

Justification for the selection of a candidate CoRAP substance

– Update –

Substance Name (Public Name):	Reaction products of 1,1'-methylenebis(4-isocyanatobenzene) in excess and 1-isocyanato-2-(4-isocyanatobenzyl)benzene in excess with 2,2'-[(methylethylene)bis(oxy)]di(methylethanol), butane-1,3-diol and propane-1,2-diol
Chemical Group:	
EC Number:	701-029-8
CAS Number:	N/A
Submitted by:	Health Board, Estonia
Date:	20/03/2013 20/03/2018 (1. Update)

Cover Note

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

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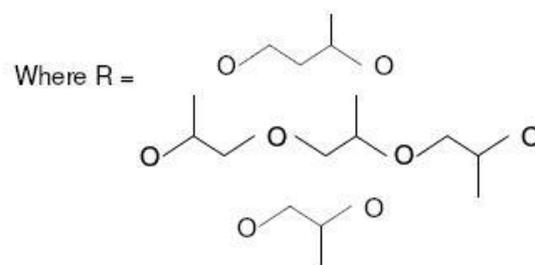
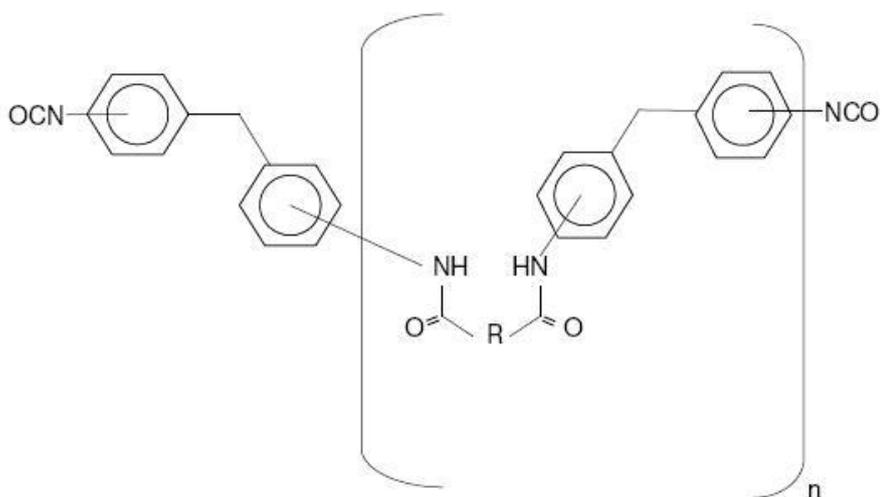
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1 IDENTITY OF THE SUBSTANCE**1.1 Name and other identifiers of the substance****Table 1: Substance identity**

Public Name:	Reaction products of 1,1'-methylenebis(4-isocyanatobenzene) in excess and 1-isocyanato-2-(4-isocyanatobenzyl)benzene in excess with 2,2'-[(methylethylene)bis(oxy)]di(methylethanol), butane-1,3-diol and propane-1,2-diol
EC number:	701-029-8
EC name:	Reaction products of 1,1'-methylenebis(4-isocyanatobenzene) in excess and 1-isocyanato-2-(4-isocyanatobenzyl)benzene in excess with 2,2'-[(methylethylene)bis(oxy)]di(methylethanol), butane-1,3-diol and propane-1,2-diol
CAS number (in the EC inventory):	-
CAS number:	-
CAS name:	
IUPAC name:	
Index number in Annex VI of the CLP Regulation	
Molecular formula:	C ₁₄ H ₁₀ N O (R C ₁₅ H ₁₂ N ₂ O ₂) _n NCO where R = C ₄ H ₈ O ₂ and C ₉ H ₁₈ O ₄ and C ₃ H ₆ O ₂
Molecular weight or molecular weight range:	ca. 365.0
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:

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.
- STOT Sing. 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.
- EUH204: Contains isocyanates. May produce an allergic reaction.

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(2) (refined prioritisation criteria for substance evaluation)
- Article 45(5) (Member State priority)

3.2 Grounds for concern

<input checked="" type="checkbox"/> (Suspected) CMR	<input checked="" type="checkbox"/> Wide dispersive use	<input type="checkbox"/> Cumulative exposure
<input checked="" type="checkbox"/> (Suspected) Sensitiser	<input checked="" type="checkbox"/> Consumer use	<input type="checkbox"/> High RCR
<input type="checkbox"/> (Suspected) PBT	<input type="checkbox"/> Exposure of sensitive populations	<input type="checkbox"/> Aggregated tonnage
<input type="checkbox"/> Suspected endocrine disruptor	<input type="checkbox"/> Other (provide further details below)	
<p>It needs to be clarified how the hydrolysis product contributes to the associated risks at use. The genotoxic potential of the substance needs to be assessed.</p>		

3.3 Information on aggregated tonnage and uses

<input type="checkbox"/> 1 – 10 tpa	<input type="checkbox"/> 10 – 100 tpa	<input checked="" type="checkbox"/> 100 – 1000 tpa	
<input type="checkbox"/> 1000 – 10,000 tpa	<input type="checkbox"/> 10,000 – 100,000 tpa		
<input type="checkbox"/> 100,000 – 1,000,000 tpa	<input type="checkbox"/> > 1,000,000 tpa		
<input type="checkbox"/> Confidential			
<p><input checked="" type="checkbox"/> Industrial use <input checked="" type="checkbox"/> Professional use <input checked="" type="checkbox"/> Consumer use <input checked="" type="checkbox"/> Closed System</p>			
<p>Substance is used in several consumer products.</p>			

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

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

3.5 Information to be requested to clarify the suspected risk

<input checked="" type="checkbox"/> Information on toxicological properties	<input type="checkbox"/> Information on physico-chemical properties
<input checked="" type="checkbox"/> Information on fate and behaviour	<input checked="" type="checkbox"/> Information on exposure
<input type="checkbox"/> Information on ecotoxicological properties	<input type="checkbox"/> Information on uses
<input type="checkbox"/> Other (provide further details below)	
<p>Requested information should help to understand the genotoxic potential of the substance and the exposure to the substance as well as its' hydrolysis product.</p>	

3.6 Potential follow-up and link to risk management

<input type="checkbox"/> Restriction	<input checked="" type="checkbox"/> Harmonised C&L	<input checked="" type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)