

AGREEMENT OF THE MEMBER STATE COMMITTEE

ON THE IDENTIFICATION OF

4-(1,1,3,3-TETRAMETHYLBUTYL)PHENOL, (4-TERT-OCTYLPHENOL)

AS A SUBSTANCE OF VERY HIGH CONCERN

**According to Articles 57 and 59 of
Regulation (EC) 1907/2006¹**

Adopted on 9 December 2011

This agreement concerns

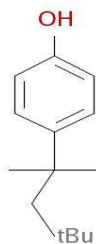
Substance name: 4-(1,1,3,3-tetramethylbutyl)phenol, (4-tert-octylphenol)

EC number: 205-426-2

CAS number: 140-66-9

Molecular formula: C₁₄H₂₂O

Structural formula:



¹Regulation (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 (23 August 2011, submission number CP006951-37) on identification of *4-(1,1,3,3-tetramethylbutyl)phenol, (4-tert-octylphenol)* as a substance of very high concern because of its endocrine disrupting properties.

The Annex XV dossier was circulated to Member States on 29 August 2011 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 by Member States and interested parties on the proposal.

The dossier was referred to the Member State Committee on 14 November 2011 and was discussed in the meeting on 7-9 December 2011 of the Member State Committee.

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

***4-(1,1,3,3-tetramethylbutyl)phenol, (4-tert-octylphenol)* is identified as a substance of very high concern in accordance with 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 gives rise to an equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57 of REACH.**

UNDERLYING ARGUMENTATION FOR IDENTIFICATION OF SUBSTANCE OF VERY HIGH CONCERN

Endocrine disrupting properties:

There is strong evidence from high quality studies of adverse effects of 4-tert-octylphenol in two fish species, which are estrogen mediated. Similar evidence is available for a third fish species but it is based on tests without statistics. In all other tested fish species the endpoints affected are known to be influenced by estrogen activity and, with one exception, an estrogen mediated mode of action was observed. According to the OECD draft guidance document for endocrine disruptors (OECD, 2011) 4-tert-octylphenol is an endocrine disruptor based on these results.

Based on the widely accepted IPCS definition for endocrine disruptors (IPCS/WHO, 2002) 4-tert-octylphenol is considered to be an endocrine disruptor in fish.

Equivalent concern

Evidence that the substance is of an equivalent level of concern include:

- Similar to certain other substances of very high concern it is difficult to quantify a safe level for 4-tert-octylphenol and therefore also the risks, using traditional risk assessment methods.
- Impairment of reproduction due to the endocrine disrupting properties of 4-tert-octylphenol may already occur after a transient short term exposure as observed in two fish species. This provides some indication that exposure in one area might influence population stability in another area (e.g. for migratory fish). With respect to 4-tert-octylphenol there is evidence of internal distribution toward embryos in viviparous fish species.
- Exposure to estrogens such as 4-tert-octylphenol may cause long lasting effects. A change in the endocrine feedback system during sensitive life stages may result in effects during the entire life. Such changes were observed after exposure to 4-tert-octylphenol with respect to development of the reproduction system and changes in sex-ratio in fish.
- The evidence presented indicates that 4-tert-octylphenol may have the potential to cause adverse effects in a range of species across different taxonomic groups.
- Exposure to 4-tert-octylphenol may result in effects that relevantly influence ecosystems with respect to the community structure and function. Comparable to other estrogens, 4-tert-octylphenol influences reproduction parameters as well as sexual development (including changes in sex-ratio) and growth and thus endpoints are affected that may impair population stability and recruitment.

In addition to the endocrine disrupting properties the concern is increased by evidence that 4-tert-octylphenol biodegrades very slowly in the environment and tends to adsorb to sediment and soil.

Conclusion:

Taking into account all available information on the intrinsic endocrine disrupting properties of 4-tert-octylphenol and its effects to the environment, it is concluded that 4-tert-octylphenol is a substance for which there is scientific evidence of probable serious effects to the environment 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.

Reference:

1. Support Document *4-(1,1,3,3-tetramethylbutyl)phenol, (4-tert-octylphenol)*
(Member State Committee, 9 December 2011)