Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

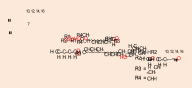
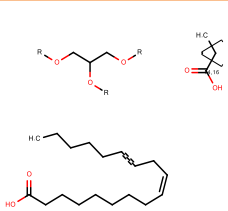
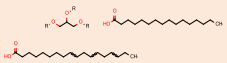
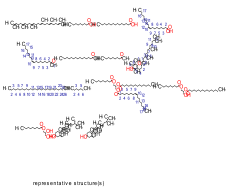
Group Name: Deodorizer distillates

General structure: "-"

Revision history

Version	*Date*	*Description*
1.0	26 February 2024	

Substances within this group:

EC/List no	CAS no	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS, cease manufacture), highest tonnage band among all the registrations (t/y) [1]
270-700-0	68476-80-2	Oils, vegetable, deodorizer distillates		Full, >1000
272-211-8	68783-88-0	Soybean oil, deodorizer distillate		Full, not (publicly) available
272-911-3	68920-03-6	Glycerides, C16-18 and C18-unsatd., deodorizer distillates		Full, 100-1000
949-820-9	-	Squalene-rich fraction obtained from vegetable oil deodorizer distillate by transesterification, crystallisation and vacuum distillation		Full, not (publicly) available

This table does not contain group members that are only notified under the CLP Regulation, however, the list is not necessarily exhaustive.

[1] The total aggregated tonnage band may be available on ECHA's webpage at https://echa.europa.eu/information-on-chemicals/registered-substances

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Foreword

The assessment of regulatory needs of a group of substances is an iterative, informal process to help authorities consider the most appropriate way to address an identified concern for a group of substances or a single substance and decide whether further regulatory risk management activities are necessary.

The grouping is mainly based on structural similarity and associations made by the registrants between substances through read-across and category approaches as well as category associations from external sources (e.g. OECD categories)[2]. These methods are different from grouping as defined in Section 1.5 of Annex XI to REACH because the scope and intended use of ECHA's grouping is different. Thus, in this context, grouping does not aim to validate read-across and category approaches according to the Annex XI requirements but rather to support a faster and more consistent approach for regulating chemicals and avoid regrettable substitution.

The focus of the assessment is largely based on information available in the registration dossiers and on properties requiring regulatory risk management action at EU level[3]. The information reported on uses is from the registration dossiers (IUCLID) and is used as a proxy for assessing how widespread uses are and whether potential for exposure to humans and releases to the environment can be expected. The chemical safety reports are not necessarily consulted and no quantitative exposure assessment is performed at this stage.

The outcome of these assessments are proposals for immediate (the first action) and subsequent regulatory action(s), including the foreseen ultimate regulatory action (last foreseen regulatory action) to address the identified concern(s) in case the potential hazards are confirmed. For example, further data generation through compliance check is suggested as a first action, to confirm the identified hazard.

Where hazards are confirmed, regulatory risk management actions could be considered for the whole group, for a subgroup or for individual substances within the group. The robustness of the group depends on the stage of assessment and the level of certainty this stage requires. For example, the needs for grouping under restriction may differ from the needs for grouping for the purpose of harmonised classification. Group membership is reconsidered accordingly throughout the iterative assessment of regulatory needs, for example, after further information is generated and the hazard has been clarified or when new insights on uses and risks are available.

The assessment of regulatory needs in itself does not represent a regulatory action, but rather a preparatory step to consider further possible regulatory actions at the level of individual substances or groups/subgroups of substances.

[2] Working with Groups - ECHA (europa.eu)

[3] Regarding hazard properties the focus is for instance on CMR (carcinogenic, mutagenic and/or toxic to reproduction), sensitiser, ED (endocrine disruptor), PBT/vPvB or equivalent (e.g. substances being persistent, mobile and toxic), aquatic toxicity hazard endpoints and therefore only those are reflected in the report. This does not mean that the substances do not have other known or potential hazards. In some specific cases, ECHA may consider additional hazards (e.g. neurotoxicity, STOT RE).

Publication of ARNs makes it easier for companies to follow the latest status of their substances of interest, anticipate potential regulatory actions and make strategic choices in their chemicals portfolio.

For more information on assessments of regulatory needs please consult ECHA's website[4].

[4] https://echa.europa.eu/understanding-assessment-regulatory-needs

Glossary

ARN	Assessment of Regulatory Needs
CCH	Compliance Check
CLH	Harmonised classification and labelling
CMR	Carcinogenic, mutagenic and/or toxic to reproduction
DEv	Dossier evaluation
ED	Endocrine disruptor
NONS	Notified new substances
OEL	Occupational exposure limit
OSII or TII	On-site isolated intermediate or transported isolated intermediate
PBT/vPvB	Persistent, bioaccumulative and toxic / very persistent and very bioaccumulative
PMT/vPvM	Persistent, mobile, and toxic / very persistent and very mobile
RDT	Repeated dose toxicity
RMOA	Regulatory management options analysis
RRM	Regulatory risk management
SEv	Substance evaluation
STOT RE	Specific target organ toxicity, repeated exposure
SVHC	Substance of very high concern
TPE	Testing proposal evaluation

1 Overview of the group

Explanations on the scope of this assessment is available in the foreword to this document. Please read it carefully before going through the report.

ECHA has grouped together similar substances based on deodorizer distillation as the common manufacturing process. The deodorizer distillates are produced from vegetable oils and their composition encompasses vegetable fatty acids, glycerides, (phyto)sterols, vitamin E, fatty acid esters, squalene and unsaponifiable matter.

There are four substances in the group, all with full registrations.

Based on information reported in the REACH registration dossiers, one substance (EC 270-700-0) has widespread uses, while the other three substances are only used in industrial settings. EC 270-700-0 is used in the following products: adhesives and sealants, biocides (e.g. disinfectants, pest control products), coating products, fillers, putties, plasters, modelling clay, hydraulic fluids, lubricants and greases, metal working fluids, plant protection products, perfumes and fragrances, pharmaceuticals, polishes and waxes, polymers, washing & cleaning products, cosmetics and personal care products and finger paints. For most of the reported uses exposure to humans and releases to the environment is expected.

Article service life is not reported in the registration dossiers, however, in some cases articles uses may occur.

All the other substances (EC 272-211-8, EC 272-911-3 and List 949-820-9) have intermediate uses in industrial settings reported in their full registrations - either in the manufacture of other chemicals or formulation or are used in energy production (i.e. use for combustion and burning).

2 Conclusions and proposed actions

The conclusions and actions proposed in the table below are based mainly on the REACH and CLP information available at the time of the assessment by ECHA. The conclusions are preliminary suggestions from a screening-level assessment done by ECHA with the aim to propose the next steps for further work (e.g., strengthening of the hazard conclusions, clarification of the uses and/or potential for exposure). The main source of information is the registration dossiers. Relevant public assessments may also be considered. When new information (e.g., on hazards through evaluation processes, or on uses) will become available, the document may be updated, and conclusions and actions revisited.

Table 1: Conclusions and proposed actions

Subgroup name, EC/List no, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
270-700-0	No hazard or unlikely hazard	Inconclusive hazard for PBT/vPvB	Industrial, widespread professional and consumer use in in polymer preparation, coatings and paints, and many other applications (e.g. polishes and wax blends, lubricants, greases, finger paint, fillers, putties, plasters, modelling clay, ink and toners, textile dyes, leather treatment products) for ECH/List ….	**First step:** CCH **Potential last action:** Currently not possible to assess the regulatory needs Justification: Information on PBT/vPvB and aquatic toxicity hazards is not sufficient to conclude

Subgroup name, EC/List no, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
272-211-8 272-911-3 949-820-9	No hazard or unlikely hazard	Inconclusive hazard for PBT/vPvB	Industrial uses with some release potential	**First step:** No action <u>Justification</u>: No action due to low exposure potential; can be revisited after CCH of EC 270-700-0

3 Justification for the (no) need for regulatory risk management action at EU level (if hazards confirmed)

Currently not possible to suggest regulatory risk management actions for ECs/Lists 270-700-0, 272-211-8, 272-911-3, 949-820-9.

It is not possible to assess the needs for regulatory risk management for ECs/Lists 270-700-0, 272-211-8, 272-911-3, 949-820-9 as information on hazard is not sufficient to conclude on PBT/vPvB properties. The needs for regulatory risk management actions will be assessed once generation of data is completed.

Information on hazard is not sufficient to conclude on PBT/vPvB for all substances.

For EC 270-700-0, available experimental data on some constituents does not indicate potential for persistence, however there is remaining uncertainty for other constituents that might be persistent and therefore no conclusions on Persistency can be made. The LogKow for some constituents indicates potential Bioaccumulation and mobility (B and M).

For EC 272-211-8 and 949-820-9 the available information indicates potential for persistency (54% degradation (O2) and 37% degradation (O2) respectively in 28-day ready biodegradability study), whereas no conclusions can be made for B and M in the absence of experimental data or LogKow.

For EC 272-911-3, there is no available data to allow conclusions on P, B and M.

EC 270-700-0 is potentially aquatic toxic based on the available data and self-classification in the registration dossier whereas for the remaining group members no conclusions on aquatic toxicity can be made due to the absence of data or inadequate data. No extrapolation from EC 270-700-0 is currently proposed due to variation in compositions between the group members.

There is no relevant environmental toxicity data available to assess potency for ENV ED of any members in the group, however, the unlikely HH ED (see below) indicates unlikely ENV ED for all group members as well.

For human health all group members are unlikely CMR/ED and skin sensitisers. This is based on the available experimental data on individual constituents of the UVCBs (glycerides, fatty acids, tocopherol) and previous screening on related groups such as fatty acids. There are no indications of potential mutagenicity or systemic toxicity.

Compliance check is proposed for EC 270-700-0. Information from this substance will provide further insight on the potential properties of the structurally similar substances in the group.

The substances ECs/Lists 270-700-0, 272-211-8, 272-911-3, 949-820-9 have a full registration under REACH. Substances ECs/Lists 272-211-8, 272-911-3, 949-820-9 only reported intermediate uses with limited potential for exposure and release into the environment. Substances ECs 272-211-8 and 272-911-3 are used in

formulations. Substance EC 270-700-0 has widespread uses, and based on these uses, exposure and releases to the environment can be assumed. The substances ECs/Lists 270-700-0, 272-211-8, 272-911-3 are used for combustion/burning.

Annex 1: Overview of classifications

Data extracted on 04/10/2023

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
270-700-0				Skin Irrit. 2 H315 Skin Corr. 1C H314 Eye Irrit. 2 H319 Eye Damage 1 H318 Aquatic Chronic 3 H412

Annex 2: Overview of uses based on information available in registration dossiers

Data extracted on 04/10/2023

Table: Overview of main uses

EC number	270-700-0	272-211-8	272-911-3	949-820-9
REACH Annex (information requirements)	Annex X	Annex IX	Annex IX	Annex IX
PC 27: Plant protection products	F, I, **P**, **C**		F, I	
PC 35: Washing and cleaning products	I, **P**, **C**			
PC 8: Biocidal products (e.g. disinfectants, pest control)	F, I, **P**, **C**			
PC 28: Perfumes, fragrances	**C**			
PC 39: Cosmetics, personal care products	I, **P**, **C**		F	
PC 29: Pharmaceuticals	**C**			
PC 31: Polishes and wax blends	F, I, **P**, **C**			
PC 24: Lubricants, greases, release products	F, I, **P**, **C**			
PC 25: Metal working fluids	F, I, **P**, **C**			
PC 17: Hydraulic fluids	F, I, **P**, **C**			
PC 13: Fuels	F, I, **P**, **C**		F, I	
PC 32: Polymer preparations and compounds	F, I, **P**, **C**			
PC 1: Adhesives, sealants	F, I, **P**, **C**			
PC 9c: Finger paint	F, I, **P**, **C**			

PC 9b: Fillers, putties, plasters, modelling clay	F, I, **P**, **C**			
PC 9a: Coatings and paints, thinners, paint removes	F, I, **P**, **C**			
PC 26: Paper and board treatment products	F, I		F, I	
PC 19: Intermediate	F, I			I
Use for combustion/burning	F, I	F, I	F, I	

F: formulation, I: industrial use, P: professional use, C: consumer use, A: article service life; P, C and A are highlighted in red to indicate widespread use with potential for exposure/release

Annex 3: Overview of completed or ongoing regulatory risk management activities

Data extracted on 04/10/2023

No completed or ongoing regulatory risk management activities for any group member.