Assessment of regulatory needs

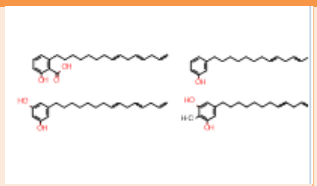
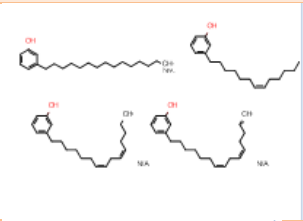
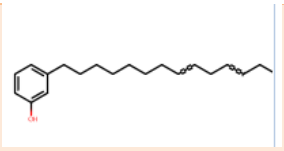
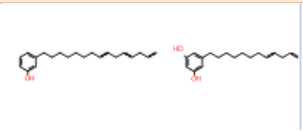
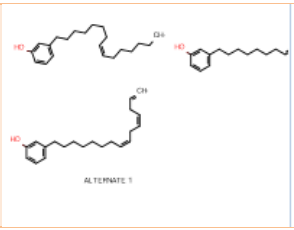
Authority: European Chemicals Agency (ECHA)

Group Name: Cardanols

Revision history

Version	*Date*	*Description*
1.0	4 February 2022	

Substances within this group:

EC / List number	CAS number	Substance name [and / or Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
232-355-4 same substance identified by registration for 700-991-6	8007-24-7	Cashew, nutshell liq.		Full, not (publicly) available
700-991-6	8007-24-7	Cashew (Anacardium occidentale) Nutshell Extract, Decarboxylated, Distilled		Full, > 1,000
941-212-1		No IUPAC name is currently defined for Cashew (Anacardium occidentale) Nutshell Extract, Decarboxylated, Distilled ("Distilled Residue Grade")		Full, > 1,000
941-216-3		No IUPAC name is currently defined for Cashew (Anacardium occidentale) Nutshell Extract, Decarboxylated ("Technical Grade").		Full, > 1,000
947-945-3 duplicate of 700-991-6		Reaction mass of Cardanol diene and Cardanol monoene and Cardanol triene		Full, not (publicly) available
609-405-2	37330-39-5	Distilled CNSL liquid (Cardanol)		C&L notification

This table contains also group members that are only notified under the CLP Regulation. However, the list is currently non-exhaustive. Should further regulatory risk management action on one or more substances in the group be considered, ECHA will make an additional search for related C&L notified substances to be included in the group and develop an assessment of regulatory needs for them.

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

Contents

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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. Assessment 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 purpose of the assessment of regulatory needs of a group of substances is to help authorities conclude on the most appropriate way to address the identified concerns for a group of substances or a single substance, i.e. the combination of the regulatory risk management instruments to be used and any intermediate steps, such as data generation, needed to initiate and introduce these regulatory measures.

An assessment of regulatory needs can conclude that regulatory risk management at EU level is required for a (group of) substance(s) (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. While the assessment is done for a group of substances, the (no) need for regulatory action can be identified for the whole group, a subgroup or for single substance(s).

The assessment of regulatory needs is an important step under ECHA's Integrated Regulatory Strategy. However, it is not part of the formal processes defined in the legislation but aims to support them.

The assessment of regulatory needs can be applied to any group of substances or single substance, i.e., any type of hazards or uses and regardless of the previous regulatory history or lack of such. It can be done based on different level of information. A Member State or ECHA can carry out this case-by-case analysis. The starting point is available information in the REACH registrations and any other REACH and CLP information. However, more extensive set of information can be available, e.g. assessment done under REACH/CLP or other EU legislation, or can be generated in some cases (e.g. further hazard information under dossier evaluation). Uncertainties associated to the level of information used should be reflected in the documentation. It will be revisited when necessary. For example, after further information is generated and the hazard has been clarified or when new insights on uses are available. It can be revisited by the same or another authority.

The responsibility for the content of this assessment rests with the authority that developed it. It is possible that other authorities do not have the same view and may develop further assessment of regulatory needs. The assessment of regulatory needs does not yet initiate any regulatory process but any authority can consequently do so and should indicate this by appropriate means, such as the Registry of Intentions.

For more information on Assessment of regulatory needs please consult ECHA website[2].

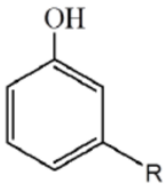
[2] https://echa.europa.eu/understanding-assessment-regulatory-needs

Glossary

CCH	Compliance Check
CLH	Harmonised classification and labelling
CMR	Carcinogenic, mutagenic and/or toxic to reproduction
CNSL	Cashew nutshell liquid
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
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
UVCB	Unknown or variable composition, complex reaction products or of biological materials.

1 Overview of the group

ECHA has grouped together structurally similar substances based on the presence of the phenol moiety shown in the figure below. The group boundaries consist of substances without any other functionality besides one phenol. All substances are of unknown or variable composition, complex reaction products or of biological materials (UVCB).



The group consists of 5 registered substances, however, some substances are after initial registration considered to be of same identity.

The three currently manufactured/imported substances i.e. List Nos. 700-991-6, 941-212-1, 941-216-3 are obtained as a by-products of the cashew nut industry. Cashew nutshell liquid (CNSL) is extracted from cashew nut shells. The CNSL is decarboxylated at high temperatures resulting in 941-216-3, the crude extract. Via distillation the substance 700-991-6 is gained, plus the remaining residue 941-212-1. All three UVCB substances are rich in unsaturated substituted phenols and well recognised as a natural alternative to petrochemically derived phenols.

The substances are manufactured at high volumes (1,000 - <10,000 t/y aggregated tonnage) and used in polymers, providing properties like quick drying, high electrical insulation and good thermal stability.

Based on information reported in the REACH registration dossiers, the substances are used at industrial sites (mainly in polymers with different functions), by professionals and consumers, leading to high potential for exposure, in particular when used in coatings, adhesives and sealants or special inks. Applications of coatings, adhesives and sealants take mainly place at building and construction sites and include spraying, brushing and dipping, for which the likelihood of exposure to professional workers and consumers is high. Although not identified in the registrations, it can be expected from the use pattern (e.g. as adhesives or coatings) that the substances end up in articles. Releases from those articles might be low but cannot be excluded based on the available information.

The substances are also indicated in registration dossiers to have biocidal effects, though none of them is listed as biocidal active substance. Additionally, the substances are also used for fuel production. The CNSL derivatives have good properties as green diesel for compression ignition engines with similar properties as petro-diesel, in particular if it is further modified (Kumar et al., 2018) [3].

[3] Shiva Kumar; Dinesha P. and Marc A. Rosen (2018): Cashew Nut Shell Liquid as a Fuel for Compression Ignition Engines: A Comprehensive Review. In: Energy Fuels 2018, 32, pp. 7237-7244

Note on the scope of ECHA's assessment of regulatory needs

Regarding hazards, the focus of ECHA's assessment is 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 table in section 3. This does not mean that the substances do not have other known or potential hazards. In some specific cases, where ECHA identifies a need for regulatory risk management action at EU level for other hazards (e.g. neurotoxicity, STOT RE), such additional hazards may be addressed in the assessment. An overview of classification is presented in Annex 1.

On the exposure side, ECHA is mainly using the information on uses reported in the registration dossiers (IUCLID) as a proxy for assessing the potential for exposure to humans and releases to the environment. The potential for release / exposure is generally considered high for "widespread" uses, i.e. professional and consumer uses and uses in articles. For these uses, normally happening at many places, the expected level of control is *à priori* considered limited. The chemical safety reports are not necessarily consulted and no quantitative exposure assessment is performed at this stage.

2 Justification for the need for regulatory risk management action at EU level

Based on currently available information, there is a need for (further) EU regulatory risk management – restriction, possibly combined with authorisation for reproductive toxicity and ED hazards due to the potential for release/ exposure of all substances in the group.

Based on ECHA's assessment of currently available hazard information, the substances in the group have potential reproductive toxicity (decreased rate of pregnancy and embryonic losses implantation) and ED properties (thyroid) for human health. Though no data is available on ED environment, phenol derivatives are in general suspected to have ED environment properties. PBT hazard is unlikely, however this would need to be confirmed by further data generation. Data generation, i.e. compliance check (CCH) is proposed to assess the potential for reproductive toxicity and ED human health and environment and to verify the unlikely PBT/vPvB properties.

The substances are seen as a natural source for phenols and therefore potential substitutes for petro-chemical phenols used in polymer production and already heavily regulated (i.e. several phenol substances with reprotoxic and/or endocrine disrupting properties on the Candidate List and/or restricted). Therefore, clarifying the hazards of these substances is particularly crucial.

After the currently ongoing testing proposal evaluation, CCH will aim at generating data on the registered substances to confirm Repr., ED human health and ED environmental hazards, while ensuring that PBT/vPvB hazard is unlikely. This might need to be followed up by substance evaluation (SEv) to further confirm ED human health and/or ED environmental hazards.

Based on the currently available information, we propose a restriction targeting the professional and consumer uses and possibly authorisation for industrial uses.

The first step of the regulatory risk management action proposed, should the hazard exist, is the confirmation of hazard via harmonised classification (CLH) as Repr. 1B.

CLH i) will require company level risk management measures (RMM) under the OSH legislation for workers, to be in place, ii) is needed or highly recommended for further regulatory processes under REACH and iii) is a prerequisite to restrict the presence of the substances in consumer mixtures, by means of the restriction entry 30.

Should the hazard exist the confirmation of hazard via SVHC identification and inclusion on the Candidate List as ED and reproductive toxicity may be considered. SVHC identification is highly recommended as a step prior to restriction and is required as a step prior to authorisation, if concluded as a parallel risk management measure. SVHC identification may take place in parallel or may be initiated ahead of a potential restriction submission.

The professional uses in coatings, adhesives, sealants and inks are expected to be widespread (at many sites and by many users). Professional use is often widespread with relatively low levels of operational controls and risk management measures but with often frequent exposures with a long duration. In addition, professional users may be self-employed and therefore not covered by occupational safety and health (OSH) legislation.

Consumers may be co-exposed to the substances used by professionals e.g. house painters/ renovators.

Therefore, a **restriction of the substance as such or in mixtures (concentration limit in mixtures) used by professionals** is suggested after CLH and SVHC identification.

Restriction of professional uses is preferred over authorisation as it is considered to be more efficient and effective to introduce controls at the level of placing on the market rather than at the level of uses.

In addition, the use of the most harmful substances by professional workers has been recognised as an area of concern under the European Commission's Chemicals Strategy for Sustainability[4] which aims to extend to professional users under REACH the level of protection granted to consumers.

Moreover, **restricting substances in articles** used by professionals or consumers should be considered in the context of the restriction of professional uses as potential exposure from articles needs further investigation first.

When considering the use as fuel additive, a restriction might be less proportionate, in particular, when comparing petro-diesel with biodiesel obtained from CNSL, also considering that the substances would be consumed during the use and no further exposure would be expected.

To avoid unwanted substitution, consistency with other restrictions of phenol substances should also be ensured when proposing the restriction, e.g., the bisphenols restriction, which have similar hazard profile.

It is suggested to cover possibly also industrial uses as part of the restriction.

[4] European Commission, *Chemical Strategy for Sustainability Towards a Toxic-Free Environment*, available at https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf

However, the need for authorisation might be considered for industrial uses excluded from the scope of the restriction as it may not be proportionate to restrict all uses.

There is also a concern related to known skin sensitisation hazard present in the group. For industrial and professional uses, sufficient and consistent self-classification by registrants for this hazard should require adequate risk management measures to be in place according to workplace legislation.

Adequate product labelling should in principle provide consumers with sufficient information to manage risks arising from the use of mixtures containing the substances.

However, there is a general concern related to skin sensitisers (potentially) present in consumer mixtures and the need to further investigate whether further regulatory actions are needed and what would be the best options to address this concern.

Such concern has already been identified in other groups of substances and was brought for further discussion to Member States. Work is ongoing on this generic issue by both Member States and ECHA which may affect the regulatory actions on substances in this group.

3 Conclusions and actions

The conclusions and actions proposed in the table below are based on the REACH and CLP information available at the time of the assessment by ECHA. 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 will be updated and conclusions and actions revisited.

EC / List number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
941-216-3 **941-212-1** **700-991-6**	Known or potential hazard for reproductive toxicity, ED, skin sensitisation	Known or potential hazard for aquatic toxicity	Industrial, professional and consumer uses in (polymer) coatings, adhesives and sealants, special inks and as fuel additive. Potential for exposure for workers and consumers and release from articles.	**Need for EU RRM: Restriction combined with authorisation** <u>Justification:</u> Releases to the environment from consumer and widespread professional uses cannot be avoided. Widespread professional uses are typically non-contained and non-automated leading to releases to the environment. Restriction of professional uses is preferred over authorisation as it is considered to be more efficient and effective to	**First step:** CCH, substance evaluation **Next steps (if hazard confirmed):** • CLH • SVHC identification • Restriction for professional uses and possibly industrial uses • Authorisation for remaining industrial uses
947-945-3 **232-355-4** **609-405-2**			Substances are duplicates or potential substitutes (C&L notification for 609-405-2) for the currently manufactured/imported substances.		

EC / List number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
				introduce controls at the level of placing on the market rather than at the level of uses. Potential exposure from articles needs further investigation, restriction for use in articles to be considered together with the restriction of professional uses. Industrial uses to be considered as part of the restriction For remaining industrial uses, authorisation may be considered. The concern related to the presence of skin sensitisers in consumer mixtures is under investigation.	

Annex 1: Overview of classifications

Data extracted on 3 May 2021.

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
232-355-4	8007-24-7	Cashew, nutshell liq.	-	*Acute Tox. 4, H312* *Skin Irrit. 2, H315* *Eye damage 1, H318* *Skin Sens. 1A, H317* *Aquatic Chronic 4, H412*	-
700-991-6	8007-24-7	Cashew (Anacardium occidentale) Nutshell Extract, Decarboxylated, Distilled	-	*Acute Tox. 4, H302* *Acute Tox. 4, H312* *Skin Irrit. 2, H315* *Eye damage 1, H318* *Skin Sens. 1A, H317* *Aquatic Acute 1, H402* *Aquatic Chronic 1, H410* *Aquatic Chronic 3, H412*	*Acute Tox. 4, H302* *Acute Tox. 4, H312* *Skin Irrit. 2, H315* *Eye Irrit. 2, H319* *Eye Dam. 1, H318* *Skin Sens. 1A, H317* *Skin Sens 1. H317*
941-212-1		No IUPAC name is currently defined for Cashew (Anacardium occidentale) Nutshell Extract, Decarboxylated, Distilled (“Distilled Residue Grade”)		*Acute Tox. 4, H302* *Acute Tox. 4, H312* *Skin Irrit. 2, H315* *Eye damage 1, H318* *Skin Sens. 1A, H317*	*Acute Tox. 4, H302* *Acute Tox. 4, H312* *Skin Irrit. 2, H315* *Eye Dam. 1, H318* *Skin Sens. 1A, H317*
941-216-3		No IUPAC name is currently defined for Cashew (Anacardium occidentale) Nutshell Extract, Decarboxylated (“Technical Grade”).		*Acute Tox. 4, H302* *Acute Tox. 4, H312* *Skin Irrit. 2, H315* *Eye Dam. 1, H318* *Skin Sens. 1A, H317*	*Acute Tox. 4, H302* *Acute Tox. 4, H312* *Skin Irrit. 2, H315* *Eye Dam. 1, H318* *Skin Sens. 1A, H317*

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
947-945-3		Reaction mass of Cardanol diene and Cardanol monoene and Cardanol triene		*Skin Irrit. 2, H315* *Eye Irrit. 2, H319* *Skin Sens 1. H317*	*Skin Irrit. 2, H315* *Eye Irrit. 2, H319* *Skin Sens 1. H317*
232-355-4	37330-39-5	Distilled CNSL liquid (Cardanol)	**-**	*Acute Tox. 4, H312* *Skin Irrit. 2, H315* *Eye damage 1, H318* *Skin Sens. 1A, H317* *Aquatic Chronic 4, H412*	-

(*) the number in brackets indicates the number of notifications received. Each notification can represent a group of notifiers, therefore the number may differ from the C&L inventory which displays number of notifiers.

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

Data extracted on 3 May 2021.

Main types of applications structured by product or article types	700-991-6 (former 232-355-4, same as 947-945-3)	941-212-1	941-216-3
Adhesives, sealants	I, **P, C, (A)**	F, I, **P, C, (A)**	F, I, **P, C, (A)**
Coatings and paints, thinners, paint removes	F, I, **P, C, (A)**	I, **P, C, (A)**	I, **P, C, (A)**
Ink and toners	F, I, **P, C, (A)**		
Intermediate use	I	F, I	F, I
Polymer preparations and compounds	I, **P, C, (A)**	I, **P, C, (A)**	I, **P, C, (A)**
Biocidal products (e.g. disinfectants, pest control)	I	I	I
Fuels	F, I, **P, C**	I	I
Fillers, putties, plasters, modelling clay	F, I	I	
Wood and paper treatment products	I		I

F: formulation, I: industrial use, P: professional use, C: consumer use, A: article service life; (A): article service life not reported in registrations but may be relevant. 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

There are no relevant completed or ongoing regulatory risk management activities substances (on 26 May 2021).