SUBSTANCE EVALUATION CONCLUSION

as required by REACH Article 48

and

EVALUATION REPORT

for

Pentan-1-ol

EC No 200-752-1

CAS No 71-41-0

Evaluating Member State(s): Lithuania

Dated: March 2017

Template Version 2.1
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Evaluating Member State Competent Authority

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Year of evaluation in CoRAP: 2016

Lithuania concluded the evaluation in March 2017 without any further need to ask more information from the registrants under Article 46(1) decision.

Further information on registered substances here:

http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances

Foreword

Substance evaluation is an evaluation process under REACH Regulation (EC) No. 1907/2006. Under this process the Member States perform the evaluation and ECHA secretariat coordinates the work. The Community rolling action plan (CoRAP) of substances subject to evaluation, is updated and published annually on the ECHA web site[1].

Substance evaluation is a concern driven process, which aims to clarify whether a substance constitutes a risk to human health or the environment. Member States evaluate assigned substances in the CoRAP with the objective to clarify the potential concern and, if necessary, to request further information from the registrant(s) concerning the substance. If the evaluating Member State concludes that no further information needs to be requested, the substance evaluation is completed. If additional information is required, this is sought by the evaluating Member State. The evaluating Member State then draws conclusions on how to use the existing and obtained information for the safe use of the substance.

This Conclusion document, as required by Article 48 of the REACH Regulation, provides the final outcome of the Substance Evaluation carried out by the evaluating Member State. The document consists of two parts i.e. A) the conclusion and B) the evaluation report. In the conclusion part A, the evaluating Member State considers how the information on the substance can be used for the purposes of regulatory risk management such as identification of substances of very high concern (SVHC), restriction and/or classification and labelling. In the evaluation report part B the document provides explanation how the evaluating Member State assessed and drew the conclusions from the information available.

With this Conclusion document the substance evaluation process is finished and the Commission, the Registrant(s) of the substance and the Competent Authorities of the other Member States are informed of the considerations of the evaluating Member State. In case the evaluating Member State proposes further regulatory risk management measures, this document shall not be considered initiating those other measures or processes. Further analyses may need to be performed which may change the proposed regulatory measures in this document. Since this document only reflects the views of the evaluating Member State, it does not preclude other Member States or the European Commission from initiating regulatory risk management measures which they deem appropriate.

[1] http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan

Contents

Part A. Conclusion

1. CONCERN(S) SUBJECT TO EVALUATION

Pentan-1-ol was originally selected for substance evaluation in order to clarify concerns about:

- suspected sensitiser;
- eye damage;
- wide dispersive use;
- consumer use;
- exposure of workers;
- high RCR.

During the evaluation no further concerns were identified.

2. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

There are no other ongoing processes.

3. CONCLUSION OF SUBSTANCE EVALUATION

The evaluation of the available information on the substance has led the evaluating Member State to the following conclusions, as summarised in the table below.

Table 1

CONCLUSION OF SUBSTANCE EVALUATION Conclusions	Tick box
Need for follow-up regulatory action at EU level	X
Harmonised Classification and Labelling	X
Identification as SVHC (authorisation)	
Restrictions	
Other EU-wide measures	
No need for regulatory follow-up action at EU level	

4. FOLLOW-UP AT EU LEVEL

4.1. Need for follow-up regulatory action at EU level

4.1.1. Harmonised Classification and Labelling

According to the evaluation of the eMSCA, the registered substance fulfills the criteria for classification as causing eye damage. The eMSCA therefore suggests to update the existing

entry in Annex VI of Regulation (EC) 1272/2008 in order to cover eye damage end-point as specified below.

4.1.2. Identification as a substance of very high concern, SVHC (first step towards authorisation)

Not applicable.

4.1.3. Restriction

Not applicable.

4.1.4. Other EU-wide regulatory risk management measures

Not applicable.

5. CURRENTLY NO FOLLOW-UP FORESEEN AT EU LEVEL

5.1. No need for regulatory follow-up at EU level

Not applicable.

5.2. Other actions

Not applicable.

6. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS (IF NECESSARY)

Indication of a tentative plan is not a formal commitment by the evaluating Member State. A commitment to prepare a REACH Annex XV dossier (SVHC, restrictions) and/or Annex VI dossier of Regulation (EC) 1272/2008 should be made via the Registry of Intentions.

Table 2

FOLLOW-UP		
Follow-up action	**Date for intention**	**Actor**
CLP dossier for updating the entry in Annex VI of the CLP in order to cover eye damage end-point	Not decided yet. In consideration of resource constraints, not prioritised for action by the evaluating MS for the time being.	*To be defined.*

Part B. Substance evaluation

7. EVALUATION REPORT

7.1. Overview of the substance evaluation performed

Pentan-1-ol was originally selected for substance evaluation in order to clarify concerns about:

- Human health: suspected sensitiser; eye damage
- Exposure: wide dispersive use, consumer use, exposure of workers, high RCR.

Human health:

The concern for sensitization by inhalation originates from classification of pentan-1-ol as Acute Tox. (inhalation) and STOT SE 3 (respiration). Deviation of pentan-1-ol harmonised classification and self classifications with regard to possible hazard for eyes should be clarified.

Exposure:

Some uses have close to 1 values of Risk Characterisation Ratio (RCR).

During the evaluation no further concerns were identified. For the sake of completeness, other human health endpoints, such as repeated dose toxicity, mutagenicity, carcinogenicity and toxicity to reproduction, were checked as well, but not in detail.

Table 3

EVALUATED ENDPOINTS	
Endpoint evaluated	**Outcome/conclusion**
Respiratory sensitisation	Based on currently available information, concern not confirmed.
Eye damage	Concern confirmed. Harmonised classification to be updated to include eye damage / irritation.
Exposure scenarios and risk characterisation for workers, professionals and consumers	Concern not substantiated. Operational conditions and risk management measures are adequately described for all the exposure scenarios. Evaluation of the available information shows that RCRs for all scenarios are below 1 and the risks are adequately managed for all scenarios. No additional risk management measures required at the moment.

7.2. Procedure

Pursuant to Article 44(2) of the REACH Regulation, Pentan-1-ol was included on the Community rolling action plan (CoRAP) for evaluation in 2016. The Competent Authority of Lithuania was appointed to carry out the evaluation. The substance evaluation commenced on 22 March 2016.

The evaluation was targeted to human health hazards and exposure. Although not the main focus of the evaluation, an assessment of the environmental hazard was also undertaken.

The main source of information for the evaluation was the original data / information submitted within REACH registration (IUCLID dossiers, Chemical Safety Reports (CSRs). The Lead Registrant updated the registration dossier on 5 August 2016. This update was taken into account during the evaluation.

The information in the registration dossier was based to a large extent on read-across from studies conducted with 2- and 3-methyl butanol isomers. This read-across is based on the hypothesis that the compounds grouped in the category "pentanols" have the same type of effects based on common underlying mechanisms. The read-across hypothesis is scientifically acceptable in the point of view of eMSCA.

Based on the evaluation of the available data and informal consultation with the Lead Registrant, the eMSCA concluded that there was no need to request futher information in order to clarify the initial concerns.

The results of the evaluation are documented in this report.

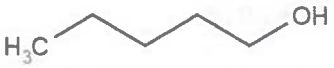
7.3. Identity of the substance

Table 4

SUBSTANCE IDENTITY	
Public name:	Pentan-1-ol
EC number:	200-752-1
CAS number:	71-41-0
Index number in Annex VI of the CLP Regulation:	603-200-00-1
Molecular formula:	C5H12O
Molecular weight range:	88.1482
Synonyms:	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:



7.4. Physico-chemical properties

Table 5

OVERVIEW OF PHYSICOCHEMICAL PROPERTIES	
Property	**Value**
Physical state at 20°C and 101.3 kPa	Liquid
Vapour pressure	2.04 hPa at 20 °C
Water solubility	21.0 g/L at 20 °C
Partition coefficient n-octanol/water (Log Kow)	1.33 - 1.53 at 20 - 25 °C
Flammability	Flammable liquid
Explosive properties	Non explosive
Oxidising properties	No oxidising properties
Granulometry	Not applicable
Stability in organic solvents and identity of relevant degradation products	Not applicable
Dissociation constant	16.26 pKa
Melting / freezing point	-78.6 °C at 1013 hPa
Boiling point	138 °C at 1013.25 hPa
Relative density	0.81 at 20 °C
Flash point	47 °C at 1013.25 hPa
Autoflammability / self-ignition temperature	300 °C at 1004 to 1008 hPa
Viscosity	3.441 mPa s at 24.9°C

7.5. Manufacture and uses

7.5.1. Quantities

Table 6

AGGREGATED TONNAGE (PER YEAR)				
☐ 1 – 10 t	☐ 10 – 100 t	☒ 100 – 1000 t	☐ 1000- 10,000 t	☐ 10,000-50,000 t

☐ 50,000 – 100,000 t	☐ 100,000 – 500,000 t	☐ 500,000 – 1000,000 t	☐ > 1000,000 t	☐ Confidential

7.5.2. Overview of uses

Table 7

USES	Use(s)
Uses as intermediate	Use in production of another chemicals at industrial site.
Formulation	Formulation & (re)packing of substances and mixtures; Distribution of substances.
Uses at industrial sites	Manufacture; Distribution of substances; Formulation & (re)packing of substances and mixtures; Use in coatings, cleaning agents, lubricants, as binders and release agents; Use as intermediate; Use in laboratories; Use in polymer processing.
Uses by professional workers	Use in coatings, cleaning agents, lubricants, as binders and release agents; Use in laboratories; Use in polymer processing; Use in agrochemicals.
Consumer Uses	Use in coatings (adhesives, sealants, polishes and wax blends, finger paints, anti-freeze and de-icing products, etc.); Use in cleaning agents (air care product, finger paints, etc.) Use in lubricants; Agrochemical use; Consumer application (fragrances, perfumes, cosmetics, personal care products, etc.).
Article service life	-

7.6. Classification and Labelling

7.6.1. Harmonised Classification (Annex VI of CLP)

Table 8

HARMONISED CLASSIFICATION ACCORDING TO ANNEX VI OF CLP REGULATION (REGULATION (EC) 1272/2008)						
Index No	International Chemical Identification	EC No	CAS No	Classification	Spec. Conc. Limits, M-factors	Notes
				Hazard Class and	Hazard statement code(s)	

				Category 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		

7.6.2. Self-classification

In the registrations:

In addition to harmonized classification (Annex VI of Regulation (EC) 1272/2008), registrations include additionally classification as Eye damage 1 (H318 Causes serious eye damage).

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

- Eye Dam.1, H318 Causes serious eye damage;
- Eye Irrit.2, H319 Causes serious eye irritation;
- Skin.Corr.1C, H314 Causes severe eye burns and eye damage.

7.7. Environmental fate properties

Not evaluated as not relevant for this substance evaluation.

7.8. Environmental hazard assessment

Not evaluated as not relevant for this substance evaluation.

7.9. Human Health hazard assessment

The information of pentan-1-ol human health hazard assessment was based on read-across approach. This read-across is based on the hypothesis that the compounds grouped in the category "pentanols" have the same type of effects based on common underlying mechanisms. The read-across hypothesis is scientifically acceptable in the point of view of eMSCA.

7.9.1. Toxicokinetics

A number of available studies presented by registrants showed that pentan-1-ol is metabolised rapidly and to high extent. The main metabolic pathway is via oxidation by alcohol dehydrogenase to aldehydes and subsequently to the acids. Additionally, oxidation of pentanols via hepatic CYP P450 enzymes and glucuronidation were observed. The metabolised products are renally excreted. No bioaccumulation potential was observed.

7.9.2. Acute toxicity and Corrosion/Irritation

Acute toxicity

According to available studies on acute oral and dermal toxicity, LD50 values were above 2000 mg/kg. Even more, no studies have been identified confirming a harmonised classification according to Annex VI of CLP Regulation (No 1272/2008) as Acute Tox. 4* with H332 (Harmful if inhaled): no mortality was observed in acute inhalation toxicity studies conducted with vapours of pentan-1-ol or the read across substances. One category member of pentanols was tested as an aerosol, revealing an LC50 value below 14 mg/L in mice, but above 14 mg/L in rats and guinea pigs, which is well above the upper limit for

classification. Nevertheless, the eMSCA does not consider this to be conclusive enough to propose a change of the current harmonised classification.

Corrosion / irritation

Skin:

A number of studies on skin irritation in animals and exposure-related observations in humans showed that the substance is not necessarily skin irritating according to the criteria of CLP Regulation (No 1272/2008). Nevertheless, pentan-1-ol is classified as skin irritant category 2 according to Annex VI of CLP Regulation (No 1272/2008). The registrants expressed the opinion that this classification shall be retained in order to ensure the safety of workers and general population. The eMSCA supports this opinion.

Eye:

Harmonised classification of the substance does not include classification for eye hazard, but it is included in the majority of self-classifications in the C&L Inventory. The registrants also propose classification of pentan-1-ol into eye damage category 1 under CLP Regulation (No 1272/2008) with H318 (Causes serious eye damage).

A number of reliable studies with non-human information (rabbits) were presented by the registrants. The studies were performed with test substance itself or with its structural analogues. Effects observed were not reversible within the observation period of 8 days and it cannot be proven that the effects would have been fully reversible within 21 days, what is specified as an observation period according to the test methods and classification criteria. Based on these results, the substance needs to be considered corrosive to eyes, even though the results might be over-predictive due to the mentioned differences in observation period. The eMSCA supports registrants proposal for pentan-1-ol classification with regard to eye hazard.

Respiratory irritation:

The presented experimental data endorsed classification of pentan-1-ol as respiratory tract irritant according to Annex VI of CLP Regulation (No 1272/2008). The eMSCA supports the conclusion.

7.9.3. Sensitisation

Skin sensitisation

A study on skin sensitisation conducted with another member of the category "pentanols", and four case reports presenting the skin sensitisation potential of the test substance itself have been considered in the assessment.

Data are available in a human maximization test conducted with 3-methylbutan-1-ol (Kligman, 1976). In this study, the sensitization to skin was evaluated in 25 human volunteers, who received an application of 8% 3-methylbutan-1-ol in a 2.5% aqueous sodium lauryl sulphate solution. The substance was applied via an occlusive patch test to the same site on the volar forearm or back of all subjects for five alternate-day 48 hour periods. Evaluation of the skin sites revealed that none of the 25 individuals showed any signs of sensitisation.

Some positive skin reactions for pentan-1-ol were found in test persons as described in case reports, but the human volunteers of the tests had been exhibiting dermatitis or skin reactions towards other alcohols before. Therefore the eMSCA supports registrants opinion

and confirms a conclusion that pentan-1-ol does not require a classification as skin sensitiser.

Respiratory sensitisation

The concern for respiratory sensitisation was based on pentan-1-ol acute toxicity if inhaled and its ability to cause respiratory irritation. Data on sensitisation by inhalation were not available as not identified neither by the registrants, nor by eMSCA.

It needs to be noted that respiratory sensitisation is not a standard information requirement under REACH. Presently there are neither scientifically valid nor adopted *in vitro* tests available to assess respiratory sensitisation. Although a number of *in vivo* test protocols have been published to detect respiratory allergens of low molecular weight, none of these are validated nor are these widely accepted (ECHA, 2016).

There is no structural alert suggesting respiratory sensitisation potential of pentan-1-ol (OECD QSAR Toolbox (ver. 3.4). The substance has a wide dispersive use, and the absence of reports on observed human respiratory reactions (by registered substance or by other members of the category) also suggests that pentan-1-ol might not be a respiratory sensitiser.

In conclusion, the available data are sufficient to conclude that pentan-1-ol is not a sensitiser. Therefore the initial concern does not persist.

7.9.4. Repeated dose toxicity

In order to achieve completeness repeated dose toxicity was checked as well but not in detail. There are available studies on repeated dose toxicity after oral administration, which demonstrated that the substance does not require classification for repeated dose toxicity.

7.9.5. Mutagenicity

In the interest of completeness of the assessment, mutagenicity of pentan-1-ol was assesed but not comprehensively. According to the presented *in vivo* study (with another member of the category of pentanols) and a number of *in vitro* studies, which are considered reliable and suitable for classification purposes under Regulation (EC) No.1272/2008 (CLP), no positive result has been observed in any of the assays. The registrants concluded that the substance is not classified for genetic toxicity. Based on the available information, the eMSCA can agree with this conclusion.

7.9.6. Carcinogenicity

In order to maintain completeness carcinogenicity of pentan-1-ol was checked as well but not in detail. Assessment of carcinogenicity was based on available non-human information (rat and mouse), and complemented by *in vitro* and *in vivo* genotoxicity and repeated toxicity results. The registrants concluded that carcinogenicity is not an endpoint of concern and the substance is not classified for carcinogenicity. Based on the available information, the eMSCA can agree with this conclusion.

7.9.7. Toxicity to reproduction (effects on fertility and developmental toxicity)

For the sake of completeness of the evaluation toxicity to reproduction was checked as well, but not in detail. Registrants have identified a number of studies with non-human information. The given information is sufficient to evaluate whether there is an imminent concern for fertility and developmental toxicity. The arguments to waive the two generation study is convincing. Pentan-1-ol and its structural analogue 3-methylbutan-1-ol were tested in two 90d repeated dose studies (Butterworth et al. 1978[redacted], in a Combined Repeated-Dose / Reproductive Developmental Toxicity study according to OECD

TG 422 and in prenatal developmental studies in rats and rabbits. None of these studies showed any concern regarding reproductive toxicity of pentan-1-ol or 3-methylbutan-1-ol. Thus, further studies are not requested as it is not necessary for this substance evaluation.

No indications of effects on fertility or development toxicity were seen. As a result, the registrants concluded that there is no reason to classify pentan-1-ol for toxicity to reproduction or development toxicity. Based on the available information, the eMSCA can agree with this conclusion.

7.9.8. Hazard assessment of physico-chemical properties

Pentan-1-ol is classified as flammable liquid. No other physico-chemical properties immediately impacting human health have been identified, and the eMSCA does not see any further concern here.

Explosivity: There are no chemical groups associated with explosive properties present in the molecule. Not explosive.

Flammability: Flammable liquid. Flash point 47 °C at 1013.25 hPa (ISO 13736:1997); 49.5 °C at 1013.25 hPa (German Standard DIN 51 755).

Oxidising potential: No oxidising properties.

7.9.9. Selection of the critical DNEL(s)/DMEL(s) and/or qualitative/semi-quantitative descriptors for critical health effects

The eMSCA concluded that DNEL(s) provided by the registrants for the exposure assessment are acceptable.

7.9.10. Conclusions of the human health hazard assessment and related classification and labelling

Based on the available data, it is evident that pentan-1-ol requires a classification for its eye damage / irritation. Currently the eMSCA supports the opinion of the registrants to classify the substance as eye damage category 1 with H318 (Causes serious eye damage). At present the studies available had a shorter observation period than 21 days.

Classification of pentan-1-ol as a respiratory sensitiser is not proposed, as evidence for such a classification is not available. There is no structural alert suggesting respiratory sensitisation potential of pentan-1-ol, and the absence of reports on observed human respiratory reactions in a view of widespread use of the substance also does not suggest pentan-1-ol being a respiratory sensitiser.

Although classification of pentan-1-ol as harmful if inhaled and as causing skin irritation has not been clearly confirmed by the studies available, it is considered that for precautionary reasons the existing harmonised classification must be retained.

7.10. Assessment of endocrine disrupting (ED) properties

Not evaluated.

7.11. PBT and VPVB assessment

Not relevant for this substance evaluation.

7.12. Exposure assessment

7.12.1. Human health

The Registrant generated exposure scenarios and made exposure assessment for manufacture, formulation and all the identified end uses using EasyTRA model. Exposure scenarios for consumers have been addressed using ConsExpo.

1) Manufacture
2) Distribution of substances
3) Formulation and (re)packing of substances and mixtures
4) Uses in coatings
5) Use in cleaning agents
6) Lubricants
7) Use as binders and release agents
8) Intermediate
9) Use in laboratories
10) Polymer processing
11) Uses in coatings (professional and consumer)
12) Use in cleaning agents (professional and consumer)
13) Lubricants (professional and consumer)
14) Use as binders and release agents (professional)
15) Use in laboratories (professional)
16) Polymer processing (professional)
17) Use in agrochemicals (professional)
18) Agrochemical use (consumer)
19) Consumer application

As pentan-1-ol is classified for skin irritation Cat. 2 and for respiratory irritation STOT single exposure Cat. 3 according to 1272/2008/EC, effects on the skin and eyes have been assessed qualitatively.

In the eMSCA opinion the registrant has adequately described the operational conditions and risk management measures for all the scenarios.

7.12.1.1. *Worker*

The highest exposure value was estimated for workers for inhalation long-term local route for the lubricants professional end use (PROC 17: Lubrication at high energy conditions and in partly open process). Nevertheless the level of exposure is at an acceptable level. In the eMSCA's opinion no additional risk management measures are required at the moment.

7.12.1.2. *Consumer*

The highest exposure value was estimated for consumers inhalation short-term local route for the uses in coatings (PC1: Uses in coatings). Nevertheless the level of exposure is at an acceptable level. In the eMSCA's opinion no additional risk management measures are required at the moment.

7.12.2. Environment

The environmental exposure assessment was not addressed under substance evaluation.

7.12.3. Combined exposure assessment

7.13. Risk characterisation

Risk characterisation ratio, although being close to, but still did not exceed 1 in the worst case scenarious, calculated with the maximum exposures. Therefore under normal conditions, which prevail, the risk is not expected to be unacceptable.

7.14. References

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The report and recommendations of ECVAM Workshop 60. Altern Lab Anim 35:243-65.

7.15. Abbreviations

DNEL	Derived no-effect level
eMSCA	Evaluating Member State Competent Authority
LC50	Median lethal concentration. The concentration causing 50 % lethality
OECD	Organisation for Economic Cooperation and Development
PC	Chemical product categories
PROC	Process category
QSAR	Quantitative Structure-Activity Relationship models

RCR	Risk characterisation ratio
SVHC	Substances of very high concern
STOT SE	Specific target organ toxicity, single exposure