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December 21, 2006

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

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Subject: Comments on the HPV test plan for C.I. Pigment Yellow 14

Dear Administrator Johnson:

The following comments on the Color Pigment Manufacturers Association (CPMA) test plan for C.I. Pigment Yellow 14 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.

CPMA submitted its test plan in June 2006 for the chemical C.I. Pigment Yellow 14 (Yellow 14) (CAS RN 5468-75-7). According to the test plan, Yellow 14 is one of several structurally-related diarylide pigments, used in the production of printing inks, paints, and plastics. It appears that data are available for all HPV endpoints for the test chemical or at least one of the three offered analogs. CPMA lists C.I. Pigment Yellow 13 (Yellow 13) (CAS RN 5102-83-0), C.I. Pigment Yellow 12 (Yellow 12) (CAS RN 6358-85-6), and C.I. Pigment Yellow 83 (Yellow 83) (CAS RN 5567-15-7) as analogs with similar chemical structure and physicochemical properties to the test chemical, Yellow 14.

We support this thoughtful toxicology approach. A number of companies have used data analogs to fulfill HPV data endpoints in the Challenge program. We do however have a few suggestions that could improve the test plan.

Often, in order to show the appropriateness of analogous chemicals, sponsors will construct a table comparing the known properties of the test chemical and any analogs. CPMA has started to do this on page 6 of the test plan, but perhaps an organized table, with more physicochemical and/or toxicity data, if available, would be helpful in determining the suitability of the three analogs. Even modeled data for each property and chemical would assist in the evaluation.

We also believe it would be helpful to those interpreting the Robust Summaries if the common names were listed in addition to the chemical names for each pigment. This is done in some cases but not all.

According to the test plan, the yellow pigments are not absorbed in any appreciable amounts through the GI tract after oral exposure, or by the dermal route. Given this observation, the available data and submitted test plan are more than adequate to fulfill the screening-level HPV program. Additional animal testing via the oral exposure route would not provide useful information.

This test plan is an example of the thoughtful toxicology that is needed to be consistent with the EPA's stated goal of maximizing the use of existing data in order to limit additional animal testing and to avoid a mere box-checking approach to the HPV program. Thank you for your attention to these comments. We may be reached at 202-686-2210, ext. 335, or via e-mail at kstoick@pcrm.org with any further questions.

Sincerely,

Kristie M Stoick, M.P.H.
Research Analyst

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Director of Research