

**CALIFORNIA DEPARTMENT OF PESTICIDE REGULATION
PUBLIC REPORT 2007-1**

**Spirodiclofen
Tracking ID Number 213001**

DESCRIPTION OF ACTION

Bayer Cropscience LP submitted an application seeking California registration of Envidor 2 SC Miticide, EPA Reg. No. 264-831. Envidor 2 SC Miticide contains the new active ingredient spirodiclofen. It is a miticide intended for application to citrus, grapes, pome fruit, stone fruit and tree nuts.

The Department of Pesticide Regulation (DPR) evaluated the product label and data and found it acceptable to support registration of Envidor 2 SC Miticide. Precautionary and first aid statements on the product label, as well as label directions requiring personal protective equipment (PPE) and other protective measures adequately mitigate potential health risks to persons who may come in contact with the pesticide during application. DPR does not expect significant adverse environmental impacts to result from registration of Envidor 2 SC Miticide. The U.S. Environmental Protection Agency (U.S. EPA) registered Envidor 2 SC Miticide on June 30, 2005.

BACKGROUND

Registrant:	Bayer Cropscience LP
Common name:	Spirodiclofen
Chemical name:	Butanoic acid, 2,2-dimethyl-,3-(2,4-dichlorophenyl)-2-oxo-1-oxaspiro[4.5]dec-3-en-4-yl ester
Brand name:	Envidor 2 SC Miticide
Uses:	To control mites on citrus, grapes, pome fruit, stone fruit and tree nuts
Pests controlled:	Controls a wide range of mite species, including European red mite, Apple rust mite, Pacific spider mite, and Two spotted spider mite
Type of registration:	Full registration

Envidor 2 SC Miticide is a liquid concentrate containing 22.3% spirodiclofen as the active ingredient (a.i.). The product is intended for application to citrus, grapes, pome fruit, stone fruit and tree nuts, and may be mixed with other recommended pesticides, fertilizers and micronutrients. The mode of action of Envidor 2 SC Miticide is as a lipid biosynthesis inhibitor (LBI). At the application rates recommended on the product label, it has contact activity on mite eggs, all nymphal stages, all quiescent stages and adult females. Adult males are not affected.

SCIENTIFIC REVIEW

A. Chemistry

1. **Product Chemistry:** DPR evaluated the submitted chemistry studies for Envidor 2 SC Miticide. The submitted data support registration of Previcur Flex Fungicide. The results are summarized in Table I.

Table I. Physical and Chemical Properties of Envidor 2 SC Miticide

Properties	Values
Physical state	Liquid
Color	Off-White
Density (20°)	1.09 grams/cubic centimeter
PH (1% solution)	3.3 (10% suspension)
Solubility a.i. (water)	>50 ppb@ 20° and pH 4
Vapor pressure a.i.	5 X 10 ⁻⁹ mm Hg (25°C)
Viscosity	723 cps @ 25°C
Henry's Law Constant 20°C a.i.	2.3 X 10 ⁻⁸ atm-m ³ /mole @ 20°C
Octanol/Water Partition Coefficient a.i.	680,000 @ 20°C and pH 4
log Kow a.i.	5.83

2. **Residues in Food and Animal Feed:** An adequate residue analytical method was submitted. Submitted data indicate that residues of spirodiclofen are not likely to exceed the established tolerances. The U.S. EPA established tolerances in 40 Code of Federal Regulations (CFR) § 180.608 for residues of spirodiclofen on citrus, grapes, pome fruit, stone fruit and tree nuts are summarized in Table II.

Table II. U.S. EPA Established Tolerances for Spirodiclofen residues

Commodity	Tolerance
Almond, hulls	20.0 ppm
Apple, wet pomace	2.0 ppm
Citrus, fruit (group 10)	0.50 ppm
Citrus, juice	0.60 ppm
Citrus, oil	20.0 ppm
Fruit, pome (group 11)	0.80 ppm
Fruit, stone (group 12)	1.0 ppm
Grape, fruit	2.0 ppm
Grape, juice	2.4 ppm
Grape, raisin	4.0 ppm
Nut, tree (group 14)	0.10 ppm
Pistachio	0.10 ppm

3. **Environmental Fate:** The spirodiclofen environmental fate data include studies on soil adsorption, aerobic soil metabolism, anaerobic soil metabolism, and field dissipation. DPR found the studies to be satisfactory. Both U.S. EPA and DPR have developed criteria to help predict the potential of a chemical to reach ground water. When the physicochemical and environmental parameter values for spirodiclofen are compared with the U.S. EPA and DPR

criteria, DPR scientists concluded that is unlikely that spirodiclofen will leach to ground water as summarized in Table III.

Table III. Comparison of U.S. EPA and DPR Groundwater Leaching Criteria with Environmental Fate Study Results for Spirodiclofen.

	U.S. EPA	California EPA		
Parameter	Potential to Leach Value	Potential to Leach Value	Experimental Value	Criteria Exceeded
Water Solubility	> 30 ppm	> 3 ppm	50 ppb @ 20°C and pH 4	No
Soil Adsorption Coefficient (Kp)	< 5 ml/g		0.671-5.20 ml/g	Yes
Koc		<1,900 ml/g	31,00 ml/g	No
Hydrolytic Half Life	> 30 days	> 14 days	1.9-63.6 days	Yes
Aerobic Soil Metabolic Half Life	> 21 days	> 610 days	7.2-9.8 days	No
Anaerobic Soil Metabolic Half Life	> 21 days	> 9 days	Aquatic: 11.5 days	Yes
Field Dissipation Half life	> 21 days		3.3-4.2 days	No

The water solubility value for spirodiclofen is well below that established by both U.S. EPA and California EPA for the potential to leach, indicating that the chemical is only very slightly soluble in water. Also, the Koc value (mobility in soil) for spirodiclofen is well above the value set by California EPA identifying the potential to leach, indicating that spirodiclofen is immobile in soil. Even though three of the test values in Table III exceed the criteria identifying a leacher, considering the water solubility and the Koc value for spirodiclofen, it can be concluded that Envidor 2 SC Miticide is unlikely to present a threat to California groundwater when used according to the label use directions. The submitted product, environmental fate, and residue chemistry data support registration of Envidor 2 SC Miticide.

B. Toxicology

Bayer Cropscience LP submitted adequate toxicology studies to conduct complete toxicological evaluations of Envidor 2 SC Miticide. DPR evaluated the submitted data to determine the potential for adverse health effects. The acute toxicity parameters for Envidor 2 SC Miticide are summarized in Table IV.

Table IV. Acute Toxicity of Previcur Flex Fungicide

Type of Study	Acute Toxicity Values	Acute Toxicity Category
Acute Oral	LD ₅₀ 2000 mg/kg	III
Acute Dermal	LD ₅₀ 2000 mg/kg	III
Acute inhalation	LC ₅₀ >5.030 mg/l	IV
Primary eye irritation	Acceptable	IV
Primary dermal irritation	Acceptable	IV
Dermal Sensitization	Acceptable	Sensitizer

Signal word	Acceptable	CAUTION
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DPR's evaluation of the acute toxicity studies indicates that the studies are adequate for a complete toxicological evaluation. (*should cover why eye and dermal irritation studies are not required*) The product label adequately identifies the potential acute toxicity hazards indicated by the data reviewed. The first aid statements and PPE are adequate for the indicated acute toxicity hazards.

DPR found the submitted toxicology studies for spiroadiclofen sufficient to satisfy the data requirements of the Birth Defects Prevention Act (Food and Agricultural Code section 13121 et al). Possible adverse effects were noted in the chronic dog toxicity, rat oncogenicity, mouse oncogenicity, and rat reproduction studies.

DPR prioritizes pesticide active ingredients for risk assessment based on the nature of the potential adverse health effects, number of potential adverse effects, number of species affected, no effect levels (NOELs), potential for human exposure, use patterns and similar factors. Based on these criteria, pesticides with the greatest potential for health problems are placed in high priority, with other chemicals being in moderate or low priority. The purpose of the risk assessment would be to appraise the potential for spiroadiclofen to cause adverse health effects in humans if exposed to the pesticide as a result of legal use. DPR placed spiroadiclofen into high priority for risk assessment. If the risk assessment conducted by DPR determines that exposure to spiroadiclofen may result in unacceptable margins of exposure, further restrictions will be placed on the use of spiroadiclofen at that time. Further toxicity information is available for spiroadiclofen on DPR's public website in the Summary of Toxicology Data, available at: <http://www.cdpr.ca.gov/docs/toxsums/pdfs/5857.pdf>.

C. Health & Safety

An evaluation of the medical management information on the Envidor 2 SC Miticide label and the acute toxicity study results indicate that the product label bears all of the required statements and warnings regarding safety to handlers and other persons who may be exposed to the pesticide. The product label bears an adequate First Aid statement. In addition, the product label requires applicators, mixers, loaders and other handlers to wear long sleeved shirt and long pants, waterproof gloves, and shoes plus socks. The label instructs handlers to remove and wash contaminated clothing before reuse, and to wash their hands before eating, drinking, chewing gum, using tobacco, or using the toilet. The label also gives the instruction to remove personal protective equipment immediately after handling this product, and to wash the outside of gloves before removing. The label also prohibits worker reentry into treated areas during the restricted entry interval (REI) of 12 hours. An REI of 6 days is required for the activities of vine girdling, cane turning, and cane tying of raisin and table grapes.

D. Fish & Wildlife

The registrant submitted fish and wildlife toxicity studies, including studies on bluegill sunfish, rainbow trout, *Daphnia magna*, sheepshead minnow, mysid shrimp, oysters, bobwhite quail, mallard ducks, *Chironomus riparius* and honey bees . The submitted data are adequate to characterize the toxicity to wildlife and aquatic animals from an environmental exposure. Table V summarizes the results of these studies.

Table V. Summary of Fish & Wildlife Toxicity Values*

Test Animal	Type of Study	Acute Toxicity Value	Relative Toxicity
Bobwhite quail	Single acute oral dose	>2000 mg/kg (LD ₅₀)	Relatively non-toxic
Mallard duck	Feeding study (5 day)	>5000 mg/kg (LC ₅₀)	Relatively non-toxic
Bobwhite quail	Feeding study (5 day)	>5000 mg/kg (LC ₅₀)	Relatively non-toxic
Bobwhite quail	Reproduct study (19 wk)	720 ppm NOEC	Relatively non-toxic
Mallard duck	Reproduct study (20 wk)	>734 ppm NOEC	Relatively non-toxic
Bluegill sunfish	Water exposure (96 hrs)	>45.5 µg a.i./l (LC ₅₀)	Extremely-toxic
Bluegill sunfish	Depuration study (29day)	Half-life 1-2 days	N/A
Rainbow trout	Water exposure (96 hrs)	>35.1 µg a.i./l (LC ₅₀)	Extremely -toxic
Rainbow trout	Early life stage exposure (97 day)	3.81 µg a.i./l NOEC	N/A
<i>Daphnia magna</i>	Water exposure (48 hrs)	>50.8 µg a.i./l (EC ₅₀)	Extremely -toxic
<i>Daphnia magna</i>	Water exposure (21 day)	11.1 µg a.i./l (NOEC) 20.2 µg a.i./l (LOEC)	N/A
Sheepshead minnow	Water exposure (96 hrs)	>35.2 µg a.i./l (LC ₅₀)	Extremely -toxic
Sheepshead minnow	Chronic toxicity water exposure (111 Days)	190 µg a.i./l (NOEC) >190 µg a.i./l (LOEC)	N/A
Eastern oyster	Water exposure (96 hrs)	>43 µg a.i./l (EC ₅₀) 23 µg a.i./l (NOEC)	Extremely -toxic
Mysid shrimp	Water exposure (96 hrs)	>37 µg a.i./l (EC ₅₀)	Extremely -toxic
<i>Chironomus riparius</i>	Water exposure (28 day)	1.0 mg a.i./l NOEC	N/A
Honey Bee	Acute oral dose Acute contact dose	>100 µg a.i./bee (LD ₅₀) >100 µg a.i./bee (LD ₅₀)	Slightly-toxic

* The test substance used for the studies was the technical active ingredient.

The data indicate that spirodiclofen is relatively non-toxic to birds, but is highly-toxic to bluegill sunfish, rainbow trout, sheepshead minnows, *Daphnia magna*, eastern oyster, mysid shrimp, *Chironomus riparius*, and honey bees. To mitigate the hazards to aquatic organisms and honey bees the Envidor 2 SC Miticide label contains the following environmental hazard warnings:

“This product is toxic to fish and aquatic invertebrates. Avoid contamination of surface water through spray drift. Do not contaminate water when disposing of equipment wash water or rinsate. Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark.”

“This product is toxic to honey bees through direct contamination of pollen and nectar. The persistence of residues suggests the possibility of chronic toxic risk to honey bee larvae and the eventual stability of the hive. Do not apply to blooming, pollen-shedding or nectar-producing parts of plants if bees forage on the plants.”

E. Efficacy & Phytotoxicity

Submitted efficacy data indicate that Envidor 2 SC Miticide provides effective control of Yuma spider mite, European red mite, Pacific spider mite, Willamette mite, Apple rust mite, McDaniel spider mite and Pear rust mite, Broad mite, Citrus rust mite, Six spotted mite, and Two spotted spider mite on citrus, grapes, pome fruit, stone fruit and tree nuts. At the label recommended rate

of 13.0 to 20.0 fluid ounces /acre, Envidor 2 SC Miticide has contact activity on mite eggs, all nymphal stages, all quiescent stages and adult females. Adult males are not affected. Because spirodiclofen interferes with biochemical processes associated with mite development, the speed of knockdown is slightly slower than other miticides. Envidor 2 SC Miticide is to be applied by foliar ground application, with only with one post bloom application per year. At the recommended application rate, test data demonstrate a reduced negative impact on beneficial predatory mites and other beneficial insects, such as lacewings and parasitic wasps. Envidor 2 SC Miticide can be mixed with many registered pesticides and fertilizers or micronutrients. The label recommends that applicators who are considering mixing Envidor with other products, first contact the supplier for advice. The product label also contains directions for jar testing to determine compatibility with tank mix chemicals that have not been fully investigated. Submitted phytotoxicity data indicate that little or no phytotoxicity problems were encountered at the label recommended rates.

ALTERNATIVES

The active ingredient in Envidor 2 SC Miticide is spirodiclofen, which is a tetrionic acid with acaricidal action. Envidor is a liquid formulation for field applications on citrus, grapes, pome fruit, stone fruit and tree nuts. The product is effective against a wide range of mite species and acts by interfering with development of mite eggs, all nymphal stages, all quiescent stages and adult females. Envidor 2 SC Miticide can be used in Integrated Pest Management (IPM) programs because it is active on multiple mite life stages, its limited action on predatory mites and beneficial insects, and its compatibility as a tank mix with many other chemicals. There are a number of other active ingredients registered as miticides. However, an effective integrated pest management strategy requires the flexibility of a large number of comparable, but not exactly equivalent, pesticides in order to reduce the development of resistance.

CONCLUSION

DPR evaluated the product label and scientific data submitted to support the registration of Envidor 2 SC Miticide. The label and data were found acceptable to support full registration. The acute health risks to human from exposure to spirodiclofen are minimal due to its low mammalian toxicity. The precautionary and first aid statements on the product label, and the recommended protective measures mitigate potential health risks to persons who may be exposed to this pesticide. If a risk assessment conducted by DPR determines that exposure to spirodiclofen may result in unacceptable margins of exposure, further restrictions will be placed on the use of the chemical at that time. Submitted data indicate that no significant adverse environmental impacts are expected to occur from the use of Envidor 2 SC Miticide and that when used in accordance with label directions, the product will be effective for its intended use.