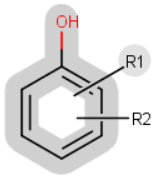
Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Date: 26/09/2022

Group Name: Hydrocarbylphenols

General structure:



R1= hydrocarbyl

R2=other variable structural fragment

Revision history

Version	Date	Description
1	26.09.2022	

Contents

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Foreword

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

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

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

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

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

For more information on Assessment of regulatory needs please consult ECHA website[1].

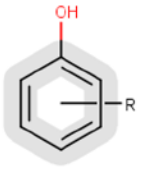
[1] https://echa.europa.eu/understanding-assessment-regulatory-needs

Glossary

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

1 Overview of the group

ECHA is assessing the regulatory needs of several groups of structurally related hydrocarbylphenols (i.e. phenols with any kind of saturated or unsaturated hydrocarbon substituent(s) on the phenol ring). The starting point of the grouping was the presence of the hydrocarbylphenol moiety in the structure of the substance. The hydrocarbylphenol moiety consists of a phenol, with any type of hydrocarbyl substituent(s). The substitution can vary in terms of number and position of the hydrocarbyl substituent(s) on the phenol. The hydrocarbylphenol moiety is shown in the figure below:



R=hydrocarbyl

hydrocarbyl phenol moiety

Some hydrocarbylphenols have already been scrutinised by Member State Competent Authorities. For some others, regulatory activities are ongoing. Several RMOAs have been concluded highlighting that emissions to the environment are of particular concern and proposing as a next step SVHC identification for endocrine disrupting (ED) properties, potentially followed by restriction to address also uses for which authorisation has limited effect (e.g. intermediates). Several hydrocarbylphenol substances have (subsequently) been identified as SVHCs and included in the Candidate List due to their endocrine disrupting properties for the environment, human health and/or reproductive toxicity. Furthermore, some of these substances already have a harmonised classification for skin sensitisation, aquatic toxicity and/or CMR properties (among others) whereas again some others are currently under substance evaluation to clarify ED and/or PBT properties.

Hydrocarbylphenols with confirmed ED properties are also found as minor constituents[2] in other (hydrocarbylphenol) substances.

The use of hydrocarbylphenols as such, as a minor constituent of other substances, in mixtures or articles is of concern because of their (potential) endocrine properties (ED), toxicity to reproduction and/or PBT/vPvB properties and potential exposure to human health and the environment. For this reason there was a need to develop an overall strategy to address this large group of substances focusing in particular on i) identifying the substances to cover, and ii) considering the most appropriate regulatory instrument to address the substances as such or as a minor constituent of other substances to minimise exposure and release to hydrocarbylphenols with hazardous properties.

This report documents the overall strategy proposed to identify and regulate a large group of hydrocarbylphenols. The assessment of regulatory needs of the specific

[2] A minor constituent is understood as a constituent the presence of which in a substance is not defined based on the name of that substance. A minor constituent would typically be an “impurity” of a well-defined substance. It can also for instance be a constituent in a UVCB substance. Knowledge on the presence of minor constituents varies depending on the substance type. For well-defined substances, any impurity that is present at a concentration level of at least 1% or that is relevant for the Classification and Labelling under CLP (C&L) or PBT assessment of the substance must be reported. However for UVCB substances, any constituent that is present at a concentration level of at least 10% or that is relevant for the C&L or PBT assessment of the substance must be reported.

sub-groups that fall within the scope of this hydrocarbylphenol umbrella group are or will be documented in separate reports (see Annex 1).

Several aspects relevant for regulating hydrocarbylphenols have been considered in this assessment and as a result, a wide scope of substances (more than 300) are covered including hydrocarbylphenol substances as such, substances containing hydrocarbylphenols as minor constituents, precursors that degrade to hydrocarbylphenols and other substances potentially relevant due to structural similarity to hazardous hydrocarbylphenols.

Based on information reported in the REACH registration dossiers and already assessed by ECHA for some of the groups of substances falling in the hydrocarbylphenol group, roughly 60% of the substances assessed have an Article 10 registration, 25% have an intermediate registration only and the remainder 15% are not registered. Substances registered according to Article 10 are most often used as intermediates in the production of other chemicals, in polymer preparations and compounds, paints/coatings, adhesives, lubricants, and washing/cleaning products. Their main reported function is as intermediate or monomer, followed by stabilising agent and antioxidant. The majority of registered substances have widespread uses and are used by professionals, consumers and/or end up in articles (mainly in production of rubber and plastic articles) where high potential for release/exposure is expected. Despite differences in chemical features across the different groups, there appears to be a high degree of similarity in reported product categories (PCs) mainly corresponding to the most common uses listed above. From the available information, some degree of interchangeability may be expected within the wide group of hydrocarbylphenol substances and consequently potential for regrettable substitution.

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.

On the exposure side, ECHA is mainly using the information on uses reported in the registration dossiers (IUCLID) as a proxy for assessing the potential for exposure to humans and releases to the environment. The potential for release / exposure is generally considered high for "widespread" uses, i.e. professional and consumer uses and uses in articles. For these uses, normally happening at many places, the expected level of control is *à priori* considered limited. The chemical safety reports are not necessarily consulted and no quantitative exposure assessment is performed at this stage.

2 Justification for the need for regulatory risk management action at EU level

2.1 Hazard

Based on information collected from the available assessment of regulatory needs reports and SVHC support documents, ECHA investigated the structure-activity relationship of hydrocarbylphenol substances. ECHA identified common functional features that could potentially drive the hazards identified, with a focus on ED properties and to some extent the repro and PBT/vPvB properties. The hydrocarbylphenol driving the hazard can be either:

- a registered substance as such,
- present as a minor constituent in other substance(s), and/or
- formed as a degradation product of precursor(s).

Based on the available process documentation[3,4] (SVHC and restriction) and further supported by evidence found in literature[5], a potential generic structure (Figure 1 below) has been defined for alkylphenols with ED ENV and HH properties. Key findings from literature are summarised in Table 1. Alkylphenols are a subset of hydrocarbylphenols that have aliphatic saturated hydrocarbyl substituents on the phenol; the hydrocarbylphenol group currently covers mainly alkylphenol members, in addition to a few others e.g. phenols with aliphatic unsaturated substituents.

NB: It is of note that most hydrocarbylphenol members are on the Candidate List only due to ED properties for the environment; however, according to the SVHC background document on 4-heptylphenol, branched and linear, effects observed in a "*28 day repeated dose study might indicate an estrogen mode of action*". Furthermore, due to adverse effects observed in a reproductive screening assay, "*effects on male and female reproduction cannot be excluded"*. Nevertheless, it was concluded that "*due to the scarce data set, no conclusions regarding endocrine disruptive effects can be drawn for human health assessment*". Therefore, ECHA assumes that the proposed generic structure for ED can be linked to both HH and ENV effects, unless it can be proven otherwise.

[3] SVHC identification document (4-heptylphenol, branched and linear); SVHC identification document (PDDP)

[4] Background document to RAC/SEAC on nonylphenol and nonylphenol ethoxylate

[5] Structural Features of Alkylphenolic Chemicals Associated with Estrogenic Activity

Figure 1: Generic structure of alkylphenols with ED ENV/HH properties[3]

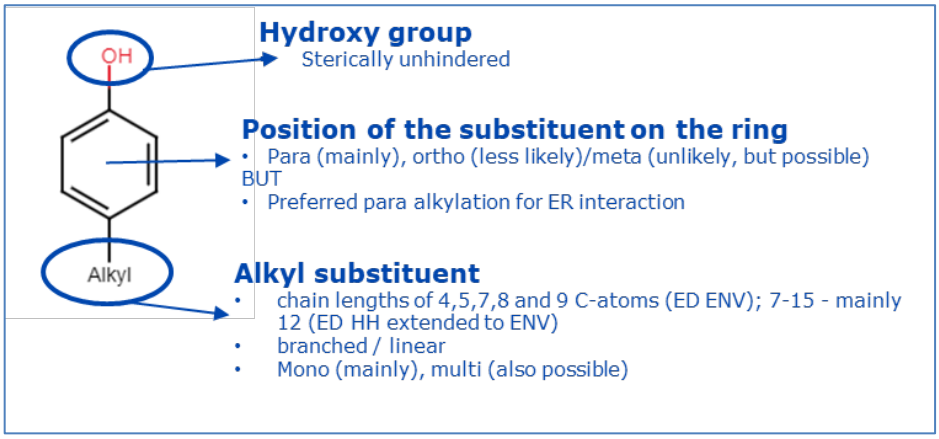


Table 1: Structural elements and impact on ED activity[4,5]

Alkyl group:	
Size	Estrogenic activity appears and increases from C3 to C8; it starts to decrease when C above 8 (for 4-tert-branching structures)
Degree of branching	Tertiary more potent but trend not so well defined (reversed in certain cases)
Position	Para for optimal estrogenic activity. It is possible that meta/ortho derivatives, if active, are very weak
Effect of di-substitution (alkyl groups similar in size)	Likely reduces or abolishes estrogenic activity. Importance of unhindered ring structure.
Hydroxyl group:	
Substitution (e.g. ethoxylation)	Short chain ethoxylates are less active than the unsubstituted nonylphenol equivalent
Hindrance	Unhindered OH required for optimal activity

With regard to structural features of alkylphenols with ED properties, the overall findings suggest that:

- the alkyl group can vary in size, number, branching and position on the phenyl ring;
- phenol with unhindered OH appears to be necessary, however ED concern for substances with hindered OH cannot be fully excluded;
- alkyl substitution is reported primarily in the para position (and seems preferrable for optimal ED activity), however it may occur in the ortho/meta position as well, with variable likelihood;
- there is a variable carbon chain length, ranging from 4-15 carbon atoms;
- alkyl chain can be both linear and branched, however branched seems preferable for optimal ED activity;

- position and degree of branching of the alkyl group impacts the level of estrogenic activity such that para > meta > ortho and tertiary > secondary = normal.

➢ Features most likely associated with optimal ED activity are single tertiary branched alkyl group (C6-8) in para position.

Strategy for the hazard assessment:

Assessment of regulatory needs for many hydrocarbylphenol members is still ongoing and data generation is often proposed as the next step for many substances. Therefore, as a first step in the overall strategy for the wide group of hydrocarbylphenols, it is proposed to clarify the hazard of hydrocarbylphenols and progress with data generation where needed.

2.2 Use and exposure

The following considerations refer only to the subset (majority) of hydrocarbylphenol members that have been or are currently under assessment for regulatory needs.

The majority of assessed hydrocarbylphenol members have Article 10 registrations, however a significant portion are registered only as intermediates (OSII or TII).

Uses and technical functions

Most common uses reported in the REACH registration dossiers are: paints/coatings, polymer preparations and compounds, intermediates, lubricants, adhesives/sealants and washing/cleaning products. The (partially) shared use pattern and structural similarities between many hydrocarbylphenols suggest that some degree of interchangeability may be expected however further investigation is needed to clarify the potential for regrettable substitution. For some members, these uses are intended i.e. the hydrocarbylphenol constituent contributes to the technical function of the substance; however for some others, the use may be unintended i.e. the hydrocarbylphenol constituent is present as an impurity or formed unintentionally during the production process[6].

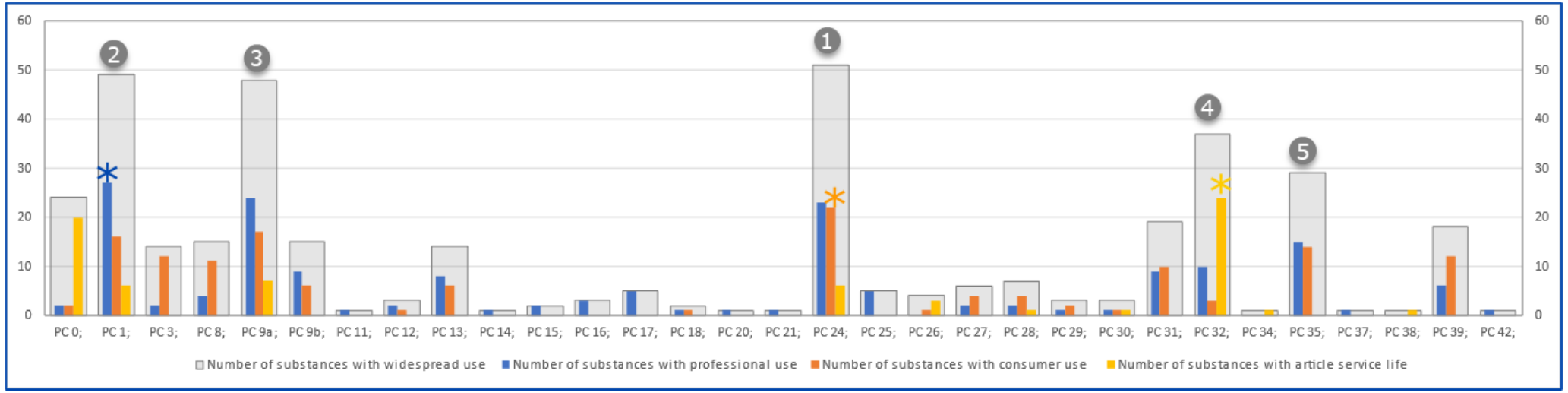
Many technical functions have been reported in the registration dossiers however most common are: intermediate/monomer, stabilizing agent, antioxidant, lubricating agent, fragrance.

[6] Based on an investigation of the production process of substances containing 4-TBP, ECHA has concluded that low concentrations of 4-TBP are likely to correlate with a lack of function however investigation of the production process of other hydrocarbylphenols is still needed. ARN for Substances containing 4-TBP

Around 70% of assessed registered hydrocarbylphenols have widespread uses reported (professional, consumers and article service life). An overview of all reported widespread uses (by PC) according to lifecycle stage is shown in Figure 2 below. The most common reported use per lifecycle stage is indicated below with (*) in the respective colour code.

Figure 2: Distribution of widespread uses by PC[7]

Top 5 PCs with P, C, or A :
1. PC 24: Lubricants, greases, release products
2. PC 1: Adhesives, sealants
3. PC 9a: Coatings and paints, thinners, paint removers
4. PC 32: Polymer preparations and compounds
5. PC 35: Washing and cleaning products



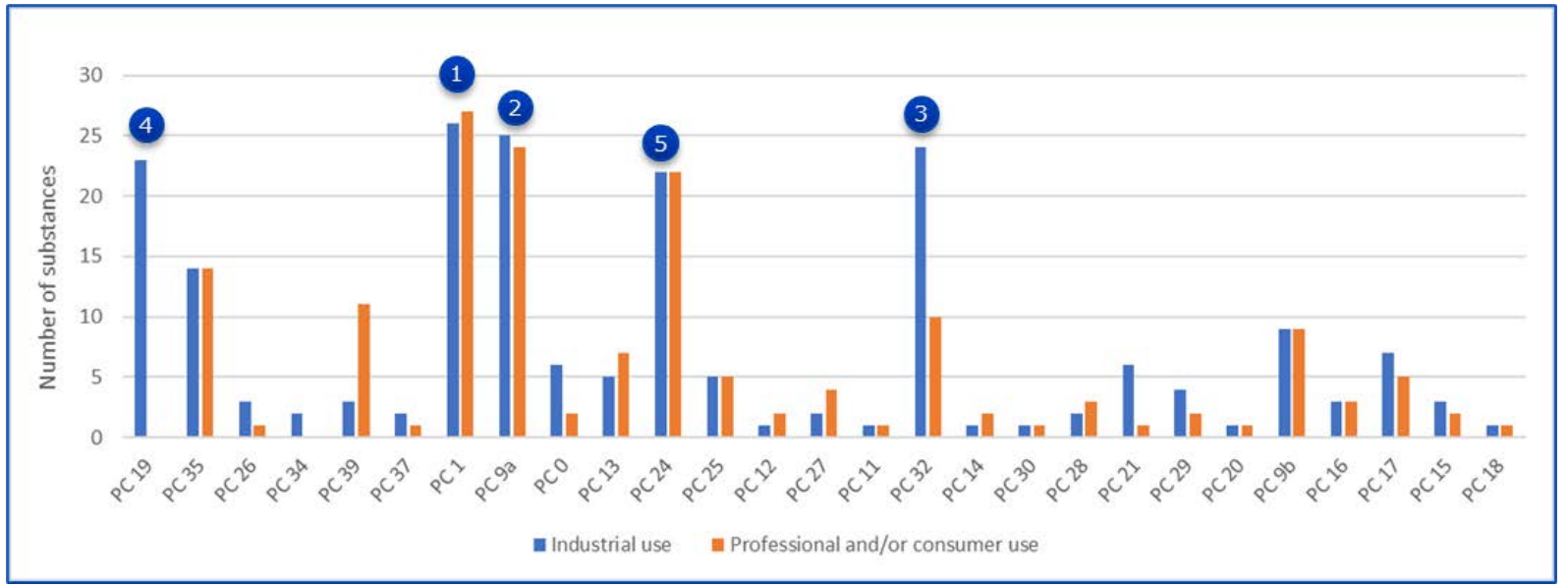
[7] PCs and corresponding names are listed in ECHA's Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.12: Use description

All assessed registered hydrocarbylphenols have industrial uses reported. Overview of reported industrial uses (by PC) is shown in blue bars in Figure 3 below.

Figure 3: Distribution of industrial uses by PC

Top 5 PCs for industrial uses:

1. PC 1: Adhesives, sealants
2. PC 9a: Coatings and paints, thinners, paint removers
3. PC 32: Polymer preparations and compounds
4. PC 19: Intermediate
5. PC 24: Lubricants, greases, release products

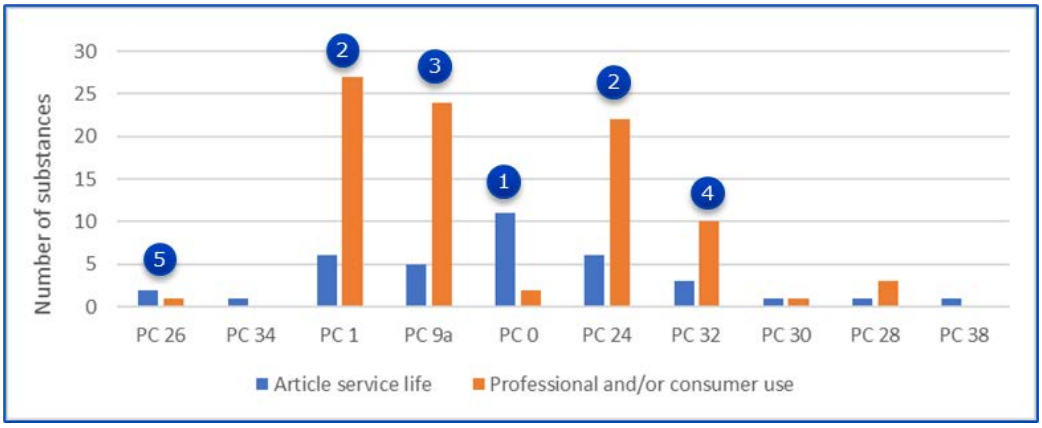


Some assessed registered hydrocarbylphenols are used in articles. An overview of the PCs reported and related to article service lifecycle stage is shown in Figure 4 below. The (likely) most common technical functions reported for these PCs are lubricating agent, antioxidant and/or stabilizing agent. Technical functions are provided at substance level and not related to a specific use, however there is an indication that hydrocarbylphenols may remain in the produced article and potentially lead to release and exposure.

Figure 4: Overview of PCs with related article service life

Top 5 PCs relating to ASL:

1. PC 0: Other - can refer to rubber, plastics, fragrance, scented articles, construction materials
2. PC 1: Adhesives, sealants & PC 24: Lubricants, greases, release products
3. PC 9a: Coatings and paints, thinners, paint removers
4. PC 32: Polymer preparations and compounds
5. PC 26: Paper and board treatment products



Exposure (environment)

From the assessment done on 4 tert-butylphenol (4-TBP) and substances containing 4-TBP, releases to the environment are expected during manufacturing and from resulting products. The concentration of 4-TBP as a minor constituent is often low (even below 0.1%), however it is suspected that the sum of low-level emissions from many widespread sources may contribute significantly to the overall release of 4-TBP to the environment. Furthermore, combined effects as a result of co-exposure to multiple substances acting via a similar mode of endocrine action cannot be excluded.

A similar assessment has not yet been carried out for other hydrocarbylphenols and further investigation is needed to clarify to what extent releases of other hydrocarbylphenols, including from their presence as constituents in other substances, might contribute to the overall emissions of hydrocarbylphenols to the environment.

In order to estimate the potential impact to the environment from different uses (based on PCs) the different PCs have been assigned a default emission release factor to water. For substances with multiple uses where more than one release factor could be applied, the worst case scenario (highest release factor) was used. To assess the total amount of substance released to water, the upper limit of the maximum registered tonnage band for the substance was considered. This value was multiplied by the release factor to water in order to provide a preliminary indication of potential release to the environment.

The main uncertainties from using this approach are:

i. information in registration dossiers usually does not specify the amount of substance dedicated to each use, therefore it is not possible to have an exact indication on the impact of a specific use on the exposure to the environment and the release to water is most probably overestimated.

ii. this estimation is based on predicted ERCs based on reported PCs, therefore the release factors used do not necessarily reflect ERCs reported in the registration dossiers.

Despite the uncertainties, the preliminary findings suggest that substances with the **highest estimated releases** are most often used in **washing and cleaning products, paints and coatings, lubricants and adhesives**. In addition, the scenario related to use in **articles** is common and has the third highest release factor to water. However, it is important to highlight that some (potentially common) PCs were not represented in the scenarios used and therefore some uses and/or substances were not considered in this estimation. In particular, substances reporting PCs corresponding to intermediates, polymer preparations and compounds and ore extraction were not included.

Strategy for uses and exposure:

Assessment of regulatory needs for many hydrocarbylphenol members is still ongoing and many uncertainties remain regarding use and exposure. Further work is needed to clarify, in particular: potential for substitution, the (predicted) presence of hydrocarbylphenols (other than 4-TBP) as a minor constituent in other substances, the function (or lack of) of identified hydrocarbylphenol constituents, and a refined assessment of the overall release to the environment (including from low-level emissions).

2.3 Restriction as last foreseen regulatory action

Based on currently available information, a need for further EU regulatory risk management is foreseen with restriction as last foreseen action. Confirmation of a clear relationship between chemical structure and hazard properties (such as ED) is the first step for the identification of Regulatory Risk Management (RRM) actions to address risks from uses of hydrocarbylphenols. In addition to ED properties, most hydrocarbylphenols have potential reproductive toxicity and some of them potential PBT/vPvB properties. Both hazards have been investigated in assessment of regulatory needs reports and often data generation is required first to clarify the hazard. For many groups, toxicity to reproduction and ED properties seem to be related to the same structural features, however the link between hazard and structure is often not clear and requires further investigation. Based on the preliminary assessment covered by this work, there is a concern with a broad range of hydrocarbylphenol-related substances with a potential for release and exposure. It is suspected that most hydrocarbylphenol members share a similar hazard profile - in particular ED properties potentially driven by a (relatively generic) fragment present in their structure, namely a phenol with unhindered OH group and alkyl substitution reported primarily in para position. Although there are several such hydrocarbylphenols that have been included in the Candidate List due to confirmed ED properties, for many substances in the group further data generation is still needed or already ongoing to clarify the hazard.

Nevertheless, there is a **potential concern with any substance where this hydrocarbylphenol-type structure may be present** including hydrocarbylphenol substances as such, substances containing hydrocarbylphenols

as minor constituents, precursors that degrade to hydrocarbylphenols and other substances potentially relevant due to structural similarity.

Once the hazard will be clarified, SVHC identification for ED and/or PBT/vPvB properties is proposed as a first step after data generation in the overall regulatory strategy for hydrocarbylphenols to confirm the hazard. Depending on the outcome of hazard confirmation for ED properties, a harmonised classification for toxicity to reproduction may also be needed to ensure adequate protection of human health. It should be considered whether a group approach based on similar mode of action is possible or whether a substance-by-by substance approach would be needed. It is important to highlight that the existing (and future) SVHC identification or CLH of several hydrocarbylphenols as repro, ED or PBT/vPvB is already sufficient for confirming the hazard as repro, ED or PBT/vPvB of all substances containing those hydrocarbylphenols as constituents (when present in the substance above the relevant regulatory threshold). Therefore, only hydrocarbylphenols as such and not substances containing hydrocarbylphenols as minor constituents are recommended for CLH or inclusion in the Candidate List.

Restriction under REACH has been identified as the most suitable regulatory risk management tool to address the wider group of (relevant) hydrocarbylphenols due to their (potential) ED, reproductive toxicity and/or PBT/vPvB hazards, potential for release and exposure and potential for regrettable substitution. The identified need for restriction to address the wider group of hydrocarbylphenols has been included as an entry ("Substances containing 4-tert-butylphenol (4-TBP), 4-nonylphenol and other alkylphenols") in the Restrictions Roadmap under the Chemicals Strategy for Sustainability[8] and is the outcome of preliminary discussions between ECHA, Member States and the Commission.

As a first option, a restriction may potentially target a group of hydrocarbylphenols as defined by a common structure. This option is considered as the most appropriate regulatory instrument to address the wide group.

As an alternative, a restriction with a (semi) automated inclusion mechanism based on SVHC identification or CLH embedded in the entry could potentially be considered to ensure that hydrocarbylphenols confirmed as hazardous in the future would also be covered. It is expected that such a restriction would:

- motivate Industry to look for non-intended presence of hydrocarbylphenols with confirmed hazards in their substances and reduce their concentration in all substances, mixtures and articles brought onto the market;
- prevent the introduction of new, toxicologically and structurally similar hydrocarbylphenols onto the market;
- prevent regrettable substitution;
- address the additivity effect of many low-level emissions to the environment.

A more detailed elaboration on restriction under REACH as the identified regulatory need as well as considerations of alternative or additional regulatory actions can be found in the assessment of regulatory needs for substances containing 4-TBP[9]; although the assessment primarily focuses on 4-tert-butylphenol as such and as a minor constituent, the same considerations and principles can be applied to the wide group of hydrocarbylphenols.

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[8] Restrictions Roadmap under the Chemicals Strategy for Sustainability

[9] Further elaboration on restriction under REACH as the identified regulatory need as well as considerations of alternative or additional regulatory actions can be found in the assessment of regulatory needs for substances containing 4-TBP: ARN for Substances containing 4-TBP

Having in mind that the target is still to cover the wide group of hydrocarbylphenols, a stepwise approach can be considered to implement the broad restriction. As a first step, it is suggested to focus on hydrocarbylphenols with confirmed environmental effects (ED ENV and/or PBT/vPvB), with demonstrable potential for emission to the environment and real possibility for regrettable substitution. The initial entry would potentially address emissions from production and use. Further refinement of the entry could be considered to target specific uses, depending on their relevance for emission to the environment. It should be considered whether hazard confirmation for other hydrocarbylphenols could be carried out in parallel, so as to not delay regulatory action for those already confirmed.

The impact of the initial restriction entry may be monitored to quantify the effects on minimisation of release and exposure to the wide group of hazardous hydrocarbylphenols. Result of monitoring may be used to identify further aspects to take into consideration for future expansion of the scope of the restriction: e.g. identification and inclusion of relevant precursors and the need for additional measures to ensure adequate protection of workers.

3 Conclusions and actions

The conclusions and actions proposed in the table below are based on the REACH and CLP information available at the time of the assessment by ECHA. The main source of information is the registration dossiers. Relevant public assessments may also be considered. When new information (e.g. on hazards through evaluation processes, or on uses) will become available, the document will be updated and conclusions and actions revisited.

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
Hydrocarbylphenol members with **confirmed ED**, **Repro** and/or **PBT** properties	Known hazard for ED Known hazard for reproductive toxicity	Known hazard for ED Known hazard for PBT/vPvB	Many widespread uses reported with a high potential for release and exposure. Most common widespread uses reported in registration dossiers are: lubricants, adhesives, coatings/paints, polymer preparations, and washing/cleaning products. Exposure as a result of release from articles cannot be excluded. Most of the substances are also used as intermediates in the production of other chemicals. Potential for release to the environment from industrial uses and production is expected however further assessment is needed to clarify.	**Need for EU RRM: Restriction** <u>Justification:</u> Restriction of hydrocarbylphenols as substances, constituents in other substances, mixtures and articles up to a certain threshold is proposed to ensure minimisation of release and exposure. A stepwise approach can be considered with an initial focus on confirmed environmental effects, regrettable substitution potential and emissions from production and use.	**Next steps (if hazard confirmed):** Restriction
Hydrocarbylphenol members with **potential ED**, **Repro** and/or **PBT** properties	Potential hazard for ED Potential hazard for reproductive toxicity	Potential hazard for ED Potential hazard for PBT/vPvB			**First step:** • CCH and/or SEv • SVHC identification and/or CLH **Next steps (if hazard confirmed):** Restriction

Annex 1: Overview of completed or ongoing regulatory risk management activities

Data extracted in July 2021

EC / List number	RMOA	Authorisation		Restriction*	CLH
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)
201-280-9	x	ED ENV			
202-679-0	x	ED ENV			x
205-426-2		ED ENV			x
276-743-1		ED ENV			
310-154-3	x	Repro ED HH ED ENV			x
701-028-2	x	ED ENV			
201-861-7		Repro			x
203-199-4		ED ENV			
246-672-0		ED ENV			x
284-325-5		ED ENV			
500-045-0		ED ENV	x	x	
640-104-9	x	Repro ED HH ED ENV			
939-460-0	x	ED ENV			
401-720-1	x	Repro			x
4-OP ethoxylates		ED ENV	x		
202-987-5					x
203-441-9					x
247-979-2					ongoing
701-135-4					ongoing
247-759-6					x

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

Annex 2: Approach for estimating emissions to the environment

Criteria for the definition of the scenarios[10]

	Scenario	Users	Product categories included	Default release factor to water
1	Formulation of mixtures	Industrial	PC4, PC35, PC8, PC28, PC3, PC39, PC31 (cleaners, polishes, de-icers)	0.001
2	Industrial use, low water contact	Industrial	PC1, PC9c, PC9b, PC9a, PC18 (coatings, inks, adhesives) PC24, PC16, PC17, PC13 (functional fluids and fuels inclosed systems)	0.003
3	Industrial, water-based processing into/onto article matrix (ERC 5); 90% onsite RMM assumed	Industrial	PC26, PC34, PC23, PC14 (textile, paper, leather, metal surface finishing products)	0.02
4	Widespread use of down the drain products	professional, consumers	PC4, PC35, PC8, PC28, PC3, PC39, PC31 (cleaners, polishes, de-icers, cosmetics)	1
5	Widespread use in coatings, adhesives, inks, motor oil, break fluids	professional, consumers	PC1, PC9c, PC9b, PC9a, PC18 (coatings, inks, adhesives) PC24, PC16, PC17, PC13 (functional fluids and fuels in closed systems)	0.05
6	Widespread service life	professional, consumers	No specific material/article assumed	0.03

[10] Based on default values listed in ECHA's Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.12: Use description and Chapter R.16: Environmental exposure assessment