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Init. [signature]

To: Product Manager 21 (Henry Jacoby)
Registration Division (TS-767)

From: Carolyn Offutt [signature]
Head, Modeling and Guidelines Section
Environmental Fate Branch, HED (TS-769)

Attached please find the environmental fate review of:

Reg./File No.: 2F2704 and 3125-320

Chemical: Bayleton

Type Product: Fungicide

Product name: BAYLETON 50-WP

Company name: Mobay

Submission Purposes: Petition to remove label restriction for women of child bearing age supported by human exposure studies for mixers, loaders, and applicators

Code: Other — Action Code 233 and 331

Date In: 10/3/82 — EFB #: 2 and 3

Date Completed: 12/9/82 — TAIS (Level II) 62 — Days 8

Referrals To:

Ecological Effects Branch

Residue Chemistry Branch

Toxicology Branch

REVIEW OF BAYLETON MIXER/LOADER/APPLICATOR EXPOSURE DATA

ACCESION NUMBERS 070826 AND 07828

Intoduction:

Mobay contends that a "precautionary statement regarding 'women of childbearing age' is not necessary" for Bayleton. As support for their contention, Mobay has asked for a review of an exposure study performed in California by UC, Berkeley, (UCB) staff. This report is a review of that study and Mobay's analysis of the data from that study.

Review of the test procedures and data:

The procedures used by UCB are adequate and appropriate for assessment of exposure during mixing and loading of non-packaged Bayleton 50-WP. The procedures used to assess exposure to Bayleton 50-WP during application to vineyards are also adequate and appropriate.

The results of the sudies show that maximum exposure to workers occurs during mixing and loading and that the area most exposed is the hands. The data also show that cotton coveralls reduce exposure to the covered body by at least 90 percent.

Urinary excretion of Bayleton residues were monitored as part of this study, but the procedures used do not necessarily support their conclusion that only about 2 percent of the dermal dosage of Bayleton penetrates through worker skin. Toxicology Branch should review this part of the data since it affects the margin of safety (MOS).

The total dermal dosage rates, considering the protection afforded by cotton coveralls, for three workers were 10.08, 16.061, and 7.726 mg/hr. UCB averaged these values, divided the mean by 70 Kg, and multiplied by 8 hours to give an eight hour daily dose as 1.23 mg/Kg/day. I do not agree with their calculations. First, the mean of 10.08, 16.061, and 7.726 is 11.29 and not 10.8 as they claim. Second, for calculations of this type, either the highest value obtained or the mean plus a standard deviation should be used. Third, a 60-Kg body weight would be more appropriate for these calculations than the 70 Kg-weight they used since the toxic responses (teratotoxicity and fetotoxicity) being considered are specific for women and 60 Kg (132 lbs) is a more common weight for women than 70 Kg (154 lbs). Assuming 16.1 mg/hr exposure rate, a 60-Kg female worker, and an eight hour day, the exposure is 1.15 mg/Kg/day rather than 1.23.

Conclusions and Recomendations:

This data should be referred to Toxicology Branch for analysis of the margins of safety with respect to fetotoxicity and teratotoxicity. The Environmental Fate Branch recommends that the margins of safety should be calculated using exposure to 60-Kg women mixers/loaders of 2.15 mg/Kg/8-hr. Toxicology Branch should also be made aware of the dermal penetration aspects of this study.

James D. Adams

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