



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

AUG 19 1987

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Reg.#10163-78
[RCB:#2215]
[MRID: #40167201]

Azinphos-methyl [Guthion®]:
Amended Registration on
Almonds in California only;
New residue Data included.

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The Gowan Company of Yuma, Arizona has submitted an amendment to reduce the PHI from 45 days to 28 days for Gowan Azinphos® M-WP[EPA Reg.#10163-78] used on almonds. The insecticide is to be applied in California only, for control of the navel orangeworm and the peach twig borer.

This is the registrants second submission. A first submission, without residue data, was previously reviewed by RCB [Memo:W.Anthony, 7/9/86].

According to the registrant, a 28 day PHI is the same PHI approved for Mobay's Guthion 50% Wettable Powder Insecticide, EPA Reg. #3125-301, SLN No. CA-820045 dated 6/15/82. The use only involves almonds in California and is based on an approved SLN label.

Tolerances

Tolerances for residues of the active ingredient azinphos-methyl [O,O-dimethyl S-[(4-oxo-1,2,3-benzotriazin-3(4H)-yl) methyl]phosphorodithioate in/on almond meats and almond hulls exist at 0.3 and 10 ppm, respectively [40 CFR 180.154].

Tolerance for residues of azinphos-methyl and/or its metabolites calculated as azinphos-methyl exists at 0.04 ppm in milk[40 CFR 180.154a].

Registered Use for Almonds

The 50% WP and 2 lb/gal EC formulations are registered for foliar applications (using ground or aerial equipment) at 0.375 to 0.5 lb a.i./100 gal finished spray. Up to 500 gal may be applied per acre; therefore, up to 2.5 lb ai/A may be applied per treatment. No more than two applications per year may be made. Applications must be made at least 30 days apart. Livestock may not be grazed in treated areas for 21 days after treatment. A 60-day PHI is in effect.

A Registration Standard has been completed for azinphos-methyl (Residue Chemistry Chapter, 4/4/86).

Proposed Use

On 4/30/86, the registrant, Gowan Company, requested an amended registration to reduce the PHI from 60 days to 28 days (Memo:E. Nigh to L. Schnaubelt, EPA). No new residue data were submitted.

Previous RCB Conclusion

RCB concluded on that amendment, "...residues of azinphos-methyl and its oxygen analog in/on almond hulls may exceed the established tolerance of 10 ppm as a result of proposed use . . ." [Memo:W.Anthony 7/9/86]. This conclusion was based on the following available data, which included:

- I. Twenty-four(24) studies in California submitted by Mobay Chemical in 1981 [Memo:E. Zager, 2/12/82.],
- II. Eight(8) studies also submitted by Mobay on 3/12/79 [Memo:J. Shaughnessy, 8/3/79], and
- III. Original petition, PP# #7F0582, D. Reed, 12/20/67, which showed some of the higher residues.

A brief discussion of these data follows:

Previous Residue Data

- I. Three aerial or ground applications of GUTHION®50-WP were made to almond trees at the rate of 2 lb a.i./A in 19.7 to 400 gal/A. In 12 of the studies, the first 2 applications were made postbloom; in the remaining 12 tests the first application was made when the trees were dormant and the second application was made postbloom. In all tests the third application was made at 10 % hull split. Almonds were harvested at 28 days after the last treatment. Residues of Guthion ranged from ND (< 0.01 ppm) to 0.04 ppm in almond meats and from 0.02 to 3.58 ppm in the hulls. No detectable residues (< 0.02 ppm) of the oxygen analog were found.

Residue data submitted with this request were obtained using GLC with Flame Photometric Detection (FPD) in the phosphorus mode [Memo:E. Zager, 2/12/82].

II. However, higher residues were reported in Mobay's Guthion Residue Chemistry on Almonds, Addition #2, 3/12/79. The data [reviewed by J. Shaughnessy, 8/3/79] reflect eight studies from California. Following two to three applications at the rate of 1.9 to 2 lb a.i./A, residues ranged from <0.1 to 0.21 ppm in or on almond meats at PHIs ranging from 36 to 82 days. The highest residues in the hulls, 8.24 and 5.09 ppm, were observed at 60 days following two postbloom applications of 2 lb a.i./A.

III. Even higher residues were reported in PP#7F0582. A total of 14 studies were conducted. Following three applications at the rate of 2 lb ai/A, residues ranged from ND (<0.1 ppm) to 0.3 ppm in almond meats and from 7.6 to 208 ppm in almond hulls at PHIs ranging from 30 to 33 days.

While the 208 ppm value appears aberrant, a residue of 14.0 ppm was found in almond hulls at 32 days following one application of 2 lb ai/A. Also, a residue of 9.3 ppm was found in almond hulls at 61 days following three applications of 2 lb ai/A [Memo:D. Reed, 12/20/67].

Additionally, a residue decline study submitted in connection with PP#7F0582 showed residues of azinphosmethyl were 24.6, 30.8, 14.0, 9.1, and 3.1 ppm in or on almond hulls harvested 0, 14, 32, 43, and 85 days, respectively, after a single 0.8X treatment.

Note: Residue data submitted in II and III above were analyzed by the colorimetric method of W.R. Meagher et al., J. Agr. Food Chem., 8, (1960) p. 282; Method II, PAM II.

Residue Data

New residue data have been submitted with this submission to support 28-day PHI.

During the summer of 1986, Gowan's Azinphos-M 50 WP was applied by ground spray to a nonpareil variety of almonds at two locations, viz., Ripon and Modesto, California.

Two applications at 28-day intervals were applied at the rate of 2.0 lb a.i./A. The spray volume used at the Ripon site was 400 GPA; at the Modesto site, 100 GPA. Four treated samples obtained 28 days after the second application from each site were analyzed in duplicate:

Summary - Azinphos-methyl 50 WP Residue Data on Almonds

<u>Meats</u>	<u># Samples</u>	<u>Parts per Million</u>
Controls	4	0.01 to 0.011
Treated	4	[0.024, 0.028, 0.050, 0.076]
 <u>Hulls</u>		
Controls	4	0.016 to 0.226
Treated	4	[2.50, 5.00, 7.96, 9.63]

Analysis

The above almond meat and hull data submitted by Mobay were analyzed by Morse Laboratories, Inc., Sacramento, California, using Mobay's Analytical Method No. 69523 with modifications. The details of the analytical procedure were not included.

Two samples spiked with 0.5 ppm azinphos-methyl indicated recoveries of 93% and 120 %; two samples spiked with 0.01 ppm of the same active ingredient had recoveries of 74 % and 91 %. The detection limit reported for the treated samples was 0.01 ppm; for the control samples, the limit was 0.05 ppm.

RCB Comments

The registrant's second amendment submitted 4/15/87, had requested that a "correction" be made on their Gowan Azinphos-M 50 WP label [approved by RD on July 26, 1985] from an "erroneous" 45 days be corrected to read 28 days.

To our knowledge, approval of a 45-day PHI was never recommended by RCB as part of the registered use for control of navel orangeworm and peach twig borer.

Although virtually all almonds grown in the United States are grown in California, the supplemental label dated June 15, 1982 issued under 24(c), CA-82-0045 was for a temporary SLN and cannot be used as a basis for reducing the PHI to 28 days. Additionally, RCB has no record of having reviewed this 24(c) request. The 24(c) use would also be likely to result in tolerance exceeding residues. Based on 40 CFR 162.154(1)(b)(ii), viz., "May result in a residue on food or feed exceeding...a tolerance, exemption, or other clearance under the federal food, Drug and Cosmetic Act(21 U.S.C 345a et seq.", RCB recommends that the 24(c) registration, CA-82-0045, be disapproved at this time.

The registrant's recent submission of residue data collected at the Ripon and Modesto sites shows that the four samples analyzed for residues were <10 ppm. RCB notes that the limited number of samples analyzed and the wide variations in the results suggest a wide deviation in the application of the insecticide or flaws in the analytical procedure.

Based on the quantity of residue data in our files, no amount of residue data for almond hulls showing residues less than the tolerance at a 28-day PHI could counter the available data showing residues exceeding the tolerance at PHIs less than 60 days and residues very close to the tolerance at a 61-day PHI.

Based again on all the available data, we conclude that the residues of azinphos-methyl and its oxygen analog may exceed the existing tolerance of 10 ppm if the PHI is shortened to <60 days. Alternatively, Tox Branch considerations permitting, the registrant could petition for a higher tolerance for residues of azinphos-methyl in/on almonds.

Conclusion

1. The residues of azinphos-methyl and its oxygen analog may exceed 10 ppm if the present registered use in/on almonds is reduced to a <60-day PHI.
2. The 45-day PHI currently on the registrant's label cannot be supported and should be raised to 60 days.

Note: Alternatively, TB considerations permitting, the registrant could petition for a higher tolerance. At that time, we could recommend for the proposed amendment.

3. The 24(c), CA-82-0045, is also likely to result in a tolerance exceeding residues on almond hulls. It should also be noted that RCB has no record of having reviewed this 24(c) request.

Recommendation

For reasons given in Conclusion #1 above, we recommend against this amended registration. We recommend that the registration be amended to return the PHI to 60 days. We recommend that the 24(c) use, CA-82-0045, be disapproved at this time, under the provisions of 40 CFR 162.154(l)(b)(ii).

The registrant should be informed that an alternative would be to petition for a higher tolerance for azinphos-methyl on almonds - Tox Branch permitting. At the time the tolerance is raised, we could recommend for the proposed amendment.

cc: RF;SF(Azinphos-methyl);Circu;PM#12;PMSD/ISB.
RDI: E.Zager,Sec.Head;SVHummel,7/6/87;RDSchmitt,7/6/87.
RCB/HED:TS-769;Rm812;wla;X557-4351.
92027;W.Anthony;C.Disk;KENCO;7/9/87;NeeCee;lisa;ek;teg.