



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 14, 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 and Formulation Amendment –
Remove Use Restrictions and Update Storage Statements on the Labeling, and Update
the Viability Statement on the Labeling and Confidential Statements of Formula (Basic
and Alternate #1)
Product Name: Livamol with Bioworma
EPA Registration Number: 91253-2
Application Date: June 23, 2020
Action Code Case Number: 00134798
OPP Decision Number: 564104

Dear Ms. Huddy:

The amended labeling and Confidential Statements of Formula (CSFs) 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 CSFs:

- Basic CSF dated 04/09/2021
- Alternate CSF #1 dated 04/09/2021

Any CSFs other than those listed above are superseded/no longer valid.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

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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 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,



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

Enclosure

Livamol® with BioWorma®

Biological control product that may be fed alone where animals have access to pasture (moist growing pasture with a height of approximately 4 inches or more), may be further mixed into feed, feed supplements, premixes or concentrates and that contains 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* 2.200%

Other Ingredients:.....97.800%

Total.....100.000%

*Contains a minimum of 20,000 Colony Forming Units/gram of active ingredient.

GUARANTEED ANALYSIS

Crude Protein (Min)	20%
Crude Fat (Min)	5%
Crude Fiber (Max)	16%
Calcium (Min)	4%
Calcium (Max)	6%
Phosphorus (Min)	1.5%
Fluorine (Max)	0.025%
Vitamin A (Min)	27,000 IU/lb
Vitamin D3 (Min)	54,000 IU/lb
Manganese (Min)	104 ppm

INGREDIENTS: Plant Protein Products, Processed Grain By-Products, Dicalcium Phosphate, Calcium Carbonate, Sugar, Cane Molasses, Fish Oil, Propylene Glycol, Benzoic Acid (preservative), Manganous Oxide, FD&C Blue No. 1, Butylated Hydroxytoluene (preservative), Vitamin D3 Supplement, Vitamin A Supplement, Copper Sulfate, Zinc Oxide, Citric Acid (preservative), Salt, Sodium Phosphate, Vitamin B12 Supplement, Riboflavin, Pyridoxine Hydrochloride, Thiamine Mononitrate, Cobalt Sulfate, and Sodium Iodide

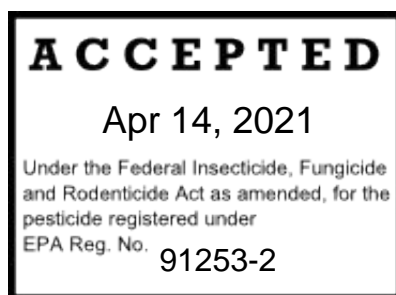
**KEEP OUT OF REACH OF CHILDREN
CAUTION/PRECAUCIÓN**

[See back panel for First Aid and 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.)

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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.)



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	
<p>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.</p>	

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

Livamol® with BioWorma® is a palatable feed supplement that may be fed alone where animals have access to pasture (moist growing pasture with a height of approximately 4 inches or more), or may be further mixed into feed, feed supplements, premixes or concentrates and that contains the spores of *Duddingtonia flagrans* strain IAH 1297 as **BioWorma®**, a fungus found in soil and pasture that has been combined with **Livamol®** (see below). **BioWorma®** is a biological control for the free-living stages of the listed 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

Livamol® with BioWorma® 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., *Cylicocycylus* 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

Dose **Livamol® with BioWorma®** at 1.6 ounces product per 100 pounds bodyweight, up to 1200 pounds, using

the heaviest animal in the group to determine the appropriate amount of **Livamol® with BioWorma®** to use. When the largest animal is greater than 1200 pounds, use an additional 1.6 ounces of Livamol® with BioWorma® for each 100 pounds of bodyweight.

Dose **Livamol® with BioWorma®** according to bodyweight. For oral administration.

Bodyweight* (lbs)	50	100	200	300	500	750	1000	1200
Usage rate** (oz. per animal per day)	0.8	1.6	3.2	4.8	8.0	12.0	16.0	19.2

*Apply according to heaviest animal in the group.

**Use additional 1.6 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 **Livamol® with 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 Livamol® with BioWorma® with feed, and commence daily administration of the resultant mixture to minimize pasture infectivity and maintain the low worm status of the animals.
5. **Livamol® with 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. **Livamol® with 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 **Livamol® with 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 or feed supplements. 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 LIVAMOL[®] WITH 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 for your personal use as an end customer to be further mixed with feed and administered to your grazing animals in accordance with the manufacturer's instructions. This product is for end-use only. Do not use it for or in connection with: (a) manufacturing, reselling or resupplying the product or its biological control on a stand-alone basis or as an ingredient in any other product; (b) isolating, purifying or culturing the biological control to create a similar or competing product; or (c) extracting, replicating, modifying or otherwise using any part of the biological control, including its nucleic acid or proteins, to create any product for personal use or for manufacture, resale or resupply.

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: