

Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

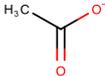
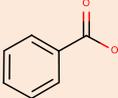
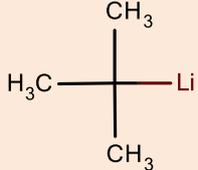
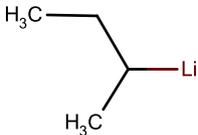
Date: 17/01/2022

Group Name: Simple Lithium Compounds

Revision history

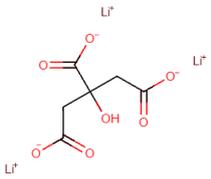
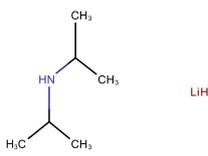
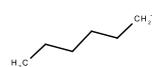
<i>Version</i>	<i>Date</i>	<i>Description</i>
1.0	17/01/2022	

Substances within this group:

EC/List number	CAS number	Substance name	Chemical structure / molecular formula	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) ¹
203-698-7	109-72-8	Butyllithium		Full, OSII or TII, n/a
208-914-3	546-89-4	Lithium acetate	Li^+ 	Full, n/a
209-042-6	553-54-8	Lithium benzoate	Li^+ 	Full, 10-100
209-062-5	554-13-2	Lithium carbonate	Li_2CO_3	Full, > 1000
209-831-5	594-19-4	tert-butyllithium		OSII or TII
209-927-7	598-30-1	sec-butyllithium		OSII or TII
212-737-7	865-34-9	Lithium methanolate	Li^+ 	OSII or TII

¹ n/a: not publicly available

ASSESSMENT OF REGULATORY NEEDS

213-026-4	917-54-4	Methyl lithium	$\text{H}_3\text{C}-\text{Li}$	OSII or TII
213-045-8	919-16-4	Trilithium citrate		n/a
215-183-4	1310-65-2	Lithium hydroxide	LiOH	Full, > 1000
217-611-5	1907-33-1	Lithium 2-methylpropan-2-olate	Li^+ 	OSII or TII
223-893-0	4111-54-0	Lithium diisopropylamide		OSII or TII
231-102-5	7439-93-2	Lithium	Li	Full, OSII or TII, 100-1000
231-212-3	7447-41-8	Lithium chloride	LiCl	Full, > 1000
231-439-8	7550-35-8	Lithium bromide	LiBr	Full, 10-100
231-484-3	7580-67-8	Lithium hydride	LiH	OSII or TII
231-968-4	7782-89-0	Lithium amide	$\text{Li}(\text{NH}_2)$	Full, OSII or TII, n/a
232-152-0	7789-24-4	Lithium fluoride	LiF	Full, 10-100
232-218-9	7790-69-4	Lithium nitrate	LiNO_3	Full, 100-1000
232-237-2	7791-03-9	Lithium perchlorate	LiClO_4	Full, n/a
233-820-4	10377-48-7	Lithium sulphate	Li_2SO_4	Full, 100-1000
233-823-0	10377-52-3	Trilithium orthophosphate	Li_3PO_4	Full, 10-100
235-228-1	12136-58-2	Lithium sulphide, anhydrous	Li_2S	OSII or TII
235-730-0	12627-14-4	Silicic acid, lithium salt	LiSiO_3	Full, n/a
237-558-1	13840-33-0	Lithium hypochlorite	LiOCl	n/a
244-334-7	21324-40-3	Lithium hexafluorophosphate(1-)	LiPF_6	Full, > 1000
247-475-2	26134-62-3	Trilithium nitride	Li_3N	Full, n/a
404-950-0	21369-64-2	n-hexyllithium	Li^+ 	OSII or TII

ASSESSMENT OF REGULATORY NEEDS

424-140-0	2388-10-5	Lithium isopropoxide		OSII or TII
440-620-2	920-36-5	(2-methylpropyl)lithium; isobutyllithium		OSII or TII
460-000-5	20246-63-3	Lithium-2-methoxyethoxide		OSII or TII
485-110-0	-	Lithium 1,1-dimethylpropoxide		OSII or TII
603-454-3	1310-66-3	Lithium hydroxide, monohydrate	LiOH · H ₂ O	n/a
612-032-8	6080-58-6	Lithium Citrate Tetrahydrate		Full, n/a
612-081-5	6108-17-4	Lithium acetate dihydrate		n/a
600-157-0	10102-25-7	Lithium sulfate monohydrate	Li ₂ SO ₄ · H ₂ O	n/a
643-080-8	24389-25-1	Lithium phosphorodifluoridate	LiPO ₂ F ₂	Full, 100-1000

This table contains also group members that are not registered (yet) but have a C&L notification under the CLP Regulation. However, the list is currently non-exhaustive. Once further regulatory risk management action on one or more registered substances is being considered, ECHA will make an additional search for related C&L notified substances to be included in the group and develop a regulatory strategy for them.

Contents

Foreword	6
Glossary	7
1 Overview of the group	8
2 Justification for the need for regulatory risk management action at EU level	9
3 Conclusions and actions	11
Annex 1: Harmonised classifications and self-classifications reported by registrants	14
Annex 2: Overview of uses based on information available in registration dossiers	18
Annex 3: Overview of completed or ongoing regulatory risk management activities	22

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. 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 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 website².

² <https://echa.europa.eu/understanding-assessment-regulatory-needs>

Glossary

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 simple lithium compounds where lithium ions are expected to be the toxicity driver. All the substances are mono-constituent substances, with the main constituent present at a concentration of 80 % or more.

Based on information reported in the REACH registration dossiers, the main use applications for many of the substances are: electrolytes for batteries, absorbents, pharmaceuticals, heat transfer and hydraulic fluids, polymer preparations and compounds, adhesives/sealants, fillers and putties, coatings and paints, paper and board treatment products, textile dyes, metal and non-metal surface treatment products, base- metals and alloys.

Many widespread uses (Professionals, Consumers) in almost all use applications have been reported especially for the three inorganic lithium substances: EC 215-183-4 (lithium hydroxide), EC 209-062-5 (lithium carbonate) and EC 231-212-3 (lithium chloride). For those substances which react vigorously with water, releasing the Li cation, mostly intermediate uses only have been reported; EC 231-968-4 and EC 231-102-5 are also used in industrial settings and the latter also by professionals (base metals and alloys).

Within the whole group, article service life has been reported for EC 233-820-4 (adhesives, sealants and fillers, putties, plasters, modelling clay), EC 231-212-3 (paper and board treatment products), EC 215-183-4 (electrical etc articles, batteries, plaster, cement etc articles, textiles, metal articles; textile dyes and metal surface treatment products), EC 232-152-0 (welding and soldering products, flux products), EC 232-218-9 (fireworks), EC 209-062-5 (plaster, cement etc articles, textiles, metal articles, paper articles) and EC 232-237-2 (batteries).

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 EU regulatory risk management – harmonised classification for reproductive toxicity for all the substances in the group, except those that already have that harmonised classification (EC 209-062-5, 231-212-3 and 215-183-4).

ECHA's Risk Assessment Committee (RAC) has recently adopted its opinion³ regarding the harmonised classification of three lithium salts (lithium content ranging from 9% to 29% w/w) under the CLP Regulation for their reproductive toxic properties. The classification is based on the intrinsic properties of the lithium cation.

It is suggested to look at the possibility to classify all lithium salts substances together on the basis of the toxicity of the lithium cation rather than going one by one, to ensure that all the relevant known and future substances would be classified as reprotoxic. However, bioavailability of the lithium cation may need to be taken into account in scoping the CLH entry, as more information on this property would be needed to address all lithium-containing substances.

Based on the above, for this group, the need for harmonised classification as Repr. 1A is due to the presence of lithium, and is based on the intrinsic properties of the lithium cation (Li^+). As the substances in the group are either lithium salts or react with water to produce lithium hydroxide, which in turn is fully dissociated into the ions in water solution, the release of the lithium cation is relevant for all the substances. The counterions contribute to the hazards of the substances only in the cases of EC 231-439-8 (bromide ion, which has been the basis for the harmonised classification of ammonium bromide as Repr 1B, STOT RE 2), and EC 460-000-5 (based on the harmonised classification of EC 203-713-7 as Repr 1B). The self-classifications for List nr 643-080-8 and EC 244-334-7 as STOT RE 1 also seem to be due to the counterions.

As the lithium cation is considered responsible for the systemic toxicity of these simple lithium compounds, a grouping approach for harmonised classification to cover all the substances in this group is recommended. The use of Note 1 in Annex VI to CLP could be considered for addressing the classification of mixtures containing these substances (*"The concentration stated or, in the absence of such concentrations, the generic concentrations set out in this Regulation are the percentages by weight of the metallic element calculated with reference to the total weight of the mixture."*). Therefore, no distinction is made in this group between substances used as intermediates and those used by professionals or consumers in final products.

The harmonised classification as Repr. 1A i) will trigger company level risk management measures (RMM) under OSH legislation for workers, 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.

In further consideration, it is noted that two of the substances, lithium carbonate EC 209-062-5 and lithium hydroxide EC 215-183-4, have been reported for use in

³ <https://echa.europa.eu/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e18270066e>

textile articles, with article service life. Both of these substances already have an agreed harmonised classification as Repr. 1A. It is not described in the registration dossiers whether the lithium ion would actually remain in the final textile product or be washed away already during production. Because of the high water-solubility of Li^+ , it is not possible to determine whether the presence of Li^+ would be of concern and in order to determine whether a restriction would be required, further data on the use and the fate of the ion would be needed. If this were the case, the substance could be included in entry 72 of Annex XVII to REACH.

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
208-914-3 209-042-6 209-831-5 209-927-7 212-737-7 213-026-4 217-611-5 223-893-0 231-102-5 231-439-8 231-484-3 231-968-4 232-152-0	Known or potential hazard for reproductive toxicity for all substances for STOT RE for EC 231-439-8, EC 643-080-8, EC 244-334-7	No hazard or unlikely hazard Except 440-620-2, which has a harmonised classification as Aquatic Acute 1 and Aquatic Chronic 1	Low to moderate exposure potential for most of the substances (intermediate use, industrial uses). However, EC 232-152-0 and EC 233-820-4 have also potentially high exposure professional and consumer uses in welding products, base metals and alloys for the former, and adhesives, plasters and coatings for the latter. Regarding uses in articles, it should be	Need for EU RRM: CLH Justification: Due to the intrinsic Repr 1A property of the lithium ion and little or no contribution from the counterions, a group CLH is proposed.	First step: CLH

ASSESSMENT OF REGULATORY NEEDS

232-218-9			noted that several of the substances are used as source of lithium for lithium batteries.		
232-237-2					
233-820-4					
233-823-0					
235-228-1					
244-334-7					
247-475-2					
404-950-0					
424-140-0					
440-620-2					
460-000-5					
485-110-0					
612-032-8					
643-080-8					
203-698-7					
209-062-5	Known or potential hazard for reproductive toxicity	No hazard or unlikely hazard	High exposure potential from a large number of uses including professional and consumer uses. For example, uses in adsorbents, biocidal	Need for EU RRM: CLH	First step: No action
215-183-4					Justification: These substances already have a CLH
231-212-3					

ASSESSMENT OF REGULATORY NEEDS

			products, cosmetics, pharmaceuticals, lubricants, adhesives and textile dyes have been indicated.		
--	--	--	---	--	--

Annex 1: Harmonised classifications and self-classifications reported by registrants

Data consulted on October 2021

EC/ List No	CAS number	Substance name	Harmonised classification	Classification in registrations ⁴
203-698-7	109-72-8	butyllithium		Pyr. Liquid 1 H250 Water React. Flam. Gas 1 H260 Skin Corr. 1B H314
209-831-5	594-19-4	tert-butyllithium		Water React. Flam. Gas 1 H260 Skin Corr. 1 H314 Pyr. Solid 1 H250 Eye Damage 1 H318
209-927-7	598-30-1	sec-butyllithium		Pyr. Liquid 1 H250 Skin Corr. 1B H314 Water React. Flam. Gas 1 H260
213-026-4	917-54-4	methyllithium		Eye Damage 1 H318 Pyr. Liquid 1 H250 Skin Corr. 1B H314 Water React. Flam. Gas 1 H260
231-102-5	7439-93-2	lithium (metal)	Water-react. 1 Skin Corr. 1B	Water React. Flam. Gas 1 H260 Skin Corr. 1B H314
231-484-3	7580-67-8	lithium hydride		Skin Corr. 1B H314 Water React. Flam. Gas 1 H260
231-968-4	7782-89-0	lithium amide		Self Heat. 1 H251 Water React. Flam. Gas 2 H261 Skin Corr. 1 H314 Eye Damage 1 H318 Aquatic Chronic 3

⁴ 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 column "Classifications in registrations" is empty if there are no Registrations (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). Further Classifications in C&L notifications are available at <https://echa.europa.eu/fi/information-on-chemicals/cl-inventory-database>

ASSESSMENT OF REGULATORY NEEDS

				H412 Skin Corr. 1A H314
247-475-2	26134-62-3	trilithium nitride		Pyr. Solid 1 H250 Water React. Flam. Gas 1 H260 Skin Corr. 1B H314 Eye Damage 1 H318 Aquatic Chronic 3 H412
404-950-0	21369-64-2	n-hexyllithium	Pyr. Sol. 1 Water-react. 1 Skin Corr. 1A	Pyr. Liquid 1 H250 Water React. Flam. Gas 1 H260 Skin Corr. 1A H314
440-620-2	920-36-5	(2-methylpropyl)lithium; isobutyllithium	Pyr. Liq. 1 Water-react. 1 STOT SE 3 Skin Corr. 1A Aquatic Acute 1 Aquatic Chronic 1	Water React. Flam. Gas 1 H260 Aquatic Chronic 1 H410 Pyr. Liquid 1 H250 STOT Single Exp. 3 H336, affected organs: Skin Corr. 1A H314
223-893-0	4111-54-0	lithium diisopropylamide		Pyr. Solid 1 H250 Skin Corr. 1B H314 Flam. Solid 1 H228
208-914-3	546-89-4	lithium acetate		Acute Tox. 4 H302 Eye Irrit. 2 H319
209-042-6	553-54-8	lithium benzoate		Acute Tox. 4 H302 Skin Irrit. 2 H315 Eye Damage 1 H318
209-062-5	554-13-2	lithium carbonate		Acute Tox. 4 H302 Eye Irrit. 2 H319
212-737-7	865-34-9	lithium methanolate	Group (methanolate): 204-699-5 [1] 212-736-1 [2] 212-737-7 [3] Self-heat. 1 Skin Corr. 1B	Self Heat. 1 H251 Eye Damage 1 H318 Skin Corr. 1B H314
215-183-4	1310-65-2	lithium hydroxide		Acute Tox. 4 H302 Skin Corr. 1B H314 Eye Damage 1 H318
217-611-5	1907-33-1	lithium 2- methylpropan-2-olate		Skin Corr. 1B H314 Acute Tox. 4 H302

ASSESSMENT OF REGULATORY NEEDS

				Eye Damage 1 H318 Flam. Solid 1 H228
231-212-3	7447-41-8	lithium chloride		Acute Tox. 4 H302 Skin Irrit. 2 H315 Eye Irrit. 2 H319
231-439-8	7550-35-8	lithium bromide		Acute Tox. 4 H302 Skin Irrit. 2 H315 Eye Irrit. 2 H319 Skin Sens. 1 H317
232-152-0	7789-24-4	lithium fluoride		Acute Tox. 4 H302 Eye Irrit. 2 H319
232-218-9	7790-69-4	lithium nitrate		Oxid. Solid 3 H272 Acute Tox. 4 H302 Eye Irrit. 2 H319
232-237-2	7791-03-9	lithium perchlorate		Skin Corr. 1 H314 [Article 10 (inactive)] Eye Damage 1 H318 [Article 10 (inactive)] Acute Tox. 4 H302 [Article 10 (inactive)] Oxid. Solid 1 H271 [Article 10 (inactive)]
233-820-4	10377-48-7	lithium sulphate		Acute Tox. 4 H302 Eye Irrit. 2 H319
233-823-0	10377-52-3	lithium orthophosphate		Acute Tox. 4 H302 Skin Corr. 1B H314 Eye Damage 1 H318 Eye Irrit. 2A H319 [intermediate (inactive)]
235-228-1	12136-58-2	lithium sulphide, anhydrous		Acute Tox. 3 H301 Eye Damage 1 H318 Skin Corr. 1B H314
244-334-7	21324-40-3	lithium hexafluorophosphate(1-)		Acute Tox. 3 H301 Skin Corr. 1A H314 Eye Damage 1 H318 STOT Rep. Exp. 1 H372, affected organs: Bones, teeth
424-140-0	2388-10-5	Lithium isopropoxide		Skin Corr. 1A H314 Flam. Solid 2 H228
460-000-5	20246-63-3	Lithium-2-methoxyethoxide		Acute Tox. 4 H302 Acute Tox. 4 H332 Repr. 1B H360,

ASSESSMENT OF REGULATORY NEEDS

				specific effect:May damage fertility. May damage the unborn child. Flam. Solid 1 H228 Skin Corr. 1A H314 Acute Tox. 4 H312
485-110-0	-	Lithium 1,1-dimethylpropoxide		Skin Corr. 1B H314 Flam. Solid 1 H228 Acute Tox. 4 H332
612-032-8	6080-58-6	Lithium Citrate Tetrahydrate		Acute Tox. 4 H302
643-080-8	24389-25-1	Lithium phosphorodifluoridate		Acute Tox. 3 H301 Acute Tox. 4 H312 Skin Corr. 1 H314 Eye Damage 1 H318 STOT Rep. Exp. 1 H372, affected organs: Stomach, Kidney Aquatic Chronic 2 H411
235-730-0	12627-14-4	Silicic acid, lithium salt		Eye Irrit. 2 H320 Eye Damage 1 H318 STOT Single Exp. 3 H335, affected organs: respiratory organs
213-045-8	919-16-4	trilithium citrate		-
600-157-0	10102-25-7	Lithium sulfate monohydrate		-
612-081-5	6108-17-4	Lithium acetate dihydrate		-
603-454-3	1310-66-3	Lithium hydroxide, monohydrate		-
237-558-1	13840-33-0	lithium hypochlorite		-

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

Data consulted on 20/10/2021

EC /List number	231-102-5	231-439-8	612-032-8	247-475-2	231-212-3	208-914-3	232-218-9	209-062-5	215-183-4 603-454-3	209-042-6	643-080-8	232-237-2	233-820-4	244-334-7	233-823-0	485-110-0	235-730-0	232-152-0	231-968-4	203-698-7	213-026-4	209-831-5	209-977-7	212-737-7	217-611-5	223-893-0	231-484-3	235-228-1	404-950-0	440-620-2	424-140-0	460-000-5	213-045-8	600-157-0	612-081-5	603-454-3	237-558-1			
PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents					I, P, C			I, P, C	I, C	F			I, P		F, I		F, I	I																						
PC 37: Water treatment chemicals									I, C,																														*	
PC 2: Adsorbents		F, I	F		C	F	F	F, C	F, C								F																							
PC 11: Explosives									F	I																														
PC 4: Anti-freeze and de-icing products		F, I, P							F																															
PC 35: Washing and cleaning products								F, I, P, C	F		I			I																										
PC 8: Biocidal products (e.g. disinfectants, pest control)					C				F, I, P, C																															
PC 28: Perfumes, fragrances									C																															
PC 3: Air care products					C				F																															

ASSESSMENT OF REGULATORY NEEDS

EC /List number	231-102-5	231-439-8	612-032-8	247-475-2	231-212-3	208-914-3	232-218-9	209-062-5	215-183-4 603-454-3	209-042-6	643-080-8	232-237-2	233-820-4	244-334-7	233-823-0	485-110-0	235-730-0	232-152-0	231-968-4	203-698-7	213-026-4	209-831-5	209-927-7	212-737-7	217-611-5	223-893-0	231-484-3	235-228-1	404-950-0	440-620-2	424-140-0	460-000-5	213-045-8	600-157-0	612-081-5	603-454-3	237-558-1			
PC 39: Cosmetics, personal care products									C																															
PC 29: Pharmaceuticals	I	I	I		F, C			C	I, C	I			F						I															*	*					
PC 31: Polishes and wax blends					C																																			
PC 15: Non-metal-surface treatment products					C			F, I, P, C	C						F, I																									
PC 24: Lubricants, greases, release products		I							F, I, P, C																															
PC 25: Metal working fluids									F, I, P, C																															
PC 16: Heat transfer fluids		F, I, P	F, I, P			F, I, P	F, I	F, I, P	F, I, P									F, I																						
PC 17: Hydraulic fluids	I	I							F, I, P, C		I																													
PC 13: Fuels									F,																															
PC 32: Polymer preparations and compounds		I			C	I	I, P		F, I, C	F, I			I		I			I	I																					
PC 1: Adhesives, sealants					C			F, I, P, C	F, I, P, C				P, C, A																											
PC 9c: Finger paint									F																															
PC 9b: Fillers, putties, plasters, modelling clay								F, I, P, C	F, I, P, C				F, P, C, A																											

ASSESSMENT OF REGULATORY NEEDS

EC /List number	231-102-5	231-439-8	612-032-8	247-475-2	231-212-3	208-914-3	232-218-9	209-062-5	215-183-4 603-454-3	209-042-6	643-080-8	232-237-2	233-820-4	244-334-7	233-823-0	485-110-0	235-730-0	232-152-0	231-968-4	203-698-7	213-026-4	209-831-5	209-927-7	212-737-7	217-611-5	223-893-0	231-484-3	235-228-1	404-950-0	440-620-2	424-140-0	460-000-5	213-045-8	600-157-0	612-081-5	603-454-3	237-558-1						
PC 9a: Coatings and paints, thinners, paint removes					C			F, I, P, C	F, C	F, I			P, C		F, I																												
PC 18: Ink and toners					C				I	F, I																																	
PC 26: Paper and board treatment products					F, I, A			I, P																																			
PC 34: Textile dyes, and impregnating products								F, I, P, C	I, C, A																																		
PC 23: Leather treatment products									I, C																																		
PC 14: Metal surface treatment products					C		F, I	F, I	F, I, A						F, I																												
PC 38: Welding and soldering products, flux products		F			I, C			F, I, P, C										F, I, P, C, A																									
PC 7: Base metals and alloys	F, I, P							F, I, P, C	F									F, I, P, C																									
PC 21: Laboratory chemicals	I	I	P		F, I, P			I	F, I, P			I	F, I, P		F, I			P																								*	
PC 19: Intermediate	I	I, P	I		I	I		F, I	F, I	I			I			F, I			I	F, I			F, I				F, I	F, I		F, I													
PC41: Oil and gas exploration or production products		I, P								I																																	
PC42: Electrolytes for batteries	I	F, I									F, I	I		I																												*	

ASSESSMENT OF REGULATORY NEEDS

EC /List number	231-102-5	231-439-8	612-032-8	247-475-2	231-212-3	208-914-3	232-218-9	209-062-5	215-183-4 603-454-3	209-042-6	643-080-8	232-237-2	233-820-4	244-334-7	233-823-0	485-110-0	235-730-0	232-152-0	231-968-4	203-698-7	213-026-4	209-831-5	209-927-7	212-737-7	217-611-5	223-893-0	231-484-3	235-228-1	404-950-0	440-620-2	424-140-0	460-000-5	213-045-8	600-157-0	612-081-5	603-454-3	237-558-1		
PC 30: Photo-chemicals					C				C																														

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

Note: List number 603-454-3 is the hydrated molecule of EC 215-183-4, and therefore covered in the same registration dossier, with same indicated uses.

* Substances not registered, but uses identified from external sources have been indicated with an asterisk

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

Data consulted on 14/10/2021

EC/List number	RMOA	Authorisation		Restriction		CLH	Actions not under REACH/ CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)		
209-062-5						YES	
215-183-4						YES	
231-212-3						YES	

No relevant completed or ongoing regulatory risk management activities for the other substances.