16



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON DC 20460

AUG -2 2012

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Stephen A Covell
Biological Scientist
US Forest Service
1601 North Kent Street RPC 7
Arlington VA 22209

Re TM Biocontrol 1

EPA Reg No 27586 1

Submission dated 8/3/2011 and subsequent revisions

Decision No 452893

Dear Mr Covell

The Agency has reviewed your request to amend the subject product registration which includes the following changes to the product label

The First Aid statements have been revised to conform to the Label Review Manual Net Contents has been changed to net weight and is expressed in US Customary Units of Measure

Precautionary statements have been revised to conform to the toxicology data and the Label Review Manual the PPE statements have been revised to reflect the toxicology data and MPB guidance

The Directions for Use have been revised to clarify which statements are mandatory. The mixing instructions have been revised in accordance with the PR Notice 82.1. Ground and Aerial Application instructions have been revised to delete references to recommended. A subsection entitled Aerial Drift Reduction Information has been added.

The Storage and Disposal statements have been revised to conform to the Container Handling regulations and the Label Review Manual

The Warranty statement was revised in accordance with the Label Review Manual

The amendment referred to above submitted in connection with registration under FIFRA section 3(c)(7)(A) is acceptable provided that you

- Submit and/or cite all data required for registration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data
- 2 Submit two (2) copies of your final printed labeling before you release the product for shipment Refer to the A 79 enclosure for a further description of a final printed label

If these conditions are not complied with the registration will be subject to cancellation in accordance with FIFRA section 6(e) Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions

A stamped copy of the label is enclosed for your records

The confidential statement of formula is addressed in the confidential attachment to this letter

If you have questions please contact Ann Sibold by phone at (703) 305 6502 or by email at sibold ann@epa gov

Sincerely

Kımberly Nescı

Acting Chief Microbial Pesticides Branch Biopesticides and Pollution Prevention Division (Mail Code 7511P)

Enclosures (2) A 79 Stamped Label Confidential Attachment

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TM Biocontrol-1			
For Douglas fir Tussock Moth (Orygia pseudotsugata)			
Biological Insecticide Wettable Powder	EPA Reg No 27586 1	EPA Establishment	No 047104 OR 001
ACTIVE INGREDIENT * Douglas fir tussock moth nu INERT INGREDIENTS Insect parts/inert solids TOTAL	, •	4%	
*equivalent to at least 1 28 x 10 ¹⁰ occlusion bodies (OB) per gram			
There is no direct relationship between intended activity (potency) and the percent active ingredient			
by weight			C. C. Fr. Vil
	KEEP OUT OF REACH OF	CHILDREN	ALIC G. AAIA
WARNING			AUG -2 2012
			s my -
	AVISO	!	E C(2 3
RI	EAD FIRST AID TREATMENT	BEFORE USE	27586-/
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 TREATMENT			
IF IN EYES Hold eye open and rinse slowly and gently with water for 15 to 20 minutes Remove contact lenses if present after the first 5 minutes then continue rinsing			
IF ON SKIN Take off contaminated clothing Rinse skin immediately with plenty of water for 15 20 minutes			
IF INHALED Move person to fresh air. If person is not breathing call 911 or an ambulance then give artificial respiration preferably mouth to mouth if possible			
Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor or going in for treatment.			
For emergency information on product (including health concerns or pesticide incidents) call the National Pesticides Information Center at 1 800 858 7378 6 30 AM to 4 30 PM Pacific Time (PT) seven days a week During other times call the poison control center 1 800 222 1222			
USDA Forest Service 180 Canfield Street Morgantown WV 26505			

Lot No _____

Net Contents ____Pounds___ounces (avoirdupois)

46

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

WARNING

Causes substantial but temporary eye injury Do not get in eyes or on clothing. Wear goggles or face shield. Harmful if absorbed through the skin. Avoid contact with skin. Wash thoroughly with soap and water after handling and before eating drinking chewing gum using tobacco or using toilet. Remove and wash contaminated clothing before reuse. Repeated exposure to high concentration of microbial proteins can cause allergic sensitization.

Personal Protective Equipment (PPE)

Mixers and handlers must wear

- Protective eyewear (goggles or face shield)
- Long sleeved shirt and pants
- Shoes plus socks
- Waterproof gloves
- A dust/mist filtering respirator meeting NIOSH standards of at least N 95 R 95 or P 95 Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization

Mixers/loaders and applicators not using enclosed cabs or aircraft must also use

- Protective eyewear (goggles or face shield)
- Long sleeved shirt and pants
- Shoes plus socks
- Waterproof gloves
- A dust/mist filtering respirator meeting NIOSH standards of at least N 95 R 95 or P 95 Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization

After product is diluted in accordance with the directions for use protective eyewear and respirators are not required. Follow manufacturers instructions for cleaning and maintaining PPE. If no such instructions for washables 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. Remove PPE immediately after handling this product. Wash outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

Environmental Hazards

For terrestrial uses Except under the forest canopy 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

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 the discharge. Do not discharge effluent containing this product into 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

Only for use as a biological insecticide to manage Douglas fir tussock moth infestations in wide area public pest control programs sponsored by governmental entities.

Application of this product is limited to forest trees and ornamental or non-commercial trees in urban parks golf courses lawns and landscapes. Tree species include Douglas—fir grand fir white fir red fir subalpine fir blue spruce and Engelmann spruce.

Do not apply this product in a way that will contact workers or other persons either directly or through drift. Only protected handlers may be in the area during application. Keep unprotected persons out of the treated areas until sprays have dried. Do not apply this product through any type of irrigation system. Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment and weather related factors determine the potential for spray drift. The applicator and the treatment coordinator are responsible for considering all of these factors when making decisions. For any requirements specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation.

This product is sensitive to environmental conditions. Store in a cool dark place prior to use (read STORAGE AND DISPOSAL section)

Product Information

TM Biocontrol 1 contains a virus that is toxic to larvae of the Douglas fir tussock moth. Orgyia pseudotsugata. Maximum efficacy is achieved when a lethal dose of the viral agent is consumed by early instar larvae. TM Biocontrol 1 should be applied soon after egg hatch, when first and second instar larvae are actively feeding, and new needles are expanding (May to mid July). Best results are expected when applications are made early in the morning on dry foliage. Rainy weather may necessitate repeated applications. Spray application is not recommended if rain is predicted within 12 hours.

Mixing Instructions

Add TM Biocontrol 1 to diluent water and recommended carrier in the proper ratio for per acre dosages and agitate to maintain suspension. Consult USDA Forest Service for currently recommended carriers in tank mix. **Never Use chlorinated water in the spray formulation**. If water pH is less than 6.0 or greater than 7.2 add appropriate amount of acid or base to adjust to within acceptable pH range. This product may be mixed with products in accordance with the most restrictive of label limitations and precautions. No label dosage rates may be exceeded.

Application Rates

- **Ground Application** Apply up to 0.4 oz (1.4 x 10¹¹ OB) of TM Biocontrol 1 per acre one or more times with a high volume hydraulic sprayer at a rate of 100 gallons per acre of tank mix to woodlots and small acreages. Spray individual large trees once to provide thorough coverage. If needed a second spray may be applied within 5 days.
- Aerial Application Apply one treatment of up to 0 2 oz (7 0 x 10¹⁰ OB) of TM Biocontrol 1 per acre. For tank mix volumes use 1/2 to 2 gallons per acre. If needed a second spray may be applied within 5 days.
- Aerial Drift Reduction Information Avoiding spray drift at the application is the
 responsibility of the applicator. The interaction of many equipment and weather related factors
 determine the potential for spray drift. The applicator is responsible for considering these
 factors when making decisions. Where states have more stringent regulations, they must be
 observed.

For general information on this pesticide product (including health concerns or pesticide incidents) call the National Pesticide Information Center at 1 800 858 7378 For additional technical information and assistance contact USDA Forest Service Pacific Northwest Region La Grand OR telephone (503) 808 2915

STORAGE AND DISPOSAL

Do not contaminate water food or feed by storage or disposal of waste

Storage & Transport Direct sunlight or temperatures above 80° F will impair activity. Store in sealed containers in cool dry place. Temperatures below 32° F improve long term storage. Within locked storage provide separation of pesticides and prevent cross contamination of other pesticides fertilizer food and feed. Transport in sealed storage container and locate in a compartment separate from passengers and driver.

Pesticide Disposal Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility in accordance with federal and local regulations

Container Handling Nonrefillable container Do not reuse or refill this container Completely empty bag into application equipment by shaking and tapping sides and bottom to loosen clinging particles When completely empty offer for recycling if available or dispose of bag in a sanitary landfill or by incineration or if allowed by State and local authorities by burning. If burned stay out of smoke

NOTICE

To the extent consistent with applicable law USDA Forest Service neither makes nor authorizes any agent or representative to make any warranty guarantee or representation express or implied of merchantability and/or fitness concerning this material except those contained on the label