Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

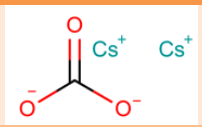
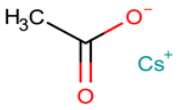
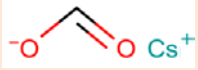
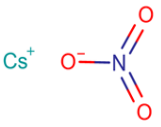
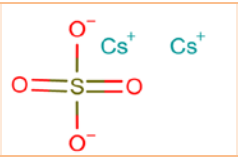
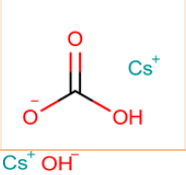
Date: 25 March 2022

Group Name: Caesium compounds

Revision history

Version	*Date*	*Description*
1.0	11.05.2022	

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]
208-591-9	534-17-8	Caesium carbonate		Full, 100-1000
222-248-0	3396-11-0	Caesium acetate		Full, not (publicly) available
222-492-8	3495-36-1	Caesium formate		Full, not (publicly) available
231-600-2	7647-17-8	Caesium chloride		Full, not (publicly) available
232-145-2	7789-17-5	Caesium iodide		Full, 100-1000
232-146-8	7789-18-6	Caesium nitrate		Full, not (publicly) available
233-662-6	10294-54-9	Caesium sulphate		Full, 100-1000
236-487-3	13400-13-0	Caesium fluoride		Full, not (publicly) available
239-554-5	15519-28-5	Caesium bicarbonate		Full, not (publicly) available
244-344-1	21351-79-1	Caesium hydroxide		Full, 100-1000
627-088-9	35103-79-8	Caesium hydroxide monohydrate		C&L notification

This table also contains 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.

[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

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 caesium ion. The group consists of 11 substances with 10 full dossier registrations and 1 notification for CLP. The group is constituted mainly of inorganic caesium salts (including halides, carbonates, nitrate and sulfate), salts of simple carboxylic acids (formate and acetate) and hydroxides.

Based on information reported in the REACH registration dossiers, five substances in the group are used as catalyst or catalyst components in adsorbents, non-metal-surface treatment, intermediates and laboratory chemicals. In addition, substances in the group are used as anticaking agent, density gradient, electrolyte, flow promoter, lubricating agent, intermediate, scintillator material or strong base in explosives, lubricants, greases, release products, laboratory chemicals and other (undefined) products. For all of the substances in the group the uses are industrial (including industrial articles service life in fuel cells etc) except for EC 208-591-9 which has a professional use as a laboratory chemical and an article use in special glass. Industrial uses, professional laboratory uses, and article uses generally have low potential for exposure and release. However, potential for exposure may not be excluded for industrial and professional laboratory workers and may to some extent depend on the type of use. Potential for exposure from special glass production and articles is expected to be low and mainly concern workers. Nevertheless there are uncertainties considering exposure and whether consumers may be exposed.

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 currently available information, there is a need for (further) EU regulatory risk management – harmonised classification (CLH) for reproductive toxicity and potential STOT RE hazards due to the potential for release/exposure of all the substances in the group.

Based on ECHA's assessment of currently available hazard information, potential hazards were identified for human health. The available information indicates potential for reproductive toxicity due to findings in two sub-chronic toxicity studies showing defects on spermatogenesis. The findings are observed with the test substances EC/list no. 627-088-9 and 231-600-2, which are substances in this group and used in registration dossiers of the other group members (read-across adaptation). All registered substances are self-classified as Repr. 2, but further data generation may lead to a need for classification as Repr. 1B.

The available information also indicates potential for STOT RE due to findings in a limited number of repeated dose toxicity studies with the test substances EC 231-600-2 and 627-088-9, which are substances in this group and used in registration dossiers of the other group members (read-across adaptation). The following substances are self-classified as STOT RE 2: EC 244-344-1, 233-662-6 and 236-487-3 with target organs kidneys and adrenals; EC 222-248-0 with target organs testes, epididymis and spermatogenesis; EC 208-591-9, with target organs adrenal glands, kidneys and testes; EC 222-492-8 with target organs adrenals, kidneys, nervous system and blood. Some indications for endocrine disruption were observed in a limited number of sub-chronic repeated dose toxicity studies (with test substances EC 231-600-2 and list no. 627-088-9) and a screening study with EC 232-146-8 (decreased weight of reproductive organs), but only at levels where other systemic toxic effects were also observed. As such, ED is currently considered unlikely with notable uncertainty.

Based on ECHA's assessment of currently available environmental hazard information, all the substances in this group are likely aquatic toxic, except EC 222-492-8 and 222-248-0. This hazard is identified based on aquatic toxicity for algae and long-term toxicity to invertebrates and fish with observed effects from a very limited number of substances within the group (EC 244-344-1 mainly). Based on structural similarity the findings from the toxicity studies are extrapolated to the substances where there is limited information for this endpoint. However, the registrants only self-classified two substances, accounting for the counterion effects, for which one as Aquatic acute 1 (EC 232-145-2) and the other as Chronic 3 (EC 236-487-3). In addition, caesium itself and all of the inorganic counterions are considered persistent; however, all substances in this group are unlikely to fulfil the PBT/vPvB screening criteria, because they are all inorganic salts or Organo Metallic Salts for which the organic part is readily degradable. They do not enter in the PBT/vPvB assessment as inorganics they are outside the PBT considerations.

Data will be generated through CCH to clarify aquatic toxicity and suspected reproductive toxicity for the following substances: EC 208-591-9, EC 222-492-8, EC 232-145-2, EC 232-146-8, EC 244-344-1 and EC 233-662-6. It is expected that following data generation for aquatic toxicity registrants would adequately self-classify the substances and implement necessary RMMs to ensure safe use.

The substances have mainly intermediate, industrial, and professional uses with low potential for exposure for workers and consumers. In contrast, two substances have uses in articles in special glass (EC 208-591-9) and in medical-imaging detectors as scintillator material (EC 232-145-2) while one substance (EC 222-492-

8) is used as lubricant in industrial offshore drilling operations with certain industrial activities requiring direct handling and extensive contact. These article uses and the industrial lubricant use have higher potential for worker exposure than the other uses registered for the substances in this group. It should be noted that while there may be potential for exposure for workers (and for consumers) for the substances, currently there is a lack of strong evidence to confirm this. Based on the registrations of EC 208-591-9, it is unclear (i) how the substance is incorporated in the glass i.e., is it incorporated into the matrix or as a layer on the surface, and (ii) who are the users of the glass e.g. are consumers expected to use this special glass. By default, releases of substances from a glass matrix as well as industrial uses are expected to be low while releases from an article surface may be higher and certain industrial activities have higher exposure than others. Considering the uncertainties above, for now we propose CLH for the substances in this group. This ensures that appropriate RMM measures are in place to protect industrial workers from potential exposure overall and thus provide sufficient level of protection. In addition, CLH should cover most uses for these substances. Finally, we recommend the registrants to further clarify the afore-mentioned uncertainties, e.g. way of incorporation into the glass and user groups, when updating their registrations to ensure that no further regulatory action on EU level is necessary.

Due to the potential hazard, uses and potential for exposure to workers for certain uses, the first step of the regulatory risk management action proposed, should the hazard exist, is the confirmation of hazard via harmonised classification (CLH) as CMR cat. 1A/B.

CLH i) will require company level risk management measures (RMM) under the OSH legislation for workers, to be in place, and ii) is needed or highly recommended for further regulatory processes under REACH.

CLH may trigger regulatory action under other regulations. For instance, in this specific case: harmonised classification as CMR cat. 1 will trigger regulatory action on EC 232-145-2 as scintillator material in medical-imaging detectors under the Medical devices regulation (EU) 2017/745, since CMR cat. 1 substances are restricted with derogations by this regulation.

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
222-492-8 **208-591-9**	Known or potential hazard for reproductive toxicity and for STOT RE	No hazard or unlikely hazard for aquatic toxicity For EC 222-492-8 Known or potential hazard for aquatic toxicity For EC 208-591-9	Intermediate, industrial, and professional uses in lubricants, fuel cells and laboratory chemicals. Widespread article use in special glass. Generally low exposure potential but for some uses exposure to workers or consumers cannot be excluded.	Need for EU RRM: CLH Justification: Likely low exposure potential mainly to workers. Uncertainties in exposure from article uses to consumers due to lack of descriptions in registrations. Harmonised classification followed by implementation of necessary RRMs should be sufficient to ensure safe use for workers.	**First step:** CCH **Next steps (if hazard confirmed):** CLH
232-145-2	Known or potential hazard	Known or potential hazard	Intermediate and widespread industrial	Need for EU RRM: CLH	**First step:** CCH

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
232-146-8 **244-344-1** **233-662-6**	for reproductive toxicity and for STOT RE	for aquatic toxicity	uses in adsorbents, catalysts, explosives and non-metal surface treatment products. Widespread article uses (EC 232-145-2) with low exposure potential to workers or consumers.	Justification: Low exposure potential mainly to workers. Harmonised classification followed by implementation of necessary RRMs should be sufficient to ensure safe use for workers.	**Next steps (if hazard confirmed):** CLH
236-487-3 **231-600-2** **239-554-5** **222-248-0**	Known or potential hazard for reproductive toxicity and for STOT RE	Known or potential hazard for aquatic toxicity Unlikely aquatic toxicity for EC 222-248-0	Intermediate uses. Widespread industrial uses as catalyst, laboratory chemical with low exposure potential to workers and consumers.	Need for EU RRM: CLH Justification: Low tonnage with low exposure potential only, proposal is CLH Repr. 1B if confirmed for other Cs compounds	**First step:** Pending action **Next steps (if hazard confirmed):** CLH
627-088-9	Known or potential hazard for reproductive toxicity and for STOT RE	Known or potential hazard for aquatic toxicity	No uses, no exposure.	Need for EU RRM: CLH Justification: CnL substance, proposal is CLH Repr. 1B if confirmed for other Cs compounds	**First step:** Pending action **Next steps (if hazard confirmed):** CLH

Annex 1: Overview of classifications

Data extracted on 14/01/2022.

EC / List No	CAS No	Substance name	Harmo-nised classi-fication	Classification in registrations	Classification in C&L notifications (*)
208-591-9	534-17-8	caesium carbonate	-	Repr. 2 H361 Eye Damage 1 H318 STOT Rep. Exp. 2 H373	STOT Rep. Exp. 2 H373, affected organs: organs[2 out of 25] STOT Single Exp. 3 H335, affected organs: lungs[7 out of 25] STOT Single Exp. 3 H335[2 out of 25] Skin Irrit. 2 H315[18 out of 25] Eye Irrit. 2 H319[15 out of 25] STOT Single Exp. 3 H335, affected organs: respiratory tract[4 out of 25] STOT Single Exp. 3 H335, affected organs: lung[2 out of 25]
222-248-0	3396-11-0	caesium acetate	-	Repr. 2 H361, specific effect:testis, epididymis, spermatogenesis Acute Tox. 4 H302 Eye Irrit. 2 H319 STOT Rep. Exp. 2 H373	Repr. 2 H361[1 out of 4] STOT Single Exp. 3 H336, affected organs: central nervous system[1 out of 4]
222-492-8	3495-36-1	caesium formate	-	Repr. 2 H361 Acute Tox. 4 H302 Eye Irrit. 2 H319 STOT Rep. Exp. 2 H373	STOT Single Exp. 2 H371, affected organs: nervous system[1 out of 10] STOT Rep. Exp. 2 H373, affected organs: Heart, Blood, Central Nervous System (CNS)[1 out of 10] STOT Rep. Exp. 2 H373, affected organs: Organs[1 out of 10] Skin Irrit. 2 H315[2 out of 10] STOT Single Exp. 2 H371, affected organs: Organs[1 out of 10] STOT Single Exp. 3 H335[2 out of 10] STOT Rep. Exp. 2 H373, affected organs: multiple organs, nervous system and blood[1 out of 10]
231-600-2	7647-17-8	caesium chloride	-	Repr. 2 H361, specific effect:Interference with the male reproductive system (testis, epididymis, spermatogenesis)	STOT Rep. Exp. 2 H373, affected organs: testes, epididymides[1 out of 20] Eye Irrit. 2 H319[2 out of 20] Repr. 2 H361[5 out of 20] STOT Single Exp. 3 H335, affected organs: lungs[1 out of 20] Acute Tox. 4 H302[1 out of 20] STOT Rep. Exp. 2 H373[1 out of 20] STOT Single Exp. 3 H335[1 out of 20] Repr. 2 H361, specific effect:fertility; testes[1 out of 20] Muta. 2 H341[1 out of 20] Skin Irrit. 2 H315[2 out of 20]
232-145-2	7789-17-5	caesium iodide	-	Repr. 2 H361, specific effect:Interference with the male reproductive system (testis, epididymis, spermatogenesis) Aquatic Acute 1 H400	Skin Sens. 1 H317[2 out of 11] Skin Irrit. 2 H315[3 out of 11] STOT Rep. Exp. 2 H373, affected organs: Male reproductive system[1 out of 11] STOT Single Exp. 3 H335[2 out of 11] Acute Tox. 4 H302[1 out of 11] Eye Irrit. 2 H319[3 out of 11] Repr. 2 H361[2 out of 11]

EC / List No	CAS No	Substance name	Harmo-nised classi-fication	Classification in registrations	Classification in C&L notifications (*)
232-146-8	7789-18-6	caesium nitrate	-	Repr. 2 H361, specific effect:Interference with the male reproductive system (testis, epididymis, spermatogenesis) Oxid. Solid 1 H271 Acute Tox. 4 H302	Eye Irrit. 2 H319[8 out of 13] STOT Single Exp. 3 H335, affected organs: respiratory[1 out of 13] Oxid. Solid 3 H272[6 out of 13] Oxid. Solid 2 H272[6 out of 13] Skin Irrit. 2 H315[8 out of 13] STOT Single Exp. 3 H335, affected organs: respiratory tracts[3 out of 13] STOT Single Exp. 3 H335[4 out of 13]
233-662-6	10294-54-9	caesium sulphate	-	Repr. 2 H361, specific effect:Interference with the male reproductive system (testis, epididymis, spermatogenesis) Acute Tox. 4 H302 STOT Rep. Exp. 2 H373	Repr. 2 H361[1 out of 12] Repr. 2 H361, specific effect:f[1 out of 12] Aquatic Chronic 3 H412[1 out of 12]
236-487-3	13400-13-0	caesium fluoride	-	Repr. 2 H361 Acute Tox. 4 H302 Skin Irrit. 2 H315 Eye Damage 1 H318 STOT Rep. Exp. 2 H373 Aquatic Chronic 3 H412	Repr. 2 H361, specific effect:Suspected of damaging fertility.[3 out of 11] Acute Tox. 3 H301[9 out of 11] Skin Corr. 1B H314[3 out of 11] Acute Tox. 3 H331[9 out of 11] Acute Tox. 3 H311[9 out of 11] Skin Corr. 1C H314[1 out of 11]
239-554-5	15519-28-5	caesium bicarbonate	-	Repr. 2 H361 Eye Irrit. 2 H319 Eye Damage 1 H318	-
244-344-1	21351-79-1	caesium hydroxide	-	Repr. 2 H361, specific effect:Suspected of damaging fertility Acute Tox. 4 H302 Skin Corr. 1A H314 Eye Damage 1 H318 STOT Rep. Exp. 2 H373	Repr. 2 H361, specific effect:Interference with the male reproductive system (testis, epididymis, spermatogenesis)[2 out of 11] Skin Corr. 1B H314[4 out of 11] STOT Rep. Exp. 2 H373, affected organs: Testis, epididymids[2 out of 11]
627-088-9	35103-79-8	caesium hydroxide monohydrate	-	-	Skin Corr. 1A H314[3 out of 6] Acute Tox. 4 H302[3 out of 6]

(*) 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 14/01/2022.

Main types of applications structured by product or article types	EC/ List 208-591-9	EC/ List 222-248-0	EC/ List 222-492-8	EC/ List 231-600-2	EC/ List 232-145-2	EC/ List 232-146-8	EC/ List 233-662-6	EC/ List 236-487-3	EC/ List 244-344-1
PC 0: Other	A			I	I, A*	I	I	I	
PC 2: Adsorbents				F		F			F
PC 11: Explosives						I			
PC 15: Non-metal-surface treatment products									F, I
PC 24: Lubricants, greases, release products			I						
PC 13: Fuels	A*								
PC 19: Intermediate			I			I			I
PC 21: Laboratory chemicals	P	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.
*= not initially registered as article use but ECHA considers these as article uses.

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

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