

# OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

August 9, 2024

Nandita Chowdhury Global Regulatory Manager Clarke Mosquito Control Products, Inc. 675 Sidwell Ct. St. Charles, IL 60174

Subject: Label Amendment – Adding Required Mitigation Language from Spinosad

Interim Decision; Adding Optional Referral Statements, Application Direction Table; Adding and Revising Marketing Claims; and Other Minor Revisions

Product Name: NATULAR® DT

EPA Registration Number: 8329-602

Application Dates: January 16, 2018; August 6, 2019

Case Numbers: 479857; 473521

# Dear Nandita Chowdhury:

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.

The Agency, in accordance with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, has completed reviewing all of the information submitted with your application to support the Registration Review of the above referenced product in connection with the **Spinosad Interim Registration Review Decision Case Number 7421 (December 2018)**, and has concluded that your submission is acceptable.

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 12 months from the date of this letter. After 12 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.

Page 2 of 2 EPA Reg. No. 8329-602 Case No. 479857; 473521

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 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 Christopher Taylor at 202-566-2928 or at taylor.christopher.m@epa.gov.

Sincerely,

Michael Walsh

Product Manager 11

Invertebrate & Vertebrate Branch 2

**Registration Division** 

Office of Pesticide Programs

Attachment

## OCCUPATIONAL LABEL

{Note to Reviewer: Text in brackets [ ] denotes optional text. In instances where a word or phrase has multiple optional text options, at least one will be used to ensure that the entire statement is clear and understandable. Text in braces { } denotes explanatory text that will not be included on the final printed label.}

SPINOSAD GROUP 5 INSECTICIDE

# Natular® DT

{Alternate Brand Name:} [Novus™ DT]

{Alternate Brand Name (consumer label):} [Natular® DT Residential]

{Alternate Brand name (consumer label):} [Natular® DT Fizzies™]

[An insecticide for the control of mosquito larvae]

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

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

{Note to Reviewer: The following bracketed statements are optional and will be included on the final label based on applicability to commercial packaging and label design:}

[Peel back book here and reseal after opening.]

[See First Aid Statement inside of booklet.]

[See First Aid Statement in booklet.]

[See additional Precautionary Statements and Directions for Use in booklet.]

[Refer to inside of label booklet for Precautionary Statements and Directions for Use including Storage and Disposal.]

[Refer to inside of label booklet for First Aid, Precautionary Statements and Directions for Use including Storage and Disposal.]

[See label booklet for additional Precautionary Statements, Directions for Use, and Storage and Disposal.]

[See other panel(s) for additional Precautionary Statements and First Aid.]

[See other panel(s) for additional Precautionary Statements, First Aid, Directions for Use including Storage and Disposal.]

#### **Active Ingredient:**

Spinosad (a mixture of Spinosyn A and Spinosyn D)

7.48% 92.52%

Other Ingredients

100.00%

Total

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.

IU.S. Patent No. 5.362.634 and 5.496.9311

# Keep Out of Reach of Children CAUTION

# ACCEPTED

08/09/2024

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 2000 200

8329-602

# **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. 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 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® 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.
- Monitor after application for unexpected target pest survival. If the level of survival suggests the presence of resistance, consult with your local university specialist or Clarke representative.
- 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 resistant pest problems.
- 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.

[[1] [one] tablet treats up to 50 gallons [192 liters] for [60 days] [2 months] [5-6 weeks].] [For shallow [stagnant][standing] water holding areas ([<][less than][8 inches deep]), 1 tablet treats up to 10 square feet of surface area.]

[For shallow [stagnant][standing] water holding areas ([<][less than][4 inches deep]), 1 [one] tablet treats up to 20 square feet of surface area.]

If gallons [liters] of water are not easy to determine, use [this] [the] table [below] [to the right] [to the left] [on the next panel] [on the front] [on the back] to determine the [surface] area [(sq.f.t)] [(square feet)] [(ft²)] [1] [one] [each] tablet treats.

| Application Chart                           |                                    |  |  |  |
|---|------------------------------------|--|--|--|
| [Average] Water Depth<br>[(in.)] [(inches)] | Surface Area [(sq.ft.)]<br>[(ft²)] |  |  |  |
| 8   | 10                                 |  |  |  |
| 4   | 20                                 |  |  |  |
| 2   | 40                                 |  |  |  |
| 1   | 80                                 |  |  |  |

[For applications to contained sites smaller than a rate of [1] [one] tablet per 50 gallons, use [1] [one] tablet per contained site [(e.g., cesspools and septic tanks, transformer vaults, abandoned pools, and other small artificial water-holding containers)].]

**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:           |  |

[Natular® [is a Registered] Trademark of Clarke Mosquito Control Products, Inc.] [Naturalyte® [is a Registered] Trademark of Corteva Agriscience]

## CONSUMER SUBLABEL

{Note to Reviewer: Text in brackets [ ] denotes optional text. In instances where a word or phrase has multiple optional text options, at least one will be used to ensure that the entire statement is clear and understandable. Text in braces { } denotes explanatory text that will not be included on the final printed label.}

{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] [mosquito larvae] which may transmit [Zika,] [West Nile Virus,] [Eastern Equine Encephalitis,] [St. Louis Encephalitis,] [Dengue,] [or] [Chikungunya]
- [[Uniquely Engineered] [Patented] [Bi-Layer] Tablet]
- [Watch It Work!]
- [Mosquito Larvae Control Tablets]
- [Pond][Fizzies] for mosquito larvae control]
- [[Pond Fizzies] [Effervescent] Larval Mosquito Pre-treatment]
- [[Effervescence] [Top layer] [Starts] [begins] to immediately [release active ingredient into the water]]
- [No Float Design]
- [[Tablet][Treatment][Natular® DT] stays where you [put][place] it]
- [[Tablet][Treatment][ Natular® DT] sinks to treat [entire] [all the] water [column]]
- [No [mixing] [or] [measuring] needed, simply [apply] [place] [drop] in standing water]
- [[720][600][360][300] Day Control with [12][10][6][5] pack]
- [[1][One][A] year of [control][protection from emerging adult mosquitoes] with a 6 pack]
- [[Controls][Kills] mosquito larvae all season long with continued use]
- [Kills [mosquito] larvae in treated areas]
- [[Mosquito] Larvae in the treated water will die for 60 days]
- [[One Tablet] [One Natular® DT tablet] permeates up to 50 gallons of water so larvae [can't][cannot] hide]
- [[Each] [One] [Extended- Release] [Tablet] [Treatment] works 60 days]
- [[Effectively] [Controls] for [60 days][2 months][5-6 weeks]]
- [Long lasting [60 day][2 month][5-6 week] control for your [house][yard][property]] {at least one of the time qualifiers will appear with the term "Long lasting"}
- [[Sustained][Extended][Continuous] release [formula]]
- [[Each] [One] [Bi-Layer] Tablet Kills Mosquito Larvae for [60 days] [2 months] [5-6 weeks]]
- [[Each] [One] [Bi-Layer] Tablet Provides Protection from emerging adult mosquitoes for [60 days] [2 months] [5-6 weeks]]
- [[Bottom layer of tablet] [One treatment] Provides Protection from emerging adult mosquitoes for [60 days][2 months][5-6 weeks]]
- [[Natular® DT]keeps working for [60 days][2months][5-6 weeks]]
- [Kills continuously for [60 days][2 months][5-6 weeks]]
- [[Bottom layer of tablet] [One treatment] keeps killing for [60 days][2 months][5-6 weeks]]
- [Tablet fizzes to kill larvae that are present and continues working for [60 days][2 months][5-6 weeks]]
- [Easy to Use]
- [Easy to Apply]
- [Won't [Will Not] Float Away]

- [Effective Control]
- [Can be [applied to] [used in] [sites] [areas] that contain Fish and Plants]
- [Spinosad is biologically derived from a naturally occurring soil organism [bacterium]]
- [Naturally derived larvicide]
- [[Extended-Release] [Bi-layer] Tablet controls mosquito larvae]
- [Targets mosquito larvae]
- [[Extended-Release] [Bi-layer] Tablet controls mosquito larvae, including [mosquito] species which may transmit [Zika,] [West Nile Virus,] [Eastern Equine Encephalitis,] [St. Louis Encephalitis,] [Dengue,] [or] [Chikungunya]]
- [Same [technology] [active ingredient] used by public health and mosquito control agencies]
- [[Kills][Controls] mosquito larvae in standing[stagnant] water [where adult mosquitoes breed]]
- [Kills mosquito larvae before they [can become] [are] [biting] [adults]]
- [Attack mosquito larvae before they become adults and attack you]
- [Stop mosquitoes before they start biting, by killing larvae]
- [Preventative]
- [Prevents future mosquito populations by killing larvae]
- [[Kills][Controls][Treats] mosquito larvae at the source]
- [A [spring][pre-season][preventative] approach to [control][reduce][limit] mosquito larvae [populations] [infestations]]
- [Mosquito Larvicide]
- [An insecticide for the control of mosquito larvae]
- [[Use][Apply][Treat] in early spring to prevent development of mosquito larvae in standing water]
- [[Apply][Use in][Place in][Drop in][Treat] standing [stagnant] water [to prevent emerging adult mosquitoes] [where mosquitoes breed] in or around your [house] [yard] [property]]
- [[Apply][Use in][Place in][Drop in][Treat] standing [stagnant] water [to prevent emerging adult mosquitoes] [where mosquitoes breed]]

{Note to Reviewer: The following bracketed statements are optional and will be included on the final label based on applicability to commercial packaging and label design:}

[Peel back book here and reseal after opening.]

[See First Aid Statement inside of booklet.]

[See First Aid Statement in booklet.]

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[See other panel(s) for additional Precautionary Statements and First Aid.]

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## **Active Ingredient:**

Spinosad (a mixture of Spinosyn A and Spinosyn D)

7.48% 92.52%

# Other Ingredients

Total

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 going for treatment. You may also contact 1-800-214-7753 for emergency medical treatment |  |  |
| information  | 3 ,  |  |

#### **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 may pose a serious threat to people and animals by transmitting [Zika,] [West Nile Virus,] [Eastern Equine Encephalitis,] [St. Louis Encephalitis,] [Dengue,] [or] [Chikungunya] [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 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 control of existing mosquito larvae. The [bottom][tan] layer provides a[n] [extended][slow] release of active ingredient that continually controls mosquito larvae in the water for [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 [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**

[1] [one] tablet treats up to 50 gallons [192 liters] for [60 days] [2 months] [5-6 weeks]. [For shallow [stagnant][standing] water holding areas ([<][less than][8 inches deep]), 1 tablet treats up to 10 square feet of surface area.]

[For shallow [stagnant][standing] water holding areas ([<][less than][4 inches deep]), 1 [one] tablet treats up to 20 square feet of surface area.]

If gallons [liters] of water are not easy to determine, use [this] [the] table [below] [to the right] [to the left] [on the next panel] [on the front] [on the back] to determine the [surface] area [(sq.f.t)] [(square feet)] [(ft²)] [1] [one] [each] tablet treats.

| Application Chart                           |                                    |  |  |  |
|---|------------------------------------|--|--|--|
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| 4   | 20                                 |  |  |  |
| 2   | 40                                 |  |  |  |
| 1   | 80                                 |  |  |  |

[For applications to contained sites smaller than a rate of [1] [one] tablet per 50 gallons, use [1] [one] tablet per contained site [(e.g., cesspools and septic tanks, transformer vaults, abandoned pools, and other small artificial water-holding containers)].]

# 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.

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: | [Lot][/][Batch] Code: |  |  |  |
|--|---------------|-----------------------|--|--|--|
| [Tablet Weight: 1.35g]   |               |                       |  |  |  |
| [Natular® [is a Registered] Trademark of Clarke Mosquito Control Products, Inc.] |               |                       |  |  |  |

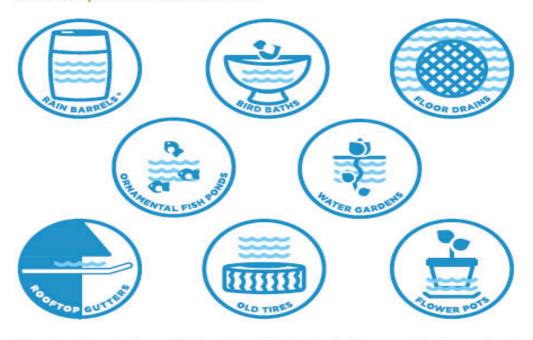
{The following Graphics and Text are Optional for the Consumer Sublabel:}



# NATULAR® DT MOSQUITO LARVICIDE



# Use in places like these:



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