LATVIJAS VIDES, ĢEOLOĢIJAS UN METEOROLOĢIJAS CENTRS

Justification Document for the Selection of a CoRAP Substance

Substance Name (public name): m-phenylenediamine

EC Number: **203-584-7**

CAS Number: **108-45-2**

Authority: **LV MSCA**

Date: **22/03/2016**

Note

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

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1 IDENTITY OF THE SUBSTANCE

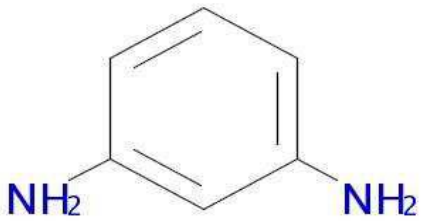
1.1 Other identifiers of the substance

Table: Other Substance identifiers

EC name (public):	m-phenylenediamine
IUPAC name (public):	benzene-1,3-diamine
Index number in Annex VI of the CLP Regulation:	612-147-00-3
Molecular formula:	C6H8N2
Molecular weight or molecular weight range:	108.1 g/mol
Synonyms:	m-diaminobenzene m-aminoaniline

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

Structural formula:



1.2 Similar substances/grouping possibilities

Not relevant

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
		☐ CoRAP and Substance Evaluation
	Authorisation	☐ Candidate List
		☐ Annex XIV
	Restric -tion	☐ Annex XVII[1]
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)	

[1] Please specify the relevant entry.

Further details	Seveso Directive substance Directive 2012/18/EU (Seveso-III) which repeals the Seveso II Directive 96/82/EC, Category E1, H2.

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)*		
612-147-00-3	m-phenylenediamine	203-584-7	108-45-2	Acute Tox3 Acute Tox 3 Skin Sens 1 Eye Irrit 2 Acute Tox 3 Muta 2 Aquatic Acute 1 Aquatic Chr. 1	H301 H311 H317 H319 H331 H341 H400 H410		

*H301: Toxic if swallowed.
H311: toxic in contact with skin.
H331: Toxic if inhaled.
H319: Causes serious eye irritation.
H317: May cause an allergic skin reaction.
H341: Suspected of causing genetic defects <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.

3.1.2 Self classification

In the registration:

- The harmonized classification of m-phenylenediamine is used by registrant in joint submission. For the labelling the dossier submitter using the combined H statement: H301+H311+H331: Toxic if swallowed, in contact with skin or if inhaled.
- In the individual submission of registration for intermediate the harmonised classification of m-phenylenediamine is used. However, in the section of labelling H400 and H410 are not indicated, instead of that the H411 (Toxic to aquatic life with long lasting effects) is included.
- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:

Hazard Class and Categroy code(s)	Hazard Statement Code(s)
STOT RE 2	H373
Not indicated	H411

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES[2]

(AUGUST 20T[H], 2015)

4.1 Tonnage and registration status

Table: Tonnage and registration status

From ECHA dissemination site		
☒ 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

4.2 Overview of uses

It is used as manufacture of polymer, industrial processing.
Use advised against: Use of the substance in any form other than as a reacted monomer within an imported polymer.

Table: Uses

Part 1:

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

[2] *Please provide here the date when the dissemination site was accessed.*

Part 2:

	Use(s)
Uses as intermediate	In the joint submission: Intermediate under strictly controlled conditions. Manufacture of substance In the individual submission: Intermediate for duestuff and other chemical synthesis under strictly controlled conditions, use in closed batch proceses
Formulation	-
Uses at industrial sites	In the joint submission: Transport isolated intermediate used under Strictly Cotntrolled Conditions Manufacture of polymer Industrial processing

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[3]	
☐ 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)

[3] 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

Human health:

Waiving of a mammalian cell gene mutation assay may be incorrectly justified.

Screening for reproductive toxicity and developmental toxicity is waived because of exposure considerations. A two-generation reproductive study is also waived because of exposure considerations. These waivings may be incorrectly justified. A prenatal developmental toxicity study (OECD 414) showed developmental effects which the registrants claims to be caused by maternal toxicity. This should be verified.

A carcinogenicity study is only performed in mice and with exposure only for 78 weeks.

Inhalation from m-phenylenediamine is suspected of causing respiratory sensitization (is also classified as a skin sensitizer). Short time exposure from high levels of p-phenylenediamine may cause irritation to skin, eyes and asthma. o-p- and m-form of phenylenediamine is often discussed together, and then as a substance causing sensitization to the respiratory system and as for causing asthma. http://www.epa.gov/ttn/atw/hlthef/phenylen.html

Exposure:

The only use reported is polymerization and industrial processing (no use descriptors are given on dissemination page). According to the Nordic Spin database (www.spin2000.net), the substance also has other uses, e.g. in adhesive hardeners and building materials and additives.

5.4. Preliminary indication of information that may need to be requested to 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)
More information may be requested for clarification reprotoxicity, sensitization and exposure.	

5.5. Potential follow-up and link to risk management

☒ Harmonised C&L	☐ Restriction	☐ Authorisation	☐ Other (provide further details)
Follow up actions will be considered taking into account the evaluated information. The above ticked follow-up processes are only indicative.			