

10308-33

8/19/2010

1 of 11



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (H7505P)
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

EPA Reg. Number:
10308-33

Date of Issuance:
AUG 19 2010

Term of Issuance:
Conditional

Name of Pesticide Product:
Sumilarv 0.5G Sachets

NOTICE OF PESTICIDE:

- Registration
- Reregistration

(Under FIFRA as amended)

Name and Address of Registrant (include ZIP Code):

Sumitomo Chemical Company, Ltd.
1600 Rivera Avenue, Suite 200
Walnut Creek CA, 94596 USA

Note: Changes in labeling and/or substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product, always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided:

1. You will submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.
2. You will submit the listed data below, conducted in accordance with the 40 CFR Part 158 test guidelines referred to below:

Title of Study	OCSPP Guideline	Date Due
Acute spiked sediment toxicity study with freshwater benthic invertebrates	850.1735	January 18, 2012
Chronic spiked sediment toxicity study with freshwater benthic invertebrates	850.1790	January 18, 2012
Product Performance Study	810.3400	January 18, 2012

Continued on the next page

Signature of Approving Official:

Richard Gebken

Date:

AUG 19 2010

Richard Gebken, Product Manager, RD/IB (7505P)

3. You make the following label changes before releasing the product for shipment:

a) Page 1

- i. Revise the EPA Registration Number to read "EPA Reg. No.10308-33".
- ii. Remove: "Very effective at extremely low doses".
- iii. Remove: "photostable" and "potable water" claims. Remove "Allowed by WHO to be used in potable drinking water in several dengue endemic countries to control mosquito breeding in these containers."
- iv. Align the decimal point for the active and other ingredient percentages.
- v. Remove "clothing" from the section entitled: "Hazards to Humans and Domestic Animals."
- vi. Add the telephone number(s) of a contact(s) for medical emergencies and pesticide incidents.
- vii. Environmental Hazards statement. Add: "Do not apply directly to treated, finished drinking water reservoirs or drinking water receptacles when the water is intended for human consumption. Change "This product must only be applied to catch basins and listed sites that do not drain into natural water bodies." to read: "This product must only be applied to catch basins and listed sites, which do not drain into natural water bodies. Change "Do not contaminate water by cleaning of equipment or disposal of waste" to read: "Do not contaminate water when disposing of equipment washwater or rinsate."
- viii. Replace the Japanese address with the USA address for the Sumitomo Chemical Company, Ltd.

b) Page 2

- i. Remove references to "photostable".
Remove the reference to acting on the "adult life stage" of the mosquito
Remove "columns" and "catch basins" from the first paragraph because many sites are listed on the label.
Change "1 to 100ppb" to "1 ppb or greater"
- ii. Change: "Direction" to "Directions" in order for the second sentence to read:
"READ ALL DIRECTIONS COMPLETELY BEFORE USE."
- iii. Add the following statements below the heading entitled: "Directions for Use":
A) "Before making the first application of the season, it is advisable to consult with the state or tribal agency with primary responsibility for pesticide regulation to determine if other regulatory requirements exist"

- B) "Do not apply more than 0.1 lbs pyriproxyfen per acre per year."
- C) "Do not apply or allow drift onto pastureland, cropland, or potable water supplies. In the treatment of corral lots, feedlots, swinelots and zoos, cover any exposed drinking water, drinking water fountains, and animal feed before application."

iv. Change the heading "Application Sites" to "Application to Catch Basins". Move this heading below the statement: "READ ALL DIRECTIONS COMPLETELY BEFORE USE"

v. Delete: "Mosquito season, species and sizes of catch basins vary from region to region in USA. Well informed and trained professionals should use their experience to decide on the application time and dose rate." from the directions for use.

vi. Application to Catch Basins. Revise this section to read:
 "Individual catch basins are one of the main breeding sites for mosquitoes that can transmit West Nile virus and cause biting nuisance in urban, suburban, and rural environments. Sumilarv 0.5G sachets can be applied to catch basins by dropping them in at the rate specified on this label. The sachets may be applied as a pre-treatment to mosquito breeding catch basins or during the season to catch basins containing mosquito larvae. Once applied, Sumilarv 0.5G sachets will be unaffected by dry, hot, cold or sunny conditions and will begin working when the catch basin is flooded during rain events until the active ingredient degrades below effective levels. Treatments should be repeated every 5-7 weeks (35-45 days). More frequent applications may be necessary to achieve control of mosquito larvae if frequent rain events flush pyriproxyfen out of the catch basins."

c) Page 3

- i. Add the heading "Application Rates to Use for the Control of Mosquito Larvae" to the table. Remove the phrase "Catch Basin Sizes" from the table. Remove the parenthesis from the phrase "Volume* of Water in Gallons"
- ii. Remove the heading "Other Application Sites" from the label.
- iii. Revise "Sumilarv 0.5G sachets can be applied only to sites which do not drain into natural water bodies." to read "Sumilarv 0.5G sachets can be applied only to sites that do not drain into natural water bodies. Apply at the rate specified in the application rate table above to the following sites."
- iv. Remove "sewage effluent" from the list of sites because the effluent may be discharged into a natural body of water. Move the sites "landfills, salvage yards, tire dumps, vehicle impounds, and junkyards" from the section entitled "Natural and artificial water holding containers" to the section entitled: "Temporary or permanent water holding sites"

v. Add "tires" to the list of natural and artificial water holding containers.

d) Page 4

i. The diagram of a "typical catch basin" should be moved to page 2 or page 3.

ii. Remove: "Pyriproxyfen is one of the most effective Insect Growth Regulators against mosquitoes." Also remove the term "other pathogens"

e) Page 5

i. Remove the diagram of the mosquito life cycle from the label.

ii. Add: "and veterinary supplies" after the word "fertilizers" in the "Pesticide Storage" statement.

iii. Container handling: Delete: "If empty: Do not reuse this container. Place in trash or offer for recycling if available. If partly filled: call your local solid waster agency for disposal instructions. Never place any unused product down any indoor or outdoor drain." Replace with: "Offer for recycling, if available, or puncture and dispose of empty container in a sanitary landfill or by incineration. Do not burn unless allowed by state and local ordinances."

4. The acute toxicity studies were reviewed and classified as acceptable. The acute toxicity profile for this product is:

Acute oral toxicity	IV	Acceptable
Acute dermal toxicity	IV	Acceptable
Acute inhalation toxicity	IV	Waived
Primary eye irritation	III	Acceptable
Primary skin irritation	IV	Acceptable
Dermal sensitization	Negative	Acceptable

5. The basic Confidential Statement of Formula (CSF) dated May 21, 2010 is acceptable and supersedes all previous CSFs to become the basic CSF of record.

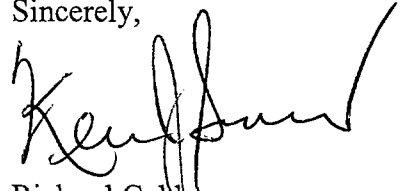
6. An EPA Establishment Number is required for site of production. The site named on the CSF does not have an EPA Establishment Number. You must receive an EPA Establishment Number before selling this product and that number must appear on the final product label.

Please submit three (3) copies of your final printed labeling within 60 days of the date of this notice but before releasing the product for shipment. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing amended labeling constitutes acceptance of these conditions. The data evaluation reviews and a stamped copy of the label are enclosed for your records.

5011

If you have any questions regarding this registration action, please contact Kevin Sweeney at (703) 305-5063. Thank you for your cooperation in this matter.

Sincerely,



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Richard Gebken
Product Manager
Insecticide Branch
Registration Division (7505P)

Enclosure

60911

Sumilarv® 0.5G Sachets (WSP)

Sumilarv® 0.5G Sachets WSP (Water Soluble Packaging) contain a controlled release insect growth regulator formulation to break mosquito life-cycle and prevent their emergence

- Conveniently packed in targeted dose sizes
- Very effective at extremely low doses
- Photostable (provides 35-45 d control), work well even in areas that dry out and rewet
- Allowed by WHO to be used in potable drinking water in several dengue endemic countries to control mosquito breeding in these containers

ACTIVE INGREDIENT:

2[1-Methyl-2-(4-phenoxyphenoxy) ethoxy] pyridine.....	0.50%
OTHER INGREDIENTS.....	99.50%
Total	<u>100.00%</u>

KEEP OUT OF REACH OF CHILDREN CAUTION

FIRST AID	
IF IN EYES:	<ul style="list-style-type: none"> ▪ Hold eye open and rinse slowly and gently with water for 15-20 minutes. ▪ Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eyes. ▪ Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor or going for treatment.	

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic invertebrates. This product must only be applied to catch basins and listed sites that do not drain into natural water bodies. Do not apply to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of waste.

Net Weight: _____

Manufactured by
SUMITOMO CHEMICAL COMPANY, LTD.
27-1, SHINKAWA 2-CHOME, CHUO-KU
TOKYO 104-8260

EPA Reg. No. 10308-Unassigned

ACCEPTED
with COMMENTS
In EPA Letter Dated
AUG 19 2010

Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
10308-33

70611

Sumilarv® 0.5G Sachets:

Each Sumilarv® 0.5G sachets contains 0.5% w:w of the active ingredient pyriproxyfen. Sumilarv® 0.5G sachets come in two different sizes; 10 and 25g. Each contains pyriproxyfen granules packed in a water soluble and biodegradable PVA (Poly Vinyl Alcohol) film. Pyriproxyfen is a photostable insect growth regulator which is similar to a naturally occurring insect growth regulator (Juvenile Hormone) and acts on the immature and adult life stages of mosquitoes. When mosquito larvae are exposed to pyriproxyfen, it inhibits the emergence of adult mosquitoes. In treated water, larvae do not develop into normal pupae, and these are unable to emerge as adults. These granules are specifically designed to release sufficient dose of pyriproxyfen for 35 to 45 days in standing (polluted/unpolluted) water columns of catch basins to prevent emergence of adult mosquitoes. At the recommended dose, effective levels of pyriproxyfen (approx. 1 to 100 parts per billion) are reached in a given volume of water column within a day of placement or after an exchange of water in the catch basin receptacle after treatment.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

READ ALL DIRECTION COMPLETELY BEFORE USE

Mosquito season, species, and sizes of catch basins vary from region to region in USA. Well informed and trained professional should use their experience to decide on the application time and dose rate. Sumilarv® 0.5G sachets can be placed in the catch basins during or before the start of the mosquito season. These sachets are specifically designed to release effective levels of pyriproxyfen in catch basin water for 35-45 days in typical environmental conditions. The optimum size of the granules allows a uniform distribution of the active ingredient in the catch basin environment. The treatment should be repeated every 5 to 7 weeks or as necessary depending on the length of the mosquito season, rain events, and level of control achieved. Once applied, Sumilarv® 0.5G sachets will be unaffected by dry, hot, and sunny situations and will begin working again during the wetting events until the entire active ingredient degrades below effective levels.

APPLICATION SITES

Sumilarv® 0.5G sachets can be easily used to treat individual catch basins which are one of the main breeding sites for mosquitoes which can transmit West Nile Virus (WNV) and cause biting nuisance in urban, suburban, and rural environments. Sachets can be dropped into individual catch basins by hand. Depending on the amount of water in the catch basins, water flow, and rain events, treatments can be repeated as needed during the mosquito season. A trained professional can use the following table to determine how many sachets to treat a catch basin with.

80911

Catch Basin Sizes (Volume* of Water in Gallons)	Water Depth Less than or Equal to (ft)	No. of Sumilarv® 0.5G Sachets		lb AI Sumilarv®/acre based on 1 or 2 basins/acre
		10 g	25 g	
0 - 500	1	1	-	0.00022 or 0.00055
500 - 1500	2	3	1	0.00022 or 0.00055
1500 - 3000	4	6	3	0.00022 or 0.00055
3000 - 4500	6	9	4	0.00022 or 0.00055
4500 - 6000	8	12	5-6	0.00022 or 0.00055

*Water volume in the treated area (V) = length (ft) x width (ft) x average depth (ft)

Other Application Sites:

Sumilarv® 0.5G sachets can be applied only to sites which do not drain into natural water bodies.

Temporary or permanent water holding sites which can be treated:

- ornamental ponds, fountains, cesspools, abandoned swimming pools, gutters, construction site depressions, septic tanks, flooded basements, gutters, animal waste lagoons, livestock runoff lagoons, sewers, sewage effluent, waste water impoundments associated with organic pollutants & industrial run offs, waste settling ponds, tire tracks, manmade depressions and vegetation-choked phosphate pits.

Natural and artificial water holding containers which can be treated:

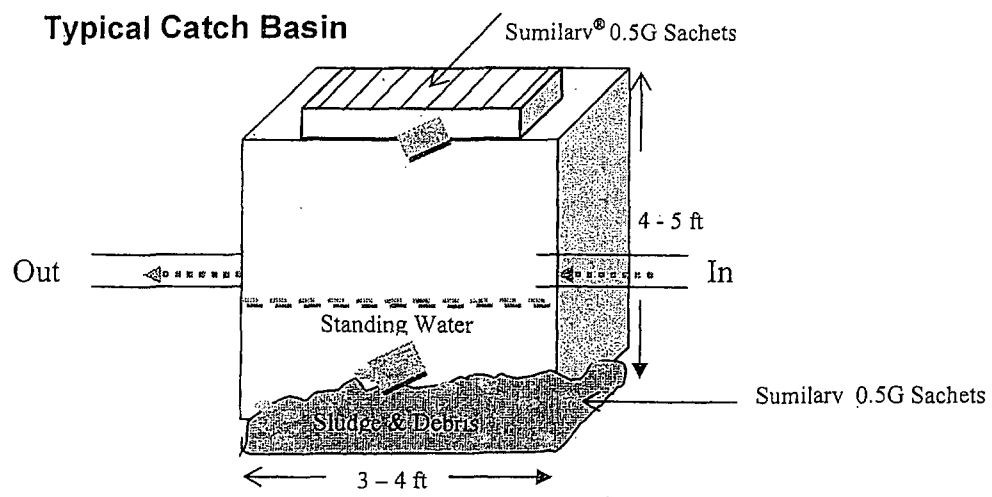
- hollow trees and tree holes, potted plants, bird baths, tire dumps, landfills, rain barrels, flooded roof tops, flower pots, buckets, salvage yards, abandoned vehicles, vehicle impounds, and junkyards.

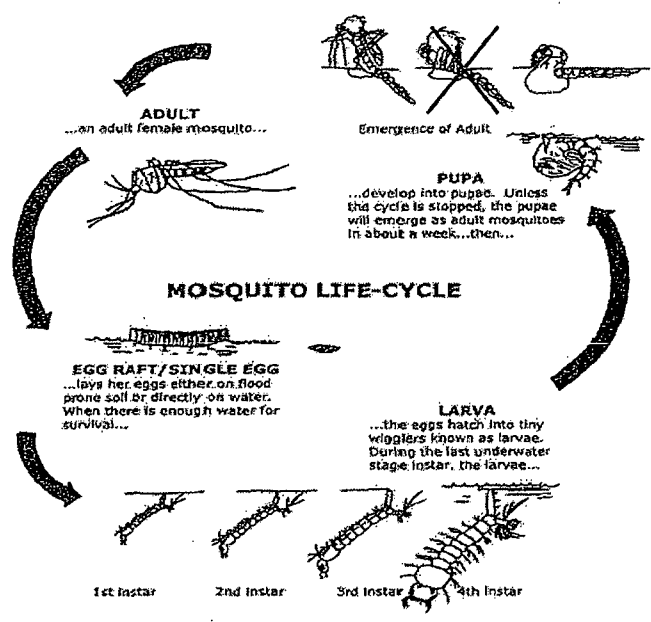
MOSQUITO SPECIES CONTROLLED:

Pyriproxyfen is one of the most effective Insect Growth Regulators against mosquitoes World Wide. It effectively controls several mosquito species which can vector West Nile Virus, dengue, eastern equine encephalitis (EEE), western equine encephalitis (WEE), and St. Louis encephalitis (SLE), dog heartworm and other pathogens in the USA.

These include:

- Aedes aegypti*,
- Ae. albopictus*
- Ae. vexans*
- Anopheles quadrimaculatus*
- Culex pipiens*,
- Cx quinquefasciatus*,
- Cx. tarsalis*,
- Cx. restuans* and other *Cx spp.*
- Ochlerotatus stimulans*
- Ochlerotatus nigromaculis*
- Ochlerotatus taeniorhynchus*
- Ochlerotatus sollicitans*
- Ochlerotatus triseriatus*
- Psorophora columbiae*





STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

PESTICIDE STORAGE: Store in a cool, dry area. Always store pesticides in the original container. Store away from food, pet food, feed, seed, and fertilizers. Place liquid formulations on lower shelves and dry formulations above.

PESTICIDE DISPOSAL: To avoid wastes, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program.

CONTAINER HANDLING: Nonrefillable Container. Do not reuse or refill this container.

If empty: Do not reuse this container. Place in trash or offer for recycling if available.

If partly filled: Call your local solid waste agency for disposal instructions. Never place any unused product down any indoor or outdoor drain.

110911

DRAFT TEXT FOR PRINTING ON WSP COVERING EACH SACHET

Sumilarv[®] 0.5 Sachet (WSP)

ACTIVE INGREDIENT:

2[1-Methyl-2-(4-phenoxyphenoxy) ethoxy] pyridine.....	0.50%
OTHER INGREDIENTS.....	<u>99.50%</u>

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

Refer to main label for the proper use, storage and disposal of this product

EPA Reg. No. 10308-Unassigned

Net Weight: _____

Manufactured by
SUMITOMO CHEMICAL COMPANY, LTD.
27-1, SHINKAWA 2-CHOME, CHUO-KU
TOKYO 104-8260