



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

**Response Letter for Exclusive-Use Period Extension  
Request for Data Protection Period for Buprofezin**

**August 20, 2012**



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

OFFICE OF  
CHEMICAL SAFETY  
AND POLLUTION PREVENTION

AUG 20 2012

Marie Maks  
Nichino America, Inc.  
4550 New Linden Hill Road, Suite 501  
Wilmington, Delaware 19808

**Subject: Buprofezin**  
**Exclusive-use period extension request for data protection**  
**Original submission dated September 2007 and various resubmissions**  
**Buprofezin Technical; EPA Reg. No. 71711-16; D439352**  
**Exclusive Use Extension Granted until September 7, 2013**

Dear Ms. Maks:

This letter responds to your request dated September 2007 and subsequent resubmissions that data associated with the September 2000 original registration for the active ingredient buprofezin, receive a three year extension of the original ten year exclusive-use protection period, from September 7, 2010 to September 7, 2013.

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 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 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

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-

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 plays or will play a significant part in an integrated pest management program.”

The Agency determined that the following nine minor uses were registered within seven years of the original registration of Buprofezin Technical: (1) Banana, (2) Cantaloupe, (3) Greenhouse Ornamentals/Nursery Crops, (4) Greenhouse Tomatoes, (5) Lettuce, (6) Lychee, (7) Papaya, (8) Peach, and (9) Pear. EPA also notes that the PPLS system contains active end use product registrations with these nine sites (EPA Reg. No. 71711-20, -21, -32, and -33).

### **Summary of Findings**

EPA evaluated information about characteristics of buprofezin, pest control claims, and production practices for nine crop sites. The registrant had submitted 12 minor crops, and the Agency reviewed the first 9 that met the criteria.

Buprofezin is a non-systemic narrow spectrum foliar insecticide in the thiadiazine class that is registered for use on a broad range of crops to control a variety of homopteran pests (e.g. whiteflies, mealybugs, leafhoppers, planthoppers, psylla, and scales). Buprofezin is an insect growth regulator/ chitin synthesis inhibitor that prevents proper formation of exoskeleton after molting. Buprofezin is the only member of the Insecticide Resistance Action Committee's (IRAC) Group 16 (inhibitors of chitin biosynthesis, type 1) (IRAC, 2012). While buprofezin is most effective against the nymphal stages of homopteran pests, Nichino claims that it also suppresses oviposition of adults and reduces the viability of eggs.

All four end use products for buprofezin contain resistance management language. The following is the Integrated Pest Management language on the label for resistance management for products 71711-20 and 71711-21:

“BRAND NAME insect growth regulator is classified by IRAC in Group 16 - chitin biosynthesis inhibitors and is not known to be cross-resistant to other classes of insecticides. However, insect

buprofezin. The Agency considered situations where growers had limited options in managing specific pests and where buprofezin is known to be an effective treatment.

*Requirements for Criterion III:* The Agency determined that Criterion III had been met in situations where there was compelling 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 insects have already developed resistance to alternative insecticides. For example, whiteflies, which were listed on several crops as a target pest which require resistance management, have 561 resistance reports in the Arthropod Resistance Management Database (2012).

*Requirements for Criterion IV:* 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 beneficial insects are well suited for incorporation into IPM programs. The Agency determined that Criterion IV had been met in situations where there was compelling information that buprofezin was important in managing insects as part of a larger IPM program that is intended to control the range of key pests in a given crop.

### **Banana**

Nichino cited portions of the Pest Management Strategic Plan (PMSP) for Banana Production in Hawaii (University of Hawaii, 2003) which reports that buprofezin "provides excellent efficacy against the coconut scale [*Aspidiotus destructor*]" and is target pest specific and "soft on natural enemies." The banana PMSP also mentioned that buprofezin was the only product registered for control of the spiraling whitefly [*Aleurodicus disperses*].

Based on the review of the submitted information, the Agency concludes that buprofezin satisfies criteria I and IV for bananas.

### **Cantaloupe**

Nichino cited portions of pest management guidelines for whitefly control in California (University of California, 2011) and an efficacy study from Arizona (Palumbo, 2009) in support of Criterion IV: the minor use pesticide plays or will play a significant part in an integrated pest management program. The University of California (2011) reference recommends the use of buprofezin in IPM programs to control whiteflies on cucurbits. The Palumbo (2009) reference concluded that buprofezin is a selective insecticide with a unique mode of action that is as good as or better than foliar and soil-applied neonicotinoid treatments in controlling immature whitefly populations. EPA concludes that the cited references provide support that buprofezin is a selective insecticide and an effective management tool for controlling whiteflies on cantaloupe.

Based on the review of the submitted information, the Agency concludes that buprofezin satisfies criterion IV for cantaloupe.

buprofezin in lettuce integrated pest management programs (Criterion IV). The first reference (USDA, 2003: Pest Management Strategic Plan for lettuce in Arizona and California) reports that buprofezin provides excellent control of whitefly in lettuce and is very safe to the beneficial arthropods including lady beetles, lacewings, syrphid flies, parasitic wasps, tachinid flies, big-eyed bugs, minute pirate bugs, and assassin bugs. The second reference (Ohio State University, 2010b) lists buprofezin control of whiteflies on lettuce and also reports that buprofezin has low to moderate toxicity to beneficial arthropods. Because buprofezin is relatively nontoxic to beneficial insects, its use is compatible with predator and parasitoid augmentation programs that are sometimes employed in IPM programs.

Based on the review of the submitted information, the Agency concludes that buprofezin satisfies criterion IV for lettuce.

### **Lychee**

Nichino provided one reference (University of Florida, 2009a) documenting the importance of buprofezin in managing whitefly resistance (Criterion III) on lychee grown in Arizona and California. The Agency's review of the provided reference led to the conclusion that only a few insecticides (imidacloprid, pyriproxyfen, and buprofezin) are available to lychee growers for whitefly control and that buprofezin would be useful for resistance management.

The Agency agrees that having such a small number of registered insecticides could lead to repeated applications of insecticides with the same mode of action which could result in development of resistant populations. Whiteflies have 561 resistance reports in the Arthropod Resistance Management Database (2012) and thus are particularly prone to resistance development.

Based on the review of the submitted information, the Agency concludes that buprofezin satisfies criterion III for lychee.

### **Papaya**

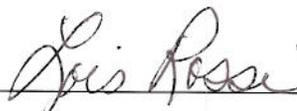
Nichino provided two references documenting the importance of buprofezin in papaya integrated pest management programs (Criterion IV). The first reference (University of Hawaii, 2008: Pest Management Strategic Plan for Papaya) lists buprofezin as an option for control of papaya mealybug, a recently established pest. This reference also judged buprofezin has excellent efficacy against the white peach scale. Lastly this strategic plan judged buprofezin as having low impact on nine groups of beneficial insects commonly found on papaya in Hawaii. The second reference (University of Florida, 2009b) mentions buprofezin as a registered product for use in papaya in Florida. This reference also lists papaya whitefly and papaya mealybug as important pests of papaya in Florida, and notes that buprofezin is labeled for the control of these pests.

Based on the review of the submitted information, the Agency concludes that buprofezin satisfies criterion IV for papaya.

### **Peach**

Nichino provided two references documenting the importance of buprofezin in managing

programs. Therefore, the Agency **GRANTS** your request for a three year extension of exclusive-use data protection for selected data under EPA Registration No. 71711-16. 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 7, 2013.

A handwritten signature in cursive script, reading "Lois Rossi", is positioned above a horizontal line.

Lois Rossi, Director  
Registration Division  
Office of Pesticide Programs

cc: Marion Johnson  
Mark Suarez  
Michele Knorr  
Arnet Jones  
David Brassard