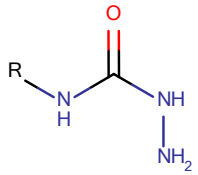
# Assessment of regulatory needs

**Authority: European Chemicals Agency (ECHA)**

## Group Name: Aminoureas, aminoguanidines and nitroguanidines

## General structure:

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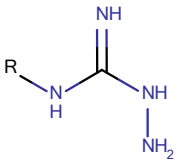


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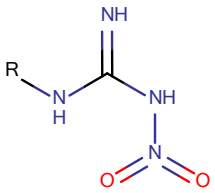
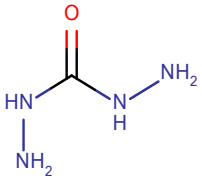
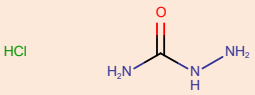
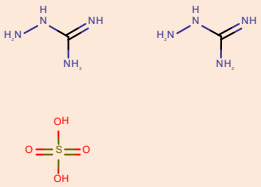
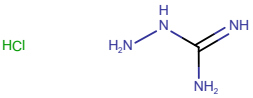
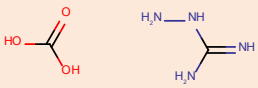
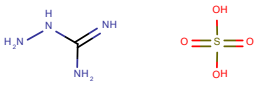
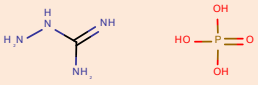
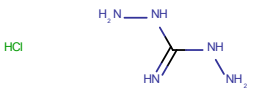
**or**



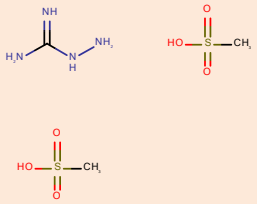
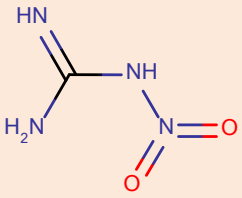
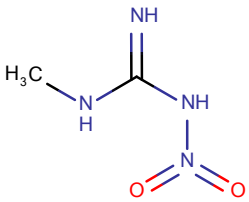
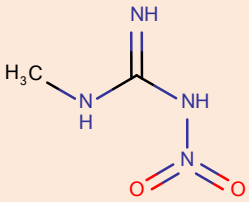

**Revision history**

| *Version* | *Date* | *Description* |
|---|---|---|
| **1.0** | 09 February 2023 | |
| | | |
| | | |

**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] |
|---|---|---|---|---|
| **Subgroup 1: Aminoureas** | | | | |
| **207-837-2** | 497-18-7 | carbonohydrazide |  | Full, 10-100 |
| **209-247-0** | 563-41-7 | semicarbazide hydrochloride |  | Full, 10-100 |
| **Subgroup 2: Aminoguanidines** | | | | |
| **213-628-7** | 996-19-0 | di(carbazamidine) sulphate |  | OSII or TII |
| **217-707-7** | 1937-19-5 | carbazamidine monohydrochloride |  | Full, not (publicly) available |
| **219-956-7** | 2582-30-1 | aminoguanidinium hydrogen carbonate |  | Full, 100-1000 |
| **220-605-5** | 2834-84-6 | carbazamidine sulphate |  | Full, not (publicly) available |
| **246-237-5** | 24413-21-6 | carbazamidine phosphate |  | Full, not (publicly) available |
| **252-854-0** | 36062-19-8 | 1,3-diaminoguanidine hydrochloride |  | 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

| | | | | |
|---|---|---|---|---|
| **918-488-7** | | hydrazinecarboximidamide dimethanesulfonate |  | OSII or TII |
| **Subgroup 3: Nitroguanidines** | | | | |
| **209-143-5** | 556-88-7 | 1-nitroguanidine |  | Full, not (publicly) available |
| **433-400-2*** | 4245-76-5 | Guanidine, N-methyl-N'-nitro- |  | OSII or TII |
| **610-029-6*** | 4245-76-5 | 1-Methyl-3-nitroguanidine |  | CLP notification |

(*) When a dossier is submitted without EC number, REACH-IT automatically assigns a List number to the dossier. Sometimes, due to IT technical limitations, duplicate List numbers are created. In this Group the following are considered duplicate entries: List nr 610-029-6 and EC 433-400-2. In general EC numbers take precedence over List numbers.

This table contains a group member that is only notified under the CLP Regulation. 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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# 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 |
| 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 aminourea or aminoguanidyl or nitroguanidyl moieties shown in Figure 1 below.

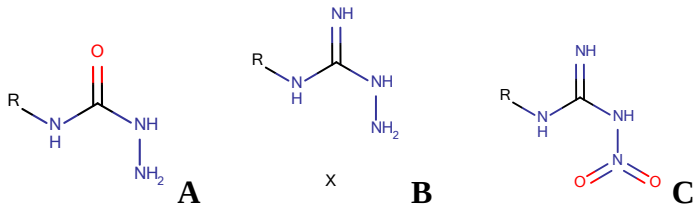


**Figure 1: A: Subgroup 1 – Aminoureas, B: Subgroup 2 – Aminoguanidines, C: Subgroup 3 - Nitroguanidines**

This group 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] The subgroup 1 “Aminoureas” does not belong to Guanidyls. However, both share the hydrazine group and therefore Aminoureas are part of this group.

The group consists of twelve substances in total, out of which seven have a full registration within REACH, four are registered as intermediates. Six registered substances are notified in the C&L Inventory (EC 207-837-2, EC 209-247-0, EC 217-707-7, EC 252-854-0, EC 219-956-7, EC 209-143-5), whereas the not registered substance (List number 610-029-6) has only CLP notification. There is no harmonised classification and labelling.

Based on information reported in the REACH registration dossiers, the substances are mainly used in industrial settings in various uses, e.g. water treatment non-surface metal treatment, fillers, plasters, paper and board treatment, intermediate. One substance has also potential for exposure/release due to professional and consumer use and potential for article service life exposure and has various uses as fertiliser, in washing and cleaning products, in paper and board treatment and leather treatment products. One substance also has potential for exposure/release via professional use as pH-regulator, neutralising agent and two substances via professional use as flame retardant in non-metal surface treatment products, fillers, putties, plasters and coatings and paints.

[3] These groups are a) Guanidine and simple guanidinium salts, b) Aromatic guanidines, c) Guanidylureas, cyanoguanidines and biguanides and d) Non-aromatic guanidines.

**Note on the scope of ECHA's assessment of regulatory needs**

Regarding hazards, the focus of ECHA's assessment is on CMR (carcinogenic, mutagenic and/or toxic to reproduction), sensitiser, ED (endocrine disruptor), PBT/vPvB or equivalent (e.g. substances being persistent, mobile and toxic), aquatic toxicity hazard endpoints and therefore only those are reflected in the table in section 3. This does not mean that the substances do not have other known or potential hazards. In some specific cases, where ECHA identifies a need for regulatory risk management action at EU level for other hazards (e.g. neurotoxicity, STOT RE), such additional hazards may be addressed in the assessment. An overview of classification is presented in Annex 1.

On the exposure side, ECHA is mainly using the information on uses reported in the registration dossiers (IUCLID) as a proxy for assessing the potential for exposure to humans and releases to the environment. The potential for release / exposure is generally considered high for "widespread" uses, i.e. professional and consumer uses and uses in articles. For these uses, normally happening at many places, the expected level of control is *à priori* considered limited. The chemical safety reports are not necessarily consulted and no quantitative exposure assessment is performed at this stage.

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

Based on ECHA's assessment of hazard information currently available in the registration dossiers and considerations of structural similarity and presence of common functional moiety all the substances in subgroup 1 and subgroup 2 have (potentially) the following human health hazards: reproductive toxicity and skin sensitisation (EC 207-837-2, EC 209-247-0, EC 217-707-7; EC 219-956-7; EC 220-605-5; EC 246-237-5; EC 213-628-7; EC 252-854-0; EC 918-488-7). Subgroup 1 member EC 207-837-2 is self-classified as skin sens 1B based on *in vivo* and *in vitro* data. Data generation is ongoing to address developmental concerns. Subgroup 1 member EC 209-247-0 is self-classified STOT RE 2 based on toxicological effects seen following sub-chronic exposure and Repro 2 in a non-guideline repro study based on cleft palate and resorptions at mid and high doses. However, no further data generation can be requested because of the registration status and relevant information requirements.

Subgroup 2 members have one common identical structure and that is the guanidine moiety. EC 219-956-7 is self-classified as Repro 1B based on the results of an OECD TG 421 study. Harmonised classification and labelling could be proposed to address the existing self-classification Repr Cat 1B of EC 219-956-7 and the related salts in this group (EC 246-237-5 and EC 220-605-5). However, uncertainty remains for EC 252-854-0 due to the difference in chemical structure and absence of data compared to the others in subgroup 2.

Based on ECHA's assessment of currently available hazard information, potential environmental hazards were identified for subgroup 1 members of aminoureas (EC 207-837-2 and EC 209-247-0). The available information indicates potential for aquatic toxicity, with long term toxicity values for algae below 1 mg/L. Compliance

check is proposed for EC 207-837-2 to verify the test material used in the aquatic toxicity studies. Substances in the sub-group of aminoureas are unlikely P, this conclusion is based on available biodegradation studies in marine water suggesting high degradation rate.

Based on ECHA's assessment of currently available hazard information, unlikely aquatic toxicity hazard was identified for subgroup 2 members of aminoguanidines. A self-classification as aquatic chronic 2 (H411) is reported in registration dossiers of three substances in this subgroup: EC 213-628-7, EC 219-956-7 and EC 217-707-7. EC 213-628-7 and EC 217-707-7 rely both on data for EC 219-956-7 to support this classification. However available dataset for EC 219-956-7 does not support any classification according to the criteria set out in the CLP Regulation (see Annex I, Section 4.1, Table 4.1.0 of EU Regulation 1272/2008). The substances EC 217-707-7 and EC 219-956-7 in the sub-group of aminoguanidines fulfil the P/vP criteria and are expected to be mobile in the environment: they are not readily or inherently biodegradable and have $LogK_{oc}$ below 4 and/or $LogD_{ow}$ below 4.5. However, the substances in this group are unlikely to fulfil the PBT/vPvB screening criteria, because they have a low potential for bioaccumulation. This conclusion is based on physical-chemical properties of substances (low molecular weight, high solubility, polarity) and the high structural similarity with substances regularly excreted from animals (i.e., urea, guanidine). Compliance check is proposed for EC 219-956-7 to clarify the potential persistency and mobility and to clarify aquatic toxicity of the substance and for EC 220-605-5 and EC 246-237-5 to clarify the validity of the proposed read across.

**Based on currently available information, there is a need for (further) EU regulatory risk management – harmonised classification** for reproductive toxicity, skin sensitisation and aquatic toxicity hazard for all substances in subgroup 1 – Aminoureas, and for reproductive toxicity and skin sensitisation for all substances in subgroup 2.

All substances in subgroups 1 and 2 are potential reprotoxic substances. The **first step** of the regulatory risk management should the hazard exist, is the confirmation of hazard via **harmonised classification (CLH**) for reproductive toxicity for these all substances. 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, by means of the restriction entry 30. For all substances in subgroup 1 (EC 207-837-2 and EC 209-247-0) harmonised classification and labelling is sufficient, as the substances are used in industrial use as a water treatment chemical, in polymer preparation and as an intermediate (EC 209-247-0). For the three substances, registered as intermediates, in subgroup 2 (EC 213-628-7 [self-classified as Repr. 1B and Skin Sens. 1B], EC 252-854-0 and EC 918-488-7) harmonised classification and labelling would be pursued to avoid potential regrettable substitution with other substances of the group. Moreover, CLH is also a prerequisite to restrict the presence of the substances in clothing (used in EC 217-707-1), other textiles, and footwear articles, by means of the restriction entry 72 of REACH Annex XVII (this would require addition of the relevant substances to Appendix 12 by the Commission through Article 68(2)). The substance EC 217-707-7 is also used as a dietary supplement. Skin sensitisation for all substances and aquatic toxicity hazard for substances in subgroup 1 are suggested to be covered in addition to the reproductive toxicity when developing the CLH proposals. In addition, it may be considered what would be the best way to develop the proposals, for instance whether to make a proposal for the group of substances, to submit them individually or jointly.

**Based on currently available information, there is a need for (further) EU regulatory risk management – restriction** for reproductive toxicity hazard as the second step for four substances (EC 217-707-7; EC 219-956-7; EC 220-605-5; EC 246-237-5) in the subgroup 2 - aminoguanidines - due to widespread professional use.

Substances EC 217-707-7; EC 219-956-7; EC 220-605-5; and EC 246-237-5) are potential reprotoxic substances and have widespread professional and/or consumer uses (e.g. fertilisers. anti-freeze and de-icing products, washing and cleaning products). **Restriction** of the substances as such or in mixtures (concentration limit in mixtures) used by professionals is suggested as the most appropriate way to address the identified concern. Moreover, restricting EC 217-707-1 (subgroup 2) in articles (e.g. paper/board and textiles) is proposed as potential for exposure from articles is also likely and in addition the substance is found to be used as a dietary supplement.

The professional uses of these four substances as fertilisers, anti-freeze and de-icing products, washing and cleaning products, non-metal surface treatment product, fillers, plasters, flame retardants in coatings 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.

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.

Related to the concern for skin sensitisation, for industrial and professional uses, sufficient and consistent self-classification by registrants should trigger adequate risk management measures according to workplace legislation. Harmonised classification and labelling can also be considered when classification and labelling is proposed for reproductive toxicity hazard.

Adequate product labelling should in principle provide consumers with sufficient information to manage risks arising from the use of mixtures.

However, there is a concern related to skin sensitisers (potentially) present in consumer mixtures and the need to further investigate whether further regulatory actions are needed and what would be the best options to address this concern.

Such concern has already been identified in other groups of substances and was brought for further discussion to Member States. Work is ongoing on this generic issue by both Member States and ECHA which may affect the regulatory actions on substances in this group.

[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

**Based on currently available information, there is no need for (further) EU regulatory risk management** for all substances in subgroup 3, the nitroguanidines (EC 209-143-5; EC 433-400-2; List number 610-029-6).

Based on ECHA's assessment of currently available hazard information, no likely potential hazards were identified for human health. These conclusions are based on in vivo studies showing low acute toxicity, skin, and eye irritation. *In vivo* skin sensitisation studies are negative. The substances were negative in in *vitro* and *in vivo* mutagenicity studies in bacteria and mammalian cells. Repeated dose sub-chronic and screening studies conducted show no adverse effects. The toxicity profile for subgroup 3 is not like subgroup 1 and subgroup 2. This is in line with the different chemical structures where the $-NH_2$ in subgroups 1 and 2 is replaced by an $-NO_2$ in subgroup 3.

The substances EC 209-143-5 and EC 433-400-2 in the sub-group 3 of nitroguanidines are potentially persistent/very persistent, mobile/very mobile: they are not readily biodegradable (0% degradation in an OECD 301A test for EC 433-400-2) or inherently biodegradable (0% degradation in an OECD 302B test for both substances); $LogK_{oc}$ values are below the trigger of 3. Compliance check is proposed to clarify the potential persistency and mobility of EC 209-143-5 due to the exposure and release of this substance to the environment. All the substances in this group are unlikely to fulfil the PBT/vPvB screening criteria, because they have a low potential for bioaccumulation. This conclusion is based on physical-chemical properties of substances (low molecular weight, high solubility, polarity) and the high structural similarity with substances regularly excreted from animals (i.e., urea, guanidine, nitroguanidine). Moreover, substances in the subgroup of nitroguanidines are unlikely T as based on the available long-term studies they do not fulfil the T criteria.

# 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/List number | Human Health Hazard | Environmental Hazard | Relevant use(s) & exposure potential | Last foreseen action | Action |
|---|---|---|---|---|---|
| **Subgroup 1: Aminoureas and Subgroup 2: Aminoguanidines** | | | | | |
| **Subgroup 1: Aminoureas**<br><br>**207-837-2**<br><br>**209-247-0**<br><br><br>**Subgroup 2: Aminoguanidines**<br><br>**217-707-7**<br><br>**219-956-7**<br><br>**220-605-5**<br><br>**246-237-5**<br><br>**213-628-7**<br><br>**252-854-0** | Known or potential hazard<br>for reproductive toxicity<br>for skin sensitisation<br><br>Known or potential hazard<br>for STOT RE for EC 209-247-0 | **Subgroup 1**<br>Known or potential hazard<br>for aquatic toxicity<br><br>**Subgroup 2**<br>Known or potential hazard<br>for persistency, mobility<br>(EC 217-707-7, EC 219-956-7, EC 220-605-5, EC 246-237-5) | **Subgroup 1**<br>EC 207-837-2 is used in industrial settings as a water treatment chemical, in polymer preparation and as an intermediate.<br><br>EC 209-247-0 has industrial use as intermediate.<br><br>For both substances limited potential for exposure and release can be assumed.<br><br>**Subgroup 2**<br>EC 217-707-1 has potential exposure for exposure/release due to professional and | **Need for EU RRM: Restriction (EC 217-707-7; EC 219-956-7; EC 220-605-5; EC 246-237-5)**<br><br>Justification:<br>The harmonised classification as Repr. 1B 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 entry.<br><br>The reported professional uses of four substances are | **Subgroup 1**<br>**First step:**<br>CCH<br><br>**Subgroup 2**<br>**First step:**<br>CLH for EC 219-956-7, 246-237-5 and 220-605-5<br>CCH<br><br>**Next steps (if hazard confirmed):**<br>CLH for all substances in subgroup 1 and 2 followed by Restriction (for four substances in subgroup 2) |

| Subgroup name, EC/List number | Human Health Hazard | Environmental Hazard | Relevant use(s) & exposure potential | Last foreseen action | Action |
|---|---|---|---|---|---|
| **918-488-7** | | | consumer use and potential for article service life exposure as it is used in various applications as washing and cleaning products, paper and board treatment. The substance is also used as a dietary supplement. The other three substances have widespread exposure due to professional use. EC 219-956-7; EC 220-605-5; EC 246-237-5)<br><br>EC 213- 628-7, EC 252-854-0 and EC 918-488-7: registered as intermediate | 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<br><br>Specific restriction for use in articles is proposed as potential exposure from articles is likely (EC 217-707-7). | |

| Subgroup name, EC/List number | Human Health Hazard | Environmental Hazard | Relevant use(s) & exposure potential | Last foreseen action | Action |
|---|---|---|---|---|---|
| | | | | | |
| **Subgroup 3 – Nitroguanidines** | | | | | |
| **Subgroup 3**<br><br>**209-143-5**<br><br>**433-400-2/**<br><br>**610-029-6** | No hazard or unlikely hazard | Known or potential hazard<br>for persistency, mobility<br>(EC 209-143-5, EC 433-400-2) | EC 209-143-5 is used as industrial use in explosives, as a formulator in biocidal use in metal surface treatment products, welding and soldering products and as an intermediate.<br><br>EC 433-400-2 registered as intermediate; EC 610-029-6: only notified under CLP regulation<br><br>Limited potential for exposure and release for the substances EC 433-400-2 and EC 610-029-6) | **Currently no need for EU RRM**<br><br><u>Justification:</u><br>Overall, no or unlikely hazard that would lead to concern for the reported uses. | CCH<br>(EC 209-143-5) |

# Annex 1: Overview of classifications

Data extracted on 18/03/2022

| EC/ List No | CAS No | Substance name | Harmonised classification | Classification in registrations |
|---|---|---|---|---|
| **Aminoureas** | | | | |
| **207-837-2** | 497-18-7 | carbonohydrazide | - | Skin Sens. 1B H317 |
| **209-247-0** | 563-41-7 | semicarbazide hydrochloride | - | Repr. 2 H361<br>Acute Tox. 3 H301<br>Eye Damage 1 H318<br>STOT Rep. Exp. 2 H373, affected organs: Bones, Aorta and Cartilages |
| **Aminoguanidines** | | | | |
| **213-628-7** | 996-19-0 | di(carbazamidine) sulphate | - | Aquatic Chronic 2 H411 [intermediate (active)]<br>Repr. 1B H360 [intermediate (active)]<br>Skin Sens. 1B H317 [intermediate (active)] |
| **217-707-7** | 1937-19-5 | carbazamidine monohydrochloride | - | Skin Sens. 1B H317<br>Aquatic Chronic 2 H411 |
| **220-605-5** | 2834-84-6 | carbazamidine sulphate | - | Acute Tox. 4 H302 |
| **252-854-0** | 36062-19-8 | 1,3-diaminoguanidine hydrochloride | - | Skin Irrit. 2 H315 [intermediate (active)]<br>STOT Single Exp. 3 H335, affected organs: UPPER TRACT [intermediate (active)]<br>Eye Irrit. 2 H319 [intermediate (active)] |
| **246-237-5** | 24413-21-6 | carbazamidine phosphate | - | Acute Tox. 4 H302 |
| **219-956-7** | 2582-30-1 | aminoguanidinium hydrogen carbonate | - | Repr. 1B H360, specific effect:Unborn Child<br>Skin Sens. 1B H317<br>Aquatic Chronic 2 H411<br>Skin Sens. 1 H317 [intermediate (active)]<br>Repr. 1B H360 [intermediate (active)] |
| **918-488-7** | - | hydrazinecarboximidamide dimethanesulfonate | - | Skin Sens. 1B H317 [intermediate (active)]<br>Acute Tox. 4 H302 [intermediate (active)] |

| EC/ List No | CAS No | Substance name | Harmonised classification | Classification in registrations |
|---|---|---|---|---|
| | | | | Acute Tox. 4 H332 [intermediate (active)] |
| **Nitroguanidines** | | | | |
| **209-143-5** | 556-88-7 | 1-nitroguanidine | - | Expl. Div. 1.1 H201 |
| **433-400-2** | - | 433-400-2 | - | - |
| **610-029-6** | | | - | - |

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

Data extracted on 18 March 2022.

The Table contains the seven fully registered substances. The Table does not include EC 213-628-7, EC 252-854-0, EC 918-488-7, EC 433-400-2, which are registered as intermediate (OSII or TII) and List nr 610-029-6, which is only notified under the CLP regulation.

Note: The substance EC 217-707-7 is found to be used as a dietary supplement.

| Main types of applications structured by product or article types | EC/ List 207-837-2 | EC / List 209-143-5 | EC / List 209-247-0 | EC / List 217-707-7 | EC / List 219-956-7 | EC / List 220-605-5 | EC / List 246-237-5 |
|---|---|---|---|---|---|---|---|
| **PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents** | | I | | | I, **P** | | |
| **PC 37: Water treatment chemicals** | F, I | | | | I | | |
| **PC 11: Explosives** | | F, I | | | | | |
| **PC 12: Fertilisers** | | | | F, **P, C** | | | |
| **PC 4: Anti-freeze and de-icing products** | | | | F, **P** | | | |
| **PC 35: Washing and cleaning products** | | | | **P** | I | | |
| **PC 8: Biocidal products (e.g. disinfectants, pest control)** | | F | | | | | |
| **PC 39: Cosmetics, personal care products** | | | | F, **C** | | | |
| **PC 15: Non-metal-surface treatment products** | | | | | | I, **P** | I, **P** |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **PC 24: Lubricants, greases, release products** | | | | | F | | |
| **PC 13: Fuels** | | | | | F | | |
| **PC 32: Polymer preparations and compounds** | I | | | I | I | | |
| **PC 9b: Fillers, putties, plasters, modelling clay** | | | | | | I, **P** | I, **P** |
| **PC 9a: Coatings and paints, thinners, paint removes** | | | | F | | I, **P** | I, **P** |
| **PC 26: Paper and board treatment products** | | | | **A** | I | | |
| **PC 34: Textile dyes, and impregnating products** | | | | **P** | | | |
| **PC 23: Leather treatment products** | | | | F, I, **A** | | | |
| **PC 14: Metal surface treatment products** | | I | | | | | |
| **PC 38: Welding and soldering products, flux products** | | **I** | | | | | |
| **PC 21: Laboratory chemicals** | | I | | F | I, **P** | | |
| **PC 19: Intermediate** | | I | I | I , **P** | I | I | 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 21/04/2022.

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