



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

**OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION**

August 2, 2022

Karen E. Warkentien
Director, Regulatory Affairs
Certis USA LLC
9145 Guilford Road, Suite 175
Columbia, MD 21046

Subject: PRIA (Pesticide Registration Improvement Act) Labeling and Formulation Amendment –
Acceptable CSF and Label Amendment
Product Name: Neem Oil TGAI
EPA Registration Number: 70051-7
EPA Receipt Date: 03/09/2022
Action Case Number: 00345500

Dear Ms. Warkentien:

The amended labeling and Confidential Statement of Formula (CSF) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, are acceptable.

This approval does not affect any terms or conditions that were previously imposed on this registration. You continue to be subject to existing terms or conditions on your registration and any deadlines connected with them.

Please note that the record for this product currently contains the following acceptable CSF:

- Basic CSF dated 03/08/2022

Any CSFs other than that listed above are superseded/no longer valid.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) copy of the final printed labeling before you release this 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 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 U.S. Environmental Protection Agency (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 EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the

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website may not substantially differ from those claims approved through the registration process. Therefore, should 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 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.

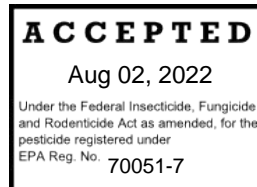
If you have any questions, please contact Alex Horansky via email at Horansky.alex@epa.gov.

Sincerely,

A handwritten signature in blue ink that reads "Andrew C. Bryceland". The signature is fluid and cursive, with a large initial "A" and "B".

Andrew Bryceland, Team Leader
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511M)
Office of Pesticide Programs

Enclosure



NEEM OIL TGAI

[MANUFACTURING USE PRODUCT]

FOR MANUFACTURING USE ONLY IN THE FORMULATION OF FUNGICIDES,
MITICIDES AND INSECTICIDES

ACTIVE INGREDIENT:

Clarified Hydrophobic Extract of Neem Oil	100%
TOTAL	100%

KEEP OUT OF REACH OF CHILDREN
CAUTION

FIRST AID
If on skin or clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.
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 further treatment advice. Have the product container or label with you when calling a poison control center or doctor, or going for treatment. Hot Line Number: 1-800-255-3924.

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Avoid breathing spray mist. Avoid contact with skin, eyes, or clothing. In case of contact, flush eyes or skin with plenty of water. Wash thoroughly with soap and water after handling.

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.

PHYSICAL & CHEMICAL HAZARDS

Do not use or store near heat or open flame.

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling. This product may be used only for the formulation of fungicides and insecticides. Formulators using this product are responsible for obtaining EPA registration for their formulated products.

{ } Symbolizes explanatory text to the reviewer
[] Indicates optional text

STORAGE & DISPOSAL

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

PESTICIDE STORAGE: Keep in original container. Store in a cool, dry place away from direct sunlight, feed, or foodstuffs. Keep container tightly sealed when not in use. Do not store below 55°F (10°C) or above 95°F (35°C).

PESTICIDE DISPOSAL: Wastes resulting from the use of this product must be disposed on on-site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container.
{container ≤5 gallons}

Triple rinse container (or equivalent) promptly after emptying. Triple Rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration.

{container >5 gallons}

Triple rinse container (or equivalent) promptly after emptying. Triple Rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Recap and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration.

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 THE FITNESS OR MERCHANTABILITY IS MADE.

MANUFACTURED BY:

Certis USA LLC
9145 Guilford Road, Suite 175
Columbia, MD 21046

EPA Reg. No. 70051-7

EPA Est. No. _____

Net Contents: _____

Lot Number: _____

