US Environmental Protection Agency
Office of Pesticide Programs

Petition for Pyriproxyfen

April 11, 2002

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Extension of the Period of Exclusive Data Use For the Active Ingredient Pyriproxyfen

Mr. Marion Johnson
Product Manager Team 10
Office of Pesticide Programs (H7505C)
Document Processing Desk (AMEND)
U.S. Environmental Protection Agency
Room 266A, Crystal City Mall 2
1921 Jefferson Davis Highway
Arlington, Virginia 22202

Dear Mr. Johnson,

Valent U.S.A. Corporation is in the seventh year of a ten-year period of exclusive data use for the active ingredient pyriproxyfen. The ten-year exclusivity statute is established under FIFRA Section 3(c)(1)(F)(i). Valent U.S.A. is eligible for and requests extension of the exclusivity period for an additional three years as established under FIFRA Section 3(c)(1)(F)(ii). The extension is determined by the number of minor use registrations for the active ingredient, with one additional year of exclusivity granted for every 3 minor use registrations, up to a maximum of three years. At this time, Valent U.S.A. has twelve minor use registrations as defined by the statute, with an additional six minor use registrations on the OPP registration Work Plan to be completed by June 2002. Therefore, pyriproxyfen qualifies for an additional three years of exclusive use data protection.

Current Pyriproxyfen Registrations

Pyriproxyfen was first granted U.S. registration on September 15, 1995 (Sumilarv Technical Grade, EPA Reg. No. 10308-11), and is the active ingredient contained in the following Valent U.S.A. end-use products:

End Use Product	EPA Reg. No.
Knack Insect Growth Regulator	59639-95
Distance Insect Growth Regulator	59639-96
Esteem Insect Growth Regulator	59639-104
Esteem Ant Bait	59639-114
Esteem 35 WP Insect Growth Regulator	59639-115

Criteria Used to Determine the Number of Minor Use Registrations for Pyriproxyfen

In determining the total number of minor use registrations to be applied toward the pyriproxyfen exclusivity extension, the following criteria were used:

A. One minor use registration for which data has been provided may be counted.
B. One minor use for each representative crop under a registered crop group may be counted. If the representative crop is major, a minor crop may be substituted and therefore counted.
C. A minor use registration may be counted regardless of a tolerance requirement. For example, a minor use registration for ornamentals is counted toward exclusivity, even though a tolerance is not required for the ornamental crop registration.

Summary of Minor Use Registrations for Pyriproxyfen

Number of Minor Uses	Criteria	Crop / End Use Product / Rationale
3	A & B	Citrus crop group- Knack IGR, Esteem IGR, Esteem 35 WP IGR, Esteem Ant Bait. Three representative crops. Minor uses include lemon, grapefruit and tangerines (substitution for orange).
3	A & B	Fruiting vegetable crop group- Knack IGR, Esteem IGR. Three representative crops. Minor uses include pepper, jalapeno and eggplant (substitution for tomato).
2	A & B	Tree nut crop group- Knack IGR, Esteem IGR, Esteem 35 WP IGR, Esteem Ant Bait. Two representative crops. Minor uses include walnut and Brazil nut (substitution for almonds).
1	A	Pear- Knack IGR, Esteem IGR, Esteem 35 WP IGR, Esteem Ant Bait.
1	C	Ornamentals- Distance IGR.
1	A	Pistachio (bearing)- Esteem Ant Bait. SLN CA-010029.
1	C	Olive (non-bearing)- Esteem Ant Bait.

Total: 12

Pending Pyriproxyfen Minor Use Registrations

EPA's third quarter work plan, which is due for completion by June 2002, includes pyriproxyfen registration on stone fruit, which includes three representative crops (all minor), guava, lychee and blueberries. If completed as scheduled, the pending registrations would add six minor use registrations toward the exclusivity extension.

Additional Requirements

In addition to meeting the minor use registration requirements, pyriproxyfen also meets the chemical characteristics and use requirements set forth under FIFRA Section 3(c)(1)(F)(ii). Pyriproxyfen is a reduced risk compound, providing control of insect species with no known toxic

effects to humans, other mammalian species or endangered species. Pyriproxyfen poses a reduced risk to the environment as well, with low use rates, rapid degradation in the environment, and low leaching potential. With its unique mode of action as a juvenile hormone mimic in insects, pyriproxyfen end-use products are an integral part of both integrated pest management programs and pest resistance management programs in minor crops.

Independent support for the value of pyriproxyfen in pest management programs for minor crops may be found through inspection of Pest Management Strategic Plans (PMSPs) which have been facilitated by USDA's Office of Pest Management Policy. Of the minor uses listed above, PMSPs have been finalized for peaches (FL, GA, MI, NC, NJ, PA, SC, CA), tart cherry (MI) and blueberry (MI).

The PMSP for peaches in FL, GA, MI, NC, NJ, PA, and SC noted a critical need for scale insect control, and a regulatory need for reduced-risk products with multiple modes of action, especially in light of current Agency scrutiny of existing organophosphate tools. This PMSP also identifies Oriental Fruit Moth as the key pest in peach production in the Midwest and Northeast. Pyriproxyfen provides excellent control of San Jose Scale and Lecanium Scale, and suppression of Peach Twig Borer and Oriental Fruit Moth, with a unique and reduced-risk mode of action. Finally, the California peach PMSP identifies registration of pyriproxyfen specifically as the number one critical need in California peach production "in order to better manage San Jose scale and reduce dependence on organophosphates."

In addition to the above-mentioned PMSPs, USDA has developed "Crop Profiles" describing production practices for many crops in many states. Although the Crop Profiles do not provide direct recommendations for pest management needs as do the PMSPs, they are instructive in describing current pest management practices which could benefit from the introduction of pyriproxyfen. Following is a table with a sampling of minor use crops, states, and current chemical controls, which are listed for use to control pests on the pyriproxyfen label. In some cases pyriproxyfen itself is already listed. All information presented in the table was excerpted from USDA Crop Profiles published at http://www.pmcenters.org/:

CROP	STATE	PEST	CHEMICAL CONTROLS
Bedding Plants	WA	Fungus gnats	bifenthrin
Bell Pepper	CA	Silverleaf Whitefly	Dimethoate, endosulfan, naled, oxamyl
Chrysanthemum	OH	Whiteflies, fungus gnats	Imidacloprid, acephate, chlorpyrifos, endosulfan, bifenthrin, fenpropathrin, azadirachtin, diflubenzuron, S-kinoprene, sulfotepp, nicotine
Citrus	CA	California Red Scale	Pyriproxyfen*, buprofezin, chlorpyrifos*, carbaryl, methidathion, oil (*also in AZ)
	CA	Cottony Cushion Scale	Pyriproxyfen, buprofezin, malathion, methidathion
	AZ	Woolly Whitefly	pyriproxyfen

	CA	Black Scale	Methidathion, carbaryl, oil
	CA	Southern Fire Ant	Chlorpyrifos, avermectin
Citrus (minor)	FL	Scales	Ethion, Chlorpyrifos, malathion, methidathion, azadirachtin
Eggplant	FL	Silverleaf Whitefly	Imidacloprid, endosulfan, permethrin
Olive	CA	Black Scale	Carbaryl, methidathion, oil
Ornamentals	FL	Whiteflies, scales, fungus gnats	Imidacloprid, acephate, diazinon, dimethoate, chlorpyrifos, endosulfan, bifenthrin, fenpropathrin, azadirachtin, S-kinoprene, oil
Pear	CA	Pear Psylla	avermectin, esfenvalerate, permethrin, amitraz, oil
	CA	Codling Moth	Azinphos-methyl, methyl parathion, phosmet
	OR	San Jose Scale	OP + oil at dormat growth stage
Plum	CA	San Jose Scale	Chlorpyrifos, diazinon, carbaryl, methidathion, methyl parathion, phosmet

Thank you for your consideration of our three-year exclusive use extension request for pyriproxyfen. If you have any questions, please contact me at (925) 256-2852 or Eric Maurer, located at Valent U.S.A.'s Washington, D.C. office, at (202) 872-4682.

Sincerely,

Harry Radke
Project Manager- Pyriproxyfen
Registration and Regulatory Affairs