



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

**Petition for the Extension of the  
Exclusive Use Period for  
Carfentrazone Technical**

**September 9, 2009**



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

SEP 09 2009

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

Callista O. Chukwunenye, Ph.D.  
FMC Corporation  
1735 Market Street  
Philadelphia, PA 19103

Re: Petition for Extension of the Exclusive Use Period for Data Protection for  
Data Submitted for Carfentrazone Technical (EPA Reg. 279-3181)

Dear Dr. Chukeunenye:

The Agency **GRANTS** your petition for an extension of exclusive use data protection under EPA Registration No. 279-3181 for an additional two (2) years. The initial registration date for carfentrazone-ethyl was on September 30, 1998 for the product named Carfentrazone Technical. Exclusive use protection for data submitted in support of this registration which complies with 49 CFR 152.83(c) will expire on September 30, 2010.

This letter is in response to your petition dated April 14, 2008 that data associated with the original registration of the active ingredient carfentrazone-ethyl receive an extension of their exclusive use protection period. 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), 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.

The first step in determining whether data qualifies for an extension of its exclusive use period is to ascertain which data currently 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, there are data associated with this registration that 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.<sup>1</sup> The registration you cited was granted on September 30, 1998 and was the first registration for carfentrazone-ethyl with the product name Carfentrazone Technical.

Please note, 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).

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<sup>1</sup> 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.

Now that the Agency has determined there are studies associated with this registration that are exclusive use studies<sup>2</sup>, we must determine whether you have met the criteria for extending the exclusive use protection period 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.

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.

In addition, the Agency must determine if the requested uses are minor uses. The definition of a "minor use" as defined in FIFRA section 2(11), as follows, pertains to the extension of exclusive use for minor use registrations provisions.

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<sup>2</sup> This response is general in nature. If the Agency receives an application for registering an identical or substantially similar pesticide during the extension period citing the requestor's data, it will then address whether those data have the extension of data protection.

2(l) MINOR USE.—The term “minor use” means the use of a pesticide on an animal, on a commercial agricultural crop or site, or for the protection of public health where—

- (1) the total United States acreage for the crop is less than 300,000 acres, as determined by the Secretary of Agriculture; or
- (2) the Administrator, in consultation with the Secretary of Agriculture, determines that, based on information provided by an applicant for registration or a registrant, the use does not provide sufficient economic incentive to support the initial registration or continuing registration of a pesticide for such use and
  - (A) there are insufficient efficacious alternative registered pesticides available for the use;
  - (B) the alternatives to the pesticide use pose greater risks to the environment or human health;
  - (C) the minor use pesticide plays or will play a significant part in managing pest resistance; or
  - (D) the minor use pesticide plays or will play a significant part in an integrated pest management program.

The status as a minor use under this subsection shall continue as long as the Administrator has not determined that, based on existing data, such use may cause an unreasonable adverse effect on the environment and the use otherwise qualifies for such status.

The initial registration of carfentrazone-ethyl occurred on September 30, 1998. FMC Corporation petitioned the Agency on April 14, 2008 to consider 12 uses for the extension of the exclusive use period: blackberries, raspberries, hops, fresh market tomatoes, eggplant, wild rice, Bermudagrass grown for seed, pistachios, prunes, nectarines, flue-cured tobacco and cotton (for stand removal). Of the twelve (12) uses, ten (10) are minor crops (blackberries, raspberries, hops, fresh market tomatoes, eggplant, wild rice, Bermudagrass grown for seed, pistachios, prunes and nectarines) and two (2) may be minor uses of major crops (flue-cured tobacco and cotton stand removal). Three of the uses, cotton, raspberries and blackberries, were registered on January 8, 2002. The remaining 9 uses, hops, fresh market tomatoes, eggplant, wild rice, Bermudagrass grown for seed, pistachios, prunes, nectarines, and flue-cured tobacco were registered on September 30, 2004. As required by statute, the aforementioned uses were all registered within the requisite seven-year period (before September 30, 2005).

The Agency determined that the following seven (7) uses qualify toward the request for extension of exclusive use data protection: blackberries, raspberries, hops, eggplant, wild rice, nectarines and Bermudagrass grown for seed. Cotton, tobacco, tomatoes, pistachios and prunes either do not meet the criteria requirements of FIFRA 3(c)(1)(F)(ii) or are not qualifying crops for the extension.

The Agency initially reviewed the petition in August, 2008 and determined that more information was needed to evaluate the request. After receiving additional information for the requested uses, a new review was done.

Carfentrazone-ethyl is a triazolinone herbicide and is classified by the Weed Science Society of America (WSSA) as a Group 14 herbicide for resistance control needs. It is applied postemergence to control broadleaf weeds. It can be applied to actively growing weeds up to four inches tall. It can also be used to defoliate or desiccate crops.

The Agency determined that tobacco does not meet the acreage definition of a minor crop as over 300,000 of tobacco are grown in the United States. FMC claims that the tobacco use qualifies as a minor crop under the economic definition of a minor crop. However, FMC did not provide any economic data, such as revenues and costs specific to carfentrazone-ethyl production for this crop, to support their position. The Agency is unable to determine if flue-cured tobacco is a minor use.

The Agency received information about this use of carfentrazone-ethyl from USDA<sup>3</sup>. If this use in tobacco can be confirmed as a minor use, then based on the information supplied by USDA, it is possible that this use will meet criterion I. However, for purposes of this petition, a finding that tobacco meets criterion I would not provide enough minor uses for an additional year extension of exclusive use data protection.

As to the cotton use, the Agency determined that this use does not meet the acreage definition of a minor crop as more than 300,000 acres of cotton are grown in the United States. FMC claims that the cotton stand removal use of carfentrazone-ethyl is a minor use under the economic definition of a minor crop. However, FMC did not provide any economic data to support their claim, such as revenues and costs specific to carfentrazone-ethyl, for this crop. The Agency is unable to determine if cotton can be considered a minor crop.

Additionally, it is unlikely that carfentrazone-ethyl's use in cotton would meet criteria I, III or IV for the extension of the exclusive use period even if it could be confirmed as a minor use based on the following information. Carfentrazone-ethyl is used in cotton as a burndown treatment to remove or kill failed cotton stands in preparation for replanting, to control morning glory, and as a harvest aid. Only about two to three percent of cotton acreage is replanted. At this time, however, less than five

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<sup>3</sup> The following is a summary of the information EPA received in its consultation with USDA concerning this use. The Agency contacted USDA to get additional information to understand the use patterns of carfentrazone-ethyl in flue-cured tobacco. Flue-cured tobacco is harvested several times over the growing season beginning with the lower leaves of the stalk. Carfentrazone-ethyl is used after the first priming, which is the removal of the lower tobacco leaves or first harvest. Carfentrazone-ethyl is the only herbicide that provides broadleaf weed control after harvest begins. Although there are no alternatives available for this specific use pattern, states producing flue-cured tobacco have expressed differing views of carfentrazone-ethyl's usefulness. North Carolina and Virginia report no use of this herbicide in flue-cured tobacco. In addition, North Carolina does not support the use of carfentrazone-ethyl because of potential for crop injury and is not aware of the registrant marketing this use pattern (Coble, 2008). Carfentrazone-ethyl is being used in Georgia after the first harvest. Its use is increasing and is estimated to be applied to 30 percent of flue-cured tobacco once per season. Producers have achieved very good results with carfentrazone-ethyl and there are no alternative available for this use pattern (Coble, 2008).

percent of replanted acreage is treated with carfentrazone-ethyl (Coble, 2008). Although carfentrazone-ethyl is effective for cotton stand removal, paraquat is mostly used for this circumstance and glufosinate is its alternative.

As to the tomato use, the Agency determined that fresh market tomatoes are grown on less than 300,000 acres in the United States. However, carfentrazone-ethyl is labeled for use on all tomatoes without any distinction for those grown for fresh market versus tomatoes for processing or other uses. The U.S. tomato crop, as a whole, does not qualify as a minor crop. Therefore, fresh market tomatoes can not be counted towards the extension of exclusive use data protection for carfentrazone-ethyl.

As to the pistachio use, the Agency determined that this use did not meet criteria I, III, or IV for extension of the exclusive use period for carfentrazone-ethyl. FMC claims that carfentrazone-ethyl fills an important niche because it can be used year-round and has a three day pre-harvest interval (PHI). However, University of California IPM Weed scientists, Hembree and Shrestha (2007), do not list carfentrazone-ethyl as a recommended herbicide for pistachio orchards. They have not recommended it for IPM or resistance management programs. In addition, there are several other herbicides they do recommend that have PHIs that are equal to or shorter than carfentrazone-ethyl, can be used on either bearing or nonbearing trees and may be used throughout the season. There are also both pre- and postemergent herbicides available. The following herbicides all have equal or shorter PHIs than carfentrazone-ethyl: 1) glyphosate has a three day PHI and can be used postemergence; 2) oxyfluorfen has a zero day PHI and can be used pre- and postemergence; 3) oryzalin also has a zero day PHI and can be used at preemergence; 4) napropamide has a zero day PHI and can be used preemergence. Growers can also use a mix of these herbicides to achieve broader-spectrum weed control.

California produces most of the pistachios grown in the United States. According to pesticide usage data obtained from the California Department of Pesticide Regulation (CPDR) and EPA proprietary data, less than five percent of pistachio acres are treated with carfentrazone-ethyl. Glyphosate and paraquat are used for postemergence weed control on over 40 and 25 percent of the pistachio acres, respectively. Therefore, the pistachio use does not meet criterion I because there are sufficient efficacious alternative registered pesticides to carfentrazone-ethyl.

The registrant also states that carfentrazone-ethyl is important for pistachio weed control because it controls little mallow, an important weed in pistachio orchards. However, University of California IPM Weed scientists, Hembree and Shrestha (2007), suggest using oxyfluorfen and glyphosate postemergence for little mallow control if preemergent herbicides are not effective.

Therefore, the pistachio minor use does not meet criteria I, III, or IV for the extension of the exclusive use period.

The Agency determined that prunes do not meet criteria I, III, or IV. FMC claims that carfentrazone-ethyl is important for prune production because of its short PHI of

three days and its availability for use year round. However, paraquat is also a postemergent herbicide that has a shorter PHI of zero days. There are several other postemergent herbicides recommended by University of California IPM weed specialists including glyphosate, oxyfluorfen, 2,4-D and fluazifop-p-butyl (Shrestha et al. 2006). While some of these have use restrictions in terms of timing, many are used on more prune acreage and in higher quantities than carfentrazone-ethyl. Less than one percent of prune acres are treated with carfentrazone-ethyl and growers rely more heavily on other postemergent herbicides (CDPR, 2005). In addition, weeds controlled by carfentrazone-ethyl can also be controlled by other labeled postemergent herbicides.

The registrant also claims that two weeds, hairy fleabane and horseweed, have demonstrated glyphosate resistance. However, carfentrazone-ethyl does not control these weeds (Shrestha, et al. 2006). In addition, the registrant points out that carfentrazone-ethyl provides some control of field bindweed, an important weed in pistachio orchards. There are several other herbicides that also provide some control of this weed.

Therefore, the Agency determined that carfentrazone-ethyl's use in prunes does not meet criteria I, III, or IV.

The Agency determined that carfentrazone-ethyl use in nectarines meets criterion I for extension of the exclusive period. The approach for weed control in nectarine orchards is similar to that in prunes. The available alternatives are the same; however, the PHI for paraquat use in nectarines is 28 days, longer than the 3 day PHI for carfentrazone-ethyl. Carfentrazone-ethyl has the shortest PHI of all recommended postemergent herbicides for nectarines (Shrestha et al., 2006). Therefore, criterion I has been met for nectarines.

The Agency determined that carfentrazone-ethyl use in raspberries and blackberries meets criterion IV for extension of the exclusive use period. Carfentrazone-ethyl has an important use in these crops specifically for caneburning. Caneburning has been shown to improve yield and lower the incidence of fungal disease (Oregon State University (OSU) Caneberry Newsletter, 2003). It is also helpful for mechanical harvest. Pelargonic acid and oxyfluorfen herbicides are also available for caneburning (DeFrancesco, 2002) however, perlargonic acid is rarely used and oxyfluorfen generally requires two applications while carfentrazone-ethyl generally requires only one treatment. In addition, a study indicated that carfentrazone-ethyl is safer for raspberry plants than oxyfluorfen. Carfentrazone-ethyl is more effective for blackberry caneburning than oxyfluorfen (OSU Caneberry Newsletter, 2003). Raspberries and blackberries are primarily grown in the Pacific Northwest states and cool weather can be problematic for using both pelargonic acid and oxyfluorfen (DeFrancesco, 2002). Oxyfluorfen and carfentrazone-ethyl can be used in an IPM program that utilizes the products in alternate years in order to reduce potential residual problems from oxyfluorfen and provide broader-spectrum weed control. Therefore, the Agency finds that carfentrazone-ethyl use in raspberries and blackberries meets criterion IV.

The Agency determined that carfentrazone-ethyl use in Bermudagrass grown for seed meets criterion I for extension of the exclusive use period. Most Bermudagrass seed production is in California and Arizona. The University of California (UC) Pest Management Guideline for Bermudagrass seed production recommends only four herbicides (2,4-D, dicamba, bromoxynil and trifluralin) other than carfentrazone-ethyl for use in Bermuda grass seed production. The other herbicides do not provide the level of control of little mallow as carfentrazone-ethyl (Tickes and Bell, 2007). Bromoxynil, dicamba and 2,4-D provide partial control of little mallow and trifluralin does not control this weed. In addition, the other herbicides have additional use restrictions compared to carfentrazone-ethyl. Bermudagrass treated with the other commonly used herbicides have livestock feeding or grazing restrictions, while carfentrazone-ethyl treated Bermudagrass does not have these restrictions. Some of the herbicides also have use restrictions in place to prevent damage to crops growing in adjacent fields. Therefore, the Agency finds that the use of carfentrazone-ethyl in Bermudagrass meets criterion I.

The Agency determined that the use of carfentrazone-ethyl in eggplant meets criteria I and III for extension of the exclusive use period. Carfentrazone-ethyl was approved for section 18 emergency exemption use in Florida on eggplant and tomato in 2002, 2003 and 2004 for control of nightshade, common groundsel and morning glory. These uses for carfentrazone-ethyl received section 3 registrations on September 30, 2004. The Agency believes that there are still limited alternatives to carfentrazone-ethyl for control of nightshade in Florida. Resistance of nightshade to paraquat has been documented in Florida (Mossler et al., 2006) and carfentrazone-ethyl is a commonly used herbicide in eggplant production (USDA IPM Center, 2004). Therefore, based on the resistance issues in Florida and continued need for an effective control for nightshade, the Agency concludes that criteria I and III have been met for eggplant.

The Agency determined that the use of carfentrazone-ethyl in hops meets criteria I for extension of the exclusive use period. Carfentrazone-ethyl is used as a desiccant in hop production to control powdery mildew, a serious disease of hops (George, 2001). Desiccants are used for sucker control in hops to manage or prevent powdery mildew infections. Paraquat and carfentrazone-ethyl are recommended by the current Pacific Northwest Weed Management Handbook (2007) for sucker control. Section 18 emergency requests were granted in 2001 through 2004 in Oregon, Washington and Idaho (the primary hop producing states in the U.S.) for powdery mildew control in hops. This use was registered on September 30, 2004. At the time the section 18 requests were made, the available desiccants, paraquat and endothall, provided limited control of the disease. Mosz and Gilbert (2003) indicate that paraquat does not provide consistent control, particularly in cool weather. In addition, some hop varieties are particularly sensitive to damage from paraquat. Multiple applications of desiccants are needed to control powdery mildew during the growing season and only three applications of paraquat are permitted to be used per season. Growers frequently need to apply more than three desiccant applications per season to control powdery mildew. Therefore, based on the continued lack of effective alternatives for powdery mildew control, the use of carfentrazone-ethyl on hops meets criterion I.

The Agency determined that the use of carfentrazone-ethyl in wild rice meets criterion I for extension of the exclusive use period. Most U.S. wild rice is grown in California and Minnesota. In California, carfentrazone-ethyl is the only herbicide that can be used during the growing season. In Minnesota, 2,4-D is available for use in addition to carfentrazone-ethyl. However, studies indicate that carfentrazone-ethyl provides better weed control than 2,4-D and results in higher yields (Chism and Smearman, 2004). Other registered herbicides include glyphosate, pelargonic acid, pyraflufen and oxyfluorfen; however, none of these can be used on the rice crop within the growing season. The Agency concludes that since carfentrazone-ethyl is either the only or best available alternative for weed control in wild rice during the growing season, criterion I has been met.

The Agency concluded that seven (7) of the requested uses met one or more of the criteria for extension of the exclusive use period. Nectarines, Bermudagrass, hops and wild rice met criterion I, eggplant met criteria I and III, and raspberries and blackberries met criterion IV. Therefore, the Agency **GRANTS** your request for an extension of exclusive use data protection under EPA registration number 279-3181 for an additional two (2) years. Exclusive use protection for data submitted in support of this registration which complies with 40 CFR 152.83(c) will expire on September 30, 2010.



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Lois Rossi, Director  
Registration Division  
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cc: Dan Kenny  
Joanne Miller  
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Pat Cimino

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