

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



OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

DATE: 01/24/2023

SUBJECT: **Azoxystrobin.** Petition to Amend the Established Tolerances for Residues of Azoxystrobin in/on Mango, Papaya and Establish a Tolerance for Residues of Azoxystrobin in/on Imported Oil Palm. **Summary of Analytical Chemistry and Residue Data.**

PC Code: 128810

Decision No.: 578208

Petition No.: IE8946

Risk Assessment Type: NA

TXR No.: NA

MRID No.: See Below

DP Barcode: D466199

Registration No.: 100-1120, 100-1220

Regulatory Action: Section 3

Case No.: 7020

CAS No.: 131860-33-8

40 CFR: §180.507

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| OCSPP 860 Series Guideline | MRID Number | Title |
|---|------------------------|---|
| 860.1500 | 51526501 | Pereira F. (2020) A13703 and A15696 - Magnitude of Residues of Fludioxonil, Azoxystrobin and its Isomer R230310 in Papaya Fruits –Brazil, 2019-2020. Report Number: LBS19052. Unpublished study prepared by Syngenta Crop Protection, LLC. 697 p. |
| 860.1500 | 51526502 | Pereira F. (2020) A13703 and A15696 - Magnitude of Residues of Fludioxonil, Azoxystrobin and its Isomer R230310 in Mango Fruits –Brazil, 2019-2020. Report Number: LBS19053. Unpublished study prepared by Syngenta Crop Protection, LLC. 693 p. |
| 860.1500 860.1520 | 51526503 | Harbin A. (2019) A13836 - Magnitude of the Residue in/on Oil Palm and Oil Palm Processed Commodities. Report Number: TK0271983. Unpublished study prepared by Syngenta Crop Protection, LLC. 395 p. |

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1.0 Executive Summary

Azoxystrobin [methyl (αE)-2-[[6-(2-cyanophenoxy)-4-pyrimidinyl]oxy]- α -(methoxymethylene)benzeneacetate] is a fungicide that is currently registered for use on a variety of field, vegetable, fruit, and nut crops as well as on ornamental plants and turf. End-use products of azoxystrobin are typically formulated as water-dispersible granular (WDG), suspension-concentrate (SC; previously referenced as flowable concentrate), and soluble-emulsion (SE) formulations. These products may be applied as in-furrow at-planting or postemergence foliar applications using ground or aerial equipment at maximum seasonal rates of 0.40-2.0 lb active ingredient (ai)/acre (A). Azoxystrobin is also registered for seed treatment of many food/feed crops as well as for postharvest uses on bananas/plantains and citrus fruits.

Tolerances are established (40 CFR §180.507) for residues of the fungicide azoxystrobin and its *Z*-isomer. Tolerances range from 0.04 ppm (asparagus) to 420 ppm (aspirated grain fractions). Current tolerances are established for residues at 2 ppm on mango and papaya.

Syngenta Crop Protection, LLC, is seeking to amend the established tolerances for residues of azoxystrobin in/on mango, papaya, and establish an import tolerance in/on oil palm. Syngenta has submitted English translations of approved foreign labels for Amistar Top®, Uniform®, and Graduate A+ for use on mango, papaya, or oil palm. Both Amistar Top® and Graduate A+ are formulated as soluble concentrates (SCs) containing 200 and 239 g ai/L, respectively. Uniform® is formulated as a suspoemulsion (SE) containing 321 g ai/L. Azoxystrobin may be used pre- and post-emergent with retreatment intervals (RTIs) ranging between 14-28 days; 0 days for post-harvest uses. For oil palm, a pre-harvest interval (PHI) of 60 days is required. The products may be applied by ground (i.e., groundboom, airblast, and handheld) equipment, as foliar applications with single maximum application rates ranging from 0.057 to 0.11 lb ai/A, and 0.286 and 0.428 lb ai/A per season. For post-harvest uses, a single application may be made either by spray or dip treatment at a maximum single application rate of 0.010 lb ai/gal.

Adequate metabolism studies on grapes, peanuts, and wheat were previously submitted. HED has determined that the residues of concern in/on plants for tolerance expression and risk assessment purposes are azoxystrobin and its *Z*-isomer.

The nature of the residue in livestock is adequately understood based on acceptable metabolism studies conducted on goats and laying hens. HED has determined that the residue of concern in livestock is azoxystrobin only.

Adequate confined rotational crop studies have previously submitted. HED has concluded that the residues of concern in rotational crops are azoxystrobin and its *Z*-isomer.

There are adequate residue analytical methods for tolerance enforcement. A gas chromatograph equipped with a nitrogen/phosphorus detector (GC/NPD) method, RAM 243/04, is available for the enforcement of tolerances for residues of azoxystrobin and its *Z*-isomer in crop commodities. A GC/NPD method, RAM 255/01, is available for the enforcement of tolerances for residues of azoxystrobin in livestock commodities. The method has been validated by Analytical Chemistry

Branch (ACB)/Biological and Economics Analysis Division (BEAD) for the analysis of milk and liver.

Syngenta Crop Protection, LLC has submitted field trial data for azoxystrobin on mango, papaya, and oil palm. The number and geographical representation of the submitted field trial data are adequate. All samples were analyzed using adequately validated methods and sufficient storage stability data are available. Based on these field trial data, HED concludes that the tolerances listed in Table 2.2.2., for residues of azoxystrobin are appropriate. A revised Section F/proposed tolerances is required to revise the proposed tolerance levels.

There are no livestock feed items associated with this petition.

2.0 Regulatory Recommendations

Provided a revised Section F is submitted, there are no residue chemistry considerations that would preclude establishing the recommended tolerances for residues of azoxystrobin in/on mango, papaya, and oil palm. The specific tolerance recommendations are discussed in Section 2.2.

2.1 Data Deficiencies/Data Needs

None.

2.2 Tolerance Considerations

2.2.1 Enforcement Analytical Method

PP#s 5F4541 & 6F4762; J. Garbus, *et al.*, D235342, 04/18/1997
PP#7F4864; D. Dotson, D249657 & D249668, 01/25/1999
PP#s 6F7106 & 7F7198; W. Cutchin, D334571 & D340016, 03/12/2008
PP#5F4541; J. Garbus, D218318 & D218448, 04/01/1996
PP#4E7851; M. Negussie, D390152, 01/04/2012

Plant Commodities: A GC/NPD method, RAM 243/04, is available for the enforcement of tolerances for residues of azoxystrobin and its *Z*-isomer in crop commodities. The method has undergone method validation by ACB/BEAD. The method was revised to incorporate comments made by BEAD, and the revised method (designated RAM 243, dated 5/15/1998) has been submitted to FDA for inclusion in Pesticide Analytical Manual (PAM), Volume II. The limit of quantitation (LOQ) is 0.01 ppm for each analyte in crop commodities.

Livestock commodities: A GC/NPD method, RAM 255/01, is available for the enforcement of tolerances for residues of azoxystrobin in livestock commodities. The method has been validated by ACB/BEAD for the analysis of milk and liver. The method LOQ is 0.0025 ppm and 0.01 ppm for each analyte in milk and tissues, respectively.

Data have previously been submitted pertaining to the multiresidue methods (MRMs) testing of azoxystrobin in conjunction with the grape petition. The data indicate that azoxystrobin could