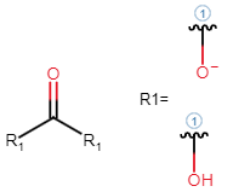
Assessment of regulatory needs

Authority: European Chemicals Agency

Group Name: Carbonates, hydrogen carbonates and percarbonate salts with counterions of low hazard

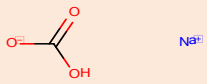
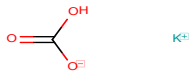
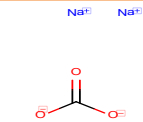
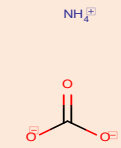
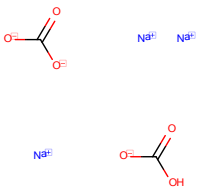
General structure:



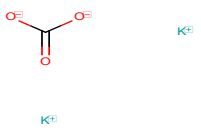
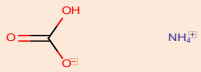
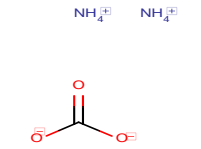
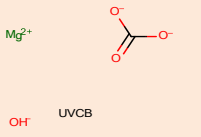
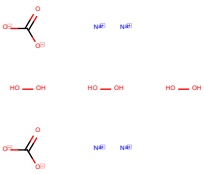
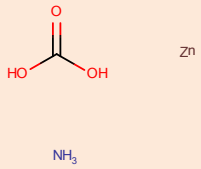
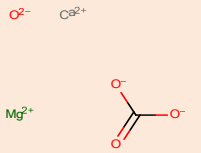
Revision history

Version	Date	Description
1.0	15 May 2024	

Substances within this group:

EC / List no	CAS no	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS, cease manufacture), highest tonnage band among all the registrations (t/y) [1]
205-633-8	144-55-8	sodium hydrogencarbonate		Full, >1000
206-059-0	298-14-6	potassium hydrogencarbonate		Full, >1000
207-439-9	471-34-1	calcium carbonate		Full, >1000
207-838-8	497-19-8	sodium carbonate		Full, >1000
208-058-0	506-87-6	diammonium carbonate		OSII or TII
208-580-9	533-96-0	trisodium hydrogendicarbonate		Full, >1000
208-915-9	546-93-0	magnesium carbonate		Full, >1000

[1] The total aggregated tonnage band may be available on ECHA's webpage at https://echa.europa.eu/information-on-chemicals/registered-substances

209-529-3	584-08-7	potassium carbonate		Full, >1000
213-911-5	1066-33-7	ammonium hydrogencarbonate		Full, >1000
233-786-0	10361-29-2	ammonium carbonate		Full, not (publicly) available
235-192-7	12125-28-9	Magnesium carbonate hydroxide		Full, 10-100
239-707-6	15630-89-4	disodium carbonate, compound with hydrogen peroxide (2:3)		Full, >1000
245-980-2	24012-08-6	carbonic acid, ammonium zinc salt		OSII or TII
254-099-2	38714-47-5	tetraamminezinc(2+) carbonate		OSII or TII
281-192-5	83897-84-1	Dolomite (CaMg(CO3)2), calcined		Full, >1000

This table does not contain group members that are only notified under the CLP Regulation, however, the list is not necessarily exhaustive.

Contents

DISCLAIMER

The author does not accept any liability with regard to the use that may be made of the information contained in this document. Usage of the information remains under the sole responsibility of the user. Statements made or information contained in the document are without prejudice to any further regulatory work that ECHA, the Member States or other regulatory agencies may initiate at a later stage. Assessments 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 assessment of regulatory needs of a group of substances is an iterative, informal process to help authorities consider the most appropriate way to address an identified concern for a group of substances or a single substance and decide whether further regulatory risk management activities are necessary.

The grouping is mainly based on structural similarity and associations made by the registrants between substances through read-across and category approaches as well as category associations from external sources (e.g. OECD categories)[2]. These methods are different from grouping as defined in Section 1.5 of Annex XI to REACH because the scope and intended use of ECHA's grouping is different. Thus, in this context, grouping does not aim to validate read-across and category approaches according to the Annex XI requirements but rather to support a faster and more consistent approach for regulating chemicals and avoid regrettable substitution.

The focus of the assessment is largely based on information available in the registration dossiers and on properties requiring regulatory risk management action at EU level[3]. The information reported on uses is from the registration dossiers (IUCLID) and is used as a proxy for assessing how widespread uses are and whether potential for exposure to humans and releases to the environment can be expected. The chemical safety reports are not necessarily consulted and no quantitative exposure assessment is performed at this stage.

The outcome of these assessments are proposals for immediate (the first action) and subsequent regulatory action(s), including the foreseen ultimate regulatory action (last foreseen regulatory action) to address the identified concern(s) in case the potential hazards are confirmed. For example, further data generation through compliance check is suggested as a first action, to confirm the identified hazard.

Where hazards are confirmed, regulatory risk management actions could be considered for the whole group, for a subgroup or for individual substances within the group. The robustness of the group depends on the stage of assessment and the level of certainty this stage requires. For example, the needs for grouping under restriction may differ from the needs for grouping for the purpose of harmonised classification. Group membership is reconsidered accordingly throughout the iterative assessment of regulatory needs, for example, after further information is generated and the hazard has been clarified or when new insights on uses and risks are available.

The assessment of regulatory needs in itself does not represent a regulatory action, but rather a preparatory step to consider further possible regulatory actions at the level of individual substances or groups/subgroups of substances.

[2] Working with Groups - ECHA (europa.eu)

[3] Regarding hazard properties the focus is for instance 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 report. This does not mean that the substances do not have other known or potential hazards. In some specific cases, ECHA may consider additional hazards (e.g. neurotoxicity, STOT RE).

Publication of ARNs makes it easier for companies to follow the latest status of their substances of interest, anticipate potential regulatory actions and make strategic choices in their chemicals portfolio.

For more information on assessments of regulatory needs please consult ECHA's website[4].

[4] 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
PMT/vPvM	Persistent, mobile, and toxic / very persistent and very mobile
RDT	Repeated dose toxicity
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
TPE	Testing proposal evaluation

1 Overview of the group

Explanations on the scope of this assessment are available in the foreword to this document. Please read it carefully before going through the report.

ECHA has grouped together structurally similar substances that can be identified as inorganic salts of carbonic acid, including carbonates and hydrogen carbonates (bicarbonates). In the group, one percarbonate is also included.

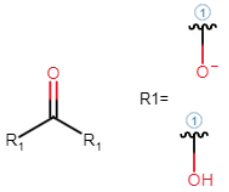


Figure 1. Generic structure of the group members. Inorganic salts of carbonic acid (with cations of low hazard, not displayed).

There are 15 substances in the group of which 12 with full registrations and 3 registered as intermediate.

Based on information reported in the REACH registration dossiers, all the substances in the group with full registrations have widespread uses (both professional and consumer uses), except for EC 233-786-0 for which professional uses are reported, and EC 208-580-9 for which consumer uses are predominantly reported. Three group members (EC 245-980-2, 254-099-2, and EC 208-058-0) have only intermediate uses. Inorganic carbonates (e.g. calcium carbonate) are naturally occurring substances. The majority of substances in the group has a wide variety of uses e.g pharmaceutical substances, food/feed stuff additive, cosmetic ingredients, water treatment chemicals, personal care products and many others. Detailed uses are presented in Annex 2 of this document. Article service life is expected for EC 205-633-8, 206-059-0, 207-439-9, 207-838-8, and 208-915-9.

2 Conclusions and proposed actions

The conclusions and actions proposed in the table below are based mainly on the REACH and CLP information available at the time of the assessment by ECHA. The conclusions are preliminary suggestions from a screening-level assessment done by ECHA with the aim to propose the next steps for further work (e.g., strengthening of the hazard conclusions, clarification of the uses and/or potential for exposure). 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 may be updated, and conclusions and actions revisited.

Table 1: Conclusions and proposed actions

Subgroup name, EC/List no, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
205-633-8 206-059-0 207-439-9 207-838-8 208-058-0 208-580-9 208-915-9 209-529-3 213-911-5 233-786-0	No hazard or unlikely hazard	No hazard or unlikely hazard	Wide dispersive uses for industrial, professional and consumers (except for EC 208-058-0, intermediate)	**First step:** No action Justification: Overall, no or unlikely hazard that would lead to concern for the reported uses.

Subgroup name, EC/List no, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
235-192-7 239-707-6 281-192-5				
245-980-2 254-099-2	Known or potential hazard for skin sensitisation	Known or potential hazard for aquatic toxicity	No (Intermediate use)	**First step:** No action <u>Justification</u>: According to the reported uses, low potential for exposure to both human health and environment is expected. Actions may be reconsidered if there is a change in the registration status and/or reported uses, when the assessment will be revisited.

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

Currently no need to suggest (further) regulatory risk management actions for all substances in the group.

Based on currently available information, for CMR, ED, STOT RE Skin Sens and aquatic toxicity hazards are considered unlikely for all substances in the group (except for EC 245-980-2 and 254-099-2 that are skin sensitisers and toxic to the aquatic environment).

All group members are expected to dissociate rapidly into the corresponding anion (carbonate) and the cations (Na+, K+, Zn2+, Ca2+, Mg2+ and ammonium).

The corresponding cations have been previously assessed in ECHA ARNs and are considered of low toxicity for human health. EC 239-707-6 contains hydrogen peroxide; hydrogen peroxide has been assessed under the EU RAR[5] and under the BPR[6] and is considered unlikely CMR/ED or skin sens.

Sodium carbonate[7] and ammonium carbonate[8], have been assessed in the past under OECD HPV programme. According to OECD SIDS on ammonium carbonate: *Bicarbonate ions are integral components of normal metabolic processes and play an essential role in the physiology of human and other species. Bicarbonate ion can be formed from CO2 and H2O and this equilibrium reaction acts as the major extracellular buffer system in blood and interstitial fluids of vertebrates. CO2 from the tissues diffuses rapidly into red blood cells, where it is hydrated with water to form carbonic acid. This reaction is accelerated by carbonic anhydrase, an enzyme present in high concentrations in red blood cells. The carbonic acid formed dissociates into bicarbonate and hydrogen ions. Most of the bicarbonate ions diffuse into the plasma.*

Carbonates are also used in human medicine and are of low toxicological concern (e.g use of calcium carbonate for indigestion). No systemic toxicity is expected.

No systemic toxicity was detected in a short-term repeated dose toxicity study with ammonium carbonate. No endocrine potential is likely in the absence of any

[5] https://echa.europa.eu/documents/10162/590965ca-33e7-43a0-a109-3a9148870d07

[6] https://echa.europa.eu/documents/10162/5e480ce0-8f18-45f1-b722-71e71fa8b969

[7] https://hpvchemicals.oecd.org/ui/handler.axd?id=5a6538be-aa30-4a72-ad1c-906d9b5413bd

[8] https://one.oecd.org/document/env/jm/mono(2016)42/en/pdf

systemic toxicity and taking into account the physiological role of carbonate in human body.

The group members are not expected to be toxic to reproduction based on available screening reproductive toxicity study with ammonium carbonate (no effects seen up to the limit dose). In addition, according to the OECD SIDS on sodium carbonate: *It can be stated that the substance will neither reach the foetus nor reach male and female reproductive organs, which shows that there is no risk for developmental toxicity and no risk for toxicity to reproduction. This was confirmed by a developmental study with rabbits, rats and mice.*

No mutagenicity potential is expected based on experimental in vitro and in vivo assays available.

All group members are not expected to be skin sensitisers based on the available information (except for EC 245-980-2 and 254-099-2).

Potential hazard has been identified for two substances (EC 245-980-2 and 254-099-2) that are self-classified for skin sensitisation. EC 254-099-2 was positive in in vitro skin sensitisation assays whereas for EC 245-980-2 no information is available to support the self-classification. The skin sensitisation potential for these two substances might be due to the presence of an ammonium/amine moiety and not considered relevant for the other group members. Both substances have only intermediate uses and therefore no exposure is expected. Therefore, no EU regulatory risk management action is currently proposed for these two 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.

All group members are inorganics and no PBT assessment is required. Group members are not expected to be toxic to the aquatic environment, except for two substances (EC 245-980-2, 254-099-2) that are self-classified as aquatic chronic 2 and aquatic chronic 1, respectively. This is likely due to the release of ammonium cation.

Annex 1: Overview of classifications

Data extracted in January 2024

EC Number	CAS Number	Substance Name	Harmonised classification	Classification in registrations
207-838-8	497-19-8	sodium carbonate	Index number: 011-005-00-2 Hazard Category: Eye Irrit. 2; Hazard Statement: H319;	Eye Irrit. 2 H319
208-915-9	546-93-0	magnesium carbonate	-	-
213-911-5	1066-33-7	ammonium hydrogencarbonate	-	Acute Tox. 4 H302
233-786-0	10361-29-2	ammonium carbonate	-	Acute Tox. 4 H302
281-192-5	83897-84-1	Dolomite (CaMg(CO3)2), calcined	-	Skin Irrit. 2 H315 Eye Damage 1 H318 STOT Single Exp. 3 H335, affected organs: Respiratory tract
205-633-8	144-55-8	sodium hydrogencarbonate	-	-

206-059-0	298-14-6	potassium hydrogencarbonate	-	-
207-439-9	471-34-1	calcium carbonate	-	Skin Irrit. 2 H315 Eye Damage 1 H318 STOT Single Exp. 3 H335, affected organs: respiratory system
208-058-0	506-87-6	diammonium carbonate	-	-
208-580-9	533-96-0	trisodium hydrogendicarbonate	-	Eye Irrit. 2 H319
209-529-3	584-08-7	potassium carbonate	-	Skin Irrit. 2 H315 Eye Irrit. 2 H319 STOT Single Exp. 3 H335, affected organs: other: respiratory system
235-192-7	12125-28-9	Magnesium carbonate hydroxide	-	-
239-707-6	15630-89-4	disodium carbonate, compound with hydrogen peroxide (2:3)	-	Oxid. Solid 3 H272 Oxid. Solid 2 H272 ; Eye Damage 1 H318, specific concentration: >=25 Eye Damage 1 H318, specific concentration: >25 Acute Tox. 4 H302 ;
245-980-2	24012-08-6	carbonic acid, ammonium zinc salt	-	Skin Irrit. 2 H315 Skin Sens. 1 H317 Aquatic Chronic 2 H411

				Eye Irrit. 2 H319 Aquatic Acute 1 H400
254-099-2	38714-47-5	tetraamminezinc(2+) carbonate	-	Aquatic Chronic 1 H410 Eye Irrit. 2 H319 Skin Sens. 1 H317 Skin Irrit. 2 H315 Aquatic Acute 1 H400

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

Data extracted in January 2024

Main types of applications structured by product or article types* EC/List number	205-633-8	206-059-0	207-439-9	207-838-8	208-580-9	208-915-9	209-529-3	213-911-5	233-786-0	235-192-7	239-707-6	281-192-5
PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents	f, i, p, c,	f, i, p, c	f, i, p, c	f, i, p, c,	c	i	f, i, p, c	f, i, p	f, p	i, p	f, i, p	f, i, p, c
PC 36: Water softeners	f, i, p, c	f, i, p, c	f, i, p, c	f, i, p, c	c		f, i				f, i, p, c	f, i, p
PC 37: Water treatment chemicals	f, i, p, c	f, i, p, c	f, i, p, c	f, i, p, c,	c		f, i, p, c				f, i, p, c	f, i, p, c
PC 2: Adsorbents	f, i, p, c	f, i	f, i, p, c	f, i, p, c,	c	c	f, i, p, c		f, i			f, i, p, c
PC 11: Explosives	f, i, p, c,		f, i, p, c	f, i, p, c,	c	c	f, i					f, i, p,
PC 12: Fertilisers	f, i, p, c	f, i, p, c	f, i, p, c, a	f, i, p, c,	c		f, i, p, c,	f, i, p, c				f, i, p, c
PC 27: Plant protection products	f, i, p, c	f, i, p, c	f, i, p, c	f, i, p, c	c		f, i, p, c	f, p, c				f, i, p
PC 4: Anti-freeze and de-icing products	f, i, p, c	f, i, p, c	f, i, p, c	f, i, p, c,	c	i	f, i, p, c,					
PC 35: Washing and cleaning products	f, i, p, c,	f, i, p, c	f i p c,	f, i, p, c, a	p, c	f	f, i, p, c,	f, c			f, i, p, c,	f, i, p,
PC 8: Biocidal products (e.g. disinfectants, pest control)	f, i, p, c,	p, c	f i p c,	f, i, p, c,	c		f, i, p, c,				f, i, p, c,	f, i, p,
PC 28: Perfumes, fragrances	f, i, p, c,	f, i	f i p c,	f, i, p, c,	c		f, i, c					f, i, p,
PC 3: Air care products	f, i, p, c,	f, i	f i p c,	f, i, p, c,	c		f, i, c					f, i, p,
PC 39: Cosmetics, personal care products	f, i, p, c, a	f, i, c	f i p c a	f, i, p, c,	c	f, i, p, c	f, i, p, c	f	f, p	f, p, c	f, i, p, c,	f, i, p, c
PC 29: Pharmaceuticals	f, i, p, c,	f, i, p, c	f i p c,	f, i, p, c,	c	f	f, i, p, c	f, i	f, p			f, i, p,
PC 31: Polishes and wax blends	f, i, p, c,		f i p c,	f, i, p, c,	c	f, i, p, c	f, i, c					f, i, p,
PC 15: Non-metal-surface treatment products	f, i, p, c,	f, i	f i p c,	f, i, p, c,	c		f, i	i	i		f, i, p,	f, i, p,
PC 24: Lubricants, greases, release products	f, i, p, c,		f i p c a	f, i, p, c,	c	f, i, p, c,	f, i, c					f, i, p,
PC 25: Metal working fluids	f, i, p, c,	f, i	f i p c,	f, i, p, c,	c	f, i, p,	f, i				f, i, p,	f, i, p,

PC 16: Heat transfer fluids	f, i, **p**, **c**,	f, i	f i **p c**,	f, i, **p**, **c**,	**c**	f, i, **p**	f, i, **c**					f, i, **p**,
PC 17: Hydraulic fluids	f, i, **p**, **c**,		f i **p c**,	f, i, **p**, **c**,	**c**	f, i, **p**	f, i, **p**, **c**					f, i, **p**,
PC 13: Fuels	f, i, **p**, **c**,	f, i		f, i, **p**, **c**,	**c**	i	f, i, **p**, **c**					f, i, **p**,
PC 32: Polymer preparations and compounds	f, i, **p**, **c**, **a**	f, i, **p**, **c**	f i **p c a**	f, i, **p**, **c**,	**c**	f, i, **a**	f, i, **p**, **c**	f		i		f, i, **p**,
PC 1: Adhesives, sealants	f, i, **p**, **c**,	f, i	f i **p c a**	f, i, **p**, **c**,	**c**	f, i, **p**, **c**	f, i, **c**					f, i, **p**,
PC 9c: Finger paint	f, i, **p**, **c**,	f, i	f i **p c**,	f, i, **p**, **c**,	**c**	i, **c**	f, i, **c**					
PC 9b: Fillers, putties, plasters, modelling clay	f, i, **p**, **c**,	f, i	f i **p c a**	f, i, **p**, **c**,	**c**	f, i, **p**, **c**	f, i, **c**					f, i, **p**, **c**
PC 9a: Coatings and paints, thinners, paint removes	f, i, **p**, **c**,	f, i, **p**, **c**	f i **p c a**	f, i, **p**, **c**,	**c**	f, i, **p**, **c**	f, i, **p**, **c**,		f, i			f, i, **p**, **c**
PC 18: Ink and toners	f, i, **p**, **c**,	f, i, **p**, **a**	f i **p c a**	f, i, **p**, **c**,	**c**	f, i, **p**, **c**	f, i, **p**, **c**,	i				f, i, **p**,
PC 26: Paper and board treatment products	f, i, **p**, **c**,	f, i, **p**, **c**	f i **p c**,	f, i, **p**, **c**, **a**	**c**	f, i, **a**	f, i, **p**, **c**	f, i				f, i, **p**,
PC 34: Textile dyes, and impregnating products	f, i, **p**, **c**,	f, i	f i **p c**,	f, i, **p**, **c**,	**c**		f, i, **p**	i, **p**			f, i, **p**,	f, i, **p**,
PC 23: Leather treatment products	f, i, **p**, **c**,	f, i, **p**, **c**	f i **p c**,	f, i, **p**, **c**,	**c**		f, i, **c**	f, i, **p**				f, i, **p**,
PC 14: Metal surface treatment products	f, i, **p**, **c**,	f, i	f i **p c**,	f, i, **p**, **c**,	**c**		f, i, **p**, **c**	f	f, i		f, i, **p**,	f, i, **p**,
PC 38: Welding and soldering products, flux products	f, i, **p**, **c**,	f, i	f i **p c**,	f, i, **p**, **c**,	**c**		f, i		f, **p**			f, i, **p**,
PC 7: Base metals and alloys	f, i, **p**, **c**,	f, i	f i **p c**,	f, i, **p**, **c**,	**c**		f, i					f, i, **p**,
PC 33: Semiconductors	f, i, **p**, **c**,		f i **p c**,	f, i, **p**, **c**,	**c**		f, i					f, i, **p**,
PC 21: Laboratory chemicals	f, i, **p**, **c**,	f, i, **p**, **c**	f i **p c**,	f, i, **p**, **c**,	**c**	f, i, **p**	f, i, **p**, **c**	f, i, **p**	f, **p**	i, **p**		f, i, **p**,
PC 19: Intermediate	f, i **p**, **c**,	f, i, **p**, **c**	f i **p**,	f, i, **p**, **c**,	**c**	f, i, **p**	f, i, **p**, **c**	f, i, **p**	f, i	i		f, i, **p**,
PC 40: Extraction agents	f, i, **p**, **c**,	f, i	f i **p c**,	f, i, **p**, **c**,	**c**		f, i					f, i, **p**,
PC41: Oil and gas exploration or production products	**c**			**p**								
PC42: Electrolytes for batteries	**c**			**p**								
PC 30: Photo-chemicals	f, i, **p**, **c**,	f, i	f i **p c**,	f, i, **p**, **c**,	**c**		f, i, **p**, **c**,					f, i, **p**,
PC x1: Food and feed additives		**c**										

*only substances with full registrations are displayed

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 in January 2024

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