MEMORANDUM


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TO: H. Jacoby/R. Forrest, PM Team #21
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SDS Biotech has submitted data "applicable to making risk assessments" of chlorothalonil [tetrachloroisophthalonitrile] on tomatoes. The registrant states that dietary study on cucumbers is in progress. A study entitled "The Fate of Chlorothalonil in the Processing of Peaches" has also been included.

Tolerances for residues of chlorothalonil and its metabolite 4-hydroxy-2,5,6-trichloroisophthalonitrile (compound SDS- or DAC-3701) have been established on various raw agricultural commodities including tomatoes at 5 ppm and peaches at 0.5 ppm [40CFR§180.275].

The chlorothalonil registration standard was issued on September 28, 1984.

Registered Use

The registered uses on field-grown tomatoes allow repeated applications, as needed, at 7- to 10-day intervals at up to 2.25 lbs ai/A/application in states other than California. In California, a maximum of 3 applications at up to 2.25 lbs/A at 10- to 14-day intervals is allowed beginning 5-6 weeks before harvest. No pre-harvest interval (PHI) is specified.

The registered use on greenhouse tomatoes allows 0.28 oz 90% pelleted/tableted formulation per 400 square feet, or 0.7 oz
20% impregnated formulation per 1000 square feet, at weekly intervals with no maximum numbers of application specified. A PHI also is not specified.

Data Gaps

According to the Registration Standard, relevant data gaps include plant metabolism studies and tomato residue data. SDS Biotech submitted a lettuce metabolism study in its March 28, 1985 submission (reviewed by M. Firestone, September 10, 1985) and stated its intention of performing additional root crop and fruiting crop metabolism studies. However, no metabolism study on any plant was submitted. The metabolism of chlorothalonil in/on tomatoes is not understood.

Tomato residue data gaps include trials from Florida at 10 x 2.22 lbs ai/A at 7-day intervals, and greenhouse tests as directed on the label. The presence and amount of HCB (hexachlorobenzene) and PCBN (pentachlorobenzonitrile) in/on tomatoes need also be addressed.

The registrant submitted 4 tomato field trials, 2 each in Florida and California. Samples (4-6 whole tomatoes per sample) were collected for field residues 1 day after the last application, of tomatoes leaving packinghouse, and of ripe tomatoes that were given to restaurant or grocery personnel. Tomatoes with 1-day PHI went through the packing house and subsequent shipping (frozen) took approximately 2 weeks to Boston area and 1 week to Freehold, NJ area for the Florida tomatoes, and approximately 2 weeks to San Diego and Fresno areas for the California tomatoes.

Florida tomatoes received either 3 x 1.04 lbs ai/A (at ca weekly intervals) or a total of 6.69 lbs ai/A resulting from 15 applications ranging from 0.17 to 1.48 lbs ai/A/application and with intervals varying from 2 days to ca 2 weeks. Those tomatoes grown in California received 2 x 2.09 lbs ai/A at a ca weekly interval.

Tomatoes that went through the packing house were generally washed initially with 125-150 ppm (aqueous) chlorine solution for 1.5-2 minutes at 100 °F, followed by clean water, then air or brush dried, and waxed with ortho-phenylphenol. Culls were removed along the way. Tomatoes from California were also treated with 125-180 ppm ethylene for 3-5 days prior to sampling.

Tomatoes sampled at restaurant or grocery store were either as received, or (un)washed, and decored/sliced/diced, or culled.

Samples were shipped frozen and kept frozen until GC/EC analysis. Samples were homogenized in acetone containing sulfuric acid and vacuum-filtered. The filtrate was diluted to a fixed volume with acetone and an aliquot was removed. To the aliquot was added paraffin oil/petroleum ether, evaporation of acetone, added sodium bicarbonate, and adjusted to pH 4.5. The residue
was extracted into petroleum ether, concentrated, cleaned up on Florisil column before analysis of chlorothalonil only on GC/EC. The procedure could detect 0.01 ppm of a "standard solution" of chlorothalonil. Recovery values (fortification values) were: 77% (0.031 ppm), 84% (0.049 ppm), 74-105% (0.099-0.52 ppm), 76-87% (1 and 2.2 ppm), and 74% (4.94 ppm). Tomatoes used in the recovery study were local (from Painesville, OH?).

Residues of chlorothalonil on tomatoes ranged from <0.01-0.03 ppm in restaurant or grocery store, to <0.01-0.07 ppm in packing house, and to 0.12-2.39 ppm in the field (raw agricultural commodity). The presence and amount of HCB and PCBN were not addressed.

The submitted residue data on tomatoes (raw agricultural commodity) are not acceptable for several reasons: the metabolite was not included in the residue results; the application rates were not high enough (should be 2.22 lbs ai/A/application) and except for one trial, the application frequency was not high enough (should be 10 applications); and the question of HCB and PCBN was not addressed.

No residue data resulting from greenhouse treatments were included.

Printouts in the submitted chromatograms are not legible.

The registrant has included a statistician report on the determination of potential dietary exposure to chlorothalonil from treated tomatoes. We defer comments on this report until adequate residue data on tomatoes are received.

As directed by the PM, we will not review the processing data submitted on peaches.

CONCLUSIONS AND RECOMMENDATION

1. No metabolism study on any plant was submitted as was indicated in SDS-Biotech's submission dated March 28, 1985. The metabolism of chlorothalonil in/on tomatoes is not understood.

2. The submitted residue data on tomatoes are not acceptable for several reasons: the metabolite 4-hydroxy-2,5,6-trichloroisophthalonitrile (compound DAC- or SDS-3701) was not included in the residue results; the application rates were not high enough (should be 2.22 lbs ai/A/application) and except for one trial, applications were not frequent enough (should be at least 10 applications); and the question of HCB and PCBN was not addressed.

3. No residue data reflecting greenhouse treatment on tomatoes were submitted.
The metabolism and residue data gaps on tomatoes regarding chlorothalonil registration standard remain outstanding.

We recommend SDS Biotech be informed of the above conclusions.

cc: Circ, SF, RF, Reg Std F (Boodee), Cheng, PMSD/ISB
RDI: EZager: 2/2/87; RDSchmitt: 2/2/87