



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460**

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

November 28, 2017

Robin Charlton  
Senior Regulatory Scientist  
Valent USA Corporation  
1600 Riviera Ave, Suite 200  
Walnut Creek, CA 94596

**Subject: Product Name: Fluopicolide Technical  
EPA Reg. No. 59639-139  
Decision: 523531  
Application Dated 11/4/2016  
EPA Finding: Extends the exclusive use data protection period by 3 years from  
January 28, 2018 to January 28, 2021**

Dear Ms. Charlton:

This letter addresses your request that data associated with the original registration of fluopicolide receive a three-year extension to the original ten-year exclusive use protection period. The original data protection period started January 28, 2008 and ends January 28, 2018. Though only nine registered minor crops are needed to support the request, the following thirteen were cited: mustard greens; broccoli; cabbage; head lettuce; leaf lettuce; celery; spinach; horseradish; ginseng; carrot; sweet potato and yam; onion, bulb; and garlic. EPA is granting the request for an exclusive use extension of three additional years to end January 28, 2021 under EPA Registration No 59639-139.

Valent U.S.A. 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(c), 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; and

(3) The study was not submitted to satisfy a data requirement imposed under FIFRA section 3(c)(2)(B); and 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.<sup>1</sup> The registration cited was granted on January 28, 2008 and was the first registration for fluopicolide with the product name "Fluopicolide Technical."

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 Valent 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), and if so, by how many years. FIFRA section 3(c)(1)(F)(ii) states, in pertinent part:

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<sup>1</sup> 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.

“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 fluopicolide, disease claims, and production practices for nine minor crops. The Fungicide Resistance Action Committee (FRAC) has designed a group classification system based on a fungicide’s mode of action. Fluopicolide is classified as a pyridinylmethyl-benzamide fungicide (FRAC Group 43), which acts to affect the fungus cytoskeleton and motor proteins. Fluopicolide is the only active ingredient in FRAC Group 43.

Valent U.S.A. Corporation identified thirteen qualifying minor crops and submitted information to substantiate that each crop met at least one of the four criteria above. The Agency determined the following nine minor uses met criterion III. The Agency also determined that the following nine minor uses were registered within seven years of the original registration of Fluopicolide Technical: mustard greens, broccoli, cabbage, head lettuce, leaf lettuce, spinach, ginseng, bulb onion, and garlic.

The Agency verified there are fluopicolide tolerance citations for the nine minor use crops in 40 CFR 180.627. Additionally, each of the end-use labels contains a resistance management section and FRAC code and resistance management information as a partner in a resistance management program. The following is a summary of each crop and the criterion that was met to count towards extending the exclusive-use period. This summary was based upon the information provided by the registrant and reviewed by EPA. Please review the supporting document “Review of Request for an Extension of Exclusive Use Period for Fluopicolide” dated September 7, 2017 for a more detailed explanation of how each crop meets the standard for extending the exclusive-use period.

**Mustard greens, broccoli, and cabbage:** Fluopicolide targets the fungal pathogen, downy mildew, which may require season-long treatment. Because many fungicides restrict use to one or two sequential applications to prevent fungicide resistance development, it is vital to provide growers with multiple

fungicides of different FRAC groups to use in rotation and tank mixes with one another. Fluopicolide use on mustard greens, broccoli, and cabbage satisfies Criterion III.

**Head lettuce and leaf lettuce:** Fluopicolide targets downy mildew, the major disease impacting leaf and head lettuce. This pathogen has developed resistance to several pesticides thus far, so resistance management is of increasing importance. Fluopicolide is used as a component of an effective resistance management program. Fluopicolide use on head lettuce and leaf lettuce satisfies Criterion III.

**Spinach:** Fluopicolide plays a significant part in managing disease resistance for control of downy mildew and white rust on spinach. Fluopicolide use on spinach satisfies Criterion III.

**Ginseng:** Tank mixing and alternation of fungicide active ingredients are required by restrictions on many pesticides labeled for use on ginseng. As the only active ingredient in Group 43, fluopicolide could serve as a useful component of effective resistance management by use as a rotation or tank mix partner to fungicides in other FRAC groups. Fluopicolide use on ginseng satisfies Criterion III.

**Bulb onion and garlic:** Fluopicolide targets the fungal pathogen, downy mildew, which can cause serious crop damage to these bulb crops. Because many fungicides restrict use to one or two sequential applications in order to prevent fungicide resistance development, it is vital to provide growers with multiple fungicides of different FRAC groups to use in rotation and tank mixes with one another. Fluopicolide use on bulb onion and garlic satisfies Criterion III.

#### **DETERMINATION**

The Agency concludes that the nine uses listed above are minor uses and were registered within seven years of the original fluopicolide registration. These minor uses were found to meet at least one of the four criteria listed above. 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.59639-139. Exclusive-use protection for data, which complies with 40 C.F.R. 152.83(c), submitted in support of this registration **will expire on January 28, 2021**. A copy of our review is enclosed.

Sincerely,



Michael Goodis, PE  
Director, Registration Division (RD)  
Office of Pesticide Programs (OPP)

Enclosure: Review of Request for an Extension of Exclusive-Use Period for Fluopicolide