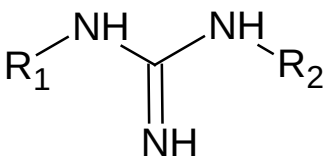
Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Date: 05/05/2022

Group Name: Non-aromatic guanidines

General structure:



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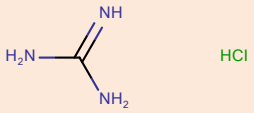
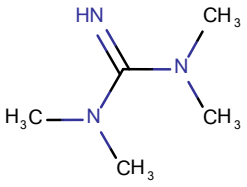
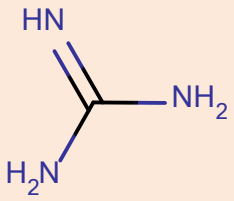
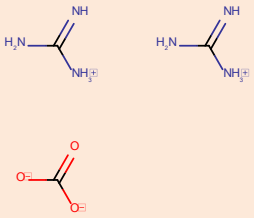
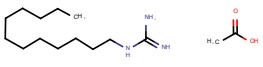
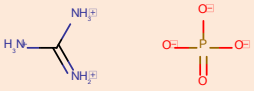
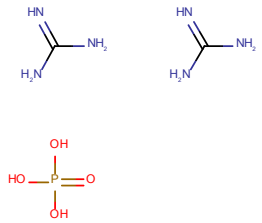
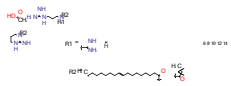
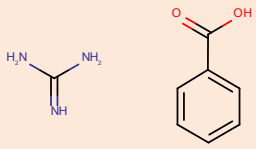
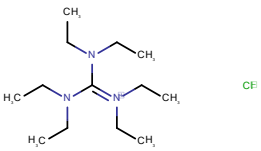
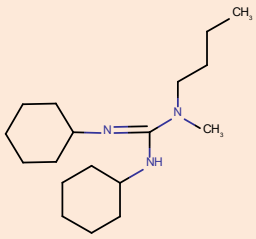
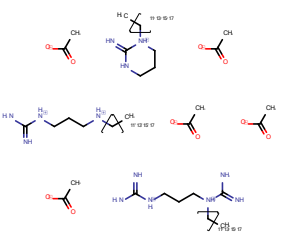
Revision history

Version	*Date*	*Description*
1.0	02/06/2022	

Substances within this group:

EC / List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
200-002-3	50-01-1	Guanidinium chloride		Full, 100-1000
201-302-7	80-70-6	1,1,3,3-tetramethylguanidine		Full, 10-100
204-021-8	113-00-8	Guanidine		OSII or TII
208-060-1	506-93-4	Guanidinium nitrate		Full, >1000
209-813-7	593-85-1	Diguanidinium carbonate		Full, 100-1000
219-459-5	2439-10-3	Dodine		C&L notification
226-551-9	5423-22-3	Guanidinium phosphate (1:1)		Full, 100-1000

[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	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
226-552-4	5423-23-4	Bisguanidinium phosphate		Full, not (publicly) available
288-198-7	85681-60-3	Guanidine, N,N'''-1,3-propanediylbis-, N-coco alkyl derivs., diacetates	N/A	C&L notification
308-757-1	98246-84-5	Guanidine, N,N'''-1,3-propanediylbis-, N-coco alkyl derivs.		Full, not (publicly) available
429-820-0	26739-54-8	Guanidinium benzoate		Full, not (publicly) available
482-110-2	-	bis(diethylamino)-N,N-diethylmethanimi nium chloride		NONS
700-163-4	-	1-butyl-2,3-dicyclohexyl-1-methylguanidine		Full, not (publicly) available
939-650-3	-	1-(C12-C18 even numbered, C18 unsaturated)alkyl-1,4,5,6-tetrahydropyrimidin-2-aminium acetate and{[3-((C12-C18 even numbered, C18 unsaturated)alkyl amino)propyl]ami		Full, not (publicly) available

EC / List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
		no}(imino)methanaminium acetate and[(3-{[ammonio(imino)methyl]amino}propyl)(C12-C18 even numbered, C18 unsaturated)alkylamino](imino)methanaminium diacetate		

This table contains also group members that are only notified under the CLP Regulation. However, the list is currently non-exhaustive. Should further regulatory risk management action on one or more substances in the group be considered, ECHA may make an additional search for related C&L notified substances to be included in the group and develop an assessment of regulatory needs for them.

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 different level of information. A Member State or ECHA can carry out this case-by-case analysis. The starting point is available information in the REACH registrations and any other REACH and CLP information. However, more extensive set of information can be available, e.g. assessment done under REACH/CLP or other EU legislation, or can be generated in some cases (e.g. further hazard information under dossier evaluation). Uncertainties associated to the level of information used should be reflected in the documentation. It will be revisited when necessary. For example, after further information is generated and the hazard has been clarified or when new insights on uses are available. It can be revisited by the same or another authority.

The responsibility for the content of this assessment rests with the authority that developed it. It is possible that other authorities do not have the same view and may develop further assessment of regulatory needs. The assessment of regulatory needs does not yet initiate any regulatory process but any authority can consequently do so and should indicate this by appropriate means, such as the Registry of Intentions.

For more information on Assessment of regulatory needs please consult ECHA website[2].

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

Glossary

ARN	Assessment of Regulatory Needs
CCH	Compliance Check
CLH	Harmonised classification and labelling
CMR	Carcinogenic, mutagenic and/or toxic to reproduction
DEv	Dossier evaluation
ED	Endocrine disruptor
NONS	Notified new substances
OEL	Occupational exposure limit
OSII or TII	On-site isolated intermediate or transported isolated intermediate
PBT/vPvB	Persistent, bioaccumulative and toxic/very persistent and very bioaccumulative
RMOA	Regulatory management options analysis
RRM	Regulatory risk management
SEv	Substance evaluation
STOT RE	Specific target organ toxicity, repeated exposure
SVHC	Substance of very high concern

1 Overview of the group

ECHA has grouped together structurally similar substances based on the presence of the guanidyl moiety shown in Figure 1. This group on 'Non-aromatic guanidines' is a subset of groups around the guanidyl moiety, which either are part of a past/future ECHA group assessments or are part of a different assessment framework.[3]

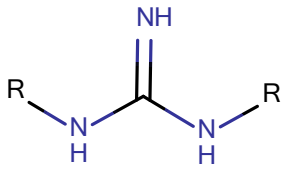

Figure 1 Guanidyl moiety

The group contains guanidines either with non-aromatic moieties (7 substances) or guanidine salts (7 substances). The substance "Guanidine" itself (EC number: 204-021-8) is also a member of this group.

This group consists in total of 14 substances. One substance is only registered as intermediate and two are not registered under REACH.

Based on information reported in the REACH registration dossiers, substances in this group are used by consumers, professionals and in industrial settings as oxidizing agents, protein denaturants, pH regulators, flame retardants, disinfectants and processing agents in a variety of uses including in the manufacture of explosives, in fertilisers, to disinfect medical devices and hard surfaces in the health-care sector, in perfumes and cosmetics, to treat leather and paper and board products, in textile dyes, coatings and paints, in surface treatment products and in laboratory uses. Uses vary from substance to substance in this group. Consumer and professional uses in perfumes, fertilisers, washing and cleaning agents, textile dyes and disinfectants have a particularly high exposure/release potential.

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] These groups are a) Guanidine and simple guanidinium salts, b) aromatic guanidines, c) Guanidylureas, cyanoguanidines and biguanides and d) aminoureas, aminoguanidines and nitroguanidines.

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 PBT/vPvB hazards due to the potential for release of the substances EC 308-757-1, EC 939-650-3, EC 219-459-5 and EC 288-198-7 in the group.

Based on ECHA's assessment of currently available hazard information, no potential hazards were identified for human health. These conclusions are based on the available data in the dossiers for mutagenicity, repeated dose toxicity, reproductive toxicity and skin sensitisation. An uncertainty remains for substance EC 939-650-3 regarding STOT RE and further data is under generation. The data generated would also be relevant for EC 308-757-1 and EC 288-198-7.

Based on ECHA's assessment of currently available hazard information, it is considered that the substances EC 308-757-1, EC 939-650-3, EC 219-459-5 and EC 288-198-7 may fulfil the PBT/vPvB screening criteria. Their structural similarity suggests that these four substances may possibly be used interchangeably. The outcome of the ongoing data generation for substance EC 939-650-3 should be awaited. Data has been requested on degradation (simulation testing on ultimate degradation in surface water, soil simulation testing, sediment simulation testing) and bioaccumulation (bioaccumulation in aquatic species). Both EC 308-757-1 and EC 939-650-3 are assumed to fulfil the T criteria set in Annex XIII (NOEC < 0.01 mg/L). Considering the structural similarity with EC 219-459-5 and EC 288-198-7, PBT potential can therefore not be excluded for these substances either.

The first step of the regulatory risk management action proposed, should the hazard exist, is the confirmation of hazard via SVHC identification and inclusion on the Candidate List as PBT.

SVHC identification is required (Authorisation) or highly recommended for further regulatory processes under REACH (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.

Confirmation of the hazard properties via SVHC identification is not considered sufficient to minimise potential releases of the substances in the environment. Therefore, in a second step, a restriction is seen as the most appropriate option as potential for exposure is expected from consumer, professional and industrial uses.

Information on uses for the two substances for which registrations exist (EC 308-757-1 and EC 939-650-3) indicates that they are largely used by professionals in products to clean or disinfect medical devices and hard surfaces in a health care setting. Despite having biocidal properties, they may not require approval as biocidal active substances under the Biocidal Products Regulation (BPR) for this particular use as/in medical devices in accordance with Art 2(2) of said regulation. Risks to human health from exposure may instead be controlled via the Medical Devices Regulation[4]. Risks from exposure may also be controlled via operational conditions given that the substances at hand are corrosive. Release and therefore

[4] See also https://www.wien.gv.at/wuawides/internet/Inhaltsstoffsuche/Detail/3668 and https://www.wien.gv.at/wuawides/internet/Inhaltsstoffsuche/Bewertungdetail/1482

risks to the environment on the other hand do not appear to be controlled and action under REACH is therefore proposed. According to registrations, the substances are further used also by consumers and industrial workers in biocidal products. It is noted that such additional uses not falling under the definition of medical devices would require approval under the BPR. It is noted that use information in REACH registration data does not support the conclusion that these substances are only used in medical devices.

Releases to the environment from consumer uses cannot be avoided.

Widespread professional uses are typically non-contained and non-automated leading to releases to the environment.

Therefore, a restriction of the substances as such or in mixtures (concentration limit in mixtures) used by consumers, professional workers and industrial workers is suggested after SVHC identification, with the aim to minimise exposure to humans and release to the environment.

The use of PBT and vPvB substances by consumers and professional workers has been recognised as an area of concern under the European Commission's Chemicals Strategy for Sustainability[5].

Moreover, **restricting substances in articles** used by professionals or consumers which may occur in the future but is not currently reported by registrants should be considered in the context of the restriction of consumer/professional uses as potential exposure from articles needs further investigation first.

It is suggested to cover possibly also industrial uses as part of the restriction. 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 all other substances in the group.

Based on ECHA's assessment of currently available hazard information, no potential hazards were identified for human health (except EC 482-110-2, which screens for skin sensitisation). These conclusions are based on the available data in the dossiers for mutagenicity, repeated dose toxicity, reproductive toxicity and skin sensitisation. Counterions in guanidinium salts (chloride, nitrate, carbonate, phosphate, benzoate) are not expected to impact the overall toxicity.

Simple guanidine salts (EC 200-002-3, EC 208-060-1, EC 209-813-7, EC 226-551-9, EC 226-552-4, EC 429-820-0), EC 204-021-8 (guanidine) and EC 201-302-7 are also unlikely to fulfil the PBT/vPvB screening criteria, because they have a low potential for persistency (except EC 201-302-7, which is likely persistent), bioaccumulation and/or are unlikely to fulfil the toxicity criterion (available toxicity values are all above the threshold for T criterion). These conclusions are based on the scientific evidence that guanidine, as a product of metabolic pathways of amino acids and nucleobases, is rapidly excreted by vertebrates and on inherent biodegradability of the guanidinium ion. All these substances have LogKoc below 4 and/or LogDow (i.e. octanol-water distribution ratio for ionisable substances) below 4.5, therefore all are potentially mobile in soil and water. Also for the environment,

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

counterions in guanidinium salts (chloride, nitrate, carbonate, phosphate, benzoate) are not expected to impact the overall toxicity.

No EU regulatory risk management action is currently proposed for the simple guanidine salts EC 200-002-3, EC 208-060-1, EC 209-813-7, EC 226-551-9, EC 226-552-4, EC 429-820-0), guanidine (EC 204-021-8) in this group due to no or unlikely hazard that would lead to concern for the reported uses. Compliance checks are proposed for EC 208-060-1 and EC 209-813-7 to confirm no or low hazard as they have widespread use including by professionals and consumers.

EC 700-163-4 potentially meets PBT/vPvB screening criteria. It is not readily biodegradable (potentially P/vP) and has a $LogK_{ow} \geq 1.78$, but having surface-active properties the B criterion set in Annex XIII of REACH regulation cannot be considered applicable to conclude on bioaccumulation potential. Available toxicity data don't fulfil the T criterion. Due to low tonnage, it is not possible to clarify the potential hazards of EC 700-163-4.

Exposure and release potential for EC 700-163-4 is however expected to be low. It is correctly self-classified by the only registrant and controlled conditions in industrial settings for this substance are expected to be in place already.

Therefore, no EU regulatory risk management action is currently proposed for EC 700-163-4 due to low exposure potential. It is worth noting however that the strategy, including the need to clarify PBT/vPvB potential, needs 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.

EC 482-110-2 also potentially meets PBT/vPvB screening criteria and is a skin sensitiser. Due to the status as inactive NONS it is not possible to clarify the potential PBT/vPvB properties. Given that the substance is self-classified as skin sensitising, and has no registered uses nor an active registration, it is proposed that there is currently no need for EU RRM action on this substance. If the registration status changes, data generation and potentially follow up actions will be re-considered when the assessment will be revisited.

3 Conclusions and actions

The conclusions and actions proposed in the table below are based on the REACH and CLP information available at the time of the assessment by ECHA. The main source of information is the registration dossiers. Relevant public assessments may also be considered. When new information (e.g. on hazards through evaluation processes, or on uses) will become available, the document will be updated and conclusions and actions revisited.

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
939-650-3, 308-757-1, 219-459-5 and 288-198-7	Inconclusive hazard for STOT RE (for 939-650-3, 308-757-1, and 288-198-7	Known or potential hazard for PBT/vPvB for aquatic toxicity	Substances used as disinfectant and biocides with medium to high release potential due to use in polishes, waxes, washing and cleaning products. Exposure potential also high due to consumer and professional uses and spray and manual applications.	Need for EU RRM: Restriction Justification: Releases to the environment from consumer and widespread professional uses cannot be avoided. Widespread professional uses are typically non-contained and non-automated leading to releases to the environment.	**First step:** CCH, TPE (ongoing for 939-650-3 and 308-757-1; pending for 219-459-5 and 288-198-7) **Next steps (if hazard confirmed):** PBT assessment CLH (aquatic tox) SVHC identification Restriction
208-060-1 and 209-813-7	No hazard or unlikely hazard	No hazard or unlikely hazard	Widespread industrial, professional and consumer uses with high exposure and	Currently no need for EU RRM Justification:	CCH

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
			release potential including as fertiliser and in perfumes and cosmetics.	CCH to confirm low hazard.	
200-002-3 201-302-7 204-021-8 226-551-9 226-552-4 482-110-2 429-820-0 700-163-4	**482-110-2:** Known or potential hazard for skin sensitisation **All others:** No hazard or unlikely hazard	**700-163-4 and 482-110-2:** Known or potential hazard for PBT/vPvB **700-163-4:** Known or potential hazard for aquatic toxicity **All others:** No hazard or unlikely hazard	**204-021-8, 429-820-0, 482-110-2 and 700-163-4:** According to the reported uses, low potential for exposure to both human health and environment is expected. **All others:** Widespread industrial and/or professional and/or consumer uses with sometimes high exposure and release potential including in leather treatment and paper and board treatment products and textile dyes.	Currently no need for EU RRM Justification: **482-110-2 and 700-163-4:** 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. **All others:** Overall, no or unlikely hazard that would lead to concern for the reported uses.	No action

Annex 1: Overview of classifications

Data extracted on 31 January 2022.

EC / List No	CAS number	Substance name	Harmonised classification	Classification in registrations[6]	Classification in C&L notifications[7]
200-002-3	50-01-1	guanidinium chloride	Acute Tox. 4 * Skin Irrit. 2 Eye Irrit. 2	Acute Tox. 4 H302 Acute Tox. 4 H332 Skin Irrit. 2 H315 Eye Irrit. 2 H319	Acute Tox. 4 H312[1 out of 62] Eye Irrit. 2A H319[1 out of 62] STOT Single Exp. 3 H335, affected organs: lungs[1 out of 62]
201-302-7	80-70-6	1,1,3,3-tetramethyl guanidine		Flam. Liquid 3 H226 Acute Tox. 4 H302 Skin Corr. 1B H314 Eye Damage 1 H318	Acute Tox. 4 H312[1 out of 46] Acute Tox. 4 H332[4 out of 46] Acute Tox. 3 H331[1 out of 46] Met. Corr. 1 H290[4 out of 46] Flam. Liquid 2 H226[1 out of 46] Skin Corr. 1A H314[1 out of 46]
204-021-8	113-00-8	guanidine		Acute Tox. 3 H331 [intermediate (active)] STOT Single Exp. 1 H370, affected	-

[6] The column gives the classifications in registrations received under REACH. Additional classifications in intermediate and in inactive registrations (if any) are annotated and displayed last. For each classification the table includes information on the hazard category, the hazard statement and any available information on specific effects (relevant for reproductive toxicity), specific concentration limits, M-Factors and affected organs. Two classifications differing in any of these aspects are considered different and are repeated in the table. The columns "Classifications in registrations" and "Classifications in C&L notifications" are empty if there are no Registrations/C&L notifications (hazard is unknown). The value '-' is displayed on the same columns when there are (relevant) submissions but they do not contain self-classifications (substance is not hazardous).

[7] The column gives the additional classifications not found in registrations but found in active or inactive C&L notifications (without distinguishing them). For each classification this column also provides the number of C&L notifications that contain the classification out of the total number of C&L notifications received for the substance. A single C&L notification file submitted by a group of notifiers is only counted once. Therefore, the numbers may differ from the dissemination site which counts number of notifiers.

				organs: liver [intermediate (active)] Skin Corr. 1A H314 [intermediate (active)] Acute Tox. 3 H311 [intermediate (active)] Acute Tox. 3 H301 [intermediate (active)] Flam. Liquid 2 H225 [intermediate (active)] Eye Damage 1 H318 [intermediate (active)]	
208-060-1	506-93-4	guanidinium nitrate		Acute Tox. 4 H302 Acute Tox. 4 H332 Eye Damage 1 H318	STOT Single Exp. 3 H335[1 out of 5] STOT Single Exp. 3 H335, affected organs: Respiratory[1 out of 5] Eye Irrit. 2 H319[3 out of 5] Oxid. Solid 3 H272[3 out of 5] Skin Irrit. 2 H315[3 out of 5]
209-813-7	593-85-1	diguanidinium carbonate		Acute Tox. 4 H302 Eye Damage 1 H318	Skin Irrit. 2 H315[10 out of 35] STOT Single Exp. 3 H335, affected organs: Respiratory system[1 out of 35] STOT Single Exp. 3 H335[1 out of 35] Aquatic Chronic 3 H412[11 out of 35] Eye Irrit. 2 H319[10 out of 35] STOT Single Exp. 3 H335, affected organs: lungs[3 out of 35]

219-459-5	2439-10-3	dodine	Acute Tox. 4 * Skin Irrit. 2 Eye Irrit. 2 Aquatic Acute 1 Aquatic Chronic 1	-	Eye Damage 1 H318[1 out of 11] Acute Tox. 4 H302[11 out of 11] Aquatic Acute 1 H400, M-factor: 100.00[1 out of 11] Aquatic Chronic 1 H410[7 out of 11] Aquatic Acute 1 H400[10 out of 11] Eye Irrit. 2 H319[10 out of 11] Skin Irrit. 2 H315[11 out of 11]
226-551-9	5423-22-3	guanidinium phosphate (1:1)		Acute Tox. 4 H302	Acute Tox. 4 H332[2 out of 8] Eye Irrit. 2 H319[2 out of 8] Skin Irrit. 2 H315[2 out of 8]
226-552-4	5423-23-4	bisguanidinium phosphate		Acute Tox. 4 H302 Eye Irrit. 2 H319 Aquatic Chronic 3 H412	Acute Tox. 4 H332[7 out of 16] Skin Irrit. 2 H315[6 out of 16] Acute Tox. 4 H312[1 out of 16]
288-198-7	85681-60-3	Guanidine, N,N'''-1,3-propanediylbis-, N-coco alkyl derivs., diacetates		-	Eye Damage 1 H318[2 out of 8] Acute Tox. 4 H302[8 out of 8] Aquatic Acute 1 H400[6 out of 8] Flam. Liquid 3 H226[3 out of 8] Skin Corr. 1B H314[8 out of 8]
308-757-1	98246-84-5	Guanidine, N,N'''-1,3-propanediylbis-, N-coco alkyl derivs.		Acute Tox. 4 H302 Skin Corr. 1C H314 Aquatic Acute 1 H400, M-factor: 10.00	Aquatic Acute 1 H400[2 out of 2] Skin Corr. 1B H314[2 out of 2]

				Aquatic Chronic 1 H410	
429-820-0	26739-54-8	guanidinium benzoate	Acute Tox. 4 *	Acute Tox. 4 H302	-
482-110-2	-	bis(diethylamino)-N,N-diethylmethaniminium chloride		Acute Tox. 4 H302 [Article 10 (inactive)] Skin Sens. 1 H317 [Article 10 (inactive)] Eye Damage 1 H318 [Article 10 (inactive)] Aquatic Chronic 3 H412 [Article 10 (inactive)] Skin Corr. 1B H314 [Article 10 (inactive)] Acute Tox. 4 H312 [Article 10 (inactive)]	-
700-163-4	-	1-butyl-2,3-dicyclohexyl-1-methylguanidine		Acute Tox. 3 H301 Skin Corr. 1C H314 Eye Damage 1 H318 Aquatic Chronic 2 H411	-
939-650-3	-	Reaction mass of 1-(3-((C12-18-(even numbered))-alkyl-amino)propyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-1-(3-guanidinopropyl)guanid		Acute Tox. 4 H302 Skin Corr. 1C H314 Aquatic Acute 1 H400, M-factor: 10.00 Aquatic Chronic 1 H410	STOT Rep. Exp. 2 H373[1 out of 1]

		ine acetate salt and 1-(C12-18-(even numbered))-alkyl-tetrahydropyrimidin-2(1H)-imine acetate salt			

(*) 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

Data extracted on 31 January 2022.

EC number	200-002-3	201-302-7	204-021-8	208-060-1	209-813-7	226-551-9	226-552-4	308-757-1	429-820-0	482-110-2	700-163-4	939-650-3
PC 1: Adhesives, sealants		F, I, **P**			F						I	
PC 8: Biocidal products (e.g. disinfectants, pest control)								F, **P**, **C**				F, I, **P**
PC 9a: Coatings and paints, thinners, paint removes		F, I, **P**		I		I	F					
PC 9b: Fillers, putties, plasters, modelling clay		I										
PC 11: Explosives				F, I, **P**, **C**								
PC 12: Fertilisers				F, **P**, **C**								
PC 14: Metal surface treatment products	I			I								
PC 15: Non-metal-surface treatment products					I, **P**	F, I	F, I					
PC 19: Intermediate	I	I	I	I	I, **C**							
PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents	F, I, **P**				I, **P**				I, **P**			
PC 21: Laboratory chemicals	F, I, **P**, **C**	F, I, **P**			F, I, **P**				F, I, **P**			
PC 23: Leather treatment products						F, I, **A**						
PC 26: Paper and board treatment products		I				F, I, **A**						

PC 28: Perfumes, fragrances					**C**							
PC 29: Pharmaceuticals	F, I	I										
PC 30: Photo-chemicals	F, I											
PC 31: Polishes and wax blends								F, **P**				
PC 32: Polymer preparations and compounds	F, I	F, I, **P**					I				I	
PC 34: Textile dyes, and impregnating products						F, I, **A**						
PC 35: Washing and cleaning products	I							F, I, **P**				F, **P**
PC 39: Cosmetics, personal care products					F, **C**							
PC 40: Extraction agents	F, I											

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 9 February 2022.

EC / List number	RMOA	Authorisation		Restriction*	CLH	Actions not under REACH / CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)	
200-002-3					Acute Tox. 4 * Skin Irrit. 2 Eye Irrit. 2	
219-459-5					Acute Tox. 4 * Skin Irrit. 2 Eye Irrit. 2 Aquatic Acute 1 Aquatic Chronic 1	
429-820-0					Acute tox 4	NONs
482-110-2						NONs

*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.