

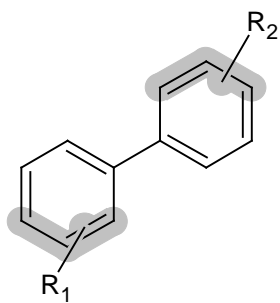
Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Group Name: Polyphenyls and its partially hydrogenated derivatives

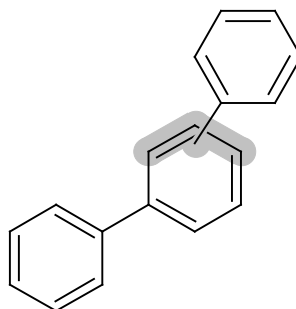
General structure:

Sub-group 1: Biphenyls

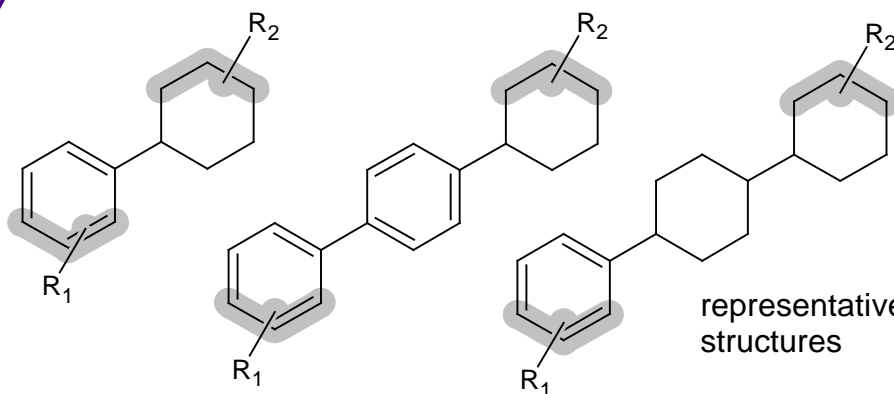


$R_1, R_2 = \text{H, alkyl, alkenyl}$

Sub-group 3: Terphenyls



Sub-group 3: Partially hydrogenated polyphenyls



representative structures

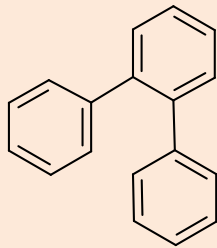
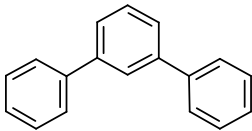
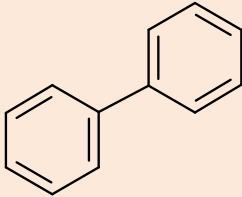
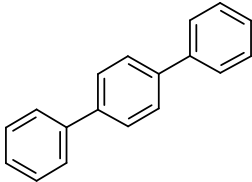
$R_1, R_2 = \text{H, alkyl, alkenyl}$

Revision history

<i>Version</i>	<i>Date</i>	<i>Description</i>
1.0	7 September 2023	

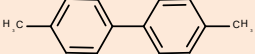
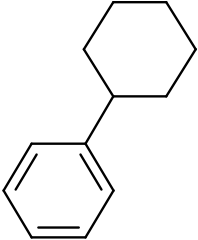
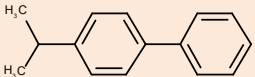
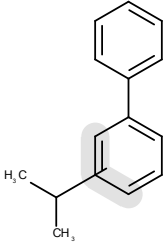
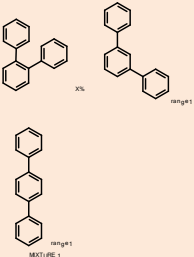
ASSESSMENT OF REGULATORY NEEDS

Substances within this group:

EC/List number	CAS number	Substance name [and/ Substance acronyms]	Chemical structures or name	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) ¹
201-517-6	84-15-1	o-terphenyl		C&L notification
202-122-1	92-06-8	m-terphenyl		C&L notification
202-163-5	92-52-4	Biphenyl		Full, >1000
202-205-2	92-94-4	p-terphenyl		C&L notification

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>

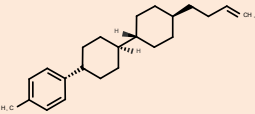
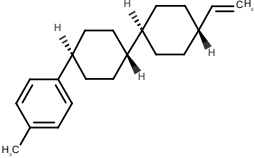
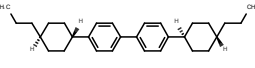
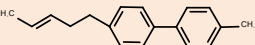
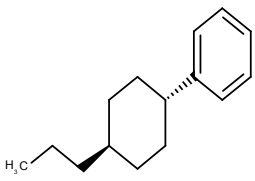
ASSESSMENT OF REGULATORY NEEDS

EC/List number	CAS number	Substance name [and/ Substance acronyms]	Chemical structures or name	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) ¹
210-337-7	613-33-2	4,4'-dimethylbiphenyl		OSII or TII
212-572-0	827-52-1	Cyclohexylbenzene		Full, 10-100
230-420-1	7116-95-2	4-isopropylbiphenyl		Not registered
247-156-8	25640-78-2	(1-methylethyl)-1,1'-biphenyl		Full, not (publicly) available
247-477-3	26140-60-3	Terphenyl		C&L notification

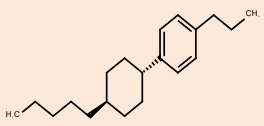
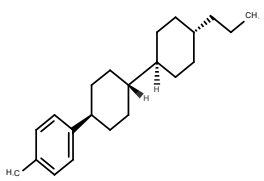
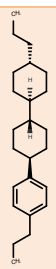
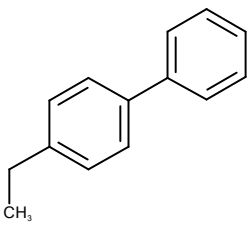
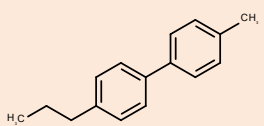
ASSESSMENT OF REGULATORY NEEDS

EC/List number	CAS number	Substance name [and/ Substance acronyms] or name	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) ¹
249-525-9	29225-91-0	Tris(1-methylethyl)-1,1'-biphenyl	No Structure	C&L notification
262-967-7	61788-32-7	Terphenyl, hydrogenated [PHT]		Full, >1000
273-316-1	68956-74-1	Polyphenyls, quater- and higher, partially hydrogenated	No Structure	C&L notification
273-683-8	69009-90-1	Diisopropyl-1,1'-biphenyl	No Structure	C&L notification
283-130-2	84540-37-4	trans-4-ethyl-4'-(4-propylcyclohexyl)-1,1'-biphenyl		Full, not (publicly) available

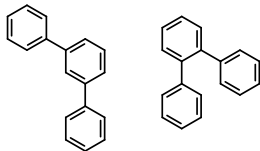
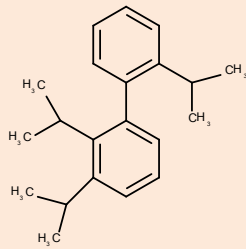
ASSESSMENT OF REGULATORY NEEDS

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
429-580-7	129738-42-7	(trans(trans))-4'-but-3-enyl-4-(4-methylphenyl)-bicyclohexyl		Full, (publicly) available not
439-730-3	155041-85-3	(trans(trans))-4'-vinyl-4-(4-methylphenyl)bicyclohexyl		Full, (publicly) available not
439-940-5	-	CVCP-V-1		NONS
450-290-1	-	BIS-4,4'-(TRANS-4-n-PROPYLCYCLOHEXYL) BIPHENYLE		NONS
473-310-0	478385-88-5	1,1'-Biphenyl, 4-methyl-4'-(3E)-3-penten-1-yl-		Full, (publicly) available not
612-101-2	61203-94-9	Benzene, (trans-4-propylcyclohexyl)-		Cease manufacture

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EC/List number	CAS number	Substance name [and/ Substance acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) ¹
617-422-1	82991-48-8	Benzene, 1-(trans-4-pentylcyclohexyl)-4-propyl-		Full, (publicly) available not
617-606-1	84656-75-7	1-Methyl-4-[(trans,trans)-4'-propyl[1,1'-bicyclohexyl]-4-yl] - benzene		Full, (publicly) available not
617-607-7	84656-77-9	1-propyl-4-[(trans,trans)-4'-propyl[1,1'-bicyclohexyl]-4-yl]- benzene		Full, (publicly) available not
679-980-2	5707-44-8	4-Ethylbiphenyl		C&L notification
815-922-6	117713-15-2	4-methyl-4'-n-propyl-[1,1-biphenyl]		Full, (publicly) available not

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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
904-797-4	-	Reaction mass of m-terphenyl and o-terphenyl		Full, (publicly) available not
915-589-8	-	Diisopropylbiphenyl and triisopropylbiphenyl		Full, (publicly) available not

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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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 level³. 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 \(europa.eu\)](https://eucha.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).

ASSESSMENT OF REGULATORY NEEDS

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 website⁴.

⁴ <https://echa.europa.eu/understanding-assessment-regulatory-needs>

Glossary

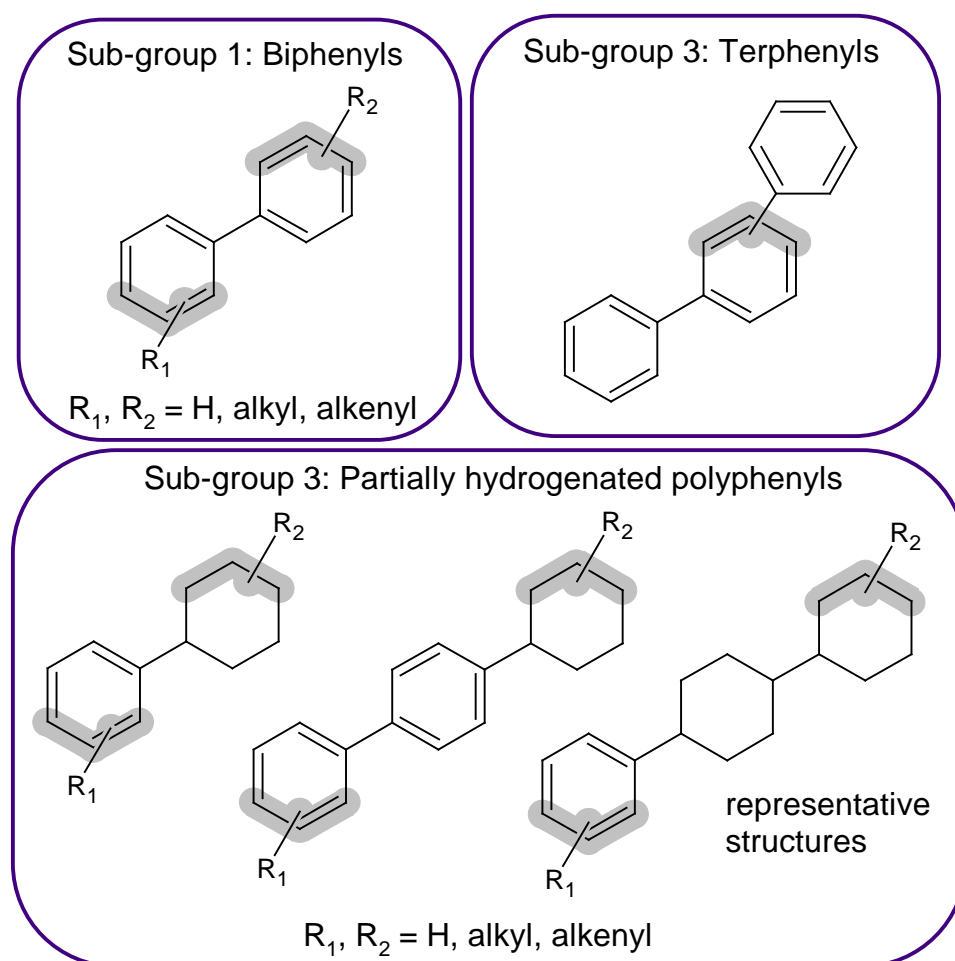
ARN	Assessment of Regulatory Needs
CCH	Compliance Check
CLH	Harmonised classification and labelling
CMR	Carcinogenic, mutagenic and/or toxic to reproduction
DEv	Dossier evaluation
ED	Endocrine disruptor
NONS	Notified new substances
OEL	Occupational exposure limit
OSII or TII	On-site isolated intermediate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

1 Overview of the group

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

ECHA has grouped together structurally similar substances based on the presence of the (partially hydrogenated) polyphenyls shown in the figure below. The group contains biphenyls, terphenyls, and partially hydrogenated polyphenyls.

There are 27 substances in the group, including 14 substances with full registrations, 2 NONS, 1 substance with intermediate registration, 8 substances with only C&L notifications, and 2 substances with no registration or ceased manufacture.



Available data on uses is sparse and limited to a few substances in the group. Based on information reported in the REACH registration dossiers, they are used as heat transfer agents, plasticisers and solvents. Most of the reported applications are linked to uses in heat transfer fluids, in polymer production, in adhesives, fillers and putties, in inks and toners and in coatings. Based on the available information, only seven of the substances have potential for release to the environment or exposure workers. This is the case for five substances (EC 202-163-5, 247-156-8, 915-589-8, 212-572-0 and 262-967-7) for which professional uses have been reported. Additionally, only EC 262-967-7 exhibits article service life. All other

reported uses are industrial and often in laboratory chemicals and intermediates, despite full registration status.

Literature research has revealed possible applications in lithium-ion batteries and next generation liquid crystal displays.

An RMOA prepared by Finland was concluded for EC 262-967-7 in 2017 followed by the identification of the substance as an SVHC due to its PBT/vPvB properties in 2018. The substance was subsequently considered for inclusion in Annex XIV.⁵ In the meantime, a restriction proposal has been submitted for the substance and RAC and SEAC opinions are expected to be adopted by June 2023.

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.

⁵ <https://echa.europa.eu/documents/10162/d4254365-2041-f5ea-4d50-6efcb94863f8>

2 Conclusions and proposed actions

The conclusions and actions proposed in the table below are based mainly on the REACH and CLP information available at the time of the assessment by ECHA. The conclusions are preliminary suggestions from a screening-level assessment done by ECHA with the aim to propose the next steps for further work (e.g., strengthening of the hazard conclusions, clarification of the uses and/or potential for exposure). The main source of information is the registration dossiers. Relevant public assessments may also be considered. When new information (e.g., on hazards through evaluation processes, or on uses) will become available, the document may be updated, and conclusions and actions revisited.

Table 1: Conclusions and proposed actions

Subgroup name, EC/List no, substance name	Human Hazard	Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
EC 212-572-0; 262-967-7; 904-797-4; 915-589-8	Known or potential hazard for reproductive toxicity for EC 212-572-0, EC 262-967-7 and 915-589-8 Known or potential hazard for carcinogenicity and ED (only EC 915-589-8)	Known or potential hazard for PBT/vPvB Known or potential hazard for aquatic toxicity for all substances for ED for EC 915-589-8	Known or potential hazard for PBT/vPvB Known or potential hazard for aquatic toxicity for all substances for ED for EC 915-589-8	Widespread industrial and professional uses in heat transfer fluids. Additional known uses in polymer preparation (including ASL). EC 262-967-7 also used in a number of additional industrial and professional uses including adhesives/sealants, coatings and paints and ink and toners (both including ASL). Widespread releases and exposure	First step: EC 262-967-7 (HH); 212-572-0, 915-589-8 (ENV): CCH Potential next steps (if hazard confirmed after data generation): EC 915-589-8; 212-572-0: CLH EC 212-572-0; 915-589-8: SVHC identification Potential last action: Restriction (already pending for 262-967-7) <u>Justification:</u>

ASSESSMENT OF REGULATORY NEEDS

Subgroup name, EC/List no, substance name	Human Hazard	Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
				<p>expected for all four substances.</p>	<p>Restriction of professional uses is preferred over authorisation as it is considered to be more efficient and effective to introduce controls at the level of placing on the market rather than at the level of uses.</p> <p>Known industrial and professional uses in heat transfer fluids should be restricted to strictly controlled conditions only.</p>
<p>EC 202-163-5; 247-156-8</p>	<p>Known or potential hazard for carcinogenicity for all substances</p> <p>Known or potential hazard for reproductive toxicity and ED (only for EC 247-156-8)</p>	<p>Known or potential hazard for aquatic toxicity for all substances for ED for EC 247-156-8</p>	<p>EC 202-163-5 has industrial and professional use in heat transfer fluids, industrial use in polymer preparations and industrial and professional uses in laboratory chemicals. Additional industrial uses in washing and cleaning products, lubricants and greases and hydraulic fluids.</p> <p>247-156-8 has professional use in coatings and paints.</p>	<p>First step: EC 202-163-5; 247-156-8: CCH (HH)</p> <p>Potential next steps (if hazard confirmed after data generation): EC 202-163-5; EC 247-156-8: CLH (EC 247-156-8 to be considered as a group with other substances flagged for CLH for Repro)</p> <p>Potential last action: OEL</p> <p><u>Justification:</u> OEL will protect workers from risks to their safety and health arising from the effects of the substances at the workplace during formulation, industrial and professional uses.</p>	

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Subgroup name, EC/List no, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
			Use information may be incomplete. Widespread exposure expected for both substances.	In addition, CLH will require company level RMMs under OSH and support action under other regulations.
EC 201-517-6; 202-122-1; 202-205-2; 247-477-3; 210-337-7; 230-420-1; 249-525-9; 273-683-8; 473-310-0; 679-980-2; 815-922-6; 273-316-1; 283-130-2; 429-580-7; 439-730-3; 439-940-5; 450-290-1; 612-101-2; 617-422-1; 617-606-1; 617-607-7	Known or potential hazard for reproductive toxicity <i>EC 210-337-7; 230-420-1; 249-525-9; 273-683-8; 473-310-0; 679-980-2; 815-922-6; 283-130-2; 429-580-7; 439-730-3; 439-940-5; 450-290-1; 617-422-1; 617-606-1; 617-607-7</i> Known or potential hazard for carcinogenicity <i>EC 210-337-7; 230-420-1; 249-525-9; 273-683-8; 473-310-0; 679-980-2; 815-922-6</i>	Known or potential hazard for aquatic toxicity for <i>EC 201-517-6; 202-122-1; 202-205-2; 247-477-3; 210-337-7; 249-525-9; 273-316-1, 273-683-8; 473-310-0; 815-922-6; 283-130-2; 429-580-7; 439-730-3; 439-940-5; 450-290-1; 617-422-1; 617-606-1; 617-607-7</i> Known or potential hazard for PBT/vPvB for EC 230-420-1, EC 249-525-9, and EC 273-683-8 Known or potential hazard	No use data available.	First step: <i>EC 473-310-0; 815-922-6; 439-730-3; 617-606-1;</i> CCH Potential last action: 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.

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Subgroup name, EC/List no, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
	Known or potential hazard for ED EC 230-420-1; EC 249-525-9; EC 273-683-8	for ED		

3 Justification for the need for regulatory risk management action at EU level (if hazards confirmed)

Based on ECHA's assessment of **human health hazard information** currently available in the registration dossiers and considerations of structural similarity,

- (potential) reproductive toxicity hazard is identified for the substances EC 212-572-0, EC 915-589-8, EC 262-967-7 and EC 247-156-8; and
- (potential) for endocrine disruption (ED; human health and environment) and EC 915-589-8 and EC 247-156-8; and
- (potential) carcinogenicity hazard for EC 202-163-5, EC 247-156-8 and EC 915-589-8.

Reproductive toxicity and ED (thyroid) hazards for EC 915-589-8 are based on the available reproductive toxicity studies showing decreased post-implantation survival index and mean litter size, and increased amplitudes in the startle response with thyroid toxicity. Based on structural similarity (isopropylated biphenyl), the reproductive toxicity and ED hazards are extrapolated to EC 247-156-8. In absence of information on ED potential for environment the potential hazard from human health is extended to environment, as a conservative approach. Data indicating potential for reproductive toxicity are also available for EC 212-572-0 and EC 262-967-7.

Compliance check is proposed for EC 262-967-7 and EC 247-156-8 to clarify the hazard.

Carcinogenicity hazard for EC 915-589-8 is extrapolated from data available for biphenyl (EC 202-163-5) showing urinary bladder tumours in rats and liver tumours in mice (borderline for meeting the criteria for Carc. 2 or Carc. 1B), expected due to the generation of hydroxylated biphenyl metabolites. Extrapolation of hazard to EC 915-589-8 is supported by possibility for generating hydroxylated biphenyl metabolites and with the available sub-chronic data for EC 915-589-8 showing bladder and liver as a target organs. Potential for hazard is also extrapolated to EC 247-156-8 based on structural similarity to EC 915-589-8 (isopropylated biphenyls).

Based on available data for the substances, no hazard is identified for the mutagenicity and skin sensitisation.

Compliance check is proposed for EC 202-163-5 with equivocal data on mutagenicity.

Based on currently available information, there is a need for (further) EU regulatory risk management namely restriction for (potential) PBT/vPvB hazards due to the potential for release/exposure of EC 212-572-0, 262-967-7, 904-797-4 and 915-589-8 in the group. In addition, potential reproductive toxicity hazards of EC 212-572-0, 262-967-7 and 915-589-8 as well as for carcinogenicity and ED hazards of EC 915-589-8 are supporting concerns (see above for human health hazards in the whole group).

Based on ECHA's assessment of the available information, two substances are

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concluded vPvB. Terphenyl, hydrogenated (262-967-7) has been identified as SVHC and concluded vPvB based on the presence of o-terphenyl (201-517-6) above 0.1%. O-terphenyl was concluded to meet the criteria P/vP [*i.e.*, degradation half-life >60 days in marine water and >120 days in soil] and the criteria B/vB [*i.e.*, BCF > 5 000], as set out in Annex XIII of REACH.

Consequently, 904-797-4 is also concluded vPvB based on the presence of o-terphenyl above 0.1%.

Additionally, based on ECHA's assessment of currently available hazard information, additional two members in the group fulfil the PBT/vPvB screening criteria (212-572-0 and 915-589-8)⁶:

- these substances are potentially persistent or very persistent (P/vP) as:
 - both substances are reported to be not readily biodegradable (*i.e.*, <60/70% degradation in an OECD 301B or based on adaptation possibilities, such as QSAR predictions);
- these substances are potentially bioaccumulative or very bioaccumulative (B/vB) as:
 - they have a high potential to partition to lipid storage (*e.g.*, log K_{ow} > 4.5);
 - both substances are predicted to meet at least the criteria B (*i.e.* BCF > 2000);
- 915-589-8 meets the T criteria set in Annex XIII as it is self-classified as repro. 2, and STOT RE 2 and has a NOEC < 0.01mg/L based on aquatic chronic data. Based on human health assessment, 212-572-0 may also meet classification criteria for reproductive toxicity, hence it potentially meets the T criteria set in Annex XIII.

Therefore, 212-572-0 and 915-589-8 are considered as potential PBT/vPvB substances.

The first step of the regulatory risk management should the supporting human health hazard exist, is the confirmation of human health hazard via **harmonised classification (CLH)** as CMR hazard for EC 915-589-8.

When preparing the proposals, other substances (EC 202-163-5, EC 247-156-8 and EC 915-589-8) should be considered. During the assessment it should also be considered what would be the best way to develop the CLH proposal, for instance whether to make a proposal for the group of substances, to submit them individually or jointly.

The next step of the regulatory risk management action proposed, should the environmental hazard exist, is the confirmation of the environmental hazard via **SVHC identification** and inclusion on the Candidate List as PBT/vPvB for EC 212-572-0 and 915-589-8.

EC 262-967-7 has already been added to the Candidate List as PBT/vPvB. RMOA performed by Finland in 2017⁷ concluded that authorisation would be the most appropriate regulatory risk management measure, largely due to the uncertainty surrounding remaining uses of the substance and the substance was added to the Candidate List. In 2021 Italy conducted an additional RMOA following new evidence

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)

⁷ <https://echa.europa.eu/assessment-regulatory-needs/-/dislist/details/0b0236e1819d4a8e>

regarding alternatives for EC 262-967-7 in heat transfer fluid uses. Italy concluded that restriction is a more suitable RRM and submitted an intention⁸ to restrict the substance. A restriction proposal regarding the placing on the market of the substance was submitted in 2022 and is currently evaluated by RAC and SEAC. Notably, the placing on the market for the use in heat transfer fluids is exempted from the proposed restriction under the condition that strictly controlled conditions are implemented.

EC 904-797-4 is already concluded vPvB based on the presence of o-terphenyl above 0.1% and therefore do not need to go through SVHC identification to confirm the PBT/vPvB properties.

For EC 212-572-0 and 915-589-8, SVHC identification is highly recommended as a step prior to restriction. In addition, SVHC identification brings immediate obligations for suppliers of the substances such as (i) supplying a safety data sheet and communicating on the safe use of the substances, (ii) responding to consumer requests within 45 days and (iii) notifying ECHA if the article they produce contains the substance above regulatory threshold.

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 professional uses, article service and industrial uses.

Professional and industrial use in heat transfer fluids is likely to account for the bulk of the tonnage based on the known uses (including from registrations and from information gathering during the aforementioned historic and ongoing regulatory risk management activity) for EC 262-967-7.

Therefore, a **restriction** of the substances as such or in mixtures (concentration limit in mixtures) used by professional workers and industrial workers in heat transfer fluids is suggested after SVHC identification, with the aim to minimise exposures and emissions to humans and the environment. An exemption for uses in heat transfer fluids under well-defined strictly controlled conditions could be considered.

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 Sustainability⁹.

Furthermore, potential for exposure and releases to the environment from articles is uncertain based on available information.

Moreover, **restricting substances in articles** used by professionals (EC 262-967-7) should be considered in the context of the restriction of professional uses as potential exposure from articles needs further investigation first.

Other known industrial uses are as plasticiser in polymer preparations, adhesives and sealants, fillers, coatings and paints, inks and toners and as solvents in washing and cleaning products. Article service life may occur, in particular in coatings and

⁸ <https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e1862d9f6a>

⁹ European Commission, *Chemical Strategy for Sustainability Towards a Toxic-Free Environment*, available at <https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf>

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paints and inks and toners. Available information on uses is however limited¹⁰ and these uses are therefore uncertain.

Such widespread industrial uses are typically non-contained and non-automated leading to releases to the environment.

It is suggested to cover possibly also industrial uses as part of the restriction. However, the need for authorisation might be considered for industrial uses excluded from the scope of the restriction as it may not be proportionate to restrict all uses.

Based on currently available information, there is a need for (further) EU regulatory risk management with binding OEL for carcinogenicity (EC 202-163-5) and for reproductive toxicity and ED (EC 247-156-8). This conclusion is based on potential for release/exposure of EC 202-163-5 and 247-156-8 in the group.

Hazards associated with the substances have already been indicated above.

Besides professional uses in heat transfer fluids and laboratory chemicals, bisphenyl (EC 202-163-5) only has industrial uses including in washing and cleaning products, hydraulic fluids and polymer preparation. Known uses of the EC 247-156-8 are limited to coatings and paints with significant potential for worker exposure and limited release potential during ASL.

The first step of the regulatory risk management should the hazard exist, is the confirmation of hazard via a **harmonised classification (CLH)** as carcinogenic cat 1B hazard for EC 202-163-5. Following data generation for EC 247-156-8, CLH for reproductive toxicity (and potential for carcinogenicity based on common non-cancer effects in bladder) for alkyl biphenyls (especially isopropylated biphenyls EC 247-156-8, EC 230-420-1, EC 249-525-9, EC 273-683-8, and EC 915-589-8) should be considered. When preparing the proposals, it may be considered what would be the best way to develop them, for instance whether to make a proposal for the group of substances, to submit them individually or jointly.

CLH will require company level risk management measures (RMM) under the OSH legislation for workers, to be in place.

The final step of the regulatory risk management should the hazard exist, is the setting of an **EU binding OEL** for EC 202-163-5 and 247-156-8. Biphenyl (EC 202-163-5) in particular is a high tonnage substance with a variety of uses that can lead to worker exposure. Both substances are suspected carcinogens and reprotoxic substances and Directive (EU) 2022/431 facilitates the development of binding OELs for these hazards. Notably, Austria, Belgium, Denmark, Finland, France, Hungary, Ireland, Latvia, Norway, Poland, Spain, Sweden, Switzerland and the UK have already set national OELs for biphenyl (EC 202-163-5). This in itself is strong indication that the substance causes adverse health effects and worker exposure is high. An EU binding OEL will harmonise the risk management of these substances across the EU. It is noteworthy that the UK Advisory Committee on Toxic Substances has expressed concern that the OEL set for the UK may not be adequate to protect the health of workers sufficiently. OELs currently existing for EU countries listed above are comparable to the UK OEL. A re-evaluation of the OEL required is therefore recommended.

¹⁰ Even known uses regarding EC 262-967-7 are uncertain despite the regulatory attention this substance has received.

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An OEL will protect workers from risks to their safety and health arising from the effects of the substances at the workplace during formulation, industrial and professional uses.

Based on currently available information, there is no need for (further) EU regulatory risk management of substances EC 201-517-6, 202-122-1, 202-205-2, 247-477-3, 210-337-7, 230-420-1, 249-525-9, 273-683-8, 473-310-0, 679-980-2, 816-922-6, 273-316-1, 283-130-2, 429-580-7, 439-730-3, 439-940-5, 450290-1, 612-101-2, 617-422-1, 617-606-1 and 617-607-7.

Based on ECHA's assessment of hazard information currently available in the registration dossiers and considerations of structural similarity for some of the substances:

- (potential) reproductive toxicity hazard is identified for the alkyl substituted biphenyls (EC 473-310-0, EC 210-337-7, EC 679-980-2, EC 815-922, 6, EC EC 230-420-1, EC 249-525-9, and EC 273-683-8) and for partially hydrogenated polyphenyls (EC 617-422-1, EC 450-290-1, EC 283-130-2, EC 429-580-7, EC 439-730-3, EC 617-606-1, EC 617-607-7), and EC 439-940-5;
- (potential) carcinogenicity hazard is identified for biphenyls (EC 473-310-0, EC 210-337-7, EC 679-980-2, EC 815-922, 6, EC 230-420-1, EC 249-525-9, and EC 273-683-8); and
- (potential) for ED hazard (human health and environment) for propyl substituted biphenyls (EC 230-420-1, EC 249-525-9, and EC 273-683-8);
- vPvB hazard is identified for substances containing o-terphenyl (201-517-6 and 247-477-3) and potential vPvB is flagged for m- and p-terphenyl isomers (202-122-1 and 202-205-2)
- (potential) PBT/vPvB is identified for substances screening P and B based on available data; and for substances with increased degree of alkylation, which is hypothesised to hinder degradation and potentially favour bioaccumulation, and that may also fulfil the T criteria based on potential reproductive and carcinogenic hazards, as indicated above (210-337-7; 249-525-9; 273-316-1; 273-683-8; 283-130-2; 429-580-7; 439-730-3; 439-940-5; 450-290-1; 473-310-0; 617-422-1; 617-606-1; 617-607-7; 815-922-6).

Reproductive toxicity hazards for alkyl substituted biphenyls and ED (thyroid) hazard for propyl substituted biphenyls are based on the available toxicity studies for the EC 915-589-8 (described above). Reproductive toxicity for alkyl substituted biphenyls is supported by lower number of offspring and dystocia reported in a screening study for the EC 679-980-2¹¹, while thyroid as a target organ is only reported for the propyl substituted biphenyls. Based on structural similarity and lack of information to confirm otherwise, the reproductive toxicity hazard is extrapolated to other alkylated biphenyls in the group, and the ED hazard to the propyl substituted biphenyls. Data showing potential for reproductive toxicity are also available for partially hydrogenated polyphenyls EC 212-572-0 and EC 439-730-3. Based on structural similarity (alkylated biphenyl) and lack of/limited information to confirm otherwise, the reproductive toxicity hazard is extrapolated to other partially hydrogenated polyphenyls in the group. Compliance check is proposed for EC 617-606-1 to confirm the hazard.

Carcinogenicity hazard is based on the available carcinogenicity studies for EC 202-163-5, with the potential mechanism related to generation of phenylphenol

¹¹ Data available (tabulated data in English) at https://dra4.nihs.go.jp/mhlw_data/jsp/FileListPageENG.jsp?parameter_csno=5707-44-8

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metabolites. Potential hazard (and generation of phenylphenol) for alkyl substituted biphenyls is supported by the sub-chronic toxicity study showing bladder and liver as a target organs for alkyl substituted EC 915-589-8. Based on structural similarity and lack of/limited information to confirm otherwise, the carcinogenicity hazard is extrapolated to other alkylated biphenyls.

Based on available data for majority of the substances, no hazard is identified for the mutagenicity and skin sensitisation.

vPvB was concluded for o-terphenyl (201-517-6), as reported above. Available data for its isomers does not allow conclusion, however, clearly indicates vPvB potential for the terphenyls.

All remaining substances have potential PBT/vPvB properties based on structural similarities and additional considerations (e.g. indication of unreliable BCF data in the group, reduction of degradation potential with increased alkylation level or indication of potential CMR hazards).

Based on reported or predicted Koc values, PMT/vPvM is considered unlikely for all substances.

Use data for many of the substances is not available. Nine of the 21 substances in this subgroup are not registered, two are NONS without upgraded tonnages, one substance has only intermediate registrations (EC 612-101-2) and the remaining ten substances have full registrations and reported uses are limited to intermediate uses reported for one substance (EC 210-337-7). None of the other registered substances have any uses reported. Three of the substances (EC 617-422-1, 617-606-1, 617-607-7) have recent registration dates and appear to be used in next generation liquid crystal displays.¹²

It is noted that use information provided by registrants is limited to eight substances only and when available also appears to be sporadic. Lack of sufficient understanding of uses also prevents a thorough analysis of substitution potential in the group.

Therefore, no EU regulatory risk management action is currently proposed for any of the aforementioned substances due to low exposure potential. 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.

¹² Geelhaar, T.; Griesar, K.; Reckmann, B. 125 Years of Liquid Crystals — A Scientific Revolution in the Home (2013), *Angew. Chem. Int. Ed.*, 52, 8798 – 8809

Annex 1: Overview of classifications

Data extracted in December 2022

EC Number	CAS Number	Substance Name	Harmonised classification	Classification in registrations
273-683-8	69009-90-1	diisopropyl-1,1'-biphenyl	-	-
202-163-5	92-52-4	biphenyl	Index number: 601-042-00-8 Hazard Category: Skin Irrit. 2 Hazard Statement: H315 Hazard Category: Eye Irrit. 2 Hazard Statement: H319 STOT SE 3 Hazard Statement: H335 Aquatic Acute 1 Statement: H400 Aquatic Chronic 1 Statement: H410	Skin Irrit. 2 H315 Eye Irrit. 2 H319 Aquatic Acute 1 H400 STOT Single Exp. 3 H335, affected organs: respiratory system Aquatic Chronic 1 H410
247-477-3	26140-60-3	terphenyl	-	-
815-922-6	117713-15-2	4-methyl-4'-propyl[biphenyl]	-	-
915-589-8	-	Diisopropylbiphenyl and triisopropylbiphenyl	-	Repr. 2 H361 Skin Irrit. 2 H315 Asp. Tox. 1 H304 STOT Rep. Exp. 2 H373, affected organs: liver, thyroid Aquatic Chronic 4 H413
212-572-0	827-52-1	cyclohexylbenzene	-	Asp. Tox. 1 H304 Aquatic Acute 1 H400 Aquatic Chronic 1 H410
617-606-1	84656-75-7	617-606-1	-	-
612-101-2	61203-94-9	612-101-2	-	Skin Irrit. 2 H315

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				[intermediate (inactive)] Eye Irrit. 2 H319 [intermediate (inactive)] Aquatic Chronic 1 H410 [intermediate (inactive)]
617-607-7	84656-77-9	trans,trans-4-(4-propylphenyl)-4'-propyl[1,1'-bi(cyclohexyl)]	-	-
202-205-2	92-94-4	p-terphenyl	-	-
473-310-0	-	473-310-0	-	-
904-797-4	-	Reaction mass of m-terphenyl and o-terphenyl	-	Aquatic Acute 1 H400, M-factor: 10.00 Aquatic Chronic 1 H410
210-337-7	613-33-2	4,4'-dimethylbiphenyl	-	-
247-156-8	25640-78-2	(1-methylethyl)-1,1'-biphenyl	-	Eye Irrit. 2 H319 Asp. Tox. 1 H304 Aquatic Acute 1 H400 Aquatic Chronic 2 H411
262-967-7	61788-32-7	Terphenyl, hydrogenated	-	Aquatic Chronic 2 H411
679-980-2	5707-44-8	679-980-2	-	-
202-122-1	92-06-8	m-terphenyl	-	-
273-316-1	68956-74-1	Polyphenyls, quater- and higher, partially hydrogenated	-	-
617-422-1	82991-48-8	617-422-1	-	-
249-525-9	29225-91-0	tris(1-methylethyl)-1,1'-biphenyl	-	-
439-730-3	-	(trans(trans))-4'-vinyl-4-(4-methylphenyl)bicyclohexyl	-	STOT Rep. Exp. 2 H373
201-517-6	84-15-1	o-terphenyl	-	-
283-130-2	84540-37-4	trans-4-ethyl-4'-(4-propylcyclohexyl)-1,1'-biphenyl	-	-
429-580-7	-	(trans(trans))-4'-but-3-enyl-4-(4-methylphenyl)-bicyclohexyl	-	-

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

Data extracted on 26 October 2022

Main types of applications structured by product or article types	EC/List 202-163-5	EC/List 210-337-7	EC/List 212-572-0	EC/List 247-156-8	EC/List 262-967-7	EC/List 283-130-2	EC/List 429-580-7	EC/List 439-730-3	EC/List 473-310-0	EC/List 612-101-2	EC/List 617-422-1	EC/List 617-606-1	EC/List 617-607-7	EC/List 815-922-6	EC/List 904-797-4	EC/List 915-589-8
	Annex X	<VII	Annex VIII	Annex VIII	Annex X	Annex VII	Annex VII	Annex VIII	Annex VII	<VII	Annex VII	Annex VIII	Annex VII	Annex VII	Annex VIII	Annex IX
PC 35: Washing and cleaning products	I															I
PC 24: Lubricants, greases, release products																I
PC 16: Heat transfer fluids	F, I, P		I		I, P										I	I, P
PC 17: Hydraulic fluids	I															
PC 32: Polymer preparations	I				F, I, A											I

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and compounds																
PC 1: Adhesives, sealants					F, I, P											
PC 9b: Fillers, putties, plasters, modelling clay					F, I, P											
PC 9a: Coatings and paints, thinners, paint removes	F			F, P, A	F, I, P, A											
PC 18: Ink and toners					F, I, P, A											
PC 21: Laboratory chemicals	F, I, P		P		I, P											I
PC 19: Intermediate	F, I, P	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

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

Data extracted on 26 October 2022.

EC/List number	RMOA	Authorisation		Restriction*		CLH	Actions not under REACH/ CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)		
202-163-5				YES		YES	
262-967-7	YES	YES	YES	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 and 75).