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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Para-Dichlorobenzene - Request for Data Waivers
Submitted by the Chlorobenzene Producers Association

TOX Chem No.: 632
Project No.: 8-0768
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Registrant: Chlorobenzene Producers Association

In response to the comprehensive Data Call-In Notice for data on para-dichlorobenzene (p-DCB), the Chlorobenzene Producers Association on behalf of its member companies (Monsanto Company, PPG Industries, Inc., and Standard Chlorine Chemical Company) is requesting data waivers for a number of studies that were identified as data gaps.

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Toxicology Branch I (TB-I) has reviewed this request and decisions for granting or denying these waivers have been reached on a case-by-case basis as follows:

1. Request for Waiver of Acute Dermal Toxicity Testing in the Rabbit

   TB-I contends that there are adequate data on the acute dermal toxicity of p-DCB in rats* so that additional testing in the rabbit will not be required. Thus, this requirement is being waived.

2. Request for Waiver of Acute Inhalation Toxicity Testing in the Rat

   Based on the fact that the most common route of exposure to p-DCB is by inhalation, TB-I is requesting that the registrant conduct an acute inhalation study in rats using the maximum possible generated p-DCB concentratrations (over 1000 ppm if possible). The highest air concentration of p-DCB, tested by the Registrant in a rat teratology study, was 500 ppm. TB-I has determined that this study did not meet EPA guideline requirements and as such it could not be used to justify waiving the requirement for the acute inhalation toxicity study in rats. Thus, this request is denied.

3. Request for Waiver or Deletion of 90-Day Feeding Toxicity Testing in the Rodent and Nonrodent (Dog)

   TB-I agrees with the registrant that a 90-day feeding study in rodents and nonrodents might not be feasible based on the reported high vapor pressure of p-DCB. Thus, the requirement for these studies is being waived. However, 90-day studies should be conducted instead, via the inhalation route, for a rodent and nonrodent.

4. Request for Waiver of 21-Day Dermal Study in Rabbits and Substitution of Rat Study

   TB-I has no objections to substituting the 21-day dermal study in rabbits with a 21-day dermal study in rats.

* Gaines, T.B. and R.F. Linder (1986). Acute Toxicity of Pesticides in Adult and Weanling Rats. Fundamental and Applied Toxicology, 7, 299-308.

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5. Request for Waiver of 90-day Inhalation Toxicity Testing in the Rat

TB-I believes that a 90-day inhalation study is absolutely required for p-DCB based on the fact that data obtained from such study will eventually be used in setting dose levels for the chronic/onco inhalation study which is also required. Thus, the request for waiving this study is denied.

6. Request for Waiver of Chronic Toxicity Testing in the Rodent and Oncogenicity Testing in the Rat and Mouse

TB-I has no objections to deferring the initiation of the chronic toxicity/oncogenicity inhalation study in rats and the oncogenicity inhalation study in mice for 24 months. Based on the projections of Dr. Alan Wilson, Toxicologist, Monsanto Company, the comprehensive metabolism and pharmacokinetic studies on p-DCB will be completed and available to the Agency for review between October and November 1990 (personal communication). Thus, the Agency will make a final decision as to the requirement of the aforementioned inhalation studies upon evaluation of the metabolism and pharmacokinetic studies (possibly by December 1990).

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