

April 24, 2017

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On behalf of Israeli Chemicals Industrial Products America, ICL-IPA, I am submitting the following comments on the rulemaking update to the Children's Safe Products Reporting Rule (CSPA Reporting Rule). The proposed update published on March 22, 2017 included recommendation to list butylated triphenyl phosphate, TBTPP. We were surprised to see a recommendation to list TBTPP as the chemical is not known to be used in the type of products covered by the rule and it has a wealth of data supporting the safety in use. The many studies performed with TBTPP confirm that the product has low mammalian toxicity, does not cause reproductive or developmental toxicity, or target organ toxicity after repeated daily exposure to high doses. It does not cause delayed peripheral neurotoxicity nor is it genotoxic. A summary of the data sets is shown below and references are attached.

Summary: A large number of studies have been performed over the last decades with butylated triphenyl phosphate (TBTPP), including acute, (semi)chronic and reproductive toxicity, neurotoxicity, genotoxicity and inhalation and dermal studies. Acute oral and dermal toxicity studies showed that the product has very low acute toxicity by both routes. This low toxicity was confirmed in an acute inhalation study in which rats exposed to the highest attainable air concentration showed minimal signs of toxicity. TBTPP can cause very mild irritation to the skin and eyes, but non sensitization was confirmed in a Human Patch. Repeated exposure in rats via the diet did not result in any adverse effects and a combined one-generation reproductive/developmental toxicity screening test in rats by the oral route, showed no treatment-related effects. TBTPP was tested separately for developmental toxicity in other studies and the data show it does not adversely affect fetal development. TBTPP did not show a potential to induce genetic mutations or chromosomal aberrations, as shown in a battery of mutagenicity tests. Various studies with hens have been performed to study the neurotoxicity potential of TBTPP, high doses caused significant plasma cholinesterase inhibition, which is a fully reversible biochemical effect. Treatment with TBTPP did not cause the percent inhibition of NTE necessary for the induction of delayed peripheral neurotoxicity and thus indicates low potential for neurotoxicity. Based on the results from the reproductive testing, it can be assumed that TBTPP does not cause any endocrine disruption when released into the environment.

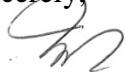
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EPA confirmed these conclusions in the study published in July 2008, in the *Initial Risk-Based Prioritization of High Production Volume Chemicals*, where the agency stated “The potential health hazard of butylated triphenyl phosphate is low.” The agency also found potential exposure to children was low, as no uses in products specifically intended to be used by children were reported nor found.

We encourage the committee to take these findings into full consideration as we believe the safety in use combined with the non-use in the children’s products should lead to a non-listing.

Sincerely,



Joel Tenney
Advocacy Manager
ICL-IP

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