



Hazard Information Relevant to Labeling of Diphenylmethane Diisocyanate (MDI)-Containing Products for the Consumer Marketplace

Introduction

This document provides information about the potential hazards from exposure to diphenylmethane diisocyanate (MDI). This information is intended to be helpful to company label writers who are responsible for communicating the potential hazards and safe handling guidelines for consumer products to prospective customers.

By providing this information, the Alliance for the Polyurethanes Industry (API) is not recommending or endorsing use of MDI for any specific purpose or in any particular products or categories of products. It is the responsibility of the manufacturer of each product that contains MDI to determine that the product is safe for its intended uses, and to ensure that appropriate warnings and instructions are provided. The hazard information contained in this document may help companies make those determinations. Additional information is available from the supplier of MDI, including a Material Safety Data Sheet for MDI, and on the API website at www.polyurethane.org.

MDI may pose serious health hazards if not used properly and if excessive exposures occur. In general, the greater the potential for exposure to MDI, the greater the potential health hazards. This document does not address products that are intended to be

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heated, sprayed or otherwise applied in a manner that may generate airborne MDI. If any such products exist, they likely would pose a greater potential for exposure compared to products that are not heated or sprayed. It is important to understand that this document is not intended to address the hazards that might be posed by these products, or the measures that might be taken to address those hazards. The use of insulating foam sealants from aerosol cans is not considered a spray application.

Labeling Laws and Regulations

This document addresses the hazards of MDI, polymeric MDI and isocyanate-terminated MDI pre-polymers only. Under applicable laws, labels for certain hazardous substances must address the hazards of the product itself, including any synergistic or antagonistic effects among the mixture ingredients,

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not just the hazards of the individual components. Thus, producers of MDI-containing products must consider the hazards of the product as a whole, including all its ingredients, and not just the hazards of MDI by itself.

The vast majority of MDI uses are for industrial applications, in which hazard communication training, medical surveillance, training in proper handling precautions and use of personal protective equipment (PPE) should be provided consistent with legal requirements and safe handling practices.

However, there are some MDI-containing products available for the general public to purchase at retail stores and which can be used in Do-It-Yourself (DIY) applications. Consumers using these products need to understand and follow appropriate safe handling practices. Good end-use product precautionary labels are one means of getting this information to the DIY user and may be required under applicable laws and U.S. Consumer Product Safety Commission (CPSC) regulations.

Products that are hazardous and available for consumers to purchase or use are subject to the labeling requirements of the Federal Hazardous Substances Act (FHSA) (15 U.S.C. Section 1261), which is administered by the CPSC. These requirements are mandatory, and failure to comply with them can result in civil and/or criminal penalties. These regulations are found in the Code of Federal Regulations at 16 C.F.R. Part 1500. The regulations specify that a label must conspicuously state, among other information:

1. Identification of the common, usual or chemical name of the hazardous component(s);

2. Any applicable signal words;
3. Statement of the hazard;
4. Definition of the health effects;
5. Precautionary measures;
6. First aid measures;
7. The name and address of manufacturer, packager, distributor or seller; and
8. The phrase "Keep out of the reach of children."

Additionally, a label writer must consider MDI and its characteristics in relationship to the quantity of MDI in the product, likely exposure scenarios to MDI in the product, and the hazards posed by the product mixture, not just MDI, including any synergistic or antagonistic effects.

The responsibility for proper cautionary labeling rests with the manufacturer or distributor making a hazardous product available for consumers; however, help in preparing labels is available from a number of sources. For example, 16 C.F.R. § 1500.128 states that a manufacturer may obtain informal comments on proposed labeling involving hazardous substances. Further information on the CPSC can be found on their website. Additionally, several industry trade associations provide specific labeling guidance to their member companies. See the "Websites and Resources" section in this document for more information.

Recognizing Potential Health Hazards of MDI

An isocyanate is any chemical that contains at least one isocyanate functional group in its structure. An isocyanate group is one nitrogen atom attached by a double bond to one carbon atom that, in turn, is attached by a second double bond to an oxygen

atom (-N=C=O). A chemical containing two such groups is called a diisocyanate. MDI is one such diisocyanate. Diphenylmethane diisocyanate, commonly referred to as MDI, is a white to yellowish solid at room temperature with no odor. Polymeric MDI, which is more commonly used, is a mixture of MDI monomer and oligomers. It is a brownish liquid at room temperature and may have a slight odor. A third type of MDI product, known commonly as “modified MDIs,” are liquid at room temperature and are either colorless or slightly yellow.

Contact with excessive amounts of MDI vapor, liquid or aerosol can be harmful to health. There are four possible ways someone may become exposed:

- Inhalation,
- Eye contact,
- Skin contact, and
- Ingestion/swallowing.

The primary hazard associated with MDI stems from the inhalation of MDI. Depending upon the concentration of MDI in the atmosphere, MDI may produce health effects, primarily of the respiratory system. Inhalation of MDI may result in the development of respiratory sensitization, irritation to the mucous

membranes of the eyes and irritation of the upper and lower respiratory tracts.

Exposures above permissible occupational limits (see Table 1) might cause tearing and burning of the eyes, tightness of the chest, difficult or labored breathing, and more severe respiratory effects, including chemical bronchitis, pneumonitis, sensitization and pulmonary edema. Headache, nausea, and vomiting have been reported in workers exposed to 0.1 ppm airborne MDI concentrations. Effects may be immediate or delayed for hours after exposure. Symptoms may increase or intensify for a few hours, but usually disappear within a day or two. However, both specific and non-specific bronchial responsiveness have in some cases persisted for months or even years¹.

Exposure above workplace limits may lead to permanent pulmonary effects. Limited evidence from laboratory animals indicates that skin contact with MDI may play a role in respiratory sensitization. Sensitized individuals may experience severe asthma-like attacks whenever they are subsequently exposed to even minute amounts of airborne diisocyanate. Once sensitized, these individuals must avoid further exposure to diisocyanates².

Table 1—Airborne Concentrations Standards/Guidelines*

OSHA	The Occupational Safety and Health Administration (OSHA) has set a Permissible Exposure Limit (Ceiling) [PEL(C)] for MDI in air of 20 parts per billion (ppb) (0.2 mg/m ³).
ACGIH	The American Conference of Governmental Industrial Hygienists (ACGIH) has adopted a Threshold Limit Value (TLV) of 5 ppb (0.051 mg/m ³) as an 8-hour Time Weighted Average (TWA).
CPSC	The Consumer Product Safety Commission has not established guidelines for MDI.

* Please read the latest version of the standards/guidelines, which should be provided on the supplier’s material safety data sheet (MSDS), to check for any updates.

Repeated or prolonged contact with liquid MDI may discolor the skin and cause redness, irritation, or swelling. Contact with MDI may also produce allergic contact dermatitis. If MDI comes into contact with the skin, the affected areas should be washed thoroughly with warm soapy water.

Special Sensitization Concerns

1. Sensitization Reactions Below Workplace

Guidelines

MDI is a known skin and respiratory sensitizer. The ACGIH TLV for MDI is based, among other things, upon the potential for sensitization and meant to protect workers from induction of this effect.

However, there is no established level to which already sensitized individuals may be safely exposed. Therefore, previously sensitized individuals should avoid further exposure⁵.

2. Cross-Sensitization

Because there is some evidence of cross-sensitization among diisocyanates, individuals who have become sensitized to any other diisocyanate should avoid exposure to MDI, as they may be sensitized to MDI as well³.

3. Non-Specific Reactions

Approximately 5% of the U.S. population is already asthmatic⁴, and asthmatic responses in these individuals may be triggered by a number of environmental agents. A person who experiences asthmatic episodes due to other factors may also have an asthmatic reaction to MDI.

Specific MDI Hazard Issues to Consider while Drafting Labeling

The primary health concerns for MDI are:

- Heating MDI-containing products or using them in a manner that causes MDI to become airborne may increase exposure.
- Inhalation or dermal contact may result in sensitization.
- Skin contact with MDI can cause irritation.
- Eye irritation is likely if liquid diisocyanate gets into the eye.
- Individuals already sensitized to MDI can have a skin or respiratory reaction from exposures to any level of diisocyanate.
- Individuals already sensitized to another diisocyanate can have a skin or respiratory reaction from exposures to any level of MDI.
- An individual with a pre-existing chronic asthma or skin condition can potentially have a reaction due to the irritant properties of MDI.
- Although MDI has low oral toxicity, ingestion should be avoided.

Table 2 summarizes considerations relating to hazard issues and preventative measures for MDI. It pertains to MDI, polymeric MDI and isocyanate terminated MDI prepolymer ingredients of consumer products that are not heated or sprayed. **For products where one or more of these MDI moieties is part of a mixture, the CPSC labeling standard requires that the hazards of the mixture, not its components, be discussed and recommends that the mixture itself should be tested.**

Table 2—MDI Labeling Issues

MDI Hazard/Property	Considerations
1. Irritant and sensitizer. Lung toxicity.	Inhalation exposure to MDI has been shown to cause pulmonary sensitization, decrease of lung function, and reactive airways disease. Under the CPSC regulations, it is the responsibility of the manufacturer to determine the appropriate signal word and describe the primary hazard(s) on the main panel. 16 C.F.R. § 1500.121.
2. Skin and eye irritant and sensitizer.	Dermal effects include allergic contact dermatitis. Dermal exposure may cause sensitization. Under the CPSC regulations, appropriate precautionary measures, such as PPE, must be placed on labels. 16 C.F.R. § 1500.121.
3. Evaporates very slowly at room temperature.	Use of products containing significant amounts of MDI monomer in very small, very poorly ventilated areas may result in ambient MDI concentrations. Under the CPSC regulations, appropriate precautionary measures, such as adequate ventilation, must be placed on labels. 16 C.F.R. § 1500.121.
4. Sensitizer. Possible cross-sensitization with other isocyanates.	A person already sensitized to MDI or other diisocyanates can react (skin or respiratory) to extremely low levels of exposure to MDI. There is also evidence that someone sensitized to one isocyanate may have a cross reactivity to another. According to ACGIH, for some sensitized individuals, avoiding exposure provides the only means to prevent the immune responses to sensitizing agents ⁵ .
5. Irritant properties.	Irritants such as MDI can cause a reaction in individuals who have asthma or another pre-existing non-specific pulmonary hyperreactivity.
6. Moderate oral toxicity.	Although MDI is not highly toxic orally, it is not intended to be ingested.
7. Vapor pressure increases at higher temperatures.	Heating MDI-containing products may increase the amount of MDI in the air and potentially increase exposure.
8. Pulmonary irritation, sensitization, and lung function decrement.	Using MDI-containing products in a manner that causes MDI to become airborne, such as by spraying, may allow MDI to be inhaled into the lung, potentially causing respiratory effects.
9. Reaction with a small amount of water generates a large amount of carbon dioxide.	If water reacts with MDI in a sealed container, the CO ₂ generated can cause swelling or even rupture of the container resulting in a possible spill or even flying container lid/pieces. There is a possible explosion and/or exposure hazard if containers are resealed and a product is contaminated with moisture.
10. Low volatility, skin effects.	Skin contact with MDI can cause localized discoloration or staining which is difficult to clean or remove. The use of appropriate PPE could help avoid skin exposure. In case of accidental exposure, washing with soap and water is recommended.

Useful Websites and Resources for Additional Guidance

1. www.cpsc.gov
Consumer Product Safety Commission webpage
2. www.access.gpo.gov/nara/cfr/waisidx_03/16cfrv2_03.html
CPSC regulations (Title 16 – Commercial Practices
Chapter II – Consumer Product Safety Commission)
3. [http://a257.g.akamaitech.net/7/257/2422/14mar20010800/
edocket.access.gpo.gov/cfr_2003/pdf/16CFR1500.128.pdf](http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/cfr_2003/pdf/16CFR1500.128.pdf)
16 C.F.R. § 1500.128; guidance on CPSC Label
Comment
4. <http://info.asaenet.org/gateway/OnlineAssocSlist.html>
American Society of Association Executives
(ASAE) gateway listing of U.S. trade associations

References

1. Lemiere, C. et. al. Outcome of specific bronchial responsiveness to occupational agents after removal from exposure, *Am J Respir Crit Care Med* 1996 Aug Vol. 154, pp 329-333
2. Bernstein, JA, Overview of diisocyanate occupational asthma, *Toxicology* 1996 Jul 17; Vol. 111, pp 181-189
3. Malo, J. et. al., Combined alveolitis and asthma due to hexamethylene diisocyanate (HDI), with demonstration of crossed respiratory and immunologic reactivities to diphenylmethane diisocyanate (MDI), *J Allergy Clin Immunol* 1983 Vol. 72, pp 413-419
4. Surveillance for asthma - United States, 1960 - 1995. *MMWR Morb Mortal Wkly Rep.* 1998; 47: 1 - 28
5. ACGIH. *TLVs® and BEIs®*, 2002 p. 7-8

This bulletin was prepared by the Alliance for the Polyurethanes Industry (API), a business unit of the American Plastics Council, which is part of The American Chemistry Council. It is intended to provide some useful information regarding labeling consumer products containing MDI. The information herein is offered in good faith and is believed to be accurate and reliable as of the date of publication; however it is offered **WITHOUT WARRANTY, EXPRESSED OR IMPLIED, AS TO MERCHANTABILITY, FITNESS FOR PARTICULAR PURPOSE, OR ANY OTHER MATTER**. Consult an attorney or other appropriate professional for specific guidance relating to your product and the labeling statements that should appear on your product.

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