Justification Document for the Selection of a CoRAP Substance

Substance Name (public name):	1-phenylethanol
EC Number:	202-707-1
CAS Number:	98-85-1
Authority:	Italy
Date:	21/03/2017

Cover 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

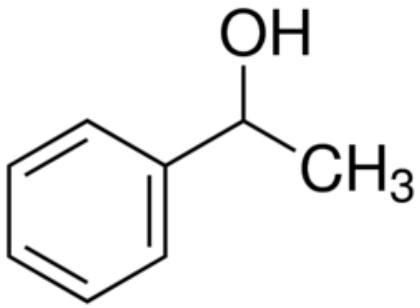
1.1 Other identifiers of the substance

Table: Other Substance identifiers

EC name (public):	1-phenylethanol
IUPAC name (public):	1-Phenylethanol
Index number in Annex VI of the CLP Regulation:	
Molecular formula:	C8H10O
Molecular weight or molecular weight range:	
Synonyms:	

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, Final decison
		☐ 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)	

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

The harmonized classification is not available for 1-phenylethanol.

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

No harmonized classification is available.

3.1.2 Self classification

- In the registration:

  Acute tox cat 4 H302

  Eye irritant cat 2 H320

- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:

  Skin Irrit. Cat 2 H315

  Eye Dam. Cat 1 H318

  Eye Irritant Cat 2 H319

  STOT SE 3 H335 (Respiratory system)

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

No proposal for harmonized classification are available for 1-phenylethanol.

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES[1]

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
Joint Submission and individual submission as Intermediate.		

4.2 Overview of uses

This substance is used in the following products: polishes and waxes, washing & cleaning products, perfumes and fragrances, cosmetics and personal care products, air care products and pharmaceuticals. This substance has an industrial use resulting in manufacture of another substance (use of intermediates).

This substance is used in the following areas: formulation of mixtures and/or re-packaging and health services. This substance is used for the manufacture of: chemicals.

Release to the environment of this substance is likely to occur from industrial use: manufacturing of the substance, in processing aids at industrial sites, as an intermediate step in further manufacturing of another substance (use of intermediates), formulation of mixtures and as processing aid. Other release to the environment of this substance is likely to occur from: indoor use as processing aid, outdoor use as processing aid and indoor use in long-life materials with high release rate (e.g. release from fabrics, textiles during washing, removal of indoor paints).

This substance is intended to be released from scented: clothes, eraser, toys, paper products and CDs.

[1] The date when the dissemination site was accessed is 22 september 2016.

Table: Uses

Part 1:

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

Part 2:

	Use(s)
Uses as intermediate	
Formulation	Compounding of perfumes and fragrances.
Uses at industrial sites	Industrial Use in Cleaning Agents and Maintenance Products Pharma application - chiral building block Manufacture of 1-Phenylethanol and other substances using 1-Phenylethanol Intermediate
Uses by professional workers	Professional Use in Cleaning Agents and Maintenance Products Professional Use of Cosmetic Products
Consumer Uses	Consumer Use in Cleaning Agents and Maintenance Products (incl. Air Care Products) Consumer Use of Cosmetic Products & Pharmaceuticals
Article service life	Service Life of Scented Articles

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[2]	
☐ 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)

[2] 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

The *in vitro* available data (gene mutation positive and Chromosome aberration positive in presence of S9 in an NTP study) suggest a genotoxic potential of 1-phenylethanol. On the other hand a new gene mutation study shows negative results in presence and absence of methabolic activation (data owner). Therefore, a definitive assessment of *in vitro* genotoxic potential trough the evaluation of the existing and new study (the original report) is necessary. Moreover the available *in vivo* micreonucleus study is considered inconclusive and no other study in compliance with the OECD GL are available. Then a substance evaluation is the most appropriate process to evaluate all the available data (done in compliance or not with the OECD GL) and definitively elucidate the identified concern on mutagenicity.

1-phenylethanol was tested for carcinogenicity by oral route in mice and rats in a two year study of the NTP. The conclusion is: some evidence of carcinogenic activity for male rats, as shown by increased incidences of renal tubular cell adenomas and adenomas or adenocarcinomas (combined); no evidence of carcinogenic activity was observed in female rats and in female and male mice. No other data are available.
1-phenylethanol is the major metabolite of ethylbenzene, a substance that causes increased tumor incidences in mice and in rat after inhalation exposure and classified by IARC as a possibly carcinogenic to humans. An Annex XV for harmonized classification was submitted by Germany, for this substance, in which the carcinogenicity was not been considered as part of the dossier. Therefore, a more in depth analysis of all the available information about the potential carcinogenic of the 1-phenylethanol is needed.

Additionally the substance has a wide dispersive use. If the substance is confirmed to be a genotoxic carcinogen this can affect the elaboration of the exposure scenarios and the definition of the RMMs.

Based on the available information there is a need to candidate the substance to the SEv process.

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 on ED potential	☐ Other (provide further details below)

A tiered approach will be adopted in order to elucidate the genotoxic potential of 1-phenylethanol and the appropriate *in vitro* studies will be requested.
The results of this assay will be used to orientate the further experimental strategy, including the possibility to request new data on somatic and germ cells or on carcinogenicity.

5.5 Potential follow-up and link to risk management

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

Pending on the results of the appropriate studies, a possible result of the SEv process could be a proposal for harmonized classification for mutagenicity and/or carcinogenicity .