

RISK MANAGEMENT OPTIONS ANALYSIS

CONCLUSION DOCUMENT

for

Toluene diisocyanate (TDI) and Methylene diphenyl diisocyanate (MDI)

Substance name: 2,2'-MDI (Diphenylmethan-2,2'-diisocyanate)

EC-number: 219-799-4

CAS-number: 2536-05-2

Substance name: 2,4'-MDI (Diphenylmethan-2,4'-diisocyanate)

EC-number: 227-534-9

CAS-number: 5873-54-1

Substance name: 4,4'-MDI (Diphenylmethan-4,4'-diisocyanate)

EC-number: 202-966-0

CAS-number: 101-68-8

Substance name: MDI - unspecified mix of isomers

EC-number: 247-714-0

CAS-number: 26447-40-5

Substance name: 2,4-TDI (2,4-toluene diisocyanate)

EC-number: 209-544-5

CAS-number: 584-84-9

Substance name: 2,6-TDI (2,6-toluene diisocyanate)

EC-number: 202-039-0

CAS-number: 91-08-7

Substance name: TDI-mixed (2,4-TDI:2.6-TDI often indicated as 80:20 and 65:35 mixes)

EC-number 247-722-4

CAS-number: 26471-62-5

Member State: Denmark

Dated: August 2014, Final version

Disclaimer: Please note that this RMOA conclusion was compiled on the basis of available information and may change in the light of new information or further assessment.

1. OVERVIEW OF OTHER REGULATORY PROCESSES / EU LEGISLATION

The RMO and the underlying surveys are a part of the review of the substances on the Danish List of undesirable substances (LOUS-review).

The Danish EPA has conducted a survey of all substances listed on the Danish List of Unwanted Substances (LOUS). Access to the surveys carried out so far can be found at the following link:

http://www.mst.dk/English/Chemicals/assessment_of_chemicals/LOUS_2012_2015/

The Danish survey carried out for MDI and TDI in 2013 provides an overview of the use and the environmental and human health aspects of the substances. The results of the survey have been used as the main background information for this RMO.

Typically TDI and MDI are reacted with polyols in the production of polyurethane (PUR), which accounts for the main application of these substances.

The main groups of PUR plastic products are:

- Flexible PUR (Traditionally TDI-based, but with increasing content of MDI);
- Rigid PUR (blown) (MDI-based)/Solid (non-blown) PUR (MDI-based), and
- Elastomeric polyurethanes used both as rubber and as thermoplastic elastomers (mainly MDI based)

Other well-known areas of use are PUR based coatings/paints/lacquers, adhesives and sealants, in which MDI as well as TDI is used and the reactive monomers form part of the curing/bonding functionality of the products.

All addressed (mixes of) monomeric MDI and TDI are subject to harmonised classification (see table 1). Both MDI and TDI isomers and mixes thereof have the same harmonised classification. MDI and TDI are classified as suspected of causing cancer, as dermal and respiratory sensitizers, as well as eye, skin and respiratory irritants. Classification differs for acute toxicity, where MDI is harmful if inhaled, TDI is classified as fatal if inhaled; and in relation to toxicity after repeated exposure, where only MDI is classified (potential to cause damage to liver and kidney).

TABLE 1

Harmonised classification of MDI and TDI according to Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)

Index No	International Chemical Identification	CAS No	Classification	
			Hazard Class and Category Code(s)	Hazard statement Code(s)
615-005-00-9	o-(p-isocyanatobenzyl)phenyl isocyanate (2,4'-MDI)	5873-54-1	Carc. 2 Acute Tox. 4 * STOT RE 2 * Eye Irrit. 2 STOT SE 3 Skin Irrit. 2 Resp. Sens. 1 Skin Sens. 1	H351 H332 H373** H319 H335 H315 H334 H317
615-005-00-9	4,4'-methylenediphenyl diisocyanate (4,4'-MDI)	101-68-8	Carc. 2 Acute Tox. 4 * STOT RE 2 * Eye Irrit. 2 STOT SE 3 Skin Irrit. 2 Resp. Sens. 1 Skin Sens. 1	H351 H332 H373** H319 H335 H315 H334 H317

Index No	International Chemical Identification	CAS No	Classification	
			Hazard Class and Category Code(s)	Hazard statement Code(s)
615-005-00-9	Methylenediphenyl diisocyanate (mix of MDI isomers)	26447-40-5	Carc. 2 Acute Tox. 4 * STOT RE 2 * Eye Irrit. 2 STOT SE 3 Skin Irrit. 2 Resp. Sens. 1 Skin Sens. 1	H351 H332 H373** H319 H335 H315 H334 H317
615-006-00-4	4-methyl-m-phenylene diisocyanate (2,4-TDI)	584-84-9	Carc. 2 Acute Tox. 2 * Eye Irrit. 2 STOT SE 3 Skin Irrit. 2 Resp. Sens. 1 Skin Sens. 1 Aquatic Chronic 3	H351 H330 H319 H335 H315 H334 H317 H412
615-006-00-4	2-methyl-m-phenylene diisocyanate (2,6-TDI)	91-08-7	Carc. 2 Acute Tox. 2 * Eye Irrit. 2 STOT SE 3 Skin Irrit. 2 Resp. Sens. 1 Skin Sens. 1 Aquatic Chronic 3	H351 H330 H319 H335 H315 H334 H317 H412

Index No	International Chemical Identification	CAS No	Classification	
			Hazard Class and Category Code(s)	Hazard statement Code(s)
615-006-00-4	m-tolylidene diisocyanate (mix of TDI isomers)	26471-62-5	Carc. 2 Acute Tox. 2 * Eye Irrit. 2 STOT SE 3 Skin Irrit. 2 Resp. Sens. 1 Skin Sens. 1 Aquatic Chronic 3	H351 H330 H319 H335 H315 H334 H317 H412

* Use of "*" in connection with a hazard category (e.g. Acute Tox. 4 *) implies that the category stated shall be considered as a minimum classification.

** Use of "***" in connection with a hazard statement code (e.g. H373**) implies that the route of exposure is not specified.

A 2005 MDI risk assessment (EU, 2005) resulted in a regulation 76/769 (now REACH annex XVII) with a restriction for consumer use of MDI-containing products. No REACH restriction for TDI exists. 2,4-TDI, 2,6-TDI, 2,4'-MDI and 4,4'-MDI are on the positive list of the plastic food contact material regulation with certain restrictions (as well as amine degradation products) and TDIs are explicitly prohibited in cosmetics. Consumer use is not supported in the registration of TDI.

"Isocyanates" (including MDI and TDI) are specifically indicated to be within the scope of the IPPC (Integrated Pollution Prevention and Control) and PRTR (Pollutant Release and Transfer Register) directives. TDI is mentioned in Annex 1, Part 2 of the Seveso Directive. Isocyanate waste (nomenclature: "08 05 01 waste isocyanates") is regulated as hazardous waste. Finally, a Commission recommendation states that Member States should address occupational diseases caused by isocyanates.

2. CONCLUSION OF RMOA

Conclusions	Tick box
Need for follow up regulatory action at EU level <i>[if a specific regulatory action is already identified then, please, select one or more of the specific follow up actions mentioned below]</i>	?
Harmonised classification and labelling	
Identification as SVHC (authorisation)	
Restrictions	?
Other EU-wide measures	
No need for regulatory follow-up action	

As products containing TDI might be available for the consumer within the EU the possibility of a restriction proposal for TDI concerning consumer products should be analysed further. For MDI it seems appropriate to await the outcome of the substance evaluation.

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