



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 30, 2019

Adora Clark

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Subject: Product Name: Pydiflumetofen Technical
EPA Reg. No. 100-1609
Decision: 543313
Application Dated 7/27/2018
EPA Finding: Extends the exclusive use data protection period by 3 years from May 23, 2028 to May 23, 2031

Dear Ms. Clark:

This letter addresses your request that data associated with the original registration of pydiflumetofen receive a three-year extension to the original ten-year exclusive use protection period. The original data protection period started May 23, 2018 and ends May 23, 2028. Though only nine registered minor crops are needed to support the request, the following fifteen were cited:

- 1C group (tuber and corm) (Rep. crop is potato)
 - o Group includes ginger as minor use
- Crop Subgroup 6C. Dried shelled pea and bean (except soybean)(Rep. Commodity: one dried cultivar of bean (*Phaseolus* spp.); and any one dried cultivar of pea)
 - o Group includes kidney bean and lentil (or chickpea)
- Fruiting veg 8-10 (Rep commodities: Tomato, standard size, and one cultivar of small tomato; bell pepper and one cultivar of small nonbell pepper.
 - o Group includes minor uses bell pepper, eggplant, okra (or goji berry or sun berry or tomatillo)
- Group 4-16A (Rep commodities: Head lettuce, leaf lettuce, and spinach)
 - o Minor uses in this group: spinach and endive
- Cucurbit Crop Group 9 (Rep. Commodities: Cucumber, muskmelon, and summer squash)
 - o Group includes minor uses squash, cantaloupe, and watermelon
- Group 13-07F (Rep. Commodity Grape)
 - o Includes Amur river grape
- Group 20A (Rep. Commodity rapeseed variety)
 - o Minor use includes rapeseed.

- Group 22B- leafy petioles (Rep. commodity celery)
 - Includes minor use celery
- Also received uses for quinoa (and oats, rye)

EPA is granting the request for an exclusive use extension of three additional years to end May 23, 2031 under EPA Registration No 100-1609. 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(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 chemical¹. The registration cited was granted on May 23, 2018 and was the first registration for pydiflumetofen. 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

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.

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 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:

“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

In the submitted Request for Exclusive Use Extension, Syngenta identified the above listed minor crops with the statement: “Because these uses were determined to be reduced risk by EPA, Syngenta believes that all of the following criteria have been met:

- (I) The alternatives to the minor use pesticide pose greater risks to the environment or human health;
- (II) The minor use pesticide plays or will play a significant part in managing pest resistance; or
- (III) The minor use pesticide plays or will play a significant part in an integrated pest management program.”

In an Agency letter dated January 29, 2018, the Reduced Risk Committee approved pydiflumetofen as a reduced risk candidate for canola, cereal grains, corn, cucurbit vegetables, fruiting vegetables, grape, leafy vegetables, peanut, dried shelled pea and bean, potato, soybean, golf course turf, and ornamentals. The letter goes on to state, "pydiflumetofen appears to have a favorable human health and environmental risk profile when compared to registered alternatives. The chemical should fit in well with integrated pest management and resistance management strategies."

Based on this determination and the attached Review of a Request for Three-Year Extension of the Exclusive Use Period for Pydiflumetofen Fungicide, the following nine minor crops will support the extension of exclusive use:

- Spinach and Endive based on the reduced risk determination for Leafy Vegetables
- Cowpea and Mung bean based on the reduced risk determination for dried shelled pea and bean
- Bell pepper, Eggplant, and Okra based on the reduced risk determination for Fruiting Vegetables
- Muskmelon and Summer Squash based on the reduced risk determination for Cucurbit Vegetables

The Agency verified there are pydiflumetofen tolerance citations for the nine minor use crops in 40 CFR 180.699. 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.

DETERMINATION

The Agency concludes that the nine uses listed above are minor uses and were registered within seven years of the original pydiflumetofen 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.100-1609. Exclusive-use protection for data, which complies with 40 C.F.R. 152.83(c), submitted in support of this registration **will expire on May 23, 2031**. A copy of our review is enclosed.

Sincerely,



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

Enclosure: Review of a Request for Three-Year Extension of the Exclusive Use Period for Pydiflumetofen Fungicide