Justification for the selection of a substance for CoRAP inclusion

Substance Name (Public Name):	pentan-1-ol
Chemical Group:	mono constituent organic substance, C5H12O
EC Number:	200-752-1
CAS Number:	71-41-0
Submitted by:	Environmental Protection Agency of Lithuania
Date:	17/03/2015

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 1: Substance identity

EC name:	pentan-1-ol
IUPAC name:	pentan-1-ol
Index number in Annex VI of the CLP Regulation	603-200-00-1
Molecular formula:	C5H12O
Molecular weight or molecular weight range:	88.1482
Synonyms/Trade names:	*1-pentanol, n-Pentanol, 1-Pentanol (9CI), Amyl alcohol, n-Amyl alcohol, Amylol, n-Butyl carbinol, Pentyl alcohol (8CI), Pentanol, n-Pentyl alcohol, 1-Pentyl alcohol, n-Pentan-1-ol, Butyl carbinol.*

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

Structural formula:

1.2 Similar substances/grouping possibilities

2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

Table 2: 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)		
603-200-00-1	1-pentanol	200-752-1	71-41-0	Flam. Liq. 3 Skin Irrit. 2 Acute Tox. 4 STOT SE 3	H226 H315 H332 H335		

2.2 Self classification

- In the registration (*if substance is in Annex VI, compare with that and include deviations)*

  Flam. Liquid 3 H226: Flammable liquid and vapour.

  Acute Tox. 4 H332: Harmful if inhaled.

  Skin Irrit. 2 H315: Causes skin irritation.

  Eye Irrit. 2A H319: Causes serious eye irritation.

  STOT Single Exp. 3 H335: May cause respiratory irritation.

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

  Eye Dam. 1 H318 Causes serious eye damage

2.3 Proposal for Harmonised Classification in Annex VI of the CLP

3 INFORMATION ON AGGREGATED TONNAGE AND USES

From ECHA 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
☒ 100+ tpa		☐ Confidential

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

4 OTHER COMPLETED/ONGOING REGULATORY PROCESSES THAT MAY AFFECT SUITABILITY FOR SUBSTANCE EVALUATION

☐ Compliance check, Final decision	☐ 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 ; Biocidal Product Regulation (Regulation (EU) 528/2012)
☐ Annex XIV (Authorisation)	☐ Other (provide further details below)
☐ Annex XVII (Restriction)	

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)

Existing data supports possible hazard for the eyes. New classification Causes serious eye irritation H319 should be evaluated.

Taking into account that substance is classified as Acute toxicity (inhaled) and STOT SE 3 (respiratory system) it would be good to obtain more data on sensitization by inhalation. Data provided in dossier on exposure related observations in humans is not sufficient.

According to CSR, some uses have RCRs close to 1 (e.g. Use in Coatings (Consumer) PC1 short-term, long-term; Use in Cleaning Agents (Consumer) PC32 long-term and etc.).

[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 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)

Existing data supports possible hazard for the eyes. New classification Causes serious eye irritation H319 should be considered.

Taking into account that Substance is classified as Acute toxicity (inhaled) and STOT SE 3 (respiratory system) it would be good to obtain more data on sensitization by inhalation. Data provided in dossier on exposure related observations in humans is not sufficient.

5.5 Potential follow-up and link to risk management

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

Update guidance on safe use should be considered