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NCIC HPV Sent by: Mary-Beth Weaver

cc: cc: Subject: Environmental Defense comments on Zinc Dibutyldithiocarbamate (CAS# 136-23-2)

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06/04/2003 10:22 AM

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Subject: Environmental Defense comments on Zinc Dibutyldithiocarbamate (CAS# 136-23-2)

(Submitted via Internet 6/02/03 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, MTC@mchsi.com, and anne lehuray@americanchemistry.com)

Environmental Defense appreciates this opportunity to submit comments on the Robust Summary/Test Plan for Zinc Dibutyldithiocarbamate (CAS# 136-23-2).

The Rubber and Plastics Additives Panel of the American Chemistry Council, in response to EPA's High Production Volume (HPV) Challenge Program, has submitted a Robust Summary/Test Plan for zinc dibutyldithiocarbamate (ZDEC) . According to the Test Plan, ZDBC has been manufactured for over 60 years and is used as a primary accelerator in natural and synthetic rubbers and as an antioxidant in rubber-based adhesives. Occupational contact is said to be limited by enforcement of appropriate industrial hygiene practices. The most likely source of consumer exposure is said to be through skin contact with rubber or latex gloves or other articles. The Test Plan states that "ZDBC is shipped extensively throughout the world", but does not mention measures taken to avoid release and exposure as a result of transport. The Test Plan also states that the "vast majority of ZDBC is used by the rubber industry", but does not mention other uses or associated sources of and potential for human or environmental exposure.

We compliment the Rubber and Plastics Additives Panel for providing a summary of most available studies; however, we note that the description of Repeated Dose Toxicity only states that such studies are available, and makes no mention of the findings of these studies. The Test Plan only briefly mentions occupational exposure potential, implying it is of no concern because "The rubber and plastics additives industry has a long safety record and only sophisticated industrial users handle this material." This statement is both vague and unreassuring; one could equally cite the significant incidence of occupational cancer associated with this industry. We would prefer to see in the Test Plan a more substantive and complete description of exposure potential and the specific measures taken to prevent human and environmental exposures.

The Robust Summary submitted for ZDBC is relatively concise, in most cases describing a single study described for each SIDS element. Whereas we would like to see more data if they are available, we realize a single study of adequate quality is sufficient for the HPV program. However, we would note that EPA's guidance on preparing robust summaries indicates the following: "In addition, a single 'best' study would contain a weight-of-the-evidence analysis in its remarks section which refers to, and ties together, the other studies." Hence, if multiple studies exist on a given endpoint, we request that the sponsor follow this procedure specified in EPA's guidance.

We also think it is appropriate that SAR-derived estimates for a closely related chemical, zinc dimethyldithiocarbamate, are used to address two SIDS elements, Biodegradation and Acute Toxicity to Plants.

For each individual SIDS element, the summarized study or studies are described in some detail and in most cases appears quite adequate. One exception is the study of Reproductive Toxicity, in which under the headings "Doses" and "Control Group" it is stated there are no data. This may be an oversight, but this study cannot be considered acceptable if there are no data for doses and control group. Assuming there are such data, they need to be included in the robust summary. If not, additional studies may be required.

(A final minor point is that in the descriptions of the individual studies we would also like to see the words zinc dibutyldithiocarbamate used under the heading "Test Substance," rather than "as described by 1.1-1.4".)

In summary, with the exception of the study on Reproductive Toxicity mentioned above, this Robust Summary/Test Plan is adequate to meet the requirements of the EPA High Production Volume Challenge.

Thank you for this opportunity to comment.

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