U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7511P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

NOTICE OF PESTICIDE:
_X_ Registration
___ Reregistration
(under FIFRA, as amended)

EPA Reg. Number:	**Date of Issuance:**
91873-1	8/7/2020

Term of Issuance:
Unconditional

Name of Pesticide Product:
Nootkatone

Name and Address of Registrant (include ZIP Code):

Evolva
Duggingerstrasse 23
4153 Reinach, Switzerland

Note: 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:

1. 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.

2. The label for the registered MP product must include the following statement and directions for use:

Using this product for formulation into other pesticide products is prohibited, unless the product meets both of the following conditions:

- This product may be used for formulation only into end-use products for which all necessary end-use product-specific data have been provided and support registration for the end-use product. Necessary end-use product-specific data include, but are not limited to, efficacy data; *in vitro* metabolism data; and dermal absorption data.

- This product may be used for formulation only into end-use products intended for the following uses that meet the following conditions:

a. For end-use products with directions for use as dermally applied insect repellents, the product:

    1. can contain no more than 20% active ingredient in the end-use product formulation;
    2. cannot be applied more than four times per day; and
    3. the maximum application rate cannot exceed 0.4 mg of Nootkatone/cm^2 skin per day.

b. For end-use products with directions for use as low volume and ultra-low-volume sprays, the product:

    1. can contain no more than 60% active ingredient in the end-use formulation;
    2. may be applied only via vehicle mounted ground spray and fixed wing rotary aerial spray at a maximum application rate up to 3 oz/acre at 60% nootkatone equivalent to up to 55 g Nootkatone/acre (0.12 lbs ai/acre);
    3. for mixers/loaders, product must be applied using PPE; waterproof gloves or nitrile gloves required;
    4. application frequency may be on an as needed, targeted basis; and
    5. the end-use product label must:
        a. either prohibit use that results in direct or indirect residues of product in or on food crops or
        b. residues in or on food from use of this product must be covered by a tolerance or exemption. A petition to establish such a tolerance or exemption must be submitted and approved by EPA under section 408 of the FFDCA, or EPA must confirm that an existing tolerance or exemption already covers such residues.

3. The following future actions will need to occur before end-use products meeting the parameters for those uses can be registered and the technical/MP product label amended, if needed.

In order to determine whether to register an end-use product(s) formulated from this MP product, EPA would need to review all product-specific data that EPA determines is necessary to support registration of the end-use product(s). This data will include, but is not limited to, efficacy data for assessing the efficacy of the end-use products and *in vitro* metabolism data and dermal absorption data to assess the potential for adverse effects on persons taking various prescription and over-the-counter drugs.

Efficacy data supporting skin-applied repellents often involves testing involving intentional exposure of human subjects, as outlined in OSCPP guideline 810.3700. In that case, requirements of EPA's Human Studies Rule (40 CFR part 26, subparts K-L) would apply, requiring the submission of a protocol and review by EPA and the Human Studies Review Board, prior to initiation of such study. A protocol for a study concerning the efficacy of the ULV/LV use would also be recommended to be submitted for EPA review prior to initiation of the study. To assess the potential for nootkatone to interact with various

drugs, EPA will require dermal absorption data for the end-use product formulation and in vitro metabolism data on potential drug interactions. EPA will accept *in vitro* dermal absorption data in human tissues tested according to OECD Guideline 428 (https://www.oecd-ilibrary.org/environment/test-no-428-skin-absorption-in-vitro-method_9789264071087-en). A protocol to be used for the *in vitro* metabolism study will need to be developed. EPA recommends using guidance from FDA's Center for Drug Evaluation and Research entitled "In Vitro Drug Interaction Studies — Cytochrome P450 Enzyme- and Transporter-Mediated Drug Interactions, Guidance for Industry" (Section III , Evaluating Metabolism-Mediated Drug Interactions; https://www.fda.gov/media/134581/download).

It is recommended that an end-use applicant meet with EPA in advance of the submission of any end-use product application in order to ensure that all data requirements for the end-use product have been identified and data will be provided in accordance with approved protocols.

4. Submit storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) data as these data requirements are not satisfied. A one-year study is required to satisfy these data requirements. You have 18 months from the date of this registration to provide these data to the EPA.

5. Make the following labeling change before you release this product for shipment:

    - Revise the EPA Registration Number to read, "EPA Reg. No. 91873-1."

6. Submit one (1) copy of the final printed labeling for the record before you release this product for shipment.

Linda A. Hollis, Chief Biochemical Pesticides Branch Biopesticides and Pollution Prevention Division (7511P) Office of Pesticide Programs	**Date:** 8/7/2020

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 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 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 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 11/22/2017

Any CSFs other than those listed above are superseded.

If you have any questions, please contact Menyon Adams of my team by phone at (703) 347-8496 or via email at adams.menyon@epa.gov.

Sincerely,

Linda A. Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs

Enclosure

Nootkatone

FOR THE FORMULATION OF INSECTICIDE/ARACHNICIDE PRODUCTS AS LOW VOLUME OR ULTRA LOW VOLUME SPRAYS AND SKIN-APPLIED REPELLENTS

Active Ingredient: Nootkatone 99.4%
Other Ingredients: 0.6%
Total: 100.0%

ACCEPTED
08/07/2020
Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 91873-1

KEEP OUT OF REACH OF CHILDREN

EPA Reg. No.: 91873- EPA Est. No.:

NET CONTENTS:
Batch No.

PRECAUTIONARY STATEMENTS

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 labelling.

Using this product for formulation into other pesticide products is prohibited, unless the product meets both of the following conditions:

(1) This product may be used for formulation only into end-use products for which all necessary end-use product specific data have been provided and support registration for the end-use product. Necessary end-use product-specific data include, but are not limited to, efficacy data; *in vitro* metabolism data; and dermal absorption data. Potential registrants of end-use products are encouraged to meet with EPA to discuss data necessary to support registration of such products prior to submitting applications for registration.

(2) This product may be used for formulation only into end-use products intended for the following uses that meet the following conditions:

   a. For end-use products with directions for use as dermally applied skin repellents, the product
      i. can contain no more than 20% active ingredient in the end-use product formulation;
      ii. cannot be applied more than four times per day; and

iii. the maximum application rate cannot exceed 0.4 mg of Nootkatone/cm^2 skin per day.

b. For end-use products with directions for use as low volume and ultra-low volume sprays, the product
   i. can contain no more than 60% active ingredient in the end-use formulation;
   ii. may be applied only via vehicle mounted ground spray and fixed wing rotary aerial spray at a maximum application rate up to 3 oz/acre at 60% nootkatone equivalent to up to 55 g Nootkatone/acre (0.12 lbs active ingredient/acre);
   iii. for mixers/loaders, product must be applied using PPE; waterproof gloves or nitrile gloves;
   iv. application frequency may be on an as needed, targeted basis; and
   v. (1) end-use product label must either prohibit use that results in direct or indirect residues of product in or on food crops or
   (2) residues in or on food from use of this product must be covered by a tolerance or exemption. A petition to establish such a tolerance or exemption must be submitted and approved by EPA under section 408 of the FFDCA, or EPA must confirm that an existing tolerance or exemption already covers such residues.

STORAGE AND DISPOSAL

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

Pesticide Storage: Keep container tightly closed when not in use. Store at 40°F (4°C).

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

Container Handling:

[for container sizes of 50 pounds and less] Non-refillable container. Do not reuse this container to hold materials other than pesticides or dilute pesticides (rinsate). After emptying and cleaning, it may be allowable to temporarily hold rinsate or other pesticide-related materials in the container. Contact your state regulatory agency to determine allowable practices in your state. 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 or reconditioning, or puncture and dispose of in a sanitary landfill, by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

[for container sizes greater than 50 pounds] Non-refillable container. Do not reuse or refill this container. 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. Replace 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 or reconditioning, if available, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

WARRANTY DISCLAIMER AND LIMITATION OF LIABILITY

Evolva warrants that this Product conforms to the specifications on this label. To the extent consistent with applicable law, Evolva makes no other warranties and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and fitness for a particular purpose. No agent of Evolva or any other person is authorized to make any representation or warranty beyond those contained herein.

It is impossible to eliminate all risks associated with this Product. Plant injury, lack of performance, or other unintended consequences may result because of factors such as use of the Product other than in strict accordance with this label's instructions, presence of other materials, the manner of application or other factors, all of which are beyond the control of Evolva or the seller. To the extent consistent with applicable law, all such risks shall be assumed by the Buyer.

To the extent consistent with applicable law, Evolva disclaims any liability whatsoever for special, incidental or consequential damages resulting from the handling or use of this Product and Evolva's liability under this label shall be limited to the amount of the purchase price or, at the election of Evolva, the free replacement of the Product.

Evolva
Duggingerstrasse 23
4153 Reinach
Switzerland