4-13-93

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

APR 13 1993

SUBJECT: REVIEW OF EXPOSURE DATA SUBMITTED IN SUPPORT OF THE EXPERIMENTAL USE OF COMPLY 25WP (FENOXYCARB) ON PEARS

FROM: Arthur O. Schlosser, Chemist Arthur O. Schlosser

TO: Richard Mountfort, Product Manager 10
Insecticide-Rodenticide Branch
Registration Division (H7505C)

THRU: Mark Dow Ph.D., Section Head Mark Dow
Special Review and Registration Section II

Larry Dorsey, Chief Mark Dow for
Occupational and Residential Exposure Branch
Health Effects Division (H7509C)

Please find below the OREB review of:

DP Barcode: D188208

Pesticide Chemical Code: 125301

EPA Reg. No.: 100-EUP-OU

EPA MRID No.: 426042-02

Review Time: 3 days

PHED: YES

Printed on Recycled Paper

I. INTRODUCTION: Registration Division (RD) has requested that OREB review exposure estimates submitted by Ciba-Geigy in support of the experimental use of the insect growth regulator, Comply (fenoxycarb), on pears.

A. Background: Comply 25 WP was formally named Tactic. Use directions are for two applications per year at 2 oz. active ingredient per acre per application using an airblast sprayer. In a letter from the registrant (February 12, 1993) the following label revisions were proposed: (1) Revised reentry statement, "Do not enter treated area without protective clothing, including a long-sleeved shirt, long pants and rubber gloves, until sprays have dried". (2) Addition of the statement, "Wear protective clothing, including a long-sleeved shirt, long pants and rubber gloves, when handling this product". For the EUP the product will be packaged in water soluble bags.

Maternal toxicity and carcinogenicity are the health effect concerns identified in a previous Section 18 OREB review (D-186143, 11 Jan 1993).

B. Purpose: Review of exposure assessment based on the Pesticide Handlers Exposure Database (PHED) submitted in support of the experimental use of fenoxycarb on pears.

II. DETAILED CONSIDERATION: The registrant has proposed mixer/loader and applicator exposure estimates using the Pesticide Handlers Exposure Data Base (PHED). For the mixer/loader the registrant used subsets for wettable powder, outdoor, open pour and excluded water soluble packets. The exposure scenario was for protective overalls over no clothing and gloves. Dermal and inhalation exposures of 243 µg/lb. a.i. and 55 µg/lb. a.i. were estimated. Similar subsetting for long-sleeve shirt, long pants and gloves gave a total exposure of 4.3 mg/lb a.i. (This may be an anomaly because of unusually high indicated exposures for three covered body parts with only two replications each.) Long-sleeve shirt, long pants and gloves are recommended on the label for mixing and loading. An OREB run with PHED indicated dermal exposure (total-no clothing or gloves) of 23 µg/lb. a.i. for a mixer/loader using water soluble bags (based on six replications). Considering the use of water soluble packets for this EUP, the dermal and inhalation exposures used by the registrant are probably in a reasonable range.

For the applicator the registrant proposed subsets for airblast and open cab, excluding grapes as a treated crop. Exposure was for long sleeves, long pants and no gloves. Dermal and inhalation exposures of 195 µg/lb. a.i. and 5.1 µg/lb. a.i. were indicated. This is acceptable for purposes of this experimental use permit.

III CONCLUSIONS/RECOMMENDATIONS: OREB accepts the basic unit exposure estimates proposed for the support of the Experimental Use of fenoxycarb on pears. Calculated combined mixer/loader/applicator (M/L/A) exposures are given below:

Combined Mixer/loader and Applicator Exposures

Small Grower-15 acre orchard

M/L/A Daily dermal exposure = 12 µg/kg/day.
M/L/A Daily inhalation exposure = 1.6 µg/kg/day

M/L/A Yearly dermal exposure = 23 µg/kg/year.
M/L/A Yearly inhalation exposure = 3.2 µg/kg/year.

M/L/A Average Daily dermal exposure = 0.064 µg/kg/day.
M/L/A Average Daily inhalation exposure = 0.0087 µg/kg/day

Commercial Grower-100 acre orchard

M/L/A Daily dermal exposure = 12 µg/kg/day.
M/L/A Daily inhalation exposure = 1.6 µg/kg/day

M/L/A Yearly dermal exposure = 160 µg/kg/year.
M/L/A Yearly inhalation exposure = 21 µg/kg/year.

M/L/A Average Daily dermal exposure = 0.43 µg/kg/day.
M/L/A Average Daily inhalation exposure = 0.06 µg/kg/day

The registrant should be advised that none of the unit exposures generated by the use of the Pesticide Handlers Data Base (PHED) and proposed for this EUP would be acceptable to support the Section 3 registration of fenoxycarb on pears. A minimum of 15 replications of A or B graded data for each body part is required. Hand rinse data graded "C" are also acceptable.

To support registration, data developed according to Pesticide Assessment Guidelines Subdivision U-Applicator Exposure Monitoring are required. If field studies are conducted, a protocol must be submitted to OREB for review and approval before work is begun. Also for registration, the registrant should discuss the potential for postapplication exposure from the use on pears. If significant post application exposure from fenoxycarb use on pears can be expected, data developed according to Pesticide Guidelines Subdivision K-Reentry Protection will also be required.

APPENDIX

Assumptions
Small grower has 15 acres in pears.
Commercial grower has 100 acres in pears.
Application rate is 2.0 oz. a.i. per acre (0.125 lb a.i./acre).
Two treatments per acre per year are applied.
A worker can treat 15 acres per day.
Worker weighs 70 Kg.

Daily Exposure
Daily dermal exposure to mixer/loader = 15 acres treated/day x 0.125 lbs a.i./acre x 243 µg/lb a.i. ÷ 70 kgBw = 6.5 µg/kg/day.

Daily inhalation exposure to mixer/loader = 15 acres treated/day x 0.125 lbs a.i./acre x 55 µg/lb a.i. ÷ 70 kgBw = 1.5 µg/kg/day.

Daily dermal exposure to applicator = 15 acres treated/day x 0.125 lbs a.i./acre x 195 µg/lb a.i. ÷ 70 kgBw = 5.2 µg/kg/day.

Daily inhalation exposure to applicator = 15 acres treated/day x 0.125 lbs a.i./acre x 5.1 µg/lb a.i. ÷ 70 kgBw = 0.14 µg/kg/day.

Yearly Exposure-Small Grower
Yearly dermal exposure to mixer/loader = 15 acres treated/day x 0.125 lbs a.i./acre x 243 µg/lb a.i. x 2 applications/year ÷ 70 kgBw = 13 µg/kg/year.

Average daily dermal exposure = 13 µg/kg/year ÷ 365 days/yr = 0.036 µg/kg/day

Yearly inhalation exposure to mixer/loader = 15 acres treated/day x 0.125 lbs a.i./acre x 55 µg/lb a.i. x 2 applications/year ÷ 70 kgBw = 2.9 µg/kg/year.

Average daily inhalation exposure = 2.9 µg/kg/year ÷ 365 days/yr = 0.008 µg/kg/day

Yearly dermal exposure to applicator = 15 acres treated/day x 0.125 lbs a.i./acre x 195 µg/lb a.i. x 2 applications/year ÷ 70 kgBw = 10 µg/kg/year.

Average daily dermal exposure = 10 µg/kg/year ÷ 365 days/yr = 0.028 µg/kg/day

Yearly inhalation exposure to applicator = 15 acres treated/day x 0.125 lbs a.i./acre x 5.1 µg/lb a.i. x 2 application/year ÷ 70 kgBw = 0.27 µg/kg/year.

Average daily inhalation exposure = 0.27 µg/kg/year ÷ 365 days/yr = 0.0007 µg/kg/day

Yearly Exposure-Commercial Grower

Yearly dermal exposure to mixer/loader = 100 acres treated x 0.125 lbs a.i./acre x 243 µg/lb a.i. x 2 applications/year ÷ 70 kgBw = 87 µg/kg/year.

Average daily dermal exposure = 87 µg/kg/year ÷ 365 days/yr = 0.24 µg/kg/day

Yearly inhalation exposure to mixer/loader = 100 acres treated x 0.125 lbs a.i./acre x 55 µg/lb a.i. x 2 application ÷ 70 kgBw = 19 µg/kg/year.

Average daily inhalation exposure = 19 µg/kg/year ÷ 365 days/yr = 0.054 µg/kg/day

Yearly dermal exposure to applicator = 100 acres treated x 0.125 lbs a.i./acre x 195 µg/lb a.i. x 2 applications/year ÷ 70 kgBw = 70 µg/kg/year.

Average daily dermal exposure = 70 µg/kg/year ÷ 365 days/yr = 0.19 µg/kg/day

Yearly inhalation exposure to applicator = 100 acres treated x 0.125 lbs a.i./acre x 5.1 µg/lb x 2 application/year ÷ 70 kgBw = 1.8 µg/kg/year.

Average daily inhalation exposure = 19 µg/kg/year ÷ 365 days/yr = 0.005 µg/kg/day

Combined Mixer/loader and Applicator Exposures

Small Grower

M/L/A Daily dermal exposure = 12 μg/kg/day.

M/L/A Daily inhalation exposure = 1.6 μg/kg/day

M/L/A Yearly dermal exposure = 23 μg/kg/year.

M/L/A Yearly inhalation exposure = 3.2 μg/kg/year.

M/L/A Average Daily dermal exposure = 0.064 μg/kg/day.

M/L/A Average Daily inhalation exposure = 0.0087 μg/kg/day

Commercial Grower

M/L/A Daily dermal exposure = 12 μg/kg/day.

M/L/A Daily inhalation exposure = 1.6 μg/kg/day

M/L/A Yearly dermal exposure = 160 μg/kg/year.

M/L/A Yearly inhalation exposure = 21 μg/kg/year.

M/L/A Average Daily dermal exposure = 0.43 μg/kg/day.

M/L/A Average Daily inhalation exposure = 0.06 μg/kg/day

One Attachment (to addressee only)
cc: A. Schlosser/OREB
Correspondence File
Chemical file/Fenoxycarb