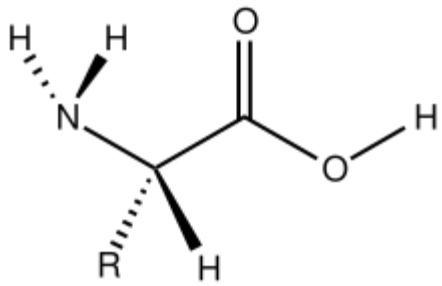
Assessment of regulatory needs

Authority: ECHA

Group Name: Alpha amino acids and salts

General structure:



Revision history

Version	*Date*	*Description*
1.0	24 September 2024	

Substances within this group:

EC/List no	CAS no	Substance name	Registration type (full, OSII or TII, NONS, cease manufacture), highest tonnage band among all the registrations (t/y) [1]
200-157-7	52-89-1	cysteine hydrochloride	full, 100-1000
200-158-2	52-90-4	L-cysteine	full, 10-100
200-272-2	56-40-6	glycine	full, 100-1000
200-273-8	56-41-7	L-alanine	full, >1000
200-274-3	56-45-1	L-serine	full, 100-1000
200-291-6	56-84-8	aspartic acid	full, 100-1000
200-292-1	56-85-9	levoglutamide	full, 10-100
200-293-7	56-86-0	glutamic acid	full, >1000
200-460-4	60-18-4	tyrosine	full, 10-100
200-522-0	61-90-5	L-leucine	full, 100-1000
200-562-9	63-68-3	L-methionine	full, 10-100
200-568-1	63-91-2	3-phenyl-L-alanine	full, 10-100
200-735-9	70-47-3	asparagine	full, 10-100
200-740-6	70-54-2	DL-lysine	OSII or TII
200-745-3	71-00-1	histidine	full, 10-100
200-773-6	72-18-4	L-valine	full, 100-1000
200-774-1	72-19-5	L-threonine	full, 10-100
200-795-6	73-22-3	L-tryptophan	full, 100-1000
200-798-2	73-32-5	L-isoleucine	full, 10-100
200-811-1	74-79-3	arginine	full, 100-1000
205-538-1	142-47-2	sodium hydrogen glutamate	full, >1000
205-702-2	147-85-3	L-proline	full, 100-1000
206-126-4	302-72-7	DL-alanine	full, >1000
206-130-6	302-84-1	DL-serine	OSII or TII
206-229-4	312-84-5	D-serine	OSII or TII
206-328-2	328-39-2	DL-leucine	OSII or TII
206-452-7	344-25-2	D-(+)-proline	OSII or TII

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

EC/List no	CAS no	Substance name	Registration type (full, OSII or TII, NONS, cease manufacture), highest tonnage band among all the registrations (t/y) [1]
211-368-9	640-68-6	D-valine	OSII or TII
211-438-9	645-35-2	L-histidine monohydrochloride	full, 1-10
211-519-9	657-27-2	lysine hydrochloride	full, >1000
211-603-5	673-06-3	D-phenylalanine	OSII or TII
214-275-1	1119-34-2	(+)-L-arginine hydrochloride	full, 100-1000
227-841-8	6000-43-7	glycine hydrochloride	full, 1-10
250-391-9	30925-07-6	L-cystine dihydrochloride	full, 1-10
274-152-3	69847-45-6	disodium L-tyrosinate	full, 1-10
424-750-7			OSII or TII
609-287-2	36760-44-8	D-tryptophan hydrochloride (1:1)	OSII or TII
611-821-4	5934-29-2	L-Histidine, hydrochloride, hydrate (1:1:1)	full, 1-10
615-117-8	7048-04-6	L-Cysteine, hydrochloride, hydrate	OSII or TII

Contents

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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

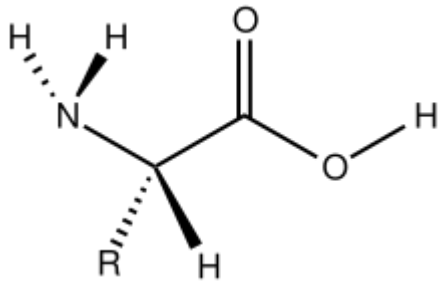
Glossary

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 is available in the foreword to this document. Please read it carefully before going through the report.

ECHA has grouped together structurally similar substances based on the presence of the alpha amino acid moiety shown in the figure below.



There are 39 substances in the group of which 29 with full registrations and 10 with intermediate registrations.

The group consists of alpha amino acids that are divided into essential amino acids (those that cannot be synthesised by humans or mammalian cells) and non-essential amino acids (that are not primarily derived from the diet and are synthesized by the body).

Essential amino acids	Non-essential amino acids & Semi-essential amino acids
histidine	alanine
isoleucine	arginine
leucine	asparagine
lysine	aspartic acid
methionine	cysteine
phenylalanine	glutamic acid
threonine	glutamine (levoglutamide)
tryptophan	glycine
valine	proline
	serine
	tyrosine

The following alpha amino acids (EC 200-294-2 L-lysine, EC 200-4332-1 DL-methionine and EC 205-756-7 DL-phenylalanine) are included in Annex IV of REACH i.e. exempted from the obligation to register in accordance with Article 2(7)(a).

Based on information reported in the REACH registration dossiers, the majority of the substances (24 substances) are used by both professionals and consumers, and are present in articles leading to a high potential for releases to the environment and exposure to workers and/or consumers. These include uses in which products are applied directly to the environment (such as biocidal products, anti-freeze and de-icing products, and fertilisers) or "down the drain" uses such as uses in

cosmetics, personal care, and washing and cleaning products. A high potential for exposure to workers and consumers arises also from uses in coatings and paints, adhesives and sealants, fillers and putties, textile dyes, polishes and waxes, photochemicals, and in lubricants and greases. The same applies to uses with intended releases such as perfumes, fragrances and air care products used by professionals and consumers.

These 24 substances commonly function as binding agents and processing aids, cleaning agents, fragrances, flavourings and nutrients, fertilisers and excipients. Releases to the environment may result from the presence of these substances in articles, such as rubber, plastic, textiles, leather, paper, metal, scented articles and electronic equipment.

For the remaining substances, a low potential for releases to the environment and exposure potential to workers and/or consumers can be assumed due to their uses being only industrial (one substance), or with limited scope as laboratory reagents and in pharmaceuticals (four substances), or due to their status as intermediates registered under Article 17 and 18 of REACH (10 substances) implying that there should be strictly controlled conditions in place for them.

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
All group members 200-157-7, cysteine hydrochloride 200-158-2, L-cysteine 200-272-2, glycine 200-273-8, L-alanine 200-274-3, L-serine 200-291-6, aspartic acid 200-292-1, levoglutamide 200-293-7, glutamic acid 200-460-4, tyrosine	No hazard or unlikely hazard	No hazard or unlikely hazard	High exposure/release potential for the majority of group members due to professional and consumer uses in various products. Low or no exposure potential due to intermediate or similarly controlled conditions for EC 200-740-6, 206-130-6, 206-229-4, 206-328-2, 206-452-7, 211-368-9, 211-603-5, 609-287-2, 615-117-8, 424-750-7, 206-126-4, 227-841-8, 250-391-9, 274-152-3, 611-821-4	No action Justification: No hazard identified

Subgroup name, EC/List no, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
200-522-0, L-leucine 200-562-9, L-methionine 200-568-1, 3-phenyl-L-alanine 200-735-9, asparagine 200-740-6, DL-lysine 200-745-3, histidine 200-773-6, L-valine 200-774-1, L-threonine 200-795-6, L-tryptophan 200-798-2, L-isoleucine 200-811-1, arginine 205-538-1, sodium hydrogen glutamate 205-702-2, L-proline 206-126-4, DL-alanine 206-130-6, DL-serine 206-229-4, D-serine 206-328-2, DL-leucine				

Subgroup name, EC/List no, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
206-452-7, D-(+)-proline 211-368-9, D-valine 211-438-9, L-histidine monohydrochloride 211-519-9, lysine hydrochloride 211-603-5, D-phenylalanine 214-275-1, (+)-L-arginine hydrochloride 227-841-8, glycine hydrochloride 250-391-9, L-cystine dihydrochloride 274-152-3, disodium L-tyrosinate 424-750-7 609-287-2, D-tryptophan hydrochloride (1:1) 611-821-4, L-Histidine, hydrochloride, hydrate (1:1:1)				

Subgroup name, EC/List no, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
615-117-8, L-Cysteine, hydrochloride, hydrate				

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

Based on currently available information, CMR/ED (carcinogenicity, mutagenicity, reproductive toxicity and endocrine disruption) , skin sensitisation, PBT/vPvB, PMT/vPvM hazards are considered unlikely for all substances in the group based on the available data.

The alpha amino acids are not persistent or bioaccumulative and therefore are not considered PBT or PMT.

The available experimental data from the registration dossiers does not indicate CMR/ED or skin sensitisation properties for any of the group members. All group members have experimental data for genotoxicity that are negative. The available experimental repeated dose toxicity studies (mostly 90-day repeated dose toxicity studies and some chronic studies) indicate either no toxicity at doses exceeding the limit dose of 1000mg/kg bw/day or indicate minor effects that represent mostly effects in some biochemistry parameters. The available reproductive toxicity studies do not indicate any potential for hazard in reproduction or development. For group members where no specific pre-natal developmental toxicity (PNDT) studies are available, the systemic toxicity studies do not indicate any toxicity in adult animals with NOAELs>1000mg/kg bw/day. No effects in reproductive or endocrine organs is seen with any group members. The group members are also not skin sensitisers. There is no concern for CMR/ED and skin sensitisation from constituents or impurities in any of the compositions of the group members based on the information available in the registration dossiers.

For the purpose of the ARN, additional information from the public domain (non exhaustive) has been considered for the assessment of the human health hazard of the alpha-amino acids.

Recommendations for protein and amino acid requirements in human nutrition are available via WHO[5], covering the essential amino acids in this ARN. The recommended intake for each of the essential amino acids ranges from 4 mg/kg/day for cysteine and tryptophan to 39 mg/kg/day for leucine with the other essential amino acids recommended intake being in between these two values. These values if taken as DNELs would in essence be translated to high NOAELs in experimental animal studies (assuming an overall assessment factor of 100, NOAELs would range from 400mg/kg bw/day to 3900 mg/kg bw/day).

[5] https://iris.who.int/bitstream/handle/10665/43411/WHO_TRS_935_eng.pdf

In addition, amino acids used as flavourings have been assessed by WHO/JEFCA and EFSA[6] and concluded no genotoxicity potential and no safety concern for the specified uses as flavourings.

ECHA has assessed some amino acid derivatives (acyl derivatives from alpha-amino acids other than glutamic acid, glycine or sarcosine) where also no concern for CMR/ED properties was identified. These derivatives are expected to some extent to metabolise to the corresponding amino acids, therefore the information is used as supportive evidence of lack of CMR/ED properties for the corresponding amino acids.

L-cysteine is an active substances in plant protection products authorised for use in the European Union (EC No 1107/2009). No CMR/ED properties have been identified during the evalution/approval process. An assessment of amino acids is available within the "Scientific Opinion on the safety and efficacy of the use of amino acids (chemical group 34) when used as flavourings for all animal species" [7] setting a safe value of around 20 mg/kg feed for all animal species.

Taking into account the essential role of amino acids in growth, various cellular processes, the homeostatic control of their amounts in human body, and all the information available from registration dossiers and the public domain no further information is needed to conclude on the unlikely hazard for CMR/ED and skin sensitisation properties.

The majority of the group members have wide dispersive uses and high exposure potential for consumers as they are used in various products; however the exposure is expected to be lower than that coming from the use of supplements and nutrition as such, which is also taken into account in the conclusions made for this ARN.

[6] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2008.870

[7] https://www.efsa.europa.eu/en/efsajournal/pub/3670

Annex 1: Overview of classifications

Data extracted on 03/06/2024

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
200-157-7	52-89-1	cysteine hydrochloride	-	Eye Irrit. 2 H319
200-158-2	52-90-4	L-cysteine	-	Acute Tox. 4 H302 [intermediate (active)]
200-272-2	56-40-6	glycine	-	-
200-273-8	56-41-7	L-alanine	-	-
200-274-3	56-45-1	L-serine	-	-
200-291-6	56-84-8	aspartic acid	-	-
200-292-1	56-85-9	levoglutamide	-	-
200-293-7	56-86-0	glutamic acid	-	-
200-460-4	60-18-4	tyrosine	-	-
200-522-0	61-90-5	L-leucine	-	-
200-562-9	63-68-3	L-methionine	-	-
200-568-1	63-91-2	3-phenyl-L-alanine	-	-
200-735-9	70-47-3	asparagine	-	-
200-740-6	70-54-2	DL-lysine	-	-
200-745-3	71-00-1	histidine	-	-
200-773-6	72-18-4	L-valine	-	-
200-774-1	72-19-5	L-threonine	-	-
200-795-6	73-22-3	L-tryptophan	-	-
200-798-2	73-32-5	L-isoleucine	-	-

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
200-811-1	74-79-3	arginine	-	-
205-538-1	142-47-2	sodium hydrogen glutamate	-	-
205-702-2	147-85-3	L-proline	-	-
206-126-4	302-72-7	DL-alanine	-	-
206-130-6	302-84-1	DL-serine	-	-
206-229-4	312-84-5	D-serine	-	-
206-328-2	328-39-2	DL-leucine	-	-
206-452-7	344-25-2	D-(+)-proline	-	-
211-368-9	640-68-6	D-valine	-	-
211-438-9	645-35-2	L-histidine monohydrochloride	-	-
211-519-9	657-27-2	lysine hydrochloride	-	-
211-603-5	673-06-3	D-phenylalanine	-	-
214-275-1	1119-34-2	(+)-L-arginine hydrochloride	-	-
227-841-8	6000-43-7	glycine hydrochloride	-	Skin Corr. 1 H314 Eye Damage 1 H318
250-391-9	30925-07-6	L-cystine dihydrochloride	-	Skin Corr. 1B H314 Eye Damage 1 H318
274-152-3	69847-45-6	disodium L-tyrosinate	-	Eye Damage 1 H318
424-750-7	-	424-750-7	-	-
609-287-2	36760-44-8	D-tryptophan hydrochloride (1:1)	-	-
611-821-4	5934-29-2	L-Histidine, hydrochloride, hydrate (1:1:1)	-	Eye Irrit. 2 H319

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
615-117-8	7048-04-6	L-Cysteine, hydrochloride, hydrate	-	STOT Single Exp. 3 H335, affected organs: Respiratory system. [intermediate (active)] Eye Irrit. 2 H319 [intermediate (active)] Skin Irrit. 2 H315 [intermediate (active)]

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

Data extracted on 03/06/2024

Uses for substance that are not registered as intermediates

Main types of applications structured by product or article types	200-157-7	200-158-2	200-272-2	200-273-8	200-274-3	200-291-6	200-292-1	200-293-7	200-460-4	200-522-0	200-562-9	200-568-1	200-735-9	200-745-3	200-773-6	200-774-1	200-795-6	200-798-2	200-811-1	205-538-1	205-702-2	211-438-9	211-519-9	214-275-1
PC 1: Adhesives, sealants	F, I, **P**, **C**		F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**, **A**	F, I, **P**, **C**, **A**	F, I, **P**, **C**, **A**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**, **A**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**, **A**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**, **A**	F, I, **P**, **C**, **A**	F, I, **P**, **C**, **A**	F, I, **P**, **C**, **A**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**, **A**
PC 9a: Coatings and paints, thinners, paint removes	F, I, **P**, **C**	I, **P**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**, **A**	F, I, **P**, **C**, **A**	F, I, **P**, **C**, **A**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**, **A**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**, **A**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**, **A**	F, I, **P**, **C**, **A**	F, I, **P**, **C**, **A**	F, I, **P**, **C**, **A**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**, **A**
PC 9b: Fillers, putties, plasters, modelling clay	F, I, **P**, **C**		F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**, **A**	F, I, **P**, **C**, **A**	F, I, **P**, **C**, **A**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**, **A**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**, **A**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**, **A**	F, I, **P**, **C**, **A**	F, I, **P**, **C**, **A**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**, **A**

Main types of applications structured by product or article types	200-157-7	200-158-2	200-272-2	200-273-8	200-274-3	200-291-6	200-292-1	200-293-7	200-460-4	200-522-0	200-562-9	200-568-1	200-735-9	200-745-3	200-773-6	200-774-1	200-795-6	200-798-2	200-811-1	205-538-1	205-702-2	211-438-9	211-519-9	214-275-1
PC 9c: Finger paint			F, **P**, **C**																					
PC 34: Textile dyes, and impregnating products	F, I, **P**	I, **P**	F, I, **P**, **C**	F, I, **P**	F, I, **P**	F, I, **P**	F, I, **P**, **C**, **A**	F, I, **P**, **C**, **A**	F, I, **P**, **C**, **A**	F, I, **P**	F, I, **P**	F, I, **P**, **C**, **A**	F, I, **P**	F, I, **P**	F, I, **P**, **C**, **A**	F, I, **P**	F, I, **P**	F, I, **P**, **C**, **A**	F, I, **P**, **C**, **A**	F, I, **P**, **C**, **A**	F, I, **P**	F, I, **P**	F, I, **P**	F, I, **P**, **C**, **A**
PC 23: Leather treatment products	F, I, **P**, **C**	I, **P**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**, **A**	F, I, **P**, **C**, **A**	F, I, **P**, **C**, **A**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**, **A**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**, **A**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**, **A**	F, I, **P**, **C**, **A**	F, I, **P**, **C**, **A**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**, **A**
PC 31: Polishes and wax blends	F, I, **P**, **C**		F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**, **A**	F, I, **P**, **C**, **A**	F, I, **P**, **C**, **A**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**, **A**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**, **A**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**, **A**	F, I, **P**, **C**, **A**	F, I, **P**, **C**, **A**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**, **A**
PC 30: Photo-chemicals	F, I, **P**		F, I, **P**, **C**	F, I, **P**	F, I, **P**	F, I, **P**	F, I, **P**	F, I, **P**	F, I, **P**	F, I, **P**	F, I, **P**	F, I, **P**	F, I, **P**	F, I, **P**	F, I, **P**	F, I, **P**	F, I, **P**	F, I, **P**	F, I, **P**	F, I, **P**	F, I, **P**	F, I, **P**	F, I, **P**	F, I, **P**

Main types of applications structured by product or article types	200-157-7	200-158-2	200-272-2	200-273-8	200-274-3	200-291-6	200-292-1	200-293-7	200-460-4	200-522-0	200-562-9	200-568-1	200-735-9	200-745-3	200-773-6	200-774-1	200-795-6	200-798-2	200-811-1	205-538-1	205-702-2	211-438-9	211-519-9	214-275-1
PC 28: Perfumes, fragrances	F, I, C, A	F, C	F, I, P, C, A	F, I, C, A	F, I, C, A	F, I, C, A	F, I, C, A	F, I, C, A	F, I, C, A	F, I, C, A	F, I, C, A	F, I, C, A	F, I, C, A	F, I, C, A	F, I, C, A	F, I, C, A	F, I, C, A	F, I, C, A	F, I, C, A	F, I, C, A	F, I, C, A	F, I, C, A	F, I, C, A	F, I, C, A
PC 3: Air care products	F, I, P, C	C	F, I, P, C	F, I, P, C	F, I, P, C	F, I, P, C	F, I, P, C, A	F, I, P, C, A	F, I, P, C, A	F, I, P, C	F, I, P, C	F, I, P, C, A	F, I, P, C	F, I, P, C	F, I, P, C, A	F, I, P, C	F, I, P, C	F, I, P, C, A	F, I, P, C, A	F, I, P, C, A	F, I, P, C	F, I, P, C	F, I, P, C	F, I, P, C, A
PC 39: Cosmetics, personal care products	F, I, P, C, A	F, P, C	F, I, P, C, A	F, I, P, C, A	F, I, P, C, A	F, I, P, C, A	F, I, P, C, A	F, I, P, C, A	F, I, P, C, A	F, I, P, C, A	F, I, P, C, A	F, I, P, C, A	F, I, P, C, A	F, I, P, C, A	F, I, P, C, A	F, I, P, C, A	F, I, P, C, A	F, I, P, C, A	F, I, P, C, A	F, I, P, C, A	F, I, P, C, A	F, I, P, C, A	F, I, P, C, A	F, I, P, C, A
PC 24: Lubricants, greases, release products	F, I, P, C		F, I, P, C	F, I, P, C	F, I, P, C	F, I, P, C	F, I, P, C	F, I, P, C	F, I, P, C	F, I, P, C	F, I, P, C	F, I, P, C	F, I, P, C	F, I, P, C	F, I, P, C	F, I, P, C	F, I, P, C	F, I, P, C	F, I, P, C	F, I, P, C	F, I, P, C	F, I, P, C	F, I, P, C	F, I, P, C
PC 4: Anti-freeze and de-icing products	F, I, P, C		F, I, P, C	F, I, P, C	F, I, P, C	F, I, P, C	F, I, P, C	F, I, P, C	F, I, P, C	F, I, P, C	F, I, P, C	F, I, P, C	F, I, P, C	F, I, P, C	F, I, P, C	F, I, P, C	F, I, P, C	F, I, P, C	F, I, P, C	F, I, P, C	F, I, P, C	F, I, P, C	F, I, P, C	F, I, P, C

Main types of applications structured by product or article types	200-157-7	200-158-2	200-272-2	200-273-8	200-274-3	200-291-6	200-292-1	200-293-7	200-460-4	200-522-0	200-562-9	200-568-1	200-735-9	200-745-3	200-773-6	200-774-1	200-795-6	200-798-2	200-811-1	205-538-1	205-702-2	211-438-9	211-519-9	214-275-1
PC 35: Washing and cleaning products	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**
PC 8: Biocidal products (e.g. disinfectants, pest control)	F, I, **P, C**		F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**
PC 21: Laboratory chemicals	F, I, **P, C**	I, **P**	F, I, **P, C**	F, I, **P**	F, I, **P**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P**	F, I, **P**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**
PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents	F, I, **P**	I, **P**	F, I, **P, C**	F, I, **P**	F, I, **P**	F, I, **P**	F, I, **P**	F, I, **P**	F, I	F, I, **P**	F, I, **P**	F, I, **P**	F, I, **P**	F, I, **P**	F, I, **P**	F, I, **P**	F, I, **P**	F, I, **P**	F, I, **P**	F, I, **P**	F, I, **P**	F, I, **P**	F, I, **P**	F, I, **P**

Main types of applications structured by product or article types	200-157-7	200-158-2	200-272-2	200-273-8	200-274-3	200-291-6	200-292-1	200-293-7	200-460-4	200-522-0	200-562-9	200-568-1	200-735-9	200-745-3	200-773-6	200-774-1	200-795-6	200-798-2	200-811-1	205-538-1	205-702-2	211-438-9	211-519-9	214-275-1
PC 12: Fertilisers	I		F, I, **P**, **C**, **A**	F, I, **C**	I	F, I, **P**	I	I, **P**, **C**	I	I	F, I, **P**, **C**	I	I	I	F, I, **P**	I	F, I, **P**, **C**	I	F, I, **P**	F, I, **P**	F, I, **P**, **C**	I	F, I, **P**	I
PC 32: Polymer preparations and compounds	I		F, I, **A**	F		F, I					F	F	F	F			F	F	F	F				
PC 18: Ink and toners	F, I	I	F, I, **P**, **C**	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I
PC 26: Paper and board treatment products			F, **P**, **C**																F, I, **P**, **A**					
PC 14 & 15: Metal/non-metal-surface treatment products			F, I, **P**, **C**																					

Main types of applications structured by product or article types	200-157-7	200-158-2	200-272-2	200-273-8	200-274-3	200-291-6	200-292-1	200-293-7	200-460-4	200-522-0	200-562-9	200-568-1	200-735-9	200-745-3	200-773-6	200-774-1	200-795-6	200-798-2	200-811-1	205-538-1	205-702-2	211-438-9	211-519-9	214-275-1
PC 27: Plant protection products	I		F, I, **C**	I	I	I	I	I	I	I	I	I	I	I	F, I	I	I, **P**, **C**	I	I	F, I	I	I	F, I, **P**	I
PC 29: Pharmaceuticals	F, I	F, I	F, I, **P**, **C**	F, I, **C**	F, I	F, I	F, I	F, I	F, I	F, I	F, I, **P**	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I, **P**, **C**	F, I, **P**, **C**	F, I	F, I	F, I	F, I
PC 2: Adsorbents	F, I		F, I, **P**, **C**	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I
PC 13: Fuels	F, I		F, I, **P**, **C**	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I, **P**	F, I	F, I	F, I	F, I
PC 36: Water softeners	F, I		F, I, **P**, **C**	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I
PC 37: Water treatment chemicals			F, I, **P**, **C**																				I	

Main types of applications structured by product or article types	200-157-7	200-158-2	200-272-2	200-273-8	200-274-3	200-291-6	200-292-1	200-293-7	200-460-4	200-522-0	200-562-9	200-568-1	200-735-9	200-745-3	200-773-6	200-774-1	200-795-6	200-798-2	200-811-1	205-538-1	205-702-2	211-438-9	211-519-9	214-275-1
PC x1: Food and feed additives	F, I		F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I, **P**, **C**	F, I	F, I	F, I	F, I	F, I
PC 17: Hydraulic fluids																				**P**				
PC41: Oil and gas exploration or production products										I		I			F, I					I, **P**			F, I	
PC 19: Intermediate	F, I	I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I	F, I
PC 40: Extraction agents																				F			I	

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

Data extracted on 03/06/2024

EC/List No	Other	Limit value TWA
200-157-7	Active substances in plant protection products authorised for use in the European Union (EC No 1107/2009)	

*Some of the broad restriction entries in the Annex XVII of REACH are not represented in the overview, e.g. when the scope of the restriction is defined by its classification or the substance identification is broad (e.g. entries 3, 28-30, 40 and 75).

There are no other relevant completed or ongoing regulatory risk management activities for the other substances