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

AUG 12 1988

OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

Memorandum

Subject: A Tolerance and Oncogenic Risk Assessment Conducted on  
the Dietary Exposure to Chlorothalonil.

To: Lois Rossi, PM# 21  
Registration Division

From: Charles Frick  
Tolerance Assessment Program  
Residue Chemistry Branch, HED

Thru: *for* Karl Arne, Ph.D. *J. Tomasi*  
Branch Senior Scientist  
Residue Chemistry Branch, HED

Action Requested

The Tolerance Assessment Program has been requested to conduct an oncogenic risk assessment from the dietary exposure to the chemical Chlorothalonil using anticipated residue values as determined by the Residue Chemistry Branch and percent of crop treated data generated by Benefits and Use Division (BUD).

## Discussion - Chlorothalonil

The Reference Dose (PADI, RFD) used in the analysis was 0.015 mg/kg/day, based on a NOEL of 1.5 mg/kg/day obtained in a two year feeding study in dogs, with an Uncertainty Factor of 100. This value has been verified by agency reference dose committees. In addition, this compound has been identified as an oncogen by the Toxicology Branch Peer Review Committee. The upper bound potency estimate ( $Q^*$ ) is  $1.1 \times 10^{-2}$  (mg/kg/day) $^{-1}$  (memo. Bernice Fisher, 7/20/87).

The food uses evaluated were tolerances published in CFR.180.275. Percent of crop treated data, provided by BUD (memo. August, 1988) were incorporated into the exposure analysis. Processing and monitoring data were available to RCB to determine Anticipated Residue values (AR) for many food crops. For a detailed outline as to how these AR values were determined, see memorandum, "Anticipated Residue Data for Chlorothalonil" Debra Edwards (RCB) to Charles Frick (TAS) 8/10/88 (attached).

Based on the published tolerance values and published tolerance values factored by percent of crop treated and anticipated residue values, the exposure for the U.S. population was calculated as 0.000071 mg/kg/day, corresponding to 0.5% of the RFD. The percent of the RFD utilized by the TMRC for the 22 population subgroups ranged from a low of 0.1% to a high of 0.7%. For a detailed breakdown by population group see Table 2 in the TAS printout.

Oncogenic risk for the overall U.S. population using percent of crop treated and anticipated residue values was calculated as follows:

$$\text{Exposure} \times Q^* = \text{Risk}$$

$$0.000071 \text{ mg/kg/day} \times 0.011 \text{ (mg/kg/day)}^{-1} = 7.8 \times 10^{-7}$$

Commodity contribution to Chlorothalonil exposure and oncogenic risk to the overall U.S. population has been calculated and compiled by Susan Stanton (TAS) and is attached to this report as Table 3.

Table 1 in the TAS printout lists the foods with published Chlorothalonil tolerances, the food forms, published tolerance values, anticipated residue values (AR), AR statistic type (origin of values) and residue values used in this analysis. As the residue values used in this analysis were often a combination of AR and percent of crop treated, the % crop treated column listing all food items at 100% is a computer function and should be disregarded.

cc. Chlorothalonil R.S., TAS File, K. Arne (RCB) C.Frick (RCB)  
E. Saito (SIPS) C. Pierce (S.R.), PMSD.