Justification for the selection of a candidate CoRAP substance

Substance Name (Public Name):	4,4'-Methylenediphenyl diisocyanate, oligomeric reaction products with butane-1,3-diol, 2,4'-diisocyanatodiphenylmethane, [(methylethylene) bis(oxy)]dipropanol and propane-1,2-diol
Chemical Group:	
EC Number:	500-312-1
CAS Number:	123714-19-2
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

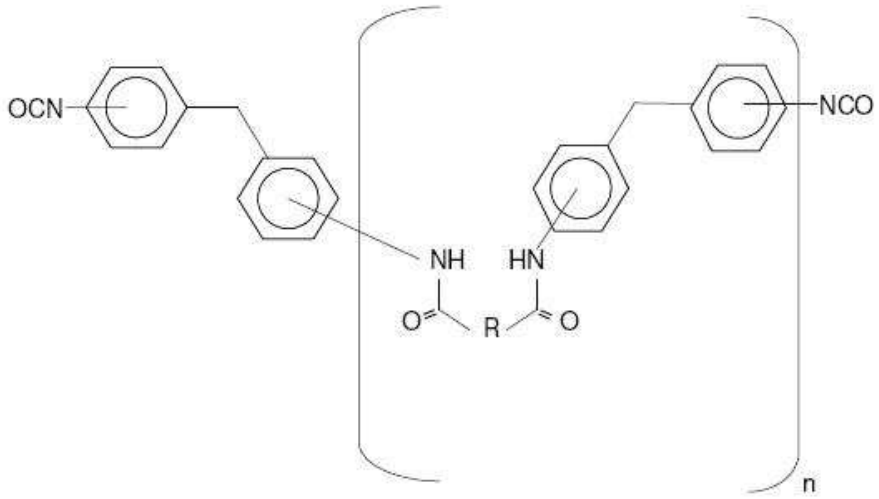
1.1 Name and other identifiers of the substance

Table 1: Substance identity

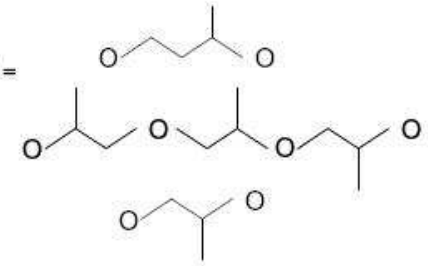
Public Name:	4,4'-Methylenediphenyl diisocyanate, oligomeric reaction products with butane-1,3-diol, 2,4'-diisocyanatodiphenylmethane,[(methylethylene) bis(oxy)]dipropanol and propane-1,2-diol
EC number:	500-312-1
EC name:	4,4'-Methylenediphenyl diisocyanate, oligomeric reaction products with butane-1,3-diol, 2,4'-diisocyanatodiphenylmethane,[(methylethylene)bis(oxy)]dipropanol and propane-1,2-diol
CAS number (in the EC inventory):	123714-19-2
CAS number:	123714-19-2
CAS name:	1,3-Butanediol, polymer with 1-isocyanato-2-[(4-isocyanatophenyl)methyl]benzene, 1,1'-methylenebis[4-isocyanatobenzene], [(1-methyl-1,2-ethanediyl)bis(oxy)]bis[propanol] and 1,2-propanediol
IUPAC name:	
Index number in Annex VI of the CLP Regulation	
Molecular formula:	C14 H10 N O (R C15 H12 N2 O2)n NCO where R = C4 H8 O2 and C9 H18 O4 and C3 H6 O2
Molecular weight or molecular weight range:	ca. 365.0
Synonyms:	

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

Structural formula:



Where R =



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(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. According to Annex X (8.7.) of the REACH regulation, reproductive toxicity study should be done.

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		
Please provide further details		

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

Substance is used in several consumer products.

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