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June 27, 2007

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 Dimethylolpropionic Acid (DMPA)

Dear Administrator Johnson:

The following comments on GEO Specialty Chemicals' test plan for Dimethylolpropionic Acid (DMPA) 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.

On January 10, 2007, GEO Specialty Chemicals submitted a test plan for DMPA (CAS RN 4767-03-7) which recommended a combined repeat dose, reproductive, and developmental toxicity screen (OECD TG422), as well as acute aquatic toxicity studies, which will consume an estimated 675 and 120 animals, respectively.

Although not stated in the test plan, DMPA is a chemical with various applications. One of its primary uses is in the preparation of resin coatings to enhance their solubility and adhesion. This plan would greatly benefit from the inclusion of just such information on how DMPA is manufactured and used including the following: whether DMPA is an isolated or closed system intermediate; how, where, and in what quantities DMPA is stored and/or transported; potential sources, levels, and routes of exposure; and occupational exposure limits, handling precautions, and disposal procedures. Some of this material can be found in GEO Specialty Chemicals',"A Complete Guide to DMPA® Brand of Dimethylolpropionic Acid'and it should be included in this test plan. (see http://www.geosc.com/DOCS/DMPA/DMPA_Complete_Guide.pdf). Without all of this information, it is difficult to assess the potential risks posed by DMPA and the most appropriate way to evaluate those risks.

As a general rule, physico-chemical and environmental fate data should be available prior to making decisions on additional tests. We note that hydrolysis testing on DMPA has not yet been conducted. If DMPA rapidly hydrolyzes to well-characterized products, further testing may not be necessary. The reproductive and developmental toxicities of the resulting products may be known, or they may have characteristics that would preclude their testing, such as a strong corrosive nature. Given that some participants have used existing data on hydrolysis products of the HPV chemicals to eliminate animal

tests (for an example, see Triisopropylborate, *http://www.epa.gov/chemrtk/triprobt/c14841tc.htm*), GEO Specialty Chemicals should first conduct the necessary hydrolysis study. The hydrolysis study should include data corresponding to mammalian stomach pH, as this may well obviate the perceived need for conducting the proposed 422

In addition, GEO Specialty Chemicals proposes redundant testing to address acute aquatic toxicity, despite the fact that existing data obtained in 2004 indicates DMPA is virtually non-toxic to aquatic organisms. These tests are consistent with the ecotoxicology parameters required in the HPV program. Disturbingly, however, GEO Specialty Chemicals proposes to conduct duplicate acute fish toxicity studies (which will kill approximately 120 fish) simply because it cannot find any details on these studies. It is unclear to us why these details are not available. It is incumbent on the company to find these details and make them available in the robust summaries, and to avoid additional proposed testing.

Indeed, the brief details provided are enough to create a "weight-of-evidence" picture of the potential ecotoxicity of the chemical that more than suffices for a screening-level program such as the HPV Program. In its publication, "A Complete Guide to DMPA® Brand of Dimethylolpropionic Acid", GEO Specialty Chemicals states that DMPA is "essentially non-toxic" (p19). This claim is supported by fish, Daphnia, algae, and rat data presented in the test plan indicating minimal toxicity. In addition, DMPA showed minimal toxicity in acute oral and intraperitoneal toxicity tests in mice. These data were not presented in the test plan, but are cited in the company's publication mentioned above (p19). Given the minimal toxicity demonstrated by these data, additional animal testing is unwarranted.

If, against our advice, GEO Specialty Chemicals decides to conduct duplicative fish toxicity testing, the least it could do is conduct a limit test protocol. Since the chemical is clearly non-toxic, using only the high dose group in a limit test design would reduce the number of fish killed from approximately 120 to 14.

Finally, there is no mention of data from structurally similar chemicals in the test plan. GEO Specialty Chemicals should heed EPA's recommendation that participants use all measures available to minimize animal testing, including use of existing data and predictions based on structure-activity (see *http://www.epa.gov/HPV/pubs/general/ceoltr2.htm*). GEO Specialty Chemicals must conduct a thorough search for data regarding eco-, developmental, reproductive, and repeat dose toxicity from structurally-similar chemicals and indicate its findings in the test plan.

In conclusion, this test plan is lacking much of the information that is required to make informed judgments on exactly what tests are warranted. 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,

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