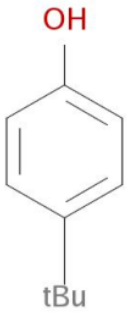
Assessment of regulatory needs

Authority: ECHA

Date: 19/11/2021

Group Name: Substances containing 4-tert-butylphenol

General structure[1]:



Revision history

Version	*Date*	*Description*
1.0	19/11/2021	

[1] To be provided only when feasible

Substances within this group:

EC/List number	CAS number	Substance name	Registration type (full, OSI or TII, NONS), highest tonnage band among all the registrations (t/y) [2]
201-280-9	80-46-6	p-(1,1-dimethylpropyl)phenol	Full, 100-1000
201-807-2*	88-18-6	2-tert-butylphenol	Full, 100-1000
201-942-7	89-81-6	6-isopropyl-3-methylcyclohex-2-enone	Intermediate (OSII or TII)
202-532-0*	96-76-4	2,4-di-tert-butylphenol	Full, 100-1000
202-678-5	98-53-3	4-tert-butylcyclohexanone	Full, 1-10
202-679-0	98-54-4	4-tert-butylphenol	Full, >1000
204-884-0*	128-39-2	2,6-di-tert-butylphenol	Full, >1000
205-426-2	140-66-9	4-(1,1,3,3-tetramethylbutyl)phenol	Full, >1000
211-989-5*	732-26-3	2,4,6-tri-tert-butylphenol	Full, 100-1000
219-006-1	2312-35-8	propargite	Full, >1000
221-453-2	3101-60-8	p-tert-butylphenyl 1-(2,3-epoxy)propyl ether	Full, 100-1000
228-985-4**	6386-38-5	methyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	Full, 1-10
276-743-1	72624-02-3	Phenol, heptyl derivs.	Full, 100-1000
294-799-5	91770-15-9	Kerosine (petroleum), sweetened	Full, >1000
310-154-3	121158-58-5	Phenol, dodecyl-, branched	Full, >1000
421-820-9	192268-65-8	A mixture of: triphenylthiophosphate and tertiary butylated phenyl derivatives	Full, 100-1000
500-300-6	111411-00-8	Formaldehyde, oligomeric reaction products with 3-aminomethyl-3,5,5-trimethylcyclohexylamine and 4-tert-butylphenol	Full, 1-10
905-392-5		Reaction mass of 4-tert-butylphenol and phenol	Intermediate (OSII or TII)
907-745-9*		Reaction mass of 2,6-di-tert-butylphenol and 2,4,6-tri-tert-butylphenol	Full, >1000
930-944-7*		[No public or meaningful name is available]	Intermediate (OSII or TII)
931-185-4		Still Bottom Residue from Amyl- and Diamylphenol manufacturing process	Intermediate (OSII or TII)
939-071-6		Reaction mass of 4-tert-butylphenol and 1,3-phenylenedimethanamine and 2-({[3-(aminomethyl)benzyl]amino}methyl)-4-tert-butylphenol	Full, 100-1000
940-894-8		Reaction mixture of 50:50 [R,R] and [S,S] Trans racemate of 2-(4-tert-butylphenoxy)cyclohexyl sulfurochloridoite	Intermediate (OSII or TII)
941-702-5		Reaction mass of 4-(2-methylbutan-2-yl)phenol and 2,4-bis(2-methylbutan-2-yl)phenol	Intermediate (OSII or TII)

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

941-802-9		Reaction products of phosphorous trichloride with phenol, 2-tert-butylphenol and 4-tert-butylphenol	Intermediate (OSII or TII)
942-988-4		Reaction mass of phenol and 3-tert-butylphenol and 4-tert-butylphenol	Intermediate (OSII or TII)

** Also member of group "Tert-alkyl hindered phenols"*
*** Also member of group "Ester-functionalised 2,6-di-tertalkylphenols"*

Contents

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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 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, 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[3]

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

Glossary

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
OSI 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

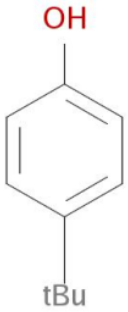
ECHA has grouped structurally related hydrocarbylphenols (i.e. phenols with any kind of saturated or unsaturated hydrocarbon substituent(s) on the phenol ring).

Some hydrocarbylphenols have already been scrutinised by Member State Competent Authorities. For some others, regulatory activities are ongoing. Several hydrocarbylphenols are already included in the Candidate List for their ED properties. Hydrocarbylphenols with confirmed ED properties are also found as constituent or impurity in other (hydrocarbylphenol) substances.

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.

ECHA is assessing the regulatory needs of several groups of hydrocarbylphenols. This report documents the assessment of regulatory needs of substances belonging to the group ***Substances containing 4-tert- butylphenol (4-TBP)***. The assessment of regulatory needs of the other groups are or will be documented in separate reports.

ECHA has grouped together 26 substances based on the presence of the constituent 4-tert-butylphenol (4-TBP) shown in the figure below.



4-TBP was included in the Candidate List in July 2019 because of its ED properties for the environment. In the Regulatory Management Option Analysis (RMOA) done by Germany (in March 2017), it was highlighted that residues of the substance may be present in high concentrations in many products with widespread uses and high potential for release and exposure. Triggered by this concern, ECHA identified from the registration database 25 more substances where 4-TBP has been reported as a constituent or impurity. This assessment of regulatory needs explores how to best regulate exposure to 4-TBP resulting from this group of 26 substances (including 4-TBP itself).

The present assessment of regulatory needs does not elaborate on other hazards of the substances in which 4-TBP has been reported.

Based on information available in the RMOA and the Annex XV dossier proposing to identify the substance as a Substance of Very High Concern (SVHC), 4-TBP is mainly used as an intermediate in the production of polymers (phenolic/epoxy resins) where residues of the substance may be present in high concentrations in

the resulting products which cover a wide variety of uses (including e.g. coatings, inks, adhesives) and all life cycle stages.

Based on the information reported in the REACH registration dossiers, many of the 25 substances containing 4-TBP have widespread uses with potential for exposure to industrial and professional workers, to the environment and to the general public (mainly via the environment). Main uses reported include uses in adhesives, coatings, inks and paints, fuel and fuel additives, lubricants, washing and cleaning products, fragrances, intermediates; in addition, some substances may be present in rubber and plastic products where exposure as a result of release from the article cannot be excluded. Some of the substances have mainly intermediate uses reported.

In addition to the potential for exposure/release of 4-TBP from the uses of the individual substances as such it is also suspected that the sum of low-level emissions from many widespread sources contributes significantly to the overall release of 4-TBP to the environment. Furthermore, monitoring data has shown that 4-TBP is present as a contaminant in freshwater bodies further suggesting that there is a potential for release to the environment.

From an analysis of the uses and the manufacturing process, it seems that the presence of 4-TBP as a constituent or impurity may be explained by the manufacturing methods of hydrocarbylphenols where alkylation of phenols and cresols or of plant extracts may lead to the formation of 4-TBP (see next section for further details).

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 EU regulatory risk management – namely restriction due to the endocrine disrupting properties of 4-TBP combined with potential for exposure/releases to the environment from the uses of the substances and the reasonable assumption that the sum of low-level emissions from many widespread sources contributes significantly to the overall release of 4-TBP to the environment. The entry would cover 4-TBP as a substance, constituent or impurity in other substances, mixtures and articles up to a certain threshold and would ideally target both emissions from production and emissions/exposure from use, however the final scope will be elaborated further when developing the restriction.

Restricting 4-TBP as such, in substances, mixtures and articles should:

- address all substances containing 4-TBP above the set threshold (substances with both low and high concentration of 4-TBP) and would anticipate the possible production of new substances containing 4-TBP.

- address the possibility that multiple substances containing 4-TBP could be used in one mixture or one (part of an) article since the restriction would target the maximum overall concentration of 4-TBP.

- address environmental emissions from the use of substances, mixtures and articles.

Although a threshold of 0.1% w/w (based on the threshold for SVHC identification for ED) could be applied, a lower threshold (e.g. the limit of detection of the analytical methods) should be considered in order to minimise emissions to the environment as much as possible and address the additivity effect of many low-level emissions. An important advantage of this type of restriction is that it will affect (pre-) polymers and resins containing residual levels of 4-TBP (impurities) and hence will address a wider spectrum of intermediate uses that cannot be addressed through authorisation. It will also address the import of articles into the EU and as such build a level playing field between EU producing companies and companies importing articles into the EU.

It is expected that this broad restriction will push industry to identify 4-TBP as a possible constituent/impurity in their substances and reduce its concentration in all substances, mixtures and articles they bring onto the market. This is especially likely for substances in which the concentration of 4-TBP is low and present as an impurity. For these substances, industry may be able to bring the concentration of 4-TBP to below the restricted threshold by e.g. improving the manufacturing process.

ECHA has investigated the production process for 19 members of the group suggesting that the presence of 4-TBP may be due to:

i) Use of 4-TBP as **one of the starting materials** in the synthesis (unreacted 4-TBP is an impurity **or main constituent**)
ii) **Unintentional formation of** 4-TBP as an impurity in the synthesis of hydrocarbylphenols **due to the presence of 'precursor impurity' in one of the starting materials**. (4-TBP is **unintentionally generated** during the synthesis and it can be found in end products)
iii) 4-TBP is generated during **the synthesis being the manufactured substance**

iv) 4-TBP may be the **result of degradation** of another substance (hypothesis to be investigated)
v) 4-TBP is present in the manufactured substance **due to the selected catalyst used**
vi) 4-TBP is present as impurity in the manufactured substance due to **carry over from one of the starting materials** in which it was already present as an impurity

In all cases where the concentration of 4-TBP is relatively low, it seems that 4-TBP is unlikely to contribute to the technical function of the substance and therefore its content can likely be reduced (e.g. by using a more selective catalyst in the production process; using reactants with higher level of purity; including a purification step to the produced substance).

Since the restriction would address 4-TBP as a substance, impurity or constituent of another substance, in mixtures or in articles and would not be limited to a fixed set of substances, it would prevent industry from substituting the one 4-TBP containing substance for a slightly different substance containing 4-TBP above threshold, and would prevent the placing on the market of new substances that would still contain 4-TBP above threshold. For industry, this would bring further clarity on how to develop towards safer alternatives and in particular towards improving the manufacturing process of those substances, which in itself would prevent regrettable substitution for this group of substances. However, for those substances that contain higher concentrations of 4-TBP and where 4-TBP has a technical function, it may not be possible for industry to reduce the 4-TBP content to below the restricted threshold and hence concentration limit could in practice mean a limitation of supported uses.

4-TBP is already included in the Candidate List. All substances in the group containing 4-TBP above 0.1% could similarly be proposed for identification as SVHC for ED ENV and be included in the Candidate list as individual entries however the existing SVHC identification of 4-TBP as environmental ED is already sufficient for confirming the hazard as ED ENV of all substances containing 4-TBP (when present in the substance above 0.1%).

As a consequence, the SVHC identification of 4-TBP should have already triggered actions by registrants (e.g. purification) on substances containing 4-TBP. This is however not reflected in current registration dossiers where presence of 4-TBP is reported for many substances. This supports the need for EU regulatory risk management action on these substances and the proposed restriction.

Authorisation, amongst other EU legislation, was also explored as a potential means to regulating this group of substances however it was assessed authorisation would be less effective than the restriction for several reasons:

- authorisation would not address environmental emissions from the production stage and would not address import of articles;

- not all uses that contribute to emissions to the environment would be addressed (e.g. intermediates are out of the scope of authorisation);

- not all substances containing 4-TBP may be identified and included in the Candidate list.

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. Note that in this specific case the hazard assessment has been focused on the presence of 4-TBP as the leading hazard for the group of substances. Other hazards of the substances containing 4-TBP will be considered in a separate assessment of regulatory needs.

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
Substances containing 4-TBP **201-280-9** **201-807-2** **201-942-7** **202-532-0** **202-678-5** **202-679-0** **204-884-0** **205-426-2** **211-989-5** **219-006-1** **221-453-2** **228-985-4** **276-743-1** **294-799-5** **310-154-3**	Human health hazards not yet assessed	Known or likely ED based on the presence of 4-TBP present in concentrations above 0.1% Other environmental hazards not yet assessed	Widespread uses with potential for exposure to the general public (mainly via the environment), industrial and professional workers as well as to the environment. The main uses reported in the registration dossiers include uses in adhesives, coatings, inks and paints, fuel and fuel additives, lubricants and grease, metal working fluid, washing and cleaning products, fragrances, intermediates; in addition, some substances may be present in rubber and plastic	**Need for EU RRM: Restriction** <u>Justification:</u> 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. Ideally the entry should address both emissions from the production stage and	Restriction

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
421-820-9 **500-300-6** **905-392-5** **907-745-9** **930-944-7** **931-185-4** **939-071-6** **940-894-8** **941-702-5** **941-802-9** **942-988-4**			products where exposure as a result of release from the article cannot be excluded.	emissions/exposure as a result of use. The entry would cover a wide scope - potentially all substances containing 4-TBP, including those that may be placed on the market in the future. This would help address the additivity effect of many low-level emissions.	

Annex 1: Overview of uses based on information available in registration dossiers

Data extracted on 12/08/2020

Main types of applications structured by product or article types	EC/ List 201-280-9	EC/ List 201-807-2	EC/ List 202-532-0	EC/ List 202-678-5	EC/ List 202-679-0	EC/ List 204-884-0	EC/ List 205-426-2	EC/ List 211-989-5	EC/ List 219-006-1	EC/ List 221-453-2	EC/ List 228-985-4	EC/ List 294-799-5	EC/ List 310-154-3	EC/ List 421-820-9	EC/ List 500-300-6	EC/ List 907-745-9	EC/ List 939-071-6
Adhesives, coatings, paints, inks					F, I, **P, C**		F, I, **P, C**			F, I, **P**		F, I, **P, C, A**			F, I, **P**		F, I, **P**
Fuel and fuel additives		F, I	F, I, **P, C**			F, I, **P, C**		F, I, **P**				F, I, **P, C**				F, **P**	
Lubricants and greases						F, I, **P, C**						F, I, **P, C**		F, I, **P**			
Metal working fluids						F, I, **P**						F, I, **P**		F, I			
Polymer preparation and compounds	I		I		I		I						I				
Washing and cleaning products				F, I, **P, C**							F, I, **P, C**	F, I, **P, C**					
Intermediate		I	I	I	I	I	I	I			I	I	I				

F: formulation, I: industrial use, P: professional use, C: consumer use, A: article service life; P, C and A are highlighted in red to indicate widespread use with potential for exposure/release

Annex 2: Overview of completed or ongoing regulatory risk management activities

Data extracted on 12/08/2020

EC/List number	RMOA	Authorisation		Restriction	CLH	Actions not under REACH/ CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)	
201-280-9	YES	YES				
201-807-2						
201-942-7						
202-532-0						
202-678-5						
202-679-0	YES	YES			Skin Irrit. 2, H315; Eye Dam. 1, H318; Repr. 2, H361f; Aquatic Chronic 1, H410	ESR EU Cosmetics
204-884-0						
205-426-2	YES	YES			Skin Irrit. 2, H315; Eye Dam. 1, H318; Aquatic Acute 1, H400; Aquatic Chronic 1, H410;	
211-989-5					Ongoing Proposed : Acute Tox. 4, H302; Skin Sens. 1B, H317; Repr. 2, H361d; STOT RE 1, H372	
219-006-1					Carc. 2, H351 ; Acute Tox. 3 *, H331; Skin Irrit. 2, H315; Eye Dam. 1, H318; Aquatic Acute 1, H400; Aquatic Chronic 1, H410;	EU Cosmetics PIC PPP
221-453-2						
228-985-4						
276-743-1		YES				
294-799-5					Asp. Tox. 1, H304;	
310-154-3	YES	YES			Skin Corr. 1C, H314; Eye Dam. 1, H318; Repr. 1B, H360F; Aquatic Acute 1, H400; Aquatic Acute 1, M-factor=10; Aquatic Chronic 1, H410; Aquatic Chronic 1, M-factor=10	
421-820-9					Aquatic Chronic 4, H413;	

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