



RISK MANAGEMENT OPTIONS ANALYSIS
CONCLUSION DOCUMENT

for

Diisocyanates
(see appendix for substance list)

EC No: see appendix

CAS No: see appendix

Member State(s): Germany

Dated: 29 August 2014

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

Annex XVII of EC 1907/2006, Entry 56: Restriction for Methylenediisocyanate (MDI) in certain consumer products (valid since 27.12.2010)

European Commission: European Union Risk Assessment Report methylenediphenyl diisocyanate (MDI). (2005)

Table 1: National Occupational Limit Values (OEL) for some diisocyanates (8h Time weighted average):

Substance	CAS Nr	Member State	Value (mg/m ³)
MDI (various isomers)	101-68-8 (and others)	Germany/ Denmark/ Belgium/ Spain	0,05
		Denmark	0,05
		France/Austria	0,1
		UK	0,02
TDI (isomer mixture)	26471-62-5 (and other isomers)	Germany/ Denmark/ Belgium	0,035
HDI	822-06-0	Germany France / Switzerland/ Denmark/ Belgium	0,035
NDI	3137-72-6	Germany/ Denmark	0,05
		Switzerland	0,09
IPDI	4098-71-9	Germany	0,046
		France/ Switzerland	0,06
		Sweden/ Denmark/ Belgium	0,05

2. CONCLUSION OF RMOA

This conclusion is based on the REACH and CLP data as well as other available relevant information taking into account the SVHC Roadmap to 2020, where appropriate.

Conclusions	Tick box
Need for follow up regulatory action at EU level	X
Harmonised classification and labelling	
Identification as SVHC (authorisation)	
Restrictions	X
Other EU-wide measures	
No need for regulatory follow-up action	

3. FOLLOW-UP OF REGULATORY RISK MANAGEMENT ACTION AT EU LEVEL

3.1 Need for follow-up regulatory action at EU level

3.1.1 Harmonised classification and labelling

3.1.2 Identification as a substance of very high concern, SVHC (first step towards authorisation)

3.1.3 Restriction

Considering all aspects from internal discussions but also with other MS and industry representatives the aMSCA has come to the conclusion that the most effective risk management option would be to integrate a certification scheme defining minimum handling conditions into a REACH restriction. This option should be investigated further to see if it is workable, even if currently details are still unclear.

The envisaged restriction would prohibit the use of substances which contain more than 0.1wt% of free diisocyanate (of whatever kind), unless a company can prove convincingly that they have an internal system in place that ensures the procedures to handle diisocyanates are strictly followed. This should also include conditions that cover health risks to bystanders (e.g. building occupants), especially from spray foam applications. Compliance to such a system should be shown by participation in a certification scheme that requires maintaining a minimum of certain use conditions.

This would have the advantage that all diisocyanates (aromatic, aliphatic, prepolymers with free diisocyanate) can be covered with one regulatory measure and a minimum level of common handling standards is defined for all of Europe.

If in the end this option would prove to be not viable, it would still be possible to initiate a SVHC/Authorisation procedure instead.

Health risks for consumers are not influenced by the proposed restriction. These risks and the related risk management options should be analysed separately considering the results of activities of other Member States and of the ongoing substance evaluation for MDI by Estonia.

3.1.4 Other Union-wide regulatory risk management measures

4. CURRENTLY NO FOLLOW-UP FORESEEN AT EU LEVEL

5. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

Indication of a tentative plan is not a formal commitment by the authority. A formal commitment to prepare a REACH Annex XV dossier (SVHC, restrictions) and/or CLP Annex VI dossier shall be made via the Registry of Intentions.

Follow-up action	Date for intention	Actor
Data collection and preparation of Annex XV Dossier for restriction	Beginning of 2016	aMSCA

Appendix : List of Diisocyanates concerned.

Name	Abbreviation	CAS Nr	EC Nr
Toluylendiisocyanate a. 2,4 Isomer b. 2,6 Isomer c. any reaction mass of a-b d. any mixtures of a-b	TDI TDI (2,4) TDI (2,6)	584-84-9 91-08-7	209-544-5 202-039-0
Methylendiphenyldiisocyanate a. 4,4' Isomer b. 2,4' Isomer c. 2,2' Isomer d. any reaction mass of a-c e. any mixtures of a-c f. any oligomers or polymers manufactured of a-e	MDI 4,4'MDI 2,4'MDI 2,2'MDI	101-68-8 5873-54-1 2536-05-02	202-966-0 227-534-9 219-799-4
1,5-Naphthyldiisocyanate	NDI	3173-72-6	221-641-4
1,1'-Biphenyl, 4,4'-diisocyanato-3,3'- dimethyl- (Tosyldiisocyanate)	TODI	91-97-4	202-112-7
Cyclohexane, 5-isocyanato-1- (isocyanatomethyl)-1,3,3-trimethyl- (Isophorondiisocyanate)	IPDI	4098-71-9	223-861-6
Hexane, 1,6-diisocyanato- (Hexamethylenediisocyanate)	HDI	822-06-0	212-485-8
Benzene, 1,3-bis(1-isocyanato-1- methylethyl)- (meta-Trimethylxylylenediisocyanate)	m-TMXDI	2778-42-9	220-474-4
Cyclohexane, 1,1'-methylenebis-4- isocyanato- (Methylendicyclohexyldiisocyanate, or Hydrogenated MDI)	H12MDI	5124-30-1	225-863-2