201- 14492

NCIC HPV
Sent by: Mary-Beth Weaver

05/23/2003 09:51 AM

To: NCIC HPV, moran.matthew@epa.gov
cc:
cc:
Subject: Environmental Defense comments on Methyl 4,6,6,6-Tetrachloro-3,3-Dimethylhexonate (CAS # 64667-33-O)

Richard_Denison@environmentaldefense.org on 05/22/2003 10:08:58 AM

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Subject: Environmental Defense comments on Methyl 4,6,6,6-Tetrachloro-3,3-Dimethylhexonate (CAS # **64667-33-0)**

(Submitted via Internet 5/22/03 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, MTC@mchsi.com, and NATALIE RUTHERFORD@fmc.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for Methyl 4,6,6,6-Tetrachloro-3,3-Dimethylhexonate (CAS # 64667-33-0).

The FMC Corporation, in response to the EPA High Production Volume (HPV) Challenge Program, has submitted a Robust Summary/Test Plan for methyl 4,6,6,6-tetrachloro-3,3-dimethylhexonate (MTD). Our review of this submission indicates FMC has done and proposes to do the bare minimum in response to the HPV Challenge. In the letter to Manufacturers/Importers, the EPA specifically states: "In analyzing the adequacy of existing data, participants shall conduct a thoughtful, qualitative analysis rather than a rote checklist approach." This submission is no more than a "rote checklist approach" that provides a scant review of information on this chemical.

The Test Plan submitted for MTD solely consists of a checklist of studies done or not done. It contains no background information on the chemical, discussion of available data or descriptions of the types of data requested that are currently unavailable. Basic information such as chemical structure, uses, transport, and possible sources of occupational, consumer or environmental exposure are not mentioned. While not all such information is strictly required under the Program, we consider this information useful if not critical to provide an assessment of possible human and environmental health risks. Thus, we consider the Test Plan inadequate.

The Robust Summary for MTD is little better. Remarkably, some of the most basic information, e.g., melting point, is said to be unavailable, whereas other basic information, e.g., boiling point, vapor pressure, and water solubility, were determined by "unknown methods" and the quality of the data is judged by FMC as "insufficient for assessment". The quality of these data are critical because they were used in generation of most of the environmental fate data, e.g., photodegradation, stability in water and fugacity, using computer models. Because the accuracy of these computer models is dependent on the quality of the data used to generate them, we must assume that the parameters generated by the computer models are also "insufficient for assessment". Thus, not only has FMC simply "checked the boxes," it has claimed as "filled" required SIDS data elements the values

for which were derived using data of insufficient quality.

Data describing aquatic toxicity are limited to a single study of toxicity to salt water fish, which indicate that MTD is quite toxic to fish. This observation indicates some degree of water solubility, as opposed to the statement in section of 2.5 of the Robust Summary that states that MTD is "insoluble" in water. The single acute toxicity study of MTD in animals indicates it has very low toxicity. However, this is not an adequate study as it used only a single bolus oral dose that may not have been absorbed from the gastrointestinal tracts of the treated animals. There are no data for repeated dose studies, yet such studies are not proposed in the Test Plan. These studies are necessary: numerous other halogenated compounds, e.g. certain insecticides, PCBs, etc., that have low acute toxicity have been shown to bioaccumulate and induce toxicity at relatively low doses with repeated exposures. And finally, reproductive toxicity and developmental toxicity/teratogenicity studies are not proposed. We defer to the EPA as to whether the proposed "Reproduction/Developmental Screen" is sufficient to address this required SIDS element.

In summary, for the reasons expressed above, we do not find this Robust Summary/Test Plan sufficient to comply with the EPA's HPV Challenge Program.

Thank you for this opportunity to comment.

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