

US EPA ARCHIVE DOCUMENT



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

May 21, 1999

MEMORANDUM

SUBJECT: PP# 7F4864. Amendment to Tolerance Petition for the use of **Azoxystrobin** on **Tree Nuts and Pistachio Nuts**

Trade Names: Heritage Fungicide: EPA Reg. No. 10182-408
ICIA5504 80WG Fungicide: EPA Reg. No. 10182-416
Abound Flowable Fungicide: EPA Reg. No. 10182-415
MRID No. 443193-07
DP Barcode: D256297
Chemical No. 128810
40 CFR: §180.507

FROM: Douglas A. Dotson, Chemist *D. Dotson*
Registration Action Branch 2
Health Effects Division (7509C)

THROUGH: Michael Doherty, Peer Reviewer *M. Doherty*
Donna Davis, Branch Chief
Registration Action Branch 2
Health Effects Division (7509C)

TO: Cynthia Giles-Parker/John Bazuin, PM Team 22
Fungicide Branch
Registration Division (7505C)

A tolerance of 0.01 ppm was recently established for residues of azoxystrobin (methyl(E)-2-{2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate) and its Z isomer (R230310) in/on the tree nuts crop group and pistachio nuts. The maximum application rate and PHI appearing on the labels are 0.2 lb a.i./A and 45 days, respectively. Although almonds are a member of the tree nuts crop group, they appear separately on the labels. The maximum application rate and PHI for almonds are 0.25 lb a.i./A and 28 days, respectively. Although the label was approved, the field trial data from the samples which had a 28-day PHI were not reviewed. A review of these data is included in this memo.

The approved use pattern for pistachios is currently the same as that for the tree nuts crop group (i.e., maximum application rate: 0.2 lb a.i./A; maximum number of applications: 6; PHI: 45 days). The petitioner is requesting that the use pattern for pistachios be the same as that for almonds, and not that of the other tree nuts. That is, the petitioner is requesting that the maximum application rate be increased to 0.25 lb a.i./A and the PHI be decreased to 28 days.

Finally, HED recommends that the tolerance for the tree nuts crop group (including almonds) and pistachios be increased to 0.02 ppm based on available field trial data.

A residue chemistry review and risk assessment were recently completed for azoxystrobin. These actions included the tree nuts crop group and pistachios. The residue chemistry review was completed on 1/25/99 (Memo, D. Dotson, PP# 7F4864, D249657). The risk assessment was completed on 1/28/99 (Memo, D. Dotson, PP#7F4864, D248888).

RECOMMENDATIONS

Pending the results of the forthcoming amendment to the human health risk assessment, HED recommends in favor of amending the pistachio nut and tree nuts crop group tolerance from 0.01 ppm to 0.02 ppm. HED also makes the following recommendations with respect to pistachio nuts: that the maximum application rate be increased from 0.2 to 0.25 lb a.i./A, and that the PHI be decreased from 45 to 28 days.

A DEEM run can be initiated using the following tolerance levels:

Tree Nuts	0.02 ppm
Pistachios	0.02 ppm

CONCLUSIONS

1. In order to obtain a tolerance for the tree nuts crop group, the petitioner submitted the results of five field residue studies on almonds (Memo, D. Dotson, PP# 7F4864, D249657, 1/25/99). The representative commodities for tree nuts are almonds and pecans. The registrant had already submitted field trial studies for pecans (Memo, J. Garbus, PP#6F4642, D221999, 6/26/96). HED concluded that the almond field trial studies were conducted in accordance with the OPPTS Test Guidelines 860. The PHI used was 43-44 days. The highest residues found in almond nutmeats were at or below the limit of quantitation of the analytical method (0.01 ppm). As a result, HED considered the proposed tolerance of 0.01 ppm to be adequate. However, in one field trial the azoxystrobin residue was 0.01 ppm and the R230310 residue was <0.01 ppm. As a result, HED has reconsidered the established tolerance level and concludes that it would be appropriate to increase the tolerance to 0.02 ppm for the combined residues of azoxystrobin and R230310 in/on tree nuts. **Pending the results of the amendment to the human health risk assessment, HED recommends in favor of increasing the tree nuts crop group tolerance from 0.01 ppm to 0.02 ppm.**

2. In addition to the field trial data from studies done at a 43-44 day PHI, the petitioner also submitted the results of five field residue studies on almonds in which a 28-day PHI was used. As with the trials conducted using a 44-day PHI, one sample had an azoxystrobin residue level of 0.01 ppm while all others had a residue level of <0.01 ppm. The residue levels of R230310 were <0.01 ppm for all samples. A tolerance of 0.02 ppm would be appropriate for the combined residues of azoxystrobin and R230310. HED therefore concludes that decreasing the PHI from 45 to 28 days will not result in a significant increase in residue levels on almonds. Pending the results of the amendment to the human health risk assessment in which a tolerance of 0.02 ppm is used for almonds, HED recommends in favor of the 28-day PHI.

3. The petitioner did not submit field trial studies for pistachios. Chemistry Branch 1 (CB1) recommended that pistachios be included with the tree nuts crop group (Memo, B. Schneider, 3/4/97). CB1 stated that pesticide residue levels in the pistachio nutmeat were expected to be similar to the levels in other nut crops that are members of the tree nut crop group. The petitioner has requested that the use pattern for pistachios be the same as that for almonds, and not that of the other tree nuts. The proposed application rate and PHI for pistachios are 0.25 lb a.i./A (maximum of 6 applications), and 28 days, respectively. The proposed tolerance is 0.02 ppm. The registrant has submitted revised Sections B for the Abound and Heritage formulations. These labels reflect the change in maximum application rate from 0.20 to 0.25 lbs a.i./A and the decrease in PHI from 45 to 28 days for pistachios. If the petitioner wishes to amend the label for ICIA5504 80WG, a revised Section B reflecting the modifications must be submitted.

DETAILED CONSIDERATIONS

Proposed Use

The petitioner originally provided specimen labels for three formulations of azoxystrobin: Abound Flowable Fungicide (23% active ingredient), Heritage Fungicide (50% active ingredient), and ICIA5504 80WG Fungicide (80% active ingredient). Azoxystrobin is the sole active ingredient.

On pistachios, Abound, Heritage, and ICIA5504 were originally proposed for up to 6 applications at 0.10-0.20 lb ai/A for a total maximum application of 1.2 lb ai/A/year. Do not apply more than four sequential sprays of fungicide before alternation with a fungicide that has a different mode of action. Applications should begin prior to, or in the early stages of, disease development and continue throughout the season on 7-21 day intervals following the resistance management guidelines. Applications may be made by ground, air, or chemigation. An adjuvant may be added at recommended rates to improve coverage. Do not apply within 45 days of harvest.

Zeneca Ag Products is proposing that the label be amended so that pistachios will have the same use pattern as almonds. Six applications are proposed at 0.10-0.25 lb ai/A for a maximum total application of 1.5 lbs ai/A/year. Do not apply within 28 days of harvest. The registrant has submitted revised Sections B which reflect these changes. Labels were submitted for the Heritage and Abound formulations only. A revised Section B for ICIA5504 was not submitted.

On almonds, Abound, Heritage, and ICIA5504 are proposed for up to six applications at 0.10-0.25 lb ai/A for a maximum total application of 1.5 lbs ai/acre/year. For blossom blight do not apply more than two sequential sprays of azoxystrobin before alternating with a fungicide that has a different mode of action. For all other almond diseases do not apply more than four sequential sprays of product before alternation with a fungicide that has a different mode of action. Applications should begin prior to, or in the early stages of, disease development and continue at 7-21 day intervals throughout the season following the resistance management guidelines. Applications may be made by ground, air, or chemigation. An adjuvant may be added at recommended rates to improve coverage. Do not apply within 28 days of harvest.

The three azoxystrobin formulations, Heritage Fungicide, ICIA5504 80WG Fungicide, and Abound Flowable Fungicide have the same restrictions. It is not permissible to graze animals or to feed clippings from treated turf areas to animals. Crops not on the label are not to be planted within 45 days of the last application. Azoxystrobin is extremely phytotoxic to certain apple varieties. Therefore, it should not be applied under conditions where there is the possibility of spray drift reaching apple trees. Sprayers used to apply azoxystrobin should not be used to spray apples. Azoxystrobin is not to be applied through any type of ultra low volume spray system. For aerial applications to non-orchard crops, azoxystrobin is to be applied in a minimum of three gallons of water per acre. For aerial applications in orchard crops, azoxystrobin is to be applied in a minimum of ten gallons of water per acre.

HED's Comments/ Conclusions

HED concludes that the revised Sections B for the Abound and Heritage formulations are adequate. These labels reflect the change in maximum application rate from 0.20 to 0.25 lbs a.i./A and the decrease in PHI from 45 to 28 days for pistachios. If the petitioner wishes to amend the label for ICIA5504 80WG, a revised Section B reflecting the modifications must be submitted. The proposed use directions for almonds are adequate.

Magnitude of Residue - Crop Field Trials

Almonds (MRID No. 443193-07)

Increase of tree nuts crop group tolerance

In order to obtain a tolerance for the tree nuts crop group, the petitioner submitted the results of five field residue studies on almonds (Memo, D. Dotson, PP# 7F4864, D249657, 1/25/99). The representative commodities for tree nuts are almonds and pecans. The registrant had already submitted field trial studies for pecans (Memo, J. Garbus, PP#6F4642, D221999, 6/26/96). HED concluded that the almond field trial studies were conducted in accordance with the OPPTS Test Guidelines 860. The PHI used was 43-44 days. The highest residues found in almond nutmeats were at or below the limit of quantitation of the analytical method (0.01 ppm). As a result, HED considered the proposed tolerance of 0.01 ppm to be adequate. After establishment of the tolerance, the California Department of Pesticide Regulation (CDPR) requested that the tolerance be increased to 0.02 ppm. This request was made specifically for pistachio nuts. However, almond field trial data were used to support the pistachio nut tolerance. In one field trial the azoxystrobin residue was 0.01 ppm and the R230310 residue was <0.01 ppm. As a result,

HED has reconsidered the established tolerance level and concludes that it would be appropriate to increase the tolerance to 0.02 ppm for the combined residues of azoxystrobin and R230310 in/on the entire tree nuts crop group as well as pistachio nuts. **Pending the results of the amendment to the human health risk assessment, HED recommends in favor of increasing the tree nuts crop group tolerance from 0.01 ppm to 0.02 ppm.**

Decrease of almond PHI from 45 to 28 days

A review has been done of five field trial studies which were conducted on almonds in California in 1996 (Memo, D. Dotson, PP#7F4864, D249657, 1/25/99). When these studies were performed, two additional samples were harvested 28-29 days after the last application. The application rate was the same as that proposed for almonds: 6 applications at a rate of 0.25 lb ai/A. The total application rate was therefore 1.5 lb ai/A. For additional details concerning sample treatment, handling, storage stability, analysis, and recovery, see residue chemistry review referenced above.

The results of the analysis of the almond nutmeat samples are given in Table 1. Residue levels of azoxystrobin in almond nutmeats were <0.01 mg/kg in all but one sample, which had residues of 0.01 mg/kg. Residues of R230310 on nutmeats were <0.01 mg/kg in all samples. No residues of azoxystrobin or R230310 were found in any untreated sample.

Trial Number Location	Sample Number	PHI (Days)	Residues (ppm)	
			Azoxystrobin	R230310
18-CA-96-301 Dinuba, CA	M301-14	29	<0.01	<0.01
	M301-15	29	<0.01	<0.01
18-CA-96-302 Madera, CA	M302-14	29	<0.01	<0.01
	M302-15	29	<0.01	<0.01
17-CA-96-303 Chico, CA	M303-14	29	<0.01	<0.01
	M303-15	29	<0.01	<0.01
17-CA-96-304 Chico, CA	M304-14	29	<0.01	<0.01
	M304-15	29	<0.01	<0.01
17-CA-96-305 Yuba City, CA	M305-14	28	<0.01	<0.01
	M305-15	28	0.01	<0.01

HED's Comments/Conclusions

HED concludes that a 28-day PHI for almonds does not result in a significant increase in residue levels over a 45-day PHI. Therefore the submitted field trial data support the 28-day PHI which was approved for almonds.

Pistachios

The petitioner did not submit field trial studies for pistachios. Chemistry Branch 1 (CB1) recommended that pistachios be included with the tree nuts crop group (Memo, B. Schneider, 3/4/97). CB1 stated that pesticide residue levels in the pistachio nutmeat were expected to be similar to the levels in other nut crops that are members of the tree nuts crop group. The petitioner has requested that the use pattern and tolerance for pistachios be the same as those for almonds, and not those of the other tree nuts. The proposed application rate and PHI for pistachios are 0.25 lb a.i./A (maximum of 6 applications), and 28 days, respectively. The proposed tolerance is 0.02 ppm.

HED's Comments/Conclusions: Pending the results of the amendment to the human health risk assessment, HED recommends in favor of increasing the tolerance for pistachio nuts from 0.01 to 0.02 ppm for the combined residues of azoxystrobin and R230310.