Butylated Triphenyl Phosphate – Comments of Environmental Defense

(Submitted via Internet March 4, 2002.)

The test plan submitted by Akzo Nobel Functional Chemicals LLC proposes additional studies on physical characteristics and environmental fate but asserts that no additional mammalian toxicity studies are needed. We are concerned about the adequacy of the mammalian toxicity data based on the information supplied in the robust summaries. The purity of the test substances used in the toxicity studies does not appear to be well characterized and does not appear to be consistent across studies. For example, the developmental toxicology study uses a test substance that is only 75-80% pure with the major contaminant being triphenyl phosphate. The repeat dose study identifies Phosphex 51B as the test substance but we are not informed of the composition of this material. Other studies on neurotoxicity use the same substance and show that it is a cholinesterase-inhibiting mixture. The reproductive toxicity studies use some kind of hydraulic fluid as the test substance. This also was not characterized in the robust summaries and the sponsor classifies this study as not reliable. Based on the above concerns, we cannot concur, at this time, that no additional studies are needed. We are particularly concerned over the lack of a reliable reproductive toxicity study, given the knowledge that this substance appears to be cholinesterase-inhibiting agent.

Finally, we note that the test plan and robust summaries do not provide any information on uses, environmental release or opportunity for human exposure. While all this may not be formally required by the HPV program, we have found it to be very helpful in reviewing other test plans where such information is supplied to help put the available toxicity data in the context of human exposure.

Thank you for this opportunity to comment.

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