An tÚdarás Sláinte agus SábháilteachtaHealth and Safety Authority

Assessment of regulatory needs

Authority: Health and Safety Authority

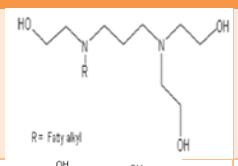
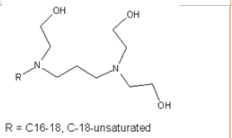
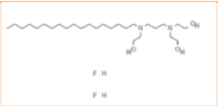
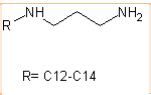
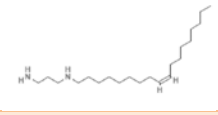
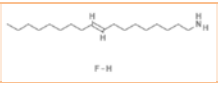
Group Name: Ethoxylated N-alkyltrimethylenediamines

General structure: -

Revision history

Version	*Date*	*Description*
1	4 May 2023	

Substances within this group:

EC number	CAS number	Substance name [and Substance name acronyms (*)]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y)
696-616-8	1268344-02-0	Amines, N-(C18 unsaturated, alkyl) trimethylenedi-, ethoxylated (NLP)		Full, Not publicly available
800-029-6	1290049-56-7	Amines, N-(C16-18 (even numbered) and C18-unsatd. alkyl) trimethylenedi-, ethoxylated(NLP)		Full, 100 to 1 000 t/y
911-915-8	-	Reaction mass of ethoxylated N-oleyl-1,3-propanediamine, hydrofluorides of and ethoxylated N-palmityl-1,3-propanediamine, hydrofluorides of and ethoxylated N-stearyl-1,3-propanediamine, hydrofluorides of and olaflur		Full, Not publicly available
435-650-8	not assigned	Alkyl(rapeseed oil), bis(2-hydroxyethyl)ammonium fluoride	Not available	
292-562-0	90640-43-0	Amines, N-C12-14-alkyltrimethylenedi-		Full, Not publicly available
230-528-9	7173-62-8	(Z)-N-9-octadecenylpropane-1,3-diamine		Full, 1 000 to 10 000 t/y
291-269-5	90367-21-8	Ethanol, 2,2'-[[3-[(2-hydroxyethyl)amino]propyl]imino]bis-, N-C12-18-alkyl derivs.	Not available	C&L notification Not registered
229-891-6	6818-37-7	Olaflur		C&L notification Not registered
291-275-8	90367-27-4	Ethanol, 2,2'-[[3-[(2-hydroxyethyl)amino]propyl]imino]bis-, N-tallow alkyl derivatives.	Not available	C&L notification Not registered
500-149-6	61790-85-0	Amines, N-tallow alkyltrimethylenedi-, ethoxylated	Not available	Not registered
not assigned	36505-83-6	(E)-octadec-9-en-1-amine;hydrofluoride		Not registered

This table contains group members that are not registered but have a C&L notification 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 will make an additional search for related C&L notified substances to be included in the group and develop a regulatory strategy 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 EC 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 voluntary, i.e., it is not part of the 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[1].

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

Glossary

BCF	Bioconcentration factor
Bw	Body weight
CA	Competent Authority
CCH	Compliance Check
CLH	Harmonised classification and labelling
CMR	Carcinogenic, mutagenic and/or toxic to reproduction
C&L	Classification and Labelling
DEv	Dossier evaluation
DNEL	Derived no effect level
DOC	Dissolved organic carbon
Dw	Dry weight
ECETOC	European Centre for Ecotoxicology and Toxicology of Chemicals
ED	Endocrine disruptor
GPMT	Guinea Pig Maximisation Test
LOAEL	Lowest observed adverse effect level
LOEC	Lowest Observed Effect Concentration
MSCA	Member State Competent Authority
NOAEL	No observed adverse effect level
NOEC	No observed effect concentration
NOEL	No observed effect level
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	Persistent, mobile in water and toxic
RCR	Risk characterisation ratio
RMOA	Regulatory management options analysis

RRM	Regulatory risk management
SDS	Safety data sheet
SEv	Substance evaluation
STOT RE	Specific target organ toxicity, repeated exposure
SVHC	Substance of very high concern
TPE	Testing proposal examination
UVCB	Unknown or variable composition, complex reaction products or of biological materials

1 Overview of the group

These ethoxylated N-alkyltrimethylenediamines are grouped based on structural similarity. The majority of substances in the group have a diamino-propane group(s) with a linear alkyl chain linked to one of the nitrogens, with one exception. The unregistered substance CAS 36505-83-6 (9-Octadecenylamine hydrofluoride) has a single amine group attached to a linear alkyl chain and was used in read across for a number of group members.

The group consists of eleven substances, 5 of which were added during the manual screening exercise completed by the Irish Competent Authority for REACH (IE CA) in 2019. The additions were based on read-across applied in the registration dossiers (see Figure 1) so that the expanded group includes the original shortened group and source substances used by these registrants for read-across. For practicality reasons, other source substances used for read-across by the registrants of these additional substances are not included in the current group. Two substances in the group (EC 230-528-9 and 292-562-0) were included in an assessment of regulatory needs (ARN) on N-fatty alkyl polypropylenepolyamines conducted by ECHA. Additionally, while EC 435-650-8, a salt of N-alkyl diethanolamine and CAS 36505-83-6, a salt of a primary aliphatic amine could be covered by the corresponding ECHA's ARNs, for the purpose of this screening assessment these substances were included due to the application of read-across adaptations in the registration dossiers.

Six of the substances are registered; EC 292-562-0, 230-528-9 and 435-650-8 (NONS) 696-616-8, 800-029-6 and 911-915-8. Five of the substances are not registered, thus data relating to them are limited: EC 229-891-6, 291-275-8, EC not assigned / CAS 36505-83-6, 291-269-5 and 500-149-6. EC 291-275-8 has been notified to the C&L inventory.

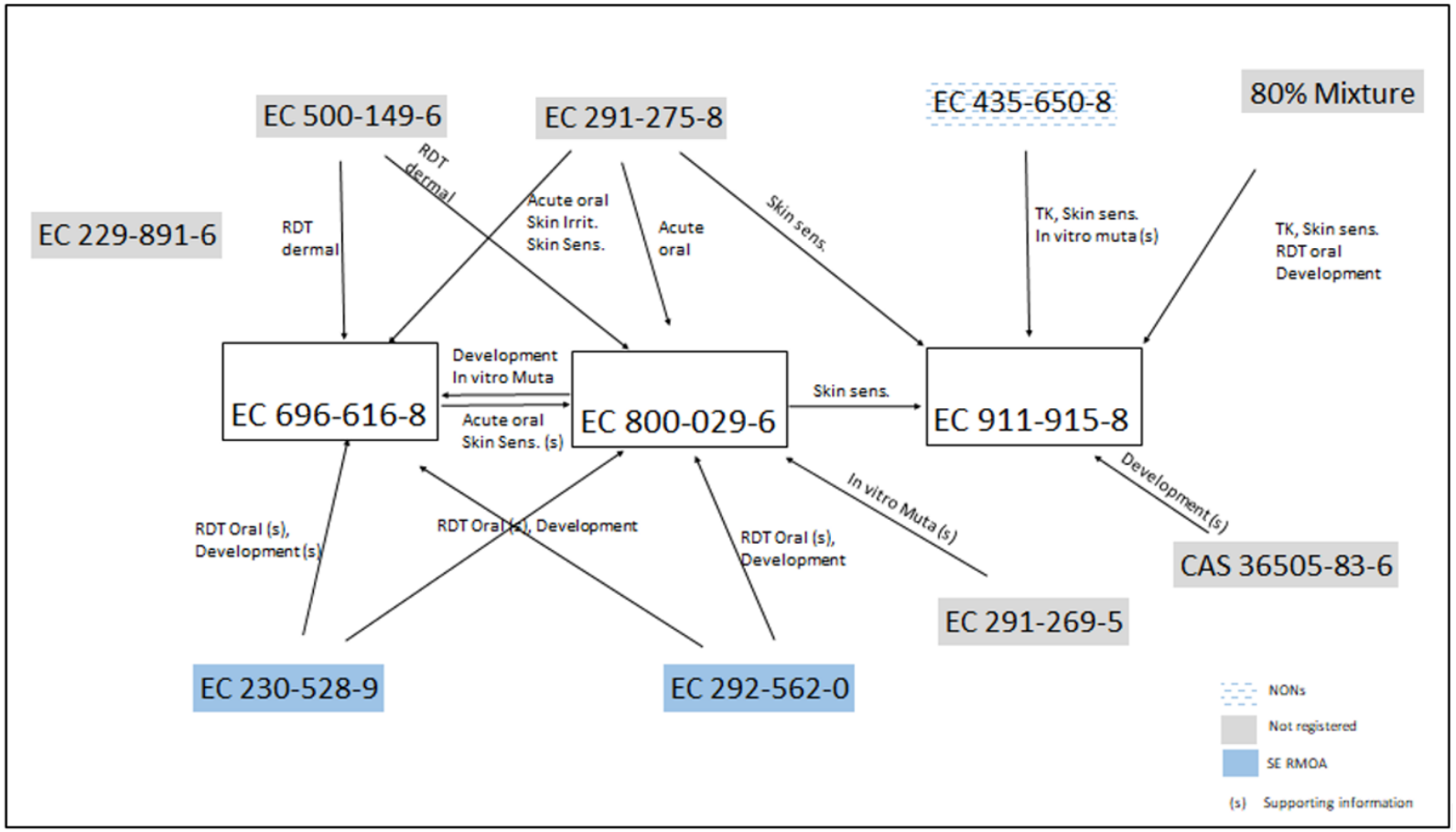
Regarding hazards, the focus of the assessment is on CMR (carcinogenic, mutagenic and/or toxic to reproduction), sensitiser, ED (endocrine disruptor), PBT/vPvB or equivalent (e.g. PMT), and aquatic toxicity hazard endpoints and therefore only those are reflected in the table in section 3. This does not mean that the substances may 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. Harmonised classification and self-classifications reported by registrants are presented in Annex 1.

Based on information reported in the REACH registration dossiers, ethoxylated N-alkyltrimethylenediamines are predominantly manufactured as multi-constituent substances and are mainly derived from natural substances including tallow (animal fat) or synthetic products of the petrochemical industry. They vary between viscous, waxy and waxy-solid depending on the average alkyl chain lengths of the polyamine products, the level of saturation and depending on temperature. Shorter alkyl chain length and higher levels of unsaturation result in lower viscosity.

These substances are manufactured under controlled conditions in either batch or continuous processes. Aerosol formation is low. There is some risk of exposure during the transfer of the substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities. They have industrial use as a surface active agent or process regulator; professional use in lubricants, greases and degreasers, metal treatment, asphalt emulsions and surface cleaning. While there is some risk to workers in the construction industry due to open processing and transfer operations with minerals/metals at elevated temperature during

asphalt preparation (asphalt adhesion and road resurfacing), in industrial and professional use settings, the use of adequate personal protective equipment (PPE) is advised to protect workers from exposure to skin and eyes. Consumers may be exposed to EC 800-029-6 and 911-915-8 in cleaning products and oral hygiene products (toothpaste and mouthwash). For substance EC 800-029-6 there is some risk of exposure to aerosols due to spraying in cleaning in professional and consumer washing and cleaning products, however, final concentrations are low and in industrial applications, much of the spraying or application is automated. Article service life is indicated in plastic articles (EC 800-029-6). EC 230-528-9 is used in asphalt emulsion distribution and in ‘down the drain’ washing fluids, thus release to the environment is likely. While not registered under REACH, EC 229-891-6 is also used in consumer personal care products (toothpastes) and in hair care products.

Figure 1: Read-across applied by registrants within ethoxylated N-alkyltrimethylenediamine group:



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

Based on available information, there is currently no need for EU regulatory risk management for all substances in this group. The majority of the substances are used in professional and industrial settings only. While the substances are acutely toxic via the oral route and are corrosive to the skin, sufficient and consistent self-classification by registrants should trigger the use of adequate risk management measures according to work place and environmental legislation. A concern for STOT RE (digestive system, oral) was identified for EC 292-562-0, 696-616-8 and 800-029-6. Consumer use of these substances in cosmetics (toothpaste and mouthwash) is assessed for safety before inclusion in the products. A data gap for an extended one-generation reproductive toxicity study was noted for EC 696-616-8, and for a screening reproductive and developmental toxicity study and an *in vivo* mutagenicity study for EC 696-616-8 and 800-029-6. However, available data and data used for read across indicate that these two substances have very low derived no-effect levels (DNELs), based on repeated dose toxicity studies, which are likely to protect against adverse effects on fertility and development as well as mutagenicity of the substances. Therefore no additional regulatory risk management at EU level is proposed at this time.

The substances in the group show acute and chronic aquatic toxicity and one group member has harmonised classification for acute and chronic aquatic toxicity (EC 435-650-8). However, as the substances are readily biodegradable and not bioaccumulative, there currently is no need for further EU regulatory risk management for these endpoints at this time.

The endocrine disrupting potential for all the group members is considered unlikely as no indication of such hazard in the environmental or human health data exists. Available environmental toxicity data does not show effects on reproduction or fertility.

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 the IE CA. 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
696-616-8	Known or likely hazard for acute toxicity, STOT RE, and skin corrosion	Known or likely hazard for aquatic toxicity	Used by professional workers in road construction in building and construction industries in asphalt emulsions	**Currently no need for EU RRM** **Justification:** Self-classification followed by implementation of necessary RRMs should be sufficient to ensure safe use at the workplace. While the substances in the group show aquatic toxicity and one group member has harmonised classification for acute and chronic aquatic toxicity (EC 435-650-8), they are	No action
800-029-6			Used as a degreaser in professional and consumer washing and cleaning products. There is some risk of inhalation exposure to aerosols for professionals due to spraying in cleaning products.		
230-528-9			Used in asphalt emulsion distribution and in ‘down the drain’ washing fluids, thus release to the		

			environment is likely. It is also used in aerosol products for cleaning and maintenance products (Non-Propellants).	readily biodegradable and not bioaccumulative. There currently is no need for further EU regulatory risk management for this endpoint.	
292-562-0			Used in the food beverage and pharmaceutical industries as a chain maintenance product. An automatic spray process is used.		
435-650-8			NONS – No data in registration dossier		
911-915-8	Known or likely hazard for acute toxicity, for skin irritation		Used in cosmetics in a mixture (toothpaste and mouthwash) therefore there is consumer exposure and environmental release is likely, however uses in cosmetics are reviewed by a safety assessor prior to inclusion in products.	**Currently no need for EU RRM**	No action
229-891-6			Not registered, only C&L notifications. Used in cosmetics in a mixture (toothpaste and mouthwash) and hair products therefore there is consumer exposure and	**Currently no need for EU RRM** **Justification:** These substances are not currently registered. Actions (including data	No action

			environmental release, however uses in cosmetics are reviewed by a safety assessor prior to inclusion.	generation) will be re-considered when the assessment will be revisited if the registration status and/or uses change.	
291-269-5 **291-275-8** **500-149-6**			Not registered, only C&L notifications		
not assigned (CAS 36505-83-6)			Not registered. No C&L notifications. Used in cosmetics in a mixture (toothpaste) with restrictions, pharmaceuticals, manufacturing, industrial manufacturing.		

Annex 1: Harmonised classifications and self-classifications reported by registrants

Data consulted on 17-01-2023

EC/ EC No	CAS No	Substance name	Harmonised classification	Classification in registrations
696-616-8	*1268344-02-0*	*Amines, N-(C18 unsaturated, alkyl) trimethylenedi-, ethoxylated (NLP)*	*None*	*Acute Tox. 4 H302, Skin Corr. 1B H314, Aquatic Acute 1 H400, Aquatic Chronic 1 H410, STOT RE 1 H372, Eye Dam 1 H318.* *1 notification*
800-029-6	*1290049-56-7*	*Amines, N-(C16-18 (even numbered) and C18-unsatd. alkyl) trimethylenedi-, ethoxylated*	*None*	*Acute Tox. 4 H302, Skin Corr. 1B H314, Aquatic Acute 1 H400, Aquatic Chronic 1 H410, STOT RE 1 H372* *4 notifications*
911-915-8	*6818-37-7*	*Reaction mass of ethoxylated N-oleyl-1,3-propanediamine, hydrofluorides of and ethoxylated N-palmityl-1,3-propanediamine, hydrofluorides of and ethoxylated N-stearyl-1,3-propanediamine, hydrofluorides of and olaflur (Olaflur)*	*None*	*Acute Tox. 4 H302, Skin Irrit. 2 H315, Aquatic Acute 1 H400, Aquatic Chronic 1 H410, Eye Dam 1 H318.* *4 notifications*
435-650-8	*not assigned*	*N-Bis(2-hydroxyethyl)oleylamine-hydrofluoride*	*Acute Tox. 4 H302, Skin Corr. 1A H314, Aquatic Acute 1 H400, Aquatic Chronic 1 H410.*	*Data classified*
292-562-0	*90640-43-0*	*N-C12,14 alkyl-1,3-diaminopropane*	*None*	*Aquatic Acute 1H400, Acute Tox. 3 H301, Skin Corr. 1B H314, STOT RE 1 H372, Aquatic Chronic 1 H410* *4 notifications*

230-528-9	*7173-62-8*	*N-Oleyl-1,3-diaminopropane (92 % N-Alkyl-1,3-diaminopropanes)*	*None*	*Aquatic Acute 1H400,* *Aquatic Chronic 1 H410,* *Acute Tox. 4 H302, Skin Corr. 1B H314,* *STOT RE 1 H372* *6 notifications*
291-269-5	*90367-21-8*	*Tris(hydroxyethyl) C12-18 alkyl diaminopropane*	*Not registered*	*Not registered*
229-891-6	*6818-37-7*	*Olaflur*	*Not registered*	*Not registered*
291-275-8	*90367-27-4*	*Ethanol, 2,2'-[[3-[(2-hydroxyethyl)amino]propyl]imino]bis-, N-tallow alkyl derivatives.*	*Not registered*	*Not registered*
500-149-6	*61790-85-0*	*Amines, N-tallow alkyltrimethylenedi-, ethoxylated*	*Not registered*	*Not registered*
CAS 36505-83-6	*36505-83-6*	*9-Octadecenylamine hydrofluoride (Dectaflur)*	*Not registered*	*Not registered*

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

Data consulted on [14-11-2022]

Main types of applications structured by product or article types	EC 696-616-8	EC 800-029-6	EC 911-915-8	EC 435-650-8	EC 292-562-0	EC 230-528-9
PC 0 : Other – surface active agents – building and construction	F, **P**	F, I				F, **P, A**
PC 0: Other – use as a laboratory reagent	I					
PC 0: Other: Accessory of medical device					F, **P**	
PC 19: Intermediate		I			I	I
PC 24: Lubricants, greases, release products		I, **P**			F, I	F, I, **P**
PC 25: Metal working fluids		F, **P**, I			I	F, I, **P**
PC 32: Polymer preparations and compounds		F, I, **A**				
PC 35: Washing and cleaning products		F, I, **P, C**			F, I, **P**	F, I, **P**
PC 37: Water treatment chemicals						I
PC 39: Cosmetics, personal care products		F, **C**	F, **C**	**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. * Note: Substance numbers EC 291-269-5, EC 229-891-6, EC 291-275-8, EC 500-149-6 and CAS number 36505-83-6 are not registered thus uses are not available. Data for EC 435-650-8 is classified.

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

Data consulted on [12-01-2023]

Completed or ongoing processes

EC number	Other REACH related work	RMOA	Actions not under REACH / CLP
696-616-8	Screening		
800-029-6	Screening		
911-915-8	Screening		
292-562-0	Screening	X	
230-528-9	Screening	X	
435-650-8	Screening		NONS
291-269-5*	Screening		
229-891-6*	Screening		
291-275-8*	Screening		
500-149-6*	Screening		
(CAS) 36505-83-6*	Screening		Cosmetic Products Regulation, Annex III - Restricted Substances

* Not registered
All substances in the group underwent manual screening by IE in 2019.

The Swedish CA conducted a risk-management options analysis (RMOA) of five UVCB-diamines in 2019. EC 292-562-0 and EC 230-528-9 were part this group. The UVCB-diamine group contained three other substances and read-across with linear and branched triamines, as well as linear tetramines. Concern was raised as to worker safety in relation to the derived no effect level (DNEL) derivation and the exposure assessment for inhalation and dermal exposure routes. The RMOA concluded that for this group of substances, there was no concern for adverse health effects based on updated registration and SDS information, recommendations for PPE and enforcement of control measures for workers. The lead registrant then updated all five registration-dossiers in January 2018 and shared the updated chemical safety assessments for the five UVCB-diamines with the members of the consortium and the (former) substance information exchange forum (SIEF). The lead registrant has also issued new extended safety data sheets (e-SDS) for downstream users.

ECHA reviewed EC 292-562-0 and EC 230-528-9 as part of the group RMOA for N-fatty alkyl polypropylenepolyamines in April 2020. While aquatic toxicity and specific organ toxicity – repeated dose was found for the group, no action was recommended at that time. Dossier evaluation was completed for EC 292-562-0, 230-528-9 and EC 911-915-8. A compliance check decision issued for EC 911-915-8 requested substance identification, composition, description of analytical methods, an *in vitro* gene mutation study in mammalian cells, an alga growth inhibition test, a *Daphnia magna* reproduction test and a fish early-life stage toxicity test. The compliance check for EC 292-562-0 and EC 230-528-9 concluded with no follow up actions.

All substances in the group were subject to a manual screening exercise by IE CA in 2019, the outcome of which was this evaluation. The screening Member State

Competent Authority (MSCA) noted that the group appears to have similar toxicological hazards; skin corrosivity, aquatic toxicity (both chronic and acute) and specific target organ toxicity.

Of the substances in the expanded group, N-Bis(2-hydroxyethyl)oleylamine-hydrofluoride (EC 435-650-8) has a harmonised classification for Acute Tox. 4 H320, Skin Corr. 1A H314, Aquatic acute 1 H400 and Aquatic chronic 1 H410