

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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

April 13, 2023

Amy Plato Roberts Director of Regulatory Affairs Danstar Ferment Ag / LALLEMAND PLANT CARE P.O. Box 990 Hailey, ID 83333

Subject: PRIA (Pesticide Registration Improvement Act) Labeling and Formulation Amendment –

Add a New Supplier of the Active Ingredient and Production Facility for the Product

and Make Minor Changes to the Label

Product Name: Streptomyces sp. Strain K61 Technical

EPA Registration Number: 64137-28

EPA Receipt Date: 10/17/2022 Action Case Number: 00401626

Dear Ms. Roberts:

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 10/17/2022

Any CSFs other than that listed above are superseded/no longer valid.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 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 website may not substantially differ from those claims approved through the registration process. Therefore, should EPA find or if it is brought to our

Page 2 of 2 EPA Reg. No. 64137-28 Action Case No. 00401626

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.

Please note, upon further review, EPA no longer considers the two issues identified in the science memorandum dated 02/28/2023 as deficiencies and they do not need to be addressed.

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 Susanne Cerrelli by phone at (202) 566-1516 or via email at cerrelli.susanne@epa.gov.

Sincerely,

Digitally signed by
Alexandra Boukedes
Date: 2023.04.13
15:57:10 -04'00'

Alexandra Boukedes, Product Manager 92 Microbial Pesticides Branch Biopesticides and Pollution Prevention Division (7511M) Office of Pesticide Programs

Enclosures

- EPA Approved Label
- Science Memorandum dated 02/28/2023

NOT TO BE USED DIRECTLY FOR TREATMENT OF PESTS FOR MANUFACTURING USE ONLY

Streptomyces sp. Strain K61 **Technical**

Active Ingredient:

KEEP OUT OF REACH OF CHILDREN CAUTION

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 poison control center or doctor for treatment advice.
	Take off contaminated clothing.
clothing	Rinse skin immediately with plenty of water for 15 – 20 minutes.
	Call a poison control center or doctor for treatment advice.
HOTI INF NUMBER	

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-222-1222 for emergency medical treatment information.

EPA Reg. No.: 64137-28 **EPA Est. No.:** (94593-BRA-1) (94593-DEU-1)

Net Weight: XX

(Batch)(Lot) No: XXXX

Manufactured for:

Danstar Ferment AG / LALLEMAND PLANT CARE

Poststrasse 30

Zug CH-6300 Switzerland

ACCEPTED

Apr 13, 2023

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under

EPA Reg. No. 64137-28



^{*} Contains not less than 1 X 10¹⁰ CFU/g.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS – CAUTION: Harmful if inhaled or absorbed through skin. Avoid breathing dust or spray mist. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

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 the 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.

FOR MANUFACTURING USE ONLY. For further manufacturing into end-use products only. Not for direct treatment of pests. Do not use from damaged, punctured or unsealed containers. For formulation into EPA-registered biofungicide products for use on labeled growing and post-harvest food and non-food crops.

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in original container under room temperature conditions (71°F, 22°C). Do not expose to heat or warm temperatures during storage.

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: Non-refillable container. Do not reuse or refill this container. Completely empty bag into manufacturing equipment, then offer for recycling if available or dispose of empty bag in a sanitary landfill or by incineration.