Assessment of regulatory needs

Authority: ECHA

Group Name: Aliphatic tertiary amines

General structure: -

Revision history

Version	*Date*	*Description*
1.0	15 September 2020	
1.1	30 June 2021	Update of report on CoRAP/Substance evaluation status of List.No. 931-292-6

Substances within this group:

EC/List number	CAS number	Substance name [and/ or Substance name acronyms]	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
Trialkylamines			
200-875-0	75-50-3	trimethylamine	Full, >1000
203-047-7	102-69-2	tripropylamine	Full, 100-1000
203-058-7	102-82-9	tributylamine	Full, >1000
203-063-4	102-87-4	tridodecylamine	OSII or TII
204-469-4	121-44-8	Triethylamine [TEA]	Full, >1000
209-940-8	598-56-1	Ethyldimethylamine	Full, >1000
213-139-9	926-63-6	dimethyl(propyl)amine	Full, >1000
213-156-1	927-62-8	N,N-dimethylbutylamine	Full, not (publicly) available
213-635-5	996-35-0	N,N-dimethylisopropylamine	Full, 100-1000
214-675-6	1184-78-7	Trimethylamine, n-oxide [TMAO]	Full, not (publicly) available
217-461-0	1860-26-0	2-ethyl-N,N-bis(2-ethylhexyl)hexylamine	Full, not (publicly) available
230-392-0	7087-68-5	ethyldiisopropylamine	Full, 100-1000
272-347-8	68814-95-9	Amines, tri-C8-10-alkyl	Full, not (publicly) available
700-199-0	2687-45-8	Triethylamine oxide	C&L notification
Methyldialkylamines			
230-990-1	7396-58-9	N-methyldidecylamine	Full, not (publicly) available
270-418-8	68439-75-8	Amines, di-C12-18-alkylmethyl	Full, not (publicly) available
627-132-7	1227096-04-9	not (publicly) available	Full, not (publicly) available
806-914-3	1499182-59-0	not (publicly) available	OSII or TII
943-504-4	-	Amines, di-C12-C14-alkylmethyl	OSII or TII
Dimethylalkylamines			
203-943-8	112-18-5	Dodecyldimethylamine	OSII or TII
203-997-2	112-69-6	Hexadecyldimethylamine	Full, 1000
204-002-4	112-75-4	Dimethyl(tetradecyl)amine	Full, not (publicly) available
204-694-8	124-28-7	Dimantine	Full, >1000
214-302-7	1120-24-7	Decyldimethylamine	Full, not (publicly) available
230-939-3	7378-99-6	dimethyl(octyl)amine	Full, not (publicly) available
244-433-5	21542-96-1	N,N-dimethyldocosylamine	OSII or TII
248-811-0	28061-69-0	N,N-dimethyloctadecenylamine	OSII or TII

[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]	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
268-220-1	68037-96-7	Amines, (C16-18 and C18-unsatd. alkyl)dimethyl	Full, not (publicly) available
269-915-2	68390-97-6	Amines, C16-18-alkyldimethyl	Full, not (publicly) available
269-923-6	68391-04-8	Amines, C12-18-alkyldimethyl	Full, >1000
270-414-6	68439-70-3	Amines, C12-16-alkyldimethyl	Full, not (publicly) available
283-464-9	84649-84-3	Amines, C12-14-alkyldimethyl	Full, >1000
296-866-4	93164-85-3	Amines, C20-22-alkyldimethyl	OSII or TII
Dimethylalkylamine oxides			
219-919-5	2571-88-2	N,N-dimethyloctadecylamine N-oxide	Full, not (publicly) available
220-020-5	2605-79-0	N,N-dimethyldecylamine N-oxide	Full, 100-1000
222-059-3	3332-27-2	N,N-dimethyltetradecylamine N-oxide	Full, 100-1000
216-700-6	1643-20-5	Dodecyldimethylamine oxide	Full, >1000
273-281-2	68955-55-5	Amines, C12-18-alkyldimethyl, N-oxides	C&L Notification
274-687-2	70592-80-2	Amines, C10-16-alkyldimethyl, N-oxides	C&L Notification
607-854-9	2605-78-9	1-Octanamine, N,N-dimethyl-, N-oxide	Full, 1-10
608-528-9	308062-28-4	Amines, C12-14 (even numbered) -alkyldimethyl, N-oxides	C&L Notification
931-292-6	308062-28-4	Amines, C12-14 (even numbered)-alkyldimethyl, N-oxides	Full, >1000
931-341-1	68955-55-5	Amines, C12-18(even numbered)-alkyldimethyl, N-oxides	Full, >1000
938-679-9	308062-29-5	not (publicly) available	Full, 100-1000
938-774-5	-	Amines, C12-16 (even numbered)-alkyldimethyl, N-oxides	Full, not (publicly) available

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.

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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
ATE	Acute toxicity estimates
CCH	Compliance Check
CLH	Harmonised classification and labelling
CMR	Carcinogenic, mutagenic and/or toxic to reproduction
CoRAP	Community rolling action plan
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	Persistent, mobile in water and toxic
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 aliphatic tertiary amines containing either three alkyl substitutions being the same or a combination of methyl or dimethyl with a longer alkyl chain.

The group consists of 45 substances, 41 are registered, six of them only as intermediates. In addition, there are four C&L notifications. The substances can be divided into smaller groups based on the constitution of their alkylchains: (1) trialkylamines (14 substances), (2) methyldialkylamines (5 substances) and (3) dimethylalkylamines (26 substances). Dimethylalkylamines is further divided in amines and amine oxides.

Four substances are under data generation requested under compliance check (CCH). Trimethylamine (EC 204-469-4) is currently under harmonised classification and labelling (CLH) opinion development for the addition of acute toxicity estimates (ATEs for Acute toxicity) and Eye Dam. 1 to the existing CLH. Substance List.No. 931-292-6 is listed in community rolling action plan (CoRAP) for substance evaluation (SEv), due to suspected reprotoxicity and eye effects[3].

Based on information reported in the REACH registration dossiers, many of the substances have widespread uses i.e. industrial, professional and consumer uses as e.g. catalyst/pH regulator, surfactant, lubricant, defoamer in coatings, adhesives & sealants, lubricants and greases, metalworking fluids, detergents and cosmetics. Article service life has been reported for four substances for use in paper, textile and leather production and formulation with concrete. The substances that are reported to be used in coatings as well as in adhesives & sealants can be considered to end up in articles although article service life is not explicitly reported.

Overall, potential for exposure and release to the environment can be assumed for most of the substances in the group.

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.

[3] Withdrawn in 2021.

2 Justification for the need for regulatory risk management action at EU level

Based on currently available information, there is a need for (further) EU regulatory risk management - restriction for reproductive toxicity hazard due to the potential for release/ exposure of the substances ECs/Lists 203-058-7, 204-469-4, 209-940-8, 213-635-5, 214-675-6, 230-990-1, 627-132-7, 203-943-8, 203-997-2, 204-002-4, 204-694-8, 214-302-7, 230-939-3, 268-220-1, 269-915-2, 269-923-6, 270-414-6, 283-464-9, 200-875-0, 203-047-7, 213-139-9, 213-156-1, 217-461-0, 230-392-0, 272-347-8, 270-418-8 in the group.

Based on ECHA's assessment of hazard information currently available in the registration dossiers and considerations of structural similarity all the substances in the group, except dimethylalkylamine oxides, have (potentially) reproductive toxicity hazard.

For amines, tri-C8-10-alkyl (EC 272-347-8) reduced testes and epididymis weights, and increased post-implantation losses were observed in a screening study (OECD 422) via oral routes in rats. The substance has self-classification as Repr. 1B.

Potential reproductive toxicity and ED-related findings have been observed also for other trialkylamines. For example, available 90-day studies on 2-ethyl-N,N-bis(2-ethylhexyl)hexylamine (EC 217-461-0) and ethyldimethylamine (EC 209-940-8) show dose-dependent alterations of ovary weight.

Based on the structural similarity of trialkylamines and the remaining uncertainty for reproductive toxicity due to the absence of adequate information, currently the potential reproductive toxicity (fertility and development) and ED applies to all trialkylamines. Therefore, further information is needed to confirm the presence or absence of these hazards for trialkylamines.

The provided information on dimethylalkylamines, as well as on the corresponding oxides that are the main metabolites of these substances, does not indicate concern for reproductive toxicity. However, the latest findings from the screening study require further assessment of adequacy of the provided information regarding the potential hazard for all dimethylalkylamines. Based on the structural similarity, currently the potential hazards identified for reproductive toxicity and ED apply provisionally to all dimethylalkylamines.

Methyldialkylamines are structurally similar to dimethylalkylamines. Therefore, the potential hazards identified for reproductive toxicity and ED for dimethylalkyamines apply also to all methyldialkylamines.

The ED potential is not strong based on the information available and stems from the potential reproductive toxicity where an endocrine mode of action might be relevant. Should the ED hazard be confirmed after generation of further information actions will be reconsidered when the assessment of regulatory needs will be revisited.

The hazard for STOT RE identified for many of the substances will not lead to additional regulatory risk management measures compared to the potential reproductive toxicity for the same subgroup. Therefore apart from CCH and potential need for CLH no other EU RRM process is indicated specifically for this hazard class.

The potential PBT is due to remaining uncertainty for some substances where the criterion for persistence is marginally met. PBT potential has been identified for

substances that have only industrial uses (EC 272-347-8 as processing aid/catalyst, EC 230-392-0 and EC 217-461-0 in coatings).

The first step of the regulatory risk management action proposed, should the hazard exist, is the confirmation of hazard via harmonised classification (CLH) as R1A/B.

CLH i) will require company level risk management measures (RMM) under the OSH legislation for workers, to be in place, ii) is needed or highly recommended for further regulatory processes under REACH and iii) is a prerequisite to restrict the presence of the substances in consumer mixtures (EC 214-675-6 in fertilisers, EC 204-694-8 in lubricants& greases) by means of the restriction entry 30.

CLH is also a prerequisite to restrict the presence of the substance EC 204-469-4 in clothing, other textiles, and footwear articles, by means of the restriction entry 72 of REACH Annex XVII (this would require addition of the substance to Appendix 12 by the Commission through Article 68(2)).

CLH will also support regulatory action under other regulations. For instance, in this specific case harmonised classification as CMR cat. 1 will trigger regulatory action under the biocidal product regulation (EU) 528/2012, which does not allow the use by the general public of a product containing substances (e.g. EC 283-464-9) above the concentration limit leading to classification of the mixture as CMR cat 1.

- harmonised classification as CMR cat 1 would render the substances unacceptable co-formulants in plant protection products

harmonised classification as CMR cat. 1 will trigger the restriction of use of these substances in toys. According to the safety requirements set for chemicals in toys under the Toy Safety Directive (2009/48/EC), substances or mixtures that are classified as CMR category 1 shall not be used in toys, in components of toys or in micro-structurally distinct parts of toys unless they meet the criteria for a derogation. In addition, harmonised classification will facilitate conformity assessment and declaration, particularly when the toy manufacturer bearing obligations is located outside the EU and therefore self-classification in registration dossiers is not applicable to them.
Furthermore, the new Fertilising Products Regulation requires that 'EU fertilising products shall not present a risk to human, animal or plant health, to safety or to the environment', which could be considered as preventing the use of a Repr 1B substance (e.g. EC 214-675-6) in a fertiliser.

PBT/vPvB potential has been identified for EC 272-347-8, EC 230-392-0 and EC 217-461-0 with only industrial uses as intermediate, processing aid/catalyst and in coatings. The first step of the regulatory risk management action proposed for these substances, should the hazard exist, is the confirmation of hazard via SVHC identification and inclusion on the Candidate List as PBT/vPvB.

SVHC identification is required as a step prior to authorisation or highly recommended as a step prior to restriction. In addition, SVHC identification brings immediate obligations for suppliers of the substances such as (i) supplying a safety data sheet and communicating on the safe use of the substances, (ii) responding to consumer requests within 45 days and (iii) notifying ECHA if the article they produce contains the substance above regulatory threshold.

The professional uses in lubricants & greases, coatings, adhesives & sealants, foundry & mining, gas treatment and formulation with concrete are expected to be widespread (at many sites and by many users). Professional use is often widespread with relatively low levels of operational controls and risk management measures but with often frequent exposures with a long duration. In addition, professional users may be self-employed and therefore not covered by occupational

safety and health (OSH) legislation.

Consumers may be co-exposed to the substances used by professionals e.g. house painters & renovators.

Therefore, a **restriction of the substance as such or in mixtures (concentration limit in mixtures) used by professionals** is suggested after CLH.

Restriction of professional uses is preferred over authorisation as it is considered to be more efficient and effective to introduce controls at the level of placing on the market rather than at the level of uses.

In addition, the use of the most harmful substances by professional workers has been recognised as an area of concern under the European Commission's Chemicals Strategy for Sustainability[4] which aims to extend to professional users under REACH the level of protection granted to consumers.

Moreover, **restricting substances in articles** used by professionals or consumers *(*reported for substances EC 203-943-8, 214-302-7 and 204-469-4*)* is proposed as potential for exposure from articles is likely.

As mentioned before, the existing restriction on CMR-substances in textiles (Annex XVII, entry 72) could potentially cover these uses of the substance EC 204-469-4 (TEA) in textile applications. However, restriction would also be recommended for the substance because of the wide variety of uses and incorporation in articles other than textiles.

It is suggested to cover possibly also industrial uses as part of the restriction with the aim to minimise exposures and emissions to humans and the environment. Mainly, all uses indicated as processing aid/ catalyst or in formulation of metalworking, as the substance might be released to the environment unless there is adequate waste (water) treatment.

However, the need for authorisation might be considered for industrial uses excluded from the scope of the restriction as it may not be proportionate to restrict all uses.

Based on currently available information, there is no need for (further) EU regulatory risk management for reproductive toxicity/ ED/ PBT/ aquatic toxicity hazards of the remaining substances in the group.

(Potential) hazards (Repro/ Repro& PBT) have been identified for substances EC 203-063-4, EC 700-199-0, EC 806-914-3, EC 943-504-4, EC 244-433-5, EC 248-811-0, EC 296-866-4 however, exposure potential is expected to be low e.g. they are only registered as intermediates or not registered. Potential PBT for EC 203-063-4 needs to be confirmed after compliance check on the analogue EC 272-347-8.

Therefore, no EU regulatory risk management action is currently proposed for any of the aforementioned substances due to low exposure potential. It is worth noting however that the strategy may need to be revisited and need for further regulatory action reconsidered if there is a change in the registration status or reported uses for any of these substances.

[4] European Commission, *Chemical Strategy for Sustainability Towards a Toxic-Free Environment*, available at https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf

The substances ECs/Lists 219-919-5, 220-020-5, 222-059-3, 216-700-6, 273-281-2, 274-687-2, 607-854-9, 608-528-9, 931-292-6, 931-341-1, 938-679-9, 938-774-5 are not expected to have severe human health hazards and they are already appropriately self-classified for aquatic toxicity. Therefore, despite widespread consumer uses, these substances are not considered to require further regulatory risk management.

NOTE:

The potential of all the substances in the group to react with nitrosating agents and to form potential carcinogenic nitrosamines has not been explored further in terms of actions. A common approach needs to be developed further regarding substances with a potential to form nitrosamines as part of co-exposure with nitrosating agents, and the subsequent regulatory measures where relevant. This is a more generic topic that is of relevance also for other groups of substances.

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/ List number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
203-058-7 204-469-4 209-940-8 213-635-5 214-675-6 230-990-1 627-132-7	Known or potential hazard for reproductive toxicity, ED	Known or potential hazard for aquatic toxicity for all except 214-675-6	Widespread use i.e. industrial, professional and consumer use in coatings, mining, article production, fertilisers, adhesives, lubricants, formulation with concrete. High potential for exposure for industrial& professional workers and consumers, release from articles	**Need for EU RRM: Restriction** <u>Justification:</u> The harmonised classification as R 1 – would trigger the restriction entry 30 and by that ensure that the substances are not included in consumer mixtures above the limits specified in that	**First step:** CCH for 204-469-4, 214-675-6, 627-132-7, 203-943-8, 203-997-2, 204-694-8, 214-302-7, 269-915-2, 269-923-6, 283-464-9, 200-875-0, 203-047-7, 217-461-0, 272-347-8, 213-139-9, 270-418-8, 230-939-3

EC/ List number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
203-943-8 203-997-2 204-002-4 204-694-8 214-302-7 268-220-1 269-915-2 269-923-6 270-414-6 283-464-9			and release to the environment.	entry. The reported professional uses are widespread (at many sites and many users) with relatively low levels of operational controls and risk management measures but with often frequent exposures with a long duration. Restriction of professional uses is preferred over authorisation as it is considered to be more efficient and effective to introduce controls at the level of placing on the market rather than at the level of uses. Specific restriction for use in articles is proposed as potential exposure from articles is likely.	**Next steps (if hazard confirmed):** CLH SVHC identification for 272-347-8, 230-392-0, 217-461-0 Restriction
200-875-0 203-047-7 213-139-9 213-156-1 217-461-0 230-392-0 230-939-3 272-347-8 270-418-8	Known or potential hazard for reproductive toxicity, ED	Known or potential hazard for PBT/vPvB For 272-347-8, 230-392-0 and 217-461-0. Known or potential hazard for aquatic toxicity for 203-047-7, 213-139-9, 213-156-1, , 270-418-8, 230-939-3	Industrial use as intermediate, in processing aid/ catalyst and in coatings. Potential for exposure for industrial workers and release to the environment.		

EC/ List number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
				Industrial uses to be considered as part of the restriction.	
203-063-4 806-914-3 943-504-4 244-433-5 248-811-0 296-866-4 700-199-0	Known or potential hazard for reproductive toxicity, ED	Known or potential hazard for PBT/vPvB for 203-063-4 Known or potential hazard for aquatic toxicity for 806-914-3, 943-504-4, 244-433-5, 248-811-0, 296-866-4	Intermediate use in industrial setting/ not registered (700-199-0). Low potential for exposure/release.	**Currently no need for EU RRM** <u>Justification:</u> According to the reported uses, low potential for exposure to both human health and environment is expected. Actions (including data generation) will be re-considered when the assessment will be revisited if the registration status and/or uses change.	Hazards to be confirmed after compliance checks for other group members/ analogue.
219-919-5 220-020-5 222-059-3 216-700-6	No hazard or unlikely hazard	Known or potential hazard for aquatic toxicity	Widespread use i.e. industrial, professional and consumer use in lubricants, detergents and cosmetics, leather & textile articles. High potential for exposure for workers and	**Currently no need for EU RRM** <u>Justification:</u> Overall, no or unlikely hazard that would lead to concern for the	Await for ongoing CCH for 931-292-6

EC/ List number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
273-281-2 274-687-2 607-854-9 608-528-9 931-292-6 931-341-1 938-679-9 938-774-5			consumers and release to the environment. Not registered i.e. no use: 273-281-2, 274-687-2, 608-528-9.	reported uses. Harmonised/self classification followed by implementation of necessary RRMs should be sufficient to ensure safe use for environment. When CCH results available for 931-292-6, actions to be reviewed accordingly. Uses in detergents and cosmetic products would be subject to the relevant legislations.	

Annex 1: Overview of classifications

Data extracted on 2 March 2020.

EC / List No	Substance name	Harmonised classification	Classification in registrations
200-875-0	Trimethylamine	*Flam. Gas 1 H220* *Skin Irrit. 2 H315* *Eye Dam. 1 H318* *Acute Tox. 4 H332* *STOT SE 3 H335*	*Acute Tox. 4 H332* *Flam. Liq. 1 H224* *Skin Corr. 1B H314* *Acute Tox. 4 H302* *STOT SE 3 H335* *Eye Dam. 1 H318* *Flam. Gas 1 H220* *Skin Irrit. 2 H315* *Press. Gas (Liq.) H280*
203-047-7	Tripropylamine		*Flam. Liq. 3 H226* *Acute Tox. 3 H301* *Acute Tox. 4 H332* *Acute Tox. 3 H311* *STOT SE 3 H335* *Skin Corr. 1B H314* *Aquatic Chronic 3 H412*
203-058-7	Tributylamine		*Acute Tox. 4 H302* *Skin Irrit. 2 H315* *Acute Tox. 2 H310* *Acute Tox. 1 H330*
203-063-4	Tridodecylamine		*Eye Irrit. 2 H319* *Skin Irrit. 2 H315* *Aquatic Chronic 2 H411* *Repr. 1B H360* *STOT RE 1 H372*
203-943-8	dodecyldimethylamine		*Acute Tox. 4 H302* *Aquatic Acute 1 H400* *Skin Corr. 1B H314* *Aquatic Chronic 1 H410*
203-997-2	hexadecyldimethylamine		*Skin Corr. 1B H314* *Aquatic Acute 1 H400* *Acute Tox. 4 H302* *Aquatic Chronic 1 H410*
204-002-4	dimethyl(tetradecyl)amine		*Acute Tox. 4 H302* *Aquatic Acute 1 H400* *Skin Corr. 1B H314* *Aquatic Chronic 1 H410*
204-469-4	Triethylamine (TEA)	*Flam. Liq. 2 H225* *Acute Tox. 4 H302* *Skin Corr. 1A H314* *Acute Tox. 4 H332* *Acute Tox. 4 H312*	*STOT SE 3 H335* *Acute Tox. 3 H311* *Acute Tox. 3 H331* *Eye Dam. 1 H318*
204-694-8	Dimantine		*Acute Tox. 4 H302* *Aquatic Acute 1 H400* *Skin Corr. 1B H314* *Aquatic Chronic 1 H410*
209-940-8	Ethyldimethylamine	*Flam. Liq. 2 H225* *Acute Tox. 4 H302* *Skin Corr. 1B H314* *Acute Tox. 4 H332*	*Eye Dam. 1 H318* *Acute Tox. 3 H331* *Skin Corr. 1A H314* *STOT SE 3 H335*
213-139-9	dimethyl(propyl)amine		*Flam. Liq. 2 H225* *Acute Tox. 4 H302* *Eye Dam. 1 H318* *Skin Irrit. 2 H315*

EC/ List No	Substance name	Harmonised classification	Classification in registrations
			Acute Tox. 3 H331 *STOT SE 3 H335*
213-156-1	N,N-dimethylbutylamine		*Flam. Liq. 2 H225* *Acute Tox. 3 H301* *Eye Dam. 1 H318* *Skin Corr. 1A H314* *STOT SE 3 H335*
213-635-5	N,N-dimethylisopropylamine		*Flam. Liq. 2 H225* *Aquatic Chronic 2 H411* *Acute Tox. 4 H302* *Acute Tox. 3 H331* *Skin Corr. 1A H314* *Eye Dam. 1 H318* *STOT SE 3 H335*
214-302-7	Decyldimethylamine		*Acute Tox. 4 H302* *Skin Corr. 1B H314* *Aquatic Acute 1 H400* *Aquatic Chronic 1 H410*
214-675-6	Trimethylamine, n-oxide (TMAO)		*Acute Tox. 4 H302* *Acute Tox. 4 H332*
216-700-6	Dodecyldimethylamine oxide		*Skin Irrit. 2 H315* *Eye Dam. 1 H318* *Aquatic Acute 1 H400* *Acute Tox. 4 H302* *Aquatic Chronic 2 H411*
217-461-0	2-ethyl-N,N-bis(2-ethylhexyl)hexylamine		*Repr. 2 H361* *STOT RE 2 H373*
219-919-5	N,N-dimethyloctadecylamine N-oxide		*Aquatic Acute 1 H400* *Eye Dam. 1 H318* *Skin Irrit. 2 H315* *Acute Tox. 4 H302* *Aquatic Chronic 2 H411*
220-020-5	N,N-dimethyldecylamine N-oxide		*Aquatic Acute 1 H400* *Eye Dam. 1 H318* *Acute Tox. 4 H302* *Aquatic Chronic 2 H411*
222-059-3	N,N-dimethyltetradecylamine N-oxide		*Skin Irrit. 2 H315* *Aquatic Acute 1 H400* *Eye Dam. 1 H318* *Acute Tox. 4 H302* *Aquatic Chronic 2 H411*
230-392-0	ethyldiisopropylamine		*Flam. Liq. 2 H225* *Eye Dam. 1 H318* *Acute Tox. 4 H302* *Acute Tox. 3 H331* *STOT SE 3 H335*
230-939-3	dimethyl(octyl)amine		*Acute Tox. 3 H301* *Skin Corr. 1B H314* *Eye Dam. 1 H318* *Aquatic Acute 1 H400* *Acute Tox. 2 H330* *Repr. 1B H360*

EC/ List No	Substance name	Harmonised classification	Classification in registrations
			Aquatic Chronic 1 H410 *Skin Sens. 1B H317*
230-990-1	N-methyldidecylamine		*Acute Tox. 4 H302* *Aquatic Acute 1 H400* *Skin Irrit. 2 H315* *Aquatic Chronic 1 H410*
244-433-5	N,N-dimethyldocosylamine		*Skin Corr. 1B H314* *Aquatic Acute 1 H400* *Acute Tox. 4 H302* *Aquatic Chronic 1 H410*
248-811-0	N,N-dimethyloctadecenylamine		*Aquatic Acute 1 H400* *Acute Tox. 4 H302* *Skin Corr. 1B H314* *Aquatic Chronic 1 H410*
268-220-1	Amines, (C16-18 and C18-unsatd. alkyl)dimethyl		*Skin Corr. 1B H314* *Aquatic Acute 1 H400* *Aquatic Chronic 1 H410* *Acute Tox. 4 H302*
269-915-2	Amines, C16-18-alkyldimethyl		*Skin Corr. 1B H314* *Aquatic Acute 1 H400* *Acute Tox. 4 H302* *Aquatic Chronic 1 H410*
269-923-6	Amines, C12-18-alkyldimethyl		*Acute Tox. 4 H302* *Aquatic Acute 1 H400* *Skin Corr. 1B H314* *Aquatic Chronic 1 H410*
270-414-6	Amines, C12-16-alkyldimethyl		*Skin Corr. 1B H314* *Aquatic Acute 1 H400* *Acute Tox. 4 H302* *Aquatic Chronic 1 H410*
270-418-8	Amines, di-C12-18-alkylmethyl		*Aquatic Acute 1 H400* *Skin Irrit. 2 H315*
272-347-8	Amines, tri-C8-10-alkyl		*Skin Irrit. 2 H315* *Aquatic Chronic 2 H411* *Eye Irrit. 2 H319* *Repr. 1B H360* *STOT RE 1 H372*
273-281-2	Amines, C12-18-alkyldimethyl, N-oxides		
274-687-2	Amines, C10-16-alkyldimethyl, N-oxides		
283-464-9	Amines, C12-14-alkyldimethyl		*Skin Corr. 1B H314* *Aquatic Acute 1 H400* *Acute Tox. 4 H302* *Aquatic Chronic 1 H410*
296-866-4	Amines, C20-22-alkyldimethyl		*Skin Corr. 1B H314* *Aquatic Acute 1 H400* *Acute Tox. 4 H302*
607-854-9	not (publicly) available		*Eye Dam. 1 H318*

EC/ List No	Substance name	Harmonised classification	Classification in registrations
608-528-9	Amines, C12-14 (even numbered) -alkyldimethyl, N-oxides		
627-132-7	-		*Aquatic Acute 1 H400* *Aquatic Chronic 1 H410*
700-199-0	Triethylamine oxide		
806-914-3	-		*Aquatic Acute 1 H400* *Aquatic Chronic 1 H410* *Skin Irrit. 2 H315*
931-292-6	Amines, C12-14 (even numbered)-alkyldimethyl, N-oxides		*Aquatic Acute 1 H400* *Acute Tox. 4 H302* *Eye Dam. 1 H318* *Skin Irrit. 2 H315* *Aquatic Chronic 2 H411*
931-341-1	Amines, C12-18(even numbered)-alkyldimethyl, N-oxides		*Aquatic Acute 1 H400* *Acute Tox. 4 H302* *Eye Dam. 1 H318* *Skin Irrit. 2 H315* *Aquatic Chronic 2 H411*
938-679-9	not (publicly) available		*Aquatic Acute 1 H400* *Aquatic Chronic 2 H411* *Acute Tox. 4 H302* *Eye Dam. 1 H318* *Skin Irrit. 2 H315*
938-774-5	Amines, C12-16 (even numbered)-alkyldimethyl, N-oxides		*Aquatic Acute 1 H400* *Aquatic Chronic 2 H411* *Acute Tox. 4 H302* *Eye Dam. 1 H318* *Skin Irrit. 2 H315*
943-504-4	Amines, di-C12-C14-alkylmethyl		*Aquatic Acute 1 H400* *Eye Dam. 1 H318* *Skin Irrit. 2 H315*

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

Data extracted on 2 March 2020

Trialkylamines.

EC/ List number	Inter-mediate	Polyme-risation	Labora-tory	Use in coatings	Foundry and mining	Paper, textile and leather product-ion	Processing aid/ catalyst	Ferti-lisers	Medical diag-nostic reagent	Gas treat-ment
200-875-0	I, **P**	F, I	I				I			
203-047-7	I		I, **P**				I		F	
203-058-7	I		I	F, I, **P**			I			
203-063-4	I									
204-469-4	F, I	F, I	**P**	F, I, **P**	F, I, **P**	F, I, **A**	F, I			I, **P**
214-675-6								F, I, **P, C**		
217-461-0		F		I			I			
230-392-0	I		**P**	I			I			
272-347-8							I			
209-940-8	I	I, **P**	I							
213-139-9	I	I	I, **P**		I					
213-156-1	I						I			
213-635-5	I	I, **P**	F, **P**				I			

F: formulation, I: industrial use, P: professional use, C: consumer use, A: article service life; C and A are highlighted in red to indicate widespread use with potential for exposure/release.

Methyldialkylamines.

EC/ List number	Intermediate	Adhesives, sealants	Catalyst	Lubricants, greases
230-990-1	I	F, **P**		
270-418-8	I		I	
627-132-7	I			F, I, **P**
806-914-3	I			
943-504-4	I			

F: formulation, I: industrial use, P: professional use, C: consumer use, A: article service life; C and A are highlighted in red to indicate widespread use with potential for exposure/release.

Dimethylalkylamines.

EC/ List number	Interme-diate	Polymeri-sation	Formula-tion with concrete	Metal-working fluid	Lubricants and greases	Deterg-ents	Cosmetic products	Processing aid	Catalyst
203-943-8	I		F, I, **P, A**						
203-997-2	I	F, I		F	I, **P**				I
204-002-4	I	F, I		F	I, **P**				
204-694-8	I	I		F	I, **P, C**				
214-302-7	I		F, I, **P, A**						
216-700-6						F, I, **P, C**	**C**		
219-919-5						F, I, **P, C**			
220-020-5						F, I, **P, C**	**C**		
222-059-3						F, I, **P, C**	**C**		
230-939-3	I							I	

EC/ List number	Interme-diate	Polymeri-sation	Formula-tion with concrete	Metal-working fluid	Lubricants and greases	Deterg-ents	Cosmetic products	Processing aid	Catalyst
244-433-5	I	I							
248-811-0	I								
268-220-1	I			F	F, I, **P**				
269-915-2	I			F	F, I, **P**				

F: formulation, I: industrial use, P: professional use, C: consumer use, A: article service life; C and A are highlighted in red to indicate widespread use with potential for exposure/release.

Dimethylalkylamine oxides.

EC/ List number	Inter-mediate	Polymeri sation	Metal-working fluid	Lubri-cants and greases	Deter-gents / cleaning agent	Cos-metics	Pro-cessing aid	Leather and textiles	Dipping
269-923-6	I		F	F, I, **P**					
270-414-6	I		F	F, I, **P**					
283-464-9		F	F	I, **P**					I, **P**
296-866-4	I								
607-854-9					I, **P**				
931-292-6					F, I, **P, C**	F, I, **P, C**			
931-341-1					I, **P, C**		I	F, I, **A**	
938-679-9					F, I, **P, C**				
938-774-5					F, I, **P, C**				

F: formulation, I: industrial use, P: professional use, C: consumer use, A: article service life; 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 4 March 2020.

EC / List number	RMOA	Authorisation		Restriction*	CLH	Actions not under REACH / CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)	
204-469-4					YES	
274-687-2						Active substance approval under BPR

*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.