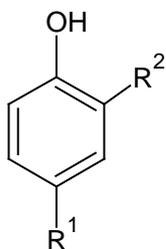


Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Group Name: 4-hydrocarbylphenols (other than styrenated phenols)

General structure:



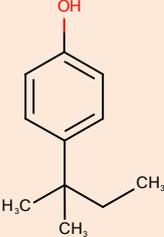
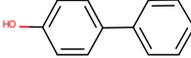
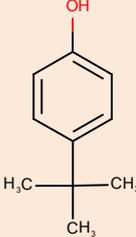
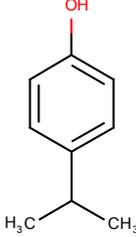
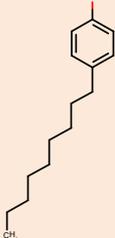
R1: alkyl, cyclohexyl, phenyl

R2: alkyl (optional)

Revision history

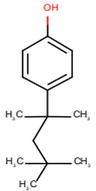
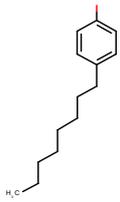
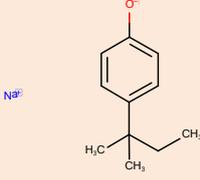
<i>Version</i>	<i>Date</i>	<i>Description</i>
1.0	4 December 2023	

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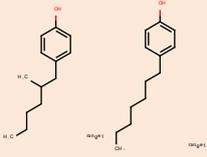
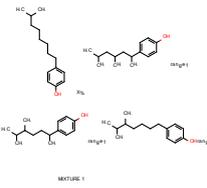
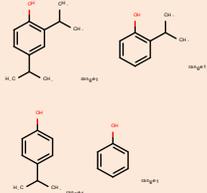
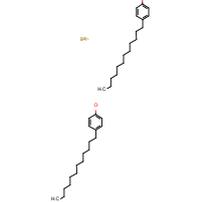
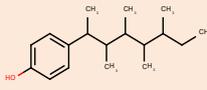
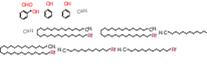
EC/List number	CAS number	Substance name [and/ or Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) ¹
201-280-9	80-46-6	p-(1,1-dimethylpropyl)phenol		Full, 100-1000
202-179-2	92-69-3	Biphenyl-4-ol		OSII or TII
202-679-0	98-54-4	4-tert-butylphenol		Full, >1000
202-798-8	99-89-8	p-isopropylphenol		OSII or TII
203-199-4	104-40-5	p-nonylphenol		Full, not (publicly) available

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>

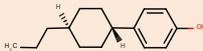
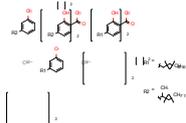
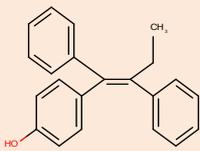
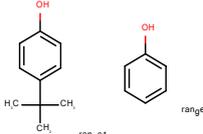
ASSESSMENT OF REGULATORY NEEDS

EC/List number	CAS number	Substance name [and/ or Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) ¹
205-426-2	140-66-9	4-(1,1,3,3-tetramethylbutyl)phenol		Full, >1000
214-465-4	1131-60-8	4-cyclohexylphenol		OSII or TII
217-302-5	1806-26-4	p-octylphenol		C&L notification
234-284-4	11066-49-2	Isononylphenol	-	C&L notification
234-304-1	11081-15-5	Isooctylphenol	-	Not registered
246-672-0	25154-52-3	Nonylphenol	-	C&L notification
247-770-6	26543-97-5	p-isononylphenol	-	Not registered
248-310-7	27193-28-8	(1,1,3,3-tetramethylbutyl)phenol	-	C&L notification
248-312-8	27193-86-8	Dodecylphenol	-	C&L notification
250-595-8	31366-95-7	Sodium 4-(1,1-dimethylpropyl)phenolate		Not registered
266-717-8	67554-50-1	Octylphenol	-	C&L notification

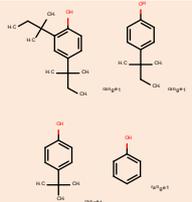
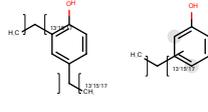
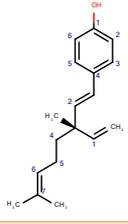
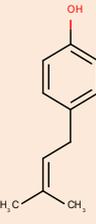
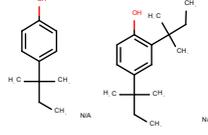
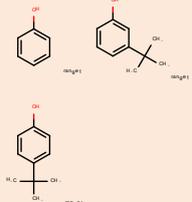
ASSESSMENT OF REGULATORY NEEDS

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
276-743-1	72624-02-3	Phenol, heptyl derivs.		Full, 100-1000
284-325-5	84852-15-3	Phenol, 4-nonyl-, branched		Full, >1000
291-826-2	90480-88-9	Phenol, isopropylated		OSII or TII
300-141-0	93922-04-4	Barium 4-dodecylphenolate		Full, 10-100
310-154-3	121158-58-5	Phenol, dodecyl-, branched		Full, >1000
430-180-1	-	A mixture of: calcium bis(C10-14 branched alkyl salicylate); calcium bis(C18-30-alkyl salicylate); calcium C10-14 branched alkylsalicylato-C18-30-alkyl salicylate; calcium bis (C10-14 branched alkyl phenolate); calcium bis (C18-30-alkyl phenolate); calcium C10-14 branched alkylphenolato-		NONS

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
		C18-30-alkyl phenolate; C10-14 branched alkyl phenol; C18-30-alkyl phenol		
440-740-5	81936-33-6	4-(4-trans-propylcyclohexyl)phenol		OSII or TII
455-880-2	-	A mixture of: calcium bis(C10-14 branched alkylsalicylate); calcium bis(C18-30 alkyl salicylate); calcium bis(C18-30 alkyl phenolate); calcium bis(C10-14 branched alkyl phenolate); lubricating oil (C15-30)		NONS
616-100-8	74499-35-7	phenol, (tetrapropenyl) derivatives	-	C&L notification
925-479-1	-	C14-16-18 Alkyl phenol	-	Not registered
614-707-2	68684-63-9	Phenol, 4-(1,2-diphenyl-1-buten-1-yl)-		OSII or TII
905-392-5	-	Reaction mass of 4-tert-butylphenol and phenol		OSII or TII

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
931-185-4	-	Still Bottom Residue from Amyl- and Diamylphenol manufacturing process		OSII or TII
931-468-2	1190625-94-5	Phenol, C14-18-alkyl derivs.		Full, not (publicly) available
640-104-9	210555-94-5	phenol, 4-dodecyl-, branched		C&L notification
685-515-4	10309-37-2	Phenol, 4-[(1E,3S)-3-ethenyl-3,7-dimethyl-1,6-octadien-1-yl]-		Full, not (publicly) available
686-822-6	1200-09-5	Phenol, 4-(3-methyl-2-buten-1-yl)-		OSII or TII
941-702-5	-	Reaction mass of 4-(2-methylbutan-2-yl)phenol and 2,4-bis(2-methylbutan-2-yl)phenol		OSII or TII
942-988-4	-	Reaction mass of 3-tert-Butylphenol, 4-tert-Butylphenol and phenol		OSII or TII
947-217-5	-	Phenol, mono-C24-28 (even)-sec-alkyl derivs, ortho- and para-	-	Full, not (publicly) available

ASSESSMENT OF REGULATORY NEEDS

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

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

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

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

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

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

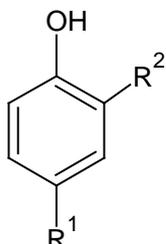
² <https://echa.europa.eu/understanding-assessment-regulatory-needs>

Glossary

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

1 Overview of the group

ECHA has grouped together 36 structurally similar substances based on the presence of the 'phenol' moiety which is always substituted in position 4 and for some substances in the group also in position 2. The term 'hydrocarbyl' means any univalent radical, derived from a hydrocarbon, such as methyl, ethyl etc. A generic structure common in all substances is shown in the figure below.



R1: alkyl, cyclohexyl, phenyl

R2: alkyl (optional)

The group consists of 10 mono-constituents, 4 multi-constituent and 10 UVCB substances. The registration status of the substances is the following: 11 with full (Article 10) registrations, 8 with C&L notifications, 11 intermediate registrations, 2 NONS, 4 not registered.

Some of the substances with confirmed ED properties (e.g. 4-tert-butylphenol, 4-nonylphenol) are also present as constituents or impurities in other members of the group. Several substances in the group³ have also been assessed for regulatory needs as part of the group "substances containing 4-tert-butylphenol"⁴, with the aim to regulate them based on the presence of a common constituent of concern.

Based on information reported in the REACH registration dossiers, the most common uses reported in the group are as intermediates and in polymer preparations and compounds. In addition, many substances report uses in adhesives/sealants, coatings/paints, and inks/toners. Information on technical function is not clear (many functions reported and usually repeated for all uses) however the most relevant are likely monomer or intermediate. Professional and consumer uses are reported for some of these substances as well as article service life (ASL), however they are often not reflected in the dossiers of the lead (and some members) of the joint registration which mainly report industrial uses. In many cases it is not clear whether these widespread uses refer to the registered substance or rather to the end use of the manufactured chemical or polymer. One substance in the group (List 685-515-4) appears to be an outlier and is used only in the formulation of cosmetics and personal care products.

There is a potential for release and exposure as a result of professional, consumer and industrial uses. Industrial uses are potentially widespread as for many substances there are multiple registrants and high overall volumes (e.g. registered tonnage bands of 100 t/y or more) suggesting the industrial uses can occur across multiple sites and/or by many users. Furthermore, previous RMOAs carried out by

³ EC/List 201-280-9, 202-679-0, 205-426-2, 276-743-1, 310-154-3, 905-392-5, 931-185-4 and 941-702-5, 942-988-4

⁴ <https://echa.europa.eu/assessment-regulatory-needs/-/dislist/details/Ob0236e186f71323>

authorities suggest that there is a concern with several substances in the group and their release to the environment, noting that relevant sources of emission are likely industrial wastewater and residues present in many products with widespread uses. Exposure as a result of release from articles cannot be excluded. ASL has been reported for uses in polymers (e.g. production of plastic and rubber articles) and for applications of mixtures such as coatings, paints and adhesives leading to the inclusion in articles. However, it is not clear whether and to what extent releases of the substances from those articles could be expected.

p-(1,1-dimethylpropyl)phenol (ptPP) and 4-tert-butylphenol (4-TBP) have been highlighted in previous RMOAs by Germany as possible substitutes for 4-nonylphenol (4-NP) and 4-tert-octylphenol (4-OP) for uses in phenolic and epoxy resins^{5,6}. Due to the structural similarities between all group members some degree of interchangeability could be expected for the whole group. However, this will depend on specific uses and is particularly uncertain for intermediate uses where small changes in chemical structure are expected to have a strong impact on function. Nevertheless, there is likely a potential for regrettable substitution for some uses.

There is an ongoing substance evaluation for several members (EC 201-280-9, 202-679-0, 284-325-5) to clarify ED, PBT/vPvB and/or exposure potential. In addition, several RMOAs (EC/List 201-280-9, 202-679-0, 310-154-3, 616-100-8, 640-104-9) have been concluded often 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. Several substances (EC/List 201-280-9, 202-679-0, 203-199-4, 205-426-2, 234-284-4, 246-672-0, 247-770-6, 276-743-1, 284-325-5, 310-154-3, 616-100-8, 640-104-9) 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. None of these substances have been prioritised for inclusion in Annex XIV⁷ because the majority of their reported uses (intermediate, monomer in polymer production) are out of scope for Authorisation or not considered for priority assessment (monomer imported as part of polymer). Nonylphenol (EC 246-672-0) is also restricted for certain uses such as cleaning and textile/leather processing under Entry 46⁸ of Annex XVII.

It is important to note that 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). Some hydrocarbylphenols have already been scrutinised by Member State Competent Authorities. For some others, regulatory activities are ongoing. The use of hydrocarbylphenols as such, as a constituent/impurity, in mixtures or articles with (potential) endocrine properties (ED), toxicity to reproduction and/or PBT/vPvB properties and potential exposure to human health and the environment is of concern. ECHA, Member States and the Commission are working together to i) identify those substances, and ii) consider the most appropriate regulatory instrument to address the substances as such or as a constituent to minimise exposure to those hydrocarbylphenols with hazardous properties. This report documents the assessment of regulatory needs of substances belonging to the

⁵ [RMOA conclusion document on 4-tert-butylphenol](#)

⁶ [RMOA conclusion document on p-\(1,1-dimethylpropyl\)phenol](#)

⁷ [11th recommendation round: results of prioritisation assessment for inclusion in Annex XIV](#)

⁸ [Entry 46 of Annex XVII to REACH](#)

group **4-hydrocarbylphenols (other than styrenated phenols)**. The assessment of regulatory needs of the other hydrocarbylphenol-related groups and the overall regulatory strategy for the wider group of hydrocarbylphenols are or will be documented in separate reports.

Note on the scope of ECHA's assessment of regulatory needs

Regarding hazards, the focus of ECHA's assessment is on CMR (carcinogenic, mutagenic and/or toxic to reproduction), sensitiser, ED (endocrine disruptor), PBT/vPvB or equivalent (e.g. substances being persistent, mobile and toxic), aquatic toxicity hazard endpoints and therefore only those are reflected in the table in section 3. This does not mean that the substances do not have other known or potential hazards. In some specific cases, where ECHA identifies a need for regulatory risk management action at EU level for other hazards (e.g. neurotoxicity, STOT RE), such additional hazards may be addressed in the assessment. An overview of classification is presented in Annex 1.

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

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

Based on currently available information, there is a need for (further) EU regulatory risk management – restriction for all substances for ED properties for human health and the environment and/or reproductive toxicity hazards due to the potential for release/ exposure or the potential for regrettable substitution.

Based on ECHA's assessment of hazard information currently available in the registration dossiers and considerations of structural similarity and presence of common functional moiety all the substances in the group have (potentially) the following human health/environmental hazards: reproductive toxicity, endocrine disrupting properties for human health and the environment. These hazards are identified based on several observed effects in available studies and/or legal confirmation of hazards under REACH/CLP from a high number of substances in the group. Based on structural similarity the findings from the toxicity studies are extrapolated to the substances where there is limited information for these endpoints.

All substances in the group have known or potential ED properties. The ED HH, ED ENV and/or reproductive toxicity for several substances in the group have been confirmed through inclusion in the Candidate list and/or Annex VI to CLP (see Annex 3 for full overview). In addition, several other members (List 905-392-5, 931-185-4, 941-702-5, 942-988-4) contain one or more of these substances (e.g. 4-TBP)

as constituents above the regulatory threshold and are therefore also considered as confirmed ED ENV.

Based on ECHA's preliminary assessment, it is suspected that reproductive toxicity and ED effects may be driven by structural similarity to the natural steroid hormone estradiol and the consequent potential of the group members to mimic its estrogenic effects. According to findings in literature, structural features of alkylphenolic compounds such as size of the alkyl group and degree of branching influence estrogenic potency⁹. In particular, it is suspected that hindrance of the hydroxyl group plays an important role and that an unhindered hydroxyl group may be required for optimal ED activity. All substances in the group contain unhindered constituents and some of them also hindered derivatives. Nevertheless, it is assumed here that all substances have potential ED properties even if potency is expected to vary within the group.

In addition to ED and repro effects, all substances are toxic to the aquatic environment and several have potential skin sensitisation and/or PBT/vPvB properties. However, the available data on skin sens and bioaccumulation provide a mixed picture. Therefore, no clear trend was identified that could be extrapolated to the whole group. Nevertheless, no additional action is currently proposed for these hazards - it is expected that a restriction targeting ED effects would introduce sufficiently stringent measures to address any potential PBT and skin sensitisation properties as well.

Compliance checks will be opened for substances EC/List 300-141-0, 931-468-2, 947-217-5 to further clarify the hazards, most notably ED and PBT/vPvB properties. Two of these substances have a partly hindered hydroxyl group and further data may bring insight into the impact of this structural feature on potential ED hazards. It is important to note that, whilst data generation could bring additional clarity on the impact of hindrance on the potency of ED effects, all substances in the group also contain unhindered constituents. In addition, all substances in the group are closely related in terms of structural similarity and ED properties have been legally confirmed at the EU-level for many. Consequently, there may be a sufficient basis for extrapolating and confirming the ED hazard at the group level with the data currently available. Therefore, in order to avoid a delay in regulatory action, it would be recommended to proceed in parallel with the regulatory strategy proposed below.

The first step of the regulatory risk management action proposed, should the hazard exist, is the confirmation of hazard via SVHC identification and inclusion on the Candidate List¹⁰ as ED. It should be considered whether a group approach based on similar mode of action is possible or whether a substance-by-substance approach would be needed (note that one third of the group already is SVHC for ED ENV). 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.

⁹ [Structural Features of Alkylphenolic Chemicals Associated with Estrogenic Activity](#)

¹⁰ Note that the Commission published the new hazard classes in CLP (PBT/vPvB, PMT/vPvM, ED): [CLP Delegated Act \(europa.eu\)](#). Therefore, if/when these hazard classes will be implemented in CLP, instead of SVHC identification under REACH, these hazards may be confirmed via CLH. It is not yet clear when to use which way for the time being.

SVHC identification is highly recommended as a step prior to restriction for substances with ED properties. 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 of the substances as such, as constituents/impurities in other substances and in mixtures is seen as the most appropriate option as potential for exposure is expected from consumer, professional, and industrial uses (including potentially intermediate, monomer). Moreover, restricting substances in articles should be considered in the context of the restriction as potential exposure from articles needs further investigation first. In addition, inclusion of precursor substances that degrade under environmentally relevant conditions (e.g. 4-NP and 4-OP ethoxylates) or via metabolic transformation to members of this group would be recommended. It should be considered whether hazard confirmation for group members with potential ED properties could be carried out in parallel to the proposed restriction for group members with confirmed ED properties, so as to not delay regulatory action. Alternatively, a read-across based hazard assessment could be considered for the entire group within the context of the restriction proposal instead of hazard confirmation via SVHC.

As highlighted in the group overview, ECHA is currently assessing the regulatory needs of several groups of hydrocarbylphenols and has developed an overall regulatory strategy¹¹. **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. Furthermore, ECHA already concluded that for substances containing 4-TBP restriction is the most appropriate EU-wide regulatory risk management to mitigate the risks associated with 4-TBP¹² and stated the following: *“Restriction of 4-TBP as a substance, constituent or impurity in other substances, mixtures and articles up to a certain threshold is proposed to ensure that environmental emissions of 4-TBP are minimised”*. A similar approach could be taken to address the presence of other hydrocarbylphenols such as 4-NP or dodecylphenol. 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 Sustainability¹³ and is the outcome of preliminary discussions between ECHA, Member States and the Commission. Therefore, it is expected that all substances in this group will be further investigated and likely addressed as part of the ongoing work to develop a potential restriction on the wider group of hydrocarbylphenols, and that additional action beyond that will not be necessary. However, the need for further EU RRM will be revisited if needed, taking into account any future developments.

¹¹ [Overall strategy on hydrocarbylphenols](#)

¹² [Assessment of regulatory needs for substances containing 4-tert-butylphenol](#)

¹³ [Restrictions Roadmap under the Chemicals Strategy for Sustainability](#)

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
4-hydrocarbylphenols (other than styrenated phenols)	<p>Known or potential hazard for ED and reproductive toxicity</p> <p>Known or potential hazard for mutagenicity for EC/List 291-826-2, 614-707-2, 905-392-5, 942-988-4</p> <p>Known or potential hazard for skin sensitisation for EC/List 201-280-9, 202-179-2, 276-</p>	<p>Known or potential hazard for ED and aquatic toxicity</p> <p>Known or potential hazard for PBT/vPvB for EC/List 203-199-1, 205-426-2, 284-325-5, 291-826-2, 300-141-0, 430-180-1, 455-880-2, 685-515-4, 931-468-2, 941-702-5, 947-217-5</p>	<p>Mainly intermediates in chemical manufacturing or monomers for production of polymers; widespread (P,C and/or A) uses with potential for release/exposure (e.g. adhesives, coatings, inks) reported for some substances; potential for release to environment from industrial uses (including intermediate, monomer) and due to presence as constituents/impurities in other substances with widespread uses; potential for regrettable substitution (at least for certain uses).</p>	<p>Need for EU RRM: Restriction</p> <p><u>Justification:</u></p> <p>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. 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. Industrial uses and use in articles to be further investigated and considered as part of the restriction.</p>	<p>First step (where applicable):</p> <ul style="list-style-type: none"> SVHC identification and/or CLH <i>CCH in parallel for EC/List 300-141-0, 931-468-2, 947-217-5</i> <p>Next steps (if hazard confirmed): Restriction</p>

ASSESSMENT OF REGULATORY NEEDS

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
	743-1, 291-826-2, 455-880-2, 931-185-4, 931-468-2, 941-702-5				

Annex 1: Overview of classifications

Data extracted on 05/05/2022

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
248-312-8	27193-86-8	dodecylphenol	-	-
947-217-5	-	Phenol, mono-C24-28 (even)-sec-alkyl derivs, ortho- and para-	-	-
217-302-5	1806-26-4	p-octylphenol	-	-
614-707-2	68684-63-9	614-707-2	-	Aquatic Acute 1 H400 [intermediate (active)] Aquatic Chronic 1 H410 [intermediate (active)] Carc. 2 H351 [intermediate (active)] Repr. 2 H361, specific effect:fd [intermediate (active)] Muta. 2 H341 [intermediate (active)]
440-740-5	-	4-(4-trans-propylcyclohexyl)phenol	-	Aquatic Chronic 4 H413 [intermediate (active)]
931-185-4	-	Still Bottom Residue from Amyl- and Diamylphenol manufacturing process	-	Aquatic Chronic 2 H411 [intermediate (active)] Skin Corr. 1B H314 [intermediate (active)] STOT Rep. Exp. 2 H373, affected organs: all organs [intermediate (active)] Skin Sens. 1 H317 [intermediate (active)] Acute Tox. 3 H331 [intermediate (active)] Acute Tox. 3 H301 [intermediate (active)] Acute Tox. 3 H311 [intermediate (active)]
941-702-5	-	Reaction mass of 4-(2-methylbutan-2-yl)phenol and 2,4-bis(2-methylbutan-2-yl)phenol	-	Skin Corr. 1A H314 [intermediate (active)] Aquatic Chronic 1 H410 [intermediate (active)] Acute Tox. 4 H302 [intermediate (active)] Skin Sens. 1 H317 [intermediate (active)]
202-679-0	98-54-4	4-tert-butylphenol	Index number: 604-090-00-8 Hazard Category: Skin Irrit. 2 Hazard Statement: H315 Hazard Category: Repr. 2 Hazard Statement: H361f Hazard Category: Eye Dam. 1	Aquatic Chronic 2 H411 [intermediate (inactive)] STOT Single Exp. 3 H335, affected organs: lungs [intermediate (inactive)] Repr. 2 H361, specific effect:H361f: Suspected of damaging fertility Skin Irrit. 2 H315 Eye Damage 1 H318 Aquatic Chronic 1 H410

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
			Hazard Statement: H318 Aquatic Chronic 1 Statement: H410	
246-672-0	25154-52-3	nonylphenol	Index number: 601-053-00-8 Acute Tox. 4 Hazard Statement: H302 (Minimum classification) Hazard Category: Skin Corr. 1B Hazard Statement: H314 Hazard Category: Repr. 2 Hazard Statement: H361fd Aquatic Acute 1 Statement: H400 Aquatic Chronic 1 Statement: H410	-
291-826-2	90480-88-9	Phenol, isopropylated	-	Acute Tox. 3 H301 [intermediate (active)] Acute Tox. 4 H302 [intermediate (active)] Eye Damage 1 H318 [intermediate (active)] Skin Corr. 1B H314 [intermediate (active)] Acute Tox. 3 H311 [intermediate (active)] Aquatic Chronic 2 H411 [intermediate (active)] Acute Tox. 3 H331 [intermediate (active)] Skin Sens. 1 H317 [intermediate (active)] Muta. 2 H341 [intermediate (active)] STOT Rep. Exp. 2 H373, affected organs: kidney, liver, skin, nervous system [intermediate (active)]
234-284-4	11066-49-2	isononylphenol	-	-
686-822-6	1200-09-5	4-(3-methylbut-2-en-1-yl)phenol	-	Skin Corr. 1A H314 [intermediate (active)] Acute Tox. 4 H302 [intermediate (active)]
942-988-4	-	Reaction mass of phenol and 3-tert-butylphenol and 4-tert-butylphenol	-	Repr. 2 H361 [intermediate (active)] STOT Rep. Exp. 2 H373 [intermediate (active)] Skin Corr. 1B H314 [intermediate (active)] Aquatic Chronic 1 H410 [intermediate (active)] Acute Tox. 3 H331 [intermediate (active)] Muta. 2 H341 [intermediate (active)] Acute Tox. 3 H301 [intermediate (active)] Eye Damage 1 H318 [intermediate (active)] Acute Tox. 3 H311 [intermediate (active)]

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
310-154-3	121158-58-5	Phenol, dodecyl-, branched	Index number: 604-092-00-9 Hazard Category: Skin Corr. 1C Hazard Statement: H314 Hazard Category: Repr. 1B Hazard Statement: H360F Hazard Category: Eye Dam. 1 Hazard Statement: H318 Aquatic Acute 1 Statement: H400 Aquatic Chronic 1 Statement: H410	Repr. 1B H360, specific effect: Repr. 1B; H360F: May damage fertility Skin Corr. 1C H314 Eye Damage 1 H318 Aquatic Acute 1 H400, M-factor: 10.00 Aquatic Chronic 1 H410, M-factor: 10.00 Eye Irrit. 2 H319 [intermediate (active)] Repr. 1B H360 [intermediate (active)] Repr. 2 H361 [intermediate (active)] Aquatic Chronic 1 H410 [intermediate (active)] Skin Irrit. 2 H315 [intermediate (active)]
616-100-8	74499-35-7	616-100-8	Index number: 604-092-00-9 Hazard Category: Skin Corr. 1C Hazard Statement: H314 Hazard Category: Repr. 1B Hazard Statement: H360F Hazard Category: Eye Dam. 1 Hazard Statement: H318 Aquatic Acute 1 Statement: H400 Aquatic Chronic 1 Statement: H410	-
202-179-2	92-69-3	biphenyl-4-ol	-	Skin Corr. 1B H315 [intermediate (active)]; Article 10 (inactive)] Aquatic Chronic 2 H411 [Article 10 (inactive); intermediate (active)] Skin Irrit. 2 H315 [intermediate (active)] Skin Sens. 1B H317 [Article 10 (inactive)]
276-743-1	72624-02-3	Phenol, heptyl derivs.	-	Acute Tox. 4 H302 Skin Corr. 1C H314, specific concentration: >=25-<=100 Eye Damage 1 H318 Skin Sens. 1 H317 Aquatic Acute 1 H400 Aquatic Chronic 1 H410
300-141-0	93922-04-4	barium 4-dodecylphenolate	-	Repr. 1B H360, specific effect: adverse effects on sexual function and fertility Acute Tox. 4 H302 Acute Tox. 4 H332 Aquatic Acute 1 H400, M-factor: 10.00 Aquatic Chronic 1 H410, M-factor: 10.00

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
266-717-8	67554-50-1	octylphenol	-	-
905-392-5	-	Reaction mass of 4-tert-butylphenol and phenol	-	STOT Rep. Exp. 2 H373, affected organs: kidney, liver, skin, nervous system [intermediate (active)] Acute Tox. 3 H331 [intermediate (active)] Repr. 2 H361 [intermediate (active)] Acute Tox. 3 H301 [intermediate (active)] Muta. 2 H341 [intermediate (active)] Acute Tox. 3 H311 [intermediate (active)] STOT Single Exp. 3 H335, affected organs: respiratory tract irritation [intermediate (active)] Aquatic Chronic 1 H410 [intermediate (active)] Skin Corr. 1B H314 [intermediate (active)]
931-468-2	-	Reaction mass of Phenol, di-alkyl (ten species comprising tetradecyl, hexadecyl, octadecyl, eicosyl substituents) and Phenol, mono-eicosyl and Phenol, mono-hexadecyl and Phenol, mono-octadecyl and Phenol, mono-tetradecyl	-	Skin Sens. 1B H317 STOT Rep. Exp. 2 H373, affected organs: liver
455-880-2	-	455-880-2	-	-
201-280-9	80-46-6	p-(1,1-dimethylpropyl)phenol	-	Skin Corr. 1B H314 Eye Damage 1 H318 Skin Sens. 1 H317 Aquatic Chronic 1 H410
640-104-9	210555-94-5	640-104-9	Index number: 604-092-00-9 Hazard Category: Skin Corr. 1C Hazard Statement: H314 Hazard Category: Repr. 1B Hazard Statement: H360F Hazard Category: Eye Dam. 1 Hazard Statement: H318 Aquatic Acute 1 Statement: H400 Aquatic Chronic 1 Statement: H410	-

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
284-325-5	84852-15-3	Phenol, 4-nonyl-, branched	Index number: 601-053-00-8 Acute Tox. 4 Hazard Statement: H302 (Minimum classification) Hazard Category: Skin Corr. 1B Hazard Statement: H314 Hazard Category: Repr. 2 Hazard Statement: H361fd Aquatic Acute 1 Statement: H400 Aquatic Chronic 1 Statement: H410	Repr. 2 H361 Acute Tox. 4 H302 Skin Corr. 1B H314 Eye Damage 1 H318 Aquatic Acute 1 H400, M-factor: 10.00 Aquatic Chronic 1 H410, M-factor: 10.00
202-798-8	99-89-8	p-isopropylphenol	-	Acute Tox. 4 H332 [intermediate (active)] Acute Tox. 4 H312 [intermediate (active)] Acute Tox. 4 H302 [intermediate (active)] Skin Corr. 1B H314 [intermediate (active)]
430-180-1	-	A mixture of: calcium bis(C10-14 branched alkyl salicylate); calcium bis(C18-30-alkyl salicylate); calcium C10-14 branched alkylsalicylato-C18-30-alkyl salicylate; calcium bis (C10-14 branched alkyl phenolate); calcium bis (C18-30-alkyl phenolate); calcium C10-14 branched alkylphenolato-C18-30-alkyl phenolate; C10-14 branched alkyl phenol; C18-30-alkyl phenol	-	-
203-199-4	104-40-5	p-nonylphenol	-	Acute Tox. 4 H302 Skin Corr. 1B H314 Eye Damage 1 H318 Aquatic Acute 1 H400 Aquatic Chronic 1 H410
248-310-7	27193-28-8	(1,1,3,3-tetramethylbutyl)phenol	-	-
685-515-4	10309-37-2	4-[(1E,3S)-3,7-dimethyl-3-vinylocta-1,6-dien-1-yl]phenol	-	Aquatic Acute 1 H400 Aquatic Chronic 1 H410

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
205-426-2	140-66-9	4-(1,1,3,3-tetramethylbutyl)phenol	Index number: 604-075-00-6 Hazard Category: Skin Irrit. 2 Hazard Statement: H315 Hazard Category: Eye Dam. 1 Hazard Statement: H318 Aquatic Acute 1 Statement: H400 Aquatic Chronic 1 Statement: H410	Skin Irrit. 2 H315 Eye Damage 1 H318 Aquatic Acute 1 H400, M-factor: 10.00
214-465-4	1131-60-8	4-cyclohexylphenol	-	Aquatic Chronic 2 H411 [intermediate (active)]

(*) the number in brackets indicates the number of notifications received. Each notification can represent a group of notifiers, therefore the number may differ from the C&L inventory which displays number of notifiers.

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

Data extracted on 05/05/2022

Main types of applications structured by product or article types	EC/List 201-280-9	EC/List 202-679-0	EC/List 203-199-4	EC/List 205-426-2	EC/List 276-743-1	EC/List 284-325-5	EC/List 300-141-0	EC/List 310-154-3	EC/List 685-515-4	EC/List 931-468-2	EC/List 947-217-5
PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents				I,P							
PC 37: Water treatment chemicals						F,I					
PC 39: Cosmetics, personal care products									F,P,C		
PC 24: Lubricants, greases, release products						I					
Functional fluid e.g. PC 17: Hydraulic fluids						I					
PC 13: Fuels						F,P,C					
PC 32: Polymer preparations and compounds	I	I,A		F,I,C		F,I,C	F,I,A	I			I
PC 1: Adhesives, sealants		F,I,P,C A		F,I,P,C		F,I,P,C A					
PC 9b: Fillers, putties, plasters, modelling clay		I,A	F								
PC 9a: Coatings and paints, thinners, paint removes		F,I,P,C A	F,I,P	F,I,P,C		F,I,P,C A					
PC 18: Ink and toners		F,I,P	F	F,I,P		F,I,P					
PC 21: Laboratory chemicals				I,P							
PC 19: Intermediate	I	I		I		F,I		I		I	I
PC41: Oil and gas exploration or production products						F,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 13/05/2022

EC/List number	RMOA **	Authorisation		Restriction*		CLH	Actions not under REACH/CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)		
201-280-9	x	ED ENV					
202-679-0	x	ED ENV				x	
203-199-4		ED ENV		Entry 46			PIC, EQS
205-426-2		ED ENV					
234-284-4		ED ENV		Entry 46			PIC
246-672-0		ED ENV		Entry 46		x	
247-770-6		ED ENV		Entry 46			
276-743-1		ED ENV					
284-325-5		ED ENV		Entry 46		x	
310-154-3	x	Repro, ED HH, ED ENV				x	
616-100-8	x	Repro, ED HH, ED ENV					
640-104-9	x	Repro, ED HH, ED ENV					

*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).

**In addition, several substances have been assessed for regulatory needs by ECHA with the focus of regulating a common constituent of concern (4-tert-butylphenol)

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