Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

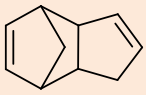
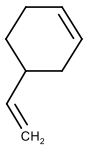
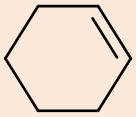
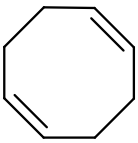
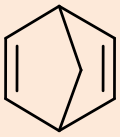
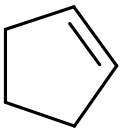
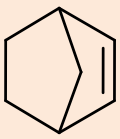
Group Name: Cycloalkenes of not-natural origin

General structure: -

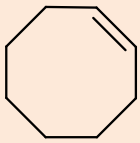
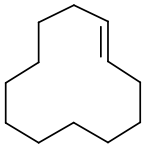
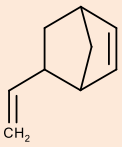
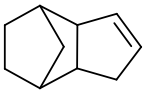
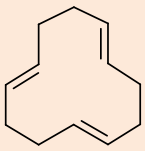
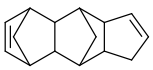
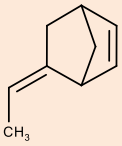
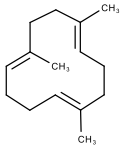
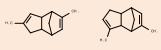
Revision history

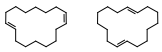
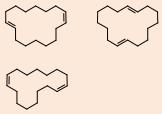
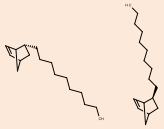
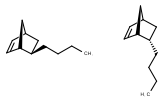
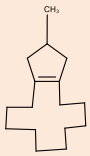
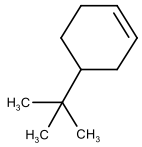
Version	*Date*	*Description*
1.0	1 March 2024	

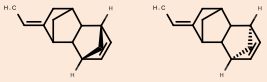
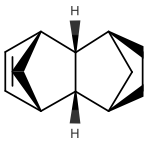
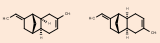
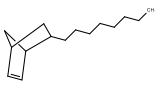
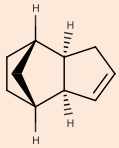
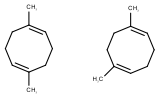
Substances within this group:

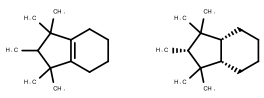
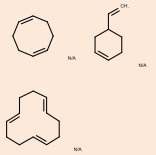
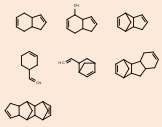
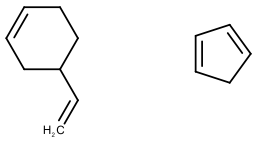
EC/List number	CAS number	Substance name [and/ or Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
201-052-9	77-73-6	3a,4,7,7a-tetrahydro-4,7-methanoindene		Full, >1000
202-848-9	100-40-3	4-vinylcyclohexene		OSII or TII
203-807-8	110-83-8	Cyclohexene		OSII or TII
203-907-1	111-78-4	Cycloocta-1,5-diene		Full, not (publicly) available
204-472-0	121-46-0	8,9,10-trinorborna-2,5-diene		Full, not (publicly) available
205-532-9	142-29-0	Cyclopentene		Full, not (publicly) available
207-866-0	498-66-8	8,9,10-trinorborn-2-ene		Full, not (publicly) available
208-835-4	542-92-7	Cyclopentadiene		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 [and/ or Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
213-243-4	931-87-3	(Z)-cyclooctene		Full, not (publicly) available
216-117-7	1501-82-2	Cyclododecene		OSII or TII
221-259-8	3048-64-4	5-vinylnorborn-2-ene		Full, 100-1000
224-778-8	4488-57-7	3a,4,5,6,7,7a-hexahydro-4,7-methano-1H-indene		Full, not (publicly) available
225-533-8	4904-61-4	Cyclododeca-1,5,9-triene		Full, not (publicly) available
230-512-1	7158-25-0	3a,4,4a,5,8,8a,9,9a-octahydro-4,9:5,8-dimethano-1H-benz[f]indene		Full, not (publicly) available
240-347-7	16219-75-3	5-ethylidene-8,9,10-trinorborn-2-ene		Full, >1000
244-218-6	21115-77-5	1,5,10-trimethylcyclododeca-1,5,9-triene		OSII or TII
247-724-5	26472-00-4	Methylcyclopentadiene		OSII or TII

EC/List number	CAS number	Substance name [and/ or Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
429-620-3	110028-14-3	cis-trans-cyclohexadeca-1,9-diene;reaction mass of: trans-trans-cyclohexadeca-1,9-diene		Not registered
431-730-1	4277-06-9	cyclohexadeca-1,9-diene		Full, not (publicly) available
435-000-3	22094-83-3	5-endo-hexyl-bicyclo[2.2.1]hept-2-ene		Not registered
435-040-1	192143-02-5	Bicyclo[2.2.1]hept-2-ene, decyl-		Not registered
435-180-3	-	5-exo-butyl-bicyclo[2.2.1]hept-2-ene (80:20);reaction mass of: 5-endo-butyl-bicyclo[2.2.1]hept-2-ene		Not registered
606-858-8	21890-09-5	1H-Cyclopentacyclododecene, 2,3,4,5,6,7,8,9,10,11,12,13-dodecahydro-2-methyl-		OSII or TII
606-973-3	2228-98-0	4-tert-butylcyclohex-1-ene		OSII or TII

EC/List number	CAS number	Substance name [and/ or Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
700-518-3	38233-76-0	1,4:5,8-Dimethanonaphthalene, 2-ethylidene-1,2,3,4,4a,5,8,8a-octahydro-		Full, not (publicly) available
700-678-4	1076-12-6	1,4:5,8-Dimethanonaphthalene, 1,2,3,4,4a,5,8,8a-octahydro-, (1R,4S,4aR,5S,8R,8aS)-rel-		Full, not (publicly) available
807-817-9	52690-72-9	Reaction mass of (1S,2E,4S,4aS,8aS)-2-ethylidene-7-methyl-1,2,3,4,4a,5,8,8a-octahydro-1,4-methanonaphthalene and (1S,2E,4S,4aS,8aS)-2-ethylidene-6-methyl-1,2,3,4,4a,5,8,8a-octahydro-1,4-methanonaphthalene		OSII or TII
814-965-8	22094-84-4	5-octylbicyclo[2.2.1]hept-2-ene		Full, not (publicly) available
838-154-3	3129-29-1	rel-(3aR,4R,7S,7aR)-3a,4,5,6,7,7a-hexahydro-1H-4,7-methanoindene		OSII or TII
911-597-0	-	Reaction mass of 1,5-Dimethylcycloocta-1,5-diene and 1,6-Dimethylcycloocta-1,5-die		OSII or TII
931-107-9	-	1,5,10-Trimethylcyclododeca-1,5,9-triene		Cease manufacture

EC/List number	CAS number	Substance name [and/ or Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
		with 1,5,9-trimethylcyclododeca-1,5,9-triene and 2-methyl-1,3-butadiene homopolymer		
939-655-0	-	Reaction mass of 2,3,4,5,6,7-hexahydro-1H-indene and (2s,3aR,7aS)-1,1,2,3,3-pentamethyloctahydro-1H-indene		OSII or TII
940-766-1	-	Reaction mass of 4-Vinylcyclohexene, Cyclododeca-1,5,9-triene (1Z,5E,9E) and Cycloocta-1,5-diene		OSII or TII
941-253-5	1689576-41-7	Cyclododecanone, reaction products with cyclized 3-chloro-2-methyl-1-propene		OSII or TII
948-406-5	-	5-ethylidene-8,9,10-trinorborn-2-ene, manufacture of, by-products from		Full, not (publicly) available
951-621-7	-	reaction mass of 4-vinylcyclohexene and 1,3-cyclopentadiene		OSII or TII

This table does not contain group members that are only notified under the CLP Regulation.

Contents

DISCLAIMER

The author does not accept any liability with regard to the use that may be made of the information contained in this document. Usage of the information remains under the sole responsibility of the user. Statements made or information contained in the document are without prejudice to any further regulatory work that ECHA, the Member States or other regulatory agencies may initiate at a later stage. Assessments of regulatory needs and their conclusions are compiled on the basis of available information and may change in light of newly available information or further assessment.

Foreword

The assessment of regulatory needs of a group of substances is an iterative, informal process to help authorities consider the most appropriate way to address an identified concern for a group of substances or a single substance and decide whether further regulatory risk management activities are necessary.

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

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

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

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

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

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

[3] Regarding hazard properties the focus is for instance on CMR (carcinogenic, mutagenic and/or toxic to reproduction), sensitiser, ED (endocrine disruptor), PBT/vPvB or equivalent (e.g. substances being persistent, mobile and toxic), aquatic toxicity hazard endpoints and therefore only those are reflected in the report. This does not mean that the substances do not have other known or potential hazards. In some specific cases, ECHA may consider additional hazards (e.g. neurotoxicity, STOT RE).

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

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

[4] https://echa.europa.eu/understanding-assessment-regulatory-needs

Glossary

ARN	Assessment of Regulatory Needs
CCH	Compliance Check
CLH	Harmonised classification and labelling
CMR	Carcinogenic, mutagenic and/or toxic to reproduction
DEv	Dossier evaluation
ED	Endocrine disruptor
NONS	Notified new substances
OEL	Occupational exposure limit
OSII or TII	On-site isolated intermediate or transported isolated intermediate
PBT/vPvB	Persistent, bioaccumulative and toxic / very persistent and very bioaccumulative
PMT/vPvM	Persistent, mobile, and toxic / very persistent and very mobile
RDT	Repeated dose toxicity
RMOA	Regulatory management options analysis
RRM	Regulatory risk management
SEv	Substance evaluation
STOT RE	Specific target organ toxicity, repeated exposure
SVHC	Substance of very high concern
TPE	Testing proposal evaluation

1 Overview of the group

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

ECHA has grouped together structurally similar substances based on the presence of the cycloalkene moieties and based on their not-natural origin.

There are 36 substances in the group of which 16 with full registrations, 15 with intermediate registration, 2 NONS and 3 with no active registration.

Based on information reported in the REACH registration dossiers, the substances of this group are used mainly in industrial sites as process regulator (e.g. in vulcanisation or polymerisation processes), intermediate (precursor), monomer, laboratory chemicals in the manufacture of other chemicals. Four substances (EC/List 201-052-9, 224-778-8, 230-512-1 and 814-965-8) have industrial and professional uses in polymer preparation and compounds. For two substances (EC/List 201-052-9 and 814-965-8) industrial, professional and consumer use in coatings and paints, thinners, paint removers are also reported. For one substance (EC 201-052-9) many other uses are reported, among which are polishes and wax blends; non-metal-surface treatment products; lubricants, greases; fuels; finger paint, fillers, putties, plasters, modelling clay; ink and toners; textile dyes, and impregnating products; leather treatment products.

Potential for exposure and release into the environment can be assumed for six substances having widespread professional uses (EC/List 201-052-9, 204-472-0, 205-532-9, 224-778-8, 230-512-1 and 814-965-8), out of which two substances having also consumer uses (EC 201-052-9 and 230-512-1), and one (EC 201-052-9) for which article service life in plastics or rubber, in clothing, other textiles, and footwear articles is reported or can be assumed. Two substances (List 700-518-3 and 700-678-4) are manufactured, polymerised outside the EU and only imported into the EU as reacted monomers of polymers and therefore there are no uses within the EU and potential for exposure and release into the environment can be considered negligible. All the other substances with full registrations within REACH have intermediate uses in industrial settings either in the manufacture of other chemicals or as monomers in the manufacture of polymers, with limited potential for exposure and release into the environment.

The substance EC 201-052-9 has undergone substance evaluation by the French CA, which concluded that CLH should be considered in order to revise the classification with regards to reprotoxicity and repeated dose toxicity following the completion of the ongoing data generation. In fact, with regards reproductive toxicity, including endocrine disruption properties, relevant data (90-day repeated dose toxicity study and two pre-natal developmental toxicity (PNDT) studies, followed by an extended one-generation reproductive toxicity study (EOGRTS))[5] is currently being generated under CCH.

[5] Substance evaluation conclusion document. ANSES, May 2022

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

EC/List no	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
201-052-9 207-866-0 240-347-7	Known or potential hazard for reproductive toxicity for ECs 201-052-9 and 207-866-0 for STOT RE for EC 240-347-7 and 201-052-9 for ED for all	Known or potential hazard for PMT/vPvM for ECs 207-866-0 and 240-347-7 for ED for all Inconclusive hazard for PBT/vPvB for ECs 201-052-9 and 207-866-0	Industrial, widespread professional and consumer use in polymer preparation, coatings and paints, and many other applications (e.g. polishes and wax blends, lubricants, greases, finger paint, fillers, putties, plasters, modelling clay, ink and toners, textile dyes, leather treatment products) for EC 201-052-9. ECs 207-866-0 and 240-347-7 have only	**First step:** CCH **Potential last action:** **CLH** <u>Justification</u>: Harmonised classification as Repr. 1B would lead to generic restriction of the substance EC 201-052-9 in consumer mixtures by means of restriction entry 30. The presence of the substances in clothing, other textiles, and footwear articles will be restricted by means of the restriction entry 72 of REACH Annex XVII. Harmonised classification as Repr. 1, ED, PMT/vPvM will require company level risk

EC/List no	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
			industrial use in polymer preparation and as intermediate. Potential for exposure and release into the environment can be assumed low for all the substances.	management for workers to be in place and for environment (minimisation of releases).
Full registrations: 205-532-9 203-907-1 213-243-4 221-259-8 225-533-8 431-730-1 700-678-4 700-518-3 948-406-5 Intermediates: 203-807-8 216-117-7 244-218-6 247-724-5 606-973-3 911-597-0 940-766-1 941-253-5	Known or potential hazard for reproductive toxicity for ECs/Lists 225-533-8, 202-848-9, 700-518-3, 948-406-5 for carcinogenicity EC 202-848-9, 225-533-8 and Lists 940-766-1, 948-406-5 and 951-621-7 for skin sensitisation Lists 700-678-4, 700-518-3, 814-965-8, 948-406-5 for STOT RE	Known or potential hazard for PBT/vPvB for all except 203-807-8, 205-532-9 and 221-259-8 Known or potential hazard for PMT/vPvM for ECs/Lists 203-807-8, 203-907-1, 205-532-9, 221-259-8, 940-766-1, 948-406-5	Fully registered substances have all industrial uses in the manufacture of other chemicals and as monomers in the manufacture of polymers. EC 205-532-9 is used in fuels in industrial and professional settings. List 814-965-8 is used by professional workers in adhesives, coatings and paints and metal surface treatment products. Lists 700-518-3 and 700-678-4 are both imported as	CCH for ECs/Lists 213-243-4, 221-259-8, 225-533-8, 431-730-1, 700-678-4, 700-518-3, 814-965-8. **Potential last action:** **Currently no need for EU RRM** Justification: Clarification of hazards will require relevant update of the registration dossiers and company level risk management measures (RMM) both for human health and the environment and communication on the safe use of the substance along the supply chain to be in place.

EC/List no	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
Not registered 429-620-3 435-040-1 435-180-3 931-107-9 (cease manufacture)	for EC 203-907-1 for ED for List 700-518-3		monomers in polymers. Limited potential for exposure and releases to the environment can be assumed based on reported information in the registration dossiers. All the others are intermediate registrations or not registered.	Harmonised/self-classification as skin sensitisers (will) require company level risk management measures (RMM) for workers to be in place. According to the reported uses, low potential for exposure to both human health and environment is expected. Actions may be re-considered if there is a change in the registration status and/or reported uses, when the assessment will be revisited.
Full registration: 814-965-8 Intermediates: 202-848-9 208-835-4 807-817-9 838-154-3 906-658-8 939-655-0 951-621-7 Not registered 435-000-3		Inconclusive hazard for PBT/vPvB except List 814-965-8 (unlikely PBT/vPvB and PMT/vPvM)		

EC/List no	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
204-472-0 224-778-8 230-512-1	Known or potential hazard for skin sensitisation except for EC 224-778-8	Inconclusive hazard for PBT/vPvB for ECs 204-472-0 and 224-778-8 Inconclusive hazard for PMT/vPvM for EC 230-512-1	Mainly industrial uses as process regulator, monomer in polymerisation processes, intermediate in the manufacture of other chemicals. Widespread professional use in polymer preparation and/or coatings and paints for ECs/Lists, 224-778-8, 230-512-1. Potential for exposure and release into the environment can be assumed.	CCH **Potential last action:** **Currently not possible to assess the regulatory needs** <u>Justification</u>: Data are not sufficient to conclude on PBT/vPvB or PMT/vPvM hazards.

3 Justification for the (no) need for regulatory risk management action at EU level (if hazards confirmed)

Group level hazard conclusions

Based on ECHA's assessment of hazard information currently available in the registration dossiers, potential or known hazards were identified for human health and for the environment for several of the group members. However, no group-level extrapolations could be performed due to structural heterogeneity and low data density. When extrapolation of hazard findings was considered possible, on a case by case basis, it has been indicated in the relevant texts below.

In total 18 substances (EC/List 203-907-1, 213-243-4, 225-533-8, 216-117-7, 940-766-1, 244-218-6, 931-107-9, 700-678-4, 700-518-3, 948-406-5, 435-180-3, 435-040-1, 247-724-5, 431-730-1, 429-620-3, 911-597-0, 606-858-8 and 941-253-5) fulfil the PBT/vPvB screening criteria[6] and are considered **potential PBT/vPvB** substances.

These substances are potentially P/vP as they are either not readily biodegradable (*i.e.,* <60/70% degradation) based on experimental data or on subgroup level extrapolation from structurally similar substances.

They are potentially B/vB as they have a high potential to partition to lipid storage (log Kow > 4.5), BCF data higher than 2000 or based on subgroup level extrapolation from structurally similar substances. Furthermore, these substances potentially meet the T criteria because they either fulfil the T human health criterion (self-classification as toxic to reproduction or mutagenicity), show high toxicity in acute toxicity tests (and lack information on long term toxicity), show high toxicity in both acute and long term tests or they are extrapolated to have high toxicity potency based on structural similarity to substances that are potentially meeting the T criteria.

Nine substances (EC/List 205-532-9, 203-907-1, 203-807-8, 940-766-1, 201-052-9, 221-259-8, 948-406-5, 207-866-0 and 240-347-7) in the group are **potentially PMT/vPvM**: the substances are not readily biodegradable (EC/List 205-532-9, 203-907-1, 203-807-8, 940-766-1, 948-406-5 and 207-866-0 do not degrade or have very low degradation in tests according OECD 301 and for EC 240-347-7 the method is not specified, EC 201-052-9 and 221-259-8 are considered not readily biodegradable based on group level extrapolation) and are potentially persistent, are mobile in the environment based on the log Koc <3 or log Kow < 4.5 and are potential T based on health hazards (EC 207-866-0, 940-766-1, 201-052-9, 948-406-5: Repro 2 and EC 240-347-7, 203-907-1, 221-259-8: STOT RE 2).

The remaining substances of the group (except for List 814-965-8) fulfil the P/vP screening criteria based on the fact that they are either not readily biodegradable in experimental data or based on group level extrapolation. However, for all those substances it is not possible to conclude on the potential for bioaccumulation and

[6] 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

mobility.

For List 814-965-8 PBT/vPvB and PMT/vPvM hazards are considered unlikely based on the available data.

Endocrine disrupting hazard for the environment is discussed below together with the human health hazards.

Potential for **carcinogenicity** is observed for several group members. EC 202-848-9 has a harmonised classification Carc 2. EC/List 225-533-8, 951-621-7, 940-766-1 and 948-406-5 all contain EC 202-848-9 and are all self-classified Carc 2 (except for List 951-621-7 which is self classified Carc 1A). EC 247-724-5 is also self-classified Carc. 2.

Potential for **mutagenicity** is observed for several group members. List 951-621-7 is self classified Muta. 1B based on the presence of constituents or impurities with harmonised classification as Muta. 1B, List 700-518-3 is self classified Muta 2 based only on a positive *in vitro* mammalian gene mutation assay. Based on the information available on composition provided in (some) registration dossiers List 931-107-9 contains as constituent or impurity a substance with harmonised classification as Muta. 1B at concentrations potentially above the generic concentration limit for Muta. 1B under the CLP Regulation, justifying the classification of the substance. Such classification is however not applied. Most substances in the group are unlikely to have the mutagenicity human health hazard, as shown by negative data for mutagenicity or do not have sufficient data to conclude on this hazard.No extrapolation of hazard can be made to these group members due to the considerable structural heterogeneity.

Potential for **reproductive/developmental toxicity** is observed for several group members. Studies are available that may warrant Repr. 1B or 2 for EC 202-848-9 (reduced ovarian follicles and abnormal estrus cyclicity). EC 201-052-9 is self-classified Repr. 2, but the effects may warrant Repr. 1B (reduction in live births, pup survival and pup weight). EC 207-866-0 is self-classified Repr. 2 based on pup weight reduction. List 700-518-3 is self-classified as Repr. 2 based on several adverse effects (reduced maternal weight gain and abnormal estrus cyclicity. Lower seminal vesicle weights. Reduced numbers of implantations and subsequent litter size). No studies with the remaining substances of the group were available. EC 225-533-8, Lists 940-766-1 and 948-406-5 are also self-classified as Repr. 2.

Potential for **ED hazard** (both for **human health** and for the **environment**) is observed for five substances, however it was not possible to conclude on the **ED** hazard of the group as a whole, as the information available on the substances is insufficient to get a holistic view. Potential ED effects were observed specifically for EC 202-848-9 (ovary effects, potential Repr.), EC 240-347-7 (reduced weight of testes and epididymides), EC 201-052-9 (thyroid effects, potential Repr.), and list no 700-518-3 (seminal weight decrease, potential Repr.). EC 207-866-0 is considered potential ED due to the Repr. consideration above. In contrast, no notable ED indications were noted in the studies with the other group members.

The available information indicates potential **STOT RE** for several group members. EC 240-347-7 (liver) and EC 201-052-9 (central nervous system, CNS) are self classified STOT RE 2, based on the observed adverse effects. OECD TG 408 and 414 studies with EC 201-052-9 showed effects that may warrant classification as STOT RE and/or STOT SE. Results potentially warranting a STOT RE classification were observed with EC 203-907-1 (minimal to mild degeneration or necrosis of nasal olfactory epithelium). For the remaining substances available RDT studies showed no notable adverse effects or no studies were available. Of these substances without RDT data, List 951-621-7, List 948-406-5, and List 931-107-9, EC 221-259-8 were self-classified STOT RE 2 based on constituents, impurities or

on read-across data.

Potential for **skin sensitisation** is observed for many substances of the group. ECs 431-730-1 and 429-620-3 have harmonised classification as Skin sens 1. ECs/Lists 201-052-9, 204-472-0, 221-259-8, 230-512-1, 240-347-7, 700-678-4, 700-518-3, 814-965-8, 948-406-5, 951-621-7 are self classified (see Annex 1).

Suggested regulatory risk management action (CLH) for substances EC 201-052-9, 207-866-0 and 240-347-7 for reproductive toxicity, ED (human health and environment), STOT RE and/or PMT/vPvM hazards, should the hazards exist.

Based on currently available information, there is a potential hazard for reproductive toxicity, ED hazard (human health and environment) for the substances Es 201-052-9, 207-866-0 and 240-347-7. The substances EC 207-866-0 and 240-347-7 show also potential PMT/vPvM hazard. The substances EC 207-866-0 and 201-052-9 show also potential STOT RE hazard.

The substances EC 207-866-0 and 240-347-7 have only industrial use in polymer preparation and as intermediate, thus potential for release into the environment is assumed to be low.

The substance EC 201-052-9 has a wide variety of uses reported in the registration dossier, mainly due to the use of polymers made from it which are integrated in mixtures and used in the production of a wide range of articles (including elastomers, paints, varnishes, flame retardants, plasticisers, resins, adhesives, inks, textile and leather treatment, etc). The potential for exposure and release from mixtures and articles is not intentional nor expected in significant amounts, as it is consumed during the process of polymer synthesis. However, unreacted monomer may remain as residues in the polymers and thus in the mixtures and articles, and exposure to this residual monomer may be possible during the use of the mixtures and the service life of the articles. Furthermore, hazardous impurities were identified in the registered compositions of the substance and are expected in this type of substance due to its manufacturing process. These impurities may remain in the polymers and may be released during the use of the mixtures and the service life of the articles, which would lead to workers exposure. The substance is not intended to be used by consumers. Therefore, no direct (primary) exposure of consumers is expected.
The registrants are invited to update their registration dossiers when appropriate, taking into account all the mentioned aspects.

The first regulatory risk management action proposed, should the hazards exist, is the confirmation of hazard via harmonised classification (CLH) as reprotoxic and ED (HH and ENV) for the three substances, as STOT RE (for ECs 207-866-0 and 201-052-9), and as PMT/vPvM (for ECs 207-866-0, 240-347-7). The clarification of some of the hazards may take longer than others and there may be the need to consider whether to initiate the CLH process to cover only some of the potential hazards where relevant.

CLH i) will require company level risk management measures (RMM) for workers and for the environment to be in place, and ii) is a prerequisite to restrict the presence of the substance EC 201-052-9 in consumer mixtures, by means of the restriction entries 30. CLH is also a prerequisite to restrict the presence of the substance EC 201-052-9 in clothing, other textiles, and footwear articles, by means of the restriction entry 72 of REACH Annex XVII (this would require addition of the relevant substances to Appendix 12 by the Commission through Article 68(2)).

Given the considerations on the expected limited potential for exposure and release for the three substances, CLH is considered sufficient at this stage as proposed last regulatory action. It is worth noting however that the strategy may need to be revised and further regulatory action reconsidered, once the data generation will be concluded and if further information will become available following update of registration dossier for any of these substances. With regard to the potential for skin sensitisation for the substances ECs 201-052-9 and 240-052-9, for industrial and professional uses of the substances sufficient and consistent self-classification by registrants should require company level risk management measures (RMM) to be in place for workers.

Adequate product labelling should in principle provide consumers with sufficient information to manage risks for skin sensitisation arising from the use of mixtures containing the substance EC 201-052-9. However, there is a concern related to the substance 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.

Currently no need to suggest (further) regulatory risk management actions for the substances EC/List 202-848-9, 203-807-8, 203-907-1, 205-532-9, 208-835-4, 213-243-4, 216-117-7, 221-259-8, 225-533-8, 244-218-6, 247-724-5, 431-730-1, 429-620-3, 435-000-3, 435-040-1, 435-180-3, 606-858-8, 700-678-4, 700-518-3, 807-817-9, 814-965-8, 838-154-3, 911-597-0, 931-107-9, 939-655-0, 940-766-1, 941-253-5, 948-406-5 and 951-621-7.

The substances EC 203-907-1, 205-532-9, 213-243-4, 221-259-8, 225-533-8 and 431-730-1 which have a full registration within REACH have all reported intermediate uses in industrial settings either in the manufacture of other chemicals or as monomers in the manufacture of polymers. The substance EC 205-532-9 has industrial and professional use reported in fuels, but minimal release is expected.

The substances List 700-518-3 and 700-678-4 are both imported as monomer in polymers, List 948-406-5 is only manufactured, EC/List 244-218-6, 216-117-7, 247-724-5, 606-858-8, 911-597-0, 940-766-1 and 941-253-5 have only intermediate registrations. Based on the information available in the registration dossiers, for these substances no or very limited potential for exposure and releases to the environment from such industrial uses can be assumed.

The substances are all potential PBT/vPvB, as explained above, but low exposure and release in the environment is anticipated and therefore it is considered that currently there is no need for further EU RMM for them.

The substances EC/List 202-848-9, 203-807-8, 208-835-4, 606-973-3, 807-817-9, 838-154-3, 939-655-0 and 951-621-7 have only intermediate registrations, thus the potential for exposure and release is anticipated to be low. They have all inconclusive PBT/vPvB and or inconclusive PMT/vPvM hazards, as explained above, but due to the low exposure and release potential no EU regulatory risk management action is currently proposed for them.

The substance List 814-965-8 is unlikely PBT/vPvB and or PMT/vPvM and it is not possible to conclude on other hazards due to fata gaps. However, due to low

tonnages it is not possible to generate data and clarify the potential hazards for them.

Similarly, the substances EC 429-620-3, 435-040-1, 435-180-3 and 435-000-3 are not registered and for List 931-107-9 the manufacture was ceased, thus it is not possible to clarify the potential hazards for them. Therefore, it is proposed that there is currently no need for EU RRM action on these substances.

With regards to the potential for skin sensitisation for the substances Lists 700-678-4, 700-518-3, 814-965-8, 948-406-5, for industrial and professional uses, sufficient and consistent self-classification by registrants should require company level risk management measures (RMM) to be in place for workers.
Therefore, it is proposed that there is currently no need for EU-wide regulatory risk management.

It is worth noting however that the strategy may need to be revisited and need for data generation and potentially follow-up regulatory action reconsidered if there is a change in the registration status or reported uses for any of these substances.

Currently not possible to suggest regulatory risk management actions for the substances EC 204-472-0, 224-778-8 and 230-512-1.

Due to inconclusive PBT/vPvB and or inconclusive PMT/vPvM hazards for the substances above, it is currently not possible to suggest regulatory risk management for the substances, until data generation will clarify the hazards.

Data generation through compliance check is proposed for clarifying hazard of the following group members with active REACH registration: EC/List 201-052-9, 204-472-0, 207-866-0, 213-243-4, 221-259-8, 224-778-8, 225-533-8, 230-512-1, 240-347-7, 431-730-1, 700-678-4, 700-518-3 and 814-965-8.

Annex 1: Overview of classifications

Data extracted on 11.04.2023

EC/List Number	CAS Number	Substance Name	Harmonised classification	Classification in registrations
201-052-9	77-73-6	3a,4,7,7a-tetrahydro-4,7-methanoindene	Index number: 601-044-00-9 Acute Tox. 4 Hazard Statement: H302 (Minimum classification) Hazard Category: Skin Irrit. 2 Hazard Statement: H315 Flam. Liq. 2 Hazard Statement: H225 Hazard Category: Eye Irrit. 2 Hazard Statement: H319 STOT SE 3 Hazard Statement: H335 Acute Tox. 4 Hazard Statement: H332 (Minimum classification) Aquatic Chronic 2 Statement: H411	Repr. 2 H361 Flam. Liquid 3 H226 Flam. Liquid 2 H225 Flam. Solid 1 H228 Acute Tox. 4 H302 Acute Tox. 4 H332 Acute Tox. 2 H330 Skin Irrit. 2 H315 Eye Irrit. 2 H319 Skin Sens. 1B H317 Asp. Tox. 1 H304 STOT Rep. Exp. 2 H373, affected system: central nervous system STOT Single Exp. 3 H335, affected organs: respiratory tract Aquatic Acute 1 H400 STOT Single Exp. 3 H335, affected organs: Respiratory tract Aquatic Chronic 2 H411
202-848-9	100-40-3	4-vinylcyclohexene	Index number: 601-088-00-9 Carc. 2 Hazard Statement: H351	Asp. Tox. 1 H304 Carc. 2 H351 Flam. Liquid 2 H225 Skin Irrit. 2 H315 Aquatic Chronic 3 H412

203-807-8	110-83-8	cyclohexene	-	Asp. Tox. 1 H304 Flam. Liquid 2 H225 Acute Tox. 4 H302 Aquatic Chronic 2 H411
203-907-1	111-78-4	cycloocta-1,5-diene	-	Flam. Liquid 3 H226 Acute Tox. 4 H302 Acute Tox. 4 H332 Asp. Tox. 1 H304 Aquatic Chronic 2 H411
204-472-0	121-46-0	8,9,10-trinorborna-2,5-diene	-	Skin Corr. 1 H314 Skin Sens. 1 H317 Eye Damage 1 H318
205-532-9	142-29-0	cyclopentene	-	Flam. Liquid 2 H225 Acute Tox. 4 H302 Acute Tox. 4 H312 Skin Irrit. 2 H315 Asp. Tox. 1 H304 Eye Irrit. 2 H319 Acute Tox. 4 H332
207-866-0	498-66-8	8,9,10-trinorborn-2-ene	-	Repr. 2 H361, specific effect:fetal body weight reduction Flam. Solid 2 H228 Eye Irrit. 2 H319 Aquatic Chronic 2 H411
208-835-4	542-92-7	cyclopentadiene	-	STOT Single Exp. 3 H335, affected organs: Respiratory tract Eye Irrit. 2 H319 Skin Irrit. 2 H315 Flam. Liquid 3 H226 Acute Tox. 3 H301 Acute Tox. 3 H311
213-243-4	931-87-3	(Z)-cyclooctene	-	Flam. Liquid 3 H226 Asp. Tox. 1 H304 Aquatic Chronic 1 H410
216-117-7	1501-82-2	cyclododecene	-	Asp. Tox. 1 H304

221-259-8	3048-64-4	5-vinylnorborn-2-ene	-	Flam. Liquid 2 H225 Skin Sens. 1B H317, specific concentration: >3 Asp. Tox. 1 H304 STOT Rep. Exp. 2 H373 Aquatic Chronic 2 H411
224-778-8	4488-57-7	3a,4,5,6,7,7a-hexahydro-4,7-methano-1H-indene	-	Flam. Liquid 3 H226 Acute Tox. 4 H302 Acute Tox. 3 H331 Skin Irrit. 2 H315 Eye Irrit. 2 H319 STOT Single Exp. 3 H335, affected organs: respiratory tract Aquatic Chronic 2 H411
225-533-8	4904-61-4	cyclododeca-1,5,9-triene	-	Asp. Tox. 1 H304 Aquatic Acute 1 H400 Aquatic Chronic 1 H410 Carc. 2 H351 Repr. 2 H361 Flam. Liquid 3 H226 Skin Irrit. 2 H315
230-512-1	7158-25-0	3a,4,4a,5,8,8a,9,9a-octahydro-4,9:5,8-dimethano-1H-benz[f]indene	-	Skin Sens. 1 H317
240-347-7	16219-75-3	5-ethylidene-8,9,10-trinorborn-2-ene	-	Flam. Liquid 3 H226 Acute Tox. 4 H332 Skin Irrit. 2 H315 Skin Sens. 1B H317, specific concentration: >3 Asp. Tox. 1 H304 STOT Rep. Exp. 2 H373, affected organs: liver, testes Aquatic Chronic 2 H411
244-218-6	21115-77-5	1,5,10-trimethylcyclododeca-1,5,9-triene	-	Skin Irrit. 2 H315 Aquatic Chronic 1 H410

247-724-5	26472-00-4	methylcyclopentadiene	-	Carc. 1A H350 Aquatic Acute 1 H400 Eye Irrit. 2 H319 Skin Irrit. 2 H315 Asp. Tox. 1 H304 Flam. Liquid 3 H226 Aquatic Chronic 1 H410 Acute Tox. 4 H332 Muta. 1B H340
429-620-3	110028-14-3	cis-trans-cyclohexadeca-1,9-diene;reaction mass of: trans-trans-cyclohexadeca-1,9-diene	Aquatic Chronic 4 H413 Skin Irrit. 2 H315 Skin Sens. 1 H317	-
431-730-1	-	cyclohexadeca-1,9-diene	Skin Irrit. 2 H315 Skin Sens. 1 H317 Aquatic Chronic 4 H413	Skin Irrit. 2 H315 Skin Sens. 1 H317 Aquatic Chronic 4 H413
435-000-3	22094-83-3	5-endo-hexyl-bicyclo[2.2.1]hept-2-ene	Skin Irrit. 2 H315 Asp. Tox. 1 H304 Aquatic Chronic 4 H413	-
435-180-3	-	5-exo-butyl-bicyclo[2.2.1]hept-2-ene (80:20);reaction mass of: 5-endo-butyl-bicyclo[2.2.1]hept-2-ene	Asp. Tox. 1 H304 Aquatic Acute 1 H400 Aquatic Chronic 1 H410	-
435-040-1	-	Bicyclo[2.2.1]hept-2-ene, decyl-	-	-
606-858-8	21890-09-5	2-methyl-2,3,4,5,6,7,8,9,10,11,12,13-dodecahydro-1H-cyclopentacyclododecene	-	-
606-973-3	2228-98-0	606-973-3	-	Aquatic Chronic 1 H410 Skin Irrit. 2 H315 Aquatic Acute 1 H400

700-518-3	-	Reaction mass of (1R, 2S, 5R, 6S, 7S, 10S)-8-(E)-ethylidene-tetracyclo[4.4.0.1^2,5.1^7,10]-3-dodecene and (1R, 2S, 5R, 6S, 7S, 10S)-8-(Z)-ethylidene-tetracyclo[4.4.0.1^2,5.1^7,10]-3-dodecene	-	Muta. 2 H341 Repr. 2 H361 Acute Tox. 4 H302 Skin Irrit. 2 H315 Skin Sens. 1 H317 Aquatic Acute 1 H400, M-factor: 10.00 Aquatic Chronic 1 H410, M-factor: 10.00
700-678-4	-	(1S,4R,4aR,5S,8R,8aS)-1,2,3,4,4a,5,8,8a-Octahydro-1,4:5,8-dimethanonaphthalene	-	Skin Irrit. 2 H315 Skin Sens. 1B H317 Aquatic Acute 1 H400 Aquatic Chronic 1 H410 Acute Tox. 4 H302
807-817-9	52690-72-9	807-817-9	-	-
814-965-8	22094-84-4	5-octylbicyclo[2.2.1]hept-2-ene	-	Skin Sens. 1B H317
838-154-3	3129-29-1	(3aR,4R,7S,7aR)-3a,4,5,6,7,7a-hexahydro-1H-4,7-methanoindene	-	Aquatic Chronic 1 H410 Flam. Liquid 3 H226 Skin Irrit. 2 H315 Eye Irrit. 2 H319
911-597-0	-	Reaction mass of 1,5-dimethylcycloocta-1,5-diene and 1,6-dimethylcycloocta-1,5-diene	-	STOT Single Exp. 3 H335, affected organs: Respiratory irritant effects Skin Irrit. 2 H315 Eye Irrit. 2 H319 Flam. Liquid 3 H226
931-107-9	-	Reaction mass of 1,5,9-trimethylcyclododeca-1,5,9-triene and 1,5,10-trimethylcyclododeca-1,5,9-triene and 618-362-9	-	STOT Rep. Exp. 2 H373 Aquatic Chronic 1 H410 Skin Irrit. 2 H315 Asp. Tox. 1 H304

939-655-0	-	Reaction mass of 2,3,4,5,6,7-hexahydro-1,1,2,3,3-pentamethyl-1H-indene and (2s,3aR,7aS)-1,1,2,3,3-pentamethyloctahydro-1H-indene	-	-
940-766-1	-	Reaction mass of (1Z,5E,9E)-cyclododeca-1,5,9-triene and cycloocta-1,5-diene and 4-vinylcyclohexene	-	Repr. 2 H361, specific effect:unborn child Aquatic Chronic 1 H410 Skin Irrit. 2 H315 Asp. Tox. 1 H304 Carc. 2 H351 Acute Tox. 4 H332 Flam. Liquid 3 H226 Aquatic Acute 1 H400
941-253-5	-	Cyclisation products from pyrolysis of 2-(2-methylprop-2-en-1-yl)cyclododecanone	-	Aquatic Chronic 1 H410 Skin Sens. 1A H317 Aquatic Acute 1 H400
948-406-5	-	By-products from the manufacture of 5-ethylidene-8,9,10-trinorborn-2-ene	-	Carc. 2 H351 Repr. 2 H361 Flam. Liquid 2 H225 Flam. Liquid 3 H226 Acute Tox. 3 H331 Skin Irrit. 2 H315 Eye Irrit. 2 H319 Skin Sens. 1 H317, specific concentration: >=3 Asp. Tox. 1 H304 STOT Rep. Exp. 2 H373 STOT Single Exp. 3 H335, affected organs: lungs Aquatic Acute 1 H400, M-factor: 10.00 Aquatic Chronic 1 H410, M-factor: 10.00

951-621-7	-	Reaction mass of 4-vinylcyclohexene and cyclopentadiene	-	Acute Tox. 4 H302 Flam. Liquid 2 H225 Acute Tox. 4 H332 Skin Sens. 1 H317 Aquatic Chronic 3 H412 STOT Rep. Exp. 2 H373 Eye Irrit. 2 H319 Muta. 1B H340 Asp. Tox. 1 H304 Carc. 1A H350 Skin Irrit. 2 H315

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

Data extracted on 11.04.2023

Main types of applications structured by product or article types	EC 201-052-9	EC 203-907-1	EC 204-472-0	EC 205-532-9	EC 207-866-0	EC 213-243-4	EC 221-259-8	EC 224-778-8	EC 225-533-8	EC 230-512-1	EC 240-347-7	EC 431-730-1	List 814-965-8
PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents	I, **P**		I, **P**										
PC 2: Adsorbents									I				
PC 4: Anti-freeze and de-icing products	**C**												
PC 31: Polishes and wax blends	**C**												
PC 15: Non-metal-surface treatment products	**P**, **C**												

Main types of applications structured by product or article types	EC 201-052-9	EC 203-907-1	EC 204-472-0	EC 205-532-9	EC 207-866-0	EC 213-243-4	EC 221-259-8	EC 224-778-8	EC 225-533-8	EC 230-512-1	EC 240-347-7	EC 431-730-1	List 814-965-8
PC 24: Lubricants, greases, release products	**C**												
PC 13: Fuels				I, **P**									
PC 32: Polymer preparations and compounds	F, I, **P**, **C**, **A**				I		I	I, **P**		F, I, **P**, **C**	I		F, I, **P**
PC 1: Adhesives, sealants	I, **C**												**P**
PC 9c: Finger paint	**C**												
PC 9b: Fillers, putties, plasters, modelling clay	**C**												
PC 9a: Coatings and paints, thinners, paint removes	**C**												F, I, **P**
PC 18: Ink and toners	I, **C**												
PC 34: Textile dyes, and impregnating	**C, A***												

Main types of applications structured by product or article types	EC 201-052-9	EC 203-907-1	EC 204-472-0	EC 205-532-9	EC 207-866-0	EC 213-243-4	EC 221-259-8	EC 224-778-8	EC 225-533-8	EC 230-512-1	EC 240-347-7	EC 431-730-1	List 814-965-8
products													
PC 23: Leather treatment products	**C, A***												
PC 14: Metal surface treatment products													**P**
PC 33: Semiconductors			F, I										
PC 21: Laboratory chemicals	F, I, **P**		F, I, **P**	I									
PC 19: Intermediate	I	I		I	I	I	I	I	I		I	I	

F: formulation, I: industrial use, P: professional use, C: consumer use, A: article service life; P, C and A are highlighted in red to indicate widespread use with potential for exposure/release. A* is not reported in the registrations but assumed by using expert judgement.

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

Data extracted on 20.04.2023

EC/List number	Restriction*	CLH	Actions not under REACH/ CLP*
	Annex XVII	Annex VI (CLP)	
201-052-9		YES	
202-848-9		YES	prohibited in cosmetic products' regulation (EC No 1223/2009, Annex II)
207-866-0			Union list of monomers and other substances authorised to be used in the manufacture of food contact plastics (EU No 10/2011, Annex I)
240-347-7			Union list of monomers and other substances authorised to be used in the manufacture of food contact plastics (EU No 10/2011, Annex I)
429-620-3		YES	
431-730-1		YES	
435-000-3		YES	
435-180-3		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, 40, 75).

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