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PCRM PHYSICIANS COMMITTEE FOR RESPONSIBLE MEDICINE

5100 WISCONSIN AVENUE, N.W. • SUITE 400
WASHINGTON, D.C. 20016
T: (202) 686-2210 • F: (202) 686-2216
PCRM@PCRM.ORG • WWW.PCRM.ORG

February 15, 2008

Stephen Johnson, Administrator
US Environmental Protection Agency
Ariel Rios Building
Room 3000, #1101-A
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Subject: Comments on the HPV test plan for Dimethyl Succinyl Succinate

Dear Administrator Johnson:

The following comments on the Color Pigments Manufacturers Association, Inc (CPMA) April 23, 2007 test plan for Dimethyl Succinyl Succinate (DMSS, CAS RN 6289-46-9) are submitted on behalf of the Physicians Committee for Responsible Medicine, People for the Ethical Treatment of Animals, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These health, animal protection, and environmental organizations have a combined membership of more than ten million Americans.

We support the test plan prepared by CPMA which uses existing data and computational models to fulfill most of the Screening Information Data Set (SIDS) endpoints requested by the HPV Challenge Program. Testing for repeat dose and reproductive toxicity endpoints are waived for this compound given that DMSS is a closed system intermediate completely consumed in the manufacturing process.

Although developmental toxicity testing is not waived under these circumstances, CPMA argues that no testing is required. This is a reasonable supposition given that: (1) DMSS is a stable insoluble solid which people are highly unlikely to ingest and (2) its use is limited to less than 5 facilities in North America. Therefore, DMSS poses minimal threat as a developmental toxicant. We hope that the EPA will be receptive to CPMA's decision not to conduct further testing based on its statement in the October 1999 "Letter to Manufacturers/Importers [of HPV chemicals]", allowing that "participants may conclude that there is sufficient data, given the totality of what is known about a chemical, including human experience, that certain endpoints need not be tested."

To further support their test plan, CPMA may want to consider a search for data from chemical analogs to add to a weight-of-evidence approach to fulfill the developmental toxicity endpoint. In the event that such data can not be located and the EPA requires testing, CPMA should consider alternatives to a traditional rodent assay including embryonic stem cell testing, the micromass assay, or the frog embryo teratogenesis assay.

In closing, CPMA has made good use of existing and computational data in order to satisfy the requirements of the HPV Challenge program and we concur with the current proposal not to conduct additional mammalian testing. Thank you for your attention to these comments. I may be reached at 202-686-2210, ext. 345, or via e-mail at nbeck@pcrm.org.

Sincerely,

Nancy Beck, Ph.D.
Policy and Science Advisor

Chad B. Sandusky, Ph.D.
Director of Research