

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

May 5, 2016

Mr. Jonathan Ostrowski Regulatory Affairs Specialist III Clarke Mosquito Control Products, Inc. 675 Sidwell Ct. St. Charles, Illinois 60174

Subject: PRIA Label Amendment – Changing Container Packaging and Adding Public

Health Claim for Dengue, Chikungunya and Zika

Product Name: Natular DT

EPA Registration Number: 8329-602 Application Date: March 16, 2016

Decision Number: 515192

## Dear Mr. Ostrowski:

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

Page 2 of 2 EPA Reg. No. 8329-602 Decision No. 515192

with FIFRA section 6. If you have any questions, please contact Katelynn E. King by phone at 703-347-0193, or via email at <a href="mailto:king.katelynn@epa.gov">king.katelynn@epa.gov</a>.

Sincerely,

Michael Walsh, Product Manager 11 Invertebrate & Vertebrate Branch 2 Registration Division

Office of Pesticide Programs

Enclosure

OCCUPATIONAL LABEL (text in brackets [ ] indicates optional text)

## Natular® DT

(Alternate Brand Name: Novus™ DT)

(Alternate Brand Name (consumer label): Natular® DT Residential) (Alternate Brand name (consumer label: Natular® DT Fizzies™)

ACCEPTED

05/05/2016

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 8329-602

[An insecticide for the control of mosquito larvae]

[Controls larvae of mosquitoes which may transmit Dengue, Chikungunya, or Zika.]

To be used in governmental mosquito control programs, by professional pest control applicators, or in other mosquito control operations.

Group	5	INSECTICIDE
Group	3	INSECTICIDE

#### **Active Ingredient:**

Spinosad (a mixture of Spinosyn A and Spinosyn D)

**Other Ingredients** 

Total

7.48% <u>92.52%</u> 100.00%

Contains 0.1 gram Spinosad per extended-release tablet. This product may absorb moisture; therefore, the weight of the tablet and percent by weight of active ingredient will vary with hydration.

U.S. Patent No. 5,362,634 and 5,496,931

# Keep Out of Reach of Children CAUTION

## **Precautionary Statements**

## **Hazards to Humans and Domestic Animals**

Caution. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wear protective eyewear (such as goggles, face shield, or safety glasses). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

First Aid		
If in eyes:	<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.</li> </ul>	
	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. You may also contact 1-800-214-7753 for emergency medical treatment information.		

## **Environmental Hazards**

This product is toxic to aquatic invertebrates. Non-target aquatic invertebrates may be killed in waters where this pesticide is used. Do not contaminate water when cleaning equipment or disposing of equipment washwaters.

#### **Directions for Use**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Read all Directions for Use carefully before applying.

NATULAR® DT is a Naturalyte<sup>®</sup> insect product for killing mosquito larvae. This product's active ingredient, spinosad, is biologically derived from the fermentation of *Saccharopolyspora spinosa*, a naturally occurring soil organism.

#### **Product Use Precautions**

#### Integrated Pest Management (IPM) Programs

NATULAR® DT is intended to kill mosquito larvae. Mosquitoes are best controlled when an IPM program is followed. Larval control efforts should be managed through habitat mapping, active adult and larval surveillance, and integrated with other control strategies such as source reduction, public education programs, harborage or barrier adult mosquito control applications, and targeted adulticide applications.

#### Insecticide Resistance Management (IRM)

NATULAR® DT contains a Group 5 insecticide. Insect biotypes with acquired resistance to Group 5 insecticides may eventually dominate the insect population if appropriate resistance management strategies are not followed. Currently, only spinetoram and spinosad active ingredients are classified as Group 5 insecticides. Resistance to other insecticide groups is not likely to impact the effectiveness of this product. Spinosad may be used in rotation with all other labeled products in a comprehensive IRM program.

To minimize the potential for resistance development, the following practices are recommended:

- Base insecticide use on comprehensive IPM programs and IRM programs.
- Do not use less than the labeled rates.
- Routinely evaluate applications for loss of effectiveness.
- Rotate with other labeled effective mosquito larvicides with different modes of action.
- Use insecticides with a different mode of action (different insecticide group) on adult mosquitoes so that both larvae and adults are not exposed to products with the same mode of action.
- Contact your local extension specialist, technical advisor, and/or Clarke [Mosquito Control] representative for insecticide resistance management and/or IPM recommendations for the specific site and area.
- For further information or to report suspected resistance, contact your Clarke [Mosquito Control] representative by calling 800-323-5727.

#### **Application Directions**

NATULAR® DT is for use in artificial containers used for water collection to control the mosquito larvae of container breeding mosquitoes.

Artificial water containers may include drums, storage tanks, jars, roof top catchments, ornamental fish ponds, ornamental pools or fountains, unused swimming pools, bird baths, old tires, flower pots and urns, water gardens, floor drains, roof gutters and other water-holding receptacles.

Draining or discarding small containers that hold water is the most effective method for preventing mosquito breeding. To treat artificial water containers that cannot be drained or discarded, use 1 tablet to treat up to 192 liters (50 gallons).

Reapply after 60 days as needed.

**Restrictions:** Do not apply directly to treated, finished drinking water supply systems. Do not apply to waters that drain into public waterways.

## **Storage and Disposal**

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

Pesticide Storage: Store in a cool dry place in original container only.

**Pesticide Disposal:** Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

**Container Handling:** Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available, or dispose of empty container in a sanitary landfill or by incineration.

#### Warranty

To the extent consistent with applicable law CLARKE MOSQUITO CONTROL PRODUCTS, INC. makes no warranty, express or implied, concerning the use of this product other than as indicated on the label. Buyer assumes all risk of use/handling of this material when use and/or handling is contrary to label instructions.

EPA Reg. No. 8329-602 EPA Est. No. [8329-IL-02] [8329-IL-03)

Produced [for] [by]
Clarke Mosquito Control Products, Inc.
159 N. Garden Ave.
Roselle, IL 60172
U.S.A.
1-800-323-5727

Net Weight:	
Net Contents (# Tablets):	
[Tablet Weight: 1.35g]	
Lot/Batch Code:	

## **CONSUMER SUBLABEL**

(text in brackets [] indicates optional text)

(Alternate Brand Name (consumer label): Natular® DT Residential)

(Alternate Brand name (consumer label: Natular® DT Fizzies™)

## **NATULAR® DT**

## For Outdoor [Residential] Use [Around the Home]

[For use in [garden ponds] [bird baths] [fish ponds] [water gardens] [rain barrels] [rainbarrels]

[fountains] [ornamental pools] [roof gutters] [and] standing water]

[Controls larvae of mosquitoes which may transmit Dengue, Chikungunya, or Zika.]

[Uniquely Engineered][Patented][Bi-Layer Tablet]

[Watch It Work!]

[Pond][Fizzies] for mosquito larvae control

[Pond Fizzies [Effervescent] Mosquito Pre-treat][ment]

[No Float Design]

[600][360][300] Day Control with [10][6][5] pack

[Kills mosquito larvae in treated areas]

[Each [Bi-Layer] Tablet Kills Mosquito Larvae for up to [60 days] [2months] [5-6 weeks]

[Each [Bi-Layer] Tablet Provides Protection for up to [60 days] [2months] [5-6 weeks]

[Keeps working for [60 days][2months][5-6 weeks]]

[Easy to Use]

[Easy to Apply]

[Won't [Will Not] Float Away]

[Effective Control]

[Can be applied to Sites that Contain Fish and Plants]

[Spinosad is biologically derived from a naturally occurring soil organism [bacterium]]

[Extended-Release [Bi-laver] Tablet controls mosquito larvae]

[Targets mosquito[es] [larvae]

[Extended-Release [Bi-layer] Tablet controls mosquito larvae, including mosquito species which may transmit West Nile Virus]

[Same [technology] [active ingredient] used by public health and mosquito control agencies]

[Kills][Controls] mosquito[es][larvae] in standing[stagnant] water [where adult mosquitoes breed]

[Kills mosquito larvae before they [can become] [are] [biting] adults]

[Preventative]

[Prevents future mosquito populations]

[Reduces mosquito populations]

[Mosquito Larvicide]

[An insecticide for the control of mosquito larvae]

[Use in early spring to prevent mosquito larvae in standing water]

[Apply][Use in][Place in][Drop in] standing [stagnant] water [to prevent] mosquitoes in or around your [house] [yard] [property]

## **Active Ingredient:**

Spinosad (a mixture of Spinosyn A and Spinosyn D)

Other Ingredients

Total

7.48% <u>92.52%</u> 100.00%

Contains 0.1 gram Spinosad per [extended-release] [Bi-Layer] tablet. This product may absorb moisture; [therefore,] the weight of the tablet and percent by weight of active ingredient will vary with hydration.

U.S. Patent No. 5,362,634 and 5,496,931

# Keep Out of Reach of Children CAUTION

#### **Precautionary Statements**

#### **Hazards to Humans and Domestic Animals**

Caution. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wear protective eyewear (such as safety glasses). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

First Aid		
If in eyes:	<ul> <li>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.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>	
Have the product container or label with you when calling a poison control center or doctor, or		

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-214-7753 for emergency medical treatment information.

#### **Environmental Hazards**

This product is toxic to aquatic invertebrates. Non-target aquatic invertebrates may be killed in waters where this pesticide is used.

#### **Directions for Use**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Read all Directions for Use carefully before applying.

## [Product Information]

[Through a single mosquito bite, adult mosquitoes can pose a serious threat to people and animals by transmitting West Nile virus and other viruses that can cause encephalitis.]

[Emptying or discarding small containers that are holding water will ensure the best results.] [In instances where small containers cannot be emptied or discarded and for other standing water around the home, using NATULAR® DT is a simple and effective way to kill developing mosquito[es][larvae] before they become breeding and biting adults.]

[NATULAR® DT is a [uniquely engineered], [patented] bi-layer tablet for use in mosquito breeding sites. The [top][white][fizzy][effervescent] layer quickly releases a dose of active ingredient that

provides rapid control of existing mosquito larvae. The [bottom][tan] layer provides a[n] [extended][slow] release of active ingredient that continually controls mosquito[es][larvae] in the water for up to [60 days][2months][5-6 weeks].] [NATULAR® DT's active ingredient, spinosad, is biologically derived from the fermentation of *Saccharopolyspora spinosa*, a naturally occurring soil organism.]

#### **Application Directions**

NATULAR® DT can be used in artificial containers and natural standing-water sites around your home to control the mosquito larvae of breeding mosquitoes. [NATULAR® DT can be applied as a preventative action (pre-flood treatment) before sites fill with water.] [NATULAR® DT may also be used in sites that intermittently fill with water; the NATULAR® DT's slow release layer will stop working when dry, and begin working again when re-wetted.] NATULAR® DT will control mosquito larvae for up to [60 days][2months][5-6 weeks] when immersed in water. Reapply after [60 days][2months][5-6 weeks] as needed.

#### Restrictions

Do not apply to natural or artificial containers of water intended for consumption by people, animals, or livestock.

[In New York State, this product is only for use in containerized sites with no outflow to the natural environment.]

## Application Sites [include]

[Bird Baths]

[Ornamental Fish Ponds]

[Garden Ponds]

[Containerized] [Water Gardens]

[Ornamental Fountains]

[Ornamental Pools or Ponds]

[Flower Pots or Planters]

[Rain Barrels]

[Urns]

[Tree Holes]

[Pool Covers]

[Unused or Abandoned Swimming Pools]

[Roof Gutters]

[Roof Top Catchments]

[Storage Tanks]

[Drums]

[Buckets]

[Wheelbarrows]

[Garbage Cans]

[Other Water-Holding Receptacles]

[Floor Drains]

[Old Tires]

[Rock Holes]

[Pot Holes]

[Tire Tracks]

[Other Natural and Man-Made Depressions]

#### **Application Rates**

For shallow [stagnant][standing] water holding areas ([<][less than][6 inches deep]), 1 tablet treats up to 25 square feet of surface area. For containers [or water holding receptacles] holding more

than 6 inches of water, apply [one tablet] [1 tablet] to treat up to 50 gallons [192 liters] per container.

## Storage and Disposal

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

Pesticide Storage: Store in a cool dry place in original container only.

**Pesticide Disposal:** Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

**Container Handling:** Nonrefillable container. Do not reuse or refill this container. **If empty:** Place in trash or offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

## [Warranty]

[To the extent consistent with applicable law seller makes no warranty, express or implied, concerning the use of this product other than as indicated on the label. Buyer assumes all risk of use/handling of this material when use and/or handling is contrary to label instructions.]

EPA Reg. No. 8329-602

EPA Est.	. No.		
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