



**US Environmental Protection Agency
Office of Pesticide Programs**

**EPA Response to Petition for
Pyriproxyfen**

June 21, 2004



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Thomas Schreier
Project Manager
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re: Request for extension of the period of exclusive use data protection for data submitted for Sumilary Technical Grade (EPA Reg. No. 10308-11)

Dear Mr. Shreier:

This is in response to your request dated April 20, 2004 that data associated with the registration of the active ingredient pyriproxyfen receive extensions for the exclusive use period protection. You cited FIFRA section 3(c)(1)(F)(ii) as the authority for the Agency to make such a determination.

The 1996 Food Quality Protection Act ("FQPA") amendments to FIFRA incorporated this new subsection under 3(c)(1)(F), the section that provides for protection of certain data submitted in support of pesticide registrations. 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 minor uses registered within the first seven years of an original registration whose data retains exclusive use protection, with a maximum of an additional three years to the exclusivity period.

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The first step in determining whether data qualifies for an extension of its exclusive use period is to ascertain which data have exclusive use protection. FIFRA section 3(c)(1)(F)(i) and its implementing regulations carefully circumscribe the set of data that is eligible for exclusive use protection. A study entitled to exclusive use protection is defined in 40 C.F.R. 152.83(c).

Pursuant to 40 CFR 152.83(c), the following requirements must be met for a study to be considered an exclusive use study:

- (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);

Provided that, 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.

Second, the data must have been submitted in support of the first registration of the new chemical.¹ The registration you cited was granted on September 15, 1995 and was the first

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 such 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. See 49 FR 30884, 30889.

registration for pyriproxyfen with the product name Sumilarv Technical.

Lastly, because exclusive use protection is not available for studies that the agency requires to maintain registration in effect under FIFRA section 3(c)(2)(B) any such data associated with this registration will not receive exclusive use protection under FIFRA section 3(c)(1)(F)(ii).

Now that the Agency has determined that studies associated with this registration are exclusive use studies², we must determine whether you have met the criteria 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 uses 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.

The registration of a pesticide for a minor use on a crop grouping established by the Administrator shall be considered for purposes of this clause 1 minor use for each representative crop for which data are provided in the crop grouping. Any additional exclusive use period under this clause shall be modified as appropriate or terminated if the registrant voluntarily cancels the product or deletes from the registration the minor uses which formed the basis for the extension of the additional exclusive use period or if the Administrator determines that the registrant is not actually marketing the product for such minor uses.

² Because the requestor did not attach a list of data they believe retain exclusive use protection, this response is general in nature. If the Agency receives a me-too application for this pesticide during the extension period citing Valent data, it will then address whether those data have the extension of protection.

After reviewing the Agency's files we have found the following.³ On April 20, 1999 and October 28, 1999 several minor uses were added to the Sumilarv Technical label. Many of the minor uses were added through the addition of crop groups.⁴ Each crop grouping contains many minor uses which are represented by the representative crop group data. The number of minor uses that can be counted toward any extension of exclusive use is limited by the number of representative crops within the crop group for which data were provided. After reviewing the currently approved label for the Sumilarv technical, the Agency has determined that the following minor uses qualify toward the request for extension of exclusive use protection⁵:
lemon, grapefruit, tangerine, pepper, jalapeno, eggplant, walnut, Brazil nut, and pear.

As required by statute, the aforementioned minor uses associated with the crop groupings were all registered within the requisite seven year period.

In addition to meeting the minor use requirements, FIFRA section 3(c)(1)(F)(ii) requires that criteria I - IV as stated above be met. Valent submitted the following responses to each of these criteria. First, EPA designated pyriproxyfen as a reduced risk compound, able to provide

³ Valent argues that the stone fruit crop group representative crops should be counted toward the extension of exclusive use protection. Those uses were added on September 24, 2002. Because the uses were not registered within the seven years, those uses have not been counted toward the total.

⁴ Data were submitted for the following crop groupings: citrus, fruiting vegetable, tree nut, and pome fruit. Studies were conducted on the following representative crops for the citrus crop group: lemon, grapefruit and orange. Studies were conducted on the following representative crops for the fruiting vegetable crop group: bell pepper, jalapeno and tomato. Studies were conducted on the following representative crops for the pome fruit crop group: pear and apple.

⁵ Because the statute sets a maximum of a three year extension for exclusive use protection provided that 9 minor uses are added within the seven year period after registration, the Agency did not list more than nine eligible minor uses. There may be additional uses not listed in this document that also count toward exclusive use protection. The agency will evaluate those uses for eligibility should Valent decide to voluntarily cancel or stop marketing any of the 9 uses currently forming the basis of the extension.

effective insect pest control while displacing or replacing other chemicals posing greater risk to humans and non-target organisms. Second, Pyriproxyfen end-use products are an integral part of integrated pest management programs and pest resistance management programs in minor crops. In support of the pest management programs, Valent provided information concerning the pest management programs for minor crops as facilitated by USDA's Office of Pest Management Strategic Plans. Valent states and the Agency agrees that pyriproxyfen provides the control necessary for the San Jose Scale and Lecanium Scale and suppression of the Peach Twig Borer and Oriental Fruit Moth as described by USDA as necessary in its pest management plan for peaches.

The Agency, therefore, **GRANTS** your request for an extension of exclusive use data protection under EPA Registration No. 10308-11 for an additional three (3) years. Exclusive use protection for data submitted in support of this registration which complies with 40 C.F.R. 152.83(c) will expire on September 15, 2008.

Lois Rossi 6/21/04

Lois Rossi, Director
Registration Division
Office of Pesticide Programs

cc: Marion Johnson
Joseph Tavano
Michele Knorr