Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Date: 7 May 2021

Group Name: Montan, carnauba and rice bran wax derivatives

General structure: -

Revision history

Version	*Date*	*Description*
1.0	15 September 2022	

Substances within this group:

EC/List number	CAS number	Substance name [and/ or Substance name acronyms]	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
232-313-5	8002-53-7	Montan wax	OSII or TII, not (publicly) available
232-399-4*	8015-86-9	Carnauba wax	Not registered
269-642-9	68308-30-5	Fatty acids, montan-wax, stearyl esters	FULL, not (publicly) available
700-660-6	-	Saponification and oxidation product of carnauba wax with acidic sodium dichromate solution	FULL, not (publicly) available
700-720-1	-	Saponification and oxidation product of carnauba wax with acidic sodium dichromate solution esterified with ethylene glycol	FULL, not (publicly) available
700-725-9	-	Saponification and oxidation product of carnauba wax with acidic sodium dichromate solution esterified with 1-methyl-1,3-propanediol and subsequent saponification with calcium dihydroxide	FULL, not (publicly) available
911-428-0	-	Reaction mass of Fatty acids, montan-wax and Fatty acids, montan-wax, ethylene esters and Fatty acids, montan wax, mixed esters with fatty acids C16-18 and ethylene glycol and Fatty acids, montan-wax, stearyl esters and Montan wax	FULL, not (publicly) available
914-459-8	-	Reaction mass of Fatty acids, montan-wax and Fatty acids, montan-wax, calcium salts and Montan wax	FULL, 100-1000
914-460-3	-	Reaction mass of Fatty acids, montan-wax and Fatty acids, montan-wax, 1-methyl-1,3-propanediyl esters and Fatty acids, montan-wax, calcium salts and Montan wax	FULL, not (publicly) available
914-461-9	-	Reaction mass of Fatty acids, montan-wax, 1-methyl-1,3-propanediyl esters and Fatty acids, montan-wax, calcium salts and Fatty acids, montan-wax, ethylene esters and Fatty acids, montan-wax and Montan wax	FULL, not (publicly) available
914-467-1	-	Reaction mass of Fatty acids, montan-wax and Glycerides, montan-wax and Glycerides, tallow mono-, di- and tri-, hydrogenated and Montan wax	FULL, not (publicly) available

[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

914-468-7	-	Reaction mass of Fatty acids, montan-wax and Montan wax	FULL, not (publicly) available
914-469-2	-	Reaction mass of Fatty acids, montan-wax and Glycerides, montan-wax and Montan wax	FULL, 100-1000
914-471-3	-	Reaction mass of fatty acids, montan-wax, 1-methyl-1,3- propanediyl esters and fatty acids, montan-wax, ethylene esters and fatty	FULL, not (publicly) available
914-475-5	-	Reaction mass of Fatty acids, montan-wax and Fatty acids, montan-wax, ethylene esters and Montan wax	FULL, not (publicly) available
914-478-1	-	Reaction mass of montan wax and fatty acids, montan-wax, mixed esters with adipic acid and trimethylolpropane and fatty acids, montan-wax and fatty acids, montan-wax, esters with trimethylolpropane	FULL, not (publicly) available
914-479-7	-	Reaction mass of Fatty acids, montan-wax and Fatty acids, montan-wax, sodium salts and Montan wax	FULL, not (publicly) available
-	-	Polar modified Rice Bran Wax	FULL, not (publicly) available
-	-	[No public or meaningful name is available]	FULL, not (publicly) available

** Exempt from registration according to REACH, Annex V*

This table contains also members that are only notified under the CLP Regulation. [However, the list is not necessarily exhaustive.] Should further regulatory risk management action on one or more substances in the group be considered, ECHA may 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.

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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 a 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, a 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

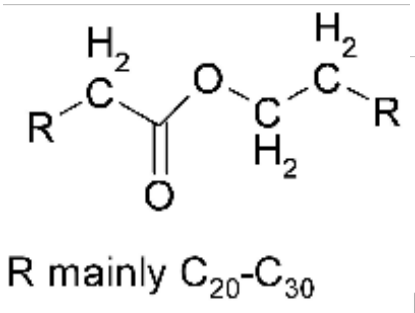
Glossary

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
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

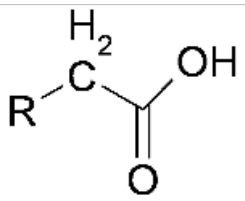
1 Overview of the group

ECHA has grouped together montan, carnauba and rice bran wax derivatives consisting of 19 complex UVCB substances. All three waxes (montan, carnauba and rice bran) are refined before derivatisation. The refinement involves oxidative bleaching, typically with chromic acid or chromates. As a result, the wax esters are hydrolysed, and the wax alcohols formed are subsequently oxidised to wax acids. The hydroxycarboxylic acids are oxidised to dicarboxylic acids and some esters remain unaltered (they are called native esters).

The oxidised waxes are derivatised by esterification reaction with alcohols (typically diols or polyols or with combination of these alcohols). Esterification reaction can also involve additional acids, besides the oxidised wax acids. Two representative structures of common components are shown below.



R mainly C_{20}-C_{30}



R mainly C_{20}-C_{30}

As a result of the derivatisation, the constituents of relatively large molecular weight are obtained. In a number of cases the content of total chromium and chromium VI was measured and proved to be below the regulatory threshold for hazard classification.

The group members are:

- Montan and carnauba wax and derivatives; they contain mostly fatty acids and esterification and saponification products of high molecular weight.
- Rice bran wax derivatives; along with esters and high molecular weight carboxylic acids, they contain also short and medium chain carboxylic acids.

Based on information reported in the REACH registration dossiers, many of the substances are used as lubricating agent, dispersing agent, mould release and stabilising agent. Several widespread uses are reported including use in leather, paper and board treatment products, use in polishes and wax blends, use in polymer preparations (including in plastics processing), use in lubricants, greases and release products and use in cosmetics. Overall, there is a potential for exposure for both industrial and professional workers, for consumers and potential for release to the environment. Furthermore, exposure as a result of article service life is likely.

Available information on uses and structural similarities indicates a similar use pattern for the majority of substances in the group; consequently, it is assumed that release and exposure cannot be excluded for all group members.

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 no need for regulatory risk management action at EU level

Based on currently available information, there is no need for (further) EU regulatory risk management for all group members due to low hazard potential for both **human health** and the **environment**.

The available information taking into account structural similarity between the group members indicates that hazard is unlikely for all group members. The substances are UVCBs with complex compositions but mainly composed of constituents unlikely to be hazardous: esters of fatty acids and alcohols (diols, polyols and their combinations), fatty acids, native esters and dicarboxylic acids. No hazardous constituents (in relevant amounts) and no hazard classifications have been reported in the registration dossiers. Most constituents in both subgroups are very large molecules and therefore have low bioavailability and consequently low potential for bioaccumulation and (aquatic) toxicity. Toxicokinetic data has been provided indicating that the waxes are expected to be metabolised and excreted or used in the same manner as other long chain fatty acids further supporting the low potential for toxicity. No skin sensitisation or mutagenicity has been observed in the available experimental data. No significant systemic toxicity, or any reproductive toxicity has been identified in the experimental data available.

The substances are unlikely to fulfil the PBT/vPvB screening criteria, because they have a low potential for bioaccumulation and are unlikely to fulfil the T criterion. None of the group members is classified for environmental hazards and no effects justifying classification were observed in available ecotoxicity tests up to the water solubility limit or the nominal limit concentration of 100 mg/L for most of the constituents.

Furthermore, from the available information, there is no indication that the substances in this group could exhibit endocrine disruption properties as no effects on endocrine system/organs has been observed in repeated dose and reproductive toxicity studies. Besides, as explained above, the bioavailability of the substances in this group is expected to be low due to their molecular weight .

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

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
For all substances within the group (cf. cover page table)	No hazard or unlikely hazard	No hazard or unlikely hazard	Widespread uses with high potential for release and exposure including use in polymer preparations (F,I,P,A); lubricants, greases, release products (F,I,P); leather, paper and board treatment products (F,I,P,C,A); polishes and wax blends (F,I,P,C).	**Currently no need for EU RRM** Justification: Overall, no or unlikely hazard that would lead to concern for the reported uses.	No action

Annex 1: Overview of classifications

Data extracted on 19 August 2022

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
232-313-5	*8002-53-7*	*Montan wax*	-	-	*STOT RE 2 (liver) H373*
232-399-4	*8015-86-9*	*Carnauba wax*	-		*Eye Irrit. 2 H319 Flam. Liq. 3 H226 Asp. Tox. 1 H304 STOT SE 3 H336 (inhalation) Skin Irrit. 2 H315*
269-642-9	*68308-30-5*	*Fatty acids, montan-wax, stearyl esters*	-	-	-
700-660-6	-	*Saponification and oxidation product of carnauba wax with acidic sodium dichromate solution*	-	-	-
700-720-1	-	*Saponification and oxidation product of carnauba wax with acidic sodium dichromate solution esterified with ethylene glycol*	-	-	-
700-725-9	-	*Saponification and oxidation product of carnauba wax with acidic sodium dichromate solution esterified with 1-methyl-1,3-propanediol and subsequent saponification with calcium dihydroxide*	-	-	-

EC / List No	CAS No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
911-428-0	-	*Reaction mass of Fatty acids, montan-wax and Fatty acids, montan-wax, ethylene esters and Fatty acids, montan wax, mixed esters with fatty acids C16-18 and ethylene glycol and Fatty acids, montan-wax, stearyl esters and Montan wax*	-	-	-
914-459-8	-	*Reaction mass of Fatty acids, montan-wax and Fatty acids, montan-wax, calcium salts and Montan wax*	-	-	-
914-460-3	-	*Reaction mass of Fatty acids, montan-wax and Fatty acids, montan-wax, 1-methyl-1,3-propanediyl esters and Fatty acids, montan-wax, calcium salts and Montan wax*	-	-	-
914-461-9	-	*Reaction mass of Fatty acids, montan-wax, 1-methyl-1,3-propanediyl esters and Fatty acids, montan-wax, calcium salts and Fatty acids, montan-wax, ethylene esters and Fatty acids, montan-wax and Montan wax*	-	-	-
914-467-1	-	*Reaction mass of Fatty acids, montan-wax and Glycerides, montan-wax and Glycerides, tallow mono-, di- and tri-, hydrogenated and Montan wax*	-	-	-
914-468-7	-	*Reaction mass of Fatty acids, montan-wax and Montan wax*	-	-	-
914-469-2	-	*Reaction mass of Fatty acids, montan-wax and Glycerides, montan-wax and Montan wax*	-	-	-

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
914-471-3	-	*Reaction mass of fatty acids, montan-wax, 1-methyl-1,3- propanediyl esters and fatty acids, montan-wax, ethylene esters and fatty*	-	-	-
914-475-5	-	*Reaction mass of Fatty acids, montan-wax and Fatty acids, montan-wax, ethylene esters and Montan wax*	-	-	-
914-478-1	-	*Reaction mass of montan wax and fatty acids, montan-wax, mixed esters with adipic acid and trimethylolpropane and fatty acids, montan-wax and fatty acids, montan-wax, esters with trimethylolpropane*	-	-	-
914-479-7	-	*Reaction mass of Fatty acids, montan-wax and Fatty acids, montan-wax, sodium salts and Montan wax*	-	-	-

(*) 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 12 March 2021

Main types of applications structured by product or article types	269-642-9	911-428-0	914-459-8	914-461-9	914-467-1	914-469-2	914-478-1
PC 18: Ink and toners	F, I, **P, C**						
PC 23: Leather treatment products		F, I, **P, C, A**		F, I, **P, C, A**			
PC 24: Lubricants, greases, release products			F, I, **P**	F, I, **P**	F, I, **P**		F, I, **P**
PC 26: Paper and board treatment products		F, I, **P, C, A**				F, I, **A**	
PC 28: Perfumes, fragrances						F, **P, C**	
PC 29: Pharmaceuticals						F, **P, C**	
PC 31: Polishes and wax blends		F, I, **P, C**				F, I, **P**	
PC 32: Polymer preparations and compounds (plastic articles)		F, I, **P**	F, I, **P, A**	F, I, **P**	F, I, **P**	F, I, **P, A**	F, I, **P, A**
PC 39: Cosmetics, personal care products						F, I, **P, C**	
PC 8: Biocidal products		F, I, **P**				F, I, **P**	
PC 1: Adhesives, sealants, PC 2: Adsorbents, PC 9a: Coatings and paints, PC 9b: Fillers, putties		*F, I,* ***P***					
PC 35: Washing and cleaning products		*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 25 February 2021

EC / List number	RMOA	Authorisation		Restriction*	CLH	Actions not under REACH / CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)	
232-313-5	-	-	-	-	-	FCM authorised
232-399-4[3]	-	-	-	-	-	FCM authorised

* Some of the broad restriction entries in the Annex XVII of REACH are not represented in the overview, e.g. when the scope of the restriction is defined by its classification or the substance identification is broad (e.g. entries 3, 28-30 and 40).

There are no relevant completed or ongoing regulatory risk management activities for the other substances.

[3] *Exempt from registration according to REACH, Annex V*