Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Date: 21 February 2019

Group Name: Alkyldimethylbetaines

General structure: -

Revision history

Version	*Date*	*Description*
1.0	21 February 2019	

Substances within this group:

EC / List number	CAS number	Substance name	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
		Alkyl betaines (ABs) group	
211-669-5	683-10-3	(carboxylatomethyl)dodecyldimethylammonium (C12AB)	Full, not (publicly) available
220-006-9	2601-33-4	(carboxylatomethyl)dimethyltetradecylammonium (C14 AB)	C&L notification
211-748-4	693-33-4	(Carboxylatomethyl)hexadecyldimethylammonium (C16 AB)	Full, 10-100
931-700-2	66455-29-6	Betaines, C12-14 (even numbered)-alkyldimethyl (C12-14 AB)	Full, 1000-10 000
270-329-4	68424-94-2	Betaines, coco alkyldimethyl (Coco AB)	C&L notification
939-682-8	-	N,N-dimethyl-C12-14-(even numbered)-alkyl-1-amines, reaction products with potassium hydroxide and chloroacetic acid (C12-14 AB)	Full, not (publicly) available
947-036-1	-	Betaines, C12-16 (even numbered) -alkyldimethyl (C12-16 AB)	Full, not (publicly) available
266-368-1	66455-29-6	Betaines, C12-14-alkyldimethyl (C12-16 AB)	C&L notification
		Alkylamidopropyl betaines (AAPBs) group	
480-680-7	120128-90-7	1-Propanaminium, N-(carboxymethyl)-3-(formylamino)-N,N-dimethyl-, inner salt (C0 AAPB)	Full, not (publicly) available
224-292-6	4292-10-8	(carboxymethyl)dimethyl-3-[(1-oxododecyl)amino]propylammonium hydroxide (C12 AAPB)	Full, 10-100
447-060-8	-	N-(carboxymethyl)-3-[(2Z)-docos-2-enoylamino]-N,N-dimethylpropan-1-aminium (C22 AAPB)	Full, not (publicly) available registration
946-191-2	-	1-Propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl-, N-(C12-14(even numbered) acyl) derivs., hydroxides, inner salts (C12-14 AAPB)	Full, 10-100
931-296-8	97862-59-4	1-Propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl-, N-C8-18(even numbered) acyl derivs., hydroxides, inner salts (C8-18 AAPB)	Full, 10-100

[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	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
308-107-7	97862-59-4	1-Propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl-, N-C8-18 acyl derivs., hydroxides, inner salts ((C8-18 AAPB)	C&L notification
931-513-6	1334422-09-1	1-Propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl-, N-(C12-18(even numbered) acyl) derivs., hydroxides, inner salts (C12-18 AAPB)	Full, 10-100
263-058-8	61789-40-0	1-Propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl-, N-coco acyl derivs., hydroxides, inner salts (Coco AAPB)	Full, not (publicly) available
931-333-8	147170-44-3	1-Propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl-, N-(C8-18(even numbered) and C18 unsaturated acyl) derivs., hydroxides, inner salts (C8-18 and C18 unsatd. AAPB)	Full, 10-100
947-523-9	-	1-Propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl-, N-(C16-18(even numbered) and C18 unsaturated acyl) derivs., hydroxides, inner salts (C16-18 and C18 unsatd. AAPB)	Full, 100-1000

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 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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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

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 structurally similar substances based on the betaine moiety.

The substances have been split in two sub-groups based on the structure:

- Alkyl betaines (AB)
- Alkylamidopropyl betaines (AAPB).

Based on information reported in the REACH registration dossiers, most substances belonging to this group are used as surfactants in industrial settings, by professional workers and by consumers. Some examples of frequent product types present in the registration dossiers are: washing and cleaning products, personal care products, cosmetics and coatings. The volumes of substances used in the EU is relatively high. Therefore, there is a significant potential for exposure to humans and/or releases to the environment originating from the uses of these substances.

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 substances in the group.

The substances in this group are unlikely to fulfil the PBT/vPvB screening criteria, because they are very likely readily biodegradable or very likely inherently biodegradable and have a low potential for bioaccumulation.

These conclusions are based on information that for 3 of the 4 of the registered sub-group AB members and for more than half of the substances in the sub-group AAPB members, there is experimental data demonstrating that the substances are either readily biodegradable or inherently biodegradable. Thus, all the group members are considered not to be P or vP. No experimental bioaccumulation studies are available for both sub-group members as the bioaccumulation potential is deemed low by the registrants mainly based on log Kow. It is noted that the bioaccumulation potential for surfactants cannot be simply predicted from log Kow or modelled and uncertainty remains. However, the potential for bioaccumulation is indeed considered to be below the B and vB criterion. Some aquatic toxicity is observed for some group members (also self-classification by the registrants). A request for experimental studies has been made for EC 931-700-2 (AB) and C12 AAPB in the ongoing CCH on the four AAPBs (ECs 224-292-6, 931-296-8, 931-513-6 and 931-333-8) and it will be assessed whether available information would justify a more stringent classification. It is expected that following data generation for aquatic toxicity registrants would adequately self-classify the substances and implement necessary RMMs to ensure safe use. Therefore, it is proposed that there is currently no need for EU-wide regulatory risk management. It is to be noted that there would be an impact on the SEVESO III Directive if testing would lead to a more stringent environmental classification.

Based on ECHA's assessment of currently available hazard information, no potential hazards were identified for human health. These conclusions are based on information that the substances in both sub-groups are considered to be of a low systemic toxicity profile. There still remains, however, a concern over substances having a self-classification as a skin sensitiser (C12 AB (EC No: 211-669-5) and C16 AB (EC 211-748-4). As regards substances in sub-group AAPB, it has been identified that there is high likelihood that the presence of an impurity (N-[3-(dimethylamino)propyl]oleamide (EC 203-661-5)) from the manufacture process can lead to skin sensitisation. Within the registration dossier of C22 AAPB (EC 447-060-8), it is mentioned that the two impurities[3] that can lead to sensitisation can be present also in other AAPBs. Not all AAPBs have followed a precautionary approach in this respect to classify accordingly. Experimental studies are available for the main common composition of all ABs in the group covering the lower chain lengths. The experimental data are adequate and reliable. Structural and compositional variations of all the read-across substances are sufficiently covered

[3] It is known from data on cocamidopropyl betaine (CAPB), a largely used member of the AAPB chemical category with C8-C18 alkyl chain length, that 3-dimethylaminopropylamine (DMAPA) and amidoamine are both sensitising impurities present in the commercially available substances.

with experimental data on C12-C14 regarding:

- Acute toxicity
- Skin and eye irritation
- Skin sensitisation
- Genotoxicity
- Repeated dose toxicity
- Reproductive toxicity.

The assessment of ABs is interrelated to the AAPBs group as the substances in both groups have the same type of effects in the available studies (forestomach lesions, GIT lesions), lack any target organ toxicity and mutagenic potential. In addition, they all lack bioavailability potential with AAPBs having better kinetic information available confirming this. No concerns have been identified for betaine (the main functional component of ABs and partly of AAPBs) in repeated dose toxicity studies, chronic and carcinogenicity studies and prenatal developmental toxicity. The information from the simple betaine part of ABs, and partly of AAPBs, can further confirm that even if the substances would be absorbed, they are unlikely to cause any specific effect that would at least be driven by the betaine moiety. Substances are unlikely ED due to absence of ED related triggers.

In conclusion, the substances are not considered to have CMR or ED properties with the current knowledge.

Uses indicate high exposure potential due to uses in detergents and cosmetic products by industrial and professional workers and by consumers. As regards skin sensitisation, for industrial and professional uses, sufficient and consistent self-classification by registrants should trigger adequate risk management measures 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 substances EC 211-669-5 and EC 211-748-4 in sub-group 1 (AB) and all substances in sub-group 2 (AAPB). 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. However, as the skin sensitisation relates to impurities, it is also recommended that the registrants take note of this assessment and consider purifying the substance ensuring that the impurities with sensitising properties are below the concentration limits.

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
Alkyl betaines (AB) 211-669-5 211-748-4 **Alkylamidopropyl betaines (AAPB)** 224-292-6 263-058-8 308-107-7 447-060-8 480-680-7 931-296-8 931-333-8 931-513-6	Known or potential hazard for skin sensitisation	Known or potential hazard for aquatic toxicity (except EC 211-748-4 in AB group and ECs 308-107-7 and 480-680-7 in AAPB group)	Most substances are used in washing and cleaning products, personal care products, cosmetics and coatings with potential exposure by industrial and professional workers and by consumers. Two substances have distinctly different uses: EC 947-523-9 has consumer use of fuel treated with fuel additives and EC 447-060-8 is manufactured and used at industrial sites in oil and gas field drilling and	**Currently no need for EU RRM** <u>Justification:</u> Data generation ongoing for some of the substances. 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. Self-classification followed by	CCH for ECs 224-292-6, 931-296-8, 931-333-8 and 931-513-6

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
946-191-2 947-523-9			production operations (mining).	implementation of necessary RRMs should be sufficient to ensure safe use for environment.	
Alkyl betaines (AB) 220-006-9 266-368-1 270-329-4 931-700-2 939-682-8 947-036-1	No hazard or unlikely hazard	No hazard or unlikely hazard	Most substances are used in washing and cleaning products, personal care products, cosmetics and coatings with potential exposure by industrial and professional workers and by consumers. One substance has distinctly different uses: EC 939-682-8 is reported to be used only in plant protection products.	**Currently no need for EU RRM** Justification: Overall, no or unlikely hazard that would lead to concern for the reported uses.	CCH and Substance evaluation for EC 931-700-2

Annex 1: Harmonised and self-classifications

Data extracted on 5 November 2018.

EC/ List No	CAS No	Harmonised classification	Classification in registrations	Classification in C&L notifications
211-669-5	683-10-3	-	Skin irrit.2 Eye irrit. 2 Skin sens. 1	Eye Dam. 1 Aquatic Acute 1 Aquatic Chronic 3 Acute Tox. 3 Acute Tox. 4 Skin Corr. 1B STOT SE2
220-006-9	2601-33-4	-	-	Skin irrit.2 Eye irrit. 2 Skin sens. 1 Eye Dam.1 Skin Corr. 1B Aquatic Chronic 3 STOT SE3
211-748-4	693-33-4	-	Skin irrit.2 Eye irrit. 2 Skin sens. 1	Acute Tox 4
931-700-2	**66455-29-6**	-	Skin corr. 1B Eye Dam.1 Aquatic Chronic 3	Skin Irrit.2
270-329-4	68424-94-2	-	-	Skin irrit.2 Eye irrit. 2 Eye Dam.1 Aquatic Acute 1 STOT SE3
939-682-8	-	-	Eye Damage 1 Aquatic Chronic 3 Skin Corr. 1B	
947-036-1	-	-	Acute Tox. 4 Aquatic Acute 1 Aquatic Chronic 2	-
266-368-1	66455-29-6	-	-	Skin irrit. 2 Eye irrit. 2 Eye Dam. 1 Skin Corr. 1B Aquatic Acute 1 Aquatic Chronic 3 STOT SE3
480-680-7	120128-90-7	-	-	-
224-292-6	4292-10-8	-	Eye Dam.1 Aquatic chronic 3	Skin Irrit.2 Eye Irrit.2
447-060-8	-	-	Skin Irrit.2 Aquatic Acute 1 Aquatic Chronic 1	
946-191-2	-	-	Eye Dam. 1 Aquatic Chronic 3	
931-296-8	97862-59-4	-	Eye Dam. 1 Aquatic Chronic 3	
308-107-7	97862-59-4	-	-	Eye Dam.1 Eye Irrit.2

EC/ List No	CAS No	Harmonised classification	Classification in registrations	Classification in C&L notifications
931-513-6	1334422-09-1	-	Eye Dam. 1 Aquatic Chronic 3	-
263-058-8	61789-40-0	-	Skin Irrit.2 Eye Irrit.2 Skin sens. 1 Aquatic Chronic 3	Aquatic Acute 1 Eye Dam.1 STOT SE3 Acute Tox 4 Acute Tox 2 Aquatic Chronic 2
931-333-8	147170-44-3	-	Eye Dam. 1 Aquatic Chronic 3	-
947-523-9	-	-	Skin corr. 1B Eye Dam. 1 Skin Sens. 1A Aquatic Acute 1 Aquatic Chronic 2 Skin Irrit. 2 Eye Irrit.2	-

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

Data extracted on 12 September 2018.

Main types of applications structured by product or article types	EC/ List 211-669-5	EC/ List 220-006-9	EC/ List 211-748-4	EC/ List 931-700-2	EC/ List 270-329-4	EC/ List 947-036-1	EC/ List 266-368-1	EC/ List 480-680-7	EC/ List 224-292-6	EC/ List 946-191-2	EC/ List 931-296-8	EC/ List 308-107-7	EC/ List 931-513-6	EC/ List 263-058-8	EC/ List 931-333-8
Personal care & cosmetic products	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Washing & cleaning products	x		x	x	x	x	x	x	x	x	x	x	x	x	x
Coatings & paints				x					x	x	x		x	x	x
Air care				x					x	x	x		x	x	x
Polishes & wax blends				x					x	x	x		x		x
Biocidal products				x		x			x	x		x	x		
Textile dyes/inks				x					x	x				x	x
Fire fighting formulations											x			x	x

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

Data extracted on 16 November 2018.

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