US Environmental Protection Agency
Office of Pesticide Programs

Petition for 3 Year Extension of Exclusive Data Use for Spirodiclofen

September 27, 2011

Bayer CropScience

September 27, 2011

Ms. Nicole Williams
Registration Division EPA 7505 P
Office of Pesticide Programs
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington DC 20460

Re: ATTENTION: Minor Use - Exclusive Use Request

Petition for 3 Years Extension of Exclusive Data Use for Spirodiclofen (EPA Reg. No. 264-830) as provided for Under FIFRA Section 3(c) (1) (F) (ii)

Dear Ms. Williams,

Bayer CropScience
RTP
P. O. Box 12014
RTP, NC 27709
Tel. 919 549-2000

Bayer CropScience hereby petition EPA to extend the period of exclusive data use for Spirodiclofen insecticide by 3 years, by applying the provision of FIFRA Section 3(c) (1) (F) (ii).

Bayer CropScience believe that Spirodiclofen meets all of the criteria required for this provision based on currently registered uses.
Residue studies supporting registration are available for 7 minor use food crops and by inclusion in specific crop groups, an additional 31 minor use crops are eligible, bringing the qualifying total for the extension of exclusive use data protection to 38 minor use crops. This will qualifies Spirodiclofen for 3 additional year data exclusivity (1 year for 3 minor uses up to a maximum of 3 years), providing the other criteria listed in FIFRA Section 3(c) (1) (F) (ii) are met. Details of how Spirodiclofen meets each of these criteria is described in attached petition.

Attached are three copies of following report for extension of exclusive data use:

Bell, J.; Movassaghi, S.; Adam, K. (2011); Petition for a Three-Year Extension of Exclusive Use Data Protection for Spirodiclofen; Report No. US0238, Bayer CropScience, 2 T.W. Alexander Dr., Research Triangle Park, NC. August 27, 2011; 11 pages.

If you have any question, please contact me either by telephone at 919-549-2156 or email at sherry.movassaghi@bayercropscience.com.

Sincerely,

Sherry Movassaghi

Sherry Movassaghi, Ph.D.
Registration Product Manager

Title

Petition for a Three-Year Extension of Exclusive Use Data Protection for Spirodiclofen

Data Requirement
Not Applicable

Authors
John Bell
Sherry Movassaghi
Kevin Adam

Date
August 27, 2011

Report Number
US0238

Submitted by
Bayer CropScience
2 T.W. Alexander Dr.
Research Triangle Park, NC 27709

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA, Section 10(d)(1)(A)(B), or *(C)*. However, these data are the property of Bayer CropScience and, as such, are considered to be trade secret and confidential for all purposes other than compliance with FIFRA Section 10. Submission of these data in compliance with FIFRA Section 10 does not constitute a waiver of any right to confidentiality which may exist under any other statute or in any country other than the USA.

Company: Bayer CropScience

Agent: Sherry Movassaghi

Sherry Movassaghi
Registration Manager
Bayer CropScience

Date: September 27, 2011

The above statement supersedes all other statements of confidentiality that may occur elsewhere in this report.

GOOD LABORATORY PRACTICE COMPLIANCE STATEMENT

This report does not meet the requirements for EPA FIFRA Good Laboratory Practice Standards, 40 CFR Part 160, and differs in the following way:

(1) This report is not subject to Good Laboratory Practices.

Submitter: _____

Sherry Movassaghi
Registration Manager
Bayer CropScience

Date: September 27, 2011

Petition for a Three-Year Extension of Exclusive Use Data Protection for Spirodiclofen

Bayer CropScience, the sole registrant of the proprietary miticide, spirodiclofen, is hereby petitioning the Environmental Protection Agency for a three-year extension of exclusive use data protection, as provided under FIFRA Section 3(c) (1) (F) (ii).

FIFRA Section 3(c) (1) (F) (ii) states that:
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.

Further, in a Question & Answer document [http://www.epa.gov/pesticides/minoruse/#questions] concerning the exclusive use extension policy, the Agency clarifies that only one of the four criteria is necessary to qualify for consideration:

"To qualify to be considered under § 3(c)(1)(F)(ii) of FIFRA for an extension of the exclusive use period, the minor uses must be registered within the first 7 years from the start of the exclusive use period and meet one of the four criteria listed in FIFRA § 3(c)(1)(F)(ii)."

Additionally, in the same Question & Answer document, the Agency states that all minor-use crops contained in a given crop grouping potentially qualify for consideration:

"If the data for the representative crops in a crop grouping have been submitted and support establishment of the crop grouping, the Agency will count the non-representative minor crops within a crop grouping provided that they were registered within 7 years of the commencement of the initial exclusive use period for the active ingredient and the registrant is marketing the product for the minor crops. However, the non-representative minor crops must meet one of the four criteria identified in § 3(c)(1)(F)(ii) in order to be eligible to be considered for extension of exclusive use data protection."

As described in this petition, spirodiclofen meets three of the four criteria cited in FIFRA Section 3(c) (1) (F) (ii). Spirodiclofen Technical (EPA Reg. No 264-830) and the end-use product ENVIDOR® 2 SC Miticide (EPA Reg. No 264-831) were registered by the EPA on June 30, 2005.

EPA registered the crops and crop groups listed below on June 30, 2005:

- Fruit, citrus, group 10
- Fruit, pome, group 11
- Fruit, stone, group 12
- Grape
- Nut, tree, group 14
- Pistachio

EPA registered the crops listed below on April 29, 2010:

- Avocado
- Black sapote
- Canistel
- Mamey sapote
- Mango
- Papaya
- Sapodilla
- Star apple

To support the above registered crops and crop groups, residue trials were conducted on the representative major and minor use crops. The minor use crops for which residue data are available are listed in Table 1.

Table 1. Minor Use Crops on which Residue Studies Have Been Conducted by Bayer CropScience.

Crop Group/Subgroup	Minor Use Crop	MRID #
10	Grapefruit	45696612
10	Lemon	45696612
11	Pear	45696606
12	Cherry	45696605
12	Peach	45696605
12	Plum	45696605
None	Avocado	47630101

Table 2. Additional Qualifying Minor Use Crops Covered by Inclusion in Crop Groupings.

Crop Group/Subgroup	Minor Use Crop
Citrus Fruits – Crop Group 10	Calamondin, Citrus citron, Citrus hybrids, Kumquat, Lime, Mandarin, Pummelo, Satsuma
Pome Fruits – Crop Group 11	Crabapple, Loquat, Mayhaw, Oriental Pear, Quince
Stone Fruits – Crop Group 12	Apricot, Nectarine, Plumcot, Prune
Tree Nuts – Crop Group 14	Beechnut, Brazil Nut, Butternut, Cashew, Chestnut, Chinquapin, Filbert, Hickory Nut, Macadamia Nut, Walnut
Tropical Fruits	Black Sapote, Canistel, Mamey Sapote, Sapodilla

Residue studies supporting registration are available for 7 minor use food crops and by inclusion in specific crop groups listed above, an additional 31 minor use crops are eligible, bringing the qualifying total for the extension of exclusive use data protection to 38 minor use crops.

Supported by the following details, we conclude that these minor crop registrations qualify spirodiclofen for an additional three years of exclusive use (one year for each three minor crop uses up to a maximum of three years exclusive use for nine qualifying minor crops).

FIFRA Criterion I: There are insufficient efficacious alternative registered pesticides available for the use

Spirodiclofen is a unique, selective, foliar miticide belonging to the chemical class of tetronic acids, developed exclusively by Bayer CropScience. The product has a new and unique mode of action classified as a lipid biosynthesis inhibitor (LBI). Spirodiclofen is active by contact against all developmental stages of mites, as well as eggs and female adults.

Spirodiclofen is highly effective against the economically important genera of mites in the U.S. that infest perennial minor-use crops, including:

- *Tetranychus* (Twospotted spider mite, Pacific spider mite)
- *Panonychus* (European red mite, Citrus red mite)
- *Phyllocoptruta* (Citrus rust mite)
- *Brevipalpus* (Citrus flat mite)
- *Aculus* (Peach silver mite, Apple rust mite)

Its performance is equal or superior to currently used miticides in the market from different chemical classes such as abamectin, bifenazate, dicofol, pyridaben, hexythiazox, clofentezine, propargite, and fenbutatin-oxide. The unique mode of action of spirodiclofen shows no cross resistance to other miticides currently in the market, making it an attractive new option for the control of phytophagous mites.

A summary of all alternative miticides presently registered for control of mite species in the minor-use crops contained in the citrus fruits, pome fruits, stone fruits, and tree nuts crop groups and the tropical fruits are contained in tables 3-7 below. As can be seen, there are a limited number of alternative products available, with several approved for non-bearing crops only and others having geographical restrictions. On some crops, particularly minor-use tropical fruit crops, only one alternative product, bifenazate, is currently approved for use.

Table 3. Alternatives to Spirodiclofen for Use on Citrus Fruits Crop Group Minor-Use Crops.

	MOA Group	Calamondin	Citrus citron	Citrus Hybrids	Grapefruit	Kumquat	Lemon	Lime	Mandarin	Pummelo	Satsuma
SPIRODICLOFEN	23	x	x	x	x	x	x	x	x	x	x
Abamectin	6	x	x	x	x	x	x	x	x	x	x
Acequinocyl	20B	x	x	x	x	x	x	x	x	x	x
Bifenazate	25	Non-bearing only	Non-bearing only	Non-bearing only	Non-bearing only	Non-bearing only	Non-bearing only	Non-bearing only	Non-bearing only	Non-bearing only	Non-bearing only
Diflubenzuron	15				x				x	x	
Fenbutatin-oxide	12B	x	x	x	x	x	x	x	x	x	x
Fenpyroximate	21A	x	x	x	x	x	x	x	x	x	x
Hexythiazox	10A	AZ,CA,TX only	AZ,CA,TX only	AZ,CA,TX only	AZ,CA,TX only	AZ,CA,TX only	AZ,CA,TX only	AZ,CA,TX only	AZ,CA,TX only	AZ,CA,TX only	AZ,CA,TX only
Propargite	12C	Non-bearing only	Non-bearing only	Non-bearing only	AZ,CA only	Non-bearing only	Non-bearing only	Non-bearing only	Non-bearing only	Non-bearing only	Non-bearing only
Pyridaben	21A	x	x	x	x	x	x	x	x	x	x

x – Section 3 registration.

Table 4. Alternatives to Spirodiclofen for Use on Pome Fruits Crop Group Minor-Use Crops.

	MOA Group	Crabapple	Loquat	Mayhaw	Oriental Pear	Pear	Quince
SPIRODICLOFEN	23	x	x	x	x	x	x
Abamectin	6					x	
Acequinocyl	20B	x	x	x	x	x	x
Bifenazate	25	x	x	x	x	x	x
Clofentezine	10A					x	
Dicofol	UN	x				x	x
Etoxazole	10B	x	x			x	x
Fenbutatin-oxide	12B					x	
Fenpyroximate	21A	x	x	x		x	x
Hexythiazox	10A	x	x	x	x	x	x
Propargite	12C					Non-bearing only	Non-bearing only
Pyridaben	21A				x	x	

x – Section 3 registration.

Table 5. Alternatives to Spirodiclofen for Use on Stone Fruits Crop Group Minor-Use Crops.

	MOA Group	Apricot	Cherry	Nectarine	Peach	Plum	Plumcot	Prune
SPIRODICLOFEN	23	x	x	x	x	x	x	x
Abamectin	6	x	x	x	x	x	x	x
Bifenazate	25	x	x	x	x	x	x	x
Clofentezine	10A	x	x	x	x			
Dicofol	UN	x	x	x	x	x		x
Etoxazole	10B	x	x	x	x	x	x	x
Fenbutatin-oxide	12B		x	x	x	x		x
Hexythiazox	10A	x	x	x	x	x	x	x
Propargite	12C	Non-bearing only	x	x	Non-bearing only	Non-bearing only		Non-bearing only
Pyridaben	21A	Except CA	Except CA	x	x	x		x

x – Section 3 registration.

Table 6. Alternatives to Spirodiclofen for Use on Tree Nuts Crop Group Minor-Use Crops.

	MOA Group	Beechnut	Brazil Nut	Butternut	Cashew	Chestnut	Chinquapin	Filbert	Hickory Nut	Macadamia	Pistachio	Walnut
SPIRODICLOFEN	23	x	x	x	x	x	x	x	x	x	x	x
Abamectin	6	x	x	x	x	x	x	x	x	x	x	x
Acequinocyl	20B	x	x	x	x	x	x	x	x	x	x	x
Bifenazate	25	x	x	x	x	x	x	x	x	x	x	x
Clofentezine	10A											x
Dicofol	UN											
Diflubenzuron	15											
Etoxazole	10B	x	x	x	x	x	x	x	x	x	x	x
Fenbutatin-oxide	12B										x	x
Fenpyroximate	21A	x	x	x	x	x	x	x	x	x	x	x
Hexythiazox	10A	x	x	x	x	x	x	x	x	x	x	x
Propargite	12C							Non-bearing only		Non-bearing only	Non-bearing only	Non-bearing only
Pyridaben	21A	x	x	x	x	x	x	x	x	x	x	x

x – Section 3 registration.

Table 7. Alternatives to Spirodiclofen for Use on Tropical Fruit Minor-Use Crops.

	MOA Group	Avocado	Black Sapote	Canistel	Mamey Sapote	Mango	Papaya	Sapodilla	Star Apple
SPIRODICLOFEN	23	x	x	x	x	x	x	x	x
Abamectin	6	2(ee)							
Bifenazate	25	x	x	x	x	x	x	x	x
Fenbutatin-oxide	12B						x		

x – Section 3 registration.

FIFRA Criterion III: The minor use pesticide plays or will play a significant part in managing pest resistance.

Heavy reliance or overuse of a single product/mode of action against a given species will likely give rise to resistance over time. The continued use of a narrow range of modes of action often results in the selection of individuals that are resistant to that product/mode of action or closely related products sharing a common mode of action. With each successive generation, these resistant individuals predominate within the population and eventually render the product(s)/mode of action ineffective against these populations. When this occurs, heavier selection pressure is then exerted on the remaining modes of action, eventually leading to the development of resistance to those products and their eventual loss from the market.

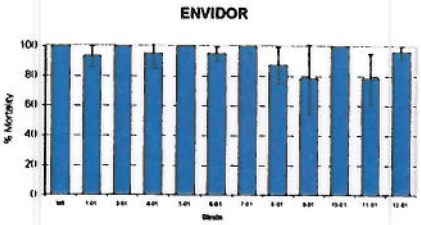
Growers must have an array of pest control options available to them and those options must be used wisely to maintain their effectiveness for as long as possible. Widespread resistance to several traditional classes of miticides creates the need for products with new modes of action to delay or reduce resistance development. Spirodiclofen is a much needed tool for resistance management due to its novel mode of action. It is a lipid biosynthesis inhibitor and is categorized in mode of action Group 23 by the Insecticide Resistance Action Committee (IRAC). As shown in Table 8, spirodiclofen is the only Group 23 product available to control mites in various perennial minor-use crops.

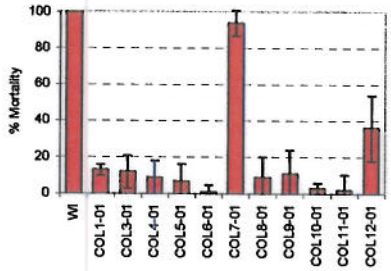
Table 8. Mode of Action and IRAC Mode of Action Grouping for Spirodiclofen and Alternative Products in Various Perennial Minor-Use Crops

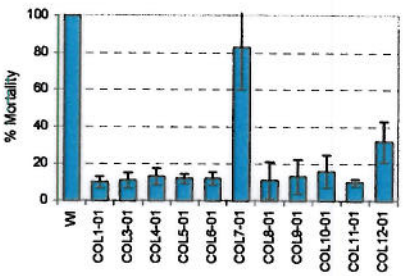
Active Ingredient	Trade Name	Mode of Action	MOA Group
SPIRODICLOFEN	ENVIDOR® 2SC Miticide	Lipid Biosynthesis Inhibitor	23
Abamectin	Agri-Mek® 0.15EC Miticide/Insecticide	Chloride Channel Activator	6
Acequinocyl	Kanemite® 15 SC Miticide	Mitochondrial Complex 3 Electron Transport Inhibitor	20B
Bifenazate	Acramite® -50WS Miticide	Neuronal Inhibitor	25
Clofentezine	Apollo	Mite Growth Inhibitor	10A
Hexythiazox	Onager® Miticide	Mite Growth Inhibitor	10A
Etoxazole	Zeal® Miticide	Mite Growth Inhibitor	10B
Dicofol	Kelthane® 50WSP Miticide	Unknown	UN
Diflubenzuron	Micromite® 80WGS Insect Growth Regulator	Chitin biosynthesis inhibitor	15
Fenbutatin-oxide	Vendex® 50WP Miticide	ATP Synthase Inhibitor	12B
Fenpyroximate	FujiMite® 5EC Miticide/Insecticide	Mitochondrial Complex 1 Electron Transport Inhibitor	21A
Pyridaben	Nexter® Miticide/Insecticide	Mitochondrial Complex 1 Electron Transport Inhibitor	21A
Propargite	Omite® -30WS Agricultural Miticide	ATP Synthase Inhibitor	12C

Resistance of spider mites to abamectin, pyridaben, and several other miticides has been well documented in various states within the U.S., as well as in several countries. In many crops, both major and minor use, mites have been exposed to a limited number of active ingredients for many years and although not all have been documented, control problems are being reported more frequently, which may indicate the evolution of resistant mite populations. Spirodiclofen is a new mode of action in the market which provides an additional rotation partner to reduce the excessive selection pressure on all commercially available products.

Laboratory studies with spirodiclofen have shown excellent control of mite strains resistant to both abamectin and pyridaben. The following graphs show the activity of the various modes of action against spider mites strains having various degrees of resistance to abamectin (Agrimek) and/or pyridaben (Nexter) (WI is a fully-susceptible laboratory strain). The excellent activity of spirodiclofen (ENVIDOR) against abamectin and pyridaben resistant strains indicates that no cross-resistance exists between spirodiclofen and these modes of action.







Aside from providing excellent control of the economically important mite species infesting minor-use crops, spirodiclofen is a powerful tool as a rotation partner in an overall resistance management program. The introduction of spirodiclofen into the market has reduced the selection pressure on existing products and helps to preserve these chemical classes for continued use in the future.

As a product stewardship measure, the use of spirodiclofen is restricted to a single application per crop season. If additional mite control is required, another product with a different mode of action should be utilized.

FIFRA Criterion IV: The minor use pesticide plays or will play a significant part in an integrated pest management program.

The USDA has defined Integrated Pest Management (IPM) as, "A sustainable approach to managing pests by combining biological, cultural, physical, and chemical tools in a way that minimizes economic, health, and environmental risks". Laboratory, semi-field and field investigations with spirodiclofen during product development, as well as since commercial introduction in 2005, have shown excellent selectivity towards beneficial arthropods used in current IPM programs.

The main challenge for products having miticidal activity are their selectivity towards predacious mites and their compliance with current IPM systems where they should only be used as a selective and corrective tool when beneficials can no longer maintain population densities below the economic injury level. In many established IPM systems, *Typhlodromus pyri* is a key natural predacious mite particularly in pome fruit crops, being able to exert a strong regulating influence on the density of the pest population. *Neoseiulus californicus* is also an important predacious mite in some systems. Selectivity towards other beneficials in IPM systems, such as ladybird beetles, minute pirate bugs, lacewings, and earwigs is also important.

Investigations have shown spirodiclofen to be compatible in IPM-starting systems as well as in stable systems. Spirodiclofen treatment is mostly needed in plantings in transition to IPM, during the first and second year after release when the population of *Typhlodromus pyri* may be at population densities insufficient to control phytophagous mites. In these situations, a spirodiclofen application may negatively impact the still fragile *Typhlodromus pyri* population but also the phytophagous mite population(s) will decrease even more dramatically, essentially regulating the start of IPM by lowering the predator:prey-ratio so that economic damage can be avoided. In this transitional phase to IPM, characterised by a sensible balance, the possible harmful effect of spirodiclofen does not compromise the within-season recovery of predacious mites.

In stable IPM systems, spirodiclofen is used to correct occasional outbreaks of phytophagous mites. The product may have slight effects on predacious mites but an even more dramatic effect on phytophagous mites, again creating a more favorable predatory:prey ratio that does not compromise the IPM compatibility of the product. Spirodiclofen has shown no effects on ladybird beetles, lacewings, minute pirate bugs, and earwigs. Beneficial populations are maintained and can perform their natural function to limit the number of pests. This IPM compatibility enables spirodiclofen to play a key regulating role when chemical treatments are still needed in IPM systems in perennial crops.

Conclusions

Spirodiclofen satisfies not only one but three of the four criteria for granting the three-year extension of exclusive use data protection as provided under FIFRA Section 3(c) (1) (F) (ii). Registrations have been granted on 38 minor use crops, greatly exceeding the nine minor crops required for an additional three-years of exclusive use. As outlined above, spirodiclofen is an extremely valuable tool for management of phytophagous mites infesting a range of minor-use perennial crops.

Spirodiclofen brings a new mode of action to a wide range of crops and mite pests. It will improve the adoption of IPM strategies by providing a much needed resistance management tool to extend the life of the other limited, commercially-available miticides in minor-use perennial crops. Bayer CropScience believes that spirodiclofen exceeds the statutory minimum number of required minor use registrations and meets 3 of the 4 criteria required for extending the exclusive use period. We look forward to receiving the additional three years of exclusive use data protection for spirodiclofen under FIFRA Section 3(c) (1) (F) (ii).

References

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