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Dr. Oscar Hernandez, Director
Risk Assessment Division
U.S. Environmental Protection Agency
P.O. Box 1473
Merrifield, VA 22116

July 8, 2005

RE: EPA Comments on Chemical RTK HPV Challenge Submission: BISCEP

Dear Dr. Hernandez:

As an active participant in the High Production Volume (HPV) Challenge program, Rhodia Inc. is pleased to provide this response to the U.S. Environmental Protection Agency's comments dated May 11, 2005, on the BISCEP Robust Summary dossier and proposed Test Plan.

The Agency's comments on the robust summaries are currently being reviewed by our scientific staff, and we are conducting a further review of our records. It is our intention to update and revise the robust summary and test plan to incorporate additional information following completion of this review. Rhodia Inc. will provide revised Robust Summaries and Test Plan to the Agency by August 31, 2005.

A summary of our initial response to the Agency's comments is enclosed with this letter.

Thank you for your helpful comments. We appreciate the opportunity to participate in the HPV Challenge Program.

Kind Regards

Ian Bartlett Ph.D.
Product Stewardship Manager

On behalf of Dr. Glenn Simon, Director of Toxicology, Rhodia Inc, 5171 Glenwood Avenue, Suite 402, Raleigh, NC 27612. Tel: (919) 786-9999; Fax: (919) 786-9154

cc. Steve Groome, Rhodia UK Ltd.
Dr. Glenn Simon, Rhodia Inc.

Response to EPA Comments on Chemical RTK HPV Challenge Submission: BISCEP

SUMMARY OF EPA COMMENTS

EPA has reviewed this submission and reached the following conclusions:

1. General. The submitter needs to better identify the test substances in robust summaries. It is unclear what the various synonyms represent. The evaluation of several studies depends on this information.

Response

BISCEP is exclusively manufactured as a mixture of 2-chloroethylphosphonic acid bis(2-chloroethyl) ester (55-70% w/w, BISCEP monomer, CAS No. 6294-34-4) and , 2-[[[(2-chloroethoxy)(2-chloroethyl)phosphinyl]-oxy]ethylphosphonic acid bis(2-chloroethyl) ester (35-40% w/w), BISCEP dimer, CAS No. 58823-09-9). All studies were conducted on the manufactured reaction product.

We will revise the robust summaries to clarify the identity of the test substance and the use of synonyms in the document.

2. Physicochemical Properties. Data for these endpoints may be adequate for the purposes of the HPV Challenge Program. However, to the extent the individual components are available, some additional testing may be needed.

Response

2-chloroethylphosphonic acid bis(2-chloroethyl) ester (55-70% w/w, BISCEP monomer, CAS No. 6294-34-4) and , 2-[[[(2-chloroethoxy)(2-chloroethyl)phosphinyl]-oxy]ethylphosphonic acid bis(2-chloroethyl) ester (35-40% w/w) are always produced together in the reactor as a mixed reaction product. Neither the monomer or dimer are manufactured independently in our production process. The BISCEP reaction product has been manufactured for over 25 years, always as the mixture of monomer and dimer (in the specified ratio). All test data has been generated on this reaction product.

We will revise the robust summaries to clarify the identity of the test substance.

3. Environmental Fate. EPA agrees with the test plan for these endpoints, except that EPA reserves judgement on the adequacy of the submitted biodegradation data pending receipt of more study details.

Response

See response to 1 regarding test substance. We will revise the robust summaries to clarify the identity of the test substance and the use of synonyms in the document.

With regard to the biodegradation study, in the summary of the test report, it is written: "BOD measurements indicated that the test material was not rapidly degraded in the dilute biological system under study". In the material and method section, it is indicated that a control was performed to check for contamination of the BOD dilution water. Therefore it is unlikely that "pure" sewage has been used.

The test report does not indicate how the inoculum was prepared and which nutrient medium was used. However the glucose/glutamic acid control yielded 99.1% biodegradation after 5 days, indicating that the test conditions were adequate for biodegradation.

The study was performed according to the test method "Standard Methods for the Examination of Water and Wastewater. 14th Ed. APHA pp 543-554 (1976)". The preparation of the inoculum and the nutrient medium should be indicated in the standard method. We are in the process of retrieving this document and will let you know as soon as possible if we manage to get more information.

4. Health Effects. The submitted data are adequate for the purposes of the HPV Challenge Program pending clarification of the test substances used.

Response

We agree with the Agency's recommendations on human health testing. We will revise the test plan to reflect the recommendations of the Agency.

See response to 1. regarding test substance identity. We will revise the robust summaries to clarify the identity of the test substance used in the studies.

5. Ecological Effects. EPA reserves judgement on the adequacy of all aquatic toxicity endpoints pending receipt of the stability-in-water test results and test substance clarification.

Response

See response to 1. regarding test substance identity. We will revise the robust summaries to clarify the identity of the test substance used in the studies. We agree to conduct a water stability test following finalization of the test plan.