

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Ms. Jean Killoren Authorized Agent MGK® 8810 10<sup>TH</sup> Avenue North Golden Valley, Minnesota 55427

MAY 6 2014

Subject:

Product Name: ESD 12101

EPA Reg. No. 1021-2618

Submission date: March 5, 2014

Label Notification: in response to Agency letter of 1/14/14 changing registration number; removing specific mosquito species and phrase "Spray-less [spray-free]

[biting] mosquito repellent [protection]."

Decision No. 489003

# Dear Registrant:

The Agency in in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated March 5, 2014 for the product ESD-12101. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action(s) requested fall within the scope of PRN 998-10.

If you have questions concerning this letter, please call Owen Beeder at 703-308-8899 or via e-email at <a href="mailto:beeder.owen@epa.gov">beeder.owen@epa.gov</a> or you may call me at 703-305-6701.

Sincerely,

Richard Gebken Product Manager 10

Insecticide Branch

Registration Division (7505P)

<b>\$EPA</b>	United State Environmental Prote Washington, DO	ction Agency	Registra Amendn	tion	O. Appropriate Appropriate 2-28-9	
	Applic	ation for Pesticide - \$	Section I		(Amita)	
1. Company/Product Number	1021-2618	2. EPA Product R. Gebke		3. Pr	oposed Classification	
4. Company/Product (Name) ESD 12101		PM#	PM# 10		None Restricted	
5. Name and Address of Ap MGK® 8810 10th Avenue No Golden Valley, Minne Check if this	orth	(b)(i), my prod to:	Reveiw. In accordar luct is similar or idention.	cal in co	mposition and labeling	
		Section - II			( ) A(II ) M (	
Notification - Explain	onse to Agency letter dated	January 14, 2014 Agend "Me T	rinted labels in repsonse by letter dated oo" Application, Explain below.			
item #2 a, b, c: all changes d: "Spray-less [spray	o Agency's letter of January 14, 20 have been made -fee][biting] mosquito repellent [property of explanation on remaining claims	otection] removed	MAY 6 2014		14014	
1. Meterial This Product Wil	I Be Packaged in:	00011017 111			I still 6M	
Child-Resistant Packaging Yes No Certification must be submitted	Unit Packaging Yes No If "Yes" Unit Packaging wgt. No. pe		g 2. Type of 0	Metal Plastic Glass Paper	pecify)	
3. Location of Net Contents	Information 4. Size(s	) Retail Container	5. Location of Label	el Directio	ns	
6. Manner in Which Label is	Affixed to Product	ithograph aper glued tenciled	Other			
		Section - IV				
1. Contact Point (Complete	items directly below for identifi	cation of individual to be conta	cted, if necessary, to pro	cess this	application.	
Name Jean Killoren		Title Authorized	Title Authorized Agent		Telephone No. (In: hude Area Code) (262) 844-7623 killoren.reg ⊈me.com	
I certify that the state I acknowledge that ar both under applicable	ments I have made on this form by knowlinglly false or misleadin	ification and all attachments thereto ar g statement may be punishable	e true, accurate and com by fine or imprisonment	nplete. or	6. Date Application Received (\$1.amped)	
2. Signature	Hillan	3. Title Auth	orized Agent			
4. Typed Name	n Killoren	5. Date Februa	ry 28, 2014			

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1021-2618

# **ESD 12101**

For Outdoor Use Only

- [Repels [protects against] [biting] mosquitoes, including those that may transmit encephalitis, [West Nile Virus], [Eastern equine encephalitis], [Western equine encephalitis], [La Crosse encephalitis], [California encephalitis], [St. Louis encephalitis] and [dengue].
- · Repels Aedes (aegypti), Anopheles (dirus) and Culex (quinquefasciatus) mosquitoes
- · Repels [biting] mosquitoes
- Provides effective mosquito protection
- · Fast-acting mosquito protection
- · Easy to Use
- Convenient
- · No Mess, no sprays, no creams
- · Non-Staining
- Odorless
- Unscented
- · Repellent you don't apply to [spray on] clothes [or skin].
- Spray less [spray-free] [biting] mosquito repellent [protection]
- · Repellent is odorless, [silent] [and invisible area of protection]]

{Additional alternate bullets at end of label}

ACTIVE INGREDIENT:	
Metofluthrin	4.0%
*OTHER INGREDIENTS	96.0%
	100.0%

\* Contains petroleum distillate

EPA Reg. No. 1021-2618

EPA Est. No.

NOTIFICATION

MAY 6 2014

# KEEP OUT OF REACH OF CHILDREN CAUTION

See [side (back) panel] [inside (outside) packaging] insert for additional precautions

PRECAUCION AL CONSUMIDOR: Si usted no lee inglés, no utilice este producto hasta que la etiqueta le haya sido explicada ampliamente.

(TO THE USER: If you cannot read English, do not use this product until the label has been fully explained to you.)

Net Contents: Contains a total of 1.52 fl oz. (45ml) to 13.52 fl. oz. (400 ml)

[Product Name with fixture]

Contains: 1 to 8 Fixture(s) [Device(s)] [Unit(s)] and 1 x 1.52 fl. oz. (45 ml) to 8 x 1.52 fl. oz. (45 ml) or 1 x 1.69 fl. oz. (50 ml) to 8 x 1.69 fl. oz. (50 ml) Bottle Name [Repellent Bottle(s)] [Repellent Cartridge(s)] [Repellent Refill(s)]]

Bottle only}

Contain(s): 1 x 1.52 fl. oz. (45 ml) to 8 x 1.52 fl. oz. (45 ml) or 1 x 1.69 fl. oz. (50 ml) to 8 x 1.69 fl. oz. (50 ml) Bottle Name [Repellent Bottle(s)] [Repellent Cartridge(s)] [Repellent Refill(s)]]

Lot Number:

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FIRST AID			
If swallowed:	<ul> <li>Immediately call a poison control center or doctor.</li> <li>Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>Do not give any liquid to the person.</li> <li>Do not give anything by mouth to an unconscious person.</li> </ul>		
	HOT LINE NUMBER		
or going for treat	container or label with you when calling a poison control center or doctor ment. In case of <i>Medical</i> emergencies or health and safety inquiries or in ng or damaged containers, information may be obtained by calling 1-877-		
	NOTE TO PHYSICIAN		
Contains petrolei	um distillate – vomiting may cause aspiration pneumonia.		

# PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

#### CAUTION

Harmful if swallowed. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

#### **ENVIRONMENTAL HAZARDS**

Do not apply to water.

#### **DIRECTIONS FOR USE**

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

For use outdoors on patios, decks, unenclosed porches, walkways, around swimming pools and other areas where mosquito protection is desired.

Do not use indoors.

Do not pry ESD12101 [Bottle Name] [Repellent Bottle] [Repellent Cartridge] [Repellent Refil] open.

For best results [protection] [coverage] [for a typical sized deck or patio] place [install] one fixture [Product Name] [Device] [Unit] every 12 to 14 ft. around [throughout] the 10 feet x 10 feet area you wish to protect [from biting mosquitoes].

A set of 4 Fixtures [Devices] [Units] provides up to 600 400 square feet of mosquito protection. [A set of 6 Fixture [Device] [Unit] provides up to 900 600 square feet of mosquito protection.]

The Vaporizer [Liquid] [Repellent] [Emanator] works [operates] independently from [with or without] the Light [Light Fixture] [Lamp] [LED].

The Vaporizer [Liquid] [Repellent] [Emanator] should be turned off when not in use.

The Vaporizer [Liquid] [Repellent] [Emanator] will get hot while in use. Always allow Vaporizer [Liquid] [Repellent] [Emanator] to cool before replacing with ESD12101 [Bottle Name] [Repellent Eligitle] [Repellent Cartridge] [Repellent Refill].

After 6 weeks of use, Open [Remove] Fixture [device] cover and visually inspect ESD12104 [Bottle Name] [Repellent Bottle] [Repellent Cartridge] [Repellent Refill] to determine usage rate.

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Replace when ESD12101 [Bottle Name] [Repellent Bottle] [Repellent Cartridge] [Repellent Refill] is empty.

Replace ESD12101 [Bottle Name] [Repellent Bottle] [Repellent Cartridge] [Repellent Refill] when power to device is [turned] off.

Do not insert [use] anything other than ESD12101 [Bottle Name] [Repellent Bottle] [Repellent Cartridge] [Repellent Refill] in [to] the Fixture [product name] [Device] [Unit].

#### **Operating Instructions:**

Use photosensor, [timer] [or switch] to operate [to turn on] Vaporizer [mosquito repellent] [repellent] [mosquito protection] [system] [device] [Liquid] [Repellent] [Emanator].

Use photosensor, [timer,] [or switch] to operate [turn on] Light [Light Fixture] [Lamp] [LED].

Use with 12v transformer and controller provided [available separately].

### Installation instructions - [Please refer to detailed instructions provided with the (Product name)]

ITurn off electricity at main circuit breaker panel before beginning installation.] Consult local building codes to ensure compliance with wiring and grounding requirements.

- 1) Attach each Fixture [Device] [Unit] to post or stem, using hardware provided making sure Fixture [Device] [Unit] is level.
- 2) Connect Vaporizer [Liquid] [Repellent] [Emanator] and Light [Light Fixture] [Lamp] [LED] wires to controlled 12v power source, [or use [Product name] Controller and Transformer].
- 3) Place [Install] one ESD12101 [product name] [Fixture] [Device] [Unit] every 12 to 14 feet 10 feet.

If you have any questions about wiring, get assistance from a professional electrical contractor.

#### When using for the first time [For first time] [Initial] Use:

How to insert ESD12101 [Bottle Name] [Repellent Bottle] [Repellent Cartridge] [Repellent Refill] Into Fixture [Device] [Unit].

- Remove 1 (one) ESD12101 [Bottle Name] [Repellent Bottle] [Repellent Cartridge] [Repellent Refill] from packaging.
- Place on a flat surface and remove protective cap.
- Unplug [Disconnect power to] Fixture [Device] [Unit].
- Open [Remove] Fixture [Device] [Unit] cover.







Disconnect and remove Vaporizer [Liquid]
 [Repellent] [Emanator] assembly from Fixture [Device] [Unit].

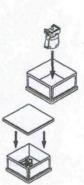


Ensuring that the cap is removed, attach ESD12101 [Bottle Name]
 [Repellent Bottle] [Repellent Cartridge] [Repellent Refill] assembly
 so that top of wick fits into Vaporizer [Liquid] [Repellent]
 [Emanator] assembly.



Connect and attach Vaporizer [Liquid] [Repellent] [Emanator] assembly to Fixture [Device] [Unit].





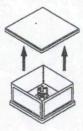
- 9. Repeat for each Fixture [Device] [Unit].
- 10. When finished, plug in Fixture [Device] [Unit] [reconnect power].

<u>How to replace empty</u> ESD12101 [Bottle Name] [Repellent Bottle] [Repellent Cartridge] [Repellent Refill] into fixture [device].

 Unplug [Disconnect power to] Fixture [Device] [Unit]. If Vaporizer [Liquid] [Repellent] [Emanator] has been operating, allow at least 1 hour to cool down before handling.



2. Open [Remove] Fixture [Device] [Unit] cover.



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3. Disconnect and remove Vaporizer [Liquid] [Repellent] [Emanator] assembly from Fixture [Device] [Unit].



4. Remove used [empty] ESD12101 [Bottle Name] [Repellent Bottle] [Repellent Cartridge] [Repellent Refill] from assembly.



5. Remove cap, attach ESD12101 [Bottle Name] [Repellent Bottle] [Repellent Cartridge] [Repellent Refill] to assembly so that top of wick fits into Vaporizer [Liquid] [Repellent] [Emanator] assembly.



6. Connect and attach Vaporizer [Liquid] [Repellent] [Emanator] assembly to Fixture [Device] [Unit].



7. Replace [re-Attach] [Fixture] [Device] [Unit] cover.



- 8. Repeat for each Fixture [Device] [Unit].
- 9. When finished, plug in Fixture [Device] [Unit]] [reconnect power].

### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal of repellent unit. Pesticide Storage: Store in a cool, dry place. Keep container tightly closed. Store refills out of direct sunlight

Pesticide Disposal and Container Handling: Non-refillable [liquid vaporizer] [bottle] [cartridge][container]. Do not reuse or refill this [liquid vaporizer] [bottle] [cartridge] [container]. If empty or at the end of the season, dispose of unused portion according to label directions: Place in trash. If partly filled: Call your local solid waste agency for disposal instruction. Never place unused product down any indoor or outdoor drain

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### IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following conditions, disclaimer of warranties and limitations of liability.

**CONDITIONS:** The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Valent BioSciences Corporation. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, VALENT BIOSCIENCES CORPORATION MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Valent BioSciences Corporation is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, Valent BioSciences Corporation disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

LIMITATIONS OF LIABILITY: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT VALENT BIOSCIENCES CORPORATION'S ELECTION. THE REPLACEMENT OF PRODUCT.

#### [Or alternate text

Note [Notice]: Seller warrants that this product complies with the specifications expressed in this label. To the extent consistent with applicable law, seller makes no other warranties, and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and fitness for the intended purpose. To the extent consistent with applicable law, seller's liability or default, breach or failure under this label shall be limited to the amount of the purchase price. To the extent consistent with applicable law, seller shall have no liability for consequential damages.]

#### [Or alternate text

Notice: To the extent consistent with applicable law, buyer assumes all responsibility for safety and use not in accordance with directions.]

©Valent BioSciences Corporation, 2013-MGK, 2014

[[Fixture] [Device] [Unit] made in (country of Origin)]
[[Bottle Name] [Repellent Bottle] [Repellent Cartridge] [Repellent Refill] made in (country of origin)]

Valent BioSciences Corporation Environmental Science Division 870 Technology Way Libertyville, IL 60048

MGK 8810 Tenth Avenue Minneapolis, MN 55427

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# {Additional alternate bullets}

- [For optimal performance activate within 15 minutes of use
- Provides protection within 15 minutes of use
- Contains 1 [2] [3] [4] [5] [6] [7] [8] ESD12101 [Bottle Name] [Repellent Bottle] [Repellent Cartridge] [Repellent Refill] [(s) [for product name].
- Includes 1 (one) [2 (two)] [3 (three)] [4 (four)] [5) (five)] [6) (six)] [7) (seven)] [8) (eight)]
   ESD12101 [Bottle Name] [Repellent Bottle] [Repellent Cartridge] [Repellent Refill]
- Available [in] single pack [multi pack] [2 pack] [4 pack] [6 pack] [8 pack]
- · Effective, season-long\* mosquito protection for your entire deck, porch or patio
- Attractive light fixtures that protect your outdoor patio, [unenclosed porch], [walkway] [or deck] area from [biting] mosquitoes all season\*
- · Attractive lights enhance your patio, unenclosed porch, deck, walkways or yard
- Each Fixture [Product Name] [Device] [Unit] contains a Vaporizer [Liquid] [Repellent] [Emanator]
   [that] releases an odorless, invisible repellent [that] [and] protects up to 455-100 square feet (sq. ft) (SF)
- Protects [up to] a 455-100 sq. ft. area
- Protects [provides] a 12 to 14 ft. diameter 10 feet x 10 feet [area] [of repellency]
- 155-100 ft2 (square feet) (SF) [area] [zone] of protection [from biting mosquitoes] from each Fixture [Product Name] [Device] [Unit]
- Use [Recommend using] four [4] Fixture [Device] [Unit] on a typical [average] sized deck, patio or outdoor area [for] [provides] over 600 400 square feet [sq ft] of coverage
- Use [Recommend using] six [6] Fixture [Device] [Unit] on a large [typical] [average] sized deck, patio or outdoor area [for] [provides] over 900 600 square feet [sq ft] of coverage
- Fixture [Product Name] [Device] [Unit] produces an invisible area [cloud] [zone] of protection which repels [biting] mosquitoes
- Fixture [Product Name] [Device] [Unit] produces invisible [odorless] vapor to repel [that repels] [biting] mosquitoes
- Vaporizer [Liquid] [Repellent] [Emanator] produces an invisible area [cloud] [zone] of protection which repels [biting] mosquitoes
- Vaporizer [Liquid] [Repellent] [Emanator] produces invisible [odorless] vapor to repel [that repels] [biting] mosquitoes
- [Each] 45 ml (1.52 fl oz) ESD12101 [Bottle Name] [Repellent Bottle] [Repellent Cartridge]
   [Repellent Refill] provide(s) Season-Long\* mosquito protection
- [Each] 45 ml (1.52 fl oz.) ESD12101 [Bottle Name] [Repellent Bottle] [Repellent Cartridge]
   [Repellent Refill] provide(s) 90 days [3 months] of mosquito protection 4.5 hours per day
- [Each] 45 ml (1.52 fl oz) ESD12101 [Bottle Name] [Repellent Bottle] [Repellent Cartridge]
   [Repellent Refill] provide(s) 400 [total] hours of mosquito protection
- [included] [Each] 50 ml (1.69 fl oz) ESD12101 [Bottle Name] [Repellent Bottle] [Repellent Cartridge] [Repellent Refill] provide(s) Season-Long\*\* mosquito protection
- [Each] 50 ml (1.69 fl oz.) ESD12101 [Bottle Name] [Repellent Bottle] [Repellent Cartridge] [Repellent Refill] provide(s) 90 days [3 months] of mosquito protection [5 hours per day]
- [Each] 50 ml (1.69 fl oz) ESD12101 [Bottle Name] [Repellent Bottle] [Repellent Cartridge] [Repellent Refill] provide(s) 455 [total] hours of mosquito protection]
- Replace ESD12101 [Bottle Name] [Repellent Bottle] [Repellent Cartridge] [Repellent Refill] for each Fixture [Device] [Unit] after [90 days] [400 hours] [455 hours] of use
- Each ESD12101 [Bottle Name] [Repellent Bottle] [Repellent Cartridge] [Repellent Refill] lasts for up to 400 [455] hours

10/11

- \*assumes <u>season as</u> 90 days [3 months]/ average use 4.5 hours per day [45 ml fill]
  \*\* assumes <u>season as</u> 90 days [3 months]/ average use 5.0 hours per day [50 m fill]
- [ESD12101 with] Mosquito Protection Technology
- Patent Pending Mosquito Protection Technology
- · Easy to install
- · No batteries [required
- · No open flame
- · No candles
- Powered by low voltage electricity
- · No butane [required]
- · No external fuel required
- Use timer [or switch] to turn on Vaporizer [mosquito repellent] [repellent] [system] [device] [mosquito protection] [Liquid] [Repellent] [Emanator].
- · Use photosensor, [timer,] [or switch] to turn on lights.
- Lights [Lighting] [Light] [Light Fixture] [Lamp] [LED] may be used independently of Vaporizer [mosquito repellent] [repellent] [system] [Liquid] [Repellent] [Emanator] [mosquito protection].
- Durable [metal and glass] construction will provide beautiful lighting [and mosquito protection] for years to come
- Efficient LEDs [use less power for year-round energy savings] [and] [last up to 20,000 [30,000] hours]
- Plus attractive, low-voltage outdoor lighting for that perfect summer evening.
- It's as easy as turning on the lights to say goodbye to [biting] mosquitoes and the old hassles of keeping them away for the entire summer!
- Use on patios, [unenclosed porches,] [decks,] [walkways,] [yards] and other outdoor areas where
  mosquito protection is desired [required] [needed].
- · Designed to mount [sit] on [existing] deck post or a stake in the ground.
- Permanent, low voltage lighting [fixtures] are easy to install using a supplied [available] transformer and low voltage wire.
- Use with 12v transformer and controller [included] [available separately]
- Control with timer, [photo sensor] [or switch] for lighting and/or repellent when you want them, [day or night]
- Vaporizer [Liquid] [Repellent] [Emanator] can operate [be used] independently of lights [with or without] [having] lights on
- Refillable light(ing) fixtures ESD12101 [Bottle Name] [Repellent Bottle] [Repellent Cartridge]
   [Repellent Refill]
- Free ESD12101 [Bottle Name] [Repellent Bottle] [Repellent Cartridge] [Repellent Refill] included
- Extra refill included
- · Buy one get one free
- Coupon [\$] Rebate(s) available [inside]
- ESD12101 [Bottle Name] [Repellent Bottle] [Repellent Cartridge] [Repellent Refill] works with [in] [product name]
- ESD12101 [Bottle Name] [Repellent Bottle] [Repellent Cartridge] [Repellent Refill]
- · Specially designed for use with [in] product name
- · For protection and added comfort outdoors
- · Works [when you want it] [day [and] [or] night]
- [Helps you] enjoy your evening activities with fewer [less] annoying [biting] mosquitoes.
- Simply turn [switch] off the Vaporizer [Liquid] [Repellent] [Emanator] when protection is not needed.
- · Won't harm plants, [flowers], [shrubs] or [and] [grass] [lawns]
- Illuminated [Green] [Yellow] [Orange] [Blue] LED indicator [light] on [fixture] [device] indicates [signals] that Vaporizer [Liquid] [Repellent] [Emanator] is operating.]

## Individual Small Bottle Label

ESD12101 [Bottle Name] [Repellent Bottle] [Repellent Cartridge] [Repellent Refill]

ACTIVE INGREDIENT:

\* Contains petroleum distillate

EPA Reg. No.

EPA Est. No.

KEEP OUT OF REACH OF CHILDREN

CAUTION

See [outside] [Bottle Name] [Repellent Bottle] [Repellent Cartridge] [Repellent Refill] packaging [carton] [insert] for precautions and directions for use