SUBSTANCE EVALUATION CONCLUSION

as required by REACH Article 48

and

EVALUATION REPORT

for

Decan-1-ol

EC No 203-956-9

CAS No 112-30-1

Evaluating Member State(s): Italy

Dated: 5 May 2017

Evaluating Member State Competent Authority

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Year of evaluation in CoRAP: 2012

Member State concluded the evaluation 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

DISCLAIMER

This document has been prepared by the evaluating Member State as a part of the substance evaluation process under the REACH Regulation (EC) No 1907/2006. The information and views set out in this document are those of the author and do not necessarily reflect the position or opinion of the European Chemicals Agency or other Member States. The Agency does not guarantee the accuracy of the information included in the document. Neither the Agency nor the evaluating Member State nor any person acting on either of their behalves may be held liable for the use which may be made of the information contained therein. Statements made or information contained in the document are without prejudice to any further regulatory work that the Agency or Member States may initiate at a later stage.

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 Registrants 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 Registrants 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

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Part A. Conclusion

1. CONCERN(S) SUBJECT TO EVALUATION

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

- Environment/Suspected long term effects on the environment;
- Exposure/Wide dispersive use;
- High aggreagted tonnage;
- Potential to contaminate surface and groundwater.

During the evaluation also other concerns were identified. The additional concerns were:

- No adequate justification by the Registrants for not deriving DNEL/DMEL;
- No adequate justification by the Registrants for the use of a dermal absorption factor of 10%;
- Eye and skin irritation, STOT SE H355 (Respiratory tract) and STOT SE 2 H371 (Central Nervous) endpoints with self-classification or CLP notifications for which an harmonized classification does not exist.

2. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

The 1-decanol is an active substance under EFSA evaluation process, in accordance with Directive 91/414/EEC and with Regulation (EC) No 1107/2009. (see EFSA's scientific views and conclusions: *Outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for 1-decanol in light of confirmatory data*- EFSA, April 2016).

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	
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

Based on information available in the CSR and registration dossiers, the eMSCA supports the human health self-classification as Eye Irrit. 2 H319 and the notified classification as Skin Irrit. 2 H315, STOT SE 3 H335 (Respiratory tract) and STOT SE 2 H371 (Central Nervous System) as further explained in the SEV report in Part B. Therefore an harmonized classification of the substance is envisaged as a follow-up at EU level for these human health endpoints.

Based on information available in the CSR and registration dossiers, the eMSCA supports the environmental self-classification as: Chronic toxicity, Cat. 3 H412 (see Section 7.8.5) as further explained in the SEV report in Part B. Therefore an harmonized environmental classification of the substance is envisaged as a follow-up at EU level for this environmental endpoint.

eMSCA recommends Registrants to refine risk assessment and risk management measures for some specific uses/scenarios in order to ensure safe RCRs, currently close to 1 (see Part B, section 7.9.9, section 7.13, section 7.1-table 4 and section 7.8.4). The outcome of the recent EFSA evaluation should be taken into account.

5. CURRENTLY NO FOLLOW-UP FORESEEN AT EU LEVEL

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

Table 2

REASON FOR REMOVED CONCERN **The concern could be removed because**	**Tick box**
Clarification of hazard properties/exposure -Environmental hazard properties: the Registrants provided the outcome of the Long-term toxicity test on fish clarifying the concern on environmental compartments as requested by ECHA - Environmental exposure: the Registrants provided all elements requested by ECHA, in particular by providing information referred specifically for 1-decanol, without using the category approach.	X
Actions by the Registrants to ensure safety, as reflected in the registration dossiers (e.g. change in supported uses, applied risk management measures, etc.)	

5.2. Other actions

Not applicable.

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

A harmonized classification of the substance is envisaged as a follow-up at EU level for indicated human health and environmental endpoints.

Part B. Substance evaluation

7. EVALUATION REPORT

The Substance evaluation has started on March 2012.

Since EFSA hypothesized an environmental classification N; R50/53 (very toxic to aquatic organisms/May cause long-term adverse effects in the aquatic environment) and the substance has high potential to contaminate surface and groundwater, on the basis of the application of EURAM index (according to the COMMPS procedure), and of the methodology proposed by Department of Pesticide Regulation (DPR) of California Environmental Protection Agency, the eMSCA decided to conduct the evaluation of the environmental endpoints.

In the course of the evaluation of the substance, the eMSCA noted that a default dermal absorption of 10% has been used by the Registrants to calculate human systemic exposures. In the opinion of the eMSCA the justification provided in the registration dossier for using this absorption factor was not scientifically based.

The Registrants has updated the IUCLID dossier with regard on basic toxicokinetic and dermal absorption.

In the course of the evaluation, the eMSCA noted that despite the evidence of adverse effects in several studies, the derivation of DNELs was not performed by the Registrants. Thus, in consideration of the ECHA guideline on information requirements, the eMSCA requested the Registrants to derive DNEL(s)/DMEL(S) for systemic effects.

Moreover since the substance is a skin irritant, the eMSCA requested the Registrants to derive DNEL/DMEL for local effects (skin irritation).

7.1. Overview of the substance evaluation performed

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

- Environment/Suspected long term effects on the environment;
- Exposure/Wide dispersive use;
- High aggreagted tonnage;
- Potential to contaminate surface and groundwater.

During the evaluation also other concerns were identified. The additional concerns were:

- No adequate justification by the Registrants for not deriving DNEL/DMEL;
- No adequate justification by the Registrants for the use of a dermal absorption factor of 10%.

Table 3

EVALUATED ENDPOINTS	
Endpoint evaluated	**Outcome/conclusion**
Endpoint 1 Risk assessment and request to derive DNEL/DMEL for systemic and local effects.	Request fulfilled by the Registrants. No further action is needed. However eMSCA is of the opinion that DNEL for workers inhalation long-term systemic effects, general population inhalation long-term systemic effects and general population oral long-term systemic effects should be calculated in consideration of an additional

	assessment factor of 2 proposed in order to take into account the possible absorption differences in route-to-route extrapolation (see section 7.9.9 and 7.13).
Endpoint 2 Justification for assuming a default dermal absorption value of 10% and resulting risk characterization for human health	Request fulfilled by the Registrants. The justification provided is considered appropriate. No further action is needed.
Endpoint 3 Adsorption/desorption	Request fulfilled by the Registrants. The result is considered to be reliable and acceptable for use in environmental exposure modelling. No further action is needed.
Endpoint 4 Long-term toxicity on fish	Request fulfilled by the Registrants. Submitted data are sufficient and suitable for CSA as well as for a definitive assessment of this endpoint. No further action is needed
Endpoint 5 Justification for deviating in use of default values in PNEC derivation for aquatic and terrestrial compartment	Request fulfilled by the Registrants. No further action is needed. Provided Justifications to apply A.F.=5 instead of 10 are considered not scientifically acceptable by eMSCA (see discussion in section 7.8.4).
Endpoint 6 Information on environmental Exposure and risk characterisation	Requests fulfilled by the Registrants. No further action is needed.
Endpoint 7 Information on exposure of soil compartment	Requests fulfilled by the Registrants. No further action is needed. The Registrants provided specific information on exposure of soil compartment. For ES 1 "Manufacture" and ES7 "Process chemical (paper/textiles industries) and ES8 "Use of cleaning products in industrial settings" , the derived RCRs for the soil compartment are close to 1. (see discussion in section 7.12 and 7.13)
Endpoint 8 Information on waste	Requests fulfilled by the Registrants. No further action is needed

7.2. Procedure

The initial finding of the evaluation induced the eMSCA to perform a complete evaluation of the substance on both human health and environment.

Therefore the eMSCA considered that further information was required to clarify the identified concerns and prepared a draft decision pursuant to Article 46(1) of the REACH Regulation to request further information.

The eMSCA submitted the draft decision to ECHA on 28 February 2013.

On 4 April 2013 ECHA sent the draft decision to the Registrants and invited them pursuant to Article 50(1) of the REACH Regulation to provide comments within 30 days of the receipt of the draft decision.

By 6 May 2013 ECHA received comments from Registrants of which it informed the eMSCA without delay.

The eMSCA considered the Registrants' comments received and did amend Section III of the draft decision.

In accordance with Article 52(1) of the REACH Regulation, on 31 October 2013 the eMSCA notified the Competent Authorities of the other Member States and ECHA of its draft decision and invited them pursuant to Articles 52(2) and 51(2) of the REACH Regulation to submit proposals to amend the draft decision within 30 days.

Subsequently, two Competent Authorities of the Member States and ECHA submitted proposals for amendment to the draft decision.

On 5 December 2013 ECHA notified the Registrants of the proposal for amendment to the draft decision and invited them pursuant to Articles 52(2) and 51(5) of the REACH Regulation to provide comments on those proposals for amendment within 30 days of the receipt of the notification.

The eMSCA has reviewed the proposals for amendment received and where considered appropriate the draft decision has been amended accordingly.

By 7 January 2014 in accordance to Article 51(5), the Registrants provided comments on the proposal(s) for amendment. In addition, the Registrants provided comments on the draft decision. The Member State Committee took the comments on the proposal(s) for amendment of the Registrants into account. The Member State Committee did not take into account the Registrants' comments on the draft decision as they were not related to the proposal(s) for amendment made and are therefore considered outside the scope of Article 51(5).

A unanimous agreement of the Member State Committee on the draft decision was reached on 21 January 2014 in a written procedure launched on 10 January 2014. ECHA took the decision on 20 May 2014 pursuant to Article 51(6) of the REACH Regulation. Subsequently the Registrants provided the requested information.

7.3. Identity of the substance

Table 4

SUBSTANCE IDENTITY	
Public name:	Decan-1-ol
EC number:	203-956-9
CAS number:	112-30-1
Index number in Annex VI of the CLP Regulation:	
Molecular formula:	$C_{10}H_{22}O$
Molecular weight range:	
Synonyms:	

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, colourless
Vapour pressure	2.93 hPa, 91 °C
Water solubility	21.1 mg/L at 20 °C
Partition coefficient n-octanol/water (Log Kow)	4.5
Flammability	Data waiving: study scientifically unjustified
Explosive properties	Data waiving
Oxidising properties	Data waiving
Granulometry	Data waiving
Stability in organic solvents and identity of relevant degradation products	Data waiving
Dissociation constant	A dissociation constant value of 15.76 was obtained using an accepted calculation method. The result is considered to be reliable.

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

This substance is manufactured and/or imported in the European Economic Area in 10000 - 100000 tonnes per year.

This substance is used in the following products: fillers, putties, plasters, modelling clay, coating products, lubricants and greases, biocides, adhesives and sealants and non-metal-surface treatment products.

This substance is used in the following areas: building & construction work and mining. This substance is used for the manufacture of: chemicals, mineral products (e.g. plasters, cement), machinery and vehicles, furniture, rubber products and plastic products.

Release to the environment of this substance is likely to occur from industrial use: in processing aids at industrial sites and in the production of articles. Other release to the environment of this substance is likely to occur from: outdoor use and indoor use (e.g. machine wash liquids/detergents, automotive care products, paints and coating or adhesives, fragrances and air fresheners).

This substance can be found in products with material based on: stone, plaster, cement, glass or ceramic (e.g. dishes, pots/pans, food storage containers, construction and isolation material), plastic (e.g. food packaging and storage, toys, mobile phones), metal (e.g. cutlery, pots, toys, jewellery), paper (e.g. tissues, feminine hygiene products, nappies, books, magazines, wallpaper) and wood (e.g. floors, furniture, toys).

Table 7

USES	Use(s)
Uses as intermediate	Chemical synthesis
Formulation	Polymer processing, professional scenario Polymer processing, industrial scenario Use as an intermediate Formulation and (re)packing of long chain alcohols and mixtures Distribution
Uses at industrial sites	Process chemical (includes use in Paper and Textiles industries) Polymer processing (industrial) Use as binders and release agents (industrial) Use as an intermediate Use in Coatings (industrial) Mining chemicals Use of cleaning products in industrial setting (industrial) Road and construction applications Metalworking fluids/rolling oils (industrial) Distribution
Uses by professional workers	Use as binders and release agents (professional) Polymer processing (professional) Use in Coatings (professional) Road and construction applications Use in Agrochemicals, professional scenario Use of cleaning products in industrial setting (professional) Metalworking fluids/rolling oils (professional)
Consumer Uses	Use in cleaning agents (consumer) Use in Coatings (paints, inks, adhesives, polishes etc) (consumer)
Article service life	Road and construction applications

	Polymer processing (industrial and professional) Use as binders and release agents (industrial) Use in Coatings (paints, inks, adhesives, polishes etc) (consumer) Use as binders and release agents (professional) Use in Coatings (industrial and profesional)

7.6. Classification and Labelling

7.6.1. Harmonised Classification (Annex VI of CLP)

The substance is not currently listed on Annex VI of CLP Regulation ((EC) No 1272/2008).

7.6.2. Self-classification

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

Eye Irrit. 2	H319
Skin Irrit. 2	H315
Acute Tox. 3	H331
Acute Tox. 4	H332
Asp. Tox. 1	H304
STOT SE 3	H335 (Respiratory tract)
STOT SE 2	H371 (Central Nervous)
Repr. 2	H361
Aquatic Chronic 2	H411
Aquatic Chronic 3	H412
Aquatic Acute 1	H400

7.7. Environmental fate properties

The test substance 1-decanol is relatively volatile and it has a solubility of 21.1 mg/l.
This registered substance is readily biodegradable (see section 7.7.1) and available information suggests that does not bioaccumulate (see section 7.7.2).
Moreover, based on tests with four soil samples and one sludge sample (OECD 106, batch equilibrium method), a Koc value of 1460 (logkoc= 3.12) was obtained (see section 7.7.2).

7.7.1. Degradation

Concerning abiotic degradation the Registrants indicated that the substance has no hydrolysable structural features and would be expected to be stable in water. Oxidation would not be expected under normal environmental conditions.
A half-life of 25.1 h for photodegradation by hydroxyl radicals in the air is estimated.
Concerning biotic degradation the Registrants provided the following studies:

- a reliable study (P&G, 2009), conducted according to an appropriate test protocol (OECD 301B) determined the substance to be readily biodegradable (74.6% CO2 evolution in 28 days), meeting the ten day window;
- a second reliable study (Richterich, 2002), conducted according to an appropriate test protocol (OECD 301D determined the substance to be readily biodegradable (88% DOC removal in 30 days), meeting the ten day window.

The Registrants concluded that the substance is readily biodegradable and based on the available information, the eMSCA can support this conclusion.

Concerning water and sediment simulation tests the Registrants proposed a data waiving. In accordance with Column 2 of REACH Annex IX, the simulation test on ultimate degradation in surface water and the sediment simulation test (required in Sections 9.2.1.2 and 9.2.1.4 respectively) do not need to be conducted as the substance is readily biodegradable, the eMSCA can support this conclusion.
The Registrants proposed a data waiving also for the soil simulation test. In accordance with Column 2 of REACH Annex IX, the full soil simulation test does not need to be conducted as the substance is readily biodegradable, and has been shown to be very rapidly degraded in non sterilised standard soils as part of method development for the soil adsorption study; the eMSCA can support this conclusion.

7.7.2. Environmental distribution

Concerning the adsorption/desorption the Registrants proposed a recent and reliable study of adsorption and desorption (2015) using the batch equilibrium method (in compliance with OECD 106) on the registered substance decan-1-ol. Based on tests with four soil samples and one sludge sample, the Koc value on average was 1460 (logkoc= 3.12). The result is considered to be reliable and acceptable for use in environmental exposure modelling.

For the determination of environmental distribution of the registered substance the Registrants proposed two models:

- The 1997 Level I model implemented as the EQC program.
- The 1999 Level III model, available on the Canadian government web site.

The Level I model results for decan-1 -ol show that upon equal release to the air, water and soil compartments, the majority of substance will partition to soil (92.5%) with low levels in air (2.5%), water (2.8%) and sediments (2.1%).

The Level III model results for decan-1-ol show that releases originally passing to air will tend to remain airborne (74%) with significant deposition to soil (22%); releases via water will largely remain in water (85%) with some adsorption to sediment (14%); releases via soil will remain in soil (>99%). The eMSCA can support these conclusions.

7.7.3. Bioaccumulation

Concerning Bioaccumulation the Registrants concluded that no reliable guideline-standard measured bioconcentration studies are available for decan-1-ol. The rapid biodegradation of the substance, combined with evidence of rapid metabolism in fish, mammals and micro-organisms (Mankura (1987)) suggest that it is unlikely that bioaccumulation would be seen in studies. Moreover, A BCF value of 20 has been calculated using SRC BCFBAF v3.01 (2010). All these considerations suggest that the registered substance does not bioaccumulate.

The Registrants concluded the substance is not bioaccumulative and based on the available information, the eMSCA can support this conclusion.

7.8. Environmental hazard assessment

7.8.1. Aquatic compartment (including sediment)

Ecotoxicity data set for decan-1-ol includes acute and chronic effect values for all three trophic levels derived from reliable studies or quantitative predictions.
Concerning short-term toxicity, reliable tests results are available for freshwater fish (*Pimephales promelas*) and invertebrates (*Nitocria spinipes*) and effect levels in green algae have been estimated using QSAR and read-across approaches.

For each trophic level a key study has been identified, with the following relevant short term values used for CSA:

- Fish: LC_{50} (96 h): 2.4 mg/l (OECD 203);
- Invertebrates: LC_{50} (96 h): 3.1 mg/l (OECD 202);
- Algae: ErC_{50} (72-96 h)1.5 mg/l (Category QSAR).

Representative chronic toxicity values for decan-1-ol are available from three trophic levels with the following reliable results:

- Fish: EC_{10} (33-day) 0.43 mg/l (based on survival) and NOEC 0.26 mg/l (based on growth (total length)(mean measured), (OECD 210);
- Invertebrates: EC_{10} (21-day): 0.21 mg/l and NOEC 0.11 mg/l (mean measured) for effects on reproduction, (OECD 211);
- Algae: ErC_{10} 0.7 mg/l (Category QSAR).

The lowest EC_{10} value was obtained in the invertebrate study with *Daphnia magna*, a 21-day EC_{10} 0.21 mg/l and this value was used for PNECs derivation.
These results are consistent with the self-classification Aquatic Chronic 3, according to Regulation (EC) No 1272/2008 (CLP).
Based on all available data, the eMSCA can support the hazard assessment for aquatic compartment.

7.8.1.1. Fish

Short term toxicity

The Registrants provided reliable test results, indicating an LC_{50} in the range of 1-10 mg/L for freshwater fish species.

A 96h LC_{50} value of 2.4 mg/l was determined for the effects of the test substance on mortality of *Pimephales promelas* in accordance with OECD 203. This study represents the lowest reliable experimental value that is available for this endpoint within the data set and it was used for the purpose of CSA.

Based on the available information, the eMSCA can support the conclusion on this endpoint.

Long term toxicity

Within the timeline specified in the final decision (27 August 2015) the Registrants submitted the requested information for long term toxicity on fish by updating the registration dossier with that new data.
Reliable measured data on chronic toxicity to fish on decan-1-ol were required, as indicated in final decision ,"*in order to investigate further effects on aquatic organisms from additional data (e.g. NOEC value) which can be used to refine the predicted no effect concentration (PNEC) value and the resulting risk characterization for the aquatic compartment."*
The Registrants provided an experimental study on this endpoint using the test method and the registered substance, as indicated in the final decision under Section III.4; it is reported as a key study with the following reliable results expressed as mean measured concentrations: EC_{10} value of 0.43 mg/L (based on survival) and NOEC of 0.26 mg/L (based on growth). These values were determined for *P. promelas* exposed to decan-1-ol (CAS. 112-30-1) in a fish early life stage test performed according to GLP and following test guideline OECD 210 - Fish, Early-Life Stage Toxicity Test (with appropriate modifications for rapid degradation of test substance).
Based on all available information, the eMSCA may conclude that the submitted data are sufficient and suitable for CSA as well as for a definitive assessment of this endpoint.
Reliable results from fish early life stage study now submitted by the Registrants can be used to definitively clarify the chronic hazard profile for fish, also in view of the initial

ground of concern relating to the suspected long-term effects on environmental compartments for decan-1-ol.
Therefore, following the assessment, the eMSCA concludes that the additional data provided meets the request specified under Section III.4 of the final decision and no further information is needed to clarify this endpoint and the related concern.

7.8.1.2. Aquatic invertebrates

Short term toxicity

The Registrants reported several values for short-term toxicity to invertebrates consistently indicating an LC_{50} in the range 1 -10 mg/l in freshwater and brackish/marine species.

The lowest reliable value for this assessment is a 96h LC_{50} value of 3.1 mg/l obtained for the effects of decan-1-ol on the mortality of the brackish copepod *Nitocra spinipes*, according to test guideline OECD 202.

Based on the available information, the eMSCA can support the conclusion on this endpoint.

Long term toxicity

The evaluation on this endpoint is based on these reliable experimental results: a 21-d EC_{10} value of 210 µg/l and NOEC value of 110 µg/l determined for the effects of decan-1-ol on the reproduction of *Daphnia magna*.

These data were obtained in accordance with standard test guideline OECD 211 using adapted method to minimize the losses of test substance due to the biodegradation. These values were taken into account for assessing long-term toxicity to aquatic invertebrates and can be considered definitive for this endpoint. Moreover, the available long-term data for the most susceptible taxonomic group, the 21-d EC_{10} value of 210 µg/l obtained in Daphnia study, was used to derive aquatic PNECs.

Based on the available information, the eMSCA can support the conclusion on this endpoint.

No further information is needed to be required to clarify chronic hazard assessment for aquatic invertebrates.

7.8.1.3. Algae and aquatic plants

The evaluation is based on the following key values from a quantitative prediction: a 72 - 96 h ErC50 value of 1.5 mg/l and an ErC10 value of 0.7 mg/l estimated for the effects of decan-1-ol on growth rate of green algae.

These results can be considered suitable and conclusive for the purpose of CSA.

Therefore, the eMSCA can support this conclusion, considering any further information on this endpoint not necessary.

7.8.1.4. Sediment organisms

Registrants provided a short-term toxicity (laboratory study) static, equivalent or similar to EPA OPPTS 850.1735 (Whole Sediment Acute Toxicity of Invertebrates, freshwater). The results is EC50 (6 d): 150 mg/kg sediment dw test mat. (nominal) based on reproduction and survival. It is a reliable non-guidance study looking at the effects in a soil and water mixture.

The Long term sediment toxicity was not provided because it is considered technically not possible, in accordance with section 2 of REACH Annex XI.

Based on the available information, the eMSCA can support the conclusion on this endpoint.

7.8.1.5. Other aquatic organisms

n/a

7.8.2. Terrestrial compartment

In general Registrants claim technical difficulties to attempt terrestrial toxicity testing of decan-1-ol, due to the very rapid biotic removal of the substance from the test system. However they reported only no reliable (Klimish score 4) tests of soil macro-organisms (short-term and long term toxicity tests) and of short-term toxicity to terrestrial arthropods.

For the toxicity to soil micro-organisms, the Registrants considered no need to conduct this study, in accordance with Column 2 of REACH Annex IX (required in Section 9.4) and because direct and indirect exposure of the soil compartment is unlikely.

However, the terrestrial chemical safety assessment has been conducted using the Equilibrium Partitioning method (EPM).

It is recognised that the aquatic PNEC used in the EPM does not take into account any indicator for effects in aquatic microorganisms. However, Registrants considered that the PNECterrestrial based on aquatic ecotoxicity test results would be protective for terrestrial microorganisms, because decan-1-ol and analogous alcohols within the Category are very rapidly biodegradable and show no significant inhibitory effects on respiration of activated sludge or specific microbial strains relevant to WWTP, at or above the limit of solubility.

Based on the available information, eMSCA concludes that the EPM approach is suitable for terrestrial hazard assessment on decan-1-ol.

For eMSCA discussion and conclusion concerning the PNECsoil extrapolation see section 7.8.4.

7.8.3. Microbiological activity in sewage treatment systems

n/a

7.8.4. PNEC derivation and other hazard conclusions

The Registrants were requested to submit the justification for deviating in use of default values in PNEC derivation for aquatic and terrestrial compartment.

<u>PNEC freshwater</u>

To calculate the PNEC-freshwater the Registrants initially provided an assessment factor (A.F.) value of 5.

In the Section III of Final Decision eMSCA explained that according to ECHA Guidance R.10, this value was not correct. The provided A.F.=5 is applicable when a large dataset from long-term tests for different taxonomic groups is available (Species sensitivity distribution, SSD method). At that stage it was justified the choice of 1000 as A.F. value, according to ECHA Guidance R.10 table R.10-4 (b).

Therefore the Registrants were required to provide an adequate justification for deviating in use of default values from recommendations made in ECHA Guidance R.10 in PNEC freshwater derivation; otherwise, the Registrants were required to derive adequately the PNEC value and to refine the related risk characterization for the aquatic compartment.

Moreover, as above explained, the Registrants provided the required additional data on long-term toxicity to fish, therefore they could refine the PNEC-freshwater according to ECHA Guidance R.10 table R.10-4.

In the updated dossier Registrants propose again an A.F. value of 5, on the basis of the specific considerations to account for uncertainty in:

1. Intra-laboratory variability
2. Inter-laboratory variability
3. Duration
4. Sensitivity of the environmental ecosystem relative to the range or organisms actually tested.

In particular below it is reported the Registrants table summarising the justification of the deviation from the default value of 10. eMSCA added a column with the remarks concluding that the scientific conditions to derive the A.F. values for each variability parameter indicated by Registrants do not exist.

A basis of understanding assessment factors and application to long-term studies with alcohols:

	Registrants rationale when three trophic levels have been studied	**A.F. proposed by Registrants**	**eMSCA remarks**
1.Intra-laboratory variability	For well-performed studies with good chemical analysis point 1 is negligible	This applies. A.F: 1	According to the ECHA Guidance it is not acceptable to fix A.F =1 because of uncertainties due to intrinsic intra-laboratory variability. (see eMSCA conclusion below)
2.Inter-laboratory variability	A factor of 2 to 5 would be realistic	For the long-chain alcohols, the inter-laboratory variation is much lower, because the substances are archetypal exemplars of non-polar narcotics. A.F: 2	Because of existing intrinsic inter-laboratory variability, however, the whole uncertainty should not be below 10 (no Species Sensitivity Distribution (SSD) was applied). (see eMSCA conclusion)
3.Duration	When a full set of long-term NOECs or ECx values are available, the contributing factor associated with point 3 (duration) is relatively minor, and can be ignored.	This is definitely the case for the ecosystem, in which alcohols are ubiquitous, so duration is irrelevant A.F: 1	eMSCA is of the opinion that the laboratory study conditions are not a real environmental ecosystem, therefore uncertainties related to the duration have to be always considered. (see eMSCA

			conclusion)
4.Sensitivity of the environmental ecosystem	For point 4 (ecosystem sensitivity), a value of 2 to 5 is realistic	For non-polar narcotics, many species of organism have been studied, so the uncertainty regarding lab to field extrapolation should also be reduced. The ecosystem is adapted to alcohols. Suggest A.F: 2.5	eMSCA is the opinion that the laboratory study conditions are not a real environmental ecosystem and the related uncertainties has to be always considered. (see eMSCA conclusion)

eMSCA conclusion on A.F.

The Registrants conclude that the final overall AF is = 5, based on the predictability of trends across the category. Therefore they proposed for decan-1-ol an assessment factor of 5 for extrapolation from the lowest NOEC or ECx value to PNEC. As already stated, the scientific conditions to derive the A.F. values for each variability parameter indicated in the table above by Registrants are not verified.

In eMSCA's opinion, although considering the category approach, Registrants reasoning to decrease the A.F. to 5 is unacceptable because the only possibility to decrease up to 5 the A.F. is when a large dataset from long-term tests for different taxonomic groups is available (Species sensitivity distribution, SSD, method) as specified by ECHA Guidance Section R.10.3.1.3 "*Calculation of PNEC for freshwater using statistical extrapolation techniques.*" For the decan-1-ol case, a full set of long-term results are not available specifically for the registered substance (see section 7.8.1.). Moreover the assumptions of the statistical extrapolation methods are missing for decan-1-ol case in terms of:

-input data: the methods should be applied on all reliable available NOECs from chronic/long-term studies, preferably on full life-cycle or multi-generation studies,

-taxonomic groups : The minimum species requirements should be: fish, a second family in the phylum Chordata (fish, amphibian, etc.); a crustacean; an insect; a family in a phylum other than Arthropoda or Chordata; a family in any order of insect or any phylum not already represented; algae; higher plants,

-minimal sample size (number of data): database should contain at least 10 NOECs (preferably more than 15) for different species covering at least 8 taxonomic groups.

In conclusion, taking into account the above mentioned general uncertainties, based on the available ecotoxicological data, it is acceptable only an overall assessment factor of 10, as considered in the Guidance, to three long term NOECs or ECx values for the aquatic compartment.

As stated in Part A, eMSCA recommends Registrants to refine risk assessment and risk management measures for some specific uses/scenarios in order to ensure safe RCRs, currently close to 1. For the outcome and recommendations on Risk Assessment, see section 7.13 where RCRs are discussed.

PNEC aquatic marine

To calculate the PNECmarine-water the Registrants provided an A.F. value of 50 based on the standard assumption of a 10x lower PNEC than PNECaquatic. As above explained eMSCA is of the opinion that the PNEC water A.F: should be 10 instead of 5, therefore the A.F. for marine compartment should be 100. (For the outcome and recommendations on Risk Assessment, see section 7.13 where RCRs are discussed).

PNEC soil

To calculate the PNECsoil, Registrants used equilibrium partitioning method. eMSCA considers that the PNECsoil should be derived from a PNECfreshwater based on A.F.: 10 instead of 5 (see PNEC freshwater discussion). (For the outcome and recommendations on Risk Assessment, see section 7.13 where RCRs are discussed).

Table 8

PNEC DERIVATION AND OTHER HAZARD CONCLUSIONS		
Hazard assessment conclusion for the environment compartment	**Hazard conclusion/Registrant Justification**	**eMSCA Remarks**
Freshwater	PNEC freshwater: 0.042 mg/l **Assessment factor: 5** Extrapolation method: assessment factor Reliable short-term and long-term effects data from three trophic levels are available from reliable studies or quantitative predictions. The aquatic ecotoxicity properties of decan-1-ol and other alcohols in the C6-24 Category are demonstrably consistent with expectations for classic narcotics. In this case, effects were observed in long-term studies in fish and invertebrates and effects are predicted in algae. The effect levels in different trophic levels are similar but the lowest EC10 value was obtained in the invertebrate study with Daphnia magna. Therefore, PNECfreshwater is based on the EC10 obtained in the Daphnia study of 0.21 mg/l (the NOEC was 0.11 mg/l). A reduced assessment factor of 5 is applicable.	**Assessment factor proposed by eMSCA: 10** based on lower Long-term results from three species representing three trophic levels. (refer to section 7.8.4)
Marine water	PNEC aqua (marine water): 0.0042 mg/l **Assessment factor: 50** Extrapolation method: assessment factor. Applied the standard assumption of a 10x lower PNEC than PNECaquatic, freshwater.	**Assessment factor proposed by eMSCA: 100**. Extrapolation method: assessment factor. Applied the standard assumption of a 10x lower PNEC than PNECfreshwater. (refer to section 7.8.4)
Soil	PNEC soil: 1.27 mg/kg soil dw Extrapolation method: partition coefficient. Toxicity tests available are not reliable and not useful as a basis for deriving PNEC for this substance. Therefore in accordance with ECHA guidance, the PNECsoil is derived from the PNECfreshwater by the equilibrium partitioning method using the following equation: PNECsoil = Ksoil-water/RHOsoil * PNECfreshwater * 1000. For decan-1-ol, this is PNECsoil = 45.2/1700 * 0.042 * 1000 = 1.12 mg/kg wwt. Conversion to dry weight gives a PNECsoil of 1.27 mg/kg dwt for decan-1-ol.	The PNECsoil should be derived from the PNECfreshwater based on A.F.: 10 instead of 5. Extrapolation method: partition coefficient. (refer to section 7.8.4)

7.8.5. Conclusions for classification and labelling

The conclusions for environmental classification and labelling are:
Based on the reliable short-term ecotoxicity values decan-1-ol is not classifiable for Acute toxicity.
Based on the lowest reliable chronic toxicity data (NOEC of 0.11 mg/l for Daphnia) and considering that decan-1-ol is readily biodegradable, eMSCA supports the environmental self-classification as: Chronic toxicity: Category 3 according to Regulation (EC) No 1272/2008.

7.9. Human Health hazard assessment

7.9.1. Toxicokinetics

Basic toxicokinetics

eMSCA can support the Registrants' conclusion.

Dermal Absorption

Based on comparative in vitro skin permeation data and dermal absorption studies in hairless mice, aliphatic alcohols show an inverse relationship between absorption potential and chain length with the shorter chain alcohols having a significant absorption potential.

The Registrant submitted several dermal absorption studies in the IUCLID dossier:

In a well conducted in vivo percutaneous absorption study using mice, the percutaneous absorption rate of decanol was ca 7%. (Iwata et al., 1987). This was confirmed in a reliable in vitro study, where the percutaneous absorption rate of decanol (10% (w/w) FRM in 9:1 (v/v) ethanol: water mixture) using unoccluded porcine skin was ca 10% (Berthauld et al., 2011).

Read across from a well conducted in vitro study using human skin and a structural analogue myristyl alcohol (C14-alcohol), gave a percutaneous absorption rate of 1.2% at 6 hours and 6.3% at 24 hours (P&G, 2008). This confirms the findings of the Iwata paper that aliphatic alcohols show an inverse relationship between absorption potential and chain length. A reliable study which investigated the in vitro percutaneous absorption of decanol using human skin over an 8 hour exposure, and occluded conditions reported a potential absorption of 66%. However it is likely that the occluded conditions of the experiment were the likely factor for such a high percutaneous absorption rate (Buist et al., 2010).

Based on the in vitro studies with mouse (Iwata et al., 1987) and porcine (Berthauld et al., 2011) skin, the absorption of decan-1-ol via intact skin under normal conditions, used in the chemical safety assessment, is to be considered of 10%.

Thus, eMSCA can support the Registrants' conclusion.

7.9.2. Acute toxicity and Corrosion/Irritation

Irritation

Skin:

The Registrant reports several studies on skin irritation in the updated dossier.

In the proposed key study (Eurofins 2008) 3 female New Zealand rabbits were treated with the registred substance with a semi-occlusive coverage for 4 h on the back region. All three treated sites exhibited well-defined erythema and very slight oedema with a primary dermal irritation index (PDII) of 2.8. The overall incidence and severity of

irritation decreased gradually with time. All animals were free of dermal irritation by day 10 (study termination). Under the conditions of this study, Alfol 10 has been classified as moderately irritating to the skin.

This results are confirmed by a well-designed study reported in the "Other supporting study" section (Bagley D M et al, 1996) and from Technical Report ECETOC "Skin irritation and corrosion" (Reference chemicals data bank. ECETOC, 1995). The study has been conducted according to OECD Guideline 404 (Acute Dermal Irritation/Corrosion) on rabbits.

Based on the results from the submitted studies on skin irritation, decan-1-ol is to be considered irritating Cat 2 (H315 Causes skin irritation) according to Regulation (EC) n. 1272/2008.

Eye:

The Registrant report several studies on eye irritation in the dossier indicating the irritation properties of decan-1-ol.

In particular the following results from the Huntingdon Life Sciences's study (1996) in rabbits warrant the eye irritation classification:

- Cornea: individual scores 2, 1.0, 0.7;

- Iris: individual scores 0.7, 0.3, 0.7;

- Conjunctivae (Redness): individual scores 2.7, 1.3, 1.3;

- Conjunctivae (Chemosis): individual scores 1.3, 0.3, 0.3.

According with the Registrant's conclusion, decan-1-ol is to be considered Eye Irrit. 2 H319: Causes serious eye irritation according to Regulation (EC) n. 1272/2008.

eMSCA can support the Registrants' conclusion.

Respiratory tract:

Different acute toxicity studies (inhalation and oral route) reported in the dossier, are indicative of effects on respiratory tract.

In an acute inhalation toxicity test in rats (Scientific Associates,1977) sign of intoxication during exposure is the gasping of the animals. Moreover, the gross necropsy revealed congestion of the lungs in all animals with no lethality during the study.

In another acute inhalation toxicity study in rats (Eurofin 2008) clinical signs following exposure, all animals exhibit abnormal respiration and/or nasal discharge. All animals recovered by day 7 and appeared active and healthy for the remainder of the 14 day observation period.

In another oral study (in mice) on saturated monoatomic alcohols, n-hexyl, n-heptyl, n-octyl, n-nonyl and n-decyl by Zaeva Fedorova (1963), respiratory tract injury (respiratory distress) is reported for decanol.

Furthermore, in an acute oral toxicity in rats, (Scientific Associates, 1997) the necropsy findings include gross abnormality on lungs.

Thus the clinical signs observed in the submitted studies suggest that the classification of decan-1-ol as STOT SE 3, H335 (Respiratory tract) has to be considered according to Regulation (EC) n. 1272/2008.

Other Specific Target Organ Toxicity – Single exposure (STOT SE):

Neurotoxicity
Several evidence of neurotoxicity are reported in acute toxicity studies submitted by the Registrant for decan-1-ol.

In an acute oral toxicity in rats.(Scientific Associates, 1997) the clinical signs of neurotoxocity are, at each dose level, one or more of thefollowing effects: hypoactivity, hypersalivation, malaise, unthriftness, hypersensitivity to touch, generalized weakness.

In an inhalation toxicity test in rats (Scientific Associates 1977) signs of intoxication during exposure included lethargy,and/or ataxia, salivation and gasping. Gross necropsy revealed congestion of the lungs in all animals. No lethality during the study.

In another inhalation toxicity study in rats (Potokar 1979) the clinical sign of intossication is the falling asleep of all the animals (the only clinical sign observed).

In inhalation limit test by Eurofin 2008 in rats, following exposure all animals were hypoactive and exhibited hunched posture. All animals recovered by day 7 and appeared active and healthy for the remainder of the 14 day observation period.

Regarding the findings in acute dermal toxicity study in rabbit by Scientific Associates Inc. (1976) clinical signs or generalised weakness and inactivity in most animals following exposure were observed.

Overall, the acute toxicity studies evaluated suggest that the classification of decan-1-ol as STOT SE 2, H371 (Central Nervous) has to be considered according to Regulation (EC) n. 1272/2008.

Corrosion
eMSCA can support the Registrants' conclusion.

7.9.3. Sensitisation
eMSCA can support the Registrants' conclusion.

7.9.4. Repeated dose toxicity

Oral:
eMSCA can support the Registrants' conclusion.

Inhalation:
The IUCLID technical dossier does not contain any evaluable study by inhalation route. The two studies submitted are poorly reported. Moreover, it is unclear how the Long-term – systemic inhalation effects DNEL has been derived by the Registrant. The eMSCA has proposed a route-to-route extrapolation from the dermal 90 days on rat as point of departure to derive the critical DNELs (see below section

eMSCA is of the opinion that further repeated toxicity inhalation studies should not be required.

Dermal:
The IUCLID technical dossier reports a 90 days dermal study in rats (Research Laboratories Inc - 1995) following OECD Guideline 411 (Subchronic Dermal Toxicity: 90-Day Study). The dose levels were: 100, 300 and 1000 mg/kg/day.

Regarding the findings of the study it should be noted that marked dermal irritation was noted in all dose groups and consisted of very slight to severe erythema, very slight to moderate edema, persistant desquamation, eschar, exfoliation, clear exudate and fissuring, thus, for only a LOAEL long term for local effects could be identified in a dose of 100 mg/kg bw/day.

Moreover it should be noted that the substance shows general toxicity effects that should be taken into account to defining systemic effect via dermal route:

- haematology (mean white blood cell counts were increased in a non dose related manner in all the test groups (not the control);

- clinical chemistry: albumin means were decreased and globulin means were increased (resulting in decreased A/G ratios);

- organ weight: increased absolute and relative adrenal weights in all dose groups;

These effects fall within the definition given by the Guidance on Information Requirements (Chapter R.7a: Endpoint specific guidance version 4.0 July 2015) being observed distant from the site of first contact

the eMSCA is of the opinion that for dermal systemic effect, a long term LOAEL of 100 mg/kg bw/day should be identified.

The conclusion on repeated dose toxicity are:

NOAEL oral systemic effects: 100 mg/kg bw/day (taking into account the haematology: dose-dependent reduction in white blood cell count, statistically significant at 500 and 2000 mg/kg bw/day)

LOAEL dermal, local effects: 100 mg/kg bw/day

LOAEL dermal, systemic effects: 100 mg/kg bw/day

The eMSCA suggests the Registrants to consider the values above mentioned for the risk characterisation (see below section 7.9.9., Table 9).

7.9.5. Mutagenicity

eMSCA can support the Registrants' conclusion.

7.9.6. Carcinogenicity

eMSCA can support the Registrants' conclusion.

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

Not relevant for this evaluation.

7.9.8. Hazard assessment of physico-chemical properties

None impacting human health.

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

In the table below are reported some considerations on the derivation of DNEL. The eMSCA suggests the Registrant to take into account the approach proposed in order to derive the DNEL values.

For the calculation of dermal, inhalatory and oral DNELs for systemic long-term effects the critical study is the 90 day repeat dose dermal study (WIL, 1995). As reported above the eMSCA is of the opinion that the substance shows general toxicity effects that should be taken into account to defining systemic effect via dermal route and a LOAEL of 100 mg/kg/day should be considered as the dose-descriptor for systemic effects.

Table 9

CRITICAL DNELS/DMELS					
Endpoint of concern	**Type of effect**	**Critical study(ies)**	**Corrected dose descriptor(s) (e.g. NOAEL, NOAEC)**	**DNEL/ DMEL**	**Justification/ Remarks**
Inhalation Workers repeated dose toxicity	Systemic effects - Long-term	DNELs derived from the data from the 90-day repeat dose dermal study (WIL, 1995) with Fatty Alcohol Blend (CAS 68603-15-6) conducted at doses of 0, 100, 300 or 1000 mg/kg/day.	Dose descriptor starting point: LOAEC 176.3 mg/m³ Derived from the dermal LOAEL of 100 mg/kg/d	2.93 mg/m³	eMSCA proposes to use the following assessment factors: AF for difference in duration of exposure: 2 (Default (sub-chronic to chronic). AF for intraspecies differences: 5 (Default (worker). An additional AF of 2 to take into account the possible absorption differences between inhalation and dermal route and an additional AF for dose response relationship: 3 (Use of LOAEC). Overall Assessment Factor: 60
Inhalation Workers irritation	Local effects - Long-term	German national maximum exposure limit (AGW) for analogous aliphatic alcohols of 20 ppm.		129 mg/m³	The long-term local effects via inhalation route are assessed on the basis of the German national maximum exposure limit (AGW) for analogous aliphatic alcohols. No

					corrections or assessment factors are applied. The conclusion that 20 ppm is an appropriate threshold level is derived from a lack of effects at exposures of approximately 20 ppm (time weighted average) read across from a shorter-chain alcohol analogue.
Dermal Workers repeated dose toxicity	Systemic effects - Long-term	DNELs derived from the data from the 90-day repeat dose dermal study (WIL, 1995) with Fatty Alcohol Blend (CAS 68603-15-6) conducted at doses of 0, 100, 300 or 1000 mg/kg/day.	LOAEL 100 mg/kg bw/day	0.83 mg/kg	AF for difference in duration of exposure: 2 (Default (sub-chronic to chronic). AF for interspecies differences (allometric scaling): 4 (Default (dermal to dermal).) AF for intraspecies differences: 5 (Default (worker). AF for dose response relationship: 3 (Use of LOAEL). Overall Assessment Factor: 120
Dermal Workers repeated dose toxicity	Local effects - Long-term	DNELs derived from the data from the 90-day repeat dose dermal study (WIL, 1995) with Fatty Alcohol Blend (CAS 68603-15-6) conducted at doses of 0, 100, 300 or 1000 mg/kg/day.	LOAEL 100 mg/kg bw/day	190 µg/cm²	AF for dose response relationship: 3 (Use of LOAEL). The LOAEL is the lowest tested level. The responses are very variable with no obvious dose response or duration response. Individual animals appear to have variable sensitivity and there are no consistent patterns.) AF for intraspecies differences: 5 (Default (workers). Overall Assessment Factor: 15
Inhalation General Population repeated dose toxicity	Systemic effects - Long-term	DNELs derived from the data from the 90-day repeat dose dermal study (WIL,	Dose descriptor starting point: LOAEC 176.3 mg/m³ Derived from	1.47 mg/m³	eMSCA proposes to use the following assessment factors: AF for difference in duration of

		1995) with Fatty Alcohol Blend (CAS 68603-15-6) conducted at doses of 0, 100, 300 or 1000 mg/kg/day.	the dermal LOAEL of 100 mg/kg/d		exposure: 2 (Default (sub-chronic to chronic). AF for intraspecies differences: 10 (Default (worker). An additional AF of 2 to take into account the possible absorption differences between inhalation and dermal route and an additional AF for dose response relationship: 3 (Use of LOAEC). Overall Assessment Factor: 120
Dermal General Population repeated dose toxicity	Systemic effects - Long-term	DNELs derived from the data from the 90-day repeat dose dermal study (WIL, 1995) with Fatty Alcohol Blend (CAS 68603-15-6) conducted at doses of 0, 100, 300 or 1000 mg/kg/day.	LOAEL 100 mg/kg bw/day	0.41 mg/kg	AF for difference in duration of exposure: 2 (Default (sub-chronic to chronic).) AF for interspecies differences (allometric scaling): 4 (Default (dermal to dermal). AF for intraspecies differences: 10 (Default (general population). AF for dose response relationship: 3 (Use of LOAEL). Overall Assessment Factor: 240
Dermal General Population repeated dose toxicity	Local effects - Long-term	DNELs derived from the data from the 90-day repeat dose dermal study (WIL, 1995) with Fatty Alcohol Blend (CAS 68603-15-6) conducted at doses of 0, 100, 300 or 1000 mg/kg/day. DNELs derived from the data from the 90-day repeat dose dermal study (WIL, 1995) with Fatty Alcohol Blend (CAS 68603-15-6) conducted at	LOAEL 100 mg/kg bw/day	67 µg/cm²	AF for dose response relationship: 3 (Use of LOAEL. The LOAEL is the lowest tested level. The responses are very variable with no obvious dose response or duration response. Individual animals appear to have variable sensitivity and there are no consistent patterns.) AF for intraspecies differences: 10 (Default (general population) Overall Assessment Factor: 30

		doses of 0, 100, 300 or 1000 mg/kg/day.			
Oral General Population repeated dose toxicity	Systemic effects - Long-term	DNELs derived from the data from the 90-day repeat dose dermal study (WIL, 1995) with Fatty Alcohol Blend (CAS 68603-15-6) conducted at doses of 0, 100, 300 or 1000 mg/kg/day.	LOAEL 100 mg/kg bw/day	0.42 mg/kg	eMSCA proposes to use the following assessment factors: AF for difference in duration of exposure: 2 (Default (sub-chronic to chronic). AF for interspecies differences (allometric scaling): 4 (Default (dermal to oral). AF for intraspecies differences: 10 (Default (general population) an additional AF for dose response relationship: 3 (Use of LOAEL) Overall Assessment Factor: 240

All the RCR values derived by the Registrant for workers, consumers and man via environment were below 1, however the eMSCA proposes to revise the DNEL. In case new RCR are calculated to be close or above 1 and representing unacceptable risks, appropriate RMM should be considered by the Registrant.

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

The conclusions of the assessment for human health hazard and classification, according to Regulation (EC) n. 1272/2008 are:

Based on the results from the submitted studies on skin irritation and taking into account that the substance is notified among the aggregated self-classifications, decan-1-ol is to be considered irritating Cat 2 (H315 Causes skin irritation).

According with the Registrant's conclusion, decan-1-ol is to be considered Eye Irrit. 2 H319: Causes serious eye irritation.

Based on the results of the submitted acute toxicity studies and taking into account that the substance is notified among the aggregated self-classifications, the classification of decan-1-ol as STOT SE 3, H335 (Respiratory tract) has to be considered.

Based on the results of the submitted acute toxicity studies and taking into account that the substance is notified among the aggregated self-classifications, the classification of decan-1-ol as STOT SE 2, H371 (Central Nervous) has to be considered.

Moreover, since the substance is also self-classified as Repr. 2, H361, an harmonized classification has to be considered.

7.10. Assessment of endocrine disrupting (ED) properties

Not relevant for this evaluation.

7.11. PBT and vPvB assessment

1) Persistence
The Registrants concluded that the substance is readily biodegradable and based on the available information, the eMSCA can support this conclusion.

2) Bioaccumulation
The Registrants concluded the substance is not bioaccumulative and based on the available information, the eMSCA can support this conclusion.

3) Toxicity
Based on ecotoxicity data set for decan-1-ol that includes acute and chronic effect values for all three trophic levels derived from reliable studies or quantitative predictions, the substance does not meet the criteria to be identified as T.

4) Overall conclusion
Taking into account the available information, the eMSCA can support the Registrant conclusion that the substance is not PBT/vPvB.

7.12. Exposure assessment

7.12.1. Human health

For the 16 exposure scenarios developed by the Registrants the relative contributing scenarios for controlling human exposure (industrial and professional workers, consumers and man exposed via the environment) and the environmental exposure have been developed where appropriate.

1. Manufacture of Long chain alcohols
2. Formulation and (re)packing of long chain alcohols and mixtures
3. Distribution
4. Use as an intermediate
5. Use in coatings, industrial scenario
6. Mining chemicals
7. Process chemical (paper/textiles industries)
8. Use of cleaning products in industrial settings
9. Use of cleaning products in professional settings
10. Use in cleaning agents, consumer scenario
11. Other consumer uses
12. Use as binders and release agents, industrial scenario
13. Use as binders and release agents, professional scenario
14. Road and construction applications
15. Polymer processing, industrial scenario
16. Use in Agrochemicals, professional scenario

The exposure scenarios have been calculated using EasyTRA 4.0.0. EasyTRA uses algorithms on the basis of the latest versions of the ECHA REACH Guidance chapters R12 (as of March 2010), R14, R15, and R16 (as of October 2012) and EUSES.

7.12.2. Environment

The substance is produced in amounts greater 10000 tons per year and it is considered a substance with dispersive uses. In order to clarify the possible impact on the environment, pursuant to Article 46(1) of the REACH Regulation, the Registrants were requested to provide justification about missing elements regarding environmental exposure assessment needed to conclude on the concern for the environment.

This concerns in particular missing or not justified assumptions regarding quantities (used amount), use descriptors and Operational Conditions (OCs) and Risk Management Measures (RMMs) as well as PEC values for all compartments.

The Registrants provided all elements about environmental exposure requested by ECHA, in particular by providing information referred specifically for 1-decanol, without using the category approach.

7.12.2.1. Aquatic compartment (incl. sediment)

The level of exposure is considered acceptable.

7.12.2.2. Terrestrial compartment

In order to answer to the ECHA Decision, the Registrants provided specific information on exposure of soil compartment. The level of exposure is considered acceptable except for uses argued below (see section 7.13).

7.12.2.3. Atmospheric compartment

n.a.

7.12.3. Combined exposure assessment

n.a.

7.13. Risk characterisation

Human Health

As a follow up of the SEV a complete quantitative risk characterization has been performed for human health with the exception of eye irritation endpoint where a qualitative risk characterisation has been developed.

DNELs were derived for workers and general population for both acute and long-term local and systemic effects, for the relevant exposure routes.

RCR values were derived where relevant for workers, consumers and indirectly exposed via the environment for all the contributing scenarios of the different exposure scenarios.

Combined exposure has been considered as well where relevant.

The Registrants are recommended to take note of the eMSCA conclusions about the reference values and assessment factors and review the appropriatness of risk management measures implemented for the some specific uses/scenarios in order to ensure safe RCRs to minimise the exposure of workers and environment. No further actions are envisaged for consumers and general population.

Workers

Taking into account the critical study(ies) and the corrected dose descriptor(s) (e.g. LOAEL, LOAEC) eMSCA concludes that for the following scenarios the RCRs are close to or above 1
ES 1: Manufacture of LCA-Production of chemicals;
ES 2: Formulation and (re)packing of long chain alcohols an mixtures;

ES 3: Distribution;
ES 4: Use as an intermediate;
ES 5: Use in coatings, industrial scenario;
ES 6: Mining chemicals;
ES 7: Process chemical (paper/ textiles industries)-industrial use of processing aids;
ES 8: Use of cleaning product in industrial settings- industrial use of processing aids;
ES 9: Use of cleaning products in professional settings:
ES 12: Use as binders and release agents, industrial scenario;
ES 13: Use as binders and release agents, professional scenario;
ES 14: Road and construction applications;
ES 15: Polimer processing, industrial scenario;
ES 16: Use in agrochemicals-wide dispersive outdoor use of processing aids in open systems.

eMSCA recommends Registrants to refine risk assessment and risk management measures for the above mentioned uses/scenarios in order to ensure safe RCRs.

Environment

Aquatic compartment (incl. sediment)

Taking into account the discussion about the Assessment Factor applied for the PNEC derivation (see section 7.8.4), eMSCA concludes that for the following scenarios the RCRs are close to or above 1:

ES 7: Process chemical (paper/ textiles industries)-industrial use of processing aids;

ES 8: Use of cleaning product in industrial settings- industrial use of processing aids;

ES 16: Use in agrochemicals-wide dispersive outdoor use of processing aids in open systems. In relation to the use as agrochemical (ES 16), eMSCA highlights that 1-decanol is an active substance under EFSA evaluation process, in accordance with Directive 91/414/EEC and with Regulation (EC) No 1107/2009 (EFSA, 2016).

eMSCA recommends Registrants to refine risk assessment and risk management measures for some specific uses/scenarios in order to ensure safe RCRs, currently close to 1 (see Part B, section 7.8.4).

Terrestrial compartment

Taking into account the discussion about the Assessment Factor applied for the PNEC derivation (see section 7.8.4), eMSCA concludes that for the following scenarios the RCRs are close to or above 1:
ES 1: Manufacture of LCA-Production of chemicals;
ES 7: Process chemical (paper/ textiles industries)-industrial use of processing aids;
ES 8: Use of cleaning product in industrial settings- industrial use of processing aids;
ES 16: Use in agrochemicals-wide dispersive outdoor use of processing aids in open systems. In relation to the use as agrochemical (ES 16), eMSCA highlights that 1-decanol is an active substance under EFSA evaluation process, in accordance with Directive 91/414/EEC and with Regulation (EC) No 1107/2009 (EFSA, 2016).

eMSCA recommends Registrants to refine risk assessment and risk management measures for some specific uses/scenarios in order to ensure safe RCRs, currently close to 1 (see Part B, section 7.8.4).

7.14. References

- EFSA's scientific views and conclusions: Outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for 1-decanol in light of confirmatory data-EFSA, April 2016.
- Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.

7.15. Abbreviations

AF Assessment factor
BW Body weight
CAS Chemical abstracts service
C&L Classification and labelling
CLP Classification, labelling and packaging (Regulation (EC) No 1272/2008)
CMR Carcinogenicity, mutagenicity and toxicity to reproduction
CSR Chemical Safety Report
DMEL Derived Minimal Effect Level
DNEL Derived no effect level
ECx Effect Concentration
EFSA European Food Safety Authority
EQPM Equilibrium Partitioning method
ES Exposure Scenario
eMSCA Evaluating Member State Competent Authority
NOAEC No Observed Adverse Effect Concentration
NOAEL No Observed Adverse Effect Level
NOEC No Observed Effect Concentration
LOAEL Lowest-Observed-Adverse-Effect Level
LOAEC Lowest-Observed-Adverse-Effect Concentration
OECD Organisation for Economic Co-operation and Development
PBT Persistent, Bioaccumulative, Toxic
PEC Predicted Environmental Concentration
PNEC Predicted No Effect Concentration
PPP Plant Protection Product
RCR Risk characterization ratio
RMMs Risk Management Measures
vPvB Very Persistent and very Bioaccumulative
SSD Species Sensitivity Distribution