Justification for the selection of a candidate CoRAP substance

Substance Name (Public Name):	Reaction mass of 4,4'-methylenediphenyl diisocyanate and o-(p-isocyanatobenzyl)phenyl isocyanate
Chemical Group:	
EC Number:	905-806-4
CAS Number:	NS
Submitted by:	Health Board, Estonia
Published:	20/03/2013

NOTE

This document has been prepared by the evaluating Member State given in the CoRAP update.

Contents

1 IDENTITY OF THE SUBSTANCE

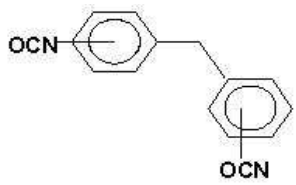
1.1 Name and other identifiers of the substance

Table 1: Substance identity

Public Name:	Reaction mass of 4,4'-methylenediphenyl diisocyanate and o-(p-isocyanatobenzyl)phenyl isocyanate
EC number:	905-806-4 (ECHA List Number)
EC name:	Reaction mass of 4,4'-methylenediphenyl diisocyanate and o-(pisocyanatobenzyl)phenyl isocyanate
CAS number (in the EC inventory):	
CAS number:	-
CAS name:	
IUPAC name:	
Index number in Annex VI of the CLP Regulation	-
Molecular formula:	C15 H10 N2 O2
Molecular weight or molecular weight range:	250.0
Synonyms:	

Type of substance ☐ Mono-constituent ☒ Multi-constituent ☐ UVCB

Structural formula:



2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

N/A

2.2 Proposal for Harmonised Classification in Annex VI of the CLP

N/A

2.3 Self classification

The registration data includes the following self-classification;
Based on Annex VI CLP entry 615-005-00-9:

According to CLP criteria:

- Acute Tox. 4; H332: Harmful if inhaled.
- Skin Irrit. 2; H315: Causes skin irritation, C ≥ 5%.
- Eye Irrit. 2; H319: Causes serious eye irritation, C ≥ 5%.
- Resp. Sens. 1; H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled, C ≥ 0.1%.
- STOT Single. Exp. 3. H335: May cause respiratory irritation, C ≥ 5%.
- STOT Rep. Exp. 2. H373: May cause damage to organs through prolonged or repeated exposure.
- Skin Sens. 1; H317: May cause an allergic skin reaction.
- Carc. 2; H351: Suspected of causing cancer

According to DSD criteria:

- Xn; R20 Harmful; Harmful by inhalation.
- Xn; R48/20 Harmful; Harmful: danger of serious damage to health by prolonged exposure through inhalation.
- Xi; R36/37/38 Irritant; Irritating to eyes, respiratory system and skin.
- R42/43 May cause sensitisation by inhalation and skin contact.
- Carc. Cat. 3; R40 Limited evidence of a carcinogenic effect.

3 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

3.1 Legal basis for the proposal

☒ Article 44(1) (refined prioritisation criteria for substance evaluation)

☐ Article 45(5) (Member State priority)

3.2 Grounds for concern

☒ (Suspected) CMR	☒ Wide dispersive use	☐ Cumulative exposure
☒ (Suspected) Sensitiser	☒ Consumer use	☐ High RCR
☒ (Suspected) PBT	☐ Exposure of sensitive populations	☒ Aggregated tonnage
☐ Suspected endocrine disruptor	☐ Other (provide further details below)	

It is unclear if hydrolysis of the substance is complete or not. There is also no information on degradation of hydrolysis products. The substance appears to meet B (bioaccumulation) and T (toxic) criteria.

Read-across isocyanic acid polymethylenepolyphenylene ester (key study) and monomeric 4,4'-methylenediphenyl diisocyanate.

The data presented by the Registrant using structurally related substances indicated NOAEL of 4 mg/m3 for maternal and fetal toxicity (Gamer et al., 1994 based on OECD guideline 414) and 12 mg/m3 for development/teratogenicity (Gamer et al., 2000). The Registrant stated that the observed fetotoxic effects and adverse effects on the embryonic development were due to the portal of entry, respiratory tract, and any other manifestations were secondary to this. However, there is a data gap to conclude at this point. According to Annex X (8.7.) of the REACH regulation, reproductive toxicity study should be done.

The known human respiratory sensitiser, MDI, was found to elicit AB responses in mice equivalent to those observed following exposure to TMA and PHA. MDI caused an increase in the serum conc. of IgE and a preferential IgG2b rather than IgG2a response. Respiratory sensitizers such as MDI cause a preferential, rather than exclusive, stimulation of Th2 cells. This accommodates the fact that MDI is able to induce contact allergy.

3.3 Information on aggregated tonnage and uses

☐ 1 – 10 tpa	☐ 10 – 100 tpa	☐ 100 – 1000 tpa
☐ 1000 – 10,000 tpa	☒ 10,000 – 100,000 tpa	
☐ 100,000 – 1000,000 tpa	☐ > 1000,000 tpa	
☐ Confidential		

☒ Industrial use	☒ Professional use	☒ Consumer use	☒ Closed System

Substance is used in several consumer products, e.g. in rigid foam, coatings, adhesives and sealants and in several areas of industrial and professional use.

3.4 Other completed/ongoing regulatory processes that may affect suitability for substance evaluation

☐ Compliance check	☐ Dangerous substances Directive 67/548/EEC
☐ Testing proposal	☐ Existing Substances Regulation 793/93/EEC
☐ Annex VI (CLP)	☐ Plant Protection Products Regulation 91/414/EEC
☐ Annex XV (SVHC)	☐ Biocidal Products Directive 98/8/EEC
☐ Annex XIV (Authorisation)	☐ Other (provide further details below)
☐ Annex XVII (Restriction)	
Please provide further details	

3.5 Information to be requested to clarify the suspected risk

☒ Information on toxicological properties	☐ Information on physico-chemical properties
☒ Information on fate and behaviour	☒ Information on exposure
☐ Information on ecotoxicological properties	☐ Information on uses
☐ Other (provide further details below)	

Requested information should help to understand how much of the substance reach to the environment, behavior in the environment, completeness of the hydrolysis, degradation of the hydrolysis products.

To fulfill the REACH requirements for reproductive toxicity endpoint.

3.6 Potential follow-up and link to risk management

☐ Restriction	☒ Harmonised C&L	☒ Authorisation	☐ Other (provide further details)
Please provide further details			