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Background document for 4-Nonylphenol, branched and linear, ethoxylated (4-NPnEO)

Document developed in the context of ECHA's 6th recommendation for the inclusion of substances in Annex XIV

ECHA is required to regularly prioritise the substances from the Candidate List and to submit to the European Commission recommendations of substances that should be subject to authorisation. This document provides background information on the prioritisation of the substance, as well as on the determination of its draft entry in the Authorisation List (Annex XIV of the REACH Regulation). Information comprising confidential comments submitted during public consultation, or relating to 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-Nonylphenol, branched and linear, ethoxylated
EC Number: -
CAS Number: -
IUPAC 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]

2. Background information for prioritisation

Priority was assessed by using the General approach for prioritisation of SVHCs for inclusion in the list of substances subject to authorisation¹. Results of the prioritisation of all substances included in the Candidate List by June 2013 and not yet included or recommended in Annex XIV of the REACH Regulation is available at

http://echa.europa.eu/documents/10162/13640/prioritisation_results_6th_rec_en.pdf

The prioritisation results of the substances included in the draft 6th recommendation have been updated as necessary after the public consultation. The updated results are available at http://echa.europa.eu/documents/10162/13640/updated_prioritisation_results_6th_axiv_rec_en.pdf.

¹ Document can be accessed at

http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf

2.1. Intrinsic properties

The substances covered by the entry '4-Nonylphenol, branched and linear, ethoxylated' 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. Therefore 4-Nonylphenol, branched and linear, ethoxylated were included in the Candidate List for authorisation on 20 June 2013, following ECHA's decision ED/69/2013.

2.2. Volume used in the scope of authorisation

According to registration information, the amount of 4-Nonylphenol, branched and linear, ethoxylated (4-NPnEO) manufactured and/or imported into the EU is in the range of 1,000 – 10,000 t/y. In addition, some of the commercially available ethoxylates of 4-nonylphenol are expected to fulfil the REACH definition of polymers and therefore are exempted from registration. Based on indications about the fraction of 4-Nonylphenol (4-NP) used to manufacture its ethoxylates (in registrations of 4-Nonylphenol) and the estimated average contribution to the molecular weight of its ethoxylates, a further volume of ethoxylates manufactured in the EU is roughly estimated to be in the range of 10,000 – 50,000 t/y. Finally, import of 4-NPnEO cannot be excluded.

All tonnage appears to be in the scope of authorisation, apart from (minor) uses in Scientific Research and Development (RCOM, 2013). Therefore, in conclusion, the volume in the scope of authorisation is estimated to be in the range of 10,000 – 50,000 t/y.

2.3. Wide-dispersiveness of uses

Based on registration information (for 4-NP and for 4-NPnEOs) and information from the Annex XV report (2013) uses of 4-NPnEO in the scope of authorisation include uses at industrial sites (e.g., formulation and use as floating agent in mining applications; formulation and use of paints; emulsion polymerisation; and potentially as reducing agent in surface treatment), and professional and consumer uses of products such as paints containing 4-NPnEO.

Furthermore, the substances are used in articles (e.g. when the article is painted with a paint that includes the substance).

2.4. Conclusions and justification

Verbal descriptions and Scores			Total Score
Inherent properties (IP)	Volume (V)	Wide dispersiveness of uses (WDU)	(= IP + V + WDU)
<p>4-NPnEO meet the criteria of Article 57 (f) because, through their degradation, they are substances with endocrine disrupting properties and cause 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</p> <p>Score: 7</p>	<p>The amount of 4-NPnEO used in the scope of authorisation is > 10,000 t/y.</p> <p>Score: 15</p>	<p>4-NPnEO are used at industrial sites and by professional workers and by consumers.</p> <p>Score:15</p> <p>Furthermore, the substances are used in articles.</p>	37

Conclusion

On the basis of the prioritisation criteria, 4-Nonylphenol, branched and linear, ethoxylated receives high priority among the substances in the Candidate List (refer to link to the prioritisation results above). Therefore, 4-Nonylphenol, branched and linear, ethoxylated is recommended for inclusion in Annex XIV.

3. Further information on uses

Registered 4-NPnEO comprise short ethoxy-chain nonylphenol ethoxylates. The registrants indicate a grade of ethoxylation of 1 to 2.5. The uses identified in those registrations include mainly formulation and use as floating agent in mining applications, and the tonnage corresponding to those uses is in the range of 1,000 – 10,000 t/y. A further minor registered (1 – 10t/y) use as reducing agent in metal surface treatment may also regard 4-NPnEO.

Further uses of 4-NPnEO, which actually seem to correspond to a higher total volume in the EU (10,000 – 50,000 t/y), are indicated in registrations of 4-Nonylphenol (which is used to manufacture 4-NPnEO). According to the Annex XV report (2013), commercially relevant 4-NPnEO are most often expected to have a chain length longer than three ethoxylate groups (commonly in the ranges 7-15 and 30-70, with a broad distribution of the chain length of ethoxylate group). Such NPnEO are indeed expected to differ in their uses from short ethoxy-chain 4-NPnEO and may be the ones described in the registrations of 4-Nonylphenol.

Uses of 4-NPnEO reported in registrations of 4-Nonylphenol include formulation of paints at industrial sites, end-use of products (e.g. paints), and use in emulsion polymerisation.

In the SVHC public consultation (RCOM, 2013) an application of emulsion polymerisation is described by a company. In that case, 4-NPnEO is used as emulsifier during the manufacture of fine chemicals, which are further used in the manufacture and purification of active pharmaceutical ingredients. Finally, another company reported a use in the formulation of products for scientific research and development.

There is little further information available on the uses of 4-NPnEO due to the lack of registrations for major part of the substances covered by this group. During the public consultation on draft Annex XIV recommendation (ComRef, 2015) admixtures for concrete,

polyurethane systems, auxiliaries in the textile industry, emulsion polymerization and emulsifying wax, and auxiliaries for oil extraction were identified as further uses.

4. Background information for the proposed Annex XIV entry

Draft Annex XIV entries were determined on the basis of the General approach for preparation of draft Annex XIV entries for substances to be included in Annex XIV². The draft Annex XIV entries for substances included in the 6th recommendation are available at http://echa.europa.eu/documents/10162/13640/6th_axiv_recommendation_july2015_en.pdf. The section below provides background for allocation of the substance to the Latest Application Dates slots.

The LAD slots are set in 3 months intervals (normally 18, 21 and 24 months after inclusion in Annex XIV but more slots can be considered on a case-by-case basis).

Allocation of (group of) substances to LAD slots aims at an even workload for all parties during the opinion forming and decision making on the authorisation applications. All substances can therefore not be set at the same LAD. ECHA proposes to allocate those substances to the "later" LAD slots (21 months or more) for which the available information indicates a relatively high number of uses. Substances with no registration requirement are also allocated to the later slots.

In this context, 4-Nonylphenol, branched and linear, ethoxylated is assigned to the 3rd LAD slot (24 months after inclusion in Annex XIV) due to the fact that polymers, which appear to represent the majority of the volume, are exempted from the provisions on registration of Title II of REACH (Article 2(9)).

² Document can be accessed at http://echa.europa.eu/documents/10162/13640/draft_axiv_entries_gen_approach_6th_en.pdf

5. References

- Annex XV report (2013): Proposal for identification of a substance as a CMR Cat 1A or 1B, PBT, vPvB or a substance of an equivalent level of concern. 4-Nonylphenol, branched and linear, ethoxylated - covering well-defined substances and UVCB substances, polymers and homologues. Submitted by Germany. February 2013.
<http://echa.europa.eu/documents/10162/7e8d561d-95ac-4d61-af70-c650d40f3d0a>
- ComRef (2015): "Comments and references to responses" document for 4-Nonylphenol, branched and linear, ethoxylated. Document compiling comments and references to respective answers from commenting period [01/09/2014-01/12/2014] on ECHA's proposal to include Pentalead tetraoxide sulphate in its 6th recommendation of priority substances for inclusion in the list of substances subject to authorisation (Annex XIV).
http://echa.europa.eu/documents/10162/13640/6th_axiv_rec_comref_4-NPnEO_en.pdf
- RCOM (2013): "*Responses to comments*" document. Document compiled by Germany from the commenting period 04/03/2013-18/04/2013 on the proposal to identify 4-Nonylphenol, branched and linear, ethoxylated as a Substance of Very High Concern.
<http://echa.europa.eu/candidate-list-table/-/substance/3201/search/+/term>