U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Biopesticides and Pollution Prevention Division (7511P) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460	EPA Reg. Number: 70051-122	Date of Issuance: 5/29/2019	
NOTICE OF PESTICIDE: <u>X</u> Registration (under FIFRA, as amended)	Term of Issuance:		
	Unconditional		
	Name of Pesticide Product: Btt SDTC		
Name and Address of Registrant (include ZIP Code): Certis USA LLC 9145 Guilford Road, Suite 175 Columbia, MD 21046			
<b>Note:</b> Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product, always refer to the above EPA Registration Number.			
On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA or the Act). Registration is in no way to be construed as an endorsement or recommendation of this product by the U.S. Environmental Protection Agency (EPA). In order to protect health and the environment, the Administrator, on his or her motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under the Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others. This product is unconditionally registered in accordance with FIFRA section 3(c)(5) provided that you:			
<ol> <li>Submit and/or cite all data required for registration or registration review of your product when the EPA requires all registrants of similar products to submit such data.</li> </ol>			
Signature of Approving Official:	Date:		
Jeannine Kausch, Product Manager 92	5/29/20	)19	
Microbial Pesticides Branch Biopesticides and Pollution Prevention Division (7511P) Office of Pesticide Programs EPA Form 8570-6			

- 2. Producers of Btt SDTC will conduct the following production quality control measures to detect contamination or changes in the parent strain:
  - a. Spore preparations of *Bacillus thuringiensis* subspecies *tenebrionis* strain SA-10 shall be produced by pure culture fermentation procedures with adequate quality control measures during production to detect any changes from the characteristics of the parent strain or contamination by other microorganisms.
  - b. Each lot of spore preparation, prior to the addition of other materials, shall be tested by subcutaneous injection of at least 1 million spores into each of 5 laboratory mice weighing 17 grams to 23 grams. Such test shall show no evidence of infection or injury in the test animals when observed for 7 days following injection.
  - c. Spore preparations shall be free of the *Bacillus thuringiensis*  $\beta$ -exotoxin when tested with the fly larvae toxicity test ("Microbial Control of Insects and Mites," R.P.M. Bond *et al.*, p. 280 ff., 1971). This specification can be satisfied either by determining that each master seed lot brought into production is a *Bacillus thuringiensis* strain that does not produce  $\beta$ -exotoxin under standardized manufacturing conditions or by periodically determining that  $\beta$ -exotoxin synthesized during spore production is eliminated by the subsequent spore-harvesting procedure.
  - d. Producers of Btt SDTC will maintain records of the production quality control measures described directly above (see #2a–2c) for a period <u>of at least 5 years</u> from the date each batch is released for production.
- 3. Make the following labeling change before you release this product for shipment:
  - Revise the EPA Registration Number to read, "EPA Reg. No. 70051-122."
- 4. Submit one (1) copy of the final printed labeling for the record before you release this product for shipment.

Should you wish to add/retain a reference to your company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the EPA. If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the 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 EPA find or if it is brought to our attention that a website contains statements or claims substantially differing from statements or claims made in connection with obtaining a FIFRA section 3 registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

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

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stamped copy of the labeling is enclosed for your records. Please also note that the record for this product currently contains the following acceptable Confidential Statement of Formula (CSF):

• Basic CSF dated 05/20/2019

Any CSFs other than that listed above are superseded.

If you have any questions, please contact Donna Kamarei by phone at (703) 347-0443 or via email at kamarei.donna@epa.gov.

Sincerely,

Jeannine Kausch, Product Manager 92 Microbial Pesticides Branch Biopesticides and Pollution Prevention Division (7511P) Office of Pesticide Programs

Enclosure

# Btt SDTC

TECHNICAL GRADE ACTIVE INGREDIENT

#### FOR MANUFACTURING USE ONLY {Alternate Brand Names: None}

#### ACTIVE INGREDIENT:

Bacillus thuringiensis subspecies tenebrionis strain SA-10 fermentation solids, spores,		
and insecticidal toxins*	<u>100%</u>	
Total:		

\*Potency: at least 20,000 Tenebrionis Units/mg of product

The percentage active ingredient does not indicate product performance and potency measurements are not federally standardized.

## KEEP OUT OF REACH OF CHILDREN CAUTION

[See [side][back][inside][other] panel for additional [first aid] [and] [precautionary] statements]

#### MANUFACTURED BY:

Certis USA LLC 9145 Guilford Road, Suite 175 Columbia, MD 21046 EPA Reg. No. 70051-REE EPA Est. No. 70051-CA-1

Net Weight: Lot Number:



Not for sale or use after: [date stamped/placed on labeling will be 9 months after the date of manufacture]



Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 20051 122

70051-122

### FIRST AID

**If inhaled**: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for treatment advice.

**If in eyes**: 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 eye. Call a poison control center or doctor for treatment advice.

**If on skin or clothing**: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

**Hotline Number:** Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergencies, call 1-800-255-3924.

### PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**CAUTION**: Harmful if inhaled. Causes moderate eye irritation. Avoid breathing dust. Avoid contact with eyes, skin, or clothing. Remove and wash contaminated clothing before reuse. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

#### ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

#### DIRECTIONS FOR USE

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

Btt SDTC is a Technical Grade Active Ingredient used only in the manufacture of biological insecticide formulations for use on food and non-food crops.

### STORAGE AND DISPOSAL

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

**Pesticide Storage**: Store in a cool, dry area away from food or feed. Product may be stored refrigerated (4°C) or at room temperature (20°C).

**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 puncture and dispose of in a sanitary landfill or by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

#### WARRANTY

Certis USA LLC warrants that the material contained herein conforms to the description on the label and is reasonably fit for the purposes referred to in the directions for use. To the extent consistent with applicable law, Buyer assumes all risks of use, storage or handling of this material not in strict accordance with directions given herein. NO OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY IS MADE.