

MAINE BOARD OF PESTICIDES CONTROL**POLICY CONCERNING DEFINITION OF BIOLOGICAL PESTICIDE****Adopted X X, 2017**

The Board listened to a concern raised by Maine Forest Service entomologists regarding the term “biological pesticide” as used in Section 5 of Chapter 29, which regulates pesticide applications for control of browntail moth adjacent to marine waters. The staff pointed out that when this rule was originally written, it contemplated that “biological pesticide” would primarily include strains of *Bacillus thuringiensis* and similar microbial pesticides. With the recent increase in browntail moth populations, questions have arisen about other active ingredients which are derived from organisms. Staff indicated that the term “biological pesticide” is now commonly perceived to include any single cellular biological organism or biologically derived product used to control, repel or mitigate a pest. For the purpose of clarifying the term “biological pesticide” as used specifically in Chapter 29, Section 5, the staff drafted two options that define the term, and those options were presented to the Board at the January 11, 2017 meeting for consideration.

- 1. Biological pesticide.** “Biological pesticide” includes any pesticide product with active ingredients limited to organisms and/or any biochemical derivatives from organisms.
- 2. Biological pesticide.** "Biological pesticide" includes any microbial pesticide that contains the microorganism and byproducts normally associated with the organism.



PAUL R. LEPAGE
GOVERNOR

STATE OF MAINE
DEPARTMENT OF AGRICULTURE, CONSERVATION AND FORESTRY
BOARD OF PESTICIDES CONTROL
28 STATE HOUSE STATION
AUGUSTA, MAINE 04333

WALTER E. WHITCOMB
COMMISSIONER

**MAINE BOARD OF PESTICIDES CONTROL POLICY—DEFINITION OF
BIOLOGICAL PESTICIDE AS IT RELATES TO CHAPTER 29 SECTION 5**

Adopted January 11, 2017

BACKGROUND

The Board discussed questions that arose during the spring of 2016 relative to interpretation of the term “biological pesticide” as used in Section 5 of Chapter 29, which regulates pesticide applications for control of browntail moth adjacent to marine waters. The staff pointed out that when this rule was originally written, it contemplated that “biological pesticide” would primarily include strains of *Bacillus thuringiensis* and similar microbial pesticides. With the recent increase in browntail moth populations, questions have arisen about other active ingredients which are derived from organisms. Staff indicated that the term “biological pesticide” is now commonly perceived to include pesticide active ingredients consisting of single cell organisms or products derived from organisms. At the January 11, 2017 meeting, the Board reviewed various options and adopted the following interpretation of the term “biological pesticide.”

POLICY

For the purposes of Chapter 29, Section 5, the term “biological pesticide” includes:

- pesticides that contain micro-organisms as the active ingredient, or
- pesticides that contain biological derivatives of micro-organisms as the active ingredient, and are approved by the Board.

HENRY JENNINGS, DIRECTOR
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BOARD OF PESTICIDES CONTROL
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 AUGUSTA, MAINE 04333

PAUL R. LEPAGE
 GOVERNOR

WALTER E. WHITCOMB
 COMMISSIONER

TO: Board Members
 FROM: Lebelles Hicks PhD DABT
 RE: Review of *Bacillus thuringiensis* variety *kurstaki* and Azadirachtin
 DATE: March 22, 2017

Pursuant to Chapter 29 section 5, active ingredients in insecticide products which may be applied as a foliar application within the 50 to 250 feet of the mean high tide mark zone for the control of Browntail moth require Board approval. There are restrictions for foliar applications in the 50 to 250 foot zone as well as the 0 to 50 foot zone. The 25 foot zone buffer for all bodies of water (Chapter 29 section 6) is not part of this review. "Biological" products used within both zones (0 to 250 feet) are exempt from the restrictions. In an effort to clarify the rule, the Board adopted a policy defining "biological" at the January 11, 2017 meeting (attached).

Biologicals as defined in the current policy include those:

- Pesticides that contain micro-organisms as the active ingredient, or
- Pesticides that contain biological derivatives of micro-organisms as the active ingredient, and are approved by the Board

Currently, products with the active ingredient spinosad are on the list for foliar use in the 50 to 250 zone and within the 0 to 50 foot zone. Two other types of "biological" active ingredients, currently registered and labeled for foliar use on ornamental landscape trees, are 1) *Bacillus thuringiensis* subspecies *kurstaki* (Btk), fermentation solids, spores, and insecticidal toxins and 2) azadirachtin derived from neem.

***Bacillus thuringiensis* subspecies *kurstaki* (Btk)**

Bacillus thuringiensis subspecies *kurstaki* (Btk) was not reviewed in the first batch of active ingredients because of a lack of efficacy data for control of Browntail moth. The Maine Forest Service has reviewed a recent study from Poland and concluded that it provides information that Browntail moth larvae are controlled with these types of products (Struble letter, 2017). Table 1 contains the current status of the Btk strains registered for this use and summaries of the freshwater and marine toxicity data for these active ingredients.

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Table 1. Aquatic Invertebrate toxicity <i>Bacillus thuringiensis</i> variety <i>kurstaki</i> (Btk) Active ingredients (EPA 1998b, 2014I, 2015bn)		
Btk Strain	Freshwater Invertebrates	Marine Invertebrates
Btk ABTS-351 (8 products)	Daphnia Acute “moderately toxic”; units ul/L 21-Day LC50 between 5 and 50 ppm (mg ai/L)	Grass shrimp “practically non-toxic” units colony forming units/gram food Aqueous LC50 = 4.9 ul/L Oral LC50 = > 2.5 nl/gram food
		Copepod: NOEL = 500 mg/kg sediment
Btk strain SA-11 (1 product)	Satisfied by previously reviewed studies Accession No. 127354; MRID No. 96533	Not required – Products with this active ingredient are not intended for direct application into estuarine or marine environments and are not expected to enter these environments in significant concentrations.
Btk strain SA-12 (1 product)		

Aquatic Toxicity in Invertebrates

Given the descriptors in Table 1 of “moderately” to “practically nontoxic,” the risk to aquatic invertebrates may be considered low. In addition, the crystalline toxins require activation in the alkaline (high pH) gut and the presence of *Bt* specific receptors in the guts of the susceptible insects. These conditions are not found in either the mammalian (low pH) or lobster gut (pH of 5.5 in larvae and 4.6 to 5 in adults).

Azadirachtin

Azadirachtin is extracted from the seeds of the Neem plant. The technical product Neemazal contains 37% azadirachtin (EPA# 71908-2) and is registered federally, but not in Maine. The 12 products which are registered in Maine that meet the criteria for control of Browntail moth on landscape ornamental trees in residential areas have azadirachtin concentrations ranging from 1.2 to 4.5%.

There are very few aquatic toxicity studies available for azadirachtin. According to Certis USA, “No environmental toxicity data have been generated or submitted to EPA in support of Azadirachtin as they are not required. They are not triggered by the Tiered Data Requirements for Biochemical Pesticides established by EPA.” This is supported by EPA’s conclusions in there 2008 Preliminary Work Plan for Azadirachtin (EPA 2008w) and the 2009 Final Work Plan (EPA 2009y).

“Ecological effects of Azadirachtin have been regularly evaluated since products containing this active ingredient were first registered in 1985. In each case, non-target data and/or various non-target waiver requests were sufficient to determine that the proposed uses of the pesticides containing this active ingredient posed negligible to nonexistent ecological risk (EPA 2008w)”

One aquatic toxicity data set was submitted by Kelly registration services on behalf of Parry America Inc. the basic producer for azadirachtin. These studies included quantitative information on technical

neemazal (37% azadirachtin) in *Daphnia* in acute and 21-day reproduction study. The 21 day reproductive study was chosen as the most relevant endpoint because azadirachtin is an insect growth regulator. The measured NOEC from this study was 0.67 mg azadirachtin/L. The resulting modified risk quotient is 0.14 which is below the cutoff of modified Risk Quotient of 500 agreed on at the January meeting.

Conclusions

Products containing Btk or azadirachtin meet the criteria for foliar use in the 0 to 250 foot zones found in Chapter 29 section 5.

References

BPC 2017, Policy on Definition of Biological Pesticide as it Relates to Chapter 29 Section 5.

BPC 2014, Chapter 29: STANDARDS FOR WATER QUALITY PROTECTION Section 5, Restrictions on Pesticide Applications to Control Browntail Moths Near Marine Waters

EPA 1998b, Registration Eligibility Decision Document for *Bacillus thuringiensis*

EPA 2008w, Azadirachtin; Summary Document Registration Review Initial Docket

EPA 2009y, Azadirachtin Final Work Plan Registration Review Case 6021

EPA 2014l, *Bacillus thuringiensis*, Revised Preliminary Work Plan and Summary Document Registration Review: Initial Docket September 2014

EPA 2015bn, *Bacillus thuringiensis* Final Work Plan Registration Review Case Number 0247

Parry America 1995 Aquatic Toxicity Studies Submitted to EPA

Struble 2017 Letter to the board of Pesticides Control



STATE OF MAINE
DEPARTMENT OF AGRICULTURE, CONSERVATION & FORESTRY
MAINE FOREST SERVICE
22 STATE HOUSE STATION
AUGUSTA, MAINE 04333

PAUL R. LEPAGE
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WALTER E. WHITCOMB
COMMISSIONER

March 22, 2017

Maine Board of Pesticide Control
28 State House Station
Augusta, ME 04333

Attn: Ann Chamberlain

Re: Adding *Btk* to the list of biologicals approved for application against Browntail Moth within 250 feet of the mean high water mark.

As I understand the process adopted in the recent MBPC meetings, only pesticides contained in the approved list can be used in the 0-250 foot zone. I am requesting that the Board add appropriately registered formulations of *Btk* (*Bacillus thuringiensis kurstaki*) to that list.

As was detailed in the January 11, 2017 meeting of the Board, the only reason *Btk* was omitted from the initial list of approved materials was that, at that time, the Board felt that they lacked sufficient evidence supporting claims of potential treatment efficacy. In response to a question from Katy Green (MOFGA) Dr. Hicks answered that if they [the Board] were to get data showing that *Bt* is efficacious it could be added to the list.

Since then I have acquired a recent (November 2016) report of trials conducted by Dr. Alicja Sierpinska in Poland, using *Btk* (Foray 76B) against browntail moth: "A Study on the Effectiveness of the Foray 76B Plant Protection Formulation in the Protection of IV Age Class Oak Stands Against Brown-Tail, *Euproctis chrysorrhoea*, (Lepidoptera: Lymantriidae) in the Krotoszyn Forest Inspectorate. Final Report from Study # INS/2016/2."

This report details a single aerial application of *Btk* on approximately 58 acres of infested oaks, using a PZL M-18 Domader agricultural aircraft outfitted with Micronair atomizers. The rates and application reported were congruent with the Foray 76B label-USA (EPA Reg # 73049-49). Regarding efficacy, the report asserts that in the 58 acre treated block oaks lost an average of 1.22% of their foliage compared to 69.96% loss on untreated oaks in the 3.5 acre control block. The report also refers to presence of dead browntail larvae observed around tree trunks in the sprayed plots.

These results from a single aerial application are persuasive evidence of product efficacy against browntail moth.

While I do not expect that any spatially limited pesticide treatment to completely eliminate browntail defoliation and "itch" issues, this evidence indicates that conventional *Bt* treatment can successfully significantly reduce populations for a given season, easing the associated human health issues. In the current Maine situation where BTM populations are intensifying and expanding, the threatened public is actively seeking treatment options; this treatment can provide significant relief, while posing no threat to the sensitive shoreline environment.

Where *Btk* is a registered (several formulations and manufacturers) and available in Maine, and is efficacious in controlling BTM, I am formally requesting that at the upcoming March 31 meeting the Board add *Bt* to the list of approved materials.

Thank you for your consideration of this matter.

Dave Struble
State Entomologist
Maine Forest Service

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March 20, 2017

Maine Board of Pesticide Control
Maine Department of Agriculture, Conservation, & Forestry
28 State House Station
Augusta ME, 04333

(Via email to Anne Chamberlain)

Dear Ms. Chamberlain,

Could you please ensure that the Members of the Board receive this document; I hope that it will initiate further discussion, and from my perspective, some resolution. Thank you for your time with this matter.

Control of Browntail Moth with Foray Btk

I am writing to express my concerns about the exclusion of *Bacillus thuringiensis* var. *kurstaki* (Btk) from the list of allowable pesticides that may be used to control Browntail Moth in the State of Maine. In fact I am surprised to see that several broad spectrum chemical insecticides are considered as acceptable/allowable for use in the 50 to 250 foot (from the high water mark) zone but that Btk, the most widely used biological pesticide in the world, is not.

This seems contrary to Integrated Pest Management programs practiced by many forest health agencies in that the Board of Pesticide Control approves and allows the use of broad spectrum chemical insecticides, but biological (microbial) insecticides such as Btk are not approved and allowed for use against the Browntail Moth.

Browntail Moth Control - Early Research Results:

I have compiled and attached a brief summary of all known laboratory, ground and aerial trials that have been conducted in Maine against the Browntail Moth over the last 25 years. A variety of microbial products have been used and at different rates and at different times during the insect's life cycle. It is difficult to compare all products 'across the board' but most of the microbial insecticides tested seemed to provide some level of control; results obtained range from 'unsatisfactory' to >98% larval mortality.

There was a concern, expressed 20+ years ago, that the currently available formulations of Btk did not contain the protoxins that may be most effective against the Browntail Moth. Commercial Btk products contain a mix of crystal-shaped protein toxins and in fact the Cry 1Ac toxin mentioned in some of the research work and correspondence is a component of the current strains and formulations of Foray.

A review of the results of the research work conducted to control BTM in Maine indicates that the best results in Dr. Dubois's lab studies were obtained with Foray 48B, (86% larval mortality) and it was also applied at half the dose rate of other Bt products. Some of the field and lab trials conducted in CT and ME included various combinations of Foray and other engineered Bt products such as MVP11, a commercial product based upon the Cry1Ac toxin. However most of these other products were not commercially successful and have long since disappeared from the marketplace.

Efficacy:

Foray 48B has NOT been used operationally to control Browntail Moth in Maine; Foray 48B was used experimentally in 1992 and again in 1993 to treat about 65 acres on Little Diamond Island. Ground applications of Foray were conducted in 1997 and in 1998 an aerial spray was conducted on Peeks Island. There are references in a Dubois paper about further trials post-1998, but I can find no evidence of such work having been conducted against the Browntail Moth.

Laboratory, ground and aerial trials conducted in the early 1990's against Browntail Moth in Maine by Bradbury, Dubois and others indicated that high levels of BTM larval mortality were achieved, but that levels of defoliation were inadequate.

Browntail moth has been a periodic pest in Europe and several aerial application programs have been conducted throughout southern and eastern Europe to control BTM. Bulgaria, Croatia, Poland, Ukraine have all been involved in BTM control, but reports are difficult to obtain. Additionally, most countries in Eastern EU have traditionally relied upon chemical insecticides or insect growth regulators to control BTM and as such, we can learn very little about control strategies that would be applicable in Maine. In recent years, some countries have used Foray Btk formulations, including Bulgaria (85-90 % larval mortality) in 1999-2000 and more recently in 2016, on a smaller scale, in Poland with Foray 76B (defoliation in treated area >70%, compared to <2% in sprayed area). Based on these results we are optimistic that Foray will be increasingly used to control BTM in Europe in the future.

Current Status and Conclusions:

Having reviewed all available literature on the control of Browntail Moth in North America, it is apparent that an aerial application of Foray will and DOES provide acceptable levels of larval mortality and, perhaps to a lesser extent, foliage protection. However, it would seem that the unacceptable levels of defoliation experienced in those application trials can be mostly attributed to spray timing and insect behaviour.

Due to the fact that the early instars are hidden in their overwintering webs/nests in the spring, it can be challenging to time the aerial application when they larvae are actively feeding, especially if they are devouring foliage as quickly as the buds break. Some foliage must be exposed and expanding in order for the Foray to be deposited upon and the larvae to consume, so there will always be some defoliation.

There is a second opportunity for control again in the late summer/early fall, before the larvae return to their webs where they will overwinter.

Most of the least successful results are not attributable to the incorrect toxin ratio, or the lack of a specific toxin, but rather to the timing of the applications and the weather conditions experienced before or after the applications occurred.

Over the last 2 decades, we have learned a great deal about Btk and the appropriate application parameters required to ensure that Btk applications are applied in the right place, at the right time, and at the right dose. In general, Btk formulations are more robust than in the past, and they are consistent in terms of viscosity, ease of application, and spray deposit. Extensive research has been focused on determining the appropriate Btk droplet sizes needed to maximize efficacy, and research into application weather and insect behaviour has proven beneficial too. We now know that post-spray weather is as important as insect development. We also know that spray timing is critical but we still have much to learn about the timing of the spring and fall applications to help optimize our results and to significantly reduce larval populations.

Browntail Moth is a periodic insect pest here in North America that erupts every decade or more; consequently there are few experienced individuals available who were involved during the 90's infestation to help develop a microbial-based control strategy. Fortunately there are still one or two 'Browntail Moth veterans' in Maine that have some experience and are willing to revisit this issue and help develop a microbial-based control strategy.

The USDA Forest Service seems to share no interest in developing appropriate control techniques and as a commercial entity, our research resources are limited; however we are willing to work with and support the Maine Forest Service in its efforts to control the Browntail Moth. The Browntail Moth is not a threat to commercial forests like the Gypsy Moth or the Spruce Budworm, but it poses a much larger threat as a public health issue affecting the residents of infested areas due to the urticating hairs shed by the larvae. These hairs can last for a long time in the environment and they can serve as a continued source of irritation and discomfort for nearby residents and visitors alike.

This is an important issue and one that we (Valent BioSciences) often deal with when working overseas to develop Btk-based control strategies for similar pests such as the Processionary Moth complex which like the Browntail, are prodigious producers of urticating hairs. We have worked with local forest health and public health authorities in southern Europe to develop Btk-based control techniques for pests that are very similar in physiology, behaviour, and impact.

This 'approved-unapproved' issue becomes a circuitous argument in that the Board of Pesticide Control has not approved the use of Btk, so landowners and municipalities will not use a product that is not allowed or approved. In my opinion, communities are NOT going to support the wide-scale application of most of the insecticides included on the current BPC list, and denying communities the right to obtain some relief with a microbial insecticide is incorrect. Additionally, as long as Btk is not allowed and not approved, there is no incentive for forest health managers, landowners, the arboricultural trade, and even Btk manufacturers to work together to develop a suitable Btk-based control strategy.

For many years, we heard that microbial insecticides like Foray 48B will not provide the same level of efficacy and foliage protection as chemical insecticides do, but we can now challenge that assumption.

In two decades, our knowledge of the mode of action of Btk, when applied with well-defined application parameters and application technology, to insects whose behaviour we now understand as critical to our success as forest pest managers has made microbial insecticides the product of choice when controlling lepidopteran forest pests.

I suspect that residents of BTM infested areas would gladly welcome 'adequate to very good' levels of larval mortality and foliage protection; these are achievable.

Please revisit the list of pesticides allowed and approved for use against the Browntail Moth; I firmly believe that Btk should be included on that list.

Regards,

A handwritten signature in black ink, appearing to read "Stephen Nicholson", with a long horizontal flourish extending to the right.

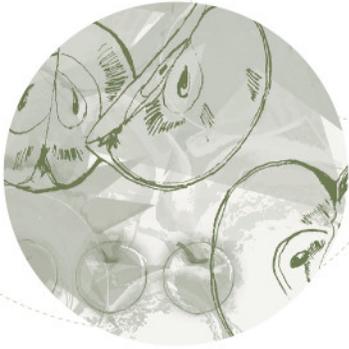
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(Attch.: Foray labels, OMRI certificate, BTM Trial Summary)



OMRI Listed®

The following product is OMRI Listed. It may be used in certified organic production or food processing and handling according to the USDA National Organic Program Rule.

Product

Foray® 48B Biological Insecticide Flowable Concentrate

Company

Valent BioSciences® Corp.
Ms. Maria Pilar Herrero
870 Technology Way, Suite 100
Libertyville, IL 60048

Status

Allowed with Restrictions

Category

NOP: Bacillus thuringiensis

Issue date

07-Dec-2006

Product number

abb-0522

Class

Crop Pest, Weed, and Disease Control

Expiration date

01-Mar-2018

Restrictions

May be used as a pesticide if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and disease management practices.

Executive Director

Product review is conducted according to the policies in the current *OMRI Policy Manual*® and based on the standards in the current *OMRI Standards Manual*®. To verify the current status of this or any OMRI Listed product, view the most current version of the *OMRI Products List*® at OMRI.org. OMRI listing is not equivalent to organic certification and is not a product endorsement. It cannot be construed as such. Final decisions on the acceptability of a product for use in a certified organic system are the responsibility of a USDA accredited certification agent. It is the operator's responsibility to properly use the product, including following any restrictions.



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Foray[®] 48B

BIOLOGICAL INSECTICIDE

FLOWABLE CONCENTRATE

For Commercial Forestry and Wide-Area
Pest Treatment—Aerial Application Only

 FOR ORGANIC PRODUCTION

ACTIVE INGREDIENT:

Bacillus thuringiensis, subsp. *kurstaki*, strain
ABTS-351, fermentation solids, spores and
insecticidal toxins 12.65%

OTHER INGREDIENTS 87.35%

TOTAL 100.00%

Potency: 10,600 Cabbage Looper Units (CLU) per mg of
product (equivalent to 48 billion CLU per gallon).

The percent active ingredient does not indicate product performance
and potency measurements are not federally standardized.

EPA Reg. No. 73049-427

EPA Est. No. 33762-IA-001

List No. 60181

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KEEP OUT OF REACH OF CHILDREN
CAUTION

1.0

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.
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HOT LINE 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 1-877-315-9819 (24 hours) for emergency medical treatment and/or transport emergency information. For all other information, call 1-800-323-9597.

2.0 PRECAUTIONARY STATEMENTS

2.1 HAZARDS TO HUMANS AND DOMESTIC ANIMALS 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.

2.2 Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Waterproof gloves
- Shoes plus socks

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

2.3 Agricultural Use Requirements:

Mixers/loaders and applicators must wear 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.

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

IMPORTANT: When reduced PPE is worn because a closed system is being used, handlers must provide all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as spill or equipment breakdown.

2.4 Non-agricultural Use Requirements:

Mixers/loaders and applicators must wear 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.

2.5 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 the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

CONTINUED

2.6 Environmental Hazards

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 cleaning equipment or disposing of equipment washwaters.

This product must not be applied aerially within 1/4 mile of any habitats of threatened or endangered lepidoptera.

3.0 DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. For any requirements specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation.

4.0 AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. Refer to supplemental labeling under "Agricultural Use Requirements" in the Directions For Use section for information about this standard.

Refer to the Directions For Use (below) for further directions.

5.0 STORAGE AND DISPOSAL

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

Pesticide Storage: Store in a cool, dry place. Keep containers tightly closed when not in use. Store in temperatures above freezing and below 32 degrees C (90 degrees F).

Pesticide Disposal: To avoid wastes, use all material in this container by application according to label directions. If wastes can not be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

Container Disposal: Nonrefillable 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 and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 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 if available or puncture and dispose of in a sanitary landfill, or by incineration. Do not burn, unless allowed by state and local ordinances.

Refillable Container: Refill this container with pesticide only. Do not use this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times.

6.0 WARRANTY AND DISCLAIMER

To the extent permitted by applicable law, seller makes no warranty, express or implied, of merchantability, fitness or otherwise concerning the use of this product other than as indicated on the label. User assumes all risks of use, storage or handling not in strict accordance with accompanying directions.

7.0 DIRECTIONS FOR USE BOOKLET

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. For any requirements specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation.

Apply this product only through aerial application.

8.0 AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

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.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 4 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard (that involves contact with anything that has been treated, such as plants, soil, or water) is:

- Coveralls
- Waterproof gloves
- Shoes plus socks

9.0 NON-AGRICULTURAL USE REQUIREMENTS

The requirements in this box apply to uses that are NOT within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries or greenhouses.

10.0 APPLICATION

Apply Foray 48B, undiluted or with quantities of water sufficient to provide thorough coverage of plant parts to be protected, only by aerial equipment. The amount of water needed per acre will depend upon crop size, weather, spray equipment, and local experience.

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 grower/treatment coordinator are responsible for considering all of these factors when making decisions.

11.0 HANDLING & MIXING

If Foray 48B is applied undiluted, the operator must ensure that the bulk quantity is well agitated and homogenous.

When Foray 48B is shipped by bulk tankers and transferred via a closed-loop mixing/loading system, the material is measured by passing through in-line flow meters directly into the aircraft, minimizing exposure to ground handling personnel.

In a similar manner, smaller containers of Foray 48B are also to be used with a closed-loop mixing/loading system to minimize the potential for accidental spills and exposure of ground handling personnel.

If dilution with water is needed for full crop coverage, fill tank with approximately 3/4 of the water required for dilution. Begin agitation and pump Foray 48B into the water while maintaining continuous agitation. Agitate as necessary to maintain suspension. Do not allow diluted mixture to remain in the tank for more than 72 hours.

When applying a diluted spray mixture, the use of a spreader-sticker approved for use on growing crops will improve the weather-fastness of the spray deposits. Add the spray adjuvant to the tank after the Foray 48B is added, and before the final volume of water is added to complete the mixture. Reduce or momentarily halt tank agitation and then add the required amount of adjuvant to the diluted mix. Use a closed-loop system to siphon the required quantity of adjuvant or pour the adjuvant into the top hatch of the tank. Once added, close tank opening, and resume agitation; add the rest of the water to complete the spray mix.

Combinations with commonly used spray tank adjuvants are generally not deleterious to Foray 48B, if the mix is used promptly. Before mixing in the spray tank, identify possible problems with physical compatibility by mixing all components in a small container in proportionate quantities. Check with an adjuvant supplier for advice on spray adjuvants that are compatible with biological pesticides such as Foray 48B to avoid incompatibilities.

12.0 SPRAY VOLUMES

12.1 Aerial Application: Use appropriate amount of Foray 48B, as indicated in the tables that follow, in aerial equipment undiluted or with quantities of water sufficient to provide thorough coverage of plant parts to be protected. In the western U.S., use a normal minimum of 5-10 gallons per acre; in the eastern regions, use a normal minimum of 2-3 gallons. The minimum amount of water needed per acre will depend upon crop size, weather conditions, spray equipment used and local experience.

13.0 GENERAL AGRICULTURAL USE INSTRUCTIONS

Foray 48B is a biological insecticide for the control of lepidopterous larvae. It contains the spores and endotoxin crystals of *Bacillus thuringiensis kurstaki*. Foray 48B must be ingested by the larvae to be effective. For consistent control, apply at first sign of newly hatched larvae (1st and 2nd instar larvae). Susceptible larvae that ingest Foray 48B cease feeding within a few hours and die within 2-5 days. Foray 48B may be applied up to and on the day of harvest. For maximum effectiveness, follow the instructions listed below:

Monitor fields to detect early infestations.

Apply Foray 48B when eggs start hatching and larvae are small (early instars) and before significant crop damage occurs. Larvae must be actively feeding to be affected.

Repeat applications every 3 to 14 days to maintain control and protect new plant growth. Factors affecting spray interval include rate of plant growth, weather conditions, and reinfestation. Monitor populations of pests and beneficials to determine proper timing of applications.

Under conditions of heavy pest pressures or when large worms are present use the higher rate, shorten the application interval, and/or improve spray coverage to enhance control. When these conditions are present, consider use of contact insecticide to enhance control.

Thorough coverage is essential for optimum performance.

Crop	Pests	Rate ¹ (fl. oz./acre)
Forests, Shade Trees, Ornamentals, Shrubs, Sugar Maple Trees, Seed Orchards, Ornamental Fruit, Nut and Citrus Trees ²	Gypsy Moth & Asian Gypsy Moth, Elm Spanworm Spruce Budworm, Browntail Moth, Douglas Fir Tussock Moth, Coneworm, Buck Moth Tussock Moths, Pine Butterfly, Bagworm, Leafrollers, Tortrix, Mimosa Webworm, Tent Caterpillar, Jackpine Budworm, Blackheaded Budworm, Saddled Prominent, Saddleback Caterpillar, Eastern and Western Hemlock Looper, Orangestriped Oakworm, Satin Moth Redhumped Caterpillars, Spring and Fall Cankerworm, California Oakworm, Fall Webworm	21 - 107 21 - 80 16 - 43 11 - 31

Special Instructions:

¹ Use the higher rates on advanced larval stages or under high density larval populations.

² In treating Gypsy Moth and Asian Gypsy Moth infected trees and shrubs in urban, rural, and semi-rural areas, exposure of non-target vegetation including, but not limited to, native and ornamental species and food or feed crops is permitted.

Use and mix this product with other pesticides only in accordance with the most restrictive of label limitations and precautions. Do not mix this product with any product containing a label prohibition against such mixing. Do not exceed label dosage rates.

14.0 GENERAL NON-AGRICULTURAL USE INSTRUCTIONS

Not for use on plants being grown for sale or other commercial use, or for commercial seed production, or for research purposes. For use on plants intended for aesthetic purposes or climatic modification and being grown in ornamental gardens or parks, or on golf courses or lawns and grounds.

Not for use on trees being grown for sale or other commercial use, or for commercial seed production, or for the production of timber or wood products, or for research purposes except wide-area public pest control programs sponsored by government entities, such as mosquito abatement, Gypsy Moth control, and Mediterranean Fruit Fly eradication.

Foray 48B contains the spores and endotoxin crystals of *Bacillus thuringiensis kurstaki*. Foray 48B is a stomach poison and is effective against lepidopterous larvae. After ingestion, larvae stop feeding within hours and die 2-5 days later. Maximum activity is exhibited against early instar larvae. Apply Foray 48B only by aerial application.

Use Foray 48B with a closed-loop mixing/loading system that will minimize the potential for accidental spills and exposure of ground handling personnel.

If dilution with water is needed for full crop coverage, fill tank with approximately 3/4 of the water required for dilution. Begin agitation and pump Foray 48B into the water while maintaining continuous agitation. Agitate as necessary to maintain suspension. Do not allow diluted mixture to remain in the tank for more than 72 hours.

Monitor to detect early infestations.

Crop	Pests	Rate ¹ (fl. oz./acre)
Forests, Shade Trees, Ornamentals, Shrubs, Sugar Maple Trees, Seed Orchards, Ornamental Fruit, Nut and Citrus Trees ²	Gypsy Moth & Asian Gypsy Moth, Elm Spanworm Spruce Budworm, Browntail Moth, Douglas Fir Tussock Moth, Coneworm, Buck Moth Tussock Moths, Pine Butterfly, Bagworm, Leafrollers, Tortrix, Mimosa Webworm, Tent Caterpillar, Jackpine Budworm, Blackheaded Budworm, Saddled Prominent, Saddleback Caterpillar, Eastern and Western Hemlock Looper, Orangestriped Oakworm, Satin Moth Redhumped Caterpillars, Spring and Fall Cankerworm, California Oakworm, Fall Webworm	21 - 107 21 - 80 16 - 43 11 - 31

Special Instructions:

¹ Use the higher rates on advanced larval stages or under high density larval populations.

² In treating Gypsy Moth and Asian Gypsy Moth infected trees and shrubs in urban, rural, and semi-rural areas, exposure of non-target vegetation including, but not limited to, native and ornamental species and food or feed crops is permitted.

Use and mix this product with other pesticides only in accordance with the most restrictive of label limitations and precautions. Do not mix this product with any product containing a label prohibition against such mixing. Do not exceed label dosage rates.

15.0 AERIAL APPLICATION

Apply Foray 48B, either alone or diluted with water, aerially at the rates per acre shown in the application rates table. Spray volumes of 32-107 fluid ounces of product per acre give optimum coverage. Best results are expected when Foray 48B is applied to dry foliage.

For smaller spray volumes, mix the proper number of teaspoons of Foray 48B from the following chart to attain the desired rates:

If the rate is:	Add this amount per gallon of mix:
8 fl. oz. (0.5 pt.)/acre	1/2 teaspoon
16 fl. oz. (1.0 pts.)/acre	1 teaspoon
24 fl. oz. (1.5 pts.)/acre	1-1/2 teaspoons
32 fl. oz. (2.0 pts.)/acre	2 teaspoons
48 fl. oz. (3.0 pts.)/acre	3 teaspoons
64 fl. oz. (4.0 pts.)/acre	4 teaspoons

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SUMMARY OF BROWNTAIL MOTH TREATMENTS WITH FORAY 48B & OTHER BT PRODUCTS

DATE	TREATMENT	LAB	GROUND	AERIAL ¹	RATE/AC ²	RESULTS & COMMENTS
1974	DiPel flowable, 1X and Thuricide 16B, 1X May and August	X		X f/w	1-8 BIU/ac, lab 8 BIU/ac, aerial Diluted with water?	McLane et al; > 95% larval mortality (L2) in lab. Aerial results spotty: lack of foliage development in May, Aug treatment a failure as larvae were feeding in the web by the time spraying occurred. (Spray timing issues.) First known Btk applications.
June '92	F 48B, 2X, 10 days apart			r/w	30 BIU, 1 gpa	Little Diamond Island, 60 ac, applications too late, weather delays, equipment problems, cold wet weather post-spray.
Sept '92	F 48B , 1X			f/w	30 BIU, 3 gpa	application delayed, suggested sublethal dose?
May '93	F 48B, MPVII 2X, 13 days apart	X	X	f/w	24 BIU, undiluted	Cold wet wx, no feeding after 1 st app. 2 nd app delayed due to weather, larvae had defoliated overwintering sites and migrated to new foliage so no assessment conducted. Results were unsatisfactory.
1995	Lab bioassays	X				Artificial diet problems. Results n/a.
1996	Foray 48B and others Foliar bioassay	X			4 BIU	86% larval mortality with Foray @ 4BIU, other products applied @ 8 BIU/ac.
1997	F 48B, MPVII, Condor		Mistblower		40 BIU	98% larval mortality, mix of Foray (84%) and MPVII (14%).
May '98	F 48B, with MPVII (40:60) 1X			f/w	14.8 BIU (45 fl. oz.) Foray + 46 gm (68 fl. oz.) MPVII, total of 113 fl. oz./ac.	Peaks Island, 200 acres. 72% larval mortality as per text, 78% larval mortality as per chart.

1) f/w: airplane
r/w: helicopter

2) Potency referred to as BIU's, now referred to as CLU's (Cabbage Looper Units).

References:

Bradbury, Richard. Efficacy Trials with Foray 48B against Browntail Moth, Maine Forest Service, Insect & Disease Management, Technical Report #35, May 1995

Dubois, Norman et al. Implementation of a Program to Optimize the use of *Bacillus Thuringiensis* against the Browntail Moth, USDA Forest Service, Northeastern Research Center. (Presented at IUFRO Conference, Victoria BC, 1999, pg 37-44, in proceedings by Leibhold et al., Integrated Management and Dynamics of Forest Defoliating Insects, 2001) Also shown as USDA Forest Service, Newtown Square PA, General Technical Report NE 277.

McLane, W.H., Finney & Schwalbe. Field Evaluation of Aerially Applied *Bacillus thuringiensis* (Berliner) Against the Browntail Moth, *Nygmia phaeorrhoea* (Donov.) USDA APHIS PPQ, Otis AFB MA. APHIS Report 81-30, April 1978

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