

201-15165

Anh Nguyen

04/01/04 01:44 PM

To: NCIC HPV@EPA

cc:

Subject: Environmental Defense comments on 2-naphthalenesulfonic acid, 6-hydroxy-5-[(2-methoxy-5-methyl-4-sulfophenyl)azo]-, disodium salt (CAS# 25956-17-6)

----- Forwarded by Anh Nguyen/DC/USEPA/US on 04/01/2004 01:42 PM -----



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To: NCIC OPPT@EPA, ChemRTK HPV@EPA, Rtk Chem@EPA, Karen Boswell/DC/USEPA/US@EPA, Tadams@therobertsgroup.net

cc: MTC@mchsi.com, kflorini@environmentaldefense.org, rdenison@environmentaldefense.org

Subject: Environmental Defense comments on 2-naphthalenesulfonic acid, 6-hydroxy-5-[(2-methoxy-5-methyl-4-sulfophenyl)azo]-, disodium salt (CAS# 25956-17-6)

(Submitted via Internet 4/1/04 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, MTC@mchsi.com, and Tadams@therobertsgroup.net)

Environmental Defense appreciates this opportunity to submit comments on the Robust Summaries and Test Plan for 2-naphthalenesulfonic acid, 6-hydroxy-5-[(2-methoxy-5-methyl-4-sulfophenyl)azo]-, disodium salt (CAS# 25956-17-6).

The International Association of Color Manufacturers' HPV Committee, in response to EPA's High Production Volume Challenge, has submitted Robust Summaries and a Test Plan describing data for 2-naphthalenesulfonic acid, 6-hydroxy-5-[(2-methoxy-5-methyl-4-sulfophenyl)azo]-, disodium salt, to address each of the SIDS elements requested under the HPV Challenge. According to this submission, this chemical is one of only seven food color additives certified for use in food, drugs and cosmetics by the U.S. FDA. It has also been evaluated and approved by the World Health Organization's Food and Agriculture Organization Joint Expert Committee for the Evaluation of Food Additives. Quality of currently produced material is said to be further assured by the fact that the FDA, for compliance with specifications set for purity, tests each batch of this chemical. As would be expected of a chemical that has been so closely examined and approved for use in food, this chemical has been the subject of extensive research and testing to determine any possible adverse effects it might exert on human or environmental health. According to this submission, significant adverse effects have been observed in multiple studies.

Our review of the Test Plan and Robust Summaries indicates that both are very well-organized and thorough. Numerous studies, many published in the open literature, are referenced in both the Test Plan and Robust Summaries. Experimental data are available to address most required SIDS elements. In the few instances where experimental data are not available to address a required SIDS element, an estimate of the respective parameter has been generated by an EPA-approved computer model or bridged from a closely related chemical. Since 2-naphthalenesulfonic acid, 6-hydroxy-5-[(2-methoxy-5-methyl-4-sulfophenyl)azo]-, disodium salt has been in use for quite some time, some of the studies cited were not conducted under GLP; however, our review of the Test Plan and Robust Summaries indicate those studies were carefully conducted and satisfactory

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to address the respective SIDS elements. We compliment the International Association of Color Manufacturers' HPV Committee on a well-written and thorough submission, and we concur that no additional work on this chemical is needed to meet the objectives of the HPV Challenge.

Thank you for this opportunity to comment.

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