



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 1, 2021

Lisa A. Setliff
Regulatory Agent
K-I Chemical U.S.A., Inc.
c/o Landis International, Inc.
PO Box 5126
Valdosta, GA 31603-5126

Subject: Product Name: Pyroxasulfone Technical
EPA Reg. No.: 63588-91
Decision No.: 558702
Application Date: December 30, 2019
EPA Finding: Extend the exclusive use data protection period for pyroxasulfone by 3 years from February 15, 2022 to February 15, 2025.

Dear Ms. Setliff:

This letter addresses your request that certain data associated with the original registration of pyroxasulfone receive a three-year extension to the ten-year exclusive use protection period. Pyroxasulfone technical (EPA Reg. No. 63588-91) was first registered by the agency on February 15, 2012, and the data protection period will expire on February 15, 2022. Though only nine registered minor crops are needed to support the request, the following eleven were cited:

Crop Group/Subgroup	Crop Data Submitted ^a	Minor Use Represented ^b
Onion, bulb, subgroup (Crop subgroup 3-07A)	Onion bulb	Onion bulb
Onion, green, subgroup (Crop subgroup 3-07B)	Onion greens	Leek
Dried shelled pea and bean (except soybean) subgroup (Crop Subgroup 6C)	Dry beans	Faba (Broad) bean
Grass Forage, Fodder, and Hay Group (Crop Group 17)	Tall fescue	Fescue
Grass Forage, Fodder, and Hay Group (Crop Group 17)	Perennial ryegrass	Perennial ryegrass
Grass Forage, Fodder, and Hay Group (Crop Group 17)	Bluegrass	Orchard grass
Sunflower subgroup (Crop subgroup 20B)	Sunflower	Safflower
Leaf petiole vegetable subgroup	Celery	Celery

(Crop Subgroup 22B)		
Mint, Peppermint	Peppermint	Peppermint
Mint, Spearmint	Spearmint	Spearmint
Corn (field, pop and sweet)	Corn	Popcorn

^a All residue data submitted by registrant were conducted on representative crops listed in this column

^b Minor use sites proposed by the registrant

EPA is granting the request for an exclusive use extension of three additional years to end on February 15, 2025, under the EPA Registration No. 63588-91. Landis International 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. All of the minor use crop candidates were registered within the requisite seven years period, prior to February 15, 2019, and are grown on less than 300,000 acres per year.

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

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

registration cited was granted on February 15, 2012 and was the first registration for pyroxasulfone. 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.

Although, EPA has determined that there is 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 Landis International 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;

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.

- (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 pyroxasulfone, weed management claims, and production practices for the minor crops submitted. The Herbicide Resistance Action Committee (HRAC) has designed a group classification system based on an herbicide's mode of action. Pyroxasulfone is classified as a HRAC Group 15 herbicide. The mode of action of pyroxasulfone on annual grasses, sedges, and annual broadleaf weeds is inhibition of very long-chain fatty acid synthesis required for cell growth and division.

Landis International identified eleven 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 either criterion III or IV. The Agency also determined that the following nine minor uses were registered within seven years of the original registration of Pyroxasulfone Technical: faba bean, fescue, orchardgrass, perennial ryegrass, peppermint, spearmint, popcorn, onions, and leeks.

Further, the Agency verified there are pyroxasulfone tolerance citations for the nine minor use crops in 40 CFR 180.659. Additionally, each of the end-use labels contains a resistance management section and HRAC code and resistance management information. 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 Landis America's Request for an Extension of the Exclusive Use Period for Pyroxasulfone" dated November 23, 2020 for a more detailed explanation of how each crop meets the standard for extending the exclusive use period.

Applicability of Criterion III to pyroxasulfone:

Faba Bean, Fescue, Perennial Ryegrass, Orchardgrass, Peppermint, Spearmint, and Popcorn:

Pyroxasulfone controls a number of weed species such as lambs quarters, pigweeds, water hemp, and various annual grasses. Resistance management has become increasingly important among these weed species which have demonstrated herbicide resistance. The registrant has provided information illustrating that pyroxasulfone can be effectively used in the management of resistant weed populations across several crop species. EPA agrees with the information provided by the registrant and finds that pyroxasulfone satisfies criterion III and will play an important role in resistance management of problematic weed species in faba bean, fescue, perennial ryegrass, orchardgrass, peppermint, spearmint, and popcorn.

Applicability of Criterion IV to pyroxasulfone:

Dry Bulb Onions and Leeks: EPA has concluded that pyroxasulfone is a fit for use in IPM programs within the production of dry bulb onions and leeks. Advantages include its ability to effectively perform on muck soils and, when timed properly, elimination of manual weed removal, which can significantly reduce labor costs. Furthermore, the registrant provided evidence demonstrating pyroxasulfone's high level of weed control. EPA reviewed this information and agrees with the determination of high level weed control. This is illustrated in that integration of pyroxasulfone into weed management programs can reduce annual herbicide applications from 10 to 13 applications to just 4 applications per year. As established by the aforementioned benefits, pyroxasulfone is an effective tool that enables growers to practice field management strategies which are generally compatible with IPM principles. Therefore, the Agency finds dry bulb onions and leeks to meet criterion IV for extension of data exclusivity.

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 IV and these uses were registered within seven years of the original pyroxasulfone registration. The minor use registrations which support this overall finding are faba bean, fescue, orchardgrass, perennial ryegrass, peppermint, spearmint, popcorn, onions, and leeks. 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. 63588-91. Exclusive-use protection for data, which complies with 40 C.F.R. I 52.83(c), submitted in support of this registration **will expire on February 15, 2025**. A copy of our review is enclosed.

Sincerely,



for
Marietta Echeverria,
Acting Director, Registration Division (RD)
Office of Pesticide Programs (OPP)

Enclosure: Review of Landis America's Request for an Extension of the Exclusive Use Period for Pyroxasulfone.