

AR201-13855



July 1, 2002

Functional Chemicals

02 JUL 11 PM 1:07

Oscar Hernandez, Director
U.S. Environmental Protection Agency
P.O. Box 1473
Merrifield, VA 22116
Attn: Right-To-Know

02 JUL 11 PM 12:52

RECEIVED
OPPT CBIC

Re: Response to EPA Comments on HPV Test Plan for Butylated Triphenyl Phosphate

Dear Mr. Hernandez:

Akzo Nobel Functional Chemicals LLC is pleased to respond to your letter of April 30, 2002, and to the comments on our proposed Test Plan that you sent on behalf of the Office of Pollution Prevention and Toxics (OPPT). We are in agreement with the OPPT comments and have prepared a revised Butylated Triphenyl Phosphate Test Plan, a copy of which accompanies this letter.

Our company is committed to the principles of the October 14, 1999 letter, which emphasizes the analysis and use of existing, scientifically adequate data wherever possible. To be sure that all available butylated triphenyl phosphate data was being examined, we searched company files for reports and other documents, reviewed several electronic databases for published information on the product, and asked trade associations to conduct searches of their respective records. All of the reports, publications, correspondence, and other documents pertaining to butylated triphenyl phosphate were carefully examined and where possible, data from these documents were included in the robust summaries. This effort has significantly reduced our testing requirements.

Many of the Agency's comments pertain to the identity of the test substance used in the various studies. In essentially all of the referenced studies in the robust summaries, the test substance consisted of the commercial product, which is sold under several product names. The commercial product consists of a mixture of tert-butylated triphenyl phosphate isomers. Typically, the commercial product contains about 20-25% Triphenyl Phosphate. Additional information on the identification of the product will be included in Akzo Nobel's revised robust summaries. Since the various tests are conducted to obtain an understanding of the potential actions of the commercial product on human health and the environment, the commercial product was evaluated in the tests reported in the robust summaries. Thus, the results provide a valid assessment of the commercial product.

In the Butylated Triphenyl Phosphate Test Plan originally submitted to the Agency, Akzo Nobel Functional Chemicals LLC committed to conduct boiling point, hydrolysis (stability in water) and partition coefficient tests. In its revised Test Plan (copy enclosed), the company commits to conducting a vapor pressure test in addition to the boiling point, hydrolysis, and partition coefficient tests. Also, we are committed to including additional toxicology details, if identified, and revising the appropriate robust summaries.

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MR-60320

Akzo Nobel supports the Agency conclusion that the available reproductive toxicity data are inadequate and will conduct additional testing. EPA's October 14, 1999 letter emphasizes the need to minimize animal usage wherever possible. Since Akzo Nobel Functional Chemicals LLC strongly supports this policy, it will conduct a reproductive toxicity test according to OECD Guideline 421, which utilizes far fewer animals than the standard multigeneration reproduction test identified in OECD Guideline 416.

We appreciate EPA OPPT's comments on our robust summaries and the Agency's testing recommendations. We believe the revised Test Plan now includes all of the test required to measure the SIDS endpoint while minimizing the use of laboratory animals.

Sincerely yours,

William F. Gentit
Manager, Regulatory Affairs

Cc: Richard Hefter – EPA
Jim Keith – ACC
John Morris – ACC
Steve Russell – ACC

REVISED

TEST PLAN

For

BUTYLATED TRIPHENYL PHOSPHATE

CAS No. 220352-35-2

Prepared by

Akzo Nobel Functional Chemicals LLC
5 Livingstone Avenue
Dobbs Ferry, NY 10522

June 19, 2002

REVISED TEST PLAN

BUTYLATED TRIPHENYL PHOSPHATE (CAS #220352-35-2)

<u>Study Type</u>	<u>Testing Required</u>	<u>OECD Guideline</u>	<u>Time (Months)</u>
Physical/Chemical Characteristics			
Boiling Point	Yes	103	3
Vapor Pressure	Yes	104	3
Partition Coefficient	Yes	107	3
Water Solubility	No	NA	
Environmental Fate			
Photodegradation	No	NA	
Stability in Water	Yes	111	3
Biodegradation	No	NA	
Fugacity	Yes	EPA/OECD Model	
Ecotoxicity			
Acute Toxicity to Fish	No	NA	
Acute Toxicity to Aquatic Invert.	No	NA	
Toxicity to Aquatic Plants	No	NA	
Human Health Effects			
Acute Toxicity	No	NA	
General Toxicity (Repeated Dose)	No	NA	
Genetic Toxicity	No	NA	
Reproductive Toxicity	Yes	421	11
Developmental Toxicity	No	NA	

NA = Not Applicable

Reproductive toxicity test to be preceded by a dose rangefinding test which is essential to identify appropriate doses for the definitive reproductive toxicity test

Prepared June 19, 2002