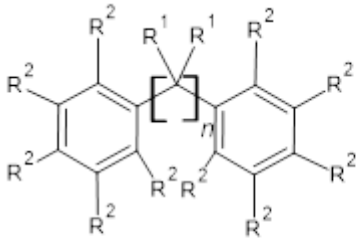
Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Group Name: Polyphenylalkanes_alkenes

General structure:



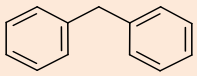
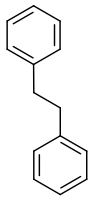
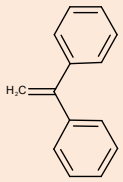
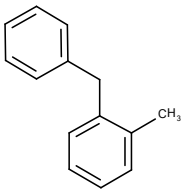
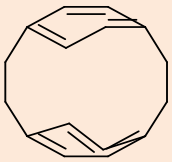
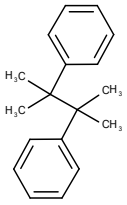
R1: hydrogen, saturated and unsaturated alkyl, unsaturated cyclic derivatives
R2: hydrogen, alkyl, substituted benzyl derivatives, cyclic (tetralin) derivatives

n: 1-2

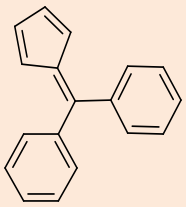
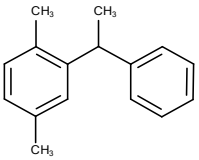
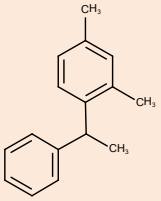
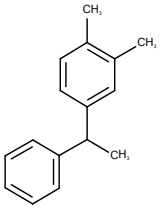
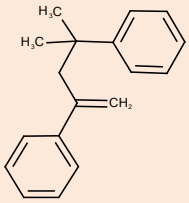
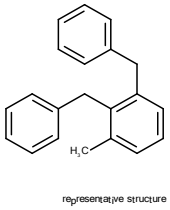
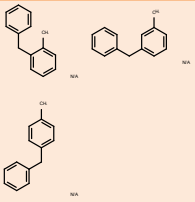
Revision history

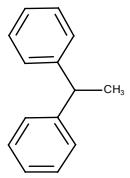
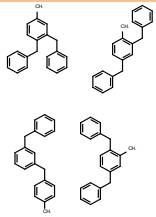
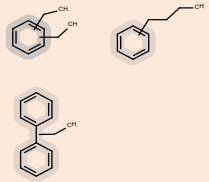
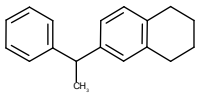
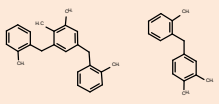
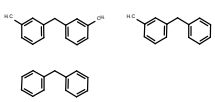
Version	Date	Description
1.0	12 January 2024	

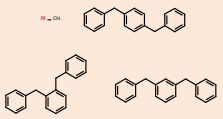
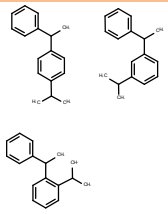
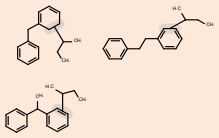
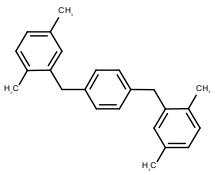
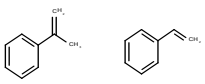
Substances within this group:

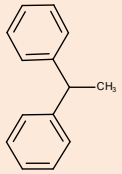
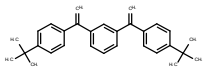
EC / List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
202-978-6	101-81-5	Diphenylmethane		OSII or TII
203-096-4	103-29-7	1,2-diphenylethane		OSII or TII
208-482-6	530-48-3	1,1-diphenylethylene		OSII or TII
211-927-7	713-36-0	o-benzyltoluene		C&L notification
216-644-2	1633-22-3	Tricyclo[8.2.2.24,7] hexadeca-1(12),4,6,10,13,15-hexaene		Full, not (publicly) available
217-568-2	1889-67-4	1,1'-(1,1,2,2-tetramethylethylene)dibenzene		Full, 100-1000

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

EC / List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
218-533-4	2175-90-8	6,6'-diphenylfulvene		Full, not (publicly) available
228-201-0	6165-51-1	2-(1-phenylethyl)-p-xylene		C&L notification
228-202-6	6165-52-2	4-(1-phenylethyl)-m-xylene		C&L notification
228-249-2	6196-95-8	4-(1-phenylethyl)-o-xylene		C&L notification
228-846-8	6362-80-7	1,1'-(1,1-dimethyl-3-methylene-1,3-propanediyl)bisbenzene		Full, 100-1000
248-097-0	26898-17-9	Dibenzyltoluene	 representative structure	C&L notification
248-654-8	27776-01-8	Benzyltoluene		Full, >1000

EC / List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
*254-179-7	38888-98-1	(phenylethyl)benzene		Full, not (publicly) available
255-068-6	40766-31-2	(1-phenylethyl)xylene	No Structure	C&L notification
258-649-2	53585-53-8	Dibenzylbenzene, ar-methyl derivative		Full, not (publicly) available
271-802-8	68608-82-2	Benzene, ethylenated, by-products from		Full, 10-100
400-370-7	6196-98-1	1,2,3,4-Tetrahydro-6-(1-phenylethyl)naphthalene		Full, not (publicly) available
403-970-7	-	JARYSOL XX		Full, not (publicly) available
405-470-4	73807-39-3	A mixture of isomers of: methyldiphenylmethane; dimethyldiphenylmethane		NONS

EC / List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
405-570-8	-	A mixture of isomers of: dibenzylbenzene; dibenzyl(methyl)benzene; dibenzyl(dimethyl)benzene; dibenzyl(trimethyl)benzene		NONS
430-690-2	52783-21-8	1-(2-isopropylphenyl)-1-phenylethane;1-(3-isopropylphenyl)-1-phenylethane;reaction mass of: 1-(4-isopropylphenyl)-1-phenylethane		Not registered
431-100-6	-	1-(sec-butylphenyl(phenyl)-2-phenylethane, mixed isomers;1-(sec-butylphenyl-1-phenylethane, mixed isomers;reaction mass of: sec-butylphenyl(phenyl)methane, mixed isomers		Not registered
434-150-7	-	TW-257		Not registered
449-400-0	25822-43-9	Benzene, 1,4-bis(1-methylethyl)-, homopolymer		Full, not (publicly) available
618-465-9	9011-11-4	Benzene, ethenyl-, polymer with (1-methylethenyl)benzene		Cease manufacture

EC / List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
Substance 1	612-00-0	Benzene, 1,1'-ethylidenebis-		Not registered
Substance 2	-	bis{1-[4-(branched-alkyl)phenyl]alkenyl}benzene		OSII or TII

*When a dossier is submitted without EC number, REACH-IT automatically assigns a List number to the dossier. Sometimes, due to IT technical limitations, duplicate List numbers are created. In this group, there is a duplicate to EC 254-179-7. In general EC numbers take precedence over List numbers.

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

Contents

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Foreword

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

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

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

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

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

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

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

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

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

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

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

Glossary

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

1 Overview of the group

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

ECHA has grouped together structurally similar substances based on the presence of two or more benzene rings that are substituted with different saturated or unsaturated alkyl/cyclic groups in different positions as shown in the figure below.

Representative structure:

There are 28 substances in the group of which 11 with full registrations, 4 intermediates, 3 NONS, 6 C&L notified and 4 not registered substances. The group consists of 13 mono-constituent, 1 multi-constituent and 4 UVCB registered substances.

Based on information reported in the REACH registration dossiers, considering the similarities between the substances and the uses reported, in general it is considered that the uses identified could be applicable across most of the substances in the group. The substances in this group are mainly used as intermediates in the production of other chemicals, in the production of plastics as additives providing softening or plasticising properties and in heat transfer fluids. Some substances are also reported to be used as solvents in air filtration systems (EC 248-654-8 and 258-649-2) which appear to be in a closed system and as solvents in washing and cleaning products (EC 248-654-8 and 271-802-8) from which high potential for release/exposure is expected.

While low potential for release/exposure is expected when they are used as intermediates and in heat transfer fluids (release/exposure potential limited to loading and unloading of the fluids), high potential for exposure is identified when used as plasticisers in polymeric preparations where they are assumed to be additives (not covalently bound to the polymer) and considering their molecular weight.

There is a Substance Evaluation (SEv) for EC 400-370-7 which will further clarify bioaccumulation. There are PBT assessments for EC 248-654-8, 258-649-2 and 400-370-7.

Four unregistered substances (EC 405-470-4; 405-570-8; 430-690-2; 431-100-6) have a harmonised classification of Aquatic Acute 1 H400; Aquatic Chronic 1 H410.

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 number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
All substances	Potential hazard for reproductive toxicity and ED (EC 217-568-2, 248-654-8, 258-649-2) Inconclusive for Repro and ED for EC 202-978-6, 203-096-4, 208-482-6, 211-927-7, 216-644-2 218-533-4, 228-201-0, 228-202-6, 228-249-2, 248-097-0, 255-068-6, 400-370-7	Known or potential hazard for PBT/vPvB; vPvB for all substances; PBT for the following substances: (EC 248-654-8, 258-649-2, 216-644-2, 228-201-0, 228-202-6, 228-249-2, 228-846-8) Known or potential hazard for aquatic toxicity (EC 248-654-8, 254-179-7,271-802-8, 228-846-8, 400-370-7, 449-400-0, 208-482-6, 203-096-4, 202-978-6)	Considering the similarities between the substances and the uses reported, in general it is considered that the uses identified could be applicable across most of the substances in the group. The substances in this group are mainly used as intermediates in the production of other chemicals, in the production of plastics as additives providing softening or	**First step:** CCH **Potential next steps (if hazard confirmed after data generation):** CLH **Potential last action:** **Restriction** Justification: Releases to the environment from consumer and widespread professional uses cannot be avoided. Widespread professional uses are typically non-contained and non-automated leading to releases to the environment.

EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
	Known or potential hazard for STOT RE (EC 216-644-2, 228-201-0, 228-202-6, 228-249-2, 228-846-8) Known or potential hazard for skin sensitisation for all except EC 248-654-8, 211-927-7, 449-400-0 and 258-649-2 Known or potential hazard for mutagenicity for Substance 2	Potential hazard for ED (EC 217-568-2, 248-654-8 and 258-649-2) Inconclusive for ED for ECs 202-978-6, 203-096-4, 208-482-6, 211-927-7, 216-644-2, 218-533-4, 228-201-0, 228-202-6, 228-249-2, 248-097-0, 255-068-6, 400-370-7	plasticising properties and in heat transfer fluids. High potential for release/exposure is expected when used in polymer preparations considering there are professional, and consumer uses. High potential for release/exposure is also foreseen during article service life in the absence of furthermore specific information since the molecular weight for these hydrocarbonated substances is low.	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. Specific restriction for use in articles is proposed as potential exposure from articles is likely.

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

Suggested regulatory risk management action for all substances in the group if vPvB hazards are confirmed and/or for the following 7 substances (EC 248-654-8, 258-649-2, 216-644-2, 228-201-0, 228-202-6, 228-249-2 and 228-846-8) if PBT hazards are confirmed.

Hazard

Based on currently available information, there is a potential hazard vPvB for all substances in the group. Potential PBT hazard is considered for 7 substances, only. For several substances there is a potential hazard for reproductive toxicity, ED, STOT RE, PBT and / or vPvB, or aquatic toxicity.

All the substances in the group have potential vPvB hazards, indicating potentially persistent/very persistent (P/vP) either based on a variety of OECD 301 screening test methods indicating not readily biodegradable (i.e., <60/70% degradation) or based on extrapolation due to high data density (2 registered and 17 not registered substances). There are no higher tier simulation tests, available. All the group's substances are potentially bioaccumulative or very bioaccumulative (B/vB) as they have a high potential to partition to lipid storage (e.g., log Kow > 4.5) based on OECD 117 test methods. In addition, based on OECD 305 BCF experimental testing, on the whole substance, 2 substances, EC 228-846-8 and 258-649-2 meet the criteria B/vB as set out in Annex XIII (i.e. BCF > 2 000/5 000). For EC 254-179-7, based on an OECD 305 BCF experimental testing, on the whole substance, it indicates the substance is not bioaccumulative. Nevertheless, EC 254-179-7 has a number of constituents in common with EC 248-654-8 like 1,1'-methylenedibenzene and 1,1'-ethane-1,1-diyldibenzene. EC 248-654-8 is potentially PBT/vPvB and has pending P and B information. Due to the quality of the study, EC 254-179-7 is proposed for a CCH to clarify the B hazard. Based on extrapolation due to high data density, EC 254-179-7 and 17 not registered substances, are all considered as potentially B/vB. Adaptations (read-across, waivers, weight of evidence) and QSARs are not considered for this screening exercise.

All the following substances meet the T criteria set out in Annex XIII based on Human Health (HH), conclusions, only: EC 248-654-8 and 258-649-2 are self-classified as Repr. 1B and EC 216-644-2, 228-201-0, 228-202-6, 228-249-2, 228-846-8 in the group are self-classified as STOT RE 2. The remaining substances in the group are unlikely to fulfil the T criterion as there is no extrapolation for T for HH as no mode of action could be determined. Also, there is a number of HH and Environment (Env) pending information for example for degradation, bioaccumulation, and reproductive toxicity on EC 217-568-2, 248-654-8, 258-649-2 and 400-370-7. The fulfilment of the T criterion, either from HH and/or Env can be re-considered following the review of submitted information.

In addition to the above-mentioned data generation that is already on-going for some substances, CCH to clarify potential PBT/vPvB properties is proposed for a number of substances. The potential (or lack of) PBT/vPvB hazards will be confirmed after the information becomes available. For the substances for which no data generation is possible, the conclusion may be revisited based on the PBT/vPvB hazards (or lack of hazards) that may be found for similar substances in this group after data generation.

Three substances in this group, EC 217-568-2, 248-654-8 and 258-649-2, only have potential **ENV ED** hazard (with uncertainty) based on indications of ED properties from the available HH data, only for which further HH data generation is ongoing or proposed. For these substances, conclusion, and further actions on ENV ED may be considered when the HH information is reviewed. Inconclusive for ED for EC: 202-978-6, 203-096-4, 208-482-6, 211-927-7, 216-644-2, 218-533-4, 228-201-0, 228-202-6, 228-249-2, 248-097-0, 255-068-6, 400-370-7. The remaining substances in the group are unlikely to fulfil the ED criterion as there is no extrapolation for ED for HH possible as there is no other positive data for the remaining substances and/or due to limited data.

The substances EC 217-568-2, 248-654-8 and 258-649-2 in the group have (potentially) the following human health hazards: **Reproductive toxicity** and **ED**. The available information indicates potential for *reproductive toxicity and endocrine disrupting properties* for three group members. EC 248-654-8 and 258-649-2 are self-classified as Repr. 1B. The main effects were observed in three reproduction/developmental toxicity screening tests, and one prenatal developmental toxicity studies in rabbits. The main observed effects include reproductive toxicity effects on sexual function and fertility and developmental effects; ED effect on thyroid hormone in pups: decrease T4 at all dose-levels in males and females (despite absence of maternal toxicity); effects on thyroid hormone in parents (decrease T4: males at all dose levels, females at high dose). Further data generation on reproduction and ED toxicity is ongoing for EC 217-568-2. Notably, the group includes substances with studies indicating no relevant toxicological effects for human health, including three reproduction/developmental toxicity screening tests, and three prenatal developmental toxicity studies in rats (EC 449-400-0, 228-846-8, 254-179-7). Moreover, within the group, we could not identify a trend between chemical structure and potential toxicity. Thus, we do not extrapolate the potential reproductive toxicity and ED hazard to other members of the group with no or limited data.

These hazards are identified based on a few observed effects from a limited number of substances in the group. The potential mechanism of toxicity is unclear, and it could not be linked to a specific moiety in this group. ECHA considers the hazard conclusions on reproductive toxicity and ED as subject to uncertainty considering the moderate data availability. For substance EC 258-649-2 there is sufficient evidence for toxicity to reproduction that may warrant classification, as a second action. Inconclusive for Reprod and ED for EC 202-978-6, 203-096-4, 208-482-6, 211-927-7, 216-644-2, 218-533-4, 228-201-0, 228-202-6, 228-249-2, 248-097-0, 255-068-6, 400-370-7. The rest of the group are unlikely to fulfil the ED criterion as there is no extrapolation for ED for HH possible as there is no other positive data for the remaining substances and/or due to limited data.

All the substances in the group (except EC 248-654-8, 449-400-0 and 258-649-2) have (potentially) the following human health hazard: **Skin Sensitisation.**

The available information indicates potential for skin sensitisation. The conclusion is based on three OECD 429 studies on three registered substances, self-classifications, and notifications from the registrants. We extrapolate the finding on

skin sensitisation to the substances with no data. We do not extrapolate the hazard conclusion to EC 248-654-8, 449-400-0 and 258-649-2 because four negative OECD 406 are available.

The Substance 2 in the group has (potentially) the following human health hazard: **mutagenicity.** The substance is registered as an intermediate and it is self-classified as Muta 2, based on a positive OECD 471.

The substances EC 216-644-2, 228-201-0, 228-202-6, 228-249-2, 228-846-8 in the group have (potentially) the following human health hazard: **STOT RE 2.** The 5 substances are self-classified as STOT RE 2.

Based on ECHA's assessment of currently available hazard information, there are 4 C&L notified substances, with a harmonised classification of Aquatic Acute 1 and Aquatic Chronic 1 (EC 405-470-4, 405-570-8, 430-690-2 and 431-100-6). In addition, there are 10 substances, with self-classifications ranging from Aquatic Acute 1 to Aquatic Chronic 4 (EC 248-654-8, 254-179-7, 271-802-8, 228-846-8, 258-649-2, 400-370-7, 449-400-0, 208-482-6, 203-096-4, 202-978-6). Considering the low data density currently and the low water solubility for the majority of substances, no group extrapolation is considered for aquatic toxicity hazard. Thus, the rest of the group are considered as inconclusive for the aquatic toxicity hazard. This decision can be re-considered following the review of any submitted information.

Compliance check is proposed for a number of substances in the group to clarify various adaptations, biodegradation, bioaccumulation and/or aquatic toxicity and HH endpoints.

Based on currently available information, for (PMT/vPvM) , hazards are considered unlikely for all substances in the group, based on the available data.

No or unlikely persistency, mobility, and toxicity hazards (PMT/vPvM) were identified for all the group members. Based on ECHA's screening of currently available hazard information, zero members in the group are considered to have PMT/vPvM properties. Whilst as outlined above, all the group members are considered P/vP and 7 substances are considered as T based on HH data, only, there are 5 substances with log Koc OECD 121 values indicating log Koc values of > 3, based on the whole substances with a single value or a range provided. There is no other experimental Log Koc data. But based on experimental Log Kow values all experimental data indicated > 4.5. Due to the structural similarity, while the Log Koc data density is low, using the Log Kow experimental data which consistently indicated > 4.5, a group extrapolation is considered possible indicating a low potential for mobility in the group, **unlikely M/M hazard for the group**.

Regulatory risk management

Regarding the use profile, the substances in this group are mainly used as intermediates in the production of other chemicals, in the production of plastics as additives providing softening or plasticising properties and/or in heat transfer fluids.

While low potential for exposure is expected when used as intermediates (in almost all the cases used in strictly controlled conditions), high potential for release/exposure is expected when used in polymer preparations considering there are professional, and consumer uses. In the registration dossiers several of these substances have been explicitly identified as "non-reactive" and although it is not immediately clear this applies to all the substances from the information available,

since they are identified as plasticisers it is assumed they are additives (not covalently bounded to the polymer). Consequently, high potential for exposure is also foreseen during article service life from articles made with plastics containing the substances in the absence of furthermore specific information since the molecular weight for these hydrocarbonated substances is low. Article service life has not been systematically identified for several substances but nevertheless assumed since it is considered that the uses identified could be applicable across most of the substances in the group based on information reported in the REACH registration dossiers and considering the similarities between the substances.

The use in heat transfer fluids is in closed systems from which opportunities for exposure is limited to loading and unloading of the fluids. Nevertheless, this task should be carried out by qualified personnel and so limited potential for exposure and release is expected. In this regard it is noted that substances EC 271-802-8, 258-649-2 and 400-370-7 were identified as alternatives in the restriction proposal for Terphenyl, hydrogenated (EC 262-967-7) in heat transfer fluids.[5]

Some substances (EC 248-654-8 and 258-649-2) are used as solvents in air filtration systems which seems to be also in a closed system. According to the information in the registration dossiers, leakages or releases from the system used to purify air (including during maintenance) must be prevented or captured, contained and managed to prevent release to water or soil.

Additionally, substances EC 248-654-8 and 271-802-8 are reported to be used in washing and cleaning products (unclear whether they are used as solvents and/or as heat transfer fluids) from which high potential for release/exposure may be expected.

The first step of the regulatory risk management action proposed, should the hazard exist, is the confirmation of hazard via harmonised classification (CLH[6]) as PBT/vPvB, ED and/or reprotoxic the substances EC 217-568-2, 248-654-8 and 258-649-2 are considered as potential for reproductive toxicity and endocrine disrupting properties and substances EC 248-654-8 and 258-649-2 are already self-classified as Repr. 1B. However, considering the potential hazard as vPvB for all the substances in the group and PBT for 7 substances, it is proposed that the ED and reproductive toxicity hazards will be considered together with the PBT/vPvB hazard, once it is clarified. Since the substances are already self-classified as Repr. 1B it is expected that this is already communicated downstream.

CLH is highly recommended as a step prior to restriction. For the human health endpoints, CLH i) will require company level risk management measures (RMM) for workers, to be in place, and ii) is a prerequisite to restrict the presence of the substances in consumer mixtures, by means of the restriction entries 28, 29 and 30

Confirmation of the hazard properties via CLH is not considered sufficient to minimise potential releases of the substances in the environment. A restriction is

[5] https://www.echa.europa.eu/web/guest/registry-of-restriction-intentions/-/dislist/details/0b0236e1862d9f6a

[6] The hazard classes PBT/vPvB, PMT/vPvM, ED have been introduced in CLP: CLP Delegated Act (europa.eu). Therefore, instead of SVHC identification under REACH, these hazards may be confirmed via CLH. It is not clear when to use which legal route (SVHC under REACH or CLH under CLP) during the period that both legal options are available.

seen as the most appropriate option as potential for exposure is expected from consumer uses, professional uses, article service life and industrial uses.

Releases to the environment from consumer uses (identified in polymeric preparations) cannot be avoided.

Widespread professional uses are typically non-contained and non-automated leading to releases to the environment. Professional uses have been identified in polymeric preparations, washing and cleaning products and heat transfer fluids.

Furthermore, potential for exposure and releases to the environment from articles is likely based on available information. Articles categories identified in textiles, plastic articles, machinery, mechanical appliances, electric and electronic articles, electrical batteries, and accumulators.

Therefore, **a restriction of the substances as such or in mixtures (concentration limit in mixtures) used by consumers, professional workers and industrial workers** is suggested after CLH, with the aim to minimise or control emissions to the environment and exposure to humans.

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 Sustainability[7].

Moreover, **restricting substances in articles** used by professionals or consumers is proposed as potential for exposure from articles is likely.

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

Annex 1: Overview of classifications

Data extracted on 30 January 2023

EC Number	CAS Number	Substance Name	Harmonised Classification	Classification in registrations
202-978-6	101-81-5	diphenylmethane		Aquatic Acute 1 H400 Aquatic Chronic 1 H410
203-096-4	103-29-7	1,2-diphenylethane		Aquatic Chronic 4 H413
208-482-6	530-48-3	1,1-diphenylethylene		Aquatic Chronic 2 H411
211-927-7	713-36-0	o-benzyltoluene		-
216-644-2	1633-22-3	tricyclo[8.2.2.24,7]hexadeca-1(12),4,6,10,13,15-hexaene		Skin Sens. 1B H317 STOT Rep. Exp. 2 H373
217-568-2	1889-67-4	1,1'-(1,1,2,2-tetramethylethylene)dibenzene		Skin Sens. 1B H317
218-533-4	2175-90-8	6,6'-diphenylfulvene		-

228-201-0	6165-51-1	2-(1-phenylethyl)-p-xylene		-
228-202-6	6165-52-2	4-(1-phenylethyl)-m-xylene		-
228-249-2	6196-95-8	4-(1-phenylethyl)-o-xylene		-
228-846-8	6362-80-7	1,1'-(1,1-dimethyl-3-methylene-1,3-propanediyl)bisbenzene		Skin Sens. 1 H317 STOT Rep. Exp. 2 H373, affected organs: liver Aquatic Acute 1 H400, M-factor: 10.00 Aquatic Chronic 1 H410, M-factor: 10.00 Acute Tox. 4 H302
248-097-0	26898-17-9	dibenzyltoluene		-
248-654-8	27776-01-8	benzyltoluene		Repr. 1B H360FD: May damage fertility. May damage the unborn child. Acute Tox. 4 H332 Skin Irrit. 2 H315 Asp. Tox. 1 H304 Aquatic Acute 1 H400 Aquatic Chronic 1 H410

254-179-7	38888-98-1	(phenylethyl)benzene		Acute Tox. 4 H332 Skin Irrit. 2 H315 Asp. Tox. 1 H304 Aquatic Acute 1 H400 Aquatic Chronic 1 H410
255-068-6	40766-31-2	(1-phenylethyl)xylene		-
258-649-2	53585-53-8	dibenzylbenzene, ar-methyl derivative		Repr. 1B H360, specific effect:H360FD (fertility effects, fetal kidney malformation) Asp. Tox. 1 H304 Aquatic Chronic 4 H413 Aquatic Chronic 1 H410, M-factor: 10.00
271-802-8	68608-82-2	Benzene, ethylenated, by-products from		Skin Irrit. 2 H315 Skin Sens. 1B H317 Asp. Tox. 1 H304 Aquatic Acute 1 H400 Aquatic Chronic 1 H410
400-370-7	-	6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene		Aquatic Chronic 1 H410
403-970-7	-	403-970-7		-
449-400-0	-	449-400-0		Aquatic Chronic 4 H413

618-465-9	9011-11-4	618-465-9		-
405-470-4	73807-39-3	A mixture of isomers of: methyldiphenylmethane; dimethyldiphenylmethane	Skin Irrit. 2 Aquatic Acute 1 H400; Aquatic Chronic 1 H410	
405-570-8	-	A mixture of isomers of: dibenzylbenzene; dibenzyl(methyl)benzene; dibenzyl(dimethyl)benzene; dibenzyl(trimethyl)benzene	Aquatic Acute 1 H400; Aquatic Chronic 1 H410	
430-690-2	52783-21-8	1-(2-isopropylphenyl)-1-phenylethane;1-(3-isopropylphenyl)-1-phenylethane;reaction mass of: 1-(4-isopropylphenyl)-1-phenylethane	Skin Irrit. 2 Aquatic Acute 1 H400; Aquatic Chronic 1 H410	
431-100-6	-	1-(sec-butylphenyl(phenyl)-2-phenylethane, mixed isomers;1-(sec-butylphenyl-1-phenylethane, mixed isomers;reaction mass of: sec-butylphenyl(phenyl)methane, mixed isomers	Aquatic Acute 1 H400; Aquatic Chronic 1 H410	
Substance 2	154643-91-1	1,3-bis[1-(4-tert-butylphenyl)vinyl]benzene		Muta. 2 H341

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

Data extracted on 30 January 2023

Main types of applications by product category	202-978-6	203-096-4	217-568-2	248-654-8	254-179-7	271-802-8	403-970-7	449-400-0	208-482-6	216-644-2	218-533-4	228-846-8	400-370-7	258-649-2	618-465-9	Substance 2
PC 35: Washing and cleaning products				I, **P**		I										
PC 3: Air care products				I										I		
PC 16: Heat transfer fluids				I, **P**	I	I							I	I, **P**		
PC 13: Fuels						I										
PC 32: Polymer preparations and compounds			F,I, **P**,**C**, (**A**)	F, (**I**), (**A**)				I, **C**, (**A**)			F, I, (**A**)	F, I, **P**, (**A**)		F, **A**		I, (**A**)
PC 9a: Coatings and paints, thinners, paint removes										I						
PC 21: Laboratory chemicals				I												
PC 19: Intermediate	I	I							I	I		I			I	
PC 26: Paper and board treatment products*							I, (**A**)									

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 9 February 2023

EC / List No	RMOA, ARN	Authorisation		Restriction*	CLH	Actions not under REACH / CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)	
258-649-2	YES					
405-470-4[2]				YES	YES	
405-570-8[2]					YES	
430-690-2[2]				YES	YES	
431-100-6[2]					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).

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