



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

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January 5, 2016

Subject: Product Name: Kixor Herbicide Technical
EPA Reg. No. 7969-275; Decision: 498566; Application Dated 12/15/2014
EPA Finding: Extends the exclusive-use data protection period by 3 years from
September 3, 2019 to September 3, 2022

Dear Dr. Kleppe:

This letter addresses your request that data associated with the original registration of Saflufenacil receive a three-year extension to the original ten-year exclusive-use protection period pursuant to FIFRA section 3(c)(1)(F)(ii). The original data protection period started September 3, 2009 and ends September 3, 2019. Supporting information was submitted for sixteen crops. Because three minor uses are needed to meet the criteria for a one-year extension, nine registered minor uses are required to meet at least one of the criteria for a three-year extension, which is the maximum allowed. The Agency selected nine of the crops for consideration and determined that the use of saflufenacil on grapefruit, mandarin, tangelo, lemon, lime, pomelo, olive, crambe, and gold of pleasure met the criteria to support the extension of the exclusive-use period. Therefore, the Agency is granting the request for an exclusive-use extension of three additional years to end September 3, 2022, under EPA Registration No. 7969-275.

BASF Corporation cited FIFRA section 3(c)(1)(F)(ii) as the authority for EPA to make such a determination. 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.

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 chemical.¹ The registration cited was granted on September 3, 2009, (EPA Registration No. 7969-275) and was the first registration for saflufenacil under the trade name “Kixor Technical Herbicide”.

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 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 are 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 BASF Corporation data, it may 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:

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 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.

“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.”

SUMMARY OF FINDINGS

Saflufenacil is a protoporphyrinogen IX oxidase (PPO) inhibiting herbicide belonging to the herbicide Mechanism of Action (MOA) Group 14 (WSSA)/Group E (HRAC). Saflufenacil is used for the control of broadleaf weeds, especially weeds that have developed resistance to glyphosate and paraquat and is also used as a harvest aid desiccant in oilseed crops.

BASF Corporation identified 16 potential qualifying minor crops and submitted information to substantiate that each crop met at least one of the criteria above in their petition submitted to the Agency on 12/14/14. The Agency determined that at least nine of the proposed minor uses -- grapefruit, mandarin, tangelo, lemon, lime, pomelo, olive, crambe, and gold of pleasure-- met criterion I or criterion III under section 3(c)(1)(F)(ii) of FIFRA. All nine crops considered (grapefruit, mandarin, tangelo, lemon, lime, pumelo, olive, crambe and gold of pleasure) meet the standard definition of “minor use” because the total U.S. acreage for each crop is less than 300,000.

The Agency considers that Criterion I under section 3(c)(1)(F)(ii) of FIFRA has been met in situations where there is reliable information that the chemical being evaluated 1) fills a void in a crop production program, 2) controls a broader range of pests than currently registered alternatives, 3) controls a target pest in a different life stage than alternatives, or 4) provides a crucial timing advantage. The Agency determined that saflufenacil meets the qualification of criterion I under section 3(c)(1)(F)(ii) of FIFRA for gold of pleasure. The Agency did not find any other pesticides registered for use as a harvest aid desiccant in the production of gold of pleasure. Therefore, there are insufficient efficacious alternatives to saflufenacil and saflufenacil fills a void in the production of gold of pleasure.

The Agency considers that Criterion III under section 3(c)(1)(F)(ii) of FIFRA has been met in situations where there is reliable information that the herbicide being evaluated is used 1) to delay the development of pest resistance to other herbicides 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 chemical. Numerous studies were cited in the petition indicating that saflufenacil is effective at controlling glyphosate-resistant horseweed and glyphosate-resistant, paraquat-resistant hairy fleabane. The Agency confirms that horseweed and hairy fleabane have been ongoing problems in tree crop systems in the Central Valley of California since at least 2003, and glyphosate-resistant biotypes have contributed to the proliferation of these pest species. These two pest species proliferate most effectively in no-till environments such as orchards and vineyard berms, roadsides, and ditch banks in California. Information about hairy fleabane and horseweed can be applied generally to all tree crop systems in the Central Valley of California because populations of these weeds are present in California and tree crop systems generally contain undisturbed soil between crop rows. Both of these weeds compete significantly for water and nutrients, particularly in low-water irrigation systems and during the first two years of crop establishment. Other post-emergence group 14 herbicides registered for use on California tree and vine crops include carfentrazone, flumioxazin, and oxyflourfen. Flumioxazin and oxyflourfen are for use with non-bearing trees only, while saflufenacil and carfentrazone may be used with bearing and non-bearing trees. According to the University of California, Davis extension literature, carfentrazone provides only partial control of hairy fleabane and horseweed, while saflufenacil provides good control of hairy fleabane and horseweed. Saflufenacil can be applied alone or tank mixed with other herbicides to increase control efficacy. Using tank mixes where possible helps delay or prevent resistance in hairy fleabane in California. In addition, the University of Florida IFAS Extension identifies herbicide rotation as integral to resistance management, and also identifies saflufenacil as a resistance management tool for post-emergence broadleaf weeds in citrus. Saflufenacil controls glyphosate-resistant ragweed parthenium in Florida and no pest species in the U.S. have documented resistance to saflufenacil.

In addition, hairy fleabane is identified by the University of California, Davis Extension as a problematic weed in olives in the Central Valley. Considering that saflufenacil provides good control of hairy fleabane and glyphosate-resistant populations are spreading in the Central Valley of California, saflufenacil can be used as a tool to prevent the proliferation of glyphosate-resistant biotypes. Therefore, saflufenacil plays or will likely play a significant role in managing resistance in olives production, as well.

Amaranthus, *Conyza*, *Ambrosia*, and *Kochia* are common weed species in crambe and have glyphosate-resistant biotypes which cause difficulties in *Crambe abyssinica*. Only two species from these genera (*Amaranthus palmeri* and *Ambrosia artimifolia*) have confirmed resistance to group 14 herbicides in North America in soybean cropping systems. Saflufenacil is not a novel MoA in *Crambe abyssinica* because carfentrazone is labeled for use in crambe, as well; however, some extension documents indicate that saflufenacil provides better control of *Conyza* species than carfentrazone. Greater control of glyphosate-resistant biotypes may reduce the spread of glyphosate-resistance in *Conyza* species because fewer plants may go to seed. Therefore, saflufenacil plays a significant role in managing herbicide resistance in *Crambe abyssinica* production.

The Agency determined that saflufenacil met criteria III under section 3(c)(1)(F)(ii) of FIFRA because saflufenacil plays or will likely play a significant part in managing pest resistance in mandarin, grapefruit, tangelo, lemon, lime, pomelo, olive, and crambe. The presence of glyphosate-resistant weeds in these crops and the efficacy of the chemical for controlling these weeds satisfies criterion III for saflufenacil.

The Agency has confirmed that the end use product labels currently listing these minor uses (EPA Reg. No. 7969-276 for mandarin, grapefruit, tangelo, lemon, lime, pomelo and olive; and EPA Reg. No. 7969-278 for crambe and gold of pleasure) carry the resistance-management labeling statements as described by PR Notice 2001-5.

The Agency also determined that these nine crops were registered within seven years of the original registration of Kixor Technical Herbicide, EPA Reg. No. 7969-275 which was first registered on 09/03/09. The citrus crops --grapefruit, mandarin, tangelo, lemon, lime, and pumelo-- were first registered on the end-use product TREEVIX powered by KIXOR Herbicide, EPA Reg. No. 7969-276 on 09/15/09. The olive crop use was first registered on the end-use product TREEVIX powered by KIXOR Herbicide, EPA Reg. No. 7969-276 on 09/16/14. The crambe and gold of pleasure crops were first registered on the end-use product Sharpen Powered by Kixor Herbicide, EPA Reg.No. 7969-278 on 05/19/11. The Agency has verified that the end-use product labels for TREEVIX powered by KIXOR Herbicide, EPA Reg. No. 7969-276 and Sharpen Powered by Kixor Herbicide, EPA Reg. No. 7969-278 are currently being marketed, are publically available on the Pesticide Product Label System (PPLS) website, and contain the minor uses under this review. In addition, the Agency verified there are saflufenacil tolerance citations for the nine minor use crops in 40 CFR 180.649. For additional information regarding the tolerances established for saflufenacil on these nine crops please refer to the following *Federal Register* citations: 74 FR 46683 09/11/09; for citrus fruit crop group 10, which includes grapefruit, lemon, lime, pumelo, mandarin, and tangelo crop and 70 FR 52215 9/03/14 for the olive crop use and 76 FR 27256 05/11/11 for the rapeseed subgroup 20A, which includes crambe and gold of pleasure.

The following is a summary of each crop and the criterion that was met to support 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 a Request for an Extension of the Exclusive Use Period for Saflufenacil” dated 01/05/2016 for a more detailed explanation of how each crop meets the standard for extending the exclusive-use period.

Grapefruit: Saflufenacil was registered for use on grapefruit for end users on TREEVIX Powered by KIXOR Herbicide, EPA Reg. No. 7969-276 on 09/15/09. Also, the Agency determined that the use of saflufenacil on grapefruit met criteria III under section 3(c)(1)(F)(ii) of FIFRA because of the presence of glyphosate-resistant weeds and the efficacy of the chemical for controlling these weeds and because of the significant role this chemical will likely play in managing pest resistance. For grapefruit, saflufenacil is important for controlling glyphosate-resistant horseweed/marestail and glyphosate-resistant, hairy fleabane in Central Valley, California. It is also important for controlling glyphosate-resistant ragweed parthenium for grapefruit in Florida.

Mandarin: Saflufenacil was registered for use on mandarin for end users on TREEVIX Powered by KIXOR Herbicide, EPA Reg. No. 7969-276 on 09/15/09. Also, the Agency determined that the use of saflufenacil on mandarin met criteria III under section 3(c)(1)(F)(ii) of FIFRA because of the presence of glyphosate-resistant weeds and the efficacy of the chemical for controlling these weeds and because of the significant role this chemical will likely play in managing pest resistance. For mandarin, saflufenacil is important for controlling glyphosate-resistant horseweed/marestail and glyphosate-

resistant, hairy fleabane in Central Valley, California and ragweed parthenium in Florida.

Tangelo: Saflufenacil was registered for use on tangelo for end users on TREEVIX Powered by KIXOR Herbicide, EPA Reg. No. 7969-276 on 09/15/09. Also, the Agency determined that the use of saflufenacil on tangelo met criteria III under section 3(c)(1)(F)(ii) of FIFRA because of the presence of glyphosate-resistant weeds and the efficacy of the chemical for controlling these weeds and because of the significant role this chemical will likely play in managing pest resistance. For tangelo, saflufenacil is important for controlling glyphosate-resistant ragweed parthenium in Florida.

Lemon: Saflufenacil was registered for use on lemon for end users on TREEVIX Powered by KIXOR Herbicide, EPA Reg. No. 7969-276 on 09/15/09. Also, the Agency determined that the use of saflufenacil on lemon met criteria III under section 3(c)(1)(F)(ii) of FIFRA because of the presence of glyphosate-resistant weeds and the efficacy of the chemical for controlling these weeds and because of the significant role this chemical will likely play in managing pest resistance. For lemon, saflufenacil is important for controlling glyphosate-resistant horseweed/marestail and glyphosate-resistant, hairy fleabane in Central Valley, California.

Lime: Saflufenacil was registered for use for end users on lime on TREEVIX Powered by KIXOR Herbicide, EPA Reg. No. 7969-276 on 09/15/09. Also, the Agency determined that the use of saflufenacil on lime crops met criteria III under section 3(c)(1)(F)(ii) of FIFRA because of the presence of glyphosate-resistant weeds and the efficacy of the chemical for controlling these weeds and because of the significant role this chemical will likely play in managing pest resistance. For lime crops, saflufenacil is important for controlling glyphosate-resistant horseweed/marestail and glyphosate-resistant, hairy fleabane in Central Valley, California.

Pumelo: Saflufenacil was registered for use on pumelo for end users on TREEVIX Powered by KIXOR Herbicide, EPA Reg. No. 7969-276 on 09/15/09. Also, the Agency determined that the use of saflufenacil on pumelo met criteria III under section 3(c)(1)(F)(ii) of FIFRA because of the presence of glyphosate-resistant weeds and the efficacy of the chemical for controlling these weeds and because of the significant role this chemical will likely play in managing pest resistance. For pumelo, saflufenacil is important for controlling glyphosate-resistant horseweed/marestail and glyphosate-resistant, hairy fleabane in Central Valley, California.

Olive: Saflufenacil was registered for use on olives for end users on TREEVIX Powered by KIXOR Herbicide, EPA Reg. No. 7969-276 on 09/16/14. Also, the Agency determined that the use of saflufenacil on olive met criteria III under section 3(c)(1)(F)(ii) of FIFRA because of the presence of glyphosate resistant weeds and the efficacy of the chemical for controlling these weeds and because of the significant role this chemical will likely play in managing pest resistance. For olives, saflufenacil is important for controlling glyphosate-resistant, hairy fleabane in Central Valley, California.

Crambe: Saflufenacil was registered for use on crambe for end users on Sharpen Powered by Kixor Herbicide, EPA Reg. No. 7969-278 on 05/19/11. Also, the Agency determined that the use of saflufenacil on crambe met criteria III under section 3(c)(1)(F)(ii) of FIFRA because of the presence of glyphosate-resistant weeds and the efficacy of the chemical for controlling these weeds and because of

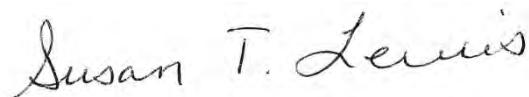
the significant role this chemical will likely play in managing pest resistance. For crambe, saflufenacil is important for controlling glyphosate-resistant *Amaranthus*, *Conyza*, *Ambrosia*, and *Kochia* in North Dakota, Montana, and the Midwest states.

Gold of Pleasure: Saflufenacil was registered for use on gold of pleasure for end users on Sharpen Powered by Kixor Herbicide, EPA Reg. No. 7969-278 on 05/19/11. Also, the Agency determined that the use of Saflufenacil on gold of pleasure met criteria I under section 3(c)(1)(F)(ii) of FIFRA because the Agency found that there are no other efficacious alternatives to saflufenacil registered for the use as a harvest aid desiccant in the production of gold of pleasure.

DETERMINATION

The Agency concludes that the nine uses listed above are minor uses and were registered within seven years of the original saflufenacil registration. The Agency concludes that saflufenacil meets the criterion I or criterion III for at least 9 minor use crops, thus supporting the extension of exclusive use under FIFRA section 3(c)(1)(F)(ii) for an additional three years. 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. 7969-275. Exclusive-use protection for data, which complies with 40 C.F.R. 152.83(c), submitted in support of this registration **will expire on September 3, 2022**. A copy of our review is enclosed.

Sincerely,



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

Enclosure