



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460**

**OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION**

September 19, 2023

Thomas Lennan
Senior Regulatory Affairs Specialist
McLaughlin Gormley King Company
d/b/a MGK
7325 Aspen Lane N
Minneapolis, MN 55428

Subject: PRIA Label Amendment – Adding Residual Efficacy Claims for Mosquitoes in Catch Basins
Product Name: Sumilarv 0.5G Sachets (WSP)
EPA Registration Number: 1021-2818
Application Date: January 20, 2023
Decision Number: 589768

Dear Mr. Lennan:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. “To distribute or sell” is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) lists examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims

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substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6.

If you have any questions, please contact Linda Boccuzzo at 202-566-1121 or at boccuzzo.linda@epa.gov.

Sincerely,



Tamica Cain, Product Manager 10
Invertebrate & Vertebrate Branch 2
Registration Division (7505T)

Attachment

PYRIPROXYFEN	GROUP	7C	INSECTICIDE
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NOTE: Bold, Italicized text is information for the reader and is not part of the label. Information in [brackets] is optional text. Text separated by “/” denotes and/or options.

Sumilarv® 0.5G Sachets (WSP)

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

Controlled release insect growth regulator formulation to break mosquito life-cycle and prevent their emergence

- [Provides up to 150 days (21 weeks) residual control of mosquitoes with an application of (75 g or 3 WSP in storm water catch basins.]
- [Provides up to 28 days (4 weeks) residual control of mosquitoes with an application of (25 gm or 1 WSP) in storm water catch basins.]
- [Sumilarv will provide up to 150 days] residual control of mosquitoes with an application of (75g or 3 WSPs) in storm water catch basins]
- [Sumilarv will provide up to 28 days (4 weeks) residual control of mosquitos with an application of (25 gm or 1WSP) in storm water catch basins.]
- [Extended-release insect growth regulator formulation to stop mosquito life-cycle]
- For resistance management, Sumilarv 0.5G can be rotated with Bacillus species Group 11 insecticides for mosquito control.
- [Prevents adult mosquito emergence, including those which may transmit [West Nile], [Zika], [Yellow Fever], [Dengue], [Eastern Equine Encephalitis], [Western Equine Encephalitis], [Chikungunya], [St. Louis Encephalitis], and [La Crosse Encephalitis] virus[es] and [Dog Heartworm parasites]]
- [Prevents mosquitoes from becoming breeding, biting adults]
- [Novel class of chemistry for public health]
- [Easy to apply WSP]
- [Non-flushing formulation (stays-put)]
- [Sumilarv’s sand granule formulation stays-put and will not flush from application site]
- [Sumilarv’s sand granule formulation is heavy enough to penetrate algae or weed choked sites]
- [Works well even in areas that dry out and rewet]
- [Remains active after large rain events]
- [Dosing Flexibility allows the user to apply varying amounts of product for their desired duration of control]
- **(Note to reviewer: See description below for optional Marketing label images)**
- [Representative image [Illustration] [picture] of listed use sites [areas] on label]
- [Representative image [Illustration] [picture] of listed pests [insects]

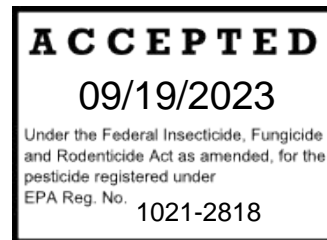
ACTIVE INGREDIENTS:

2-[1-Methyl-2-(4-phenoxyphenoxy) ethoxy] pyridine 0.50%

OTHER INGREDIENTS 99.50%

100.00%

Sumilarv® is a registered trademark of Sumitomo Chemical Co., Ltd.
 MGK® is a registered trademark of McLaughlin Gormley King Company.



[See inside booklet for Precautionary Statements, Directions for Use and Storage and Disposal]

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. ▪ Call a poison control center or doctor for treatment advice.
<p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For information regarding medical emergencies or pesticide incidents, call 1-888-740-8712.</p>	

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS
<p>CAUTION: Causes moderate eye irritation. Avoid contact with eyes. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.</p>
ENVIRONMENTAL HAZARDS
<p>This pesticide is toxic to fish and aquatic invertebrates. Do not apply directly to treated, finished drinking water reservoirs or drinking water receptacles when the water is intended for human consumption. Do not apply to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate.</p>

Manufactured by:

 7325 Aspen Lane North
 Minneapolis MN 55428

EPA Reg. No. 1021-2818 EPA Est. No. 1021-MN-2
 Net Weight: _

Sumilarv® 0.5G Sachets (WSP):

Each Sumilarv® 0.5G Sachets (WSP) contains 0.5% w/w of the active ingredient pyriproxyfen. Sumilarv 0.5G Sachets (WSP) come packaged in 25g pouches or sachets. Each contains pyriproxyfen granules packed in a water soluble and biodegradable PVA (Poly Vinyl Alcohol) film.

Pyriproxyfen is an insect growth regulator which is similar to a naturally-occurring insect growth regulator (Juvenile Hormone) and acts on the immature 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 in standing (polluted/unpolluted) water to prevent emergence of adult mosquitoes. At the labeled dose, effective levels of pyriproxyfen (approx. 1 part per billion or greater) are reached in a given volume of water within a day of placement or after an exchange of water in the 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 DIRECTIONS COMPLETELY BEFORE USE**USE RESTRICTIONS:**

- Apply this product only as specified on the EPA approved label and any supplemental labeling.
- Do not apply more than 0.1 lbs. pyriproxyfen per acre per year or 20 lbs. of Sumilarv 0.5G Sachets (WSP) per year.
- In the treatment of corral lots, feedlots, swine lots and zoos, cover any exposed drinking water, drinking water fountains, and animal feed before application.
- For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

PESTICIDE RESISTANCE MANAGEMENT

For resistance-management, Sumilarv 0.5G Sachets (WSP) contains a Group 7 insecticide. Any insect population may contain individuals naturally resistant to Sumilarv 0.5G Sachets (WSP) and other Group 7 insecticides. The resistant individuals may dominate the insect population if this group of insecticides are used repeatedly in the same use sites. Appropriate resistance-management strategies should be followed. To reduce the potential for developing insect resistance, rotate to an insecticide with a different mode of action. Monitor treated pest populations for resistance development. Read product label before applying any insecticide and follow label directions.

To delay insecticide resistance, take the following steps:

- Rotate the use of Sumilarv 0.5G Sachets (WSP) or other Group 7 insecticides with different groups that control the same pests. Avoid application of more than the maximum seasonal use rate Sumilarv 0.5G Sachets (WSP).
- Do not rely on the same mixture repeatedly for the same pest population. Consider any known cross-resistance issues (for the targeted pests) between the individual components of a mixture. In addition, consider the following recommendations provided by the Insecticide Resistance Action Committee (IRAC):
 - Individual insecticides selected for use in mixtures should be highly effective and be applied at the rates at which they are individually registered for use against the target species.
 - Mixtures with components having the same IRAC mode of action classification are not recommended for insect resistance-management.
 - When using mixtures, consider any known cross-resistance issues between the individual components for the targeted pest(s).
 - Mixtures become less effective if resistance is already developing to one or both active ingredients, but they may still provide pest management benefits.
 - The insect resistance-management benefits of an insecticide mixture are greatest if the two components have similar periods of residual insecticidal activity. Mixtures of insecticides with unequal periods of residual insecticide activity may offer an insect resistance management benefit only for the period where both insecticides are active.
- Adopt an integrated pest management program for insecticide use that includes scouting, uses historical information related to pesticide use, record keeping, and which considers cultural, biological and other chemical control practices.

Monitor after application for unexpected target pest survival. The Sumilarv 0.5G Sachets (WSP) only targets juvenile insects. If the level of pest emergence suggests the presence of resistance, consult with your local university specialist or certified pest control advisor.

- Contact your local extension specialist for any additional pesticide resistance-management and/or IPM recommendations for the specific site and pest problems in your area.

For further information or to report suspected resistance contact MGK Company representatives at 1-888-740-8712.

Sumilarv 0.5G Sachets (WSP) contain a Group 7C insecticide. Insect biotypes with acquired resistance to Group 7C may eventually dominate the insect population if Group 7 insecticides are used repeatedly or in successive years as the primary method of control for targeted species. This may result in partial or total loss of control of those species by Sumilarv 0.5G Sachets (WSP) or other Group 7 insecticides.

To delay insecticide resistance consider:

- Avoiding the consecutive use of Sumilarv 0.5G Sachets (WSP) or other Group 7 insecticides that have a similar target site of action, on the same insect species.
- Basing insecticide use on a comprehensive IPM program.
- Monitoring treated insect population for loss of field efficacy.

MOSQUITO GENERA CONTROLLED:

Pyriproxyfen effectively controls several mosquito species which can vector West Nile disease, Eastern equine encephalitis (EEE), Western equine encephalitis (WEE), St. Louis encephalitis (SLE), La Crosse encephalitis, Yellow Fever, Chikungunya, and dog heartworm in the USA. Including mosquitoes in the following genera:

- Aedes*
- Culex*
- Anopheles*

Introduction of Sumilarv 0.5G Sachets (WSP) into larval habitats where mosquitoes breed and develop will prevent adult mosquito emergence and affects reproductive viability of exposed mosquito eggs and adult female mosquitoes. Frequency of application will depend on three factors: dose rate, water quality (e.g. pollution) and dilution caused by rainfall or removal and replenishment of water within the treatment site. Note: presence of actively swimming larvae after a Sumilarv 0.5G Sachets (WSP) treatment is normal. Sumilarv 0.5G Sachets (WSP) does not act until the pupal stage of a mosquito.

APPLICATION TO CATCH BASINS

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 (WSP) can be applied to catch basins by dropping them in at the rate specified on this label.

The granules 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 (WSP) 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.

For urban or suburban catch basin applications, Sumilarv 0.5G Sachets (WSP) provides up to 21 weeks or 150 days of continuous control with a 3 WSP [packet] (75g) application [or up to 4 weeks or 28 days with a 1 WSP[packet] (25 gm) application.] Sumilarv 0.5G Sachets (WSP) non-flushing sand granule evenly distributes within the catch basin and slowly releases active ingredient (AI) to an elution point. During dry periods, Sumilarv 0.5G Sachets (WSP) remains active and will continue to deliver results once water returns to the catch basin. This non- flushing formulation stays in the catch basin while providing slow and consistent release of the active ingredient (AI). Sumilarv 0.5G Sachets (WSP) is a novel mode of action in Vector control and enhances vector control treatment protocols while providing additional resistance management solutions to their integrated mosquito management programs.

A 3 WSP [packet] (75g) application of Sumilarv 0.5G Sachets (WSP) will provide up to 150 days of continuous control, even when exposed to significant rain events. Simply drop 3 WSP packets through the grate of the catch basin. Application rates can be adjusted for desired duration of mosquito control according to the table below:

Recommended Application per Catch Basin.	Residual Performance Expectations
[1 WSP (25 grams)]	[Up to 28 days of control]
3 WSP (75 grams)	Up to 150 days of control

APPLICATION TO WATER RETENTION or WATER DETENTION PONDS

Typical Water Retention Pond or Storm Water Detention Pond/Basin

To determine the volume of water in gallons for a specific treatment site, use the following formulation and calculation method:

Total cu. ft. of target treatment site (ft. ³) = surface area (ft. ²) x average depth (ft.)

Note: 7.5 gallons per cu. ft.

Total water volume = Total cu. ft. of treatment site x 7.5 gallons

APPLICATION RATES TO USE FOR THE CONTROL OF MOSQUITO LARVAE

Treatment site (Volume of Water in Gallons)	Water Depth Less than or Equal to (ft.)	Number of Sachets Sumilarv WSP	Lb. AI
0 – 500	1	1	0.00028
500 – 1500	2	2	0.00056
1500 – 3000	4	3	0.00083
3000 – 4500	6	4	0.0011
4500 – 6000	8	5	0.00138

Treatments should be made every 4-5 weeks for water retention or water detention ponds depending on the volume water or frequency of rain events. Apply at the rate specified in the application rate table above to the following sites:

TEMPORARY OR PERMANENT WATER HOLDING SITES:

Ornamental ponds, fountains, cesspools, abandoned swimming pools, gutters, construction site depressions, septic tanks, flooded basements, gutters, animal waste lagoons, livestock runoff lagoons, sewers, waste water impoundments associated with organic pollutants & industrial runoffs, waste settling ponds, tire tracks, landfills, salvage yards, tire dumps, vehicle impounds, junk yards, manmade depressions and vegetation-choked phosphate pits.

NATURAL AND ARTIFICIAL WATER HOLDING CONTAINERS:

Tires, hollow trees and tree holes, potted plants, bird baths, rain barrels, flooded roof tops, flower pots, buckets, and abandoned vehicles.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Keep this product in its tightly closed original container. Store in a cool dry (preferably locked) area that is away from water, other pesticides fertilizers, veterinary supplies, food or feed, in a place that is inaccessible to children and animals.

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: Non-refillable container. Do not reuse or refill this container. Offer for recycling if available, or puncture and dispose of empty container in a sanitary landfill, or by other procedures approved by state and local authorities.