



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

March 11, 2023

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: A Review of Corteva's Petition for Extension of Exclusive Use for Oxathiapiprolin (PC: 128111) (DP#466883; MRID# 51876601)

FROM: Tara Chandgoyal, Plant Pathologist *Tara Chandgoyal*
Biological Analysis Branch
Biological and Economic Analysis Division (7503M)

THRU: Monisha Kaul, Chief *Monisha Kaul*
Biological Analysis Branch
Biological and Economic Analysis Division (7503M)

TO: Nancy Fitz, Use Team Leader
Eric Bohnenblust, Branch Chief
Minor Use and Emergency Response Branch (7505M)

Nathan Mellor, Product Manager
Cynthia Giles-Parker, Chief
Fungicide Branch
Registration Division (7505M)

Product Review Panel Date: February 22, 2023

SUMMARY

Corteva AgriScience, LLC (Corteva) petitioned the Environmental Protection Agency (EPA), under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 3(c)(1)(F)(ii), to extend the exclusive use period for data supporting oxathiapiprolin fungicide for three years. Corteva claims oxathiapiprolin fills a void in current fungal disease control programs and/or plays or will play a part in risk reduction, fungicide resistance management, and integrated pest management programs corresponding to criteria I, II, III and IV as defined under FIFRA 3(c)(1)(F)(ii) in all claimed crops.

BEAD finds that thirteen crop use sites (out of fourteen) claimed by Corteva meet the criterion for minor use designation based on bearing or harvested acreage (less than 300,000 acres) and

are supported by residue data submitted by the registrant.

BEAD finds the registrant submitted sufficient evidence for ten minor use sites (blueberry [high bush], strawberry, blackberry, lemon, grapefruit, tangerine, hazelnut, macadamia nut, avocado, pomegranate) to satisfy criterion III for three years of extension of exclusive use for oxathiapiprolin under FIFRA Section 3(c)(1)(F)(ii).

BACKGROUND

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides certain data protection rights to data submitters for their registered pesticides. Section 3(c)(1)(F)(i) states that the original data submitter has a 10-year exclusive use period from the date of registration for the data submitted in support of the original registration. The period of exclusive use may be extended one year for each three minor uses registered, up to a total of three additional years, if registered within seven years of the commencement of the exclusive use period and the registrant demonstrates that:

- (I) there are insufficient efficacious alternative registered pesticides available for the use,
- (II) the alternatives to the minor use pesticide pose greater risks to the environment or human health,
- (III) the minor use pesticide plays or will play a significant part in managing pest resistance or
- (IV) the minor use pesticide plays or will play a significant part in an integrated pest management program.

A minor use is defined in FIFRA Section 2(II) as the use of a pesticide on an animal, on a commercial agricultural crop or site, or the protection of public health where “(1) the total U.S. acreage for the crop is less than 300,000 acres, as determined by the Secretary of Agriculture, or (2) the use does not provide sufficient economic incentive to support the initial registration or continuing registration of a pesticide for such use.”

In the case of crop groupings, FIFRA 3(c)(1)(F)(ii) states that “the registration of a pesticide for a minor use on a crop grouping . . . shall be considered for one minor use for each representative crop for which data are provided.” The maximum number of eligible distinct minor uses for a crop subgroup is equal to the number of representative crops for which residue data have been submitted. Greenhouse uses are considered separate use sites from field crops in cases where distinct residue data for field-grown crops are submitted to support the registration.

The Biological and Economic Analysis Division (BEAD) evaluates whether up to nine use sites submitted in the registrant’s petition meet the statutory requirement for an extension of data exclusivity by verifying that residue trials were submitted on a one-for-one basis with use sites, verifying minor crop acreage, and validating the claimed criteria.

REGISTRANT SUBMISSION

Oxathiapiprolin is relatively a new fungicide that has a new mode of action against multiple phytopathogenic fungi and belongs to code 49 as per Fungicide Resistance Action Committee (FRAC, 2022). It is effective against oomycete fungi (such as *Pythium*, *Phytophthora*) that cause downy mildews, root rot, crown rot and blights (Link *et al.*, 2002) and its mode of action is different than fungicides registered for controlling oomycete fungi (FRAC, 2022). The registrant claimed that oxathiapiprolin satisfies the FIFRA Section 3(c)(1)(F)(ii) requirements for 14 use sites (blueberry [high bush], strawberry, blackberry, lemon, grapefruit, tangerine, orange (postharvest), basil, hops, asparagus, hazelnut, macadamia nuts, avocado and pomegranate) as each crop is grown on less than 300,000 acres and are supported by residue trials (Table 1). The registrant claimed that there are insufficient registered alternatives to control fungal pests and oxathiapiprolin plays or will play a part in risk reduction, fungicide resistance management, and/or an integrated pest management program (criteria I, II, III, and/or IV) for each of the claimed minor use sites. The claimed criterion for each crop is presented in Table 2.

REQUIREMENTS TO QUALIFY FOR THE CLAIMED CRITERIA

Requirements for Criterion I, there are insufficient efficacious alternative registered pesticides for the use site. EPA considers Criterion I to be met in situations where the pesticide: 1) fills a void in the current pest control program (e.g., unique timing window); 2) controls a broader spectrum of pests than currently registered alternatives; 3) controls a different life stage for the pest; or 4) provides a crucial timing advantage (e.g., shorter pre-harvest interval or restricted entry interval).

Requirements for Criterion II, the alternatives to the minor use pesticide pose greater risks to the environment or human health. BEAD cannot evaluate risks and does not provide the Registration Division with information related to Criterion II.

Requirements for Criterion III, the minor use pesticide plays or will play a significant part in managing pest resistance. EPA considers Criterion III to be met in situations where there is reliable information that the chemical being evaluated is used either to delay the development of pest resistance to other chemicals with different modes of action or where one or more of the target pests have already developed resistance in the U.S. to alternative chemicals.

Requirements for Criterion IV, the minor use pesticide plays or will play a significant part in an integrated pest management program. EPA considers Criterion IV to be met in situations where there is reliable information that the chemical being evaluated is useful in managing target pests while having low-to-no impact on other aspects of integrated pest management (IPM), such as inclusion of non-chemical pest control strategies (such as biological control, cultural practices).

BEAD ANALYSIS

BEAD first confirms that residue trial data are sufficient such that there is a one-for-one relationship for each use site. Then, BEAD confirms that each crop meets the definition of a

minor crop per FIFRA Section 2(l)(1), wherein each crop must be grown on less than 300,000 acres in the U.S. by consulting the most recent Census of Agriculture conducted by the United States Department of Agriculture (USDA) National Agricultural Statistics Service (NASS). Finally, BEAD evaluates the claimed evidence submitted by the registrant to determine if the claimed criteria are met. Nine qualifying use sites must satisfy a minimum of one criterion for three-year extension of exclusive use for oxathiopiprolin under FIFRA Section 3(c)(1)(F)(ii).

Residue Trial Analysis

The registrant's submission showed that all crops (except orange [postharvest]) are supported by residue data (Table 1). The registrant can claim these crops (except orange [postharvest]) as minor uses, as crops are cultivated on less than 300,000 acres.

Table 1. Oxathiopiprolin* proposed crops and representative residue data by crop/ crop subgroup.

Minor Use Claimed	Crop Group (subgroup) (Date Registered)	Residue Data Submitted for Crop Group/ Subgroup (MRID # and date) *	Maximum Number of Minor Use Sites Allowed
Blueberry, highbush	Crop subgroup 13B (08/17/2020)	Blueberry (50683001, 1/27/2019)	1
Strawberry	Crop subgroup 13-07G (08/17/2020)	Strawberry (50615201, 4/2/2019)	1
Blackberry	Crop subgroup 13-07A (11/14/2016)	Raspberry & blackberry (49784104, 12/24/2015)	1
Lemon	Crop group 10-10 (11/14/2016)	Orange, grapefruit, and lemon – all field use (49712902, 12/29/2015)	3
Grapefruit			
Tangerine			
Orange, post-harvest	Crop group 10-10, post-harvest (11/14/2016)	RD is not sure if residue data were submitted	NC
Basil	Crop subgroup 19A (11/14/2016)	Basil-field (49784105, 12/24/2015); Basil-greenhouse (49784106, 12/24/2015)	2
Hops	No crop group/subgroup (08/17/2020)	Hops (50615204, 4/2/2019)	1
Asparagus	Crop subgroup 22A (11/14/2016)	Asparagus-soil application (49784101, 12/24/2015); (Asparagus-crown soak application (49784102, 12/24/2015)	1
Hazelnut	Crop group 14-12 (08/17/2020)	Pecan and Almond (50683002, 1/27/2019)	1
Macadamia nut			1
Avocado	Crop subgroup 24B (08/17/2020)	Avocado (50615202, 4/2/2019)	1
Pomegranate		Pomegranate (50615203, 4/2/2019)	1

*Oxathiopiprolin technical (Zorvec, 352-890) was registered August 31, 2015.

NC: Not Considered. A maximum of three crops (lemon, grapefruit, and tangerine) representing crop

subgroup 10-10 have been claimed.

Minor Use Analysis and Criteria Claimed

The Environmental Protection Agency (EPA) relies on the United States Department of Agriculture (USDA) Census of Agriculture for data on crops grown in the United States (EPA 2018: USDA 2017). If a crop is not listed in the Census of Agriculture, the acreage of the crop can be assumed to be less than 300,000 (EPA, 2018). For the minor use qualification, fruit and tree nut crops are evaluated for bearing acreage, and other crops are evaluated for harvested acreage. For each of the 14 use sites listed in Table 1, the total U.S. acreage is less than 300,000 acres (except orange [postharvest]) for each site qualifying them as minor crops. In addition, orange-postharvest use cannot be considered because a maximum of three representative crops (lemon, grapefruit, and tangerine) allowed for crop subgroup 10-10 have been claimed.

Table 2. Acreage of crops and criteria claimed by registrant for extension of exclusive use for oxathiapiprolin.

Minor Use Site	Crop Acres Grown ¹	Criteria Claimed
Blueberry, Highbush	153,258	III, IV
Strawberry	60,162	III, IV
Blackberry	16,671	III, IV
Lemon	66,501	III
Grapefruit	68,390	III
Tangerine	77,701	III
Orange (Postharvest)	NC	I, III
Basil	Not in Census ²	I
Hops	59,429	I
Asparagus	29,907	I
Hazelnut	70,091	III
Macadamia Nut	18,403	III
Avocado	64,455	III, IV
Pomegranate	31,472	III, IV

¹USDA NASS 2017.

²The USDA NASS does not survey basil, indicating that crop acreage is below 300,000.

NC: Not Considered. A maximum of three crops (lemon, grapefruit, and tangerine) representing crop subgroup 10-10 have been claimed.

BEAD Assessment of Claimed Criteria for Minor Use Sites

BEAD overview of claimed criteria for oxathiapiprolin showed that criterion III was claimed for 11 crops (Table 2) and therefore BEAD's assessment focused on criterion III to determine if nine or more crops meet this criterion for eligibility of a three-year extension of exclusive use for oxathiapiprolin.

Applicability of Criterion III to oxathiapiprolin.

The registrant claims that oxathiapiprolin plays or will play a significant part in managing pest resistance in 11 crops (blueberry [highbush], strawberry, blackberry, lemon, grapefruit, tangerine,

orange (postharvest treatment), hazelnut, macadamia nut, avocado and pomegranate). BEAD considers this criterion to be met in ten claimed crops. Orange (postharvest) is not assessed because three crops (lemon, grapefruit, and tangerine) representing crop subgroup 10-10 have been claimed.

Oxathiapiprolin is the only registered fungicide in the Fungicide Resistance Action committee (FRAC) group 49 for control of *Phytophthora* diseases in blueberry (root rot), strawberry (crown and root rot) and highbush blackberry (root rot) (Corteva, 2022). In these crops, fungicides recommended for use to control *Phytophthora* diseases include metalaxyl, mefenoxam, fosetyl-Al, and phosphites (Corteva, 2022; Smith and Miller-Butler, 2017; Koike, *et al.*, 2018; Koike, *et al.*, 2015); these fungicides have different mode of action than oxathiapiprolin (FRAC, 2022). Given its unique mode of action, oxathiapiprolin can be applied in rotation and/or combination with other registered fungicides and therefore plays a significant role in fungicide resistance management.

Oxathiapiprolin is the only registered fungicide in the Fungicide Resistance Action committee (FRAC) group 49 for control of *Phytophthora* spp. (Corteva, 2022) causing root rot in citrus trees (lemon, grapefruit, tangerine) resulting in trees decline and death (Corteva, 2022). The recommended alternatives for controlling *Phytophthora* spp. citrus root rot include metalaxyl, mefenoxam, and phosphite (Corteva, 2022; Hao, *et al.*, 2019; Citrus Industry, 2019). Oxathiapiprolin has different mode of action than alternative recommended fungicides and can be applied in rotation and/or combination with other registered fungicides therefore oxathiapiprolin plays a significant role in fungicide resistance management. Orange (postharvest treatment) is not assessed because a maximum of three crops (lemon, grapefruit, and tangerine) representing crop subgroup 10-10 have been claimed.

In hazelnut, macadamia nuts, avocado and pomegranate, oxathiapiprolin is the only fungicide in the Fungicide Resistance Action committee (FRAC) group 49 for control of *Phytophthora* spp. (FRAC, 2022). *Phytophthora* spp. cause root rot of hazelnut trees (Corteva, 2022; Olsen *et al.*, 2013), macadamia tree decline (Corteva, 2022; Akinsanmi and Drenth, 2013), root rot of avocado (Corteva, 2022; Eskalen *et al.*, 2017) and root and collar rot of pomegranate (Corteva, 2022; Kurbetli *et al.*, 2020). For controlling *Phytophthora* spp. on these crops, metalaxyl, mefenoxam, phosphorus acid is recommended (Corteva, 2022; Akinsanmi and Drenth, 2013; Eskalan *et al.*, 2017). Oxathiapiprolin has different mode of action than recommended fungicides and can be applied in rotation and/or combination with other registered fungicides and therefore plays a significant role in fungicide resistance management.

CONCLUSION

BEAD finds that the registrant submitted sufficient evidence for ten use sites (blueberry [highbush]), strawberry, blackberry, lemon, grapefruit, tangerine, hazelnut, macadamia nut, avocado and pomegranate) to satisfy criterion III for three-year extension of exclusive use for oxathiapiprolin under FIFRA Section 3(c)(1)(F)(ii).

REFERENCES

Akinsanmi, OA and Drenth, A. 2013. Phosphite and metalaxyl rejuvenate macadamia trees in decline caused by *Phytophthora cinnamomi*. accessed on March 7, 2023.
<https://www.sciencedirect.com/science/article/pii/S0261219413001543>

Citrus Industry. 2019. *Phytophthora*: an old problem with new challenges. Accessed on February 7, 2023. [https://citrusindustry.net/2019/03/12/phytophthora-an-old-problem-with-new-challenges/#:~:text=Phytophthora%20root%20rot%20is%20the, and%20sloughing%20\(Figure%201\)](https://citrusindustry.net/2019/03/12/phytophthora-an-old-problem-with-new-challenges/#:~:text=Phytophthora%20root%20rot%20is%20the, and%20sloughing%20(Figure%201))

Eskalen, A., Faber, B., Bender, G and Rios, S. 2013. *Phytophthora* root rot of avocado and management strategies. Accessed on March 8, 2023. chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://ucanr.edu/sites/eskalenlab/files/292710.pdf

EPA. 2018. Determination of Minor Use under Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 2(11). <https://www.regulations.gov/document/EPA-HQ-OPP-2015-0814-0016>

FRAC. 2022. Fungicide Resistance Action Committee (FRAC)). Fungal control agents sorted by cross-resistance pattern and mode of action (including coding for FRAC Groups on product labels). https://www.frac.info/docs/default-source/publications/frac-code-list/frac-code-list-2022--final.pdf?sfvrsn=b6024e9a_2

Hao, W., Gray, MA., Foster, H and Adaskaveg, JE. 2019. Evaluation of oömycota fungicides for management of *Phytophthora* root rot of citrus in California. Plant Disease 103: 619-628. Accessed on February 9, 2023. <https://apsjournals.apsnet.org/doi/full/10.1094/PDIS-07-18-1152-RE>

Koike, ST., Bolda, MP., Gubler, WD and Bettiga, LJ. 2015. UC IPM pest management guidelines: caneberries. Accessed on February 10, 2023. <https://ipm.ucanr.edu/agriculture/caneberries/phytophthora-root-rot/>

Koike, ST., Browne, GT., Gordon, TR and Bolda, MP. 2018. UC IPM pest management guidelines: strawberry. Accessed on February 10, 2023. <https://ipm.ucanr.edu/agriculture/strawberry/phytophthora-crown-and-root-rot/#:~:text=Symptoms%20and%20Signs,-Initially%2C%20symptoms%20typically&text=As%20the%20season%20progresses%2C%20plant,brown%20to%20black%20root%20rot.>

Kurbetli, I, Karaca, G., Aydogdu and Sulu, G. 2020. *Phytophthora* species causing root rot and collar rot of pomegranate in Turkey. Accessed on March 8, 2023. <https://link.springer.com/article/10.1007/s10658-020-02007-8>

Link, VH., Powelson, ML and Johnson, KB. 2012. Oomycetes. Accessed on February 14, 2023. <https://www.apsnet.org/edcenter/disandpath/oomycete/labexercises/Pages/Oomycetes.aspx>

Olsen, J., Pscheidt, JW and Walton, V. 2013. Growing hazelnut in the pacific Northwest. Integrated pest management. Accessed on March 2023. <https://catalog.extension.oregonstate.edu/em9081>

Smith, BJ and Miller-Butler, MA. 2017. Effect of cultural practices and fungicide treatments on plant vigor and mortality of blueberries grown in *Phytophthora* infested soil. Accessed on February 8, 2013. https://www.actahort.org/books/1180/1180_8.htm