



UNITED STATES ENVIRONMENTAL PROTECTION  
AGENCY WASHINGTON, DC 20460

OFFICE OF  
CHEMICAL SAFETY  
AND POLLUTION  
PREVENTION

October 11, 2023

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Subject: Product Name: Benzovindiflupyr Technical  
EPA Reg. No.: 100-1478  
Decision No.: 581361  
Application Date: January 19, 2022  
EPA Finding: Extend the exclusive use data protection period for  
benzovindiflupyr by 3 years from August 28, 2025 to August 28, 2028

Dear Dr. Clark:

This letter addresses your request that certain data associated with the original registration of benzovindiflupyr receive a three-year extension to the ten-year exclusive use protection period. Benzovindiflupyr Technical (EPA Reg. No. 100-1478) was first registered by the agency on August 28, 2015. Without an extension of exclusive use protection, the data protection period would expire on August 28, 2025. Though only nine registered minor crops are needed to support this request, the following twenty were cited: blueberry (lowbush), sweet potato, triticale, garlic, green onion, ginseng, dry lima bean, dry southern pea, bell pepper, non-bell pepper, eggplant, tomatillo, cucumber, watermelon, squash, pear, quince, kiwifruit (hardy), sesame, and fescue grass.

After review of this petition, EPA is granting the request for an exclusive use extension of three additional years to end on August 28, 2028, for EPA Registration No. 100-1478.

Syngenta Crop Protection, LLC 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 chemical<sup>1</sup>. The registration cited was granted on August 28, 2015 and was the first registration for benzovindiflupyr. 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 Syngenta Crop Protection, 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 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:

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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 benzovindiflupyr, 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. Benzovindiflupyr is classified in FRAC Group 7 which includes succinate-dehydrogenase inhibitors (SDHIs).

Syngenta Crop Protection, LLC identified twenty minor crops and submitted information to substantiate that each crop met at least one of the four criteria above. The criteria claimed for each crop are shown in Table 1. Syngenta Crop Protection, LLC claimed criterion III (playing a significant part in managing pest resistance) for all of the crops except blueberry and kiwifruit. Criterion I (insufficient efficacious registered alternatives) was claimed for ten crops; criterion II (alternatives pose greater risks) was claimed for three crops; and criterion IV (playing a significant part in integrated pest management) was claimed for fourteen crops. EPA determined that all of the minor crops are supported by residue data and all twenty qualify as minor uses, as the crops are cultivated on less than 300,000 acres. 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.

The Agency determined that all twenty of these minor uses were registered within seven years of the original registration of Benzovindiflupyr Technical, EPA Registration No. 100-1478 and are on active end use product labels. Further, the Agency verified that there are benzovindiflupyr tolerance citations for these twenty minor uses. EPA also confirmed that the relevant end use product labels include substantive resistance management sections as stated in 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, applying early to keep fungal pressures low and other resistance management steps.

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

Minor Use Claimed	Date Registered	Crop Group or Subgroup, if Registered	Number of Minor Use Sites Allowed (a)	Criteria Claimed
Blueberry (lowbush) (b)	12/17/2020	Not applicable	1	IV
Sweet potato (b)	8/28/2015	Subgroup 1C	1	I, III
Triticale (b)	8/28/2015	Not applicable	1	I, III
Garlic (b)	12/21/2017	Subgroup 3-07A	1	I, III, IV
Onion, green	12/21/2017	Subgroup 3-07B	1	I, III, IV
Ginseng	12/17/2020	Subgroup 1B	1	III, IV
Dry lima bean	8/28/2015	Subgroup 6C	2	I, III
Dry southern pea				
Bell pepper (b)	8/28/2015	Group 8-10	4	III, IV
Non-bell pepper (b)				I, III, IV
Eggplant				
Tomatillo				
Cucumber (b)	8/28/2015	Group 9	3	III, IV
Watermelon (b)				
Squash (b)				
Pear	8/28/2015	Group 11-10	2	I, II, III
Quince				
Kiwifruit (hardy)	8/28/2015	Subgroup 13-07F	1	II, IV
Sesame	8/28/2015	Subgroup 20A	1	III, IV
Fescue Grass	6/14/2018	Not applicable	1	III, IV

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) These are the nine minor uses that EPA reviewed and determined each one met at least one of the claimed criteria.

EPA reviewed the claimed criteria for blueberry (lowbush), sweet potato, triticale, garlic, bell pepper, non-bell pepper, cucumber, watermelon and squash and determined that at least one of the claimed criteria was met for each of these crops. The other eleven crops were not evaluated because those nine crops met at least one criterion and thus supported the maximum three-year extension of the exclusive use for benzovindiflupyr.

The following is a summary of how each of the nine reviewed crops meets at least one of the criteria 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 Syngenta’s Petition for Extension of Exclusive Use for Benzovindiflupyr” dated May 8, 2023. This document contains a more detailed explanation of how each crop meets the standard for extending the exclusive use period.

***Blueberry (lowbush)***

Syngenta Crop Protection, LLC claimed that benzovindiflupyr will play an important role in integrated management of rust disease in blueberry as the pathogen can survive on alternate host (hemlock) that can result in rust disease epidemic and that benzovindiflupyr is effective in

controlling rust disease. Conventional fungicides dominantly used by growers for controlling rust disease in blueberry (lowbush) include strobilurins (e.g., azoxystrobin and pyraclostrobin) and triazoles (e.g., propiconazole, metconazole and prothioconazole). External crop production experts find that benzovindiflupyr is effective in controlling rust disease on blueberry; and its mode of action is different than commonly used fungicides for controlling the disease and therefore can play a role in resistance management. EPA finds that benzovindiflupyr can play an important role in an integrated pest management program for controlling rust disease in blueberry (lowbush) when used with cultural practices (such as removal of alternate host [hemlock]) to reduce pathogen inoculum and with fungicides having different mode of action. Based on submitted and available information, EPA finds that claimed criterion IV is met.

### ***Sweet Potato***

Syngenta Crop Protection, LLC claimed that *Rhizoctonia* disease of sweet potatoes can severely affect crop yields and quality. External crop production experts identify azoxystrobin (a strobilurin fungicide, FRAC Group 11) as a widely used fungicide for controlling *Rhizoctonia* disease due to its high efficacy but Syngenta Crop Protection, LLC states that resistance development in the pest is a major concern for growers as it has single site mode of action. The submitted data show that benzovindiflupyr fungicide has high efficacy in controlling *Rhizoctonia* and belongs to another class of fungicides (SDHI fungicides, FRAC Group 7). EPA finds that there are inadequate number of effective registered alternatives in controlling *Rhizoctonia* in sweet potatoes. EPA also finds that benzovindiflupyr can play a role in fungicide resistance management as its mode of action is different than azoxystrobin. Based on submitted and available information, EPA finds that claimed criteria I and III are met.

### ***Triticale***

Syngenta Crop Protection, LLC claimed that benzovindiflupyr is highly effective in controlling rust and glume blotch diseases of cereals including triticale and that strobilurin (e.g., azoxystrobin and pyraclostrobin) and triazole (such as propiconazole and tebuconazole) fungicides are dominantly used in controlling rust and glume blotch diseases in triticale. Data show that the efficacy of strobilurins and triazole fungicides in controlling cereals diseases is declining, after many years of continuous use, due to tolerance or resistance in fungal pests. Benzovindiflupyr has different mode of action (FRAC Group 7) than strobilurins (FRAC Group 11) and triazoles (FRAC Group 3). Based on submitted and available information, EPA finds that claimed criterion III is met.

### ***Garlic:***

Syngenta Crop Protection, LLC claimed that benzovindiflupyr is more efficacious than widely used alternatives, including tebuconazole and azoxystrobin, in controlling rust disease, and plays a role in fungicide resistance management and IPM. Review of publicly available information showed that tebuconazole (FRAC Group 3), azoxystrobin (FRAC Group 11) and mancozeb (FRAC Group M03) are recommended by external crop production experts and used for controlling garlic rust. Benzovindiflupyr has different mode of action (FRAC Group 7) than these fungicides and therefore benzovindiflupyr fungicide plays a role in fungicide resistance management when used in combination and/or rotation with fungicides having different mode of action. Based on submitted and available information, EPA finds that claimed criterion III is met.

***Bell pepper, non-bell pepper, watermelon, cucumber and squash***

Syngenta Crop Protection, LLC claimed that anthracnose disease (caused by *Colletotrichum gloeosporioides* and *C. acutatum*) in bell-pepper and non-bell peppers is highly destructive and can cause high yield losses. Syngenta Crop Protection, LLC also claims that anthracnose disease (caused by *C. orbiculare*) in cucurbits (watermelon, cucumber, and squash) is an aggressive and highly destructive disease that can result in heavy yield losses. Registered alternatives available to growers to control anthracnose disease include azoxystrobin, pyraclostrobin, trifloxystrobin, difenoconazole, famoxadone, mancozeb, copper, fluopyram, fluxapyroxad and penthiopyrad. Among the registered alternatives, data show that other FRAC Group 7 fungicides have varying levels of effectiveness in controlling *C. gloeosporioides*, *C. acutatum* and *C. orbiculare* whereas benzovindiflupyr is highly effective in controlling the pest.<sup>2</sup> Therefore, benzovindiflupyr can be used by growers in combination and/or rotation with other fungicides having different mode of action for resistance management. Based on submitted and available information, BEAD finds that claimed criterion III is met for bell pepper, non-bell pepper, watermelon, cucumber, and squash.

**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 benzovindiflupyr registration. The minor use registrations which support this overall finding are blueberry (lowbush), sweet potato, triticale, garlic, bell pepper, non-bell pepper, cucumber, watermelon and squash. 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. 100-1478. 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 28, 2028**. A copy of our review is enclosed.

Sincerely,

Charles “Billy” Smith, Director  
Registration Division (7505T)  
Office of Pesticide Programs  
U.S. Environmental Protection Agency

Enclosure: A Review of Syngenta’s Petition for Extension of Exclusive Use for Benzovindiflupyr.

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<sup>2</sup> Ishii, H., Watanabe, H., Yamaoka, Y and Schnabel, G. 2022. Sensitivity to fungicides in isolates of *Colletotrichum gloeosporioides* and *C. acutatum* species complexes and efficacy against anthracnose diseases. Accessed on March 27, 2023. <https://www.sciencedirect.com/science/article/pii/S0048357522000165> and Ishii, H., Zhen, F., Hu, M., Li, X and Schnabel. 2016. Efficacy of SDHI fungicides, including benzovindiflupyr, against *Colletotrichum* species. Accessed on March 27, 2023. <https://onlinelibrary.wiley.com/doi/full/10.1002/ps.4216>.