

## 7. REGULATIONS AND ADVISORIES

The international, national, and state regulations and guidelines regarding 4,4'-methylenedianiline in air, water, and other media are summarized in Table 7-1.

ATSDR has derived an acute oral MRL of 0.2 mg/kg/day based on a minimal LOAEL for liver effects observed in rats treated with a single dose of 4,4'-methylenedianiline (Bailie et al. 1993).

ATSDR has derived an intermediate oral MRL of 0.08 mg/kg/day based on a NOAEL for liver effects observed in rats treated daily with gavage doses of 4,4'-methylenedianiline for 12 weeks (Pludro et al. 1969).

Neither a reference dose nor a reference concentration for 4,4'-methylenedianiline is available at this time.

The International Agency for Research on Cancer (IARC) has classified 4,4'-methylenedianiline as 2B, probably carcinogenic to humans, based on limited evidence of carcinogenicity in humans but sufficient evidence of carcinogenicity in animals (IARC 1987). The EPA and the National Toxicology Program (NTP) have not classified the chemical for carcinogenicity. The National Institute for Occupational Safety and Health (NIOSH) has identified 4,4'-methylenedianiline as a potential occupational carcinogen and recommends that occupational exposures to the compound be limited to the lowest feasible concentration (NIOSH 1994).

4,4'-Methylenedianiline is on the list of chemicals appearing in The Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA) (EPA 1987). Section 313 of Title III of EPCRA requires owners and operators of certain facilities that manufacture, import, process, or otherwise use the chemicals on this list to report annually their release of those chemicals to any environmental media.

OSHA requires employers of workers who are occupationally exposed to 4,4'-methylenedianiline to institute engineering controls and work practices to reduce and maintain employee exposure at or below permissible exposure limits (PEL). Except as provided by specific clauses within the standard given at 29 CFR 1910.1050 (e.g., products not capable of releasing MDA in excess of the action level;

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conditions where no dermal exposure to MDA can occur, materials in any form containing less than 0.1% MDA by weight or volume, and construction work) for all occupational exposures to MDA, the employer must use engineering and work practice controls, if feasible, to reduce exposure to or below an 8-hour time-weighted average (TWA) of 10 ppb (OSHA 1992a, 1992b). The short term exposure limit (STEL), as determined by any 15minute sampling period is 100 ppb (OSHA 1992a, 1992b). The OSHA standard for construction work is given in 29 CFR 1926.60; however, the PEL for these activities is the same as that for all other occupational exposures. The action level for occupational exposure to airborne 4,4'-methylenedianiline, including construction work, is 5 ppb, based on an 8-hour time-weighted average (OSHA 1992a, 1992b). The OSHA standard for construction work is applicable, but not limited, to activities such as alteration, repair, maintenance, or renovation of structures or substrates that contain 4,4'-methylenedianiline (OSHA 1992a, 1992b). Respirators must be provided and used during the time period necessary to install or implement feasible engineering and work practice controls (OSHA 1992a, 1992b).

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**Table 7-1. Regulations and Guidelines Applicable to 4,4'-Methylenedianiline**

| Agency               | Description  | Information   | References   |
|----------------------|--|---|--|
| <u>INTERNATIONAL</u> |  |   |  |
| Guidelines:          |  |   |  |
| WHO                  |  |   | NA   |
| IARC                 | Group (cancer ranking)   | Sufficient Evidence of Carcinogenicity to Experimental Animals Group 2B | IARC 1987  |
| <u>NATIONAL</u>      |  |   |  |
| Regulations:         |  |   |  |
| a. Air:              |  |   |  |
| OSHA                 | Permissible Exposure Limit (TWA)   | Airborne: 10 ppb as an 8-hour time-weighted average                     | 29 CFR 1910.1050<br>OSHA 1992a <sup>a</sup> and<br><br>29 CFR 1926.60<br>OSHA 1992b <sup>a</sup> |
|                      | Permissible Exposure Limit (Ceiling)   | Dermal: Eye and skin contact (not permitted)                            |  |
|                      | Short term exposure limit (STEL)   | 100 ppb   |  |
|                      | Action Level for Occupational Exposures  | 5 ppb   |  |
| EPA OAR              | Hazardous Air Pollutants (HAPs)  | Yes   | Clean Air Act<br>Amendment Title III,<br>Section 112 (b)<br>U.S. Congress 1990                   |
|                      | Standards of Performance for New Stationary Sources  |   | 40 CFR 60.489<br>EPA 1981  |
|                      | equipment leaks of VOC in the SOCMII-list of chemicals produced by affected facilities   | Yes   |  |
|                      | National Emission Standards for Hazardous Air Pollutants (NESHAPs) from Source Categories-organic hazardous air pollutants from SOCMII                       | Yes   | 40 CFR 63.106<br>EPA 1994  |
|                      | National Emission Standards for Wood Furniture Manufacturing Operations  | Yes   | 40 CFR 63, Subpart JJ<br>EPA 1995b   |
|                      | Table 2- list of volatile hazardous air pollutants; Table 4-pollutants excluded from use in cleaning and washoff-solvents; Table 6-VHAP of potential concern |   |  |
| b. Water             |  |   |  |
| EPA OW               | Effluent Guidelines and Standards organic chemicals, plastics, and synthetic fibers  | Yes   | 40 CFR 414.70<br>EPA 1992  |

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**Table 7-1. Regulations and Guidelines Applicable to 4,4'-Methylenedianiline (cont.)**

| Agency                         | Description   | Information  | References                      |
|--------------------------------|---|--|---------------------------------|
| <u>NATIONAL</u> (cont.)        |   |  |                                 |
| c. Other:                      |   |  |                                 |
| EPA OSW                        | Interim Status Standards for Owners and Operators of Hazardous Waste Treatment, Storage, and Disposal Facilities  | Yes  | 40 CFR 265, App. VI<br>EPA 1996 |
| EPA OEER                       | Designation, Reportable Quantities, and Notification<br>designations of hazardous substances  | 1 pound <sup>b</sup><br>(0.454 kg)<br>(statutory)<br><br>10 pounds<br>(4.54 kg)<br>(final RQ)          | 40 CFR 302.4<br>EPA 1995c       |
|                                | Toxic Chemical Release Reporting:<br>Community Right-to-Know -applicable<br>chemicals and chemical categories   | Effective date January 1,<br>1987)   | 40 CFR 372.65<br>EPA 1987       |
| FDA                            | Indirect Food Additives: Adhesives and<br>Components of Coatings<br>substances for use as components of<br>coatings-resinous and polymeric coatings         | Yes  | 21 CFR 175.300<br>FDA 1977a     |
|                                | Indirect Food Additives: Polymer<br>substances for use as basic components<br>of single and repeated use food contact<br>surfaces-polyurethane resins       | Yes  | 21 CFR 177.1680<br>FDA 1977b    |
|                                | substances for use only as components of<br>articles intended for repeated use-4,4'-<br>isopropylidenediphenolepichlorohydrin<br>thermosetting epoxy resins | Yes  | 21 CFR 177.2280<br>FDA 1977c    |
| Guidelines:                    |   |  |                                 |
| ACGIH                          | Ceiling Limit for Occupational Exposure (TWA)   | 0.1 ppm (skin)<br>0.81 mg/m <sup>3</sup> (skin)  | ACGIH 1996                      |
| NIOSH                          | Recommended Exposure Limit for<br>Occupational Exposure (TWA)   | Potential occupational<br>carcinogen; lowest<br>feasible concentration<br>(0.03 mg/m <sup>3</sup> LOQ) | NIOSH 1994                      |
| <u>STATE</u>                   |   |  |                                 |
| Regulations and<br>Guidelines: |   |  |                                 |
| a. Air:                        | Average Acceptable Ambient Air<br>Concentrations Guidelines or Standards  |  | NATICH 1992                     |
| CT                             | 8 hours   | 8 µg/m <sup>3</sup>  |                                 |
| FL (Ft. L'dle)                 | 8 hours   | 8x10 <sup>-3</sup> mg/m <sup>3</sup>   |                                 |
| FL (Pinellas<br>Co.)           | 8 hours<br>24 hours   | 8 µg/m <sup>3</sup><br>1.92 µg/m <sup>3</sup>  |                                 |
| KS                             | Annual  | 4x10 <sup>-2</sup> µg/m <sup>3</sup>   |                                 |
| KS-KC                          | Annual  | 4x10 <sup>-2</sup> µg/m <sup>3</sup>   |                                 |

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**Table 7-1. Regulations and Guidelines Applicable to 4,4'-Methylenedianiline (cont.)**

| Agency               | Description          | Information   | References |
|----------------------|----------------------|---|------------|
| <u>STATE</u> (cont.) |                      |   |            |
| ND                   | NA                   | BACT  |            |
| NV                   | 8 hours              | $1.90 \times 10^{-2} \text{ mg/m}^3$  |            |
| NY                   | Annual               | $2.70 \times 10^{-1} \text{ } \mu\text{g/m}^3$                                    |            |
| OK                   | 24 hours             | $8 \text{ } \mu\text{g/m}^3$  |            |
| SC                   | 24 hours             | $4 \text{ } \mu\text{g/m}^3$  |            |
| TX                   | 30 minutes<br>Annual | $8.10 \text{ } \mu\text{g/m}^3$<br>$8.10 \times 10^{-1} \text{ } \mu\text{g/m}^3$ |            |
| VA                   | 24 hours             | $8.10 \text{ } \mu\text{g/m}^3$   |            |
| WA-SWEST             | 24 hours             | $2.60 \text{ } \mu\text{g/m}^3$   |            |

<sup>a</sup> OSHA 1992 denotes the effective date (September 9, 1992) for the standard.

<sup>b</sup> Indicates that the statutory source for designation of this hazardous substance under CERCLA is CWA Section 3(b)(4).

ACGIH = American Conference of Governmental Industrial Hygienists; BACT = Best Available Control Technology; CERCLA = Comprehensive Environmental Response, Compensation, and Liability Act; CFR = Code of Federal Regulations; CWA = Clean Water Act; DOT = Department of Transportation; EPA = Environmental Protection Agency; IARC = International Agency for Research on Cancer; LOQ = Limit of Quantitation; NAAQS = National Ambient Air Quality Standard; NATICH = National Air Toxics Information Clearinghouse; NIOSH = National Institute for Occupational Safety and Health; OERR = Office of Emergency and Remedial Response; OSHA = Occupational Health and Safety Administration; OWRS = Office of Water Regulations and Standards; PAH = Polycyclic Aromatic Hydrocarbons; PEL = Permissible Exposure Limit; RCRA = Resource Conservation and Recovery Act; REL = Recommended Exposure Limit; RfD = Reference Dose; STEL = Short Term Exposure Level; TLV = Threshold Limit Value; TWA = Time Weighted Average; u.f. = Uncertainty Factor; VHAP = Volatile Hazardous Air Pollutants; WHO = World Health Organization

