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DEC -7 1982

MEMORANDUM

TO: Donald Stubbs
Product Manager No. 41
Registration Division (TS-767)

SUBJECT: Bayleton Section 18 for Tomatoes in
California PP No. 83-CA-06

On November 19, 1982 Toxicology Branch sent a memo to you and EFB containing their review of this section 18. Tox deferred to us for concurrence on their worker exposure assessments. We therefore make the following comments on this exposure analysis:

- 1) The benomyl exposure model used as a surrogate (Final Exposure Analysis for Benomyl; H. R. Day, November 28, 1978) is acceptable in this case. Note that no actual benomyl exposure data were used in the benomyl exposure analysis.
- 2) The assumptions and calculations appear reasonable and accurate.
- 3) EFB makes no comment on the dermal penetration values chosen since this matter is under the aegis of Toxicology Branch.

David J. Severn, Ph.D., Chief
Environmental Fate Branch
Hazard Evaluation Division (TS-769)

TS:769:JReinert:rmk:rm:815:X77347:12-6-82



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

E. D.
BAYLETON FILE

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM NOV 19 1982

TO: Donald Stubbs
Product Manager, No. 41
Registration Division (TS-769)
and
Environmental Fate Branch ✓

THRU: Christine F. Chaisson, Ph.D. *C.F. Chaisson*
Toxicology Branch
Hazard Evaluation Division (TS-769)

SUBJECT: Section 18; Emergency Exemption for the Use of Bayleton
on Tomatoes in California. PP No. 83 - CA - 06,
Caswell No. 862 AA.

Petitioner: State of California
Department of Food and Agriculture

Recommendations:

1. Toxicology Branch recommends the implementation of Section 18 of FIFRA as requested by the petitioner for the use of Bayleton 50% WP on fresh market tomatoes.
2. The proposed use allows adequate margins of safety for dietary exposure based on single serving and for worker exposure.
3. Since worker exposure estimates were not available to us at this time, figures from benomyl worker exposure were used for the purpose of risk assessment, therefore, we defer to the EFB for worker exposure analysis and concurrence.

Background Information:

The California Department of Food and Agriculture requests a specific exemption to use Bayleton 50% WP on fresh market tomatoes pursuant to Section 18 of FIFRA for the control of powdery mildew. This request is made for all fresh market growing areas statewide. According to the petitioner, the current producing acreage is approximately 30,000 acres in California.

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Sulfur is an alternative material for the control of powdery mildew, but only used as a preventive pesticide and will not control the disease once infection has occurred.

Bayleton 50% WP will be used at the rate of 2-5 ounces product per 20 gallons of water per acre, using ground sprayers. Up to 8 applications at 10 to 21 day intervals will be used. Pre-harvest intervals is 24 hours. The emergency exemption is requested for the period of October 21, 1982 thru October 21, 1983.

Risk Assessment:

Bayleton is teratogenic in rats (cleft palates) with a NOEL of 50 mg/kg/day for embryonic/fetal development, and 10 mg/kg/day for maternal toxicity. This fact implies that any current or future regulatory decision should be based on a complete exposure profile. This includes; exposure due to dietary ingestion of this pesticide (dietary exposure) as well as other types of exposures associated with the use of this chemical (worker exposure). The risk can be best expressed in this case by the margin of safety (MOS) which can be calculated as follows:

$$\text{MOS} = \frac{\text{NOEL (mg/kg)}}{\text{Exposure (mg/kg)}}$$

Personal communication with Ed Zager (RCB) on November 16, 1982 indicated that the expected residue as a result of this use would be 2 ppm. If we assume the worst case, a pregnant woman may consume about 100 gm of tomatoes in a single serving. This constitute 200 ug (0.2 mg) of bayleton/60 kg person or 0.0033 mg/kg. On this bases the margin of safety for dietary exposure can be calculated as follows:

$$\text{MOS terata (dietary)} = \frac{50 \text{ mg/kg}}{0.0033 \text{ mg/kg}} = 15151$$

$$\text{MOS mat. tox. (dietary)} = \frac{10 \text{ mg/kg}}{0.0033 \text{ mg/kg}} = 3030$$

Since no worker exposure analysis for this use is available at this time, and since worker exposure to any pesticide is more likely related to the kind of formulation than to specific physical and/or chemical properties of the active ingredient, therefor worker exposure data of the 50% WP Benomyl may resemble the exposure profile for Bayleton (50 WP). With the assumption that all agricultural practices for the two chemicals are the same, the following data may be applicable to Bayleton:

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Benomyl 50% W.P.:

Oz/acre 6-12 ² 4-8

Dermal exposure (X0.05) 0.002 mg/kg/hr.

Inhalation exposure (X1.0) 0.0003 mg/kg/hr ⁷

Bayleton 50% WP:

The exposure profile for Bayleton may be considered as follows:

Oz/acre 2-5

Dermal exposure (X0.10) 0.002 mg/kg/hr.

Inhalation exposure (X1.0) 0.0003 mg/kg/hr.

Dietary exposure 0.0033 mg/kg/day

Total body dose assuming 7-hours work day and including the dietary ingested pesticide

= dermal exp. + inhal. exp. + dietary exp.

= 0.0140 + 0.0021 + 0.0033

= 0.0194 mg/kg/day

MOS (terata) = $\frac{50 \text{ mg/kg}}{0.0194 \text{ mg/kg}}$ = 2577

MOS (mat. tox.) = $\frac{10 \text{ mg/kg}}{0.0194 \text{ mg/kg}}$ = 515

George Z. Ghali, Ph.D. G. Ghali 11/18/82
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