SUBSTANCE EVALUATION CONCLUSION

as required by REACH Article 48

and

EVALUATION REPORT

for

Alcohols, C7-9-iso-, C8-rich

EC No 271-231-4

CAS No 68526-83-0

Evaluating Member State: Italy

Dated: 23 June 2017

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Evaluating Member State Competent Authority

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Year of evaluation in CoRAP: 2016

Member State concluded the evaluation without any further need to ask more information from the Registrant(s) under Article 46(1) decision.

Further information on registered substances here:

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

DISCLAIMER

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

The substance Alcohols, C7-9-iso-, C8-rich was originally selected for substance evaluation in order to clarify concerns about:

- suspected C,
- suspected M,
- wide dispersive use,
- consumer use,
- exposure of workers

2. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

A testing proposal examination (TPE) according to Article 40 of the REACH Regulation for a sub-chronic toxicity study (90 day study), oral route (Annex IX, section 8.6.2; test method: EU B.26/OECD TG 408) in rats using the registered substance was performed. An ECHA testing proposal decision requesting this study was issued with the deadline of 15 October 2018.

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	
Identification as SVHC (authorisation)	
Restrictions	
Other EU-wide measures	
No need for regulatory follow-up action at EU level	X

4. FOLLOW-UP AT EU LEVEL

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

There is not need for follow up regulatory action at EU level at this point.

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	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.)	

The initial concern for Alcohols, C7-9-iso-, C8-rich was related to the presence of the substance 2-ethylhexan-1-ol (CAS number 104-76-7), a possible carcinogenic substance according to the QSAR analysis, in the Alkyl Alcohols C6-C13 category.
With this alert, the eMSCA considered that more detailed assessment was needed to consider if more information would be necessary to be requested in order to clarify the identified concern for carcinogenicity and to completely exclude a possible genotoxic mechanism in case of carcinogenicity.
eMSCA is aware that the results of the 90 day study requested following a testing proposal decision could later provide information that may need to be followed up

5.2. Other actions

During the evaluation the eMSCA noted that for skin sensitisation the Registrant(s) provided the information relevant to this endpoint using a read-across approach.

According to the Registrant(s), the substance Alcohols, C7-9-iso-, C8-rich can be grouped with other similar substances in a category for the purpose of read-across. In particular, the category proposed is composed of the following substances: Alcohols, C7-9-iso-, C8-rich; Alcohols, C8-10-iso-, C9-rich; Alcohols, C9-11-iso-, C10-rich; Alcohols, C9-11-branched; and Alcohols, C11-14-iso-, C13-rich. The rationale of the proposed category is based on the incremental and constant change of the chain length of the members. As documented in the Registrant(s)' read-across hypothesis, the Alcohols, C7-9-iso-, C8-rich is considered to be the worst case with respect to toxicological properties, having the shortest chain of carbon atoms. As such, additional testing is necessary for the Alcohols, C7-9-iso-, C8-rich, in order to define the boundaries of the category.

Based on the available data on read across substances the eMSCA does not see a particular concern for skin sensitisation. However, the eMSCA considers the read-across proposed by the Registrant(s) as not sufficiently justified in the registration dossier(s) although read-across approach can be scientifically plausible in this case.

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

Not applicable.

Part B. Substance evaluation

7. EVALUATION REPORT

7.1. Overview of the substance evaluation performed

The substance Alcohols, C7-9-iso-, C8-rich was originally selected for substance evaluation in order to clarify concerns about:

- suspected C
- suspected M
- wide dispersive use
- consumer use
- exposure of workers

During the evaluation also a potential data gap for standard information requirement for Skin sensitisation has been identified.

The substance was listed in the CoRAP for the following reasons, as specified in the Justification document for inclusion in the CoRAP:

- At the time of evaluation, the exposure assessment has not been performed since the substance has not been self-classified by the Lead Registrant. However in the ECHA C&L Inventory database the substance is self classified as Eye Dam. 1, H318 and Skin Irrit. 2, H315 by other notifiers. Moreover in the CSR the Registrant(s) presented the DN(M)EL derivation for several toxicological endpoints. Therefore the Registrant(s)s should develop the exposure scenarios and perform the exposure assessment and the risk characterization for human health. Moreover a justification should be given in the dossier on the reason for deviating from the REACH guidances in the use of the assessment factors for the DN(M)EL derivation. Indeed in the CSR no justification is given in the CSR for using the ECETOC approach instead of the REACH guidances for risk characterization.

- The available developmental toxicity studies show that only slight effects on litter are observed at dose levels inducing maternal toxicity; thus, no specific concerns for developmental toxicity are identified. It is noted that no study covering the full reproductive cycle (i.e., 1- or 2-generation study) is available. Nevertheless, the available data does not indicate priority concerns, as no effects on reproductive or endocrine organs were identified in repeated dose toxicity studies.

- No clear data are available on the *in vivo* genotoxicity and carcinogenicity. The Alcohols, C7-9-iso-, C8-rich is a member of the Alkyl Alcohols C6 to C13 category by the Registrants. In this category the substance 2-ethylhexan-1-ol showed positive results for carcinogenesis. Therefore more information may be needed in order to clarify the concern.

- In addition in the IUCLID dossier the justification document for the read-across approach is missing thus an adequate justification should be provided by the Registrant(s).

The initial concern for Alcohols, C7-9-iso-, C8-rich was related to the presence of the substance 2-ethylhexan-1-ol (CAS number 104-76-7), a possible carcinogenic substance according to the QSAR analysis, in the Alkyl Alcohols C6-C13 category.

2-ethylhexan-1-ol was evaluated by Poland in CoRAP 2014 for a concern on developmental toxicity.

The table below briefly describes the endpoints evaluated and the conlusions reached.

Table 3

EVALUATED ENDPOINTS	
Endpoint evaluated	**Outcome/conclusion**
Genotoxicity/Mutagenicity	For genotoxicity the Registrant(s) performed a read-across with the Alcohols, C9-11-iso-, C10-rich, which the eMSCA considers as possibly scientifically plausible but not being sufficiently justified. The eMSCA recommends that the Registrant(s) to better justify the read-across in the registration dossier(s).
Carcinogenicity	Not confirmed.
Sensitisation	The Registrant(s) performed a read-across with the Alcohols, C9-11-iso-, C10-rich. Based on the available data the eMSCA does not see a particular concern for skin sensitisation. The eMSCA recommends that the Registrant(s) to better justify the read-across in the registration dossier(s).
Wide dispersive use Consumer use Exposure of workers	The eMSCA noticed that in setting such RMMs/OCs the Registrant(s) did not make any distinctions between workers/professionals and consumers. The eMSCA recommends that the Registrant(s) perform an exposure assessment and risk characterisation for both workers and consumers. The outcome of those should be reported as conclusions in the relevant sections of the CSR.

7.2. Procedure

The Substance evaluation of the Alcohols, C7-9-iso-, C8-rich has started on March 2016.

The evaluation used information provided in the registration dossiers and additional information available to the eMSCA.

The eMSCA evaluated the read-across information provided for genotoxicy and skin sensitisation as well as the available data on carcinogenicity of 2-ethylhexan-1-ol (the substance that raised the concern).

eMSCA had interaction with the Registrant(s) and following that interaction, the Registrant(s) have made dossier updates.

The eMSCA, taking into account the updated dossier, considered that further information was not necessary to clarify the above mentioned concerns and thus no substance evaluation decision was issued.

7.3. Identity of the substance

Table 4

SUBSTANCE IDENTITY	
Public name:	Alcohols, C7-9-iso-, C8-rich
EC number:	271-231-4
CAS number:	68526-83-0
Index number in Annex VI of the CLP Regulation:	--
Molecular formula:	$C_nH_{2n+1}OH$ (n=7 to 9)
Molecular weight range:	116.20 (n=7) 130.23 (n=8) 144.25 (n=9)
Synonyms:	Exxal8 (trade name) Isooctanol

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

Structural formula:

$CH_3 - R - CH_2 - OH$ where R is a branched aliphatic carbon-chain (C5 to C7)

UVCB substance

Alcohols, C7-9-iso-, C8-rich is an organic UVCB substance with a minimum purity of 99.9% w/w. Alcohols, C7-9-iso-, C8-rich consists of branched-chain saturated primary alcohols, as confirmed by spectral data (IR and ^{1}H-NMR spectra). The carbon-chain number ranges from 7 to 9, where the most abundant carbon number is 8.

Table 5

Constituent			
Constituents	**Typical concentration**	**Concentration range**	**Remarks**
Branched-chain saturated primary alcohols with carbon number 7 ($C_7H_{15}OH$)	Confidential information	Confidential information	Primary alcohol isomers with different branching
Branched-chain saturated primary alcohols with carbon number 8 ($C_8H_{17}OH$)	Confidential information	Confidential information	Primary alcohol isomers with different branching
Branched-chain saturated primary alcohols with carbon number 9 ($C_9H_{19}OH$)	Confidential information	Confidential information	Primary alcohol isomers with different branching

7.4. Physico-chemical properties

Table 6

OVERVIEW OF PHYSICOCHEMICAL PROPERTIES	
Property	**Value**
Physical state at 20°C and 101.3 kPa	Clear colour-less liquid with a mild odour (Pt/Co scale: 5)
Pour point	-90°C by ASTM D5950 (deviation: no pre-heating before cooling) *NB: Determination of pour point is indeed an appropriate alternative for viscous liquids, such as Alcohols, C7-9-iso-, C8-rich, though the result is seemingly out of the temperature range the ASTM D5950 method is designed to cover (i.e. -66°C to+51°C)*
Boiling point	186-192°C at 101.3 kPa by ASTM D1078 (distillation method)
Relative density	0.83 g/cm^3 at 20°C by ASTM D4052 (oscillating densitimeter)
Vapour pressure	40.7 Pa at 25°C (calculated by EPIWIN - Syracuse Research, Inc - MPBPWIN ver. 1.43) 3.5 kPa at 100°C (the VP at different temperatures was calculated using a thermodynamic model, SIMSCI PRO II v 5.5. Values at other temperatures were obtained by interpolation, using the Clausius-Clapeyron equation)
Partition coefficient n-octanol/water (Log Kow)	ca. 3.0 at 25°C and pH 7 (OECD Guideline 117 - HPLC method; estimation based on a set of alcohols as reference standards ranging from C6-C15, with well documented Log Kow values

	ranging from 2.03 to 6.64; detection by refractive index; 'weighted' average approach)
Water solubility	814 mg/L at 25°C (estimation by WSKOWWIN version 1.42, EPISuite based on a Kow correlation method) *NB: For this endpoint, testing should almost always be possible and water solubility should usually be determined experimentally. Nevertheless, no justification for the non-submission of experimental data was presented by the Registrant(s)*
Surface tension	26.3 mN/m at 20°C by the Wilhelmy plate method (EC-M-F02) Test material: neat Alcohols, C7-9-iso-, C8-rich
Flash point	80°C at 101.3 kPa by ASTM D93 (Pensky-Martens closed-cup apparatus)
Flammability	Alcohols, C7-9-iso-, C8-rich is a liquid: please, refer to 'Flash point' above Lower and upper flammable limits (LFL & UFL) are 0.8 v/v% and 6.5 v/v%, respectively No ignition on contact with air No reaction with water observed (no flammable gases emitted)
Auto-flammability	558°C at 101.3 kPa by ASTM E659
Explosive properties	Not explosive, based on theoretical considerations (no chemical groups associated with explosive properties are present in the structure of the constituents)
Oxidising properties	Not oxidizing, based on theoretical considerations (no chemical groups associated with oxidizing properties are present in the structure of the constituents)
Stability in organic solvents	Information not considered to be critical for Alcohols, C7-9-iso-, C8-rich
Dissociation constant	Though a functional group which might be subject to dissociation is present in the structure of the constituents, alcohols are known to have an acidic constant far lower than water, so they are expected to be in their undissociated form at e.g. environmentally relevant pH values Further, none of the available test methods seem to be applicable and/or sensitive enough; therefore, it is not possible to perform a test
Kinematic viscosity	12 mm^2/s at 20°C First, dynamic viscosity was determined by ASTM D 7042 (rotational viscosimeter); then results were converted as kinematic viscosity by dividing by the density value at the same temperature

7.5. Manufacture and uses

7.5.1. Quantities

Table 7

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 10 000 - 100 000 tonnes per year.

This substance is used in the following products: adhesives and sealants, anti-freeze products, biocides (e.g. disinfectants, pest control products), coating products, fillers, putties, plasters, modelling clay, finger paints, non-metal-surface treatment products, inks and toners, leather treatment products, lubricants and greases, polishes and waxes and textile treatment products and dyes.This substance is used in the following areas: mining and formulation of mixtures and/or re-packaging.
This substance is used for the manufacture of: chemicals and fabricated metal products. Release to the environment of this substance is likely to occur from industrial use: in processing aids at industrial sites, as an intermediate step in further manufacturing of another substance (use of intermediates), formulation of mixtures, of substances in closed systems with minimal release and manufacturing of the substance. Other release to the environment of this substance is likely to occur from: indoor use and outdoor use as processing aid.

Table 8

USES	Use(s)
Uses as intermediate	-
Formulation	Formulation and repacking of substances and mixtures
Uses at industrial sites	Use at industrial site as an intermediate Use in coatings Mining chemicals (Industrial) Distribution of substance Metal working fluids/rolling oils Water treatment chemicals
Uses by professional workers	Uses in coatings Metal working fluids/rolling oils
Consumer Uses	Consumer Use [Coatings]
Article service life	-

7.6. Classification and Labelling

7.6.1. Harmonised Classification (Annex VI of CLP)

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

7.6.2. Self-classification

In the registration(s):

Skin Irrit. 2	H315
Eye Irrit.2	H319
Aquatic Chronic 3	H412

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

Acute Tox. 4	H302
Eye Dam. 1	H318
STOT SE 3	H336

7.7. Environmental fate properties

Not relevant for this evaluation.

7.8. Environmental hazard assessment

Not relevant for this evaluation.

7.9. Human Health hazard assessment

7.9.1. Toxicokinetics

The Registrant(s) did not provide information on toxicokinetic, metabolism and distribution of the registred substance.
The Lead Registrant, in the IUCLID dossier, declares that studies for Alcohols, C7-9-iso-, C8-rich (Isooctanol), CAS number 685266-83-0, and Alcohols, C11-14-iso-, C13-rich (Isotridecanol), CAS number 68526-86-3, will be conducted in 2016-2017 to determine the saturation of absorption and excretion.

7.9.2. Acute toxicity and Corrosion/Irritation

Not relevant for this evaluation.

7.9.3. Sensitisation

7.9.3.1 Skin Sensitisation

The Registrant(s) provided the information relevant to this endpoint using a weight of evidence approach, based on evidence from a read-across and QSAR models results, in

accordance with Annex XI, 1.5. The eMSCA considers that the weight of evidence approach is not sufficiently justified. The following section provides the detailed explanation of this:

According to the Registrant(s), the substance Alcohols, C7-9-iso-, C8-rich can be grouped with other similar substances in a category for the purpose of read-across. In particular, the category presented is composed of the following substances: Alcohols, C7-9-iso-, C8-rich; Alcohols, C8-10-iso-, C9-rich; Alcohols, C9-11-iso-, C10-rich; Alcohols, C9-11-branched; and Alcohols, C11-14-iso-, C13-rich. The rationale of the proposed category is based on the incremental and constant change of the chain length of the members. As documented in the read-across hypothesis, the Alcohols, C7-9-iso-, C8-rich are considered by the Registrants as the worst case with respect of toxicological properties, having the shortest chain of carbon atoms. As such, the eMSCA considers that additional information would be necessary on the Alcohols, C7-9-iso-, C8-rich, in order to assess the skin sensitization potential and define the boundaries of the category.
For what concerns QSAR models application, the eMSCA highlights the following points:

1. The two models applied provide different results for some of the substances (e.g. many components have equivocal result in the Danish EPA model), that were not discussed;
2. In the QSAR Prediction Reporting Format (QPRFs) the difference in the models used for the predictions is not clarified (sections 4 of both documents report Danish EPA model);
3. The eMSCA acknowledges the existence of a non-negative experimental result for the substance 6-methylheptan-1-ol (CAS number 26952-21-6), as reported by OECD QSAR Toolbox (Weak positive result in v. 3.3.5.17), the same software used for the QSAR prediction by the Registrant(s).

For the reasons listed, the results of the QSAR models are not acceptable.
The eMSCA does not see a particular concern for skin sensitisation and therefore considers that no further information needs to be requested under this substance evaluation. However, the eMSCA considers the weight of evidence and read-across presented by the Registrant(s) as not sufficiently justified in the registration dossier(s).

7.9.4. Repeated dose toxicity

The Registrant(s) submitted a testing proposal in accordance with Article 40(1) on 11 March 2016 asking for the sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method: EU B.26./OECD TG 408) in rats using the registered substance. An ECHA testing proposal decision requesting this study was recently issued with the deadline of 15 October 2018.

7.9.5. Mutagenicity

The Registrant(s) provided the information relevant to this endpoint using a read-across and grouping approach, in accordance with Annex XI, 1.5. According to the Registrant(s), the substance Alcohols, C7-9-iso-, C8-rich can be grouped with other similar substances in a category for the purpose of read-across. In particular, the category presented is composed of the following substances: Alcohols, C7-9-iso-, C8-rich; Alcohols, C8-10-iso-, C9-rich; Alcohols, C9-11-iso-, C10-rich; Alcohols, C9-11-branched; and Alcohols, C11-14-iso-, C13-rich. The rationale of the proposed category is based on the incremental and constant change of the chain length of the members. As documented in the read-across hypothesis, The Registrant(s) consider the Alcohols, C7-9-iso-, C8-rich as the worst case with respect of toxicological properties, having the shortest chain of carbon atoms. As such, the eMSCA considers that additional testing may be necessary for the Alcohols, C7-9-iso-, C8-rich, in order to assess the mutagenicity potential and define the boundaries of the category.

Although, the eMSCA considers the read-across justification as scientifically plausible, the read-across as presented by the Registrant(s) in its current form does not appear to be sufficiently justified.

7.9.6. Carcinogenicity

The initial carcinogenicity concern for Alcohols, C7-9-iso-, C8-rich, identified in the Justification Document, was related to the presence of the substance 2-ethylhexan-1-ol (CAS number 104-76-7), in the Alkyl Alcohols C6-C13 category, used for the assessment of the substance Alcohols, C7-9-iso, C8-rich.

Carcinogenicity information on 2-ethylexan-1-ol, retrieved with the software OECD QSAR Toolbox, revealed the carcinogenicity concern based on positive experimental results and structure alerts results. These findings were not sufficient to understand completely the mechanisms of carcinogenicity. Therefore, with this alert, the eMSCA considered that more information may be needed in order to clarify the identified concern for carcinogenicity and to completely exclude a possible genotoxic mechanism in case of carcinogenicity.
At present, the initial concern is not supported, by available information and there are not sufficient grounds to justify a request of a relevant study to address the carcinogenicity end-point.
Pending on the results of a the new 90 day study on-going for Alcohols, C7-9-iso-, C8-rich a possible follow-up could be envisaged.

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

The substance has been self-classified as irritant for both skin and eye (i.e., Skin Irritation Cat. 2 (H315: Causes skin irritation) and Eye Irritation Cat. 2 (H319: Causes serious eye irritation).
No DNEL(s)/DMEL(s) for systemic effects have been derived by the registrant. Neither DNEL(s)/DMEL(s) for local effects have been calculated by the registrant since the available data for these adverse effects do not provide quantitative dose-response information. A qualitative risk assessment has been performed by the registrant and it is considered as valid by the eMSCA.

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:

In accordance with the Registrant's conclusion, the substance Alcohols, C7-9-iso-, C8-rich, is to be considered Eye Irritant . 2 H319 (Causes serious eye irritation) and Skin Irritant Cat 2 H315 (Causes skin irritation).

7.10. Assessment of endocrine disrupting (ED) properties

Not relevant for this evaluation.

7.11. PBT and VPVB assessment

Not relevant for this evaluation.

7.12. Exposure assessment

7.12.1. Human health

For the 10 exposure scenarios developed by the Registrant(s) 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. Formulation and repacking of substances and mixtures
2. Use at industrial site as an intermediate
3. Use in coatings
4. Mining chemicals(Industrial)
5. Distribution of substance
6. Metal working fluids/rolling oils
7. Water treatment chemicals
8. Uses in coatings
9. Metal working fluids/rolling oils
10. Consumer Use [Coatings]

The esposure assessment is considered as valid by the eMSCA.

7.12.2. Environment

Not relevant for this evaluation.

7.13. Risk characterisation

Human Health

According to the data available and the self- classification of the substance, qualitative risk assessment for skin and eye has been performed. Following the local risk assessment appropriate Risk Management Measures and Operational Conditions have been set up for workers and consumers. The eMSCA believes that in consideration of the assessment performed and the Risk Management Measures adopted by the Registrant(s), the risks are under control.

However, the eMSCA has highlighted the following minor suggestions that could improve the registration dossier:

The dossier of the substance Alcohols, C7-9-iso-, C8-rich (CAS number 68526-83-0) was updated including exposure scenarios for each use identified. At the same time, considering that the substance is self-classified as Skin Irritant Cat. 2 (H315: Causes skin irritation) and Eye Irritant Cat. 2 (H319: Causes serious eye irritation) a qualitative risk assessment for the local effects was carried out.
According to the criteria set out in the REACH guidance Part E, the substance is allocated in the low hazard band (i.e., moderate hazard) and therefore the RMMs are less stringent, including minimization of the manual handling, or use procedure minimizing splashes and spills. Besides that, the eMSCA agrees with the qualitative risk assessment performed and

the OCs and RMMs set out for risk control during the use of the substance by workers and professionals.
On the other hand, eMSCA noticed that in setting such RMMs/OCs the Registrant(s) did not make any distinctions between workers/professionals and consumers. Conversely, eMSCA believes that for consumers specific task-related risk management measures should be established, instead. All the above in consideration of the fact that the hazard properties of the substance bring to mild and reversible effects which should be controlled also by consumers. In conclusion, eMSCA is of the opinion that a separate local risk assessment for each user category, one addressing RMMs/OCs for workers and professionals and the other for consumers is more appropriate. The outcome of those should be reported as conclusions in the relevant sections of the CSR.

7.14. References

Registration dossier for Alcohols, C7-9-iso-, C8-rich: European Chemicals Agency http://echa.europa.eu/

7.15. Abbreviations

CAS Chemical abstracts service
C&L Classification and labelling
CLP Classification, labelling and packaging (Regulation (EC) No 1272/2008)
CSR Chemical Safety Report
DMEL Derived Minimal Effect Level
DNEL Derived no effect level
eMSCA Evaluating Member State Competent Authority
OCs Operationa Conditions
OECD Organisation for Economic Co-operation and Development
PBT Persistent, Bioaccumulative, Toxic
QPRFs QSAR Prediction Reporting Format
RMMs Risk Management Measures
vPvB Very Persistent and very Bioaccumulative