Danish Ministry of the Environment
Environmental Protection Agency

Justification Document for the Selection of a CoRAP Substance

Substance Name (public name):	Diethylmethylbenzenediamine
EC Number:	270-877-4
CAS Number:	68479-98-1
Authority:	MSCA Denmark
Date:	22/03/2016

Note

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

Contents

1 IDENTITY OF THE SUBSTANCE

1.1 Other identifiers of the substance

Table: Other Substance identifiers

EC name (public):	Diethylmethylbenzenediamine
IUPAC name (public):	3-(1-ethylpropyl)benzene-1,2-diamine
Index number in Annex VI of the CLP Regulation:	612-130-00-0
Molecular formula:	$C_{11}H_{18}N_2$
Molecular weight or molecular weight range:	178.28
Synonyms:	

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

Structural formula:

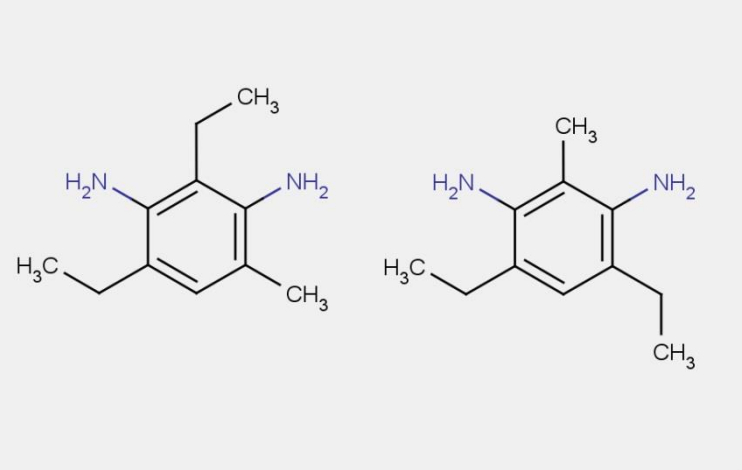


Table: Constituent

EC number:	218-256-9
EC name (public):	2,4-diamino-3,5-diethyltoluene
CAS number:	2095-02-5
CAS name (public):	2,4-diamino-3,5-diethyltoluene
IUPAC name (public):	2,4-diethyl-6-methylbenzene-1,3-diamine
Index number in Annex VI of the CLP Regulation:	612-130-00-0
Molecular formula:	$C_{11}H_{18}N_2$
Molecular weight or molecular weight range:	178.28
Synonyms:	

Structural formula:

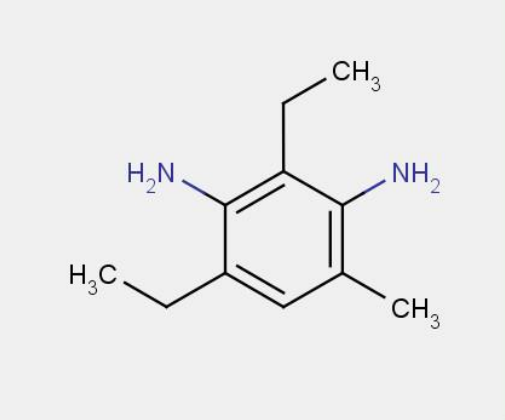
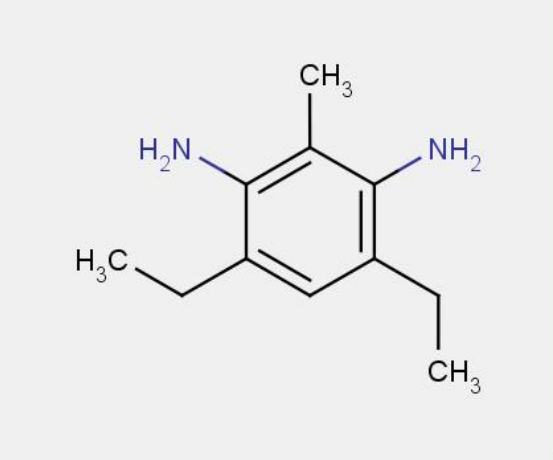


Table: Constituent

EC number:	218-255-3
EC name (public):	2,6-diamino-3,5-diethyltoluene
CAS number:	2095-01-4
CAS name (public):	2,6-diamino-3,5-diethyltoluene
IUPAC name (public):	4,6-diethyl-2-methylbenzene-1,3-diamine
Index number in Annex VI of the CLP Regulation:	612-130-00-0
Molecular formula:	$C_{11}H_{18}N_2$
Molecular weight or molecular weight range:	178.28
Synonyms:	

Structural formula:



2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table: Completed or ongoing processes

RMOA	☐ Risk Management Option Analysis (RMOA)	
REACH Processes	Evaluation	☐ Compliance check, Final decision
		☒ Testing proposal (registered substance, completed)
		☐ CoRAP and Substance Evaluation
	Authorisation	☐ Candidate List
		☐ Annex XIV
	Restri -ction	☐ Annex XVII
Harmonised C&L	☒ Annex VI (CLP) (see section 3.1)	
Processes under other EU legislation	☐ Plant Protection Products Regulation Regulation (EC) No 1107/2009	
	☐ Biocidal Product Regulation Regulation (EU) 528/2012 and amendments	
Previous legislation	☐ Dangerous substances Directive Directive 67/548/EEC (NONS)	
	☐ Existing Substances Regulation Regulation 793/93/EEC (RAR/RRS)	
(UNEP) Stockholm convention (POPs Protocol)	☐ Assessment	
	☐ In relevant Annex	
Other processes / EU legislation	☐ Other (provide further details below)	

A testing proposal for a Reproductive toxicity (pre-natal developmental toxicity) (OECD 414) was submitted by the registrant(s). This study has been carried out.

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

Table: Harmonised classification

Index No	International Chemical Identification	EC No	CAS No	Classification		Spec. Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement code(s)		
612-130-00-0	diethylmethylbenzenediamine	270-877-4	68479-98-1	Acute Tox. 4 * Acute Tox. 4 * Eye Irrit. 2 STOT RE 2 * Aquatic Acute 1 Aquatic Chronic 1	H302 H312 H319 H373 ** H400 H410		Note C

3.1.2 Self classification

- All notefiers used the harmonised classification.

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

None.

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES

4.1 Tonnage and registration status

Table: Tonnage and registration status

From ECHA dissemination site (may 21.st 2015)		
☒ Full registration(s) (Art. 10)	☐ Intermediate registration(s) (Art. 17 and/or 18)	
Tonnage band (as per dissemination site)		
☐ 1 – 10 tpa	☐ 10 – 100 tpa	☐ 100 – 1000 tpa
☒ 1000 – 10,000 tpa	☐ 10,000 – 100,000 tpa	☐ 100,000 – 1,000,000 tpa
☐ 1,000,000 – 10,000,000 tpa	☐ 10,000,000 – 100,000,000 tpa	☐ > 100,000,000 tpa
☐ <1 . . . . . >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		☐ Confidential
Joint Submission		

4.2 Overview of uses

The substance is used as a very effective chain extender of polyurethane elastomer, in particular for RIM (reaction injection molding) and SPUA (Spray Polyurea Elastomer). It can also be used as curing agent of polyurethane and epoxy resin, antioxidant of epoxy resin, industrial oil and lubricants and also serves as intermediates in organic synthesis.

Table: Uses

Part 1:

☒ Manufacture	☒ Formulation	☒ Industrial use	☒ Professional use	☐ Consumer use	☐ Article service life	☒ Closed system

5. JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

5.1. Legal basis for the proposal

☒ Article 44(2) (refined prioritisation criteria for substance evaluation)

☐ Article 45(5) (Member State priority)

5.2. Selection criteria met (why the substance qualifies for being in CoRAP)

☒ Fulfils criteria as CMR/ Suspected CMR

☐ Fulfils criteria as Sensitiser/ Suspected sensitiser

☐ Fulfils criteria as potential endocrine disrupter

☐ Fulfils criteria as PBT/vPvB / Suspected PBT/vPvB

☒ Fulfils criteria high (aggregated) tonnage (*tpa > 1000*)

☒ Fulfils exposure criteria

☐ Fulfils MS's (national) priorities

5.3 Initial grounds for concern to be clarified under Substance Evaluation

Hazard based concerns		
CMR ☐ C ☐ M ☐ R	Suspected CMR[1] ☐ C ☒ M ☒ R	☐ Potential endocrine disruptor
☐ Sensitiser	☐ Suspected Sensitiser[1]	
☐ PBT/vPvB	☐ Suspected PBT/vPvB[1]	☐ Other (please specify below)

Exposure/risk based concerns		
☐ Wide dispersive use	☐ Consumer use	☐ Exposure of sensitive populations
☐ Exposure of environment	☐ Exposure of workers	☐ Cumulative exposure
☐ High RCR	☐ High (aggregated) tonnage	☐ Other (please specify below)

Human hazard

One developmental toxicity study (OECD TG 414) was available for the substance. The test substance was given in the diet as concentrations corresponding to 0, 2.63, 7.83 and 20.45 mg/kg bw per day. In the high dose group maternal toxicity was observed as decreased food consumption during gestation resulting in body weight loss, followed by a decreased mean body weight gain and, reduced ovary weight and induction of acinar cell apoptosis and mononuclear cell inflammation in the pancreas in most of the animals of the high dose. In the mid dose group minimal induction of acinar cell apoptosis was observed in two animals and minimal mononuclear cell inflammation in one animal. Developmental toxicity was observed in the high dose group, as evidenced by a decreased number of implantation sites, live fetuses, as well as a slight retardation in ossification in the fetuses. In addition mean placenta weight and mean fetus weight were decreased, which was confirmed by an increase in incidence of small fetuses. Single incidences of hernia ventralis, one fetus being too small and one fetus showing dilated ventricles of the brain were observed.

The registered substance has several positive reliable Ames tests. However, a relevant follow up *in vivo* study for gene mutation has not been carried out. Hence there is a concern for mutagenicity.

Based on the concerns for gene mutation and toxic effects on reproduction and development diethylmethylbenzenediamine has been selected for CoRAP inclusion.

[1] CMR/Sensitiser: known carcinogenic and/or mutagenic and/or reprotoxic properties/known sensitising properties (according to CLP harmonized or registrant self-classification or CLP Inventory)
Suspected CMR/Suspected sensitiser: suspected carcinogenic and/or mutagenic and/or reprotoxic properties/suspected sensitising properties (not classified according to CLP harmonized or registrant self-classification)
Suspected PBT: Potentially Persistent, Bioaccumulative and Toxic

5.4 Preliminary indication of information that may need to be requested t clarify the concern

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

It will be evaluated if the effects observed in the prenatal developmental toxicity study can be attributed as secondary to maternal toxicity or if the substance should be classified for reproductive toxicity. If the concern cannot be clarified based on existing information further testing may be requested.

For genotoxicity it will be evaluated if further *in vivo* testing is necessary to clarify the concern for gene mutation.

5.5 Potential follow-up and link to risk management

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

If the substance is concluded to meet the criteria for classification as REPR or MUTA in category 1B a proposal for harmonised classification will be submitted.