

AGREEMENT OF THE MEMBER STATE COMMITTEE

ON THE IDENTIFICATION OF 4-NONYLPHENOL, BRANCHED AND LINEAR¹

AS A SUBSTANCE OF VERY HIGH CONCERN

**According to Articles 57 and 59 of
Regulation (EC) 1907/2006²**

Adopted on 13 December 2012

This agreement concerns

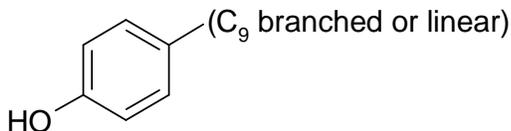
Substance name: **4-Nonylphenol, branched and linear [substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, covering also UVCB- and well-defined substances which include any of the individual isomers or a combination thereof]**

EC number: -

CAS number: -

Molecular formula: **C₁₅H₂₄O**

Structural formula:



¹Please note that the full name of the substance as it will appear in the Candidate List is: 4-Nonylphenol, branched and linear [substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, covering also UVCB- and well-defined substances which include any of the individual isomers or a combination thereof]

²Regulation (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 (6 August 2012, submission number CW002235-35) on identification of *4-Nonylphenol, branched and linear* as a substance of very high concern due to 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-Nonylphenol, branched and linear* 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-Nonylphenol, branched and linear [*substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, covering also UVCB-and well-defined substances which include any of the individual isomers or a combination thereof*] (further below called : 4-Nonylphenols) are identified as substances of very high concern in accordance with Article 57 (f) of Regulation (EC) 1907/2006 (REACH) because they are substances 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.

This conclusion is based on the fact that there is strong evidence from high quality studies of endocrine mediated adverse effects in fish species. Results for amphibians provide indication that effects in other taxa may be endocrine mediated i.e. caused by an estrogen-like mode of action, too.

According to the OECD (Organisation for Economic Co-operation and development) guidance document for endocrine disruptors (OECD, 2012) 4-nonylphenols need to be considered as endocrine disruptors based on these results. Moreover, based on the widely accepted IPCS definition for endocrine disruptors (WHO/IPCS, 2002; WHO: World Health Organization/IPCS: INSTITUTE OF PEACE & CONFLICT STUDIES) 4-nonylphenols are considered to be endocrine disruptors.

Based on the above conclusion, evidence that the substances are of an equivalent level of concern includes:

Evidence from several test data show that effects of the 4-nonylphenols on fish fit to those of other estrogen agonists which are considered to be of serious concern for the environment due to the type of effects. Effects remain manifest even after exposure has ceased and exposure during sensitive life stages may change the endocrine feedback system resulting in effects during the entire life..

- Exposure to 4-nonylphenol resulted in effects in fish on reproduction parameters (fecundity) as well as on sexual development (including changes in sex-ratio) and growth. Results for at least 3 fish species show that exposure to 4-nonylphenol may result in a complete sex reversal resulting in all female populations. Effects observed include behavioural effects that may influence the gene pool.

- Effects observed in several fish species show that transient exposure during sensitive life stages may result in effects that remain during the entire life and even in following generations. Thus exposure in one area might influence population stability in another area and effects persist even after exposure has ceased.
- In addition to the severity of effects, some results substantiate the hypothesis that, although there might be a safe level, it is difficult to estimate what that may be.
- Effects on non-traditional endpoints indicate that effects may start at much lower concentrations than those considered in OECD test guidelines.
- Exposure to 4-nonylphenols resulted in effects on reproduction and development in different invertebrates at concentrations below 1 µg/L (e.g. LOEC sex-ratio < 1 µg/l in mussels, LOEC development 0.09 µg/L in echinoderm species). Although it is not possible to clearly state that the effects are endocrine mediated, these effects fit to the knowledge that steroids are known to play an important role in invertebrates (Kendall et al., 1998). Owing to the lack of in depth knowledge of their endocrine system and the lack of test systems, it is currently nearly impossible to estimate which species are most sensitive and which concentration should be regarded as safe for the environment.

Thus in summary, effects observed after exposure to 4-nonylphenols are considered to impair population stability and recruitment. They may occur even after short term exposure and thus may result in adverse effects in regions other than those where exposure occurred. Effects persist even after exposure has ceased and may influence population level on a long term basis e.g. due to trans-generational effects or changes in the gene pool. Effects may influence a wide range of taxa. A safe level of exposure may exist but it is difficult to estimate what that may be. Consequently they are considered to be of an equivalent level of concern.

The concern is substantiated by an analysis of literature of current knowledge on endocrine disruptors which reveals strong evidence that exposure to endocrine disrupting chemicals is linked to reproductive disorder and dysfunction in wildlife. Although this is mainly due to exposure to steroidal estrogens, at some sites xenoestrogens may significantly contribute to the effect.

Reference:

1. Support Document *4-Nonylphenol, branched and linear* (Member State Committee, 13 December 2012)