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**Risk Management Scope
for
Methylenediphenyl diisocyanates
(MDIs)**

**Chemical Abstracts Service Registry Numbers
(CAS RN):**

101-68-8; 2536-05-2; 5873-54-1;

9016-87-9; 26447-40-5

Environment Canada

Health Canada

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Summary of Proposed Risk Management

This document outlines the proposed risk management actions for methylenediphenyl diisocyanates (MDIs). In particular, the Government of Canada is considering working with retailers, manufacturers and/or importers to minimize access of the general population to do-it-yourself (DIY) two-component spray polyurethane foam insulation products.

More information is needed on the following to inform risk management decision-making:

- Socio-economic impacts associated with risk managing DIY two-component spray polyurethane foam insulation products containing MDIs
- Policies, programs, or measures in place by manufacturers, importers and/or retailers in Canada or elsewhere, regarding access of the two-component spray polyurethane foam products to the general population (i.e. consumers)

The risk management options outlined in this Risk Management Scope document may evolve through consideration of assessments and risk management options published for other Chemicals Management Plan substances as required to ensure effective, coordinated, and consistent risk management decision-making.

Note: The above summary is an abridged list of actions proposed to manage these substances and to seek information on identified information gaps for risk management. Refer to section 3 of this document for more complete details in this regard.

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1. Context

The *Canadian Environmental Protection Act, 1999* (CEPA 1999) (Canada 1999) provides the authority for the Minister of the Environment and the Minister of Health (the Ministers) to conduct assessments to determine if substances are harmful or dangerous to human health and/or the environment as set out in section 64 of CEPA 1999^{1,2}, and if so to manage the associated risks.

As part of the second phase of the Chemicals Management Plan, the Ministers plan to assess and manage, where appropriate, the potential health and ecological risks associated with approximately 500 substances, in nine substance groupings. The 5 substances, listed in Annex A, and referred to throughout this document as “MDIs”, are included in the methylenediphenyl diisocyanates and diamines (MDI/MDA) Grouping of the Substance Groupings Initiative of the Chemicals Management Plan (Canada 2011). Certain MDIs were identified as priorities for action as they met categorization criteria under subsection 73(1) of CEPA 1999 and/or were considered as priority substances under the CMP based on other human health concerns.

2. Issue

2.1 Draft Screening Assessment Report Conclusion

Environment Canada and Health Canada conducted a joint scientific assessment relevant to the evaluation of MDI/MDA substances. A notice summarizing the scientific considerations of the draft screening assessment report was published for MDI/MDA by Environment Canada and Health Canada in the *Canada Gazette*, Part I, on August 16, 2014, under subsection 77(1) and paragraphs 68(b) and (c) of CEPA 1999 (Canada 2014a). It is proposed that MDIs [4,4'-MDI (CAS RN³ 101-68-8), 2,2'-MDI (CAS RN 2536-05-2), 2,4'-MDI (CAS RN 5873-54-

¹ Section 64 [of CEPA 1999]: *For the purposes of [Parts 5 and 6 of CEPA 1999], except where the expression “inherently toxic” appears, a substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions that*

(a) have or may have an immediate or long-term harmful effect on the environment or its biological diversity;

(b) constitute or may constitute a danger to the environment on which life depends; or

(c) constitute or may constitute a danger in Canada to human life or health.

² A determination of whether one or more of the criteria of section 64 are met is based upon an assessment of potential risks to the environment and/or to human health associated with exposures in the general environment. For humans, this includes, but is not limited to, exposures from ambient and indoor air, drinking water, foodstuffs, and the use of consumer products. A conclusion under *CEPA 1999* on the substances in the Chemicals Management Plan (CMP) is not relevant to, nor does it preclude, an assessment against the hazard criteria for WHMIS (Workplace Hazardous Materials Information Systems) that are specified in the Controlled Products Regulations for products intended for workplace use. Similarly, a conclusion based on the criteria contained in section 64 of CEPA 1999 does not preclude actions being taken under other sections of CEPA or other Acts.

³ CAS RN: Chemical Abstracts Service Registry Number. The Chemical Abstracts Service information is the property of the American Chemical Society and any use or redistribution, except as required in supporting regulatory requirements and/or for reports to the Government of Canada when the information and the

1), mixed MDI (CAS RN 26447-40-5) and polymeric MDI (pMDI) (CAS RN 9016-87-9)] are entering or may enter the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health and therefore is proposed to meet the criteria set out in section 64(c) of CEPA 1999.

The draft screening assessment proposes that MDIs are not entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity or that constitute or may constitute a danger to the environment on which life depends.

The draft screening assessment also proposes that MDAs [4,4'-MDA (CAS RN 101-77-9) and polymeric MDA (CAS RN 25214-70-4)] do not meet any of the criteria set out in section 64 of CEPA 1999.

The proposed risk management options described in this document and the proposed conclusion outlined in the draft Screening Assessment Report are preliminary and may be subject to change. For further information on the draft Screening Assessment Report for MDIs, refer to <http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=14B737B2-1>.

2.2 Proposed Recommendation Under CEPA 1999

As a result of screening assessments conducted under sections 68 and 74 of CEPA 1999, substances may be found to meet one or more of the criteria under section 64 of CEPA 1999. The Ministers can then propose to take no further action with respect to the substances, add the substances to the Priority Substances List (PSL) for further assessment, or recommend the addition of the substances to the List of Toxic Substances in Schedule 1 of the Act. In this case, the Ministers propose to recommend that MDIs be added to Schedule 1 of the Act.

3. Proposed Risk Management

3.1 Proposed Human Health Objective

Proposed human health objectives are quantitative or qualitative statements of what should be achieved to address human health concerns.

The proposed human health objective is to minimize the potential for respiratory sensitization to the general population from MDI exposure.

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3.2 Proposed Risk Management Objective and Options under Consideration

Proposed risk management objectives set quantitative or qualitative targets to be achieved by the implementation of risk management regulations, instrument(s) and/or tool(s) for a given substance or substances. The proposed risk management objective for MDIs is to reduce general population exposure resulting from the application of DIY two-component spray polyurethane foam insulation products containing MDIs.

The proposed risk management being considered for MDIs is to work with retailers, manufacturers and/or importers to minimize access of the general population to DIY two-component spray polyurethane foam insulation products.

In alignment with the Government of Canada's Cabinet Directive on Regulatory Management (TBS 2012a) and Red Tape Reduction Action Plan (TBS 2012b), the proposed risk management regulation(s), instrument(s) or tool(s) will be selected using a thorough, consistent and efficient approach and take into consideration the information that has been received through this initiative and other information available at that time.

3.3 Risk Management Information Gaps

More information is needed on the following to inform risk management decision-making:

- Socio economic impacts associated with risk managing DIY two-component spray polyurethane foam insulation products containing MDIs
- Policies, programs, or measures in place by manufacturers, importers and/or retailers in Canada or elsewhere, regarding access of the two-component spray polyurethane foam insulation products to the general population (i.e. consumers)

4. Background

4.1 Current Uses and Identified Sectors

Generally MDIs are widely used in the production of polyurethanes and as adhesives in the production of engineered wood products. MDIs are increasingly replacing toluene diisocyanates (TDIs) in the production of flexible and rigid foams, particle board and wood binders, paints and coatings, adhesives, sealants, elastomers, casting material and spandex fibres (ECJRC 2005; US EPA 2011; Björkner et al. 2001; Methner et al. 2010). Increasingly, MDIs are being used as a replacement to formaldehyde as a resin binder in the manufacture of oriented strand board products (Environment Canada 2012)

In the case of flexible foam, MDIs are reacted with polyetherols or polyesterols in industrial settings to form flexible slabstock or moulded parts which are then used to manufacture furniture, such as sofas and mattresses, automotive foam cushions, flooring underlay, and other packaging foam (ECJRC 2005; Hoffman and Schupp 2009).

Rigid foam and polyurethane CASE (Coatings, Adhesives, Sealants, Elastomers) are also made from MDIs, which are then used in construction, transportation, machinery, packaging and furniture sectors (ECJRC 2005). Manufactured items represent a large commercial use of MDIs. These types of product also exists in the form of DIY products used by consumers for home improvement projects, i.e., products in which MDIs are reacted with polyols to form rigid foam or CASE upon application, such as sealant around windows or doors, insulation inside walls or floor adhesive (ECJRC 2005).

Textiles and sports tracks are also minor uses of polyurethanes made from MDIs (Booth et al. 2009; Björkner et al. 2001).

In Canada, both industrial and consumer uses of MDIs were reported as a result of a survey conducted under section 71 of CEPA 1999 (Canada 2012). Several of the reported uses were considered confidential business information and cannot be disclosed. Between 10 and 100 million kilograms were reported for use in Canada, a fraction of which was available for consumer use (Environment Canada 2012).

In Canada, MDIs were reported to be used in the manufacturing of polyurethane flexible and rigid foam, elastomers, coatings, adhesives and sealants, which are then used in other sectors such as furniture, construction, and automotive. Other manufactured items like oriented strand board, particle board and other wood products are produced in Canada for further use in construction (Environment Canada 2012a). Several Canadian industrial sites use pMDI and MDI for engineered wood products, often in conjunction, in combined quantities ranging from 400 000 kg/year to near 6 000 000 kg/year, per site (Environment Canada 2012). MDIs are also used in casting material by professionals for medical purposes (Environment Canada 2012). In addition, manufactured items containing MDI substances (such as flexible packaging laminate and foam slabs) are imported for use in other sectors (i.e., furniture and automotive) (Environment Canada 2012). Consumer product uses include several DIY products such as adhesives, insulation foam, and sealants (HPD 2013; HSDB 1983-2003).

5. Exposure Sources and Identified Risks

General population exposure to MDIs is expected to result primarily during the use of DIY products in home improvement activities. MDIs are used to produce polyurethane found in insulation or adhesive/sealant products for DIY home improvement projects. In some of these products, such as spray polyurethane foam insulation, MDIs are in a free state, unreacted, and typically in a separate chamber from the polyol prior to use. These products are typically labelled “two-component” products. During application, both MDIs and polyols are “sprayed” or dispensed simultaneously to react and form polyurethane foam at the point of application (Canada 2014b).

Based on the collective information and classifications by other international regulatory agencies, critical effects for characterization of the risk to human health from exposure to MDI substances are carcinogenicity, respiratory effects including sensitization, and dermal sensitization. Available information from studies with experimental animals, human case studies and epidemiological data were used to establish critical effect levels for risk characterization (Canada 2014b).

The most significant source of exposure to MDIs for the general population of Canada is expected to be from use of DIY products. Exposure to these products would be short-term and may occur through inhalation and dermal routes. Margins of exposure for these scenarios were derived based on an effect level of 0.05 mg/m^3 identified from MDI epidemiological studies. Use of this effect level as a critical endpoint for characterizing the risk from use of consumer products is considered conservative given that it is based on observation of effects in workers exposed on a continuous basis throughout an 8-hour work day and can be repeated over a long period of time (several weeks to several years) an exposure duration longer than that of DIY product users. Therefore, margins of inhalation exposure were also estimated using an acute respiratory effect level of 0.14 mg/m^3 identified from studies conducted on healthy volunteers exposed to TDIs for a short duration (up to 2 hours). TDIs are considered to be appropriate analogues for MDIs based on similar chemical substructures, and similar respiratory effects and sensitization effects observed in humans and animals (Canada 2014b).

Although certain products containing MDIs specify personal protection measures, such as gloves or respiratory protection, exposure estimates derived do not consider that individuals are wearing personal protective equipment as such equipment is not readily accessible to consumers, nor are they trained in its proper use (Canada 2014b).

When potential exposures for homeowner application of DIY two-component spray polyurethane foam insulation products were compared to relevant critical health effect levels for respiratory effects, margins were deemed inadequate for inhalation exposures (Canada 2014b).

When potential exposures for other MDI-containing products, such as foam sealant, polyurethane sealant, floor/wall adhesive, construction glue, generic/hobby glue, super glue and hot melt adhesive were compared to relevant critical health effect levels for respiratory effects, margins were deemed adequate for inhalation exposure. The margins of exposure may not protect sensitized individuals. Sensitized individuals should avoid any exposure to MDIs to prevent allergic reactions (Canada 2014b).

A potential source of exposure to MDIs is via inhalation of ambient air for the general population residing in the vicinity of industrial sites (e.g., wood product manufacturing plant using MDIs). When potential estimated environmental concentrations from emissions of MDIs in the vicinity of industrial sites were compared to relevant critical health effect levels for respiratory effects, margins were deemed adequate for inhalation exposures (Canada 2014b).

MDIs are strong skin sensitizers based on collective evidence from experimental animal and human case studies and epidemiological data. In addition, evidence in experimental animals suggests that dermal exposure prior to inhalation exposure could trigger respiratory hypersensitivity. Effect levels may be exceeded under certain conditions of use of DIY products, highlighting the importance of minimizing dermal contact (e.g., wear appropriate gloves) (Canada 2014b).

Residents in a home who are not applicators could also potentially be exposed to airborne MDI from the presence of aerosols in the air during use of the two-component product; in the case of a professional application, homeowners would typically be asked to vacate the premises during a delivery of the product and to return several hours later to minimize exposure to MDI (Crespo and Galán 1999). Available data indicates that levels in the air drop rapidly once the foam starts curing (Canada 2014b).

If some residual MDIs remained present in the foam of already cured products, including furniture, mattresses or flooring underlay, at the time of purchase of the foam manufactured item by the consumer, residues are likely to remain in the polymer matrix. Based on available information, including MDI substances' low vapour pressure and recognition that foam is typically surrounded by an additional physical barrier of upholstery in manufactured items, inhalation and dermal exposure to residual MDIs from use by the general population of flexible foam products is considered negligible (Canada 2014b).

6. Risk Management Considerations

6.1 Alternatives and Alternate Technologies

With respect to DIY two-component spray polyurethane foam insulation, alternative building insulation products are available that do not use MDIs, however, some may not provide the same performance qualities as those products that use MDIs. Another alternative is to have professionals install spray polyurethane foam insulation, which may minimize exposure of the general population to MDIs.

6.2 Socio-economic Considerations

Socio-economic factors will be considered in the selection process for a regulation and/or instrument respecting preventive or control actions, and in the development of the risk management objective(s). Socio-economic factors will also be considered in the development of regulations, instrument(s) and/or tool(s) as identified in the *Cabinet Directive on Regulatory Management* (TBS 2012a) and the guidance provided in the Treasury Board document *Assessing, Selecting, and Implementing Instruments for Government Action* (TBS 2007).

7. Overview of Existing Risk Management

7.1 Related Canadian Risk Management Context

Existing risk management actions targeting MDIs in Canada are mostly related to presence in ambient air and tracking releases to the environment. Measures are also in place for 4,4'-MDI when present in workplace chemicals.

Federal

- 4,4'-MDI and polymeric MDI are reportable substances to the National Pollutant Release Inventory (Environment Canada 2013)
- The *Controlled Products Regulations*, established under the *Hazardous Products Act*, require 4,4'-MDI to be disclosed on the Material Safety Data Sheet that must accompany workplace chemicals when it is present at a concentration of 0.1% or greater as specified on the Ingredient Disclosure List (Canada 1988)

Provincial

- 4,4'-MDI is subject to British Columbia's *Contaminated Sites Regulation*, B.C. 375/96 for drinking water and soil (BC MOE 2013)
- 4,4'MDI and Polymeric MDI are subject to Ontario's *Regulation 419/05 Air Pollution – Local Air Quality* (Ontario MOE 2011) and Ambient Air Quality Criteria (Ontario MOE 2012)
- MDI mixed isomers is subject to an Ontario Jurisdictional Screening Level (JSL) value which is used as a screening tool for local air quality (Ontario MOE 2008)

- “MDI” (isomer unspecified) is subject to Manitoba’s Ambient Air Quality Criteria (Government of Manitoba 2005)

7.2 Pertinent International Risk Management Context

Internationally, some measures related to MDIs in consumer products have been identified as either in place or underway, specifically in the USA and the European Union as listed below.

- US EPA has initiated an Action Plan on MDI and Related Compounds. The Action Plan intends to address the use of MDIs in products and their resulting general population exposure (US EPA 2011)
- Spray polyurethane foam systems containing unreacted diisocyanates (including MDIs) were recently proposed as initial priority products under California's Safer Consumer Products Regulations due to health concerns. (California EPA 2014)
- 4,4'-MDI (HSDB 2012) and polymeric MDI (HSDB 2002) are subject to section 8(d) of the US EPA *Toxic Substances Control Act* where manufacturers, importers and processors must provide the EPA with unpublished health and safety studies (40 CFR 716.120)
- 4,4'-MDI is subject to the section 8(a) of the US EPA *Toxic Substances Control Act* which requires manufacturers of this chemical substance to report preliminary assessment information concerned with production, exposure, and use (40 CFR 712.30) (HSDB 2012)
- 4,4'-MDI is a reportable substance under the US *Comprehensive Environmental Response, Compensation, and Liability Act* (40 CFR 302.4) (HSDB 2012)
- 4,4'-MDI is a designated Hazardous Air Pollutant (HAP) under the US *Clean Air Act* (HSDB 2012)
- 4,4'-MDI, produced as an intermediate or final product, is subject to performance standards for equipment leaks of Volatile Organic Compounds in the Synthetic Organic Chemical Manufacturing Industry (40 CFR 60.489) (HSDB 2012)
- 2,4'-MDI, 4,4'-MDI and MDI mixed isomers are on the Danish List of Undesirable Substances (Danish EPA 2009)
- 2,2'-MDI, 2,4'-MDI, 4,4'-MDI and mixed MDI are classified by the Swedish Chemicals Agency (KEMI) as *priority risk reduction substances* (KEMI 2013)
- Mixed MDI is subject to REACH Annex XVII where mixtures sold to the general population must not contain greater than 0.1% by weight unless the package contains gloves that comply with Council Directive 89/686/EEC and the package is marked with specific warning labels (does not apply to hot melt adhesives) (European Commission 2009)
- 4,4'-MDI is a reportable substance to the National Pollutant Inventory in Australia (Australian Government 2013).

8. Next Steps

8.1 Public Comment Period

Industry and other interested stakeholders are invited to submit comments on the content of this Risk Management Scope or other information that would help to inform decision making. Please submit comments prior to October 15, 2014. Publication of the Risk Management Approach which will outline and seek input on the proposed risk management instrument(s) will coincide with the publication of the final screening assessment report. At that time, there will be opportunity for further consultation.

Comments and information submissions on the Risk Management Scope should be submitted to the address provided below:

Environment Canada
Chemicals Management Division
Gatineau Quebec K1A 0H3
Tel: 1-888-228-0530 / 819-956-9313
Fax: 819-953-7155
Email: Substances@ec.gc.ca

Companies who have a business interest in two-component spray polyurethane foam products containing MDIs available to consumers are encouraged to identify themselves as stakeholders. Outreach will be made with stakeholders with respect to proposals on how to achieve the risk management objective. Stakeholders will be informed of future decisions regarding MDIs and may be contacted for further information.

8.2 Timing of Actions

Electronic consultation on the Risk Management Scope: August 16, 2014 to October 15, 2014.

Publication of responses to public comments on the draft Screening Assessment Report and Risk Management Scope: on or before July 2015.

Publication of the final Screening Assessment Report and, if required, the Risk Management Approach document: on or before July 2015.

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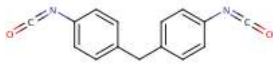
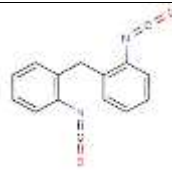
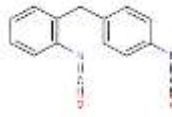
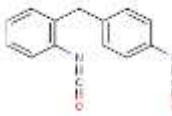
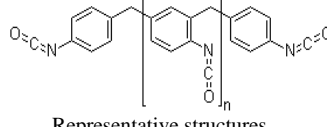
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Annex A: List of Targeted Substances

CAS RN	Substance Name	Acronym	Chemical Structure	Molecular Weight (g/mol)	Chemical Formula
101-68-8	Benzene, 1,1'-methylenebis[4-isocyanato-	4,4'-MDI		250.3	C ₁₅ H ₁₀ N ₂ O ₂
2536-05-2	Benzene, 1,1'-methylenebis[2-isocyanato-	2,2'-MDI		250.3	C ₁₅ H ₁₀ N ₂ O ₂
5873-54-1	Benzene, 1-isocyanato-2-[(4-isocyanatophenyl)methyl]-	2,4'-MDI		250.3	C ₁₅ H ₁₀ N ₂ O ₂
26447-40-5	Benzene, 1,1'-methylenebis[isocyanato-	Mixed MDI	 Representative structure	250.3	C ₁₅ H ₁₀ N ₂ O ₂
9016-87-9	Isocyanic acid, polymethylenepolyphenylene ester	pMDI	 Representative structures n = 2-5	250.3 – 774.8	N/A