligned}\text{NOAEL} &= (\text{NOAEC})(5 \text{ days/week})(6 \text{ hrs/day})(60 \text{ min/hr}) \\ &= (10,000)(5)(6)(60) = 18,000,000 \text{ ppm.min}\end{aligned}$$

Note: Six hours a day was the duration of exposure to the animals in the subchronic inhalation toxicity test.

Therefore, the aggregate consumer exposure of 24,850 ppm.minute is 724-fold less than the NOAEL.

**Data Reliability**

For information regarding data reliability, refer to the reference cited below.

**Reference**

Additional information regarding the analytical and experimental approach is described by L.J.M. Bohnenn (Aerofako). This paper was presented at the Annual Meeting of the Western Aerosol Information Bureau, Las Vegas, NV, October 16 and 17, 1980.

### METHOD 3: CONSUMER AGGREGATE EXPOSURE ESTIMATE FOR INHALED DOSE

#### Objective

The objective of this study was to calculate a conservative estimate of DME inhaled dose from airborne measurements by accounting for inhalation rates and expressing dose based on average body weight.

#### Description of Model

Predicted doses of DME can be obtained by converting the weekly ppm.min DME vapor exposure values (Method 2) to relative inhaled doses, considering average human ventilation rates and expressing the findings on the basis of per unit body weight. Female body weights were used as most consumers of the products are women. Exposure assumptions made in this calculation are as follows:

- Weekly ppm.min as shown in Method 2
- 1 ppm = 1.92 mg/m<sup>3</sup> DME @ 25°C
- 58 kg = Average (female) adult body weight
- 0.83 m<sup>3</sup>/hr = Average human ventilation rate

The exposure equation is as follows:

$$(\text{weekly exposure rate})(\text{weeks/day})(\text{ppm conversion})(\text{ventilation rate})(\text{hr/min})(1/\text{body weight})$$

#### Results

The calculation and resulting estimate for hairspray is as follows:

$$\left( \frac{9,450 \text{ ppm.min}}{\text{week}} \right) \left( \frac{1 \text{ week}}{7 \text{ days}} \right) \left( \frac{1.92 \text{ mg/m}^3}{1 \text{ ppm}} \right) \left( \frac{0.83 \text{ m}^3}{1 \text{ hour}} \right) \left( \frac{1 \text{ hour}}{60 \text{ min}} \right) \left( \frac{1}{58 \text{ kg}} \right) = 0.62 \text{ mg/kg/day}$$

The calculation and resulting estimate for insecticide is as follows:

$$\left( \frac{7,700 \text{ ppm.min}}{\text{week}} \right) \left( \frac{1 \text{ week}}{7 \text{ days}} \right) \left( \frac{1.92 \text{ mg/m}^3}{1 \text{ ppm}} \right) \left( \frac{0.83 \text{ m}^3}{1 \text{ hour}} \right) \left( \frac{1 \text{ hour}}{60 \text{ min}} \right) \left( \frac{1}{58 \text{ kg}} \right) = 0.50 \text{ mg/kg/day}$$

The calculation and resulting estimate for household spray is as follows:

$$\left( \frac{7,700 \text{ ppm.min}}{\text{week}} \right) \left( \frac{1 \text{ week}}{7 \text{ days}} \right) \left( \frac{1.92 \text{ mg/m}^3}{1 \text{ ppm}} \right) \left( \frac{0.83 \text{ m}^3}{1 \text{ hour}} \right) \left( \frac{1 \text{ hour}}{60 \text{ min}} \right) \left( \frac{1}{58 \text{ kg}} \right) = 0.50 \text{ mg/kg/day}$$

Total Exposure: 1.62 mg/kg/day

Note: This total exposure estimate assumes that all products are used on a daily basis.

### Comparison to NOAEL

Similarly, the NOAEC determined from toxicity testing (Section 3) can be converted from a ppm in air exposure concentration to an inhaled dose expressed per unit body weight. Exposure assumptions made in this calculation are as follows:

- 10,000 ppm = NOAEC
- 1 ppm = 1.92 mg/m<sup>3</sup> DME @ 25°C
- 0.25 kg = Average rat weight
- 240 ml/min = Rat ventilation rate
- 6 hour daily exposure

The NOAEL calculation is as follows:

$$\text{NOAEL} = (\text{NOAEC})(\text{ppm conversion})(\text{m}^3/\text{l conversion})(\text{l/ml conversion})(\text{ventilation rate}) \\ (\text{min/hr conversion})(\text{hour/day exposure})(1/\text{body weight})$$

$$\text{NOAEL} = (10,000 \text{ ppm}) \left( \frac{1.92 \text{ mg/m}^3}{1 \text{ ppm}} \right) \left( \frac{\text{m}^3}{1,000 \text{ l}} \right) \left( \frac{0.001 \text{ l}}{1 \text{ ml}} \right) \left( \frac{240 \text{ ml}}{\text{min}} \right) \left( \frac{60 \text{ min}}{1 \text{ hr}} \right) \left( \frac{6 \text{ hr}}{1 \text{ day}} \right) \left( \frac{1}{0.25 \text{ kg}} \right)$$

$$\text{NOAEL} = 6,638 \text{ mg/kg/day}$$

Therefore, the aggregate consumer exposure of 1.62 mg/kg/day is 4,098-fold less than the NOAEL.

### Data Reliability

For information regarding data reliability, refer to the reference cited below.

### Reference

Additional information regarding the analytical and experimental approach is described by L.J.M. Bohnenn (Aerofako). This paper was presented at the Annual Meeting of the Western Aerosol Information Bureau, Las Vegas, NV, October 16 and 17, 1980.

## METHOD 4: THEORETICAL ESTIMATE BASED ON USE OF A HAIRSPRAY PRODUCT

### Objective

The objective of this calculation was to conduct a calibration exercise by mathematically predicting human exposure to DME during use of a hairspray product based on the level of DME in the product and typical product use habits and practices. The resulting exposure was compared to the monitoring data under simulated exposure conditions.

### Description of Method

In Method 2, published values for ppm.minutes of exposure to various products formulated with DME were used to derive an aggregate estimate of daily inhaled DME following use of consumer products. In this hairspray example, the airborne DME concentration was calculated (estimated) based on a representative use scenario, incorporating the DME concentration in the finished product along with habits and practices information pertaining to product use. Then, estimated DME inhalation was calculated as in Method 3 and converted to mg/kg/day.

Assumptions regarding hairspray habits and practices and conversion factors used in this calculation were as follows:

- 35% = Maximum concentration of DME used as a hairspray propellant
- 1.5 g = Amount of product dispenses/use; product used two times per day
- 18 m<sup>3</sup> = Representative room size (8 by 10 by 8 foot bathroom) for task
- 15 min = Duration of exposure (DME release in bathroom after using hairspray)
- 58 kg = Nominal (female) adult body weight
- 0.83 m<sup>3</sup>/hr = Human ventilation rate

### Exposure Equation and Results

The exposure equation is as follows:

$$\text{NOAEL} = (\text{prod. level})(\text{g product/use})(\text{uses/day})(1/\text{room volume})(\text{ventilation rate}) \\ (\text{task duration})(\text{hr/min})(1/\text{body weight})$$

$$\text{NOAEL} = (0.35 \text{ g DME}) \left( \frac{1.5 \text{ g product}}{1 \text{ use}} \right) \left( \frac{2 \text{ uses}}{1 \text{ day}} \right) \left( \frac{1}{18 \text{ m}^3} \right) \left( \frac{0.83 \text{ m}^3}{1 \text{ hr}} \right) (15 \text{ min}) \left( \frac{1 \text{ hr}}{60 \text{ min}} \right) \left( \frac{1}{58 \text{ kg}} \right)$$

$$\text{NOAEL} = 2.1 \times 10^{-4} \text{ g/kg/day} = 0.21 \text{ mg/kg/day}$$

At a screening level, this estimate of DME exposure after using hairspray compares favorably with the estimate derived using the published ppm.min values (converted to 0.61 mg/kg/day) for exposure. Calibration calculations like these can help verify the reasonableness of other screening approaches.

### Data Reliability

Data reliability is not applicable to Method 4 as this is a theoretical calculation.

**Reference**

No references were needed as this is a theoretical calculation.