



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

Alice Wei
Senior Regulatory Manager
Regulatory and Stewardship
Valent U.S.A. LLC
4600 Norris Canyon Rd
San Ramon, CA 94583

Subject: Product Name: S-2200 Fungicide Technical
 EPA Reg. No.: 59639-201
 Case No.: 654687
 Application Date: April 21, 2025
 EPA Finding: Extend the exclusive use data protection period for mandestrobin
 by 1 year from September 30, 2026 to September 30, 2027

Dear Alice Wei:

This letter addresses your request that certain data associated with the original registration of mandestrobin qualifies you for a three-year extension to the ten-year exclusive use protection period. S-2200 Fungicide Technical (EPA Reg. No. 59639-201) was first registered by the agency on September 30, 2016. Without an extension of exclusive use protection, the data protection period would expire on September 30, 2026. Though only nine registered minor crops would be needed to support this request, the following ten were initially cited with the original request: sweet potato, lettuce (head), lettuce (leaf), strawberry, flaxseed, hardy kiwifruit, green pea, lima bean, snap bean and popcorn. In an email dated 12/15/2025, Valent withdrew strawberry and hardy kiwifruit for consideration for this request as resistance in the claimed pathogen (*Botrytis cinerae*) has been reported to strobilurin fungicides. Valent withdrew green peas and lima bean for consideration for this request after discussing with EPA in a meeting on 12/17/2025, as only one crop qualifies based on residue studies in soybean in crop group 6.

After review of this petition, EPA is granting the request for an exclusive use extension of one additional year to end on September 30, 2027, for EPA Registration No. 59639-201.

Valent U.S.A. LLC cited FIFRA section 3(c)(I)(F)(ii) as the authority for EPA to make such a determination. FIFRA section 3(c)(I)(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 chemical¹. The registration cited was granted on September 30, 2016 and was the first registration for mandestrobin. 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 U.S.A. LLC data, it will then address which of those data have exclusive-use 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.

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

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 FINDINGS

Valent U.S.A. LLC identified ten 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. Valent U.S.A. LLC claimed mandestrobin fills a void in current fungal disease control programs and/or plays or will play a part fungicide resistance management, and integrated pest management programs, thus satisfying criteria I, III and/or IV as defined under FIFRA 3(c)(1)(F)(ii) in all claimed crops.

EPA determined that eight out of the ten use sites claimed by Valent are supported by residue data and all ten meet the criterion for minor crops as each is grown 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 ten of these minor uses were registered within seven years of the original registration of S-2200 Fungicide Technical (EPA Reg. No. 59639-201) and are on active end-use product labeling. Further, the Agency verified that there are tolerances established for each claimed minor use as applicable. EPA also confirmed that the relevant end-use product labeling includes resistance management sections consistent with Pesticide Registration Notice 2017-1 "Guidance for Pesticide Registrants on Pesticide Resistance Management Labeling" by identifying the FRAC group and by recommending a resistance management strategy.

Table 1. Submitted minor crops for consideration, 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
Sweet Potato	March 8, 2023	Root and Tuber Vegetables, Crop Group 1D	1	I
Lettuce, head	June 29, 2022	n/a	2	IV Lettuce, head
Lettuce, leaf				IV Lettuce, leaf
Strawberry*	September 30, 2016	Berry and small Fruit, Crop Group 13-07G	1	III
Hardy Kiwifruit*	September 30, 2016	Berry and small Fruit, Crop Group 13-07F	1	III
Flaxseed	June 29, 2022	Oilseed Group, Crop Group 20A	1	I
Green Peas**	July 23, 2020	Crop Group 6	1	IV Green Peas
Lima Bean**				IV Lima Bean
Snap Bean				I Snap Bean
Popcorn	July 23, 2020	n/a	1	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.

* Registrant withdrew for consideration for this request as resistance in the claimed pathogen (*Botrytis cinerae*) has been reported to strobilurin fungicides.

** Registrant withdrew for consideration for this request as only one crop qualifies based on residue studies in soybean in crop group 6.

EPA reviewed the claimed criteria for sweet potato, lettuce (head), lettuce (leaf), strawberry, flaxseed, hardy kiwifruit, green pea, lima bean, snap bean and popcorn and determined that the residue trial data submitted by the registrant is sufficient such that there is a one-for-one relationship for each claimed use site. In this case, green peas and lima bean were withdrawn for consideration for this request by the registrant after discussing with EPA, as residue studies were done for only soybean in crop group 6.

The following is a summary of how each of the eight reviewed crops meets, or failed to meet, at least one of the criteria to count 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 Valent’s Petition for Extension of Exclusive Use of Mandestrobin” dated March 9, 2026. This document contains a more detailed explanation of how each crop meets, or failed to meet, the criteria for extending the exclusive-use period.

The Agency determined that the registrant submitted sufficient evidence that three minor use sites (sweet potato; lettuce, head; lettuce, leaf) satisfy a minimum of one criterion under FIFRA Section 3(c)(1)(F)(ii) for a one-year extension of exclusive use of data for mandestrobin.

Sweet Potato

EPA concludes that claimed criterion I is met because mandestrobin is the only fungicide available to growers that can be applied as in-furrow treatment at planting to control black rot disease.

Lettuce, head and Lettuce, leaf

EPA concludes that mandestrobin can play a significant role in integrated pest management in both types of lettuce when used in combination with cultural practices such as depth of seed planting, soil moisture management, plant row spacing, and/or sanitation. Based on submitted and available information, EPA finds that claimed criterion IV is met.

Strawberry

Mandestrobin has been reported to have limited efficacy in controlling gray mold in strawberry due to resistance in the pathogen. A fungicide is unlikely to play a significant part in managing pest resistance if the pest has already developed resistance against it. EPA concludes that the submitted information does not support criterion III. The registrant withdrew strawberry for consideration for this request because of documented resistance in *Botrytis cinerea* to mandestrobin and strobilurin fungicides.

Hardy Kiwifruit

Gray mold, caused by *Botrytis cinerea*, infects stem ends and sepals of kiwi fruits resulting in fruit rotting in storage. EPA determined that multiple fungicides having different MOAs are registered for controlling the disease and managing resistance in the pathogen, and that fungicide resistance and cross resistance is present in the pathogen to strobilurin fungicides including mandestrobin. A fungicide is unlikely to play a significant part in managing pest resistance if the pest has developed resistance against it. EPA concludes that the submitted information does not support criterion III. The registrant withdrew hardy kiwifruit for consideration for this request due to resistance in *Botrytis cinerea* to strobilurin fungicides.

Flaxseed and Snap Bean

EPA concludes that registered alternatives are considered effective in controlling the pathogen, *Rhizoctonia solani*, and therefore, the submitted information does not support the claimed criterion.

Popcorn

EPA concludes that registered alternatives are considered effective in controlling the pathogen, *Rhizoctonia solani*, and the information provided did not elaborate on how mandestrobin will play a role in integrated pest management programs. Therefore, the submitted information does not support the claimed criterion.

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 three minor use sites required to attain one additional year of data exclusivity under criteria I and IV, and these uses were registered within seven years of the original mandestrobin registration. The minor use registrations which support this overall finding are sweet potato, lettuce (head), and lettuce (leaf). Therefore, the Agency **GRANTS** your request for a one-year extension of the original exclusive-use data protection period for data submitted to support EPA Registration No. 59639-201. Exclusive-use protection for data, which complies with 40 C.F.R. 152.83(a), submitted in support of this registration **will expire on September 30, 2027**. 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 Valent's Petition for Extension of Exclusive Use of Mandestrobin