



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 18, 2019

Kristen B. Knox
Regulatory Affairs Manager
Nippon Soda Co., Ltd.
88 Pine Street, 14th Floor
New York, NY 10005

Subject: Product Name: Cyflufenamid Technical Fungicide
 EPA Reg. No. 8033-102
 Decision: 544634
 Application Dated 9/25/2018
 EPA Finding: Extends the exclusive use data protection period by 3 years
 from June 27, 2022 to June 27, 2025

Dear Ms. Knox:

This letter addresses your request that data associated with the original registration of cyflufenamid receive a three-year extension to the original ten-year exclusive use protection period. The original data protection period started June 27, 2012 and ends June 27, 2022. Though only nine registered minor crops are needed to support the request, the following thirteen were cited:

- Fruiting Vegetable Crop Group 8-10
 - o Group includes three minor uses: pepper, bell; pepper, non-bell; and eggplant
- Cucurbit Vegetables Crop group 9
 - o Group includes three minor uses: cantaloupe, cucumber, and summer squash
- Pome Fruits Crop Group 11
 - o Group includes two minor uses: pear and quince
- Cherry Subgroup 12-12A
 - o Includes two minor uses: sweet cherry and tart cherry
- Small Fruit Vine Climbing, except fuzzy kiwi, Subgroup 13-07F
 - o Includes the minor use gooseberry
- Low Growing Berry, except cranberry, Subgroup 13-07G
 - o Includes the minor use strawberry
- Hops

EPA is granting the request for an exclusive use extension of three additional years to end June 27, 2025 under EPA Registration No 8033-102. Nippon Soda Co., Ltd. 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 June 27, 2012 and was the first registration for cyflufenamid. 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 I 52.94(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.

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.

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 Nippon Soda 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

Cyflufenamid is a new fungicide with a new mode of action against powdery mildew fungi on all minor uses. The Fungicide Resistance Action Committee (2018) finds that this fungicide belongs to phenyl-acetamide chemical group, has unknown new mode of action, and it belongs to FRAC code U06. The fungicides with U classifications are individual fungicides with unknown target sites and of a different chemical class than other FRAC classes. Cyflufenamid is, therefore, different than other fungicides that are commonly used in controlling powdery mildew on the qualifying minor use crops. Cyflufenamid does not have cross resistance with other fungicides used for controlling powdery mildews which makes it likely to play an important role in fungicide resistance management. Therefore, cyflufenamid meets criteria III on more than nine minor crops.

The Agency verified there are cyflufenamid tolerance citations for the minor use crops in 40 CFR 180.667. 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 uses listed above are minor uses and were registered within seven years of the original cyflufenamid 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. 8033-102. Exclusive-use protection for data, which complies with 40 C.F.R. 152.83(c), submitted in support of this registration **will expire on June 27, 2025**. A copy of our review is enclosed.

Sincerely,

A handwritten signature in dark ink, appearing to read 'Michael Goodis', with a stylized, flowing script.

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 of Data for Cyflufenamid Fungicide