

6 February 2014

Background document for 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-Octylphenol ethoxylates) (4-tert-OPnEO)

Document developed in the context of ECHA's fifth Recommendation for the inclusion of substances in Annex XIV

Information comprising confidential comments submitted during the public consultation, or relating to the content of Registration dossiers which is of such nature that it may potentially harm the commercial interest of companies if it was disclosed, is provided in a confidential annex to this document.

1. Identity of the substance

Chemical name: 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues] (4-tert-Octylphenol ethoxylates) (4-tert-OPnEO)

EC Number: -

CAS Number: -

IUPAC Name: 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues]

2. Background information

2.1. Intrinsic properties

The substances covered by the entry '4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues]' were identified as substances meeting the criteria of Article 57 (f) of Regulation (EC) 1907/2006 (REACH) because (through their degradation) they are substances with endocrine disrupting properties for which there is scientific evidence of probable serious effects to the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57 of REACH. They were therefore included in the Candidate List for authorisation on 19 December 2012, following ECHA's decision ED/169/2012.

2.2. Imports, exports, manufacture and uses

2.2.1. Volume(s), imports/exports

There currently appears to be no registrations for substances in the group 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-OPnEO).

Information on the uses of 4-tert-OPnEO has been obtained from registrations of 4-(1,1,3,3-tetramethylbutyl)phenol (4-tert-octylphenol; 4-tert-OP; EC 205-426-2) which is used in the manufacture of its ethoxylates. Further information was obtained from the Annex XV report (2012) for 4-tert-OPnEO.

There are 10,000 - 100,000 t/y of 4-tert-octylphenol registered.

Based on the estimated fraction of 4-tert-octylphenol used to manufacture its ethoxylates (registrations, Annex XV report (2012)) and the estimated average contribution to the molecular weight of its ethoxylates, the volume of ethoxylates produced is assumed to be in the range of 1,000 – 10,000 t/y.

Information in the registrations and Annex XV report (2012) indicate that some of the 4-tert-OPnEO tonnage is used as intermediate (in the manufacture of ether sulphates) and that the substance may have other uses (identified in RCOM (2012)) such as in Scientific Research & Development (SRD) which are outside the scope of authorisation. The remaining amount appears to be used in applications in the scope of authorisation.

There is no information available on the export of 4-tert-OPnEO.

In conclusion, the volume in the scope of authorisation is estimated to be in the range of 1,000 – 10,000 t/y. This tonnage was confirmed by industry (European Council for Alkylphenols and Derivatives (CEPAD) and the Alkylphenols and Ethoxylates Research Council (APEREC)) in the public consultation (RCOM, 2014).

2.2.2. Manufacture and uses

2.2.2.1 Manufacture and releases from manufacture

According to the Environmental Risk Evaluation Report (Environment Agency UK, 2005) 4-tert-OPnEO are manufactured by the addition of ethylene dioxide to 4-tert-octylphenol under pressure. The ethoxylation process for technical octylphenol ethoxylates delivers a mixture of ethoxylates with a different number of ethoxy-groups. This process and the resulting technical mixture of different ethoxylation grades are also described by Leisewitz and Schwarz (1997). Technical ethoxylates are described by an ethoxylation range (e.g. 8-10) and/or by giving an average grade of ethoxylation. As different technical mixtures are often described with the same CAS-number, it is not possible to link single ethoxylation grades to specific uses (Annex XV report, 2012).

Discharges from manufacturing sites of 4-tert-OPnEO have been reported (Environment Agency UK, 2005). There appear to be 4-5 manufacturers of 4-tert-OPnEO within the EU (Annex XV report, 2012).

2.2.2.2 Uses and releases from uses

Registration dossiers for 4-tert-octylphenol indicate that its ethoxylates are used in formulation of paints, industrial end-use of paints, consumer and professional end-use of paints and other products, in emulsion polymerisation, and as an intermediate in the production of ether sulphates. It seems that almost 50% of the 4-tert-OPnEO is used as emulsifiers in emulsion polymerisation (Annex XV report). In the public consultation industry (CEPAD/APERC) stated that 4-tert-OPnEOs "are used predominantly in the formulation of paint and coating products and are used at levels of generally 1% or less in those products" (RCOM, 2014).

There are industrial, consumer and professional end uses of products containing 4-tert-OPnEO. Environmental release categories (ERCs) indicating potential for environmental release are listed in the registrations for these uses. In the public consultation industry (CEPAD/APERC) stated that "due to their role in the emulsion polymerisation process, OPEs are expected to be bound in the paint polymer and not widely dispersed to the environment". Industry also stated that "waste from paint clean-up is generally expected to be subject to treatment in waste water treatment plants" (RCOM, 2014). However, as documented in the Annex XV report - the registration dossiers and a number of published reports (e.g., COHIBA Project Consortium, 2012) indicate potential for significant releases of 4-tert-OPnEO from its use in paints.

The Annex XV report (2012) states that "products for professional and consumer uses (e.g., paints, household care products) are supposed to contain octylphenol ethoxylates in concentrations commonly between 0-10% but also up to 30% in specific products. [...] In conclusion, it can be assumed that products for consumer and professional uses will significantly contribute to the wide dispersive emissions into the environment." In the public consultation industry (CEPAD/APERC) stated that "OPEs are not reported as being used in consumer applications with high potential for human exposure or environmental release i.e., household detergents and fabric softeners and personal care products" (RCOM, 2014).

As there are no registrations for 4-tert-OPnEO, the information on current uses as outlined above is probably incomplete. In the RCOM (2012) uses of 4-tert-OPnEO identified include use in purification of human blood plasma products, in in-vitro diagnostic medical devices and in laboratory reagents.

There may be further uses of 4-tert-OPnEO as discussed in the Annex XV report (2012), including use as textile and leather auxiliaries, auxiliaries in waste water treatment processes, pore builder/foaming agents for concrete, mould release agents on construction sites and precast concrete production and auxiliaries for cleaning of machinery, constituent (emulsifier) of bitumen/wax emulsions for painting/sealing in construction industry, use in metal working fluids, in oil for lubrication or hydraulic devices, in cleaning of metal surfaces and as a component in lubricants, auxiliary in blowing agents for plastics and for retention processes in paper production, and use in pesticide formulations and veterinary medicine products. However, no further information was provided in the public consultation (RCOM, 2014) as to whether these uses currently occur in the EU, or not.

2.2.2.3. Geographical distribution and conclusions in terms of (organisation and communication in) supply chain

No conclusive information is available regarding the supply chain structure of the uses of 4-tert-OPnEO as, without registrations, it is not possible to confirm all uses.

However, given that there is industrial, professional and consumer use of products containing 4-tert-OPnEO (e.g. paints) and that the volume in the scope of authorisation is estimated to be in the range of 1,000 – 10,000 t/y it is expected that these substances are used throughout the EU at hundreds of use sites.

2.3. Availability of information on alternatives¹

In the RCOM (2012) for 4-tert-OPnEO, an industry stakeholder states that “a high degree of inter-changeability between nonylphenol and 4-tert-OP exists therefore it seems appropriate to regulate 4-tert-OPnEO and nonylphenol ethoxylates in the same way”. Indeed, the European Council for Alkylphenols and Derivatives states that one of the aims of the UK Voluntary Industry Agreement for the Reduction in Risk from nonylphenol, nonylphenol ethoxylates, octylphenol and octylphenol ethoxylates is to prevent the development of new risks from 4-tert-OP / 4-tert-OPnEO by preventing the use of 4-tert-OP / 4-tert-OPnEO as substitutes for nonylphenol and its ethoxylates for those uses of nonylphenol and its ethoxylates phased out by the REACH restriction.

The European Council for Alkylphenols and Derivatives also quotes a market report which indicates that the current restriction of the use of nonylphenol ethoxylates in dispersive markets has not led to it being replaced by octylphenol ethoxylates, but rather “other surfactants or blends of other surfactants are benefitting from the trend away from octylphenol ethoxylates in these applications” RCOM (2012).

Furthermore, industry indicates certain uses of 4-tert-OPnEO where it believes alternatives may be difficult to find e.g. use as a solvent/detergent in in-vitro diagnostic medical devices and pharmaceutical products (RCOM, 2012).

2.4. Existing specific Community legislation relevant for possible exemption

There seems to be no specific Community legislation in force that would allow consideration of exemption(s) of (categories of) uses from the authorisation requirement on the basis of Article 58(2) of the REACH Regulation.

2.5. Any other relevant information (e.g. for priority setting)

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¹ Please note that this information was not used for prioritisation.

3. Conclusions and justification

3.1. Prioritisation

These substances are used in high tonnage in products that can be assumed to lead to wide-dispersive emissions to the environment.

Verbal-argumentative approach

On the basis of the prioritisation criteria, this group of substances has a relatively high to high priority for inclusion in Annex XIV.

Scoring approach

Score			Total Score (= IP + V + WDU)
Inherent properties (IP)	Volume (V)	Uses - wide dispersiveness (WDU)	
0-1	7 (High volume in scope of authorisation.)	Overall score: $3 * 3 = 9$ Site-#: 3 (Given that there is industrial, professional and consumer use of products containing 4-tert-OPnEO, the number of sites is assumed to be high.) Release: 3 (Releases are assumed to be diffuse.)	16-17

Conclusion, taking regulatory effectiveness considerations into account

On the basis of the prioritisation criteria 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-OPnEO) gets a relatively high to high priority for inclusion in Annex XIV.

Therefore, it is proposed to recommend 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-OPnEO) for inclusion in Annex XIV.

4. References

- Annex XV report (2012): 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues]. Proposal for identification of a substance as a CMR Cat 1A or 1B, PBT, vPvB or a substance of an equivalent level of concern. Submitted by Germany, September 2012.
<http://echa.europa.eu/documents/10162/c26cbb7e-91f9-4454-a054-c2a731029219>
- COHIBA Project Consortium, 2012: Major Sources and Flows of the Baltic Sea Action Plan Hazardous Substances (Working Package 4: final report).
- Environment Agency UK. 2005. Environmental Risk Evaluation Report: 4-tert-octylphenol.
- Leisewitz A, Schwarz W. 1997. Stoffströme wichtiger endokrin wirksamer Industriechemikalien (Bisphenol A; Dibutylphthalat / Benzylbutylphthalat; Nonylphenol / Alkylphenoethoxylate). UFOPLAN-No. 106 01 076.
- RCOM (2012): "Responses to comments" document compiled by Germany from the commenting period 03/09/2012 – 18/10/2012 on the proposal to identify the substance 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues] as a Substance of Very High Concern.
<http://echa.europa.eu/candidate-list-table/-/substance/2501/search/+/del/20/col/INCLUSIONDATECL/type/desc/page/2/view>
- RCOM (2014): "Responses to comments" document for 4-tert-OPnEO. Document compiling comments and respective answers from commenting period 24/06/2013 – 23/09/2013 on ECHA's 5th draft recommendation of priority substances for inclusion in the list of substances subject to authorisation (Annex XIV).
http://echa.europa.eu/documents/10162/13640/axiv_5th_recommendation_4-tert-opneo_rcom_en.pdf