UNITED STATES ENVIRONMENTAL PROTECTION
AGENCY WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY
AND POLLUTION
PREVENTION

July 13, 2023

Brian L. Bret, PhD
U.S. Regulatory Leader
Corteva Agriscience, LLC
9330 Zionsville Road
Indianapolis, IN 46268

Subject: Product Name: Zorvec® Technical
EPA Reg. No.: 352-890
Decision No.: 583337
Application Date: April 1, 2022
EPA Finding: Extend the exclusive use data protection period for oxathiapiprolin by 3 years from August 31, 2025 to August 31, 2028.

Dear Dr. Bret:

This letter addresses your request that certain data associated with the original registration of oxathiapiprolin receive a three-year extension to the ten-year exclusive use protection period. Zorvec® Technical (EPA Reg. No. 352-890) was first registered by the agency on August 31, 2015. Without an extension of exclusive use protection, the data protection period would expire on August 31, 2025. Though only nine registered minor crops are needed to support this request, the following fourteen were cited: asparagus, avocado, basil, blackberry, blueberry (highbush), grapefruit, hazelnut, hops, lemon, macadamia nut, orange (post-harvest), pomegranate, strawberry, and tangerine.

After review of this petition, EPA is granting the request for an exclusive use extension of three additional years to end on August 31, 2028, for EPA Registration No. 352-890.

Corteva Agriscience, LLC cited FIFRA section 3(c)(l)(F)(ii) as the authority for EPA to make such a determination. The 1996 Food Quality Protection Act ("FQPA") amendments to FIFRA incorporated this subsection under 3(c)(l)(F). FIFRA section 3(c)(l)(F)(ii) sets forth the criteria for extending the period of exclusive use protection. The period of exclusivity can be extended one year for every three qualifying minor uses registered within the first seven years of an original registration whose data retains exclusive use protection, with a maximum addition of three years to the original ten-year exclusivity period. All of the minor use crop candidates were registered within the requisite seven years period, prior to August 31, 2022, and EPA confirmed

that thirteen of them (all of the minor crops other than post-harvest orange) are grown on less than 300,000 acres per year.

The first step in determining whether data qualifies for an extension of its exclusive use period is to ascertain whether there are any exclusive use data associated with a registration. FIFRA section 3(c)(1)(F)(i) and its implementing regulations specifically describe the set of data that are eligible for exclusive use protection. A study entitled to exclusive use protection is defined in 40 C.F.R. 152.83(a), and the following requirements must be met:

(1) The study pertains to a new active ingredient (new chemical) or new combination of active ingredients (new combination) first registered after September 30, 1978;
(2) The study was submitted in support of, or as a condition of approval of the application, resulting in the first registration of a product containing such new chemical or new combination (first registration), or an application to amend such registration to add a new use;
(3) The study was not submitted to satisfy a data requirement imposed under FIFRA section 3(c)(2)(B); and
(4) A study is an exclusive use study only during the 10-year period following the date of the first registration.

The following is our analysis for determining whether the data associated with the registration you have cited contains exclusive use data. First, the data associated with this registration do pertain to, or have been derived from testing on, a new active ingredient that was first registered after September 30, 1978. Second, the data were submitted in support of the first registration of the new chemical[1]. The registration cited was granted on August 31, 2015 and was the first registration for oxathiapiprolin. Third, the data were not submitted to satisfy FIFRA section 3(c)(2)(B). Data generated by IR-4 are not entitled to exclusive use protection (see 40 CFR 152.94(b)). However, the Agency will count minor uses supported by IR-4 generated data when determining how many additional years that exclusive use protection may be extended.

Although EPA has determined that there are exclusive use protected data associated with this registration, the Agency has not made individual determinations on every study associated with the above referenced registration as to exclusive use protection. If the Agency receives a me-too application for this pesticide during the extension period citing Corteva Agriscience, LLC data, it will then address which of those data have the extension of protection. Therefore, this response is a general determination that the exclusive use studies associated with this registration will receive the determined extension of exclusive use protection.

After determining that there are exclusive use data associated with this registration, EPA

[1] Data are not protected solely because they pertain to the new chemical, but because they are submitted in support of a particular product registration of a new chemical. Thus, data submitted to support an application for the second (and later) registrations, by whatever applicant, of a product containing the same new chemical acquire no exclusive use protection. Additionally, data submitted in support of subsequent amendments to add new uses to the first registration of a product containing the new chemical gain exclusive use protection, but the protection is limited to data that pertain solely to the new use. Thus, for example, if the new use is approved after eight years of registration, the data supporting that use would gain exclusive use protection for only two years, or the reminder of the original 10-year exclusive use period. See 49 FR 30884, 30889.

analyzed whether: (1) minor uses have been registered within seven years of the original registration and (2) at least one of the following required criteria were satisfied for extending the exclusive use protection pursuant to FIFRA section 3(c)(l)(F)(ii). FIFRA section 3(c)(l)(F)(ii) states, in pertinent part:

"The period of exclusive data use provided under clause (i) shall be extended 1 additional year for each 3 minor uses registered after the date of enactment of this clause, and within 7 years of the commencement of the exclusive-use period, up to a total of 3 additional years for all minor uses registered by the Administrator if the Administrator, in consultation with the Secretary of Agriculture, determines that, based on information provided by an applicant for registration or a registrant, 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."

SUMMARY OF FINDINGS

EPA evaluated information about characteristics of oxathiapiprolin, disease management claims, and production practices for the minor crops submitted. The Fungicide Resistance Action Committee (FRAC) has designed a group classification system based on a fungicide's mode of action. Oxathiapiprolin is classified in FRAC Group 49 with target site code F9 lipid homeostasis and transfer/storage.

Corteva Agriscience, LLC identified fourteen qualifying minor crops and submitted information to substantiate that each crop met at least one of the four criteria above. EPA determined that thirteen of the minor crops (the minor use sites other than orange [postharvest]) are supported by residue data and all thirteen qualify as minor uses, as the crops are cultivated on less than 300,000 acres. Orange [postharvest] was not assessed further because residue data could not easily be confirmed and, also, a maximum of three crops (lemon, grapefruit, and tangerine) representing citrus fruit crop group 10-10 had been claimed. Table 1 summarizes the minor use crops claimed by the registrant, the date those uses were registered, the relevant crop groups, and the exclusive use criteria claimed.

Table 1. Proposed minor crops, registration dates, crop groups, and exclusive use criteria claimed.

Minor Use Claimed	Date Registered	Crop Group or Subgroup	Number of Minor Use Sites Allowed (a)	Criteria Claimed
Asparagus	11/14/2016	Subgroup 22A	1	I
Basil	11/14/2016	Group 25 (b)	2 (c)	I
Blackberry	11/14/2016	Subgroup 13-07A	1	III, IV
Blueberry, highbush	8/17/2020	Subgroup 13-07B	1	III, IV
Hops	8/17/2020	None	1	I
Strawberry	8/17/2020	Subgroup 13-07G	1	III, IV
Avocado	8/17/2020	Subgroup 24B	2	III, IV
Pomegranate				III, IV
Grapefruit	11/14/2016	Group 10-10	3	III
Lemon				III
Tangerine				III
Orange, post-harvest	11/14/2016	Group 10-10, post-harvest	NC (d)	I, III
Hazelnut	8/17/2020	Group 14-12	2	III
Macadamia nut				III

Notes: (a) The number of minor use sites allowed is determined by the number of representative crops if a use on a crop group or subgroup is registered. (b) Basil is in crop group 25 but the registered use is on only basil, not a crop group or subgroup. (c) There are two minor use sites allowed for basil because it is registered for field use and greenhouse use. 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. (d) NC = not considered.

Because the petition claimed criterion III for 11 crops (Table 1), EPA'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.

The registrant claimed that oxathiapiprolin plays or will play a significant part in managing pest resistance in 11 crops (blackberry; blueberry [highbush]; strawberry; avocado; pomegranate; grapefruit; lemon; tangerine; orange (postharvest treatment); hazelnut; and macadamia nut). Orange (postharvest) was not assessed because three crops (lemon, grapefruit, and tangerine) representing crop subgroup 10-10 were claimed. EPA determined that criterion III was met in the other ten claimed crops.

The Agency determined that all ten of these minor uses (blackberry; blueberry [highbush]; strawberry; avocado; pomegranate; grapefruit; lemon; tangerine; hazelnut; and macadamia nut) were registered within seven years of the original registration of Zorvec® Technical, EPA Registration No. 352-890 and are on active end use product labels. Further, the Agency verified that there are oxathiapiprolin tolerance citations for these ten minor uses. EPA also confirmed that the relevant end use product labels include substantive resistance management sections that comply with Pesticide Registration Notice 2017-1 "Guidance for Pesticide Registrants on Pesticide Resistance Management Labeling" by identifying the FRAC group and by describing a

resistance management strategy that includes a limit of two sequential applications of the product before rotating to a fungicide with a different mode of action, using tank mixtures when permitted, and other resistant management steps.

The following is a summary of how each crop meets criterion III and thus counts towards extending the exclusive use period. This summary was based upon the information provided by the registrant and reviewed by EPA. This decision is supported by the document "A Review of Corteva's Petition for Extension of the Exclusive Use Period for Oxathiapiprolin" dated March 11, 2023. This document contains a more detailed explanation of how each crop meets the standard for extending the exclusive use period.

Applicability of Criterion III to oxathiapiprolin:

Blackberry; blueberry, highbush; and strawberry: Oxathiapiprolin is the only registered fungicide in FRAC group 49 for control of *Phytophthora* diseases in blueberry (root rot), strawberry (crown and root rot) and highbush blackberry (root rot). In these crops, conventional fungicides recommended by external crop production experts for use to control *Phytophthora* diseases include metalaxyl, mefenoxam, fosetyl-Al, and phosphites; these fungicides have different mode of action than oxathiapiprolin. 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.

Citrus trees (grapefruit; lemon; and tangerine): Oxathiapiprolin is the only registered fungicide in FRAC group 49 for control of *Phytophthora* spp. causing root rot in citrus trees (lemon, grapefruit, tangerine) resulting in tree decline and death. The alternative conventional fungicides recommended by external crop production experts for controlling *Phytophthora* spp. citrus root rot include metalaxyl, mefenoxam, and phosphite. Oxathiapiprolin has different mode of action than these alternative recommended fungicides and can be applied in rotation and/or in 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.

Avocado; pomegranate; hazelnut and macadamia nut: In hazelnut, macadamia nuts, avocado and pomegranate, oxathiapiprolin is the only fungicide in FRAC group 49 for control of *Phytophthora* spp., which cause root rot of hazelnut trees, macadamia tree decline, root rot of avocado and root and collar rot of pomegranate. For controlling *Phytophthora* spp. on these crops, metalaxyl, mefenoxam, and phosphorus acid are the conventional chemicals recommended by external crop production experts. Oxathiapiprolin has different mode of action than these 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.

DETERMINATION

The Agency concludes that you have provided sufficient evidence to support extension of exclusive use of data under FIFRA Section 3(c)(1)(F)(ii) for at least nine minor use sites required

to attain three additional years of data exclusivity under criterion III and these uses were registered within seven years of the original oxathiapiprolin registration. The minor use registrations which support this overall finding are blackberry; blueberry [highbush]; strawberry; avocado; pomegranate; grapefruit; lemon; tangerine; hazelnut; and macadamia nut. Therefore, the Agency **GRANTS** your request for a three-year extension of the original exclusive-use data protection period for data submitted to support EPA Registration No. 352-890. Exclusive-use protection for data, which complies with 40 C.F.R. 152.83(a), submitted in support of this registration **will expire on August 31, 2028.** A copy of our review is enclosed.

Sincerely,

Digitally signed by
CHARLES SMITH
Date: 2023.07.19
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Charles "Billy" Smith, Director
Registration Division (7505T)
Office of Pesticide Programs
U.S. Environmental Protection Agency

Enclosure: A Review of Corteva's Petition for Extension of the Exclusive Use Period for Oxathiapiprolin.