

**AGREEMENT OF THE MEMBER STATE COMMITTEE**  
**ON THE IDENTIFICATION OF**  
**4-(1,1,3,3-TETRAMETHYLBUTYL)PHENOL, ETHOXYLATED<sup>1</sup>**

**AS A SUBSTANCE OF VERY HIGH CONCERN**

**According to Articles 57 and 59 of**  
**Regulation (EC) 1907/2006<sup>2</sup>**

**Adopted on 12 December 2012**

**This agreement concerns**

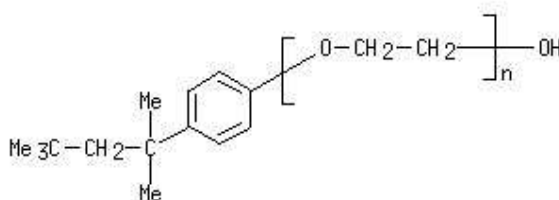
**Substance name:** 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated  
*[covering well-defined substances and UVCB substances, polymers and homologues]*

**EC number:** -

**CAS number:** -

**Molecular formula:**  $(C_2H_4O)_n C_{14}H_{22}O$

**Structural formula:**



<sup>1</sup> Please note that the full name of the substance as it will appear in the Candidate List is: 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated *[covering well-defined substances and UVCB substances, polymers and homologues]*

<sup>2</sup>Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

Germany presented a proposal in accordance with Article 59(3) and Annex XV of the REACH Regulation (28 August 2012, submission number CW014611-33) on identification of *4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated* as a substance of very high concern because of its endocrine disrupting properties.

The Annex XV dossier was circulated to Member States on 3 September 2012 and the Annex XV report was made available to interested parties on the ECHA website on the same day according to Articles 59(3) and 59(4).

Comments were received from both Member States and interested parties on the proposal.

The dossier was referred to the Member State Committee on 19 November 2012 and was discussed in the meeting on 10-13 December 2012 of the Member State Committee.

**Agreement of the Member State Committee in accordance with Article 59 (8):**

***4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated* is identified as a substance meeting the criteria of Article 57 (f) of Regulation (EC) 1907/2006 (REACH) because it is a substance 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 for other substances listed in paragraphs (a) to (e) of Article 57 of REACH.**

**UNDERLYING ARGUMENTATION  
FOR IDENTIFICATION OF SUBSTANCE OF VERY HIGH CONCERN**

**Endocrine disrupting properties:**

4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues] [4-tert-OPnEO] are identified as substances of very high concern in accordance with Article 57 (f) of Regulation (EC) 1907/2006 (REACH) because, due to their degradation, they are a relevant source in the environment of a substance of very high concern 4-(1,1,3,3-tetramethylbutyl)phenol [4-tert-OP]. Therefore, there is scientific evidence of probable serious effects to the environment from these substances, through their degradation to 4-tert-OP, which gives rise to an equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57 of REACH.

This conclusion is based on the fact that 4-tert-OPnEO degrade to 4-tert-OP, either already in wastewater treatment plants, or via further degradation processes in sediments (e.g. of aquatic bodies receiving the wastewater effluents) and soils (e.g. receiving sewage sludge). Available information for 4-tert-OPnEO and its close analogues 4-nonylphenol ethoxylates [4-NPnEO] indicate that 4-tert-OPnEO contribute to the 4-tert-OP concentration in the environment. A significant amount is either degraded to 4-tert-OP itself in waste water treatment plants or is released to rivers in a form which may undergo further degradation to 4-tert-OP. Available information for 4-NPnEO and 4-nonylphenol indicate that 4-tert-OP formed from degradation of 4-tert-OPnEO may be responsible for an increase of the 4-tert-OP load to the environment (soil, sediment and water) by 54 to 758 %. Sediment organisms may be exposed to the 4-tert-OP, which results from the degradation of 4-tert-OPnEO, either directly, downstream of the effluent or in the longer term after its adsorption to sediment and soil. Similar holds true for pelagic organisms such as fish which may be exposed via remobilisation of 4-tert-OP from sediment to the water body.

Evidence that these substances are of an equivalent level of concern includes:

- 4-tert-OP has been identified as a substance of very high concern and included in the Candidate List due to its endocrine disrupting properties which cause probable serious effects to the environment
- To be consistent with the approach implemented in Annex XIII of the REACH regulation for PBT substances, it seems reasonable to conclude

that any substance which may result in relevant exposure to a SVHC (i.e. due to degradation to this substance under environmental conditions) should be considered as SVHC itself as it results in the same equivalent level of concern.

- Once released to the environment 4-tert-OPnEO will remain a long-term source of 4-tert-OP due to the tendency of short chain ethoxylates to bind to the sediment combined with a very slow degradation in anaerobic sediments of both the ethoxylates and their degradation product 4-tert-OP. Therefore, 4-tert-OP formed by degradation of its ethoxylates may accumulate in sediment.
- Especially due to the fact, that short term exposure to 4-tert-OP may result in life time effects in aquatic organisms and due to the fact that sudden environmental events may increase short term exposure concentrations, such a long-term source for 4-tert-OP is considered of very high concern.

**Reference:**

1. Support Document *4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated* (Member State Committee, 12 December 2012)