



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

January 14, 2016

Tim McPherson
Senior U.S. Product Registration Manager
DuPont Crop Protection
PO Box 30, 1090 Elkton Road
Newark, DE 19714

Subject: Response to Request for an Extension of the Exclusive Use Period for
Chlorantraniliprole Technical
EPA Registration Number: 352-728
EPA Finding: Extends the exclusive-use data protection period by 3 years from
April 25, 2018 to April 25, 2021

Dear Tim McPherson:

This is the Office of Pesticide Programs' response to your petition dated January 5, 2011, requesting to extend the period of exclusive data use for the insecticide chlorantraniliprole by three years.

The 1996 Food Quality Protection Act (FQPA) amended FIFRA section 3(c)(1)(F) to include 3(c)(1)(F)(ii) which the applicant cites as its authority to make this request. FIFRA section 3(c)(1)(F)(ii) sets forth the criteria for the 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 retain exclusive use protection. 40 CFR section 152.83 defines the study required as part of the application for exclusive use protection where 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 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)(7)(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.

Second, the data were submitted in support of the first registration of the new chemical.¹ The registration of Dupont Rynaxpyr Technical (352-728) was granted April 25, 2008, and was the first registration for chlorantraniliprole.

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 EPA will count minor uses supported, or generated, by IR-4 when determining how many additional years that exclusive use protection may be extended.

Although the EPA has determined that there are exclusive-use-protected data associated with this registration, the EPA has not made individual determination on every study associated with the above referenced registration as to exclusive-use protection. If the EPA receives a me-too application of this pesticide during the extension period citing DuPont's data, the EPA 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, the 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 of FIFRA section 3(c)(1)(F)(ii), and if so, by how many years. FIFRA § 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, and/or
- (II) the alternatives to the minor use pesticide pose greater risks to the environment or human health, and/or

¹ Data are not protected solely because they pertain to a new chemical, but because they are submitted in support of a particular product registration of a new chemical. Thus data submitted in support of an application of 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 the data that pertain solely to the new use. Thus, for example, if the new use is approved after eight years of first registration, the data supporting that use would gain exclusive use protection for only two years.

(III) the minor use pesticide plays or will play a significant part in managing pest resistance, and/or

(IV) the minor use pesticide plays or will play a significant part in an integrated pest management (IPM) program.

Analysis of Justification for Exclusive Use Extension

The registrant, DuPont, submitted a petition to the Agency requesting that the exclusive-use period be extended for three years for data submitted in support of the chlorantraniliprole registration. Since three crops must meet the criteria for a one-year extension, at least nine crops need to meet at least one of the criteria to receive the maximum three-year extension. DuPont pointed out that several hundred minor acreage crops are registered uses, and claimed that chlorantraniliprole met all benefits related criteria for an extension. They also highlighted the reduced-risk status of this chemical as a basis for being less risky than available alternatives.

First, the following minor uses were registered within 7 years of the initial application of April 28, 2008; Artichoke, asparagus, avocado, coffee, figs, hops, mango, peppermint tops and spearmint tops, and papaya. The Agency verified there are chlorantraniliprole tolerance citations for the 10 minor use crops and crop groupings in 40 CFR 180.628. Furthermore, based on EPA's label data base it appears that growers have access to end use products under EPA registration numbers 352-729 and 352-730 for each crop use in this finding. Therefore, the first condition of exclusive use extension has been met.

Next, during the course of its review the Agency applied the statutory criteria to its evaluation and determined that Criteria III and IV would be most applicable for the extension of exclusive use for chlorantraniliprole. Firstly, the Agency considers that Criterion III is met in situations where there is reliable information that the insecticide being evaluated is used 1) to delay the development of pest resistance to other insecticides with different Modes of Action, or 2) where one or more of the target pests have already developed resistance in the U.S. to alternative insecticides.

The Agency first examined the list of registered minor acreage crops to determine whether or not chlorantraniliprole is the only available representative of its Mode of Action grouping. Since there are currently only two other insecticides in this Mode of Action group that are also commercially available (cyantraniliprole and flubendiamide), the Agency compared the lists of crops registered for each of these three chemicals. The following table shows 10 minor crops, along with the pests listed on their labels, for which chlorantraniliprole is the only registered MoA group (28) insecticide. Note there may be additional minor crops that have only chlorantraniliprole as group 28 chemistry; however, the Agency did not assess more than the 10 below. While growers have other options to manage the pests listed on the chlorantraniliprole label for these crops, the Agency reviewed relevant scientific literature and extension recommendations and concluded that for at least some of the pests for each crop, rotation of many different modes of action is an important component of delaying and managing the spread of pesticide resistance.

Crop	Target Pest
Asparagus	Armyworms (beet and western yellowstriped)
Artichoke	Artichoke plume moth
Avocado	Leafminers, leafrollers
Coffee	Coffee leafminer
Figs	Navel orangeworm
Hops	Western yellowstriped armyworm
Spearmint	Cutworms, loopers, mint root borer
Peppermint	Cutworms, loopers, mint root borer
Mango	Leafrollers, leafminers
Papaya	Leafrollers, leafminers

The Agency determined that chlorantraniliprole is currently the only insecticide in its specific MoA group (28) that is currently registered for at least ten minor uses that are included in the registrant's submission. Therefore, for these crops, the Agency concludes that chlorantraniliprole plays or will play a significant part in managing pest resistance.

These crops are: asparagus, artichoke, avocado, coffee, figs, hops, spearmint, peppermint, mango, and papaya.

The Criterion IV was also examined as a possible method exclusive use extension for chlorantraniliprole. Integrated Pest Management (IPM) is an important strategy for growers to maintain the productivity of crop land while potentially reducing the overall input and environmental impact of pest management tools such as pesticides. Among other things, IPM strategies can help minimize the impact of pesticides on beneficial organisms (such as pollinating insects, predators, and parasites). The Agency considers that Criterion IV is met in situations where there is reliable information that chlorantraniliprole is useful in managing target pests as part of a larger IPM program that is intended to control a range of key pests in a given crop.

The Agency located recent peer-reviewed research publications that confirmed that chlorantraniliprole is one of a set of relatively new chemistries that have low negative impacts on predatory and parasitic insects and mites that can be used as natural pest controls within an integrated pest management (IPM) program in most crops. Natural enemies for which the impacts of chlorantraniliprole on mortality and/or fecundity have been evaluated include the minute pirate bug (*Orius insidiosus*), green lacewing (*Chrysoperla rufilabris*), a parasitic wasp (*Aphidius colemani*), the convergent ladybeetle (*Hippodamia convergens*), and the predatory mite *Neoseiulus fallacis* (Roubos *et al.* 2014, Gradish *et al.* 2011, Lefebvre *et al.* 2012). All are natural enemies of a variety of common insect pests in many minor acreage crops.

Further, chlorantraniliprole has a mode of action that makes it selectively toxic to Lepidoptera (caterpillar) and some Diptera (flies). It has less toxicity to beneficial insects (such as lady beetles and parasitic wasps) than many other alternatives, such as organophosphates and pyrethroids. Thus, chlorantraniliprole should have a better fit than many alternatives in an IPM program. Therefore, the Agency concludes that it could serve as a significant component of IPM programs in many crop systems, including but not limited to the ten mentioned above.

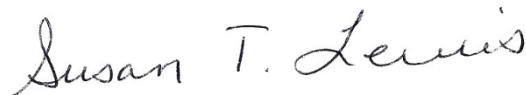
Finally, the University of California Statewide IPM Program, which provides detailed insecticide recommendations for dozens of minor crops included in chlorantraniliprole's labels, often mentions this insecticide as an option for commercial growers (see individual crop listings at <http://www.ipm.ucdavis.edu/PMG/crops-agriculture.html>).

While chlorantraniliprole is not unique in the qualities described above, the Agency concludes there is sufficient acceptable evidence that it is a useful component of IPM programs intended to control a range of pests in many crops.

Determination

EPA concludes that DuPont has satisfied the requirements necessary to extend the period of exclusive use data. EPA determined that chlorantraniliprole satisfies criterion III and IV for ten minor uses that were registered within seven years of the original registration. Therefore, EPA grants your request for a three-year extension of exclusive-use-data protection for selected data under EPA Registration Number 352-728. Exclusive-use protection for data, which complies with 40 CFR 152.83(c), submitted in support of this registration, will expire on April 25, 2021.

Sincerely,

A handwritten signature in cursive script that reads "Susan T. Lewis".

Susan Lewis, Director
Registration Division (7505P)
Office of Pesticide Programs