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February 17, 2009

Lisa P. Jackson, 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 Benzenesulfonamide, ar-methyl (o,p-TSA)

Dear Administrator Jackson:

The following comments on Day-Glo Color Corporation's July, 2008 test plan for Benzenesulfonamide, ar-methyl (o,p-TSA, CAS RN 1333-07-9) 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.

The data presented in the test plan fulfill all of the Screening Information Data Set (SIDS) toxicity endpoints for the purposes of the HPV Challenge Program. For most endpoints, data were provided for o,p-TSA mixtures as well as o-TSA and p-TSA. For o,p-TSA isomer mixtures, the sponsor used data from Ketjenflex 9 and Santicizer 9, commercial products which closely approximate the ortho/para composition of the sponsored products. Supporting data is provided for o-TSA and p-TSA based on the assertion that ortho/para mixtures are unlikely to demonstrate greater toxicity than either isomer alone. In this instance, the argument appears reasonable given the similarities in the toxicity data between the individual isomers and the mixtures, but the sponsors may want to consider expanding their rationale to better substantiate this assertion.

It is worthwhile to note that the ortho and para isomers are each very well characterized. The OECD/SIDS document on o-TSA states that it, "is not a candidate for further work because all SIDS endpoints are sufficient" [1] and for p-TSA, "no further testing is needed at present considering its exposure levels and use pattern".[2]

The only mammalian endpoint for which there are no data for the o,p-TSA mixture is a stand alone reproductive toxicity study. This requirement is met with data from OECD 422 guideline studies on both o-TSA and p-TSA. While we believe these data alone are more than sufficient, there is potential for strengthening this section of the submission by presenting any histopathological data on reproductive organs from the existing o,p-TSA repeat dose studies in

rats and dogs. These repeat dose data on o,p-TSA in conjunction with developmental data on the o,p-TSA mixture can be used for a weight of evidence approach to further address the requirement for reproductive data. If necessary, data from structurally similar chemicals, such as the fellow HPV Challenge Program chemical N-n-Butylbenzenesulfonamide (CAS RN 3622-84-2), may also be used as an additional source of support for this submission.

Further testing of this mixture is unwarranted given the abundance of available data and limited potential for exposure. According to the test plan, o,p-TSA is imported and handled by a maximum of 10 workers at one site and personal protective equipment is used. The chemical is completely consumed during manufacturing and is not present in any final products.

In closing, Day-Glo Color Corporation has satisfied the toxicity 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

1. Screening Information Data Set for High Production Volume Chemicals. 2003. o-toluenesulfonamide. p 69.

2. Screening Information Data Set for High Production Volume Chemicals. 1995. p-toluenesulfonamide. p 29.