



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

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

**FEB 28 2014**

Ms. Lindsey Sorensen  
Landis International  
P.O. Box 5126  
Valdosta, GA 31603-5126

Authorized agent for Mitsui Chemicals Agro, Inc.

Dear Ms. Sorensen:

Subject: Dinotefuran Technical  
EPA Registration Number 86203-8  
Extension of Exclusive Data Use Period Granted  
Your submissions dated December 20, 2013  
OPP Decision Number 415211

This is the Office of Pesticide Programs' response to your revised petition dated 12/20/2013, submitted on behalf of Mitsui Chemicals Agro, Inc. (referred hereafter as Mitsui), requesting to extend the period of exclusive data use for the insecticide dinotefuran by 3 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 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.<sup>1</sup> The registration you cited was granted on September 17, 2004, and was the first registration for dinotefuran with the product name Dinotefuran 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, 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 for this pesticide during the extension period citing Mitsui'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 to 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

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<sup>1</sup> 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 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 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.

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.

### **Analysis of Justification for Exclusive Use Extension**

Mitsui submitted information on the role of dinotefuran in integrated pest management, Criterion IV of FIFRA section 3(c)(1)(F)(ii), to support their petition for extension of the exclusive use period.

The EPA determined that the minor crops were registered within seven years of the original registration of Dinotefuran Technical (satisfying the criteria under FIFRA section 3(c)(1)(F)(ii)). Dinotefuran was first registered on June 30, 2005, and additional minor uses were registered on June 18, 2008 and April 29, 2010.

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) and delay pests developing resistance to some pesticides. Insecticides that are relatively nontoxic to most beneficial insects are well suited for incorporation into IPM programs. EPA would consider that Criterion IV had been met in situations where there was compelling information that dinotefuran was important in managing insects as part of a larger IPM program used for control of key pests in a given crop.

Dinotefuran is a neonicotinoid insecticide classified by the Insecticide Resistance Action Committee (IRAC) as a Group 4A insecticide. Neonicotinoids are chemically similar to the naturally occurring molecule nicotine and act on the insect central nervous system via agonism of the post-synaptic nicotinic acetylcholine receptors. Dinotefuran is a systemic insecticide registered for foliar and soil applications on a variety of crops, including cotton, leafy and fruiting vegetables, cucurbits, grapes, potatoes, and berries. Dinotefuran is applied via foliar, soil, and chemigation used to provide systemic control of numerous sap-feeding foliar insect pests. Section 18 exemptions were granted in seven mid-Atlantic states in 2011 and reauthorized in 2012 and 2013 for use of dinotefuran on stone and pome fruits for control of the invasive brown marmorated stink bug (BMSB), *Halyomorpha halys*.

To further protect pollinators, EPA recently requested that registrants add new protective language to labels with foliar application for products containing dinotefuran and other nitroguanidine neonicotinoid active ingredients (imidacloprid, thiamethoxam, and clothianidin).

This language includes restrictions on applications to blooming plants and limits application timing to hours when pollinator activity is reduced. Currently registered dinotefuran product labels with foliar application have been amended to include the required pollinator protection language.

### Information Sources

EPA examined information submitted by the registrant, as well as relevant university extension service information, USDA Crop Profiles, and Mode of Action and resistance management information available from IRAC. These additional sources were only consulted to confirm or supplement the information submitted by the registrant. It is EPA policy not to substantiate exclusive use criteria if the data submitted is lacking or inadequate.

### Minor Crop Assessments

Mitsui submitted information in support of 21 representative minor crops: Cantaloupe, Watermelon, Honeydew Melon, Muskmelon, Summer squash, Cucumber, Pumpkin, Winter Squash, Peppers-Bell, Peppers-Non-Bell, Broccoli, Brussels Sprouts, Cabbage, Cauliflower, Mustard Greens, Onions-Bulb, Onions-Green, Watercress, Peaches, Nectarines, and Blueberries. It is EPA's policy to stop evaluating once 9 of the submitted crops have been found to meet the exclusive use criteria. The remaining crops will not be analyzed for review. EPA focused its review on peach, nectarine, cantaloupe, watermelon, honeydew melon, muskmelon, cucumber, pumpkin, and squash. EPA verified that these crops met the acreage requirement for minor crops under FIFRA section 2(II)(1) using USDA National Agricultural Statistics Service (NASS) data.

### Summary of Findings

- **Peach and Nectarine:** The information submitted by Mitsui to support criterion IV for peaches and nectarines was primarily based on pest management guidelines from New Jersey. According to this information, dinotefuran is one of the two best insecticides for control of the invasive brown marmorated stink bug (BMSB), *Halyomorpha halys*, on peaches and nectarines, including indications that dinotefuran is a preferred IPM tool to pyrethroids, due to toxicity to important insect natural enemies and other beneficial insects.

Additionally, EPA granted Section 18 emergency exemptions for use of dinotefuran on pome and stone fruits (including peaches and nectarines) for control of BMSB in 7 states-- PA, NJ, MD, DE, VA, WV, and NC--for the years 2011, 2012, and 2013. Applications under this exemption are limited to post-bloom periods to minimize exposure of insect pollinators. Approval of this emergency exemption indicates that growers have limited options in managing BMSB and that other insecticides lack sufficient efficacy against BMSB. EPA therefore concludes that dinotefuran is of high importance for controlling BMSB outbreaks and that dinotefuran satisfies both Criteria I and IV for peaches and nectarines.

- **Cucurbits:** The information submitted by Mitsui to support criterion IV for cantaloupe, watermelon, honeydew melon, muskmelon, cucumber, pumpkin, and squash was primarily

based on cucurbit management guidelines for whiteflies and melon aphids in California. According to this information, dinotefuran is ranked as having a high IPM value based upon being very effective against the target pest and having lower relative risk to natural enemies and honeybees, when compared to other available options. For silverleaf and sweetpotato whiteflies, *Bemisia tabaci* biotypes, which can transmit yellow stunting disorder in cucurbits, California recommends the use of dinotefuran (applied as a soil application at planting) as the most effective chemical control for cucurbits that are transplanted. UC planting guidelines for prevention of establishment of yellow stunting in cucurbits state that dinotefuran may confer better whitefly control than other neonicotinoids. Furthermore, Mitsui cites established research indicating that dinotefuran can be used to control whiteflies that have already developed resistance to imidacloprid.

For melon aphid, *Aphis gossypii*, which also attacks all the listed crops above and causes problematic sooty mold on cucurbit fruits, control is primarily achieved using foliar insecticide applications. California ranks dinotefuran as the number one preferred foliar insecticide option for melon aphid control, again based upon efficacy and impact to beneficial insects.

It is also of note that the pre-harvest interval for foliar applications of dinotefuran is only 1 day, in comparison to 21-30 days for other available neonicotinoid insecticides. This allows for much greater flexibility in treatment timing. For outbreaks occurring close to harvest, dinotefuran would be the only neonicotinoid insecticide available for use. Based on the above information, BEAD concludes that dinotefuran satisfies criterion IV for cantaloupes, watermelons, honeydew melons, muskmelons, cucumbers, pumpkins, and squash.

### **Determination**

EPA concludes that Mitsui has satisfied the requirements necessary to extend the period of exclusive use data for the nine crops listed above. EPA determined that dinotefuran satisfies criteria I and IV for an extension of the period of exclusive use for peach, nectarine, cantaloupe, watermelon, honeydew melon, muskmelon, cucumber, pumpkin, and squash. Therefore, EPA grants your request for a three year extension of exclusive use data protection for selected data under EPA Registration Number 264-830. Exclusive use protection for data, which complies with 40 CFR 152.83(c), submitted in support of this registration, will expire on September 17, 2017.

Sincerely,



Lois Rossi, Director  
Registration Division  
Office of Pesticide Programs