



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

March 11, 2021

Nancy M. Huddy
Authorized Agent to International Animal
Health Products Pty. Ltd.
SciReg, Inc.
12733 Director's Loop
Woodbridge, VA 22192

Subject: Pesticide Registration Improvement Act (PRIA) Labeling Amendment – Remove Use
Restrictions and Update Storage Statements
Product Name: Bioworma
EPA Registration Number: 91253-1
Application Date: June 23, 2020
Action Code Case Number: 00134797
OPP Decision Number: 564106

Dear Ms. Huddy:

The amended labeling 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 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.

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 the EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims

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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.

If you have any questions, please contact Daniel Schoeff by phone at (703) 347-0143 or via email at schoeff.daniel@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'Jeannine Kausch', written over a faint circular stamp.

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

Enclosure

BioWorma®

Biological control product for further mixing into feed, feed supplements, premixes or concentrates and containing spores of a fungus that captures and consumes the labeled infective worm larvae (including chemical/anthelmintic multi-resistant larvae) within the manure of grazing animals

Active Ingredient:

Duddingtonia flagrans strain IAH 1297* 34.600%

Other Ingredients:**.....65.400%

Total.....100.000%

*Contains a minimum of 500,000 Colony Forming Units/gram of active ingredient.

**Contains Benzoic Acid as a preservative.



ACCEPTED
Mar 11, 2021
Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 91253-1

**KEEP OUT OF REACH OF CHILDREN
CAUTION/PRECAUCIÓN**

[See back panel for additional Precautionary Statements]

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
(If you do not understand the label, find someone to explain it to you in detail.)

FIRST AID	
If in eyes:	<ul style="list-style-type: none">• 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.
HOTLINE NUMBER Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also call the National Poison Control Hotline at 1-800-222-1222 for emergency medical treatment information 24 hours per day, 7 days a week.	

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Net Weight: 4.4 lbs (2.0 kg), 15 lbs (6.8 kg), 20 lbs (9.1 kg), 25 lbs (11.3 kg), 30 lbs (13.6 kg), 40 lbs (18.1 kg), 50 lbs (22.7 kg), 55 lbs (24.9 kg), or 2205 lbs (1000.0 kg) *(Note: only one of these packaging sizes will appear on the final printed label.)*

PRECAUTIONARY STATEMENTS

Hazards to Humans

CAUTION. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash

thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- protective eyewear
- long-sleeved shirt and long pants
- waterproof gloves
- shoes plus socks

Mixers/loaders and applicators must wear a NIOSH-approved particulate respirator with any N, R, or P filter with NIOSH approval number prefix TC-84A; or a NIOSH-approved powered air purifying respirator with an HE filter with NIOSH approval number prefix TC-21C. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.

Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS

Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

For terrestrial uses: Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate.

DIRECTIONS FOR USE

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

IMPORTANT: Read the entire label before using this product.

Not for use in liquid and free-choice medicated feeds.

PRODUCT INFORMATION

BioWorma[®] is a palatable feed supplement intended for further mixing into feed, feed supplements, premixes or concentrates and contains the spores of *Duddingtonia flagrans* strain IAH 1297, a fungus found in soil and pasture. It is a biological control for the free-living stages of the parasitic gastrointestinal nematodes (as listed below) of grazing animals and acts by substantially reducing the numbers of infective worm larvae (including chemical/anthelmintic multi-resistant larvae) emerging from manure onto pasture. When fed to grazing animals, the thick-walled spores remain inert (having no effect within the host animal) and resist digestion, passing through into the manure. Within the manure, the spores germinate and form trapping organs that capture, paralyze and consume emerging infective worm larvae (including chemical/anthelmintic multi-resistant larvae). The crucial re-infestation stage of the parasites' life cycle is interrupted, reducing the amount of re-infection from contaminated pasture. This interruption of the life cycle reduces parasitic nematodes on pasture.

PESTS CONTROLLED IN MANURE

BioWorma[®] is mixed into feed, feed supplements, premixes or concentrates that is fed to grazing animals to reduce nematodes.

The following is a list of roundworms/nematodes trapped by *Duddingtonia flagrans* strain IAH 1297 globally and the presence or absence of some of these nematodes may vary from region to region.

Sheep & Goats: Barber's Pole Worm or Wire Worm (*Haemonchus* spp.), Black Scour Worm or Hair Worm (*Trichostrongylus* spp.), Brown Stomach Worm (*Teladorsagia* (*Ostertagia*) spp.), Nodule Worm (*Oesophagostomum* spp.), Thin-necked Intestinal Worm (*Nematodirus* spp.), Hookworm (*Bunostomum* spp.), Intestinal Worm (*Cooperia* spp.), Large-mouthed Bowel Worm (*Chabertia* spp.), *Skrjabinema* spp., Threadworm (*Strongyloides* spp.), Whipworm (*Trichuris* spp.), *Gongylonema* spp. and *Mecistocirrus* spp.

Cattle: Barber's Pole Worm or Wire Worm (*Haemonchus* spp.), Brown Stomach Worm (*Teladorsagia* (*Ostertagia*) spp.), Black Scour Worm or Hair Worm (*Trichostrongylus* spp.), Hookworm (*Bunostomum* spp.), Intestinal Worm (*Cooperia* spp.), Thin-necked Intestinal Worm (*Nematodirus* spp.), Nodule Worm (*Oesophagostomum* spp.), Threadworm (*Strongyloides* spp.), *Toxocara vitulorum*, Whipworm (*Trichuris* spp.), *Gongylonema* spp. and *Mecistocirrus* spp.

Horses: Large Strongyles (Large Red Worms), including *Strongylus* spp., *Triodontophorus* spp. and *Oesophagodontus* spp.; Small Strongyles (Small Red Worms or Cyathostomes), including *Cyathostomum* spp., *Cylicocycclus* spp. and *Cylicostephanus* spp.; Stomach Hair Worm (*Trichostrongylus axei*); Ascarids (*Parascaris equorum*); Threadworms (*Strongyloides westeri*) and Pinworms (*Oxyuris equi*).

Other Grazing Animals (including Deer, Alpacas and Zoo Animals): Barber's Pole Worm or Wire Worm (*Haemonchus* spp.), Black Scour Worm or Hair Worm (*Trichostrongylus* spp.), Brown Stomach Worm (*Teladorsagia* (*Ostertagia*) spp.), Nodule Worm (*Oesophagostomum* spp.), Thin-necked Intestinal Worm (*Nematodirus* spp.), Hookworm (*Bunostomum* spp.), Intestinal Worm (*Cooperia* spp.), Threadworm (*Strongyloides* spp.), Whipworm (*Trichuris* spp.), Ascarids or Small Intestinal Roundworms (*Ascaris* spp.), Threadworms or Pinworms (*Strongyloides* spp.), Large Strongyles (*Strongylus* spp.) and Hairworm (*Capillaria* spp.)

There will be mixed infections with several worm species infecting the host at the same time.

DOSAGE AND ADMINISTRATION

Thoroughly mix the required amount of **BioWorma**[®] into feed, feed supplements, premixes or concentrates at 0.1 ounce product per 100 pounds animal weight, up to 1200 pounds, using the heaviest animal in the group to determine the appropriate amount of **BioWorma**[®] to use. When the largest animal is greater than 1200 pounds, use an additional 0.1 ounce of **BioWorma**[®] for each 100 pounds of bodyweight.

Dose **BioWorma**[®] according to bodyweight. For oral administration.

Bodyweight* (lbs)	25	50	100	200	300	400	500	750	1000	1200
Usage rate** (oz. per animal per day)	0.025	0.05	0.1	0.2	0.3	0.4	0.5	0.75	1.0	1.2

*Apply according to heaviest animal in the group.

**Use additional 0.1 oz. for each 100 lbs above 1200 lbs.

1. Treat animals with a suitable oral, injectable, or pour-on wormer/anthelmintic to rid the animals of worms, then begin administration of **BioWorma**[®].
2. Move the treated animals onto low worm pasture (that is, pasture that has not been grazed by the same animal species for a minimum of 6 weeks).

3. The most worm-susceptible are young animals (from 3 months up to 18-24 months of age) and periparturient females (last month of pregnancy and while producing milk), as they are the most likely to have less resistance to worm infestation due to low immunity. Do not underestimate pasture contamination by adult stock, even animals with low fecal egg counts (FECs), considering the volume of fecal material adult stock place on pasture.
4. Thoroughly mix **BioWorma**[®] with feed, feed supplements, premixes or concentrates, and commence daily administration of the resultant mixture to minimize pasture infectivity and maintain the low worm status of the animals.
5. **BioWorma**[®] will begin to work within the first day and may be fed continuously when warm, moist climatic conditions are conducive to parasitic nematode activity.
6. **BioWorma**[®] is for use during periods when conditions are conducive to larval development and transmission onto pasture at temperatures above 40° Fahrenheit (5° Celsius).
7. Use **BioWorma**[®] in conjunction with the specified worm management strategy for your area by contacting your Veterinarian, Animal Health Advisor or Government Advisory groups for a strategic Integrated Parasite Management (IPM) plan. It is important to consider the principles of refugia.
8. Periodically check the worm burden and monitor the effectiveness of the worm management system. Options include fecal egg counts (FECs), the fecal egg count reduction test (FECRT) and/or identifying worm species by using fecal larval cultures (FLCs). Re-treatment with an effective chemical wormer may be indicated (consult your Veterinarian).

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Store in a cool, dry place ($\leq 86^{\circ}\text{F}$; $\leq 30^{\circ}\text{C}$) and out of direct sunlight, and keep away from heat sources for up to 24 months from date of manufacture. Store only in original container in an area designated for pesticide storage. Keep out of reach of children. After storage times under the specified conditions have been exceeded, do not use and dispose of product in accordance with the instructions below.

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. Completely empty bag into equipment used to mix the product with feed, feed supplements, premixes or concentrates. Then offer for recycling if available, or dispose of empty bag in a sanitary landfill or by incineration. Do not burn, unless allowed by state and local ordinances. If burned, stay out of smoke.

Conditions of Sale

Seller warrants that this product consists of the ingredient specified and is reasonably fit for the purposes stated on this label when used in accordance with the directions under normal conditions of use. No one is authorized to make any other warranty or guarantee concerning this product. To the extent consistent with applicable law, any liability arising from the handling, storage and use of this product is limited to replacement of product or refund of purchase price.

IMPORTANT NOTICE – TERMS OF USE OF BIOWORMA[®]

International Animal Health Products Pty. Ltd. owns the intellectual property rights in the biological control, *Duddingtonia flagrans* strain IAH 1297, which this product contains. This product is supplied solely to Feedmills, Premixers and Veterinarians to be further mixed with feed, feed supplements, premixes or concentrates, and administered to grazing animals via their finished products, in accordance with the manufacturer's instructions. It is not to be used for any other purpose, including, without limitation: (a) manufacturing the product or its biological control on a stand-alone basis; (b) isolating, purifying or culturing the biological control; or (c) extracting, replicating or modifying any part of the

biological control.

This product is sold on the express condition that it must be used in accordance with the manufacturer's instructions for use. To the extent consistent with applicable law, no warranty, whether expressed or implied, is given for any and all damages, which may arise for goods not used in accordance with the manufacturer's instructions.

Manufactured by:



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Patent Pending

Lot No.
Manufactured on: