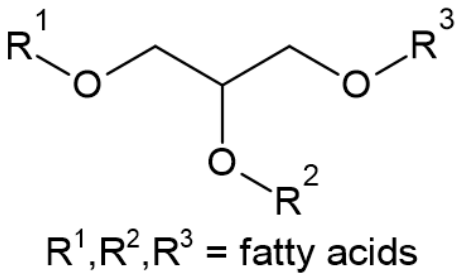
Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Group Name: Blown glycerides and peroxidised glycerides

General structure:



R^1,R^2,R^3 = fatty acids

Revision history

Version	*Date*	*Description*
1.0	26 April 2024	

Substances within this group:

EC/List no*	CAS no	Substance name	Registration type (full, OSII or TII, NONS, cease manufacture), highest tonnage band among all the registrations (t/y) [1]
269-122-1	68187-75-7	Oils, fish, oxidized	Full, 1-10t/y
269-128-4	68187-84-8	Castor oil, oxidized	Full, 100-1000t/y
272-038-8	68649-95-6	Linseed oil, oxidized	Full, >1000t/y
295-734-3	92128-40-0	Glycerides, C10-20 and C10-20-unsatd., oxidized	Full, 100-1000t/y
305-871-3	95193-59-2	Rape oil, oxidized	Full, >1000t/y
614-270-8	68082-79-1	614-270-8	TII <1000t/y
695-121-4	1178870-70-6	695-121-4	TII <1000 t/y
700-155-0	-	Corn oil (Zea mays, Gramineae), peroxidised	Full, 10-100t/y
Substance 1	-	No public or meaningful name is available	not (publicly) available

(*)When a dossier is submitted without EC/List no, REACH-IT automatically assigns a List no to the dossier. Sometimes, due to IT technical limitations, duplicate List no's are created. In this group the following is considered to have a duplicate entry: EC 700-155-0 with a confidential Substance, Substance 1. In general, EC no's take precedence over List no's.

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

Contents

DISCLAIMER

The author does not accept any liability with regard to the use that may be made of the information contained in this document. Usage of the information remains under the sole responsibility of the user. Statements made or information contained in the document are without prejudice to any further regulatory work that ECHA, the Member States or other regulatory agencies may initiate at a later stage. Assessments of regulatory needs and their conclusions are compiled on the basis of available information and may change in light of newly available information or further assessment.

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 chemical's portfolio.

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

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

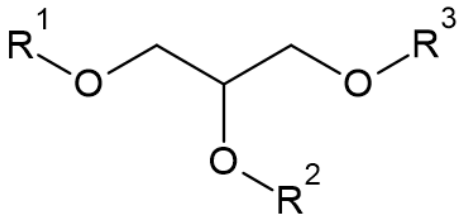
Glossary

ARN	Assessment of Regulatory Needs
ASL	Article Service Life
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 8 UVCBs which are considered as structurally similar substances based on their common manufacturing process and their sources. The sources, depicted below, are oils of vegetal or animal origin, composed of triglycerides which are formed by even numbered fatty acids chains with 12 to 20 carbon atoms, saturated or mono, di or tri unsaturated.



R^1, R^2, R^3 = fatty acids

The triglycerides are oxidised by blowing hot air (~100°C). This causes oxidation of the triglycerides, introducing hydroxyl and hydroperoxyl groups. The triglycerides consequentially oligomerise, forming dimers, trimers, and higher oligomers. This leads to an increase in viscosity. The process continues until the desired viscosity is achieved.

The group is comprised of 8 substances, 2 of which are intermediates and 6 substances have full registrations. All the substances are considered UVCBs.

These substances are structurally very similar, being thus potential candidates for regrettable substitution, if any hazards are confirmed for any of the group. However, if they remain confirmed as non-hazardous, their technical functions support similar use pattern (interchangeability).

Based on information reported in the REACH registration dossiers, most of the substances have both industrial (including intermediate and formulation) and widespread professional and consumer uses with potential for exposure and releases to the environment, including article service life. Examples include adhesives, functional fluids, leather treatment products, lubricants, paints and coatings, inks, solvents, tackifiers. Specific product legislation will address uses as cosmetics and pharmaceuticals.

No regulatory actions are initiated so far for any of the substances. In addition, it should be recognised that their starting materials, vegetable, or animal C12 – 20 fatty acids, are currently exempted from REACH by Art. 2 (5) b (food and feeding stuffs) and Annex V**.**

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
272-038-8	Inconclusive hazard for mutagenicity, carcinogenicity	Inconclusive hazard for PMT/vPvM and aquatic toxicity No hazard or unlikely hazard for PBT/vPvB	Widespread professional and consumer uses in adhesives and sealants, coatings and paints, fillers, ink, and toners, including Article Service Life (ASL) with potential for exposure and releases.	**First step:** Pending action: data generation ongoing in TPE **CCH** **Potential last action:** Currently not possible to assess the regulatory needs Justification: It is not possible to assess the needs for regulatory risk management for EC 272-038-8 as information on hazard is not sufficient to conclude on mutagenicity and PMT/vPvM potential and aquatic toxicity. The needs for regulatory risk

Subgroup name, EC/List no, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
				management actions will be assessed once generation of data is completed.
269-122-1 269-128-4, 295-734-3, 305-871-3, 700-155-0, 614-270-8*, 695-121-4*, Substance 1	No hazard or unlikely hazard for mutagenicity, carcinogenicity, reproductive toxicity, STOT RE, skin sensitisation, ED	Inconclusive hazard for PMT/vPvM and for aquatic toxicity No hazard or unlikely hazard for PBT/vPvB	Widespread professional and consumer uses such as cosmetics; pharmaceuticals; lubricants and greases (incl. ASL for EC 295-734-3); metal working, heat transfer and hydraulic fluids; adhesives and sealants; coatings and paints; fillers; ink and toners; or leather treatment including ASL (ECs 295-734-3 & 305-871-3) with potential for exposure and releases. Also, many industrial (including intermediate and formulation) uses.	**First step: CCH** suggested for 269-122-1, 269-128-4, 295-734-3, 305-871-3, 700-155-0 **Potential last action:** Currently not possible to assess the regulatory needs Justification: It is not possible to assess the needs for regulatory risk management for 269-122-1, 269-128-4, 295-734-3, 305-871-3 and 700-155-0 as information on hazard is not sufficient to conclude on PMT/vPvM potential and aquatic toxicity. The needs for regulatory risk management actions will be assessed once generation of data is completed.

*Intermediates

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 EC 272-038-8 due to inconclusive information on mutagenicity, carcinogenicity and for all the substances due to PMT/vPvM and aquatic toxicity.

Based on currently available information, for **mutagenicity and carcinogenicity,** these human health hazards are inconclusive for **EC 272-038-8**. This hypothesis for **mutagenicity** is based for EC 272-038-8 on positive *in vitro* gene mutation study in mammalian cells without an *in vivo* follow-up study confirming the hazard (ongoing Comet assay data generation). For **carcinogenicity**, hazard is considered inconclusive for EC 272-038-8 based on the uncertainty of the ongoing data generation for mutagenicity. Due to ongoing testing proposal for **EC 272-038-8 for** mutagenicity and proposal to open a CCH, it is not possible to assess the needs for regulatory risk management as information on hazard is not sufficient to conclude on mutagenicity, carcinogenicity and for PMT/vPvM and aquatic toxicity. The needs for regulatory risk management actions will be assessed once generation of data is completed for this substance.

Based on currently available information, for mutagenicity, skin sensitisation, STOT RE, reproductive toxicity, endocrine disruption (ED HH and ENV), carcinogenicity and PBT/vPvB, these hazards are considered unlikely for **ECs/List no 269-122-1, 269-128-4, 295-734-3, 305-871-3, 700-155-0, 614-270-8*[5], 695-121-4*.** For mutagenicity, these substances are considered unlikely based on negative in vitro studies for four substances in the group. For skin sensitisation this is based on three OECD 429 and one OECD 406 negative studies. For STOT RE, reproductive toxicity and ED HH, this hypothesis is based on three combined repeated dose toxicity studies (OECD 422) reporting no adverse effects up to 1000 mg/kg bw/d. These hypotheses are extrapolated to substances with no data available. Based on currently available information, for **carcinogenicity**, the hazard is considered unlikely with uncertainty. This is based on the limited number of repeated dose studies with no indication of carcinogenicity and negative in vitro mutagenicity studies.

Based on currently available information **PMT/vPvM and aquatic toxicity** are inconclusive for **all the substances in the group**. All UVCBs in the group are considered to have overlapping structurally similar areas of monomers, dimers, trimers, and higher oligomers of triglycerides. Triglyceride monomers are the majority of the composition in all registrations followed by trimers and higher oligomers. Based on available OECD 301B tests, ECs/Lists 272-038-8, 269-122-1, 700-155-0 & 305-871-3 are considered as inconclusive for P/vP. Whilst these UVCBs reach the threshold of the criteria for the OECD 301X tests, at the end of the tests, the amount of unreacted natural triglycerides does vary (ranging between 6% - 40%). While natural triglycerides are known to be biodegradable from literature, these UVCBs have been chemically modified. The triglycerides oligomerise, forming dimers, trimers, and higher oligomers. So, there is some level of uncertainty for P/vP. The remaining UVCBs, ECs/lists: 269-128-4, 295-734-3,

[5] *Intermediate

614-270-8 & 695-121-4 in the group are also considered as inconclusive for P/vP, through group extrapolation.

Regarding M/vM, there are no Log Koc values available for the group members. Two UVCBs, ECs/Lists 272-038-8, 700-155-0 have QSAR Log Kow values > 6. There are no experimental Log Kow values. These QSAR values represent the UVCB, as a whole. However, as there is no range provided or experimental Log Kow values, it is unclear, if there are constituents within the UVCB, which may be potential M/vM or not. To capture this uncertainty, the group is considered as inconclusive for M/vM. Through group extrapolation for the remaining UVCBs, they are also considered as inconclusive for M/vM, as having overlapped structurally similar areas of triglycerides.

Regarding B/vB, all substances of the group are considered unlikely to fulfil the PBT/vPvB screening criteria. These substances have high Log Kow > 4.5 values. However, they are considered as low potential for bioaccumulation as metabolisation /biotransformation/excretion via fatty acid metabolism, is likely. From Human health data, there is limited absorption expected based on low water solubility (ranging from < 1 mg/L at 20°C - < 0.0524 mg/l at 20ºC), no systemic toxicity, no effects of metabolic activation and no adverse microscopic findings in liver and kidneys.

Regarding aquatic toxicity, all the group have low water solubility (ranging from < 1 mg/L at 20°C - < 0.0524 mg/l at 20ºC), so the validity of all the acute aquatic toxicity information is in question. There are no long-term aquatic toxicity tests for any group members. Therefore, it is not possible to conclude on their potency to meet the T criteria (NOEC or EC10 < 0.01 mg/L) for the environment. No UVCBs in the group meet the T criteria for Human health. Based on currently available aquatic toxicity hazard information it is not possible to conclude on aquatic toxicity.

These substances have no indications of potential ED for human health or available data for ED for environment.

Clarification on uses: Based on information reported in the REACH registration dossiers, most of the substances have high registered tonnages, both industrial (including intermediate and formulation) and widespread professional and consumer uses with potential for exposure and releases to the environment, including article service life, with potential for exposure and releases. Most substances of this group are used as formulations. Some uses like adhesives, sealants, fillers, putties, plasters, inks and toners, paints and coatings and leather treatment products likely have an article service life. Substances registered as intermediates are expected to be used industrially as precursors under strictly controlled conditions, not ending up to professional or consumer formulations. Registrants are invited to clarify whether or not the uses reported for the substance(s) are supported and to update their dossiers accordingly. In the next iteration to this assessment of regulatory needs, all uses still present in registrations will be considered of relevance and if the potential hazard properties are confirmed, further regulatory risk management will be considered.

For substances EC 269-122-1, 269-128-4, 295-734-3, 272-038-8, 305-871-3 & 700-155-0 a CCH is proposed to be opened to clarify the available data and/or adaptations (read-across, weight of evidence and/or QSARs hazards).

Annex 1: Overview of classifications

Data extracted on 4.9.2023.

No Harmonised classification or Classification in registrations

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

Data extracted on 4.9.2023.

Main types of applications structured by product or article types	269-122-1	269-128-4	272-038-8	295-734-3	305-871-3	614-270-8	695-121-4	700-155-0
PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents					F, I			
PC 35: Washing and cleaning products	I					I	I	
PC 39: Cosmetics, personal care products				F, **P**, **C**				F, **P, C**
PC 29: Pharmaceuticals								F, **P**, **C**
PC 31: Polishes and wax blends		F						
PC 24: Lubricants, greases, release products	F, I	F		F, I, **P, C, A**	F, I, **P, C**			
PC 25: Metal working fluids				F, I	F, I, **P**			
PC 16: Heat transfer fluids				I, **P**				
PC 17: Hydraulic fluids		F		F, I, **P**	F, I, **P**			
PC 32: Polymer preparations and compounds					F, I			
PC 1: Adhesives, sealants		F, I**, P, C**	F, I, **P, C, A**					
PC 9b: Fillers, putties, plasters, modelling clay		F, I, **P, C**	F, I, **P, C, A**					

PC 9a: Coatings and paints, thinners, paint removes		F, I, **P, C**	F, I, **P, C**					
PC 18: Ink and toners		F, I**, P, C**	F, I, **P, C, A**					
PC 23: Leather treatment products	F, I			F, I, **C, A**	F, I, **A**	F, I	I	
PC 19: Intermediate	F, I			I	F, I	I, **P**	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

Based on data extracted 27.9.2023, there are no relevant completed or ongoing regulatory risk management activities for any of the substances.