AGREEMENT OF THE MEMBER STATE COMMITTEE
ON THE IDENTIFICATION OF
4-NONYLPHENOL, BRANCHED AND LINEAR, ETHOXYLATED [SUBSTANCES WITH A LINEAR AND/OR BRANCHED ALKYL CHAIN WITH A CARBON NUMBER OF 9 COVALENTLY BOUND IN POSITION 4 TO PHENOL, ETHOXYLATED COVERING UVCB- AND WELL-DEFINED SUBSTANCES, POLYMERS AND HOMOLOGUES, WHICH INCLUDE ANY OF THE INDIVIDUAL ISOMERS AND/OR COMBINATIONS THEREOF]

AS A SUBSTANCE OF VERY HIGH CONCERN

According to Articles 57 and 59 of
Regulation (EC) 1907/2006[1]

Adopted on 12 June 2013

This agreement concerns

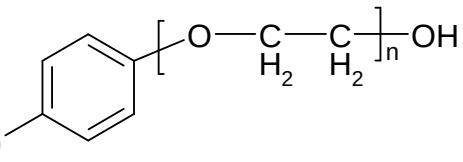
Substance name: 4-Nonylphenol, branched and linear, ethoxylated [substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and well-defined substances, polymers and homologues, which include any of the individual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

EC number: -

CAS number: **-**

Molecular formula: $(C_2H_4O)n\ C_{15}H_{24}O$, with $n \geq 1$

Structural formula:



[1]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 (27 February 2013, submission number DE004210-80) on identification of *4-Nonylphenol, branched and linear, ethoxylated [substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and well-defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof]* as a substance of very high concern because of its endocrine disrupting properties.

The Annex XV dossier was circulated to Member States on 4 March 2013 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 21 May 2013 and was discussed in the meeting on 11-14 June 2013 of the Member State Committee.

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

4-Nonylphenol, branched and linear, ethoxylated [substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and well-defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof] **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, ethoxylated *[substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and well-defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof*] 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 substances of very high concern (4-Nonylphenol, branched and linear (4-NP)). Therefore, there is scientific evidence of probable serious effects to the environment from these substances, through their degradation to 4-Nonylphenol, branched and linear, 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-Nonylphenol, branched and linear, ethoxylated (4-NPnEO) degrade to 4-Nonylphenol, branched and linear, 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-NPnEO indicate that 4-NPnEO contribute to the 4-NP concentration in the environment. A significant amount is either degraded to 4-NP itself in waste water treatment plants or is released to rivers in a form which may undergo further degradation to 4-NP. According to available data from sewage treatment plants, 4-NP formed from degradation of 4-NPnEO is responsible for an increase of the 4-NP load to the environment (soil, sediment and water) by 54 to 758 %. Sediment organisms may be exposed to the 4-NP, which results from the degradation of 4-NPnEO, 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-NP from sediment to the water body.

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

- 4-Nonylphenol, branched and linear have been identified as substances of very high concern and included in the Candidate List due to the 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-NPnEO will remain a long-term source of 4-NP due 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-NP. Therefore, 4-NP formed by degradation of its ethoxylates may accumulate in sediment.

- Especially due to the fact, that short term exposure to 4-NP 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 sink (mainly of short chain ethoxylates) and long-term source for 4-NP is considered of very high concern.

The equivalent level of concern is based on the degradation to 4-NP. However for further considerations it is important to note that available information for NPnEO indicate that short chain ethoxylates (NP1EO and NP2EO) show endocrine activity themselves: Results for *Onchorhynchus mykiss* and *Oryzias latipes* with NP1EO and NP2EO indicate that the in vivo and in vitro endocrine activity is nearly as high (factor 10) or similar to the endocrine activity of 4-nonylphenol. These tests do not include adverse endpoints. Hence, it is not possible to conclude whether 4-NP1EO and 4-NP2EO are endocrine disruptors themselves, or not. However due to the similar in vivo endocrine activity and information available for 4-NP it seems possible that these substances may cause endocrine disrupting adverse effects.

Reference:

Support Document *4-Nonylphenol, branched and linear, ethoxylated [substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and well-defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof]* (Member State Committee, 12 June 2013)