



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 27, 2020

Mr. Thomas A. Lennan
Regulatory Affairs Specialist
McLaughlin Gormley King Company D/B/A MGK
8810 10th Avenue North
Minneapolis, MN 55427-4319

Subject: PRIA Label Amendment – Approval of Amended Uses on Catch Basins and Other Registered Temporary or Permanent Water Holding Sites to Remove Restrictions Against Drainage from These Sites into Natural Water Bodies and Incorporation of Required Label Mitigation for *Registration Review*
Product Name: Sumilarv® 0.5G
EPA Registration Number: 1021-2819
Application Dates: February 15, 2019 & January 28, 2020
Decision Number: 549275 & 559167

Dear Mr. Lennan:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, 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 the Federal Insecticide Fungicide and Rodenticide Act 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) list 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 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 Mr. Carmen J. Rodia, Jr. by phone at (703) 306-0327, or via email at Rodia.Carmen@epa.gov.

Sincerely,



Shanta Adeeb, Product Manager 10
Invertebrate-Vertebrate Branch 2
Registration Division (7505P)
Office of Pesticide Programs

*Enclosures: Stamped "Accepted" Master Label
EFED Risk Assessment, dated August 13, 2020
EFED Drinking Water Assessment, dated March 4, 2020
Efficacy Review, dated December 31, 2019
HED Risk Assessment, dated April 21, 2020
PERC Response to Efficacy Rebuttal, August 17, 2020*

PYRIPROXYFEN	GROUP	7C	INSECTICIDE
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Controlled release insect growth regulator formulation to break mosquito life-cycle and prevent their emergence

- Prevents adult mosquito emergence (*including those which may transmit West Nile Virus*)
- Prevents mosquitos from becoming breeding, biting adults
- Reduced risk active ingredient
- Novel class of chemistry for public health
- Easy to apply sand granule
- Non-flushing formulation
- Works well even in areas that dry out and rewet

ACTIVE INGREDIENTS:

2-[1-Methyl-2-(4-phenoxyphenoxy) ethoxy] pyridine.....	0.50%
OTHER INGREDIENTS	99.50%
	<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. • 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. For information regarding medical emergencies or pesticide incidents, call 1-888-740-8712.	

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS
<p>CAUTION: Causes moderate eye irritation. Avoid contact with eyes. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.</p> <p>ENVIRONMENTAL HAZARDS</p> <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 wash water or rinsate.</p>

Manufactured by:

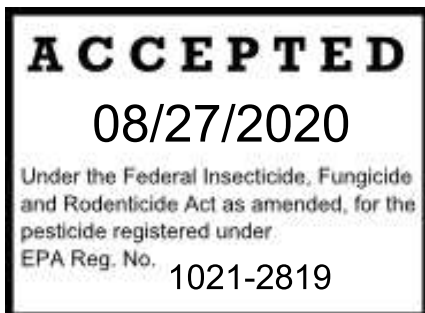


7325 Aspen Lane North
Minneapolis MN 55428

EPA Reg. No. 1021-2819

EPA Est. No. 1021-MN-2

Net Weight: _____



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 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 Sumilarve 0.5G/acre/year).
- Do not apply or allow drift onto pastureland or potable water supplies.
- 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 contains a Group 7C insecticide. Any insect population may contain individuals naturally resistant to Sumilarv® 0.5G and other Group 7C insecticides. The resistant individuals may dominate the insect population if this group of insecticides are used repeatedly in the same fields. 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 or other Group 7C insecticides with different groups that control the same pests. Avoid application of more than the maximum seasonal use rate Sumilarv® 0.5G.
- 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.

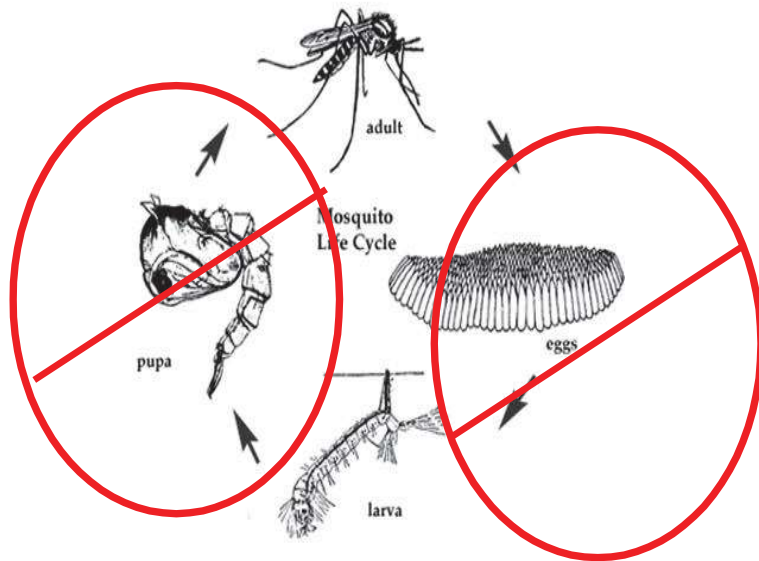
Monitor after application for unexpected target pest survival. The Sumilarv 0.5G only targets juvenile insects. If the level of pest emergence suggests the presence of resistance, consult with your local university specialist or certified pest control advisor.

- 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.

MOSQUITO SPECIES CONTROLLED:

Pyriproxyfen effectively controls several mosquito species which can vector Zika virus, West Nile Virus, Yellow Fever, Dengue, Eastern equine encephalitis (EEE), Western equine encephalitis (WEE), and St. Louis encephalitis (SLE), and dog heartworm 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*

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

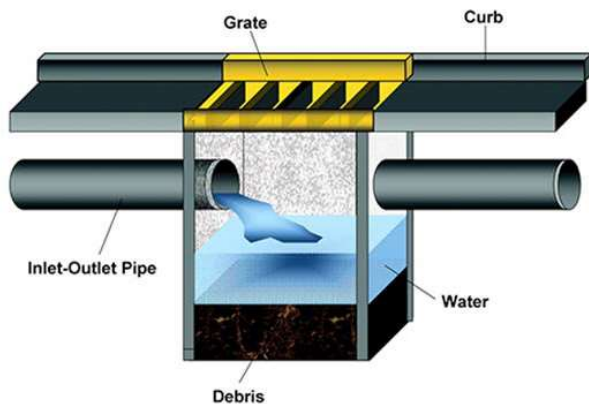
APPLICATION TO CATCH BASINS

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 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 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 provides up to 6 weeks of continuous control with one single (75g) treatment. Sumilarv 0.5G's non-flushing sand granule evenly distributes within the catch basin and slowly releases active ingredient to an elution point. During dry periods, Sumilarv 0.5G 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 AI. Sumilarv 0.5G 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.

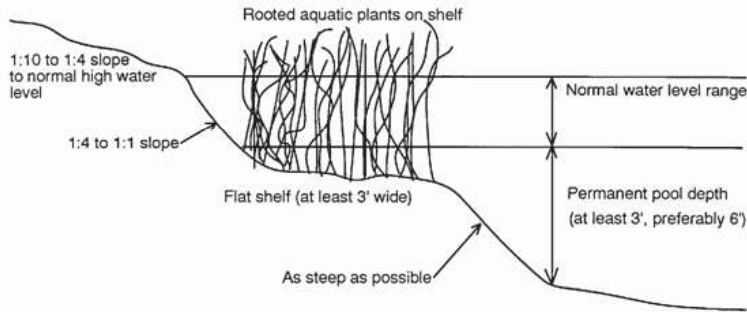
One 75g dose of Sumilarv 0.5G will provide 6 weeks of continual control, even when exposed to significant rain events. Simply scoop and scatter the non-flushing sand granules through the grate of the catch basin.



Dose per catch basin
75 grams

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 cubic ft.

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

Note: 7.5 gallons per cubic ft.

Total water volume = Total cubic feet 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.)	Amount of Sumilarv[®] 0.5G (grams)	Amount of Sumilarv[®] wt. ounces (volume equivalent)	Lb. AI Sumilarv[®]/ acre based
0 – 500	1	10	0.35 oz. (1 teaspoon)	0.00011
500 – 1500	2	30	1.05 oz. (1 tablespoon)	0.00033
1500 – 3000	4	60	2.11 oz. (2 tablespoons)	0.00066
3000 – 4500	6	90	3.17 oz. (3 tablespoons)	0.00099
4500 – 6000	8	120	4.23 oz. (4 Tablespoons)	0.00132

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.

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 run offs, 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: Nonrefillable 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.