

Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Date: 08/07/2022

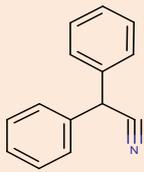
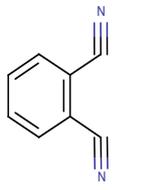
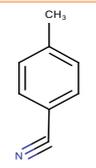
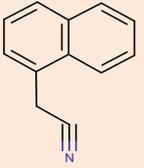
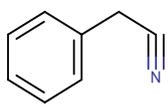
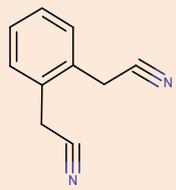
Group Name: Aromatic nitriles

General structure: -

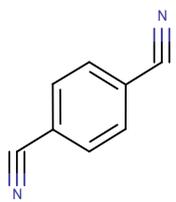
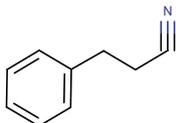
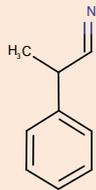
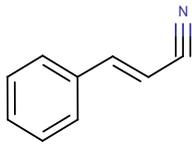
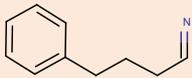
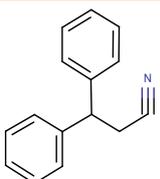
Revision history

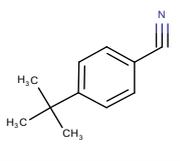
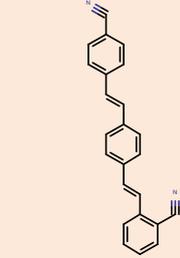
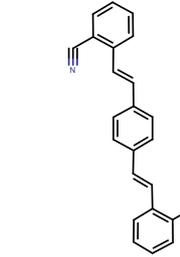
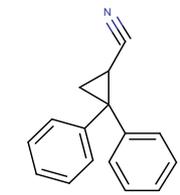
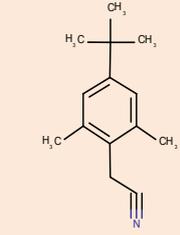
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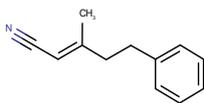
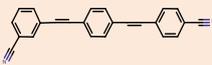
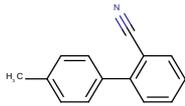
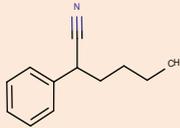
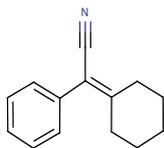
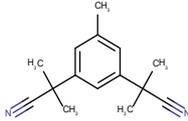
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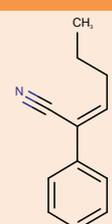
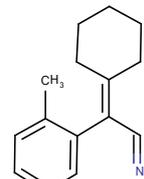
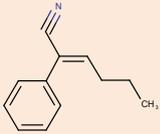
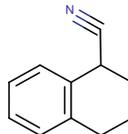
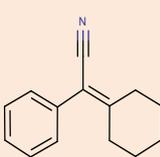
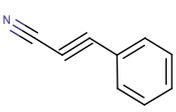
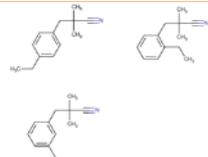
EC/List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) ¹
201-662-5	86-29-3	Diphenylacetonitrile		Full, 10-100
202-044-8	91-15-6	Phthalonitrile		Full, not (publicly) available
202-855-7	100-47-0	Benzonitrile		OSII or TII
203-244-8	104-85-8	p-toluenitrile		OSII or TII
205-078-1	132-75-2	1-naphthylacetonitrile		OSII or TII
205-410-5	140-29-4	Phenylacetonitrile		OSII or TII
210-351-3	613-73-0	o-phenylenediacetonitrile		OSII or TII

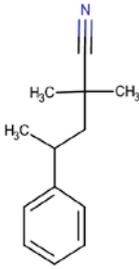
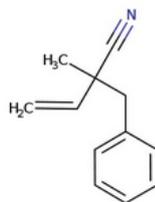
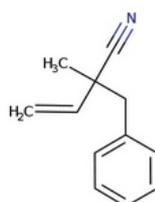
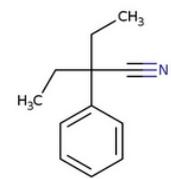
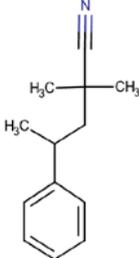
¹ Note that the total aggregated tonnage band may be available on ECHA's webpage at <https://echa.europa.eu/information-on-chemicals/registered-substances>

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
210-783-2	623-26-7	Terephthalonitrile		OSII or TII
210-933-7	626-17-5	Benzene-1,3-dicarbonitrile		Full, not (publicly) available
211-447-8	645-59-0	3-phenylpropionitrile		C&L notification
217-354-9	1823-91-2	2-phenylpropionitrile		OSII or TII
217-552-5	1885-38-7	Cinnamonitrile		Full, not (publicly) available
218-068-7	2046-18-6	4-phenylbutyronitrile		OSII or TII
218-926-0	2286-54-6	3,3-diphenylpropionitrile		OSII or TII

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
220-860-2	2920-38-9	p-phenylbenzotrile		OSII or TII
224-137-2	4210-32-6	4-tert-butylbenzotrile		OSII or TII
235-834-6	13001-38-2	2-[2-[4-[2-(4-cyanophenyl)vinyl]phenyl]vinyl]benzotrile		Full, 10-100
235-835-1	13001-39-3	2,2'-(p-phenylenediethene-2,1-diyl)bisbenzotrile		Full, 10-100
237-492-3	13816-33-6	4-isopropylbenzotrile		Full, not (publicly) available
250-397-1	30932-41-3	2,2-diphenylcyclopropanecarbonitrile		OSII or TII
284-183-4	84803-57-6	(4-tert-butyl-2,6-dimethylphenyl)acetonitrile		OSII or TII

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
299-682-2	93893-89-1	3-methyl-5-phenylpent-2-enenitrile		Full, not (publicly) available
419-060-8	79026-02-1	3-(2-{4-[2-(4-cyanophenyl)vinyl]phenyl}vinyl)benzonitrile		Full, not (publicly) available
422-310-9	114772-53-1	[1,1'-Biphenyl]-2-carbonitrile, 4'-methyl-		OSII or TII
423-460-8	3508-98-3	2-phenylhexanenitrile		NONS
423-740-1	10461-98-0	2-cyclohexylidene-2-phenylacetonitrile		NONS
426-780-6	-	V159456	-	NONS
427-220-3	120511-72-0	1,3-Benzenediacetonitrile, .alpha.1,.alpha.1,.alpha.3,.alpha.3,5-pentamethyl-		NONS
482-160-5	130786-09-3	(Z)-2-phenylhex-2-enenitrile		NONS

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
				
482-300-5	-	2-cyclohexylidene-2-(o-tolyl)acetonitrile		NONS
613-754-6	6519-09-1	(Z)-2-phenylhex-2-enenitrile		OSII or TII
611-399-1	56536-96-0	1,2,3,4-tetrahydronaphthalene-1-carbonitrile		OSII or TII
600-592-6	10461-98-0	2-cyclohexyl-2-cyclohexylidene acetonitrile		C&L notification
624-372-4	935-02-4	3-Phenyl-2-propynenitrile		C&L notification
801-876-4	3508-98-3	[No public or meaningful name is available]	-	C&L notification
944-033-7	-	[No public or meaningful name is available]	-	OSII or TII
412-660-0	134123-93-6	A mixture of: 3-(4-ethylphenyl)-2,2-dimethylpropanenitrile ; 3-(2-ethylphenyl)-2,2-dimethylpropanenitrile		NONS

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
		; 3-(3-ethylphenyl)-2,2-dimethylpropanenitrile		
422-580-8	75490-39-0	2,2,4-trimethyl-4-phenyl-butane-nitrile		NONS
407-870-4	97384-48-0	2-benzyl-2-methyl-3-butenitrile		NONS
687-584-6	97384-48-0	-		Not registered
226-257-0	5336-57-2	2-ethyl-2-phenylbutyronitrile		OSII or TII
801-874-3	75490-39-0	2,2,4-Trimethyl-4-phenylbutane- nitrile		C&L notification

This table contains also group members that are only notified under the CLP Regulation. However, the list is not necessarily 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.

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Foreword

The purpose of the assessment of regulatory needs of a group of substances is to help authorities conclude on the most appropriate way to address the identified concerns for a group of substances or a single substance, i.e. the combination of the regulatory risk management instruments to be used and any intermediate steps, such as data generation, needed to initiate and introduce these regulatory measures.

An assessment of regulatory needs can conclude that regulatory risk management at EU level is required for a (group of) substance(s) (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. While the assessment is done for a group of substances, the (no) need for regulatory action can be identified for the whole group, a subgroup or for single substance(s).

The assessment of regulatory needs is an important step under ECHA's Integrated Regulatory Strategy. However, it is not part of the formal processes defined in the legislation but aims to support them.

The assessment of regulatory needs can be applied to any group of substances or single substance, i.e., any type of hazards or uses and regardless of the previous regulatory history or lack of such. It can be done based on a different level of information. A Member State or ECHA can carry out this case-by-case analysis. The starting point is available information in the REACH registrations and any other REACH and CLP information. However, a more extensive set of information can be available, e.g. assessment done under REACH/CLP or other EU legislation, or can be generated in some cases (e.g. further hazard information under dossier evaluation). Uncertainties associated to the level of information used should be reflected in the documentation. It will be revisited when necessary. For example, after further information is generated and the hazard has been clarified or when new insights on uses are available. It can be revisited by the same or another authority.

The responsibility for the content of this assessment rests with the authority that developed it. It is possible that other authorities do not have the same view and may develop further assessment of regulatory needs. The assessment of regulatory needs does not yet initiate any regulatory process, but any authority can consequently do so and should indicate this by appropriate means, such as the Registry of Intentions.

For more information on Assessment of regulatory needs please consult ECHA website².

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 aromatic ring and the nitrile group (aromatic nitriles).

The group consists of 42 entries representing 38 substances (4 list numbers are duplicates) with 16 substances having full (REACH Article 10) registrations, 18 intermediate registrations and 4 having only C&L notifications.

Based on information reported in the REACH registration dossiers, the substances in the group are mainly used as fragrances, dyes, brighteners or intermediates in several types of applications. About half of the substances in the group have intermediate registrations, and the remaining substances have full registrations indicating mainly fragrance, brightener and dye uses in e.g. washing and cleaning, biocides, perfumes, air care products, cosmetics, polishes paper and textile. The substances with intermediate registrations or uses have low potential for exposure, while the substances used as fragrance, brightener or dye have wide-dispersive professional, consumer, and article uses with high potential for exposure for workers and consumers and release in the environment.

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 ECHA's assessment, the structural differences in the nitriles such as length of the carbon chain substituents, presence of substituents at the *alpha*-carbon, and position of double bonds in the substances can have an influence on the structural alerts related to the human health hazards as well as on the metabolism, identity of metabolites, and eventual release of cyanide (see Assessment of the regulatory needs for a group of aliphatic nitriles). The structural differences are also reflected as a variability in the toxicity profiles of the substances in the aromatic nitriles group. Due to the variability in toxicity profiles, the human health hazards identified

for certain aromatic nitriles in the group are not directly extrapolated to all substances in the group, but rather the hazards are extrapolated only within the subsets of substances where the substances have similar structural alerts and may have higher likelihood of similarities in metabolic profiles.

Based on currently available information, there is a need for (further) EU regulatory risk management – restriction for PBT/vPvB and skin sensitisation hazards due to the potential for release and exposure of the fully registered substances EC 235-834-6, EC 235-835-1, and EC 419-060-8 in the group.

Based on ECHA's assessment of hazard information currently available in the registration dossiers and considerations of structural similarity and presence of common functional moiety these substances have (potentially) the following environmental hazards: potential PBT/vPvB. These substances, which are dinitriles with the nitrile groups linked to the different aromatic rings, fulfil the PBT/vPvB screening criteria³:

- these substances are potentially persistent or very persistent (P/vP) as:
 - they are not readily biodegradable (*i.e.*, <60/70% degradation in a screening-level biodegradability test)
- these substances are potentially bioaccumulative or very bioaccumulative (B/vB) as:
 - they have a high potential to partition to lipid storage ($\log K_{ow} > 4.5$);
- they meet the T criteria set in Annex XIII: NOEC or EC₁₀ < 0.01 mg/L.

Therefore, the substances are considered as potential PBT/vPvB substances. To clarify the potential PBT/vPvB properties CCH is proposed for these substances.

Based on ECHA's assessment, the presence of structural alert related for skin sensitisation (*i.e.*, activated ethenylarene) in these substances indicates potential for skin sensitisation properties. Currently, the hazard is inadequately investigated for these substances. Therefore, further assessment is proposed for these substances (compliance check) to clarify the skin sensitisation properties.

No potential other human health hazards were identified. These conclusions are based on the negative *in vitro* mutagenicity tests and on the repeated dose toxicity study indicating lack of hazards for the subgroup following repeated exposure. Further assessment (compliance check) is proposed to confirm this conclusion.

These substances are used by industrial workers in washing and cleaning, coatings, paper and board, polymer preparations and textiles and by consumers in washing and cleaning products. In addition, the substances are incorporated into paper, plastic, and textile articles. In all these uses, the substances serve as dyes or brighteners. Washing and cleaning products are considered to have a high potential for release to the environment as they are applied on surfaces and washed down the drain. According to registrations, worker activities in the use of these substances include roller application or brushing and treatment of articles by dipping and pouring while the articles have intended or foreseeable mouth contact, skin contact in *e.g.* toys, clothing and footwear, and foreseeable impact on indoor exposure due to large indoor surface, *e.g.* flooring. Thus, due to their activities, workers have a high potential for exposure. In addition, despite brighteners and dyes in articles are expected to be bound to materials through intermolecular

³ As defined in REACH Annex XIII and R11 Guidance on PBT assessment
https://echa.europa.eu/documents/10162/17224/information_requirements_r11_en.pdf/a8cce23f-a65a-46d2-ac68-92fee1f9e54f

forces, the uses in textiles, potentially incorporated into e.g. toys and clothes, consumers have a high potential for chronic exposure. Thus, based on the information in the registrations, exposure to environment, workers and consumers via the use of the substance and use of articles cannot be excluded.

Because of the combined potential for PBT/vPvB and skin sensitisation hazards, wide-dispersive uses and high potential for environmental, worker and chronic consumer exposure of these substances, the foreseen necessary regulatory action is restriction preceded by harmonised classification (CLH) and SVHC identification. Confirmation of the hazard properties via SVHC identification is not considered sufficient to minimise potential releases of the substances in the environment. A restriction is seen as the most appropriate option as potential for exposure is expected from consumer uses, article service life and industrial uses. It should be noted that the necessity of these actions depends on the outcome of the preceding data generation to confirm the PBT and skin sensitisation hazards.

The use of PBT and vPvB substances by consumers and professional workers has been recognised as an area of concern under the European Commission's Chemicals Strategy for Sustainability⁴. Based on the available information concerning the registered uses of these substances, releases to the environment from consumer uses cannot be avoided. Furthermore, potential for exposure and releases to the environment from articles is likely, based on available information. Therefore, a restriction of the substances as such or in mixtures (concentration limit in mixtures) used by consumers and industrial workers is suggested after SVHC identification, with the aim to minimise exposures and emissions to humans and the environment. Moreover, restricting substances in articles used by professionals or consumers (reported for these substances) is proposed as potential for exposure from articles is likely.

For the moment, there is an ongoing restriction proposal from FR/SE on skin sensitisers (and skin irritants and corrosive substances) in textiles, leather, and fur and hide articles. Under the current proposal for restriction, harmonised classification (CLH) would be needed for the restriction to apply. Besides textiles, CLH will also support regulatory action under other regulations. For instance, in this specific case ban on Public Space Maintenance (cleaning products, de-icing) under Green Public Procurement (GPP) (voluntary scheme) and ban and safe use under OSH - Young people at work. Depending on the outcome of the proposed data generation, in case the skin sensitisation hazard is confirmed and the PBT hazard is not, CLH for skin sensitisation would protect workers and consumers in exposure from textiles.

Based on currently available information, there is no need for (further) EU regulatory risk management for all the other substances in the group.

Based on ECHA's assessment the available information indicates potential for skin sensitisation properties for most of the unsaturated nitriles, substances EC 423-740-1, EC 482-300-5, EC 217-552-5, EC 299-682-2, EC 482-160-5, EC 944-033-7, EC 624-372-4, EC 613-754-6, and EC 426-760-6. This conclusion is based on positive local lymph node assays (LLNA; EC 3 ranging 0.77% to 10%) for four substances (self-classified as Skin Sens 1) supported by the presence of structural alert for cyanoalkenes in all of these substances. Most of the substances either have intermediate registrations or are used as fragrances by industrial and professional workers and consumers in various products. Potential for exposure for

⁴ European Commission, *Chemical Strategy for Sustainability Towards a Toxic-Free Environment*, available at <https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf>

workers and consumers for intermediate uses is low while for fragrance uses it is high.

The available information indicates potential for reproductive toxicity and potential endocrine disruption properties for dinitriles, substances EC 202-044-8, EC 210-783-8, EC 210-933-7, EC 210-351-3 and EC 427-220-3. This conclusion is based on findings in two reproduction/developmental toxicity screening studies indicating effects on sexual function and fertility (testicular atrophy, mortality at parturition) as well as on development (reduced pre- and post-natal survival) for substances EC 202-044-8 and EC 210-933-7. However, these substances have only intermediate registrations or industrial uses as an intermediate and thus, a low potential for exposure.

Based on ECHA's assessment of currently available hazard information, no other potential human health hazards were identified for these substances (except for EC 422-310-9 and EC 220-860-2 with intermediate registrations). These conclusions are based on reasonably good experimental data coverage for *in vitro* and *in vivo* studies for genotoxicity showing negative results as well as *in vivo* subacute/subchronic repeated dose toxicity studies. There is high uncertainty on the conclusion for the reproductive toxicity due to very limited data available. The conclusion for reproductive toxicity is based on the lack of indication of reproductive toxicity based on available screening studies (OECD TG 421/422), further supported by the lack of effects on reproductive organs in the repeat dose toxicity studies. Further assessment is ongoing (EC 299-682-2) or proposed (compliance check; EC 201-662-5, EC 423-740-1, EC 235-834-6 and EC 235-835-1) to confirm this conclusion.

Based on ECHA's assessment of currently available hazard information, a number of substances in the group are potentially persistent/very persistent, mobile/very mobile and (potentially) toxic. This conclusion is based on the available data on adsorption desorption ($\log K_{oc} < 4$) and potentially P/vP based on the ready biodegradability test results. Most of the substances in the group are not readily biodegradable. All substances are also potentially toxic to aquatic environment based on self-classification and harmonised classification as Aquatic Chronic 2 (EC 423-740-1). In addition, a few substances are potentially bioaccumulative based on QSAR predictions (EC 422-310-9; EC 284-183-4; EC 423-740-1; EC 427-220-3; EC 600-592-6; EC 412-660-0). For some substances compliance checks are suggested to be opened to confirm hazard (EC 201-662-5; EC 423-740-1). However, no data generation to clarify persistency, mobility and/or toxicity is currently proposed for other substances due to their low exposure potential and/or low tonnage. If their registration status changes, data generation and potentially follow up actions will be re-considered when the assessment will be revisited.

In addition, 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. Therefore, it is proposed that there is currently no need for EU-wide regulatory risk management based on potential aquatic toxicity.

For industrial and professional uses, sufficient and consistent self-classification by registrants should require adequate risk management measures to be in place according to workplace legislation. Adequate product labelling should in principle provide consumers with sufficient information to manage risks arising from the use of mixtures containing skin sensitising substances. In addition, it is expected that following data generation registrants would adequately self-classify the substances and implement necessary RMMs to ensure safe use.

However, there is a concern related to skin sensitisers (potentially) present in consumer mixtures and the need to further investigate whether further regulatory actions are needed and what would be the best options to address this concern. Such concern has already been identified in other groups of substances and was brought for further discussion to Member States. Work is ongoing on this generic issue by both Member States and ECHA which may affect the regulatory actions on substances in this group.

Based on above, no EU regulatory risk management action is currently proposed for these substances due to low exposure potential. This is linked to the low tonnage and limitations of data generation requests to confirm severe hazards. 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. If the registration status changes for the non-registered substances and the substances subject to NONS registration, data generation and potentially follow up actions will be re-considered when the assessment will be revisited.

Therefore, no EU regulatory risk management action is currently proposed for these substances due to low hazard and exposure potential.

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
235-834-6 235-835-1 419-060-8	Known or potential hazard for skin sensitisation	Known or potential hazard for PBT/vPvB Known or potential hazard for aquatic toxicity	High potential for release to the environment and high exposure potential for workers and consumers: industrial and consumer uses in Washing and cleaning, Coatings and paints, thinners, paint removes, Paper and board treatment. Article service life in Paper, Plastic and Textile articles.	Need for EU RRM: Restriction <u>Justification:</u> Harmonised classification should provide adequate RMM for workers and include the substances under restriction proposal for skin sensitisers on textiles. Releases to the environment from consumer uses cannot be avoided. Potential exposure from articles needs further investigation, restriction for use in	First step: CCH Next steps (if hazard confirmed): CLH SVHC identification Restriction

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
				articles to be considered. Industrial uses to be considered as part of the restriction.	
201-662-5 412-660-0 422-580-8 423-460-8 237-492-3	No hazard or unlikely hazard	Known or potential hazard mobile and P/vP Known or potential hazard for aquatic toxicity	Wide-dispersive uses and high exposure potential for workers and consumers: industrial, professional and consumer uses as fragrance in washing and cleaning, biocidal, perfumes, fragrances, Air care products, Cosmetics, personal care products, Polishes and wax blends, Fuels, Finger paint, Fillers, putties, plasters, modelling clay, Coatings and paints, thinners, paint removes and intermediates. Article service life in Paper,	Currently no need for EU RRM <u>Justification:</u> Due to low tonnage no data generation is possible for the other substances to clarify the hazards currently. Actions (including data generation) will be re-considered when the assessment will be revisited if the registration status and/or uses change. Correct classification for aquatic toxicity is sufficient. After data generation registrants are expected to correctly self-classify.	CCH for 201-662-5 No action for the other substances

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
			polymer and textile articles		
217-552-5 299-682-2 407-870-4 423-740-1 482-160-5 482-300-5	Known or potential hazard for skin sensitisation except for EC 407-870-4	Known or potential hazard for aquatic toxicity	Wide-dispersive uses and high exposure potential for workers and consumers: industrial, professional and consumer uses as fragrance in Washing and cleaning, biocidal, perfumes, fragrances, Air care products, Cosmetics, personal care products, Polishes and wax blends, Fuels, Finger paint, Fillers, putties, plasters, modelling clay, Coatings and paints, thinners, paint removes paper and board and metal surface treatment.	Currently no need for EU RRM <u>Justification:</u> Low hazard, correct classification is sufficient. After data generation registrants are expected to correctly self-classify.	CCH for 423-740-1 Pending Action for EC 299-682-2 No action for the other substances
202-044-8 210-933-7	Known or potential hazard for reproductive toxicity and	Known or potential hazard mobile and P/vP	Low exposure potential. Only industrial intermediate uses	Currently no need for EU RRM <u>Justification:</u>	No action

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
	for ED	Known or potential hazard for aquatic toxicity Inconclusive hazard for ED		Only industrial intermediate uses with low exposure potential. Low tonnage so not possible to generate data.	
202-855-7 203-244-8 205-078-1 205-410-5 210-351-3 210-783-2 211-447-8 217-354-9 218-068-7 218-926-0 220-860-2 224-137-2 250-397-1 284-183-4 422-310-9 611-399-1 613-754-6 944-033-7	Known or potential hazard for carcinogenicity for EC 205-410-5 (from impurity) Known or potential hazard for reproductive toxicity and ED for EC 422-310-9, EC 220-860-2, EC 210-783-2, EC 210-351-3, and EC 427-220-3 Known or potential hazard for STOT RE for EC 220-860-2 and EC 422-310-9 Known or potential hazard for skin sensitisation for EC 624-372-4, EC	Known or potential hazard mobile and P/vP for EC 218-926-0 EC 205-078-1 EC 205-410-5 EC 217-354-9 EC 218-068-7 EC 250-397-1 EC 611-399-1 EC 284-183-4 EC 202-855-7 EC 203-244-8 EC 224-137-2 EC 422-310-9 EC 220-860-2 EC 210-351-3 EC 210-783-2 Known or potential hazard for aquatic toxicity for all Inconclusive hazard	Intermediate registrations or C&L notifications, no other uses and low exposure potential.	Currently no need for EU RRM <u>Justification:</u> According to the reported uses, low potential for exposure to both human health and environment is expected. Actions (including data generation) will be re-considered when the assessment will be revisited if the registration status and/or uses change.	No action

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
	613-754-6, EC 600-592-6, EC 687-584-6, EC 426-780-6, EC 944-033-7	for ED for EC 422-310-9, EC 220-860-2, EC 210-783-2, EC 210-351-3, and EC 427-220-3			

Annex 1: Overview of classifications

Data extracted on 03/05/2022

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
423-460-8	3508-98-3	2-phenylhexanenitrile	Acute Tox. 4 H302 Aquatic Chronic 2 H411	Acute Tox. 4 H302 Aquatic Chronic 2 H411	Aquatic Acute 1 H400 Aquatic Chronic 1 H410
801-876-4	3508-98-3	[No public or meaningful name is available]		-	Aquatic Chronic 2 H411 Acute Tox. 4 H302
201-662-5	86-29-3	diphenylacetone nitrile		Skin Irrit. 2 H315 STOT Single Exp. 3 H335, affected organs: Respiratory system Eye Irrit. 2 H319 Acute Tox. 3 H301 Aquatic Chronic 2 H411	STOT Single Exp. 3 H335 STOT Single Exp. 3 H335, affected organs: STOT Single Exp. 3 H335, affected organs: Respiratory tract Eye Irrit. 2A H319 Acute Tox. 5 H303 Aquatic Chronic 3 H412 Acute Tox. 4 H302
218-926-0	2286-54-6	3,3-diphenylpropionitrile		STOT Single Exp. 3 H335, affected organs: Respiratory system Eye Irrit. 2 H319 Skin Irrit. 2 H315	Acute Tox. 4 H332 Acute Tox. 4 H302 Acute Tox. 4 H312 STOT Single Exp. 3 H335
205-410-5	140-29-4	phenylacetone nitrile (benzyl cyanide)		Acute Tox. 1 H330 Acute Tox. 3 H301 Acute Tox. 3 H311	Acute Tox. 2 H330 STOT Single Exp. 3 H335, affected organs: Respiratory system Skin Irrit. 2 H315 Eye Irrit. 2 H319 Carc. 1B H350 Acute Tox. 4 H302
205-078-1	132-75-2	1-naphthylacetone nitrile		-	Eye Irrit. 2A H319 Acute Tox. 3 H331 Acute Tox. 4 H302 Acute Tox. 3 H301 STOT Single Exp. 3 H335, affected organs: Respiratory tract Acute Tox. 3 H311 Acute Tox. 4 H332 STOT Single Exp. 3 H335 Eye Irrit. 2 H319

					Acute Tox. 4 H312 Skin Irrit. 2 H315
211-447-8	645-59-0	3-phenylpropionitrile		-	STOT Single Exp. 3 H335 Eye Irrit. 2 H319 Acute Tox. 3 H301 Acute Tox. 4 H302 Acute Tox. 3 H311 Acute Tox. 3 H331 Skin Irrit. 2 H315
217-354-9	1823-91-2	2-phenylpropionitrile		STOT Single Exp. 3 H335 Skin Irrit. 2 H315 Acute Tox. 4 H312 Eye Irrit. 2 H319 Acute Tox. 4 H332 Acute Tox. 4 H302	Acute Tox. 3 H301 Acute Tox. 3 H311 Acute Tox. 3 H331 STOT Single Exp. 3 H335, affected organs: Respiratory tract Eye Irrit. 2A H319
218-068-7	2046-18-6	4-phenylbutyronitrile		Acute Tox. 4 H332 Acute Tox. 4 H302 Acute Tox. 4 H312	Skin Irrit. 2 H315 STOT Single Exp. 3 H335 Acute Tox. 3 H301 Eye Irrit. 2 H319
250-397-1	30932-41-3	2,2-diphenylcyclopropanecarbonitrile		Acute Tox. 4 H302	-
611-399-1	56536-96-0	611-399-1		-	STOT Single Exp. 3 H335, affected organs: Respiratory tract Acute Tox. 4 H312 Eye Irrit. 2 H319 Acute Tox. 4 H332 Skin Irrit. 2 H315 Acute Tox. 4 H302 Eye Irrit. 2A H319
284-183-4	84803-57-6	(4-tert-butyl-2,6-dimethylphenyl)acetonitrile		Aquatic Chronic 3 H412	Skin Irrit. 2 H315 Acute Tox. 4 H332 STOT Single Exp. 3 H335, affected organs: Respiratory tract Acute Tox. 4 H312 Acute Tox. 4 H302 Eye Irrit. 2A H319
412-660-0	134123-93-6	Fleuranil	-	Aquatic Chronic 2 H411	-
422-580-8	75490-39-0	Khusinil	-	Acute Tox. 4 H302	-

				Aquatic Chronic 2 H411	
801-874-3	75490-39-0	same as EC 422-580-8	Acute Tox. 4 Hazard Statement: H302 Aquatic Acute 1 Statement: H400 Aquatic Chronic 2 Statement: H411	-	Acute Tox. 4 H302 Aquatic Chronic 2 H411
226-257-0	5336-57-2	2-ethyl-2-phenylbutyronitrile		Acute Tox. 4 H302	Acute Tox. 3 H301
202-855-7	100-47-0	benzotrile	Acute Tox. 4 Hazard Statement: H302 Acute Tox. 4 Hazard Statement: H312	Acute Tox. 4 H302 Acute Tox. 4 H312	Skin Irrit. 2 H315
203-244-8	104-85-8	p-toluonitrile		Skin Irrit. 2 H315 Eye Irrit. 2 H319 STOT Single Exp. 3 H335, affected organs: lung	Resp. Sens. 1 H334 Skin Sens. 1 H317 STOT Single Exp. 2 H335 STOT Single Exp. 3 H335
224-137-2	4210-32-6	4-tert-butylbenzotrile		Aquatic Chronic 2 H411 Acute Tox. 4 H302	Acute Tox. 3 H311 Eye Irrit. 2 H319 Acute Tox. 4 H312 Acute Tox. 3 H301 Acute Tox. 3 H331 Acute Tox. 4 H332
237-492-3	13816-33-6	4-isopropylbenzotrile		Aquatic Chronic 2 H411	Eye Irrit. 2A H319 Skin Irrit. 2 H315] STOT Single Exp. 3 H335, affected organs: Respiratory tract Skin Sens. 1 H317 Eye Irrit. 2 H319 STOT Single Exp. 3 H335, affected organs: Sts Affected
422-310-9	11477-2-53-1	[1,1'-Biphenyl]-2-carbonitrile, 4'-methyl- Benzonitrile, 2-(4-methylphenyl)-		Repr. 2 H361 STOT Rep. Exp. 1 H372 STOT Rep. Exp. 1 H372, affected organs: various Acute Tox. 4 H302 Aquatic Chronic 1 H410 Aquatic Acute 1 H400 Repr. 2 H361,	Acute Tox. 4 H332 Acute Tox. 4 H312 Aquatic Chronic 2 H411 Eye Irrit. 2 H319 Skin Irrit. 2 H315

				specific effect: H361f: suspected of damaging fertility	
220-860-2	2920-38-9	p-phenylbenz onitrile		Aquatic Chronic 2 H411	Acute Tox. 4 H332 STOT Single Exp. 3 H335 Acute Tox. 4 H302 Skin Irrit. 2 H315 Acute Tox. 4 H312 Acute Tox. 3 H301 Eye Irrit. 2 H319
299-682-2	93893-89-1	3-methyl-5-phenylpent-2-enitrile		Acute Tox. 4 H302 Skin Sens. 1A H317 Aquatic Chronic 3 H412	Skin Sens. 1 H317 Acute Tox. 4 H332 Acute Tox. 4 H312
423-740-1	10461-98-0	423-740-1	Acute Tox. 4 Hazard Statement: H302 Aquatic Chronic 2 Statement: H411	Acute Tox. 4 H302 Aquatic Acute 1 H400 Aquatic Chronic 2 H411	Acute Tox. 3 H331
600-592-6				-	Aquatic Chronic 2 H411 Acute Tox. 4 H302
482-160-5	130786-09-3	(2Z)-2-phenylhex-2-enitrile; Benzeneace tonitrile, alpha-butylidene-, (Z)-		Acute Tox. 4 H302 Acute Tox. 4 H332 Skin Sens. 1B H317 Aquatic Chronic 2 H411	
217-552-5	1885-38-7	cinnamonitrile / cinnamyl nitrile		Acute Tox. 3 H301 Acute Tox. 4 H312 Skin Sens. 1 H317	Eye Irrit. 2 H319 Skin Sens. 1B H317 Acute Tox. 4 H332 STOT Single Exp. 3 H335 Acute Tox. 4 H302 Skin Irrit. 2 H315
482-300-5	916887-53-1	2-cyclohexylidene-2-(o-tolyl)acetonitrile		Skin Sens. 1B H317 Aquatic Chronic 2 H411	Skin Sens. 1 H317
613-754-6	6519-09-1	613-754-6		-	-
624-372-4	935-02-4			-	Acute Tox. 3 H311 Eye Irrit. 2 H319 Acute Tox. 3 H301

					Skin Irrit. 2 H315 Acute Tox. 3 H331
944-033-7		[No public or meaningful name is available]		Acute Tox. 4 H302 Aquatic Chronic 3 H412 Skin Sens. 1 H317	-
407-870-4	97384-48-0	2-benzyl-2-methyl-3-butenitrile CITROWAN IL B	-	Acute Tox. 4 H302 Aquatic Chronic 3 H412	-
687-584-6	97384-48-0	Same substance as EC 407-870-4	Acute Tox. 4 Hazard Statement: H302 Aquatic Chronic 3 Statement: H412	-	Acute Tox. 4 H302 Skin Irrit. 2 H315 Aquatic Chronic 3 H412
426-780-6	-	V159456		-	-
202-044-8	91-15-6	phthalonitrile		Acute Tox. 2 H300 Acute Tox. 3 H301 Acute Tox. 3 H311 Acute Tox. 3 H331 Aquatic Chronic 3 H412	STOT Single Exp. 1 H370, affected organs: Nervous System
210-351-3	613-73-0	o-phenylenediacetonitrile		Acute Tox. 4 H302	Acute Tox. 4 H332 Acute Tox. 3 H301 Skin Irrit. 2 H315 Acute Tox. 4 H312 Acute Tox. 3 H331 Eye Irrit. 2 H319 Acute Tox. 3 H311
210-783-2	623-26-7	terephthalonitrile		Eye Irrit. 2 H319 STOT Single Exp. 3 H335, affected organs: Damage to organs Skin Irrit. 2 H315	Eye Irrit. 2 H320 STOT Single Exp. 3 H335
210-933-7	626-17-5	benzene-1,3-dicarbonitrile		Acute Tox. 4 H302 Skin Sens. 1 H317 Aquatic Chronic 3 H412	Acute Tox. 4 H332 STOT Rep. Exp. 2 H373, affected organs: liver, kidney

427-220-3		427-220-3		-	Skin Irrit. 2 H315 Eye Irrit. 2 H319 Aquatic Chronic 4 H413
419-060-8	79026-02-1	3-(2-{4-[2-(4-cyanophenyl)vinyl]phenyl}vinyl)benz nitrile	Aquatic Chronic 4 Statement: H413	Aquatic Chronic 4 H413	-
235-834-6	13001-38-2	2-[2-[4-[2-(4-cyanophenyl)vinyl]phenyl]vinyl]benz nitrile		Aquatic Chronic 4 H413	Aquatic Chronic 3 H412
235-835-1	13001-39-3	2,2'-(p-phenylened iethene-2,1-diyl)bisbenz onitrile		Aquatic Chronic 4 H413	-

(*) 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 03/05/2022.

Main types of applications structured by product or article types	EC / List 201-662-5	EC / List 202-044-8	EC / List 210-933-7	EC / List 217-552-5	EC / List 235-834-6	EC / List 235-835-1	EC / List 237-492-3	EC / List 299-682-2	EC / List 407-870-4	EC / List 412-660-0	EC / List 419-060-8	EC / List 422-580-8	EC / List 423-460-8	EC / List 423-740-1	EC / List 482-160-5	EC / List 482-300-5
PC 35: Washing and cleaning products				I, P, C	F, C	F, I, C	I, P, C	I, P, C	I, P, C	I, P, C		I, P, C	I, C	F, I, P, C	P, C	F, I, P, C
PC 8: Biocidal products (e.g. disinfectants, pest control)				F, C			I, P, C	F, C	F, C	F, C		F, C	F, C	F, I, P, C	C	F, I, P, C
PC 28: Perfumes, fragrances				F, C			F, I, P, C	F, C	F, C	F, C		F, C	F, C	F, I, P, C	F	F, C
PC 3: Air care products				F, C			I, P, C	F, C	F, C	F, C		F, C	F, C	F, I, P, C	F, C	F, C
PC 39: Cosmetics, personal care products				F, P, C			I, P, C	F, P, C	F, P, C	F, P, C		F, C	F, C	I, P, C	F, C	P, C
PC 31: Polishes and wax blends				F, P, C			I, P, C	F, P, C	F, C	F, P, C		F, P, C	F, C	F, I, P, C	P, C	F, P, C
PC 13: Fuels							M, F, P, C							F, I, P, C		
PC 9c: Finger paint							F, C							F, C		
PC 9b: Fillers, putties, plasters, modelling clay							P, C							I, P, C		
PC 9a: Coatings and paints, thinners, paint removes					I	I	M, F, P, C							F, I, P, C		
PC 26: Paper and board treatment products					F, I, A	F, I, A						A		F, P		
PC 32: Polymer preparations and compounds						A*						A				
PC 34: Textile dyes, and impregnating products					F, I, A	F, I, A					F, I, A*	A*				

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

Data extracted on 29/03/2022.

EC entries	RMOA	Authorisation		Restriction	CLH	Actions not under REACH/ CLP*
		Candidate List	Annex XIV	Annex XVII	Annex VI (CLP)	
202-855-7					YES	
419-060-8					YES	REACH reg.
422-310-9						NONS, claimed
423-460-8					YES	NONS, claimed
423-740-1					YES	REACH reg.
426-780-6						NONS, claimed
427-220-3						NONS, not claimed
482-160-5						REACH reg.
482-300-5						NONS, no tpa upgr.
687-584-6					YES	
801-874-3					YES	

*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 and 40).

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