

ALKYLPHENOLS BULLETIN

An Update from the Alkylphenols & Ethoxylates Research Council

February 2, 2012

European Decision to List *para-tert*-Octylphenol as “Substance of Very High Concern” is Not a Restriction on Marketing or Use in Europe

The European Chemicals Agency (ECHA) recently added *para-tert*-Octylphenol (ptOP) to the candidate list of Substances of Very High Concern (SVHC) under the European Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). It is important to note that identification of a substance as a SVHC does not constitute a restriction of its marketing and use in Europe. Rather, it is a means to communicate prioritization of that chemical for consideration for further assessment using a process called “authorisation” under REACH.

The decision to add a compound to the SVHC list is based solely on a review of its intrinsic hazard properties and does not consider whether the current uses and exposures of the compound actually constitute a risk to human health or the environment. The SVHC list identifies those substances that, in the view of the European Member State Committee, “may have serious effects on human health or the environment” (emphasis added).

Although the meeting of the European Member State Committee on the decision to add ptOP to the SVHC list was closed to the public, it was based on a nomination dossier submitted by the German government under REACH Annex XV.¹ This dossier raised concerns about the endocrine activity of ptOP and alleged it has “serious” endocrine disrupting properties in fish. There was no concern about human health effects in the Annex XV dossier, which is consistent with other human health risk assessments that have been conducted on this compound.

Industry submitted extensive comments to ECHA that demonstrate that the Annex XV Dossier submitted for ptOP is based in part on invalid studies and flawed study interpretation and the overall assessment does not provide an adequate scientific basis to support a case that ptOP rises to a level of concern that is equivalent to a compound that has been classified as carcinogenic, mutagenic or reproductive (CMR) category 1A or 1B, or a persistent bioaccumulative toxicant (PBT).² While ptOP does not meet any of these classifications, the Annex XV dossier alleged it has endocrine disrupting properties

¹ German Federal Institute for Occupational Safety and Health (BAuA) (2011, August 29). Annex XV Dossier on 4-(1,1,3,3-tetramethylbutyl)phenol (OP). Dortmund, Germany

² European Council for Alkylphenols and Derivatives (CEPAD) and Alkylphenols & Ethoxylates Research Council (APEREC). (2011, October 13). Comments On the REACH Annex XV Report: Proposal for Identification of a Substance as a CMR Cat. 1A or 1B, PBT or vPvB, or a Substance of an Equivalent Level of Concern: 4-(1,1,3,3-tetramethylbutyl)phenol

in fish that are comparable to these classifications. The industry comments demonstrate that ptOP has only weak estrogenic activity that is 400 to 40,000 fold less potent than 17 β -estradiol (E2) and 17 α -ethynylestradiol (EE2), and that any adverse apical effects caused by ptOP are not "clearly endocrine mediated", but rather are indicative of general toxicity possibly coupled with very weakly estrogenic activity. While ptOP is very toxic to fish and other aquatic species, its effects are clearly not "comparable to other estrogens". Therefore, its classification as a SVHC is not warranted based solely on its hazard profile. In addition, the trace levels of ptOP detected in European surface waters during monitoring conducted under the European Water Framework Directive are significantly below its most sensitive (i.e., lowest) aquatic toxicity effect concentrations and do not support concern for probable and serious effects from this compound the environment.³

The [Alkylphenols & Ethoxylates Research Council](#) and the [European Council for Alkylphenols and Derivatives](#) will continue communication with the ECHA to ensure that further decisions related to ptOP are based on sound risk-based science that take into account the most relevant hazard properties, i.e., aquatic toxicity, and environmental exposures of this compound.

Finally, while the addition of ptOP to the SVHC list does not impose any restrictions on the marketing and use of ptOP in Europe, it does impart customer communication obligations to companies that manufacture, import or use the compound in the EU, whether on its own, or depending on its concentration, in preparations or articles. Please refer to the attached [Questions and Answers about the Listing of para-tert-Octylphenol as a Substance of Very High Concern](#) for more information about these communication requirements.

³European Council for Alkylphenols and Derivatives (CEPAD) and Alkylphenols & Ethoxylates Research Council (APEREC). (2011. October 13). Comments On the REACH Annex XV Report: Proposal for Identification of a Substance as a CMR Cat. 1A or 1B, PBT or vPvB, or a Substance of an Equivalent Level of Concern: 4-(1,1,3,3-tetramethylbutyl)phenol

The Alkylphenols & Ethoxylates Research Council has been in existence for over 25 years and is composed of manufacturers, processors and raw material suppliers of alkylphenols and alkylphenol ethoxylates, including NP and NPE. Its mission is to promote the safe use of AP and AP derivatives through research, product stewardship and outreach efforts, within the framework of responsible chemical management. The Research Council has sponsored over four million dollars in research and reviewed over four thousand studies on these compounds.