



CASWELL FILE

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

AUG 2 1989

OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Avermectin (Also Called Abamectin) - AGRI-MEK 0.15  
EC - PP#8F3592, FAP#8H5550 - Avermectin in/on  
Citrus - Submission of Revised Section F

Caswell No.: 63AB  
Project No.: 9-1652A  
Record No.: 247264

FROM: William Dykstra, Reviewer *William Dykstra 7/20/89*  
Review Section I  
Toxicology Branch I - Insecticide, Rodenticide Support  
Health Effects Division (H7509C)

TO: George T. LaRocca, PM 15  
Insecticide-Rodenticide Branch  
Registration Division (H7505C)

THRU: Robert Zendzian, Acting Section Head *7/15/89*  
Review Section I *7/28/89*  
Toxicology Branch I - Insecticide, Rodenticide Support  
Health Effects Division (H7509C)

Requested Action

Review revised Section F for tolerances of avermectin  
and its delta-8,9-isomers on citrus.

Conclusion and Recommendation

Toxicology Branch does not object to the revised Section  
F. The revised Section F can be toxicologically supported.

1

Review

1. No new toxicity data were submitted.
2. Revised Section F:

Section F - Proposed Permanent Tolerances

Based on the residue data reported in this petition, where:

- a. Three (3) treatments at 60-day intervals of up to 0.025 pounds abamectin active ingredient per acre are applied to citrus during the growing season, and
- b. Citrus fruit are harvested 7 days after the last treatment.

The petitioner requests amending 40 CFR Part 180 pursuant to section 408 (j) of the Federal Food, Drug, and Cosmetic Act (FFDCA) by proposing the following permanent tolerances of abamectin including its delta 8,9-isomer:

<u>Commodities</u>	<u>Tolerances</u>
Citrus whole fruit (RAC)	0.020 ppm
Cattle - meat and meat byproducts	0.020 ppm
- milk	0.005 ppm

The petitioner also requests an amendment to 21 CFR pursuant to FFDCA section 409 by proposing the following permanent food and/or animal feed additive tolerances for the combined residues of abamectin and its delta 8,9-isomer:

<u>Commodities</u>	<u>Tolerances</u>
Dried citrus pulp	0.10 ppm
Citrus oil	0.10 ppm

2

NOTE TO: George LaRocca, PM 15

SUBJECT: Corrections to the Avermectin TAS Analysis of 7/6/89

FROM: J. R. Tomerlin

*JP / Avermectin 7/7/89*

I provided a TAS analysis for proposed avermectin tolerances on citrus dated 7/6/89. This analysis contained two errors which should be corrected. First, the RfD used in the chronic analysis is 0.0004 mg/kg body weight/day, not 0.004 mg/kg/day as indicated in the memorandum.

Secondly, the acute analysis I reported used the wrong study. The NOEL for the acute exposure analysis is in fact 0.06 mg/kg body weight from a mouse teratology study, not 0.12 mg/kg body weigh from the 2 generation mouse reproduction study. I misunderstood Bill Dykstra earlier and thought he said that the NOEL from the rat study was appropriate for the acute analysis, which is not what he told me.

The change in the acute NOEL changes the Margins of Safety I reported. The average MOS reported on page 3 of my 7/6/89 memo should be 1580, not 3160. The minimum MOS using tolerances is 125, not 250; and the minimum MOS using anticipated residues is 250, not 500.

I will correct the draft FR notice to be consistent with the proper NOELs that were used in the analysis.

cc: TAS, DEB, Caswell #063AB, Dykstra (TOX-IRSB)