Assessment of regulatory needs

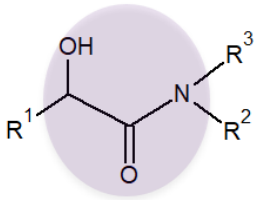
Authority: European Chemicals Agency (ECHA)

Date: 01/06/2022

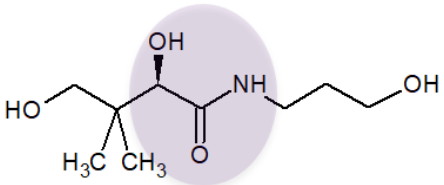
Group Name: Hydroxyacid amides

General structure:

Alpha-hydroxy amides



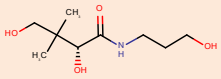
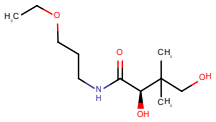
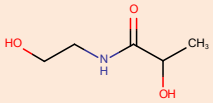
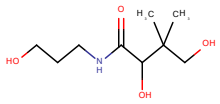
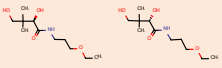
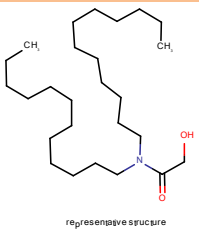
Panthenol derivatives



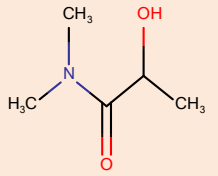
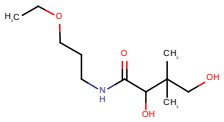
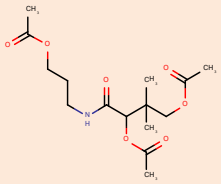
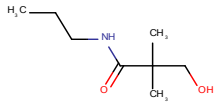
Revision history

Version	*Date*	*Description*
1.0	29/08/2022	

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]
201-327-3	81-13-0	Dexpanthenol		Full, >1000
211-569-1	667-83-4	(+)-N-(3-ethoxypropyl)-2,4-dihydroxy-3,3-dimethylbutyramide		C&L notification
226-546-1	5422-34-4	N-2-hydroxyethyllactamide		Full, not (publicly) available
240-540-6	16485-10-2	Panthenol , DL-form		Full, 100-1000
416-510-5	667-84-5	Butanamide, N-(3-ethoxypropyl)-2,4-dihydroxy-3,3-dimethyl-		Full, not (publicly) available
471-920-1	-	Reaction products of amines, dicoco alkyl and glycollic acid		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

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]
609-066-0	35123-06-9	Propanamide, 2-hydroxy-N,N-dimethyl-		Full, not (publicly) available
613-985-2	667-84-5	Butanamide, N-(3-ethoxypropyl)-2,4-dihydroxy-3,3-dimethyl-		Not registered
680-602-3	98133-47-2	4-((3-acetoxypropyl)amino)-2,2-dimethyl-4-oxobutane-1,3-diyl diacetate		Full, not (publicly) available
700-837-8	1093205-95-8	Propanamide, 3-hydroxy-2,2-dimethyl-N-propyl-		OSII or TII

This table contains also group 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.

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. 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 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
UVCB	Substances of unknown or variable composition, complex reaction products or biological materials

1 Overview of the group

ECHA has grouped together structurally similar substances based on resemblance to panthenol or the presence of the alpha-hydroxy amide moiety.

The group consists of nine mono-constituent substances and one UVCB substance. Mono-constituent substances contain short aliphatic C1-C3 chains, the UVCB substance EC 471-920-1 has C12 chains.

The 10 substances include 7 full registrations, 1 registration as intermediate, 1 with C&L notifications and 1 with pre-registration and were not subgrouped in this assessment.

All six panthenol derivatives[3] are related to each other directly or indirectly via read-across performed by registrants. All substances in the group are structurally related, hydroxy substituent near the amide moiety. As the group is small, no subgrouping was needed.

Based on information reported in the REACH registration dossiers, many of the substances are used in industrial settings and by professionals and consumers. The applications are as fragrance/ cosmetic ingredient/ lubricating agent in washing and cleaning products, perfumes & fragrances, air care products, cosmetics & personal care products, polishes and wax blends and lubricants and greases. Use in pharmaceuticals and biocidal products is also reported.

List 700-837-9 is only used as intermediate in industrial settings. Industrial use / formulation in coatings & paints, tinners, paint removers, ink and toners, paper and board treatment products, metal surface treatment products and water treatment chemicals is reported for EC 201-327-3. Article service life in paper and board treatment products is reported for EC 226-546-1.

[3] 201-327-3, 211-569-1, 240-540-6, 416-510-5, 613-985-2, 680-602-3

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 any of the substances in the group.

EC 416-510-5 is potentially P/vP and is expected to be very mobile in the environment. Since this is a substance with release potential to surface waters, soil and ground water due to the use in cosmetics and personal care products, compliance check is proposed to clarify the potential persistency and mobility of the substance. However, for the time being no EU regulatory risk management is proposed for this substance until confirmation of the hazard properties which should help identifying what the main protection goals are for this specific substance.

There are no or unlikely environmental hazards for the other substances in the group, with the exception of EC 471-920-1 that shows some aquatic toxicity and some test results show some uncertainties and are close to classification triggers. For this reason, a compliance check is suggested for EC 471-920-1.

EC 471-920-1 (UVCB) is self-classified for Skin Sens. 1B. For industrial and professional uses in washing & cleaning products and lubricants & greases, sufficient and consistent self-classification by registrants 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 (lubricants & greases) containing the substance.

However, there is a 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.

Therefore, it is proposed that there is currently no need for EU-wide regulatory risk management for the substance.

All available studies to investigate CMR and ED properties on the substances in the group showed no effects up to the limit dose. Compliance check is suggested for EC 416-510-5 and EC 201-327-3 to confirm the unlikely hazard for reproductive toxicity, and to clarify the plausibility of the read-across adaptation (for EC 201-327-3 only). No relevant structural differences that might indicate different hazard properties were identified 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

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
471-920-1	Known or potential hazard for skin sensitisation	No hazard or unlikely hazard	Use in lubricants & greases and washing & cleaning products. Potential for exposure for workers and consumers.	**Currently no need for EU RRM** Justification: Harmonised/self-classification followed by implementation of necessary RRMs should be sufficient to ensure safe use at the workplace. The concern related to the presence of skin sensitisers in consumer mixtures is under investigation.	CCH
201-327-3 416-510-5	No hazard or unlikely hazard	No hazard or unlikely hazard	Use in perfumes/ fragrances, cosmetics & personal care	**Currently no need for EU RRM**	CCH for 201-327-3, 416-510-5

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
226-546-1 609-066-0 240-540-6 680-602-3 700-837-8			products, washing & cleaning products, polishes/wax blends, pharmaceuticals, biocidal products, coatings, inks, paper and board and metal surface treatment products. Potential for exposure for workers and/or consumers. Use in fertilisers for 609-066-0. Potential for exposure for consumers. Industrial use for 700-837-8 as precursor. Potential for exposure for industrial workers.	Justification: Overall, no or unlikely hazard that would lead to concern for the reported uses	

Annex 1: Overview of classifications

Data extracted on 04/04/2022

Table 1: Harmonised classification and reported self-classification

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
201-327-3	81-13-0	Dexpanthenol			Eye Irrit. 2 H319 [3 out of 50]
211-569-1	667-83-4	(+)-N-(3-ethoxypropyl)-2,4-dihydroxy-3,3-dimethylbutyramide			
226-546-1	5422-34-4	N-2-hydroxyethyllactamide			Acute Tox. 4 H302[1 out of 14] Eye Damage 1 H318[2 out of 14] Acute Tox. 4 H312[1 out of 14] Acute Tox. 4 H332[1 out of 14]
240-540-6	16485-10-2	Panthenol , DL-form			
416-510-5	667-84-5	Butanamide, N-(3-ethoxypropyl)-2,4-dihydroxy-3,3-dimethyl-			
471-920-1	-	Reaction products of amines, dicoco alkyl and glycollic acid		Skin Sens. 1B H317	Skin Sens. 1 H317[1 out of 1]
609-066-0	35123-06-9	Propanamide, 2-hydroxy-N,N-dimethyl-			Skin Irrit. 2 H315[1 out of 4] Eye Irrit. 2 H319[1 out of 4]
613-985-2	667-84-5	Butanamide, N-(3-ethoxypropyl)-2,4-dihydroxy-3,3-dimethyl-			
680-602-3	98133-47-2	4-((3-acetoxypropyl)amino)-2,2-dimethyl-4-oxobutane-1,3-diyl diacetate			
700-837-8	1093205-95-8	Propanamide, 3-hydroxy-2,2-			

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
		dimethyl-N-propyl-			

(*) 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 4 April 2022.

EC number	471-920-1	226-546-1	201-327-3	416-510-5	609-066-0	240-540-6	680-602-3	700-837-8
PC 37: Water treatment chemicals			I					
PC 12: Fertilisers					C			
PC 35: Washing and cleaning products	F, I, P		F, I, P, C				F, I, P, C	
PC 8: Biocidal Products (e.g. disinfectants, Pest control)			C				F, I, P, C	
PC 28: Perfumes, fragrances		F, I, P, C	C			P, C	F, C	
PC 3: Air care products			P, C				F, C	
PC 39: Cosmetics, Personal care products		F, I, P, C	F, I, C	F, C		F, P, C	F, P, C	
PC 29: Pharmaceuticals		F, I, P, C	C					
PC 31: Polishes and wax blends			C				F, P, C	
PC 24: Lubricants, greases, release products	F, I, P, C							

EC number	471-920-1	226-546-1	201-327-3	416-510-5	609-066-0	240-540-6	680-602-3	700-837-8
PC 9a: Coatings and paints, thinners, paint removes			F					
PC 18: Ink and toners			F					
PC 26: Paper and board treatment Products		I, A	I					
PC 14: Metal surface treatment products			I				I	
PC 21: Laboratory chemicals	F	F, I	P					
PC 19: Intermediate								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 13 April 2022.

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