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

SEP 23 1992

SEP 23 1992

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM:

SUBJECT: Anticipated Residues of Avermectin in/on Orange Juice, Orange Pulp and Milk (Section 3 Use); and Fresh-Market Apples (EUP) to be Used in Acute Dietary Risk Assessment

FROM: Debra Edwards, Ph.D., Acting Chief
Chemistry Branch I - Tolerance Support
Health Effects Division (H7509C)

Debra Edwards
9/23/92

TO: James Kariya, Head
DRES Section
Science Analysis Branch
Health Effects Division (H7509C)

and

Karen Whitby, Acting Chief
Special Review Section
Chemical Coordination Branch (H7509C)

RD has requested that CBTS provide anticipated residue data to be used in acute dietary risk assessment for avermectin in support of a 1992/93 request for extension of a temporary tolerance and EUP for Use of Avermectin on apples (PP#1G3930/EUP-618). Because the petitioner hopes to use the product to generate efficacy data on 150 acres of this year's apple crop, a rapid response has been requested (personal communication with Adam Heyward/RD/9/23/92). DRES analyses generated by CBTS in support of recent Section 18 requests indicate that the food commodities posing the most significant acute exposure are oranges, apples and milk. Therefore, this memorandum will provide anticipated residues for these items.

Oranges

The established tolerance for residues of avermectin in or on oranges is 0.02 ppm. Frank Boyd, in a previous anticipated residue assessment for chronic exposure dated 6/29/89, cites a reduction factor on processing whole oranges to juice of 0.5x. A citrus metabolism study reviewed by L. Cheng (12/19/85) in conjunction with PP#5G3287/5H5474 indicated that residues in orange pulp will be <10% those in whole fruit even up to 12 weeks after application. The Chemistry Branches Cultural Practices File for oranges indicates that the weight percentage of orange peel relative to whole oranges is 16-24. [Our calculations will assume 25% of the orange weight is peel and 75% is pulp because we are interested in predicting the maximum potential level in pulp.] Thus, the following anticipated residues for acute exposure to avermectin residues in orange juice and pulp can be calculated:

Juice: 0.02 ppm x 0.5 = 0.01 ppm

Pulp: (0.02 ppm x 0.1)/0.75 = 0.003 ppm

Milk

The established tolerance for residues of avermectin in milk is 0.005 ppm. The established tolerance for the livestock feed item, dried citrus pulp, is 0.1 ppm. However, since the highest concentration factor reported was 4x (F. Boyd, 6/29/89), a citrus pulp value of 0.08 ppm will be used in calculating the diet for dairy animals. Since the apples harvested during the EUP are to be marketed for fresh market only, potential residues in the livestock feed, apple pomace, will not be addressed. Based on a diet consisting of 20% cottonseed (tolerance = 0.005 ppm), 15% cottonseed meal, 5% cottonseed hulls, 33% citrus pulp, and 27% corn (no avermectin use), the maximum avermectin residues expected in the livestock diet will be 28 ppb. In an avermectin feeding study submitted in conjunction with PP#7G3468, residues in milk were $\leq$ 1 ppb at the 30 ppb feeding level. No residues were detected in milk at the 10 ppb feeding level. Therefore, CBTS recommends that an anticipated residue value of 1 ppb (0.001 ppm) in milk be used in acute dietary exposure assessments for avermectin. If use on additional feed items is registered at a later time, this value may require revision.

Apples

Based on data submitted for pears in PP#9F3787, CBTS recently recommended for extension of the established temporary tolerance for residues of avermectin on apples at a level of 0.05 ppm. However, this value is based on samples harvested at a 14-day posttreatment interval and the requested use on

apples specifies a 30-day PHI. Seven of the submitted pear residue trials, including trials conducted in the major production areas of California and the Pacific Northwest, included analyses at 0, 3, 7 and 14 days after harvest. Applications were made at the 1 and 2x rate (1x rate = 0.025 lb ai/A). Although four applications were made at 30-day intervals, the proposed use allows only two applications/season. Four of the trials included both concentrate (40 gals/A) sprays and higher volume sprays (250-400 gal/A) while three of the trials included only the more dilute sprays. At each rate/spray volume/posttreatment interval combination, four composite samples were collected and analyzed.

In order to predict the highest value likely to occur 30 days after the final treatment, the highest sample value from each rate/spray volume/posttreatment interval combination was entered into a regression analysis program. The 2x rate values were extrapolated to the 1x rate by dividing by 2. The B1b isomer was often nondetectable (<2 ppb) or not quantitated (2 - 5 ppb); these were added to the B1a/delta 8,9 values at 2 and 5 ppb, respectively. The total number of values entered was 110. These values indicated a loss/day of 5.4% with a predicted value at 28 days of 5 ppb with an upper 95% confidence limit of 12 ppb. For acute exposure assessment, CBTS would usually not recommend use of a 95% confidence limit value but the highest value reported that reflects the proposed use. However, in this case, a value must be predicted based on the existing reside decline data. Therefore, CBTS recommends that an anticipated residue value of 15 ppb (0.015 ppm) in or on apples be used in acute dietary exposure assessments for avermectin.

Note: The values reported here for oranges and apples represent composite samples rather than individual commodities or serving sizes. Thus, the assumption is made that there is no significant variability in concentration of residues between individual components of each composite. This assumption is not based on data, but on current policy which may change as we develop policies and guidelines for assessment of dietary risk from acutely toxic pesticides.

cc: SF, PP#9F3787, PP#1G3930, RF, Circu