



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

April 23, 2024

Amy Dugger-Webster
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Subject: Product Name: Cyflumetofen Technical
EPA Reg. No.: 7969-355
Action Code Case No.: 472052
Application Date: December 15, 2022
EPA Finding: Extend the exclusive use data protection period for cyflumetofen by an additional year from May 9, 2026 to May 9, 2027

Dear Ms. Dugger-Webster:

This letter addresses your request that certain data associated with the original registration of cyflumetofen receive the full three-year extension after the ten-year exclusive use protection period. Cyflumetofen Technical (EPA Reg. No. 7969-355) was first registered by the agency on May 9, 2014. Without an extension of exclusive use protection, the data protection period would expire on May 9, 2024. In October 2018, EPA granted a two-year extension of the exclusive use period for cyflumetofen to May 9, 2026, because EPA determined that eight crops met the required criteria based on the Agency's analysis of the petition BASF submitted on May 30, 2017, and amended on August 14, 2017.

On December 15, 2022, BASF submitted another exclusive use petition and requested that EPA extend the exclusive use period for one additional year. The 2022 petition provided information about the following 15 minor crops: certain greenhouse-grown fruiting vegetables (tomatoes, bell pepper, non-bell pepper, and eggplant); greenhouse-grown strawberries; greenhouse-grown cucumbers; certain field grown stone fruits (peach, sweet and tart cherries, plum, plumcot, nectarines, prunes, and apricot) registered June 24, 2020; and hops registered December 8, 2021¹. After review of this petition, EPA is granting the request for an exclusive use extension of one additional year. Therefore, the data protection period will expire on May 9, 2027 for EPA Reg. No. 7969-335.

¹ This commodity (hops) was registered outside of the required 7-year period.

BASF Corporation cited FIFRA section 3(c)(1)(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)(1)(F). FIFRA section 3(c)(1)(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.

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 chemical². The registration cited was granted on May 9, 2014, and was the first registration for cyflumetofen. 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

² 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 remainder of the original 10-year exclusive use period. See 49 FR 30884, 30889.

application for this pesticide during the extension period citing BASF Corporation 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 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)(1)(F)(ii). FIFRA section 3(c)(1)(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 PREVIOUS FINDINGS

On May 30, 2017, BASF submitted a petition with information about 37 crops and requested a 3-year extension of the exclusive use period for cyflumetofen. An updated petition was submitted on August 14, 2017. EPA reviewed this request to extend the exclusive use period for cyflumetofen and, in 2018, concluded that eight of the crops submitted in that request met at least one of the required criteria, qualified as minor crops under FIFRA's acreage-based definition, and were supported by residue data. Those crops were lemons, grapefruits, pears, and strawberries, and a total of four minor crop members of the citrus, tree nut and pome fruit crop groups (e.g., tangerines, macadamia nuts, hazelnuts, and Asian pears). FIFRA specifies that the period of exclusivity can be extended one year for every three qualifying minor uses up to a maximum of three years. On October 9, 2018, EPA granted a two-year extension of the exclusive use period for cyflumetofen from May 9, 2024 to May 9, 2026.

Six of the eight qualifying crops submitted in 2017 supported that two-year extension of the cyflumetofen exclusive use period. Therefore, two of the qualifying crops identified by EPA in 2018 are available to support extending the exclusive use period for cyflumetofen by one more year and only one additional qualifying minor crop is needed to reach the FIFRA threshold of three qualifying minor uses to support a one-year extension.

SUMMARY OF FINDINGS

EPA evaluated information about characteristics of the miticide, cyflumetofen, a member of the

beta-ketonitrile derivatives class of chemistry. Cyflumetofen's mode of action is to disrupt respiration, because it is a mitochondria complex II electron transport inhibitor. It is categorized in Group 25A, according to the Insecticide Resistance Action Committee (IRAC). It is currently the only Group 25A active ingredient that is registered for use in the United States. Labeled target pests are all web spinning spider mites (Family Tetranychidae). It is a contact miticide for use against all life stages (eggs, nymphs, and adults).

In the 2022 petition, BASF Corporation identified fifteen minor crops and submitted information to substantiate that each crop met at least one of the four criteria above. BASF Corporation claimed that hops meet criterion I (insufficient efficacious registered alternatives); criterion III (playing a significant part in managing pest resistance) and criterion IV (playing a significant part in integrated pest management). BASF Corporation claimed that the other 14 crops meet criterion III and criterion IV. Table 1 summarizes the minor use crops claimed by the registrant, the date those uses were registered, and the relevant crop groups.

Table 1. Proposed minor crops, registration dates, crop groups and maximum number of use sites allowed.

Minor Use Claimed	Date Registered (added to 7969-335)	Crop Group or Subgroup, if registered (on end use label)	Residue Data Submitted for Crop Group/ Subgroup (date and MRID #)	Maximum Number of Use Sites Allowed
Greenhouse tomatoes*	6/24/2020	Fruiting vegetables group 8-10	50716501 (greenhouse (GH) tomato, includes standard size and a cultivar of a small tomato)	4
Greenhouse peppers and non-bell peppers*			50716502 (GH pepper, includes bell pepper and non-bell pepper)	
Greenhouse non-bell peppers and eggplant*				
Greenhouse strawberries*	6/24/2020	Not applicable: strawberry only	50716507 (GH strawberry)	1
Greenhouse cucumbers*	6/24/2020	Not applicable: cucumber only	50716503 (GH cucumber)	1
Peaches*	6/24/2020	Stone fruit group 12-12	50716504 (peach) 50716505 (plum) 50716506 (cherry)	3
Sweet and tart cherries*				
Plums*				
Plumcots*				
Nectarines*				
Prunes*				
Apricots*				
Hops	12/8/2021 (2)	No crop group	51047801 (hops)	1

Notes: (1) Cyflumetofen (EPA Reg. No. 7969-335) was initially registered on 5/9/14. (2) The hops use is not eligible because it was registered outside the initial 7-year period. The registrant claims that all of

the commodities marked with asterisks meet criteria III and IV to extend the exclusive use. The registrant claims that hops meet the exclusive use criteria I, III, and IV.

The Agency determined that all of the claimed minor uses in Table 1 were registered within seven years of the original registration of Cyflumetofen Technical, EPA Registration No. 7969-355, except for hops since it was registered in December 2021 and thus does not meet the requirement that a qualifying minor use must be registered within seven years of the commencement of the exclusive use period. EPA determined that all of the uses in Table 1 are on active end use product labels and verified that there are cyflumetofen tolerance citations for all of the uses listed in Table 1. EPA also confirmed that the relevant end use product labels include substantive resistance management sections as stated in Pesticide Registration (PR) Notice 2017-1 “Guidance for Pesticide Registrants on Pesticide Resistance Management Labeling” by identifying the IRAC group and by describing a resistance management strategy that includes rotating to a miticide with a different mode of action, monitoring mite populations for resistance development, using tank mixtures when possible, and listing the IRAC recommendations specified in PR Notice 2017-1.

Because only one additional crop is needed to meet the threshold of three qualifying minor uses to extend the exclusive use period by one additional year, the Agency focused its review on two of the claimed crops: peaches and plums. EPA determined that peaches and plums are minor uses because they are grown on less than 300,000 acres and that both crops meet at least one of the exclusive use criteria. The other crops in Table 1 that were registered within 7 years of the original registration of cyflumetofen technical were not evaluated because these two crops plus the two remaining qualifying crops from 2018 support the additional year of extension to reach the three-year maximum.

The following is a summary of EPA’s determination that peaches and plums meet exclusive use criterion III (playing a significant part in managing pest resistance) and criterion IV (playing a significant part in integrated pest management. EPA reviewed extension literature and the suite of available miticides for peaches and plums to confirm the criteria claimed by BASF were reasonably applicable. This summary is based upon the information provided by the registrant and reviewed by EPA. This decision is supported by the document “Review of a Petition by BASF for the Extension of Exclusive Use of Data for Cyflumetofen (PC# 138831)” dated April 17, 2024.

To support criterion III, the registrant stated that cyflumetofen is the only member of its IRAC mode of action (MOA) group that is currently registered in all listed crops in the U.S. They also stated that many of the mites it can control are prone to developing resistance to multiple MOAs frequently; they stated that this is particularly true of spider mites, which can damage all of the crops that cyflumetofen is registered for. The registrant submission also pointed out that alternating (also called “rotating”) miticide active ingredient MOAs across multiple treatments is a key basic component of reliable resistance management programs and asserted that cyflumetofen provides value as a member of effective resistance management programs aimed at mite pests in all crops, mainly because of its unique MOA.

EPA confirmed that cyflumetofen continues to be the only member of its biochemical MOA (IRAC Group 25A) that is registered in the U.S. at this time. In addition, EPA found research and extension literature indicating that spider mites (e.g., two-spotted spider mite, *Tetranychus*

urticae) are well known for their propensity to develop resistance to many miticide modes of action. Depending on the region, IRAC has determined that spider mite populations have developed at least isolated resistance to at least 10 miticide modes of action, out of a total of 16 currently registered in the U.S. Based on these findings, EPA concludes that peaches and plums meet criterion III because cyflumetofen serves as part of a pest management strategy to delay the development of pest resistance to other miticides with different modes of action and is likely used in situations where one major target pest, spider mites, have already developed resistance in the U.S. to alternative miticides.

To support criterion IV, the registrant summarized information from Koppert, a company that provides mass-reared biological control agents (insect and mite predators and parasitoids) for a wide range of pests, including the spider mites that cyflumetofen can target. In addition to providing supplies to growers and other interested parties of biological control organisms, Koppert also maintains a publicly available database of the level of mortality that several insecticides and miticides have on beneficial natural enemies such as predatory and parasitic insects and mites that should be part of Integrated Pest Management (IPM) programs. The registrant used this information to assert that criterion IV applies to cyflumetofen because it has low-to-no impact on non-chemical pest control strategies (such as biological control, cultural practices such as growing plants in nearby habitat that attract pests away from a crop or attract natural enemies of pests towards a crop field) that are part of an IPM program.

EPA considers the Koppert side-effects database a reasonably valid source of this type of information and has used it in its registration review work. EPA also reviewed scientific literature published on the effects of cyflumetofen on natural enemies of spider mites (as well as several other crop damaging mites). Results from a recent study show low to moderate lethal impacts of cyflumetofen on three predatory mites commonly used to control spider mites. That study mentions several other studies that found low negative effects of cyflumetofen on other predatory mite species. EPA concludes that peaches and plums also meet criterion IV.

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 and that these uses were registered within seven years of the original cyflumetofen registration. Eight qualifying minor uses were identified in 2018; six of those supported EPA extending the exclusive use period for cyflumetofen by two years from May 9, 2024 to May 9, 2026. (See the attached October 9, 2018 letter). The two remaining minor uses determined to qualify in 2018 plus the current determination that peaches and plums are also qualifying minor uses reach the FIFRA threshold of three qualifying minor uses supporting an extension of exclusive use protection of one year. Therefore, the Agency **GRANTS** your request for an additional one-year extension of the original exclusive-use data protection period for data submitted to support EPA Registration No. 7969-355. Exclusive-use protection for data, which complies with 40 C.F.R. 152.83(a), submitted in support of this registration **will expire on May 9, 2027**. A copy of our review and a copy of our October 9, 2018 letter are enclosed.

Sincerely,

Charles "Billy" Smith, Director
Registration Division (7505T)
Office of Pesticide Programs

Enclosures:

1. A Review of BASF's 2022 Petition for Extension of Exclusive Use for Cyflumetofen
2. EPA's October 9, 2018, response to BASF's Initial Request for the Extension of Exclusive Use for Cyflumetofen.