4-7-89 RF.

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

APR 7 1989

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: 89-CA-16. Section 18 Specific Exemption. Triadimefon (Bayleton) on Tomatoes (Fresh Market and Processing). No MRID #. DEB # 5106.

FROM: Leung Cheng, Chemist
Special Registration Section II
Dietary Exposure Branch
Health Effects Division (H7509C)

THRU: Francis Suhre, Acting Section Head
Dietary Exposure Branch
Health Effects Division (H7509C)

TO: D. Stubbs/L. Pemberton, PM Team 41
Emergency Response and Minor Use Section
Registration Support Branch
Registration Division (H7507C)

and

Toxicology Branch
Health Effects Division (TS-H7509C)

The California Department of Food and Agriculture has requested a reissuance of a Section 18 specific exemption for the use of the fungicide Bayleton on tomatoes. The active ingredient is 1-(4-chlorophenoxy)-3,3-dimethyl-1-(1H-1,2,4-triazol-yl)-2-butanone or triadimefon.

DEB had no objections to a similar request made in 1985 (85-CA-06, W. Anthony, 3/1/85). DEB concluded that levels of triadimefon and its metabolites in or on tomatoes (fresh and processed) would not exceed 2 ppm resulting from the proposed use.

The proposed use would allow applications of 1-2.5 oz ai/A in 20 or more gallons of water by ground or aerial equipment. A maximum of eight applications would be allowed. Applications would be made at 10-21 day intervals. A PHI of 1 day would be in effect.

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Tolerances for residues of triadimefon and its metabolites containing chlorophenoxy and triazole moieties have been established on a variety of commodities at levels ranging from 0.04 ppm to 145 ppm including milk, eggs, meat, fat and meat by-products of hogs and poultry at 0.04 ppm, and the meat, fat and meat byproducts of cattle, goats, horses and sheep at 1 ppm [40 CFR 180.410]. Food and feed additive tolerances have also been established on milled fractions (except flour) of barley and wheat at 4 ppm, grape pomace at 3 ppm, apple pomace at 4 ppm, and raisin waste at 7 ppm [21 CFR 193.83 and 561.93].

No Registration Standard has been done on triadimefon. The first review in connection with petition #4F3148 proposing permanent tolerances for residues of triadimefon and its metabolites in or on tomatoes at 0.2 ppm, tomato catsup and tomato paste at 1 ppm, and dry tomato pomace at 4 ppm was completed 2/14/85 (M. Firestone). The use pattern was identical to that proposed in this Section 18 request except the maximum dosage was 10 oz ai/A per season and a 0-day PHI. This petition is currently in reject status due to several deficiencies including the lack of storage stability data for metabolites KWG 1321 (1,3-diol) and KWG 1323 (hydroxylated triadimefon) and the inadequacy of the proposed food/feed tolerances (memo of S. Willett, 12/6/88).

M. Firestone's 2/14/85 review concluded that the nature of triadimefon in plants (tomatoes) and animals is adequately understood. The residues of concern consist of the parent compound and its metabolites containing the chlorophenoxy and triazole moieties.

No residue data were submitted with this Section 18 re-issuance request.

Tomato residue data were submitted in PP4F3148. The tomatoes were treated with 4 or 5 applications at 2.5 oz ai/A from major tomato growing areas. Tomatoes were analyzed for the parent compound and its metabolites. At 1-day PHI the combined residues ranged from <0.01 to 0.17 ppm. Controls had <0.01 ppm residues.

Tomatoes containing 0.09 ppm combined residues were processed. Results showed combined residues of 0.05 ppm in juice, 0.22 ppm in catsup, 0.07 ppm in puree, 0.17 ppm in paste, 0.32 ppm in wet pomace, and 1.31 ppm in dry pomace.

On the basis of the above data, DEB concludes that the combined residues of triadimefon are not likely to exceed 0.5 ppm in or on tomatoes, 1 ppm in catsup and paste, 2 ppm in wet pomace, and 7 ppm in dry pomace.

Dry pomace may be fed to cattle up to 25% of their diet and wet pomace may be fed to poultry up to 3% of their diet, equivalent to a 1.8 ppm and 0.06 ppm dietary burden, respectively.

Cattle and poultry feeding studies were performed to determine the effect of feeding a 1:1 mixture of the parent and its metabolite KWG519 (Baytan). Combined residues (parent and its metabolites) were analyzed. Total residues in cattle tissues at the 25 ppm feeding level were: kidney, 0.412 ppm; liver, 0.093 ppm; fat, 0.024 ppm; muscle, <0.01 ppm; and milk, 0.004-0.014 ppm (PP2F2665). When laying hens were fed at the 10 ppm and 25 ppm level, the maximum residues found in liver were 0.045 ppm and 0.085 ppm, and in eggs were 0.031 ppm and 0.071 ppm, respectively.

Based on these feeding studies, DEB concludes that the established meat and milk tolerances would not be exceeded as a result of this Section 18 proposed use.

Methods I and II, as described in Pesticide Analytical Manual, are adequate for enforcement purposes.

CONCLUSIONS

1. The nature of triadimefon in tomatoes and animals is adequately understood. The residues of concern consist of the parent compound and its metabolites containing the chlorophenoxy and triazole moieties.

2. The combined residues of triadimefon and its metabolites are not likely to exceed 0.5 ppm in or on tomatoes, 1 ppm in or on catsup and tomato paste, and 7 ppm in or on dry tomato pomace as a result of this Section 18 proposed use.

3. DEB concludes that the established meat and milk tolerances would not be exceeded as a result of the proposed use.

4. Methods I and II, as described in Pesticide Analytical Manual, are adequate for enforcement purposes.

5. Reference standards of triadimefon are available from the Pesticides and Industrial Chemicals Repository at RTP, NC.

RECOMMENDATION

TOX considerations permitting, DEB has no objections to the reissuance of this Section 18 exemption. An agreement should be made with FDA regarding the legal status of the treated tomatoes and tomato byproducts in commerce.

cc:Circ, RF, Section 18 F, Stanton (SACB), Cheng, Schmitt (DEB Acting Chief), PMSD/ISB
RDI:FSuhre:4/5/89:EZager:4/6/89
TS-H7509:DEB:CM#2:Rm810:Cheng:4/3/89:1:4/7/89