

Pin-18

63947-1

10410

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DEC 29 1992

54 28616 / 305  
15 / AD

Ms. Amy Plato  
Bactec Corporation  
9601 Katy Freeway, Suite 350  
Houston, Texas 77024

Subject: Final Printed Labeling for Bactec Bernan I  
Biological Larvicide  
EPA Registration Number: 63947-1

Dear Ms. Plato:

The labeling referred to above, submitted in connection with the registration under the Federal Insecticide, Fungicide, and Rodenticide Act is acceptable subject to the comments below.

1. On October 14, 1992, our Product Chemistry Review Section (PCRS) of the Registration Division of EPA received information from Stepan Company on their two surfactants, Stepsperse DF-100 and Stepsperse DF-300. After subsequent submittals of information on the composition of each surfactant, PCRS determined that both surfactants are exempt from the requirement of a tolerance when used in accordance with good agricultural practice as inert ingredients in pesticide formulations applied to growing crops and raw agricultural commodities after harvest (40 CFR 180.1001 (c)).
2. The Agency received your facsimile of December 4, 1992, requesting that the EPA consider returning to the insect bioassay and International Units of Potency as the accepted method of analysis and certification of active ingredient in a Bt formulation. In your letter, you describe the difficulties with expressing activity as a percentage of insect order active toxin. The Agency will investigate your concerns and make a determination.
3. In the interim, pending a formal response on the aforementioned concerns, the submitted labeling is acceptable without representation of the active ingredient as a percentage of lepidopteran active toxin; however, this is subject to change based on the Agency's findings and determination.

SYMBOL	H7505C						
SURNAME	AD						
DATE	12/4/92						

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

4. Until a determination can be made, remove (\_\_\_\_\_% Lepidopteran Active Toxin) from your label and resubmit 5 copies of revised labeling prior to releasing your product for shipment.

A copy of your label stamped EPA accepted with comments is enclosed. If you have any questions, you may contact Laura Dye of my staff at (703)305-6891.

Sincerely,



Phil Hutton  
Product Manager 18  
Insecticide-Rodenticide Branch  
Registration Division  
Office of Pesticide Programs

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

(bag label)

3 ct 12

# BACTEC BERNAN I BIOLOGICAL LARVICIDE

## DRY FLOWABLE

<b>ACTIVE INGREDIENT:</b>	<i>Bacillus thuringiensis, var. kurstaki</i> , BACTEC BERNAN I, 32,000 International Units of potency per milligram - 14.52 Billion International Units per pound ( _____ % Lepidopteran Active Toxin)	<b>6.4%*</b>
<b>INERT INGREDIENTS:</b>		<b>93.6%</b>
<b>TOTAL:</b>		<b>100.0%</b>

\* Potency units should not be used to adjust use rates beyond those specified in the Directions for Use section.

### KEEP OUT OF REACH OF CHILDREN

### WARNING / AVISO

**PRECAUTIONARY STATEMENTS - HAZARDS TO HUMANS AND DOMESTIC ANIMALS:** Causes substantial but temporary eye injury. Causes skin irritation. Harmful if absorbed through skin. Harmful if inhaled. Avoid breathing dust or spray mist. Do not get on skin, eyes, or clothing. Wear goggles or face shield. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

**PRECAUCION AL USUARIO:** Si usted no lee ingles, no use este producto hasta que le etiqueta haya sido explicado ampliamente.

**STATEMENT OF PRACTICAL TREATMENT:** If in eyes: hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention. If on skin: wash with plenty of soap and water. Get medical attention. If swallowed: drink promptly a large quantity of milk, egg white, gelatin solution, or if these are not available, large quantities of water. Avoid alcohol. If inhaled: remove victim to fresh air. If not breathing, give artificial respiration, preferable mouth-to-mouth. Get medical attention.

**ENVIRONMENTAL HAZARDS:** Do not contaminate water when disposing of equipment wash waters.

EPA Registration No. 63947-1

EPA Establishment No. 62171-MS-001

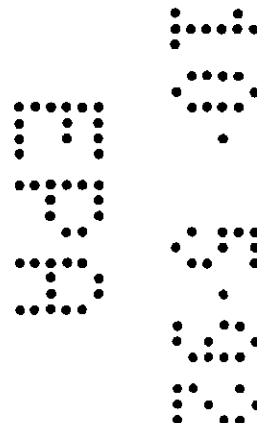
US Patent No. 4,950,471

ACCEPTED  
with COMMENTS  
to EPA Letter Dated

DEC 29 1992

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act  
as amended, for the pesticide  
registered under EPA Reg. No.

63947-1



NET WEIGHT:

**DIRECTIONS FOR USE:**

**IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING.**

**REFER TO ATTACHED DETAILED INSTRUCTIONS FOR SPECIFIC CROP USE AND APPLICATION RATES. NOT FOR HOUSEHOLD USE.**

**Do not apply this product in such a manner as to directly or through drift expose workers or other persons. The area being treated must be vacated by unprotected persons. Do not enter treated areas without protective clothing until sprays have dried or dusts have settled. Because certain states may require more restrictive re-entry intervals for various crops treated with this product, consult your State Department of Agriculture for further information.**

**BEST AVAILABLE COPY**

**Written or oral warnings must be given to workers who are expected to be in treated areas or in an area about to be treated with this product. When oral warnings are given, warnings shall be given in a language customarily understood by workers. Oral warnings must be given if there is reason to believe that written warnings cannot be understood by workers. Written warnings must include the following information: "WARNING. Area treated with BACTEC BERNAN I on (date of application). Do not enter without appropriate protective clothing."**

**GENERAL:**

**Apply BACTEC BERNAN at first sign of infestation when larvae are small and repeat at 3 to 7 day intervals as needed to maintain control below damage levels. BACTEC BERNAN destroys the larval gut and as such must be ingested by the insect to provide mortality. Thorough foliage/fruit coverage is needed to achieve maximum results. Shortly after eating a lethal dose of BACTEC BERNAN, the larvae become paralyzed, stop eating and die within 1-3 days. BACTEC BERNAN may be applied up to and including the day of harvest.**

**MIXING:**

**Use standard dry-product mixing procedures for knapsack, tractor and aerial spray applications. Apply where there is at least one (1) hour of drying time free of rain and/or heavy dews. When possible, apply early morning or evening in calm air conditions.**

**CROP APPLICATION:**

**Specific instructions are attached for each crop and insect.**

**STORAGE & DISPOSAL:**

**Do not contaminate feed, food, or water by storage or disposal. STORAGE: Tightly reclose containers of unused BACTEC BERNAN and store in a dry, well-ventilated, cool place. PRODUCT/CONTAINER DISPOSAL: Wastes resulting from the use of the product may be disposed of on site or at an approved waste disposal facility. Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill, by incineration, or if allowed by state and local authorities, by burning (if burned, stay out of smoke).**

**LIMITED WARRANTY: Manufacturer warrants that the product conforms to its description and is reasonably fit for the purpose stated on this label when used in accordance with directions under normal conditions of use; but neither this warranty nor any other warranty of merchantability of fitness for a particular purpose, expressed or implied, extends to the use of this product contrary to label instructions not reasonably foreseeable to the user; the user assumes the risk of any such use. If terms are not acceptable, return at once, unopened.**

(insert label)

# BACTEC BERNAN I BIOLOGICAL LARVICIDE

## DRY FLOWABLE

<b>ACTIVE INGREDIENT:</b>	<i>Bacillus thuringiensis, var. kurstaki</i> , BACTEC BERNAN I, 32,000 International Units of potency per milligram - 14.52 Billion International Units per pound ( _____ % Lepidopteran Active Toxin)	6.4%*
<b>INERT INGREDIENTS:</b>		93.6%
<b>TOTAL:</b>		100.0%

\* Potency units should not be used to adjust use rates beyond those specified in the Directions for Use section.

### KEEP OUT OF REACH OF CHILDREN

#### WARNING / AVISO

**PRECAUTIONARY STATEMENTS - HAZARDS TO HUMANS AND DOMESTIC ANIMALS:** Causes substantial but temporary eye injury. Causes skin irritation. Harmful if absorbed through skin. Harmful if inhaled. Avoid breathing dust or spray mist. Do not get on skin, eyes, or clothing. Wear goggles or face shield. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

**PRECAUCION AL USUARIO:** Si usted no lee ingles, no use este producto hasta que le etiqueta haya sido explicado ampliamente.

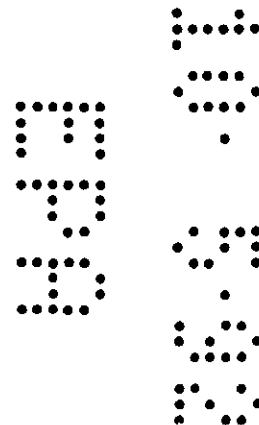
**STATEMENT OF PRACTICAL TREATMENT:** If in eyes: hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention. If on skin: wash with plenty of soap and water. Get medical attention. If swallowed: drink promptly a large quantity of milk, egg white, gelatin solution, or if these are not available, large quantities of water. Avoid alcohol. If inhaled: remove victim to fresh air. If not breathing, give artificial respiration, preferable mouth-to-mouth. Get medical attention.

**ENVIRONMENTAL HAZARDS:** Do not contaminate water when disposing of equipment wash waters.

EPA Registration No. 63947-1

EPA Establishment No. 62171-MS-001

US Patent No. 4,950,471



NET WEIGHT:

**DIRECTIONS FOR USE:**

**IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING.**

**REFER TO ATTACHED DETAILED INSTRUCTIONS FOR SPECIFIC CROP USE AND APPLICATION RATES. NOT FOR HOUSEHOLD USE.**

**Do not apply this product in such a manner as to directly or through drift expose workers or other persons. The area being treated must be vacated by unprotected persons. Do not enter treated areas without protective clothing until sprays have dried or dusts have settled. Because certain states may require more restrictive reentry intervals for various crops treated with this product, consult your State Department of Agriculture for further information.**

**Written or oral warnings must be given to workers who are expected to be in treated area or in an area about to be treated with this product. When oral warnings are given, warnings shall be given in a language customarily understood by workers. Oral warnings must be given if there is reason to believe that written warnings cannot be understood by workers. Written warnings must include the following information: "WARNING. Area treated with BACTEC BERNAN I on (date of application). Do not enter without appropriate protective clothing."**

**Do not apply this product through any type of irrigation system.**

**DAYS TO HARVEST:**

**BACTEC BERNAN may be applied up to and including the day of harvest.**

**SITES:**

**BACTEC BERNAN may be applied for control of any labeled pest in both field and greenhouse uses. BACTEC BERNAN is a highly specific larvicide to be evaluated against listed caterpillars (larvae) of lepidopterous insects. Close observation and attention to insect infestations is strongly recommended. Larvae must eat spray deposits of BACTEC BERNAN to be affected and induce mortality.**

**BEST AVAILABLE COPY**

**ALWAYS FOLLOW THESE GUIDELINES:**

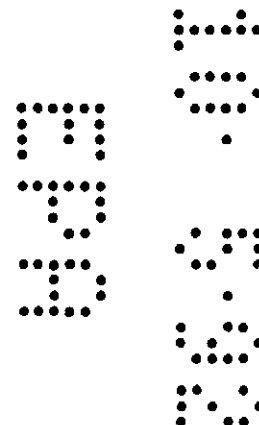
- \* Treat when larvae are young (early instars) before the crop is extensively damaged.
- \* Larvae must be actively feeding on treated, exposed plant parts.
- \* Thorough spray coverage is needed to provide a uniform deposit of BACTEC BERNAN on the sites of larval feeding. For certain crops, directed spray nozzles by ground machine are required.
- \* Under heavy pest population pressure, use the higher label rates, shorten the spray intervals, and/or raise the gallonage to improve spray coverage.
- \* Repeat applications at intervals sufficient to maintain control, usually 3 to 14 days depending on plant growth rate, moth activity, rainfall after treating, and other factors. If attempting to control a pest with a single spray, make the treatment when egg hatch is essentially complete, but before extensive crop damage occurs.
- \* The pH of the spray solution should be held within a range of 6.6 to 6.9. Use a buffering agent when spray water has a pH exceeding 8.0.
- \* A spreader-sticker which has been approved for use on growing and harvested crops may be added for hard-to-wet crops, such as cole crops, or to improve weather-fastness of the spray deposits.

After eating a lethal dose of BACTEC BERNAN, larvae usually stop feeding, develop paralysis, and die within 1 to 3 days. Dying larvae move slowly, discolor, and eventually shrivel, and die.

**MIXING & APPLICATION:** BACTEC BERNAN may be applied in conventional knapsack, tractor or aerial spray equipment with quantities of water sufficient to provide thorough coverage of infested plant parts. The amount of water needed per acre (hectare) will depend on crop size, weather, spray equipment, and local experience. Unless otherwise indicated by local instructions, use the following chart for spray volumes. When possible, apply early morning or evening in calm air conditions. Add water to the spray or mixing tank at the level that provides maximum agitation. With the agitator running, sprinkle BACTEC BERNAN into the tank and continue agitation. Then, add other spray materials, if any (a sticker, adhesive or deposit builder may be added when a heavy dew or rain is encountered). Add the balance of the water and agitate until mixed. Be sure to maintain the suspension while loading and spraying. For applications to trees, use the recommended amount of BACTEC BERNAN in 100 gallons/acre (1000 liters/hectare) of water in high-pressure, high-gallonage, hydraulic sprayers, wetting the foliage thoroughly but avoiding excessive run-off. For mist blowers, use recommended amount in 10 gallons/acre (100 liters/hectare) of water. Do not mix more BACTEC BERNAN than can be used in a 12-hour period.

SUGGESTED SPRAY VOLUMES			
VOLUME	GALLON/AC	LITER/HA	DILUTION RATE
Aerial	3 to 5	30 to 50	1 : 100
Ground	5 to 10	50 to 100	1 : 200
Knapsack	40	400	1 : 1000
Orchard	100	1000	1 : 3000

**STORAGE AND DISPOSAL:** Do not contaminate feed, food, or water by storage or disposal of this product or its container. **STORAGE:** Tightly reclose containers of unused BACTEC BERNAN and store in a dry, well-ventilated, cool place. **PRODUCT-CONTAINER DISPOSAL:** Wastes resulting from the use of the product may be disposed of on site or at an approved waste disposal facility. Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill, by incineration, or if allowed by state and local authorities, by burning (if burned, stay out of smoke).



## APPLICATION RATES

CROP	PEST (Common Name)	LBS/ACRE	GMS/HECTARE*
ALFALFA/HAY	Ailalfa Caterpillar	1/2 - 1	600 - 900 - 1200
	Loopers	1/2 - 1	600 - 900 - 1200
	Armyworms	1/2 - 1	600 - 900 - 1200
ALMONDS and WALNUTS	Redhumped Caterpillar	1/2 - 1	600 - 900 - 1200
	Tent Caterpillar	1/2 - 1	600 - 900 - 1200
	Walnut Caterpillar	1/2 - 1	600 - 900 - 1200
	Filbert Leafroller	1/2 - 1	600 - 900 - 1200
	Fall Webworm	1/2 - 1	600 - 900 - 1200
	Leafrollers Cankerworms	1/2 - 1	600 - 900 - 1200
AVOCADOS	Amorbia Moth	1/2 - 1	600 - 900 - 1200
	Omnivorous Leafroller	1/2 - 1	600 - 900 - 1200
	Omnivorous Looper	1/2 - 1	600 - 900 - 1200
	Orange Tortix	1/2 - 1	600 - 900 - 1200
	Spanworm	1/2 - 1	600 - 900 - 1200
BROCCOLI, CABBAGE, CANOLA/RAPE, CAULIFLOWER, COLLARD, MUSTARD GREENS, and TURNIP GREENS	Cabbage Looper	1/2 - 1	600 - 900 - 1200
	Imp. Cabbageworm	1/2 - 1	600 - 900 - 1200
	Diamondback Moth	1/2 - 1	600 - 900 - 1200
	Green Cloverworm	1/2 - 1	600 - 900 - 1200
	Loopers	1/2 - 1	600 - 900 - 1200
	Omnivorous Leafroller	1/2 - 1	600 - 900 - 1200
CELERY, LETTUCE, CHINESE CABBAGE, (Choysum) and POTATOES	Cabbage Looper	1/2 - 1	600 - 900 - 1200
	Hornworms	1/2 - 1	600 - 900 - 1200
	Webworm	1/2 - 1	600 - 900 - 1200
	Potato Beetle	1/2 - 1	600 - 900 - 1200
	Armyworms	1/2 - 1	600 - 900 - 1200
	Diamondback Moth	1/2 - 1	600 - 900 - 1200
	Green Cloverworm	1/2 - 1	600 - 900 - 1200
	Saltmarsh Caterpillar	1/2 - 1	600 - 900 - 1200
	Cutworms	1/2 - 1	600 - 900 - 1200
	Loopers	1/2 - 1	600 - 900 - 1200
	Omnivorous Leafroller	1/2 - 1	600 - 900 - 1200
	Heliothis spp.	1/2 - 1	600 - 900 - 1200
	Navel Orangeworm	1/2 - 1	600 - 900 - 1200
Leaf Miner	1/2 - 1	600 - 900 - 1200	
BEANS, SOYBEANS, PEAS, and PEANUTS	Velvetbean Caterpillar	1/2 - 1	600 - 900 - 1200
	Soybean Looper	1/2 - 1	600 - 900 - 1200
	Loopers	1/2 - 1	600 - 900 - 1200
	Head Moth	1/2 - 1	600 - 900 - 1200
	Green Cloverworm Saltmarsh Caterpillar Armyworms	1/2 - 1	600 - 900 - 1200
CUCUMBERS, WATERMELONS, and SQUASH	Rindworm Complex	1/2 - 1	600 - 900 - 1200
	Melonworms	1/2 - 1	600 - 900 - 1200
	Cabbage Looper	1/2 - 1	600 - 900 - 1200
	Armyworms	1/2 - 1	600 - 900 - 1200
CITRUS	Fruittree Leafroller	1/2 - 1	600 - 900 - 1200
	Orangedog	1/4 - 1	300 - 750 - 1200
	Citrus Cutworm	1/2 - 1	600 - 900 - 1200

\* Easy - Moderate - Hard to control larvae

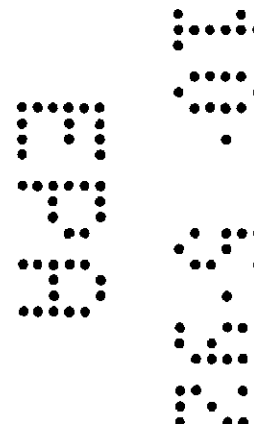
**BEST AVAILABLE COPY**



APPLICATION RATES, CONT.

CROP	PEST (Common Name)	LBS/ACRE	GMS/HECTARE*
GRAPES	Omnivorous Leafroller	1/2 - 1	600 - 900 - 1200
	Grapeleaf Skeletonizer	1/2 - 1	600 - 900 - 1200
	Roughskinned Cutworm	1/2 - 1	600 - 900 - 1200
	Grapeleaf Folder	1/2 - 1	600 - 900 - 1200
	Grape Leafroller	1/2 - 1	600 - 900 - 1200
	Saltmarsh Caterpillar	1/2 - 1	600 - 900 - 1200
	Achemia Sphinx Moth (Hornworm)	1/2 - 1	600 - 900 - 1200
	Orange Tortix	1/2 - 1	600 - 900 - 1200
	Obliquebanded Leafroller	1/2 - 1	600 - 900 - 1200
	Tobacco Budworm	1/2 - 1	600 - 900 - 1200
	Loopers Armyworms	1/2 - 1	600 - 900 - 1200
EGGPLANT, TOMATOES, and PEPPERS	Tomato Fruitworm	1/2 - 1	600 - 900 - 1200
	Tomato Hornworm	1/2 - 1	600 - 900 - 1200
	Variegated Cutworm	1/2 - 1	600 - 900 - 1200
	Saltmarsh Caterpillar	1/2 - 1	600 - 900 - 1200
	Loopers	1/2 - 1	600 - 900 - 1200
	Tomato Pinworm Armyworms	1/2 - 1	600 - 900 - 1200
FIELD CORN, SWEET CORN, and SORGHUM	Corn Earworm	1/2 - 1	600 - 900 - 1200
	Headworms	1/2 - 1	600 - 900 - 1200
	Armyworms	1/2 - 1	600 - 900 - 1200
	Corn Borer	1/2 - 1	600 - 900 - 1200
COTTON	Tobacco Budworm	1/2 - 1	600 - 900 - 1200
	Cotton Bollworm	1/2 - 1	600 - 900 - 1200
	Saltmarsh Caterpillar	1/2 - 1	600 - 900 - 1200
	Loopers	1/2 - 1	600 - 900 - 1200
	Armyworms	1/2 - 1	600 - 900 - 1200
TOBACCO	Tobacco Budworm	1/2 - 1	600 - 900 - 1200
	Tobacco Hornworm	1/4 - 1/2	300 - 450 - 600
	Loopers	1/2 - 1	600 - 900 - 1200
TURF	Sod Webworm	1/2 - 1	600 - 900 - 1200

\* Easy - Moderate - Hard to control larvae



10 0 10

STORED AGRICULTURAL COMMODITIES

APPLICATION RATES

**BEST AVAILABLE COPY**

CROP	PEST (Common Name)	LBS per 100 bushels (diluted and undiluted)	GMS
GRAINS, SOYBEANS and CROP SEED	Indian Meal Moth	3/8 - 1/2	175 - 250
	Almond Moth	3/8 - 1/2	175 - 250

To control and prevent these pests, apply BACTEC BERNAN in a constantly agitated water suspension to the top four-inch surface layer of grain in the bin. Use a sprinkler can or sprayer to apply the dosage into the grain stream as the last (top) four-inch layer is augered into the bin, applying 0.6 pint of mixture per bushel. The dosage can also be sprinkled onto the surface of the grain in the bin and mixed thoroughly with a scoop or rake to a depth of four inches. More thorough coverage may be achieved by dividing the suggested dosage into three applications and mixing the grain between applications. As a surface treatment, apply 1/2 pound or 250 grams in 5 to 10 gallons of water per 500 square feet of grain surface area; mix into top four inches. For commodities coarser than shelled corn, increase depth of treatment according to the habit of the pest.

CROP	PEST (Common Name)	LBS/TON	GMS/TON
PEANUTS	Indian Meal Moth	1/4	125
	Almond Moth	1/4	125

Apply this rate to the top four to eight feet of nuts when filling the warehouse.

To prevent and control these pests, spray an even coating of BACTEC BERNAN on the farmer stock peanuts while filling the warehouse. To make the spray solution, mix 3.75 pounds or 1700 grams per 5 gallons of water; this amount should treat 15 tons of commodity. Keep the spray suspension agitated during application and use pressures and nozzles sufficient to handle this suspension. For bagged peanuts, treat the whole mass of commodity at the suggested rate before bagging. Before a warehouse is filled, the cleaned interior can be sprayed using 1/2 pound or 250 grams per 100 gallons of water; apply to interior and spray into cracks.

CROP	PEST (Common Name)	SUGGESTED RATE/COMMODITY
FLUE-CURED TOBACCO	Tobacco Moth	0.2 ounces per 100 lbs

NOTE: 0.2 ounce is equivalent to approximately 2.5 teaspoons; mix this amount in one quart of water per 100 pounds of tobacco.

TOBACCO TO BE STORED UP TO 12 MONTHS: Spray loose leaves as the tobacco is being bundled from the curing barn. For tobacco sticks, treat both sides of the leaves.

STORED TOBACCO: For tobacco which is to be carried over, rebundle or restack sticks, stuff up tobacco and spray loose leaves. For tobacco that has been stored over three weeks, apply, at first signs of infestations; promptly open bundles, spray loose leaves, and then rebundle.

TREATMENT OF STORAGE BARNs: If tobacco has been treated, or is going to be treated, treatment of the floors and walls may be made to aid in control. Sweep out the area, especially cracks and corners, and remove all of the loose tobacco pieces where the moth might breed. Make a spray mixture containing 1/2 ounce per 2.5 gallons of water and apply at a rate of 1/2 gallon per 1000 square feet of surface area. Be sure to spray into cracks and floorboards.