

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



OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

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Subject: Clothianidin Technical (EPA Reg. No. 59639-173); D460188
Exclusive use period extension request for data protection
Submission date November 11, 2011
Exclusive Use Extension Granted until May 30, 2016

Dear Ms. Shen:

This is in response to your request, dated November 11, 2011, that data associated with the registration of the active ingredient clothianidin receive a three year extension of the original ten year exclusive use protection period from May 30, 2013 to May 30, 2016.

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 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 of an additional three years to the exclusivity period.

The first step in determining whether data qualifies for an extension of its exclusive use period is to ascertain whether there are exclusive use data associated with the 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 CFR §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.

Second, the data were submitted in support of the first registration of the new chemical¹. The registration you cited was granted on June 19, 2003, and was the first registration for clothianidin with the product name Clothianidin Technical.

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 by IR-4 generated data 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 determinations on every study associated with the above referenced registration as to exclusive use protection. If the EPA receives a me-too application for this pesticide during the extension period citing Valent U.S.A. 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 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

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 FR30884, 30889.

year for 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:

Criterion (I) there are insufficient efficacious alternative registered pesticides available for the use;

Criterion (II) the alternatives to the minor use pesticide pose greater risks to the environment or human health;

Criterion (III) the minor use pesticide plays or will play a significant part in managing pest resistance; or

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

Valent submitted information for 27 minor crops for consideration, 26 of which met the definition of a minor crop. The EPA determined that the minor crops were registered within seven years of the original registration of the Clothianidin Technical. Based on the review of the registrant’s submission, the EPA concluded that clothianidin satisfies one or more of the criteria which are prerequisites for the extension of the exclusive use period for nine crops: bulb onion, bunch onion, leek, carrot, sweet potato/yam, figs, celery, parsley, and spinach. After nine crops had been identified as meeting the extension of the exclusive use criteria, additional crops were not evaluated.

Summary of Findings

The EPA evaluated the minor crops under requirements for Criterion I for the nine crops listed above. The crops evaluated by the EPA to reach its conclusions were:

Bulb Onion: Valent cited recent Emergency Exemption (Section 18) for clothianidin to control maggots (onion and seedcorn) on bulb onion in New Jersey (Cook and Faulkner, 2008), and California (Kaul and Hill, 2008a and 2008b). Review of these assessments indicates that there is a lack of efficacious insecticides available for use to control maggots in bulb onion production. Based on these findings, the EPA concludes that clothianidin satisfies Criterion I for bulb onion.

Bunch Onion: Valent cited a Section 18 assessment for New Jersey (Cook and Faulkner, 2008) to control seedcorn maggot on bunch onion. Review of this assessment indicates a lack of efficacious insecticides available to control seed corn maggot in bunch onion production. Based on this determination, the EPA concludes that clothianidin satisfies Criterion I for bunch onion.

Leek: Valent cited a Section 18 assessment for New Jersey (Cook and Faulkner, 2008) to control seedcorn maggot on leeks. Review of this assessment indicates a lack of efficacious insecticides available to control seedcorn maggot in leek production. Based on this determination, the EPA concludes that clothianidin satisfies Criterion I for leek.

Carrot: Valent provided one reference for control of carrot rust fly on carrot in the Pacific Northwest (Pacific Northwest Insect Management Handbook, 2009). However, the EPA was able to locate a more recent edition (Pacific Northwest Insect Management Handbook, 2012). In 2012 only pyrethrin is recommended to control carrot rust fly. The lack of available alternative insecticides, particularly a seed treatment that can control the second pest generation, supports the EPA's conclusion that clothianidin satisfies Criterion I for carrot.

Sweet Potato/Yam: Valent cited a Section 18 assessment for North Carolina to control exotic white grub (Brassard and Ranville, 2009). Review of this assessment confirms the registrant claims. While imidacloprid is also effective against exotic white grub, the extended pre-harvest interval (PHI) makes its use unworkable for sweet potato production. Based on lack of other efficacious insecticides, the EPA concludes that clothianidin satisfies Criterion I for sweet potato/yam.

Figs: Valent provided one reference documenting the importance of clothianidin in fig production (UC IPM, 2009). There are only two pesticides recommended for control of dried fruit beetle on figs. Chlorpyrifos is registered for dormant application and malathion is registered for foliar application. While there is no documented efficacy problem with these insecticides sole reliance on one chemistry, organophosphate (Group 1B), has the potential to result in insect resistance. As dried fruit beetles have an extremely wide host range and will infest any ripe or fermenting fruit, there is potential for numerous exposures over multiple generations and crops. Based on the lack of available efficacious insecticides, the EPA concludes that clothianidin satisfies Criterion I for figs.

Celery: Valent provided one reference indicating lack of available efficacious insecticides to control leafminers on celery in Florida (Crop Profile for Celery in Florida, 2007). The only effective insecticides are cyromazine and abamectin. However, cyromazine is an insect growth regulator and has no effect against adult populations. While abamectin is efficacious against adult leafminers, continuous use as the sole adulticide has the potential for development of a resistant population. In the absence of an additional adulticide, producers could be left without a viable control option. In addition, rotation of clothianidin will serve to maintain the continued viability of abamectin as an efficacious insecticide. Based on the lack of effective insecticides for leafminer control on celery, the EPA concludes that clothianidin satisfies Criterion I for celery.

Parsley: Valent provided a reference documenting the need for clothianidin in parsley production in Ohio (Parsley Pest Management Strategic Plan for Ohio, 2008). The efficacy table in this document indicates no insecticides which provide excellent control of flea beetle. The four recommended insecticides (carbaryl, cyfluthrin, permethrin, and zeta-cypermethrin) to control flea beetle are only evaluated as providing good control. Based on the lack of efficacious insecticides for flea beetle control, the EPA concludes that clothianidin satisfies Criterion I for parsley.

Spinach: Valent provided a reference documenting the need for clothianidin in spinach production in Texas (Texas Spinach Pest Management Strategic Plan, 2007). The efficacy table in this document indicates no insecticides which provide excellent control of either leafminer or flea beetle. For flea beetle, only good control is achieved using bifenthrin, zeta-cypermethrin or carbaryl. Cyromazine is the only insecticide which provides good control of leafminer. Based

on the lack of efficacious insecticides, the EPA concludes that clothianidin satisfies Criterion I for spinach.

DETERMINATION:

Based on the review of the submitted information, the EPA concludes that clothianidin satisfies at least one of the criteria for an extension of the period of exclusive use for the nine crops listed above. Therefore, the EPA GRANTS your request for a three year extension of exclusive-use data protection for selected data under EPA Reg. No. 59639-173. Exclusive use protection for data, which complies with 40 CFR 152.83(c), submitted in support of this registration will expire on May 30, 2016.



Lois Rossi, Director
Registration Division
Office of Pesticide Programs