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4123 East 37th Street North
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USA

September 18, 2008

Stephen L. Johnson
Administrator
U.S. Environmental Protection Agency
PO Box 1473
Merrifield, VA 22116**Attn: Chemical Right-to-Know Program**

Dear Administrator Johnson:

INVISTA S.à r.l. is pleased to submit responses to EPA's comments along with final robust summaries and test plan documents for the chemical, Hexamethyleneimine (CASRN: 111-49-9) under the U.S. HPV Challenge Program.

This submittal is a follow up of the robust summary and test plan submitted by DuPont, the previous sponsor of the chemical, in February, 2004.

The revisions to the robust summaries and test plan provide additional information on critical studies and information requested by EPA. No further testing is proposed.

Listed below are INVISTA's responses to EPA's comments of January 15, 2003. These responses are in addition to the responses submitted by the previous sponsor:

Health Effects

EPA Comment: EPA agrees with the submitter that the following tests are needed: repeated-dose, developmental, reproductive and genetic testing for chromosomal aberrations. EPA recommends the use of OECD TG 422 and 473 for these endpoints.

Response: An OECD 422 study and an OECD 473 study have been completed and the data have been included in the revised submittals. In the OECD 422 Combined Repeated Dose Toxicity and Reproductive / Developmental Toxicity Screening study, treatment-related effects were limited to mucosal thickening of glandular / forestomach tissue observed at necropsy (without correlation to microscopic tissue damage) up to the highest dosage tested (50 mg/kg/day hexamethyleneimine (by gavage)). Additionally, no effects were observed on gonadal tissue or on reproductive parameters including mating, parturition, or lactation in parental animals. No evidence of developmental or fetal effects were seen in offspring even at the highest dosage (50 mg/kg/day) tested. In the OECD 473 *in vitro* chromosomal aberration study in human lymphocytes, no clastogenic effects were observed when hexamethyleneimine was tested with and without incorporation of a mammalian metabolic activation system.

Ecological Effects

EPA Comment: EPA agrees with the submitter that testing is needed to assess acute toxicity in fish, invertebrates, and algae. All aquatic testing should be done using a flow-through system when possible, zero head space, with total organic carbon less than 2.0%, and analytically determined exposure concentrations.

Response: Aquatic toxicity studies have been completed according to current OECD 201, 202, and 203 guidelines and the data have been included in the revised submittals. Results indicate low to moderate acute aquatic toxicity. LC₅₀/EC₅₀ values were determined to be >100 mg/L for rainbow trout and *Daphnia* and 88 mg/L (growth index) for green algae and thus were of lower toxicity than predicted by ECOSAR.

This submission includes one electronic copy in PDF format. Hard copy can be provided upon request.

Please feel free to contact me with any questions you might have regarding this submission.

Sincerely,

Heather J. Blankinship
Product Safety Capability Manager
Environmental Health and Safety

Attachments