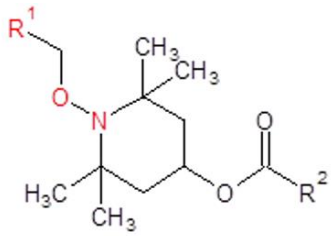
Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Date: 5 August 2020

Group Name: N-alkoxy-tetramethylpiperidines

General structure:



Revision history

Version	*Date*	*Description*
1.0	5 August 2020	

Substances within this group:

EC number	CAS number	Substance name	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
406-750-9	129757-67-1	A mixture of: bis(2,2,6,6-tetramethyl-1-octyloxypiperidin-4-yl)-1,10-decanedioate; 1,8-bis[(2,2,6,6-tetramethyl-4-((2,2,6,6-tetramethyl-1-octyloxypiperidin-4-yl)-decan-1,10-dioyl)piperidin-1-yl)oxy]octane	Full, 100-1000
425-020-0	191680-81-6	Reaction products of N,N'-ethane-1,2-diylbis(1,3-propanediamine), cyclohexane, peroxidized 4-butylamino-2,2,6,6-tetramethylpiperidine and 2,4,6-trichloro-1,3,5-triazine	Full, not (publicly) available
426-650-9	191743-75-6	2-Aminoethanol reaction products with cyclohexane and peroxidized N-butyl-2,2,6,6-tetramethyl-4-piperidinamine-2,4,6-trichloro-1,3,5-triazine reaction products	Full, not (publicly) available
433-060-5	290822-07-0	1-(2-hydroxy-2-methylpropoxy)-2,2,6,6-tetramethylpiperidin-4-yl octadecanoate	Full, not (publicly) available
482-440-7	-	bis(1-undecyloxy-2,2,6,6-tetramethylpiperidine-4-yl)carbonate	Full, not (publicly) available
687-535-9	122586-52-1	Decanedioic acid, 1,10-bis[2,2,6,6-tetramethyl-1-(octyloxy)-4-piperidinyl] ester	Full, not (publicly) available
812-927-5	1902936-62-2	Reaction products of N6,N6'-hexane-1,6-diylbis[N2,N4-dibutyl-N2,N4,N6-tris(2,2,6,6-tetramethylpiperidin-4-yl)-1,3,5-triazine-2,4,6-triamine] and allylbromide, subsequently reacted with ethaneperoxoic acid, hydrogenated	Full, not (publicly) available
700-878-1	1395069-30-3	Butanal, reaction products with N2,N2'-1,6-hexanediylbis[N4,N6-dibutyl-N2,N4,N6-tris(2,2,6,6-tetramethyl-4-piperidinyl)-1,3,5-triazine-2,4,6-triamine and hydrogen peroxide	Full, 1-10

This table [contains also / does not contain] 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.

[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 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].

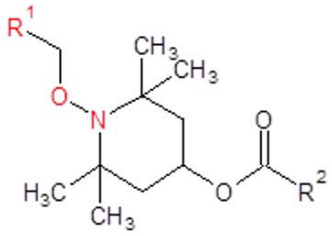
[2] https://echa.europa.eu/understanding-assessment-regulatory-needs

Glossary

AAG	Alkoxy amine group
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
HALS	Hindered amines light stabilisers
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	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 the presence of the 'N-alkoxy-2,2,6,6-tetramethylpiperidine'moiety shown in the figure below.



The group is composed of eight substances, which are mono/multi constituent substances and substances of unknown or variable composition, complex reaction products or biological materials (UVCB substances). All substances included in the group are registered under Article 10 (full registrations).

Based on their chemical structure the substances from the group can be sub-divided in the two following sub-groups; however, no clear difference in the hazard or use pattern has been observed between the substances in the 2 subgroups:

- Alkoxy amine group (AAG) short chain
- Alkoxy amine group (AAG) long chain with triazine function

The substances are associated with a wide category of substances known in the industry as 'hindered amines light stabilisers (HALS)' which are widely used in plastics and polymers.

Based on information reported in the REACH registration dossiers, all substances in the group are used as (light) stabilisers in plastic articles. Information from the PLASI[3] inventory indicates that the potential for release for this type of additives from the plastic matrix is relatively low (compared to other substances in the inventory). This is supported by the physico-chemical properties of the substances in the group: low vapour pressure, high molecular weight, low water solubility, high octanol water partition coefficient.

Additional uses are also reported for three substances. For these uses potential for releases/exposure cannot be excluded:

- Two substances, EC 406-750-9 and EC 426-650-9, are used as stabilisers in other matrix (rubber, fabrics).
- Two substances have also professional and consumer uses in adhesives and in coatings (paints/inks). These uses are mainly relevant for substance EC 406-750-9. For the other substance EC 426-650-9 the tonnage appears currently limited.

In addition, potential exposure/release from uses at industrial settings (during e.g. formulation and/or production of articles) cannot be excluded.

None of the substances have a harmonised classification and labelling. The most severe self-classification within the group is: Aquatic Chronic 4, H413 (substances

[3] https://echa.europa.eu/documents/10162/17228/plastic_additives_supplementary_en.pdf/79bea2d6-8e45-f38c-a318-7d7e812890a1

EC 482-440-7 and EC 687-535-9); Skin Sens. 1, H317 (EC 482-440-7 and EC 700-878-1).

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.

Based on information available in the registration dossiers, all the substances in the group appear to be of low toxicological human health and environmental hazards.

The substances are considered of low systemic toxicological activity based on data for each substance. Although for two substances (EC 406-750-9 and EC 482-440-7) some toxicological effects were observed at the limit dose, these are not considered severe and the potential for low hazard applies also for these substances. Further in-depth assessment will be performed (CCH) and further data generation may be considered to confirm the absence of hazard for these two substances.

Three substances are potential skin sensitiser (EC 700-878-1, EC 482-440-7 and EC 812-927-5). For the remaining substances in the group the available experimental data indicates no potential for skin sensitisation; the substances in the group have some structural differences with reactive substructures present that could also explain presence of different effects such as skin sensitisation.

All substances in this group are unlikely to fulfil the PBT/vPvB screening criteria, because they have low potential for bioaccumulation.

Regarding aquatic toxicity, the long-term fish studies are not available for any of the substance in the group, while the results for long-term daphnia study were reported for EC 406-750-9 and EC 425-020-0 (based on accepted testing proposal) and for EC 812-927-5, in all studies NOELR ≥ 10 mg/L (WAF). In general, the quality of the aquatic toxicity studies are questionable. The substances are difficult to test (high log Kow and poorly water soluble) and the information on analytical monitoring is in most cases not reported. One substance (EC 406-750-9) had a harmonised classification (Aquatic Chronic 4) which was removed based on a RAC opinion in 2014. Therefore, it seems that the effects are not seen up to the solubility limits.

The three substances (EC 700-878-1, EC 482-440-7 and EC 812-927-5) self-classified as skin sensitisers category 1 or potential skin sensitiser (EC 812-927-5) are mainly used in industrial settings with the exception of the use of articles where the main potential for exposure/releases is expected for:

- Uses at industrial settings during e.g. formulation and/or production of articles
- Uses as stabilisers in other matrix than plastic (rubber, fabrics).
- professional and consumer uses in adhesives and in coatings (paints/inks).

For industrial and professional uses, 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 containing the substances.

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.

Once skin sensitising properties are clarified for the substance EC 812-927-5 it will be assessed whether all registrants of the substances have applied the appropriate self-classification. If this is not the case further measures (e.g. harmonised classification) may be considered.

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 number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
406-750-9 425-020-0 426-650-9 433-060-5	No hazard or unlikely hazard	No hazard or unlikely hazard	Stabilisers in plastic articles, rubber, fabrics (406-750-9 and 426-650-9) Professional and consumer uses in adhesives and in coatings (paints/ink, 406-750-9 and 426-950-9)	**Currently no need for EU RRM** <u>Justification:</u> No or unlikely human health and environmental hazard	**First step:** CCH
812-927-5	Known or potential hazard for skin sensitisation	No hazard or unlikely hazard	Stabilisers in plastic articles	**Currently no need for EU RRM** <u>Justification:</u> 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.	**First step:** CCH
700-878-1					**First step:** CCH
482-440-7					No action No CCH possible as registration is a non-updated NON dossier

Annex 1: Overview of classifications

Data extracted on 1 January 2019.

EC No	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
482-440-7	-	*Skin Sens. 1, H317; Aquatic Chronic 4, H413*	-
687-535-9	-	*Aquatic Chronic 4, H413*	-
700-878-1	-	*Skin Sens. 1, H317*	-

(*) 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

Date extracted on 15 February 2019.

Main types of applications structured by product or article types	EC 406-750-9	EC 425-020-0	EC 426-650-9	EC 433-060-5	EC 482-440-7	EC 687-535-9	EC 812-927-5	EC 700-878-1
Application in plastics	F, I, **A**	F, I, **A**	F, I, **A**	F, I, **A**	F, I, **A**	F, I, **A**	F, I, **A**	F, I, **A**
Application in rubber, fabrics, textiles, (+batteries and accumulators, machinery, vehicles)	F, I, **A**		F, I, **A**		F, I, **A**			
Application in coatings (e.g. paints, inks, adhesives, sealants)	F, I, **P, C A**		F, I, **P, C, A**					

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

Date extracted on 1 January 2019.

EC/List number	RMOA	Authorisation		Restriction*	CLH	Actions not under REACH/ CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)	
406-750-9	-	-	-	-	De-classification on Aquatic chronic 4 (RAC opinion in 2014)	-

*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.