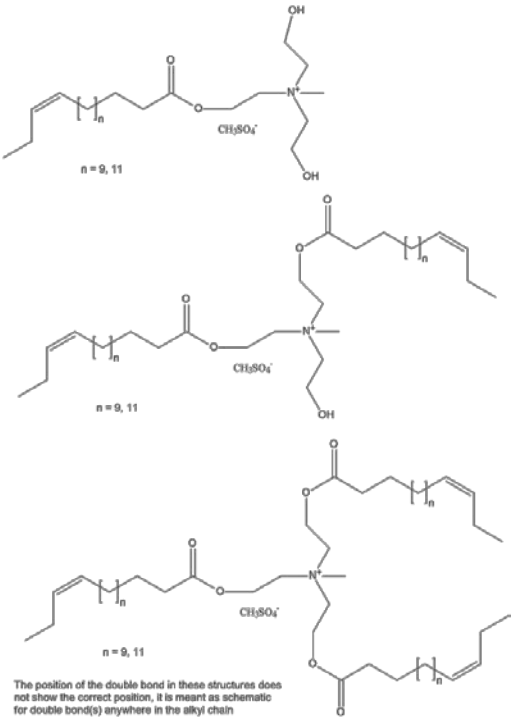
Assessment of regulatory needs

Authority: ECHA

Group Name: Reaction products of fatty acids and triethanolamine (quaternized amine)

General structure:



Revision history

Version	*Date*	*Description*
1.0	18 October 2021	

Substances within this group:

EC / List no	CAS no	Substance name [and Substance name acronyms]	Registration type (full, OSII or TII, NONS, cease manufacture), highest tonnage band among all the registrations (t/y) [1]
931-203-0	-	Fatty acids, C16-18 (even numbered) and C18 unsatd., reaction products with triethanolamine, di-Me sulfate-quaternized	Full >1000 t/y
931-209-3	-	Fatty acids, C16-18 even numbered, reaction products with triethanolamine, di-Me sulfate-quaternized	Full >1000 t/y
931-216-1	-	Reaction products of C18 (unsaturated) fatty acids and dimethyl sulfate and triethanolamine	Full >1000 t/y
943-532-7	-	Fatty acids, C18 (even numbered) and C18 unsatd., reaction products with triethanolamine, di-Me sulfate quaternized	Not (publicly) available
947-361-9	-	Fatty acids, C8-18 (even numbered) and C18 unsatd., reaction products with triethanolamine, di-Me sulfate-quaternized	Not (publicly) available
947-936-4	-	Fatty acids, C18 unsatd., mono- and diesters with triethanolamine, di-Me sulfate quaternized	Not (publicly) available

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

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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 chemicals 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
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

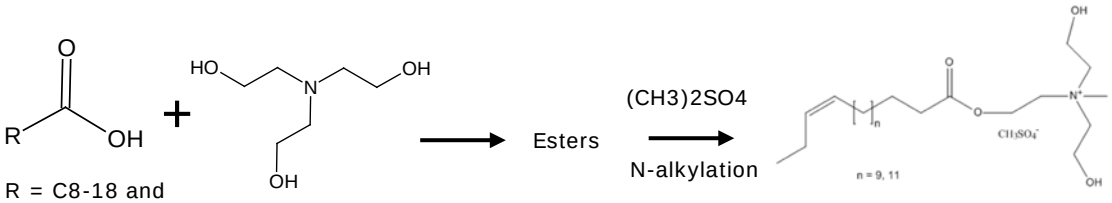
1 Overview of the group

ECHA has grouped together structurally similar substances based on the presence of the esters of quaternized amines shown in the figure below.

The 6 substances in this group are registered as UVCB, the main functional groups are esters and quaternized amines and the only variable element is the fatty acid moiety.

The substances in the group contain mainly mono-, di- and triesters of quaternized amines. In lower quantities, the substances also contain unquaternized esters of triethanolamine, unreacted free fatty acids and quaternized triethanolamine. No free triethanolamine was reported in any of the substances in the group of substances.

The esters of quaternized amines result from the initial reaction from triethanolamine with fatty acids (C8-C18 and/or C18 unsaturated), followed by a second step of the reaction where these are methylated with dimethylsulphate.



R = C8-18 and C18 unsaturated

(representative structure) mono-, di- and triesters of quaternised amines

Based on information reported in the REACH registration dossiers, the substances of the group are generally used as surface active agents and softeners in washing and cleaning, polishes and waxes, or in cosmetics and personal care products, where they are in particular used by professionals and consumers. The substances are also used in textile dyes and impregnating products or leather treatment, where they are included into leather/textile articles as softening agents (further details in Mishra & Tyagi, 2007[5]). Two of the substances are also used as co-formulants in biocidal products. List 947-936-4 is only used as functional fluid in the oil and gas exploration in the off-shore industrial sector. However, the substance seems to be structurally similar to the other substances in the group, so it might substitute the other substances in some of their uses. Therefore, all substances are considered to have high potential for exposure to humans and the environment.

The related assessment of regulatory needs for *Reaction products of fatty acids with diethanolamine and triethanolamine*, has two major differences with the current group: one being that the N-alkylation step is not part of the reaction, thus no esters of quaternized amines are expected. Secondly, since diethanolamine is used as one of the reactants, esteramide functional groups are also expected to be present. Nevertheless, some of the constituents are the same or similar to the

[5] MISHRA, S. & TYAGI, V.K. (2007): Ester Quats: The Novel Class of Cationic Fabric Softeners. In: Journal of Oleo Science, volume 56, Issue 6, pp. 269-276.

present group. Therefore, data generation from the related group could help to confirm unlikely hazards for human health or the environment.

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

EC/List no	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
931-203-0 **931-209-3** **931-216-1** **No EC/List number publicly available** (TEA esterquat) **947-361-9** **947-936-4**	No hazard or unlikely hazard	Known or potential hazard for aquatic toxicity	The substances are used as surfactant and softener in washing and cleaning, textile dyeing, cosmetics etc. by professionals and consumers. The substances are included onto articles (e.g. textiles, plastic articles). Overall, there is a high potential for exposure and release in the environment.	Pending action Await compliance checks of List 931-203-0 and the group of reaction products of fatty acids with diethanolamine and triethanolamine. This is complemented by compliance checks for the remaining substances of the group. **Currently no need for EU RRM** <u>Justification</u>: It is expected that data generation and/or correct application of read-across leads to correct classification for aquatic toxicity and respective labelling and risk management measures. Low hazard potential for other endpoints will also be confirmed.

3 Justification for the no need for regulatory risk management action at EU level

Currently no need to suggest (further) regulatory risk management actions for all substances

Based on ECHA's assessment of currently available hazard information, no likely hazards were identified for human health. These conclusions are based on in vitro mutagenicity studies in bacteria and mammalian cells, in vivo experimental studies on skin sensitisation, repeated dose sub-chronic, screening studies and reproductive toxicity or endocrine disruption conducted on close analogues with very similar chemical structure and physico-chemical properties and on the low potential toxicity profile of breakdown products. None of the group members has a self or harmonised classification for human health hazards.

The substances in this (sub)group are unlikely to fulfil the PBT/vPvB criteria, because they are very likely readily biodegradable/very likely inherently biodegradable and therefore unlikely to fulfil the P criterion.

None of the impurities reported in the substances of this group are PBT/vPvB, CMR/ED or have harmonised classification for environmental or human health hazards.

All substances in the group show a potential for aquatic toxicity. This conclusion is based on the data available for List 931-203-0 and 947-361-9 and due to structural similarity it can be extrapolated to the other substances in the group. This will be further assessed under compliance check.

The uses likely resulting in the highest exposure to the environment, are those in washing and cleaning, polishes and waxes or cosmetics by professionals and consumers. Also relevant are the uses in textile dyes and impregnating products, leather treatment or polymer preparations where the substance is bound in articles but might be released to the environment.

It is expected that after compliance check, registrants would adequately self-classify the substances for aquatic toxicity and then implement the relevant risk management measures which would be sufficient to ensure safe use at industrial sites and by professionals. Proper labelling would also help consumers to appropriately handle the substances, also considering that the M-factor for aquatic acute toxicity is expected to be low (possibly M=1).

Based on currently available information, there is no need for EU regulatory risk management for any of the substances in the group.

At this stage, the outcome of the ongoing compliance checks on List 931-203-0, and on members of the group of reaction products of fatty acids with diethanolamine and triethanolamine are awaited to confirm unlikely hazards. Afterwards remaining need for data generation within the current group will be

considered to confirm aquatic toxicity for the whole group and to confirm unlikely hazard for other endpoints.

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Annex 1: Overview of classifications

Data extracted on 17/09/2021

'None of the substances has harmonised classification'

EC/ List No	CAS No	Substance name	Classification in registrations
931-203-0	1335202-88-4	Fatty acids, C16-18 (even numbered) and C18 unsatd., reaction products with triethanolamine, di-Me sulfate-quaternized	Aquatic Chronic 3 (H412)
931-209-3	1337540-53-0	Fatty acids, C16-18 even numbered, reaction products with triethanolamine, di-Me sulfate-quaternized	Not classified
931-216-1	1335202-95-3	Reaction products of C18 (unsaturated) fatty acids and dimethyl sulfate and triethanolamine	Skin Irrit. 2 (H315) Eye Irrit. 2 (H319)
NA	-	TEA esterquat	Aquatic Chronic 3 (H412)
947-361-9	-	Fatty acids, C8-18 (even numbered) and C18 unsatd., reaction products with triethanolamine, di-Me sulfate-quaternized	Aquatic Acute 1 (H400), M=1 Aquatic Chronic 3 (H412)
947-936-4	-	Fatty acids, C18 unsatd., mono- and diesters with triethanolamine, di-Me sulfate quaternized	Eye Irrit. 2 (H319)

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

Data extracted on (16/08/2021)

Main types of applications structured by product or article types	931-209-3	931-216-1	No List number (TEA esterquat)	947-361-9	947-936-4
Use as textile dyes and impregnating products (PC34)	F, I, **P, A**	F, I, **A**	F, I, **P, (A)**		
Washing and cleaning products (PC 35)	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, **C**	
Leather treatment products	F, I, **P, (A)**		F, I, **P**		
Oil and gas exploration or production products					
Polishes and wax blends (PC 31)	F, I, **P, C**	F	F, I, **P, C**		
Polymer preparations (for textiles and leather industry)	F, I, **P, A**				
Cosmetics and personal care products	F, I, **P, C**		F, **P, C**		F, **C**
Biocidal products	F, I, **P, C**		F, **C**		
Air care products	F, I, **P, C**				

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 (19/08/2021)

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