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

RCB
3-21-84

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MAR 21 1984

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

TO: Diane Beavers PM # 21
Fungicide/Herbicide Branch
Registration Division TS-767C

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Kovacs
Full petition
RB 3/15/84

THRU: R. Bruce Jaeger, Section Head
Rev. Sec. # 1/Toxicology Branch
Hazard Evaluation Division TS-769C

Subject: PP # 3F2875: Chlorothalonil (CTN) and its 4-OH metabolite in almonds, rice, wheat and meat, milk, poultry and eggs. Petition for tolerances.

Petitioner: SDS Biotech Corp., Painesville OH.(formerly Diamond Shamrock).

Caswell #: 215B.

Tolerances Proposed

Almonds	0.05 ppm
Rice	4.0
Wheat	0.1
Almond Hulls	0.1
Meat	0.1
Milk	0.1
Poultry	0.1
Eggs	0.1

Recommendation:

1. Although data submitted in support of these tolerances contains presumptive evidence that CTN is an animal carcinogen, Toxicology Branch has no objection to establishing the proposed tolerance of 0.05 ppm combined residues in almonds and of 0.1 ppm in the animal feed item, almond hulls. Basis: The Incremental Exposure for almonds is < 1 % of the TMRC.

$$\text{Tolerance} \times \text{Food Factor} \times 1.5 \text{ kg/day} = \text{Incremental Exposure}$$

$$0.05 \text{ mg/kg} \times 0.03 \times 1.5 \text{ kg/day} = 0.000225 \text{ mg/day.}$$

$$\text{TMRC} = 0.01305 \text{ mg/day/1.5 kg.}$$

$$\text{Incr. Exp./TMRC} \times 100 = 0.2 \%$$

This is in accordance with our recommendations in the "Weight of Evidence Review", 1/31/84, D. Ritter.

Almond hulls is not a human food item. Tolerances are co-pending for residues in meat, eggs, poultry and milk. See (2.) below.

2. Those tolerances that are proposed for rice, wheat, meat, eggs, poultry and milk may not be established.

Basis: Unlike almonds, these racs represent major dietary components, with milk comprising more than 50% of the diet of infants and some elderly individuals who are on "bland" diets. Rice also figures prominently in the diet of these persons.

Thus, since toxicity data submitted in support of this petition contained presumptive evidence that CTN is an animal carcinogen, additional significant new tolerances are not appropriate, pending resolution of the oncogenicity question (Ritter, ibid.).

Review of Data

A number of new toxicity studies were submitted in this petition and were reviewed by either myself or Mr. Bruce Jaeger. The reviews are attached.

David L. Ritter 2-21-84
David L. Ritter, Toxicologist
Rev. Sec. # 1/Toxicology Branch
Hazard Evaluation Division TS-769C
H.P. U.S. 3/20/84

3-21-84

Please note that the DER's for this review are on file in the Toxicology Branch files attached to this review.

Sue S. Rathman