

47629-13

04/03/2008

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



OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

April 3, 2008

$\frac{R346}{1155}$	5-820735
$\frac{R346}{1155}$	5-827069
$\frac{345}{1155}$	5-827070
$\frac{300}{1155}$	5-827066

Woodstream Corp.
69 N. Locust Street
Lititz, PA 17543-0327

Attention: Mr. Chad Mateer

Subject Bromethalin 0.01% Pellet
EPA Reg. No. 47629-13
Your amended application of November 29, 2007
Your amended application of December 10, 2007
Your resubmissions of January 16, March 7, March 20 and 26, 2008

Purpose The purpose of these submissions, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is to revise your label, change package size/net contents, add an alternate Confidential Statement of Formula (CSF), and to change the place pack material for this product.

Labeling The labeling submitted with the above letter is acceptable, provided that you submit one (1) copy of final printed labeling to us, before you ship the product.

Note: You have agreed to change the marketing claim, "Drop N' Kill™ No-Touch Bait Bags [Bait Packs][Place Packs]", to "Place N' Kill No-Touch Bait Bags [Bait Packs][Place Packs]" at the next packaging production run.

CSF We have reviewed your alternate CSF, dated January 15, 2008, for this product and have found it acceptable with your submission of March 26, 2008.

Placepack Material The change in placepack material is acceptable, provided that you continue to use the material for which you have cited acceptable data. Be sure to include the correct establishment number on label. If they make the final product, the correct number is EPA Est. No. 61282-WI-01".

Existing stocks Stocks of product with existing labels may be used for eighteen (18) months.

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Consequence for non-compliance 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 constitutes acceptance of these conditions.

Questions If you have questions about this letter, please contact me at 703-305-5407 (by phone), 703-305-6596 (by fax), or peacock.dan@epa.gov (by E-Mail).

Sincerely yours,



Daniel B. Peacock, Biologist
Insecticide-Rodenticide Branch
Registration Division (7504C)

Enclosures

1. Stamped Label
2. Minimum Type Size Requirements for Final Printed Labels

Letter Dan Peacock, Flash Drive, 2gb, P:\Documents\Word, WP, Excel, etc\Bromethalin\47629-13\47629-13, 12-20-2007\47629-13, label changes, alt CSF, 4-2-2008.doc

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Label Amendment – (Revision of December 10, 2007 Amendment as per Agency Comments dated February 20, 2008)
March 7, 2008
Page 1 of 12

MASTER LABEL – OUTER CONTAINER FRONT PANEL (Page 1 of 1)
[Rat and Mouse Control – Placepacks Not Sold Separately]

BROMETHALIN 0.01% PELLET

[Optional Logos/Marketing Claims]

- Kills Anticoagulant Resistant Norway Rats, Roof Rats and House Mice
- Norway rats, Roof rats, and House Mice usually consume a lethal dose in a single night's feeding, but it may take two or more days from the time of bait consumption for these rodents to die. Rodents cease feeding after consuming a toxic dose. This product is effective against anticoagulant-resistant rats and mice.
- [Kills] [Controls] Rats & Mice
- Indoor/Outdoor
- For use in Attics, Kitchens, Basements, Garages
- Can be used in Attics, Kitchens, Basements, Garages
- No-Touch™ Design
- Drop N' Kill™ No-Touch Bait Bags [Bait Packs] [Place Packs]
- Place N' Kill™ No-Touch Bait Bags [Bait Packs] [Place Packs]

ACTIVE INGREDIENT:

Bromethalin.....0.01%

OTHER INGREDIENTS:.....99.99%

TOTAL:.....100.000%

ACCEPTED

APR 3 2008 BY WT.

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 47629-13

KEEP OUT OF REACH OF CHILDREN

CAUTION: (See side [back] panel for additional precautionary statements)

NET CONTENTS:

1.5 oz (2 X 0.75 oz. [place packs][bait packs][bait bags]) *[to]* 3.75 lb/60.0 oz (80 X 0.75 oz. [place packs][bait packs][bait bags])

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Label Amendment – (Revision of December 10, 2007 Amendment as per Agency Comments dated February 20, 2008)

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MASTER LABEL – OUTER CONTAINER BACK PANEL (Page 1 of 4)

[Rat and Mouse Control – Placepacks Not Sold Separately]

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION: Harmful if swallowed. Wash thoroughly with soap and water after handling, and before eating, drinking, chewing gum, or using tobacco.

FIRST AID	
Have label with you when obtaining treatment advice.	
If swallowed:	<ul style="list-style-type: none"> - Call a poison control center, doctor or 1-800-222-1212 immediately for treatment advice. - Have person sip a glass of water if able to swallow. - Do not induce vomiting unless told to do so by the poison control center or doctor. - Do not give anything by mouth to an unconscious person.
If on skin or clothing:	<ul style="list-style-type: none"> - Take off contaminated clothing. - Rinse skin immediately with plenty of water for 15-20 minutes. - Call a poison control center or doctor for treatment advice.
NOTE TO PHYSICIAN OR VETERINARIAN	
This is not and anticoagulant rodenticide. If ingested, limit absorption by either emesis or gastric lavage. Sublethal symptoms, if present, would be the result of cerebral edema and should be treated accordingly through administration of an osmotic diuretic and corticosteroid.	

ENVIRONMENTAL HAZARDS

This product is toxic to fish, birds and other wildlife. Do not apply this product directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark.

DIRECTIONS FOR USE

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

READ THIS LABEL! Read this entire label and follow all use directions and use precautions. Use only for the sites, pests, and application methods described on this label.

IMPORTANT: Do not expose children, pets, or nontarget animals to rodenticides. To help prevent accidents:

1. Store product not in use out of reach of children and pets.

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MASTER LABEL – OUTER CONTAINER BACK PANEL (Page 2 of 4)

[Rat and Mouse Control – Placepacks Not Sold Separately]

2. Apply bait in locations out of reach of children, pets, domestic animals and nontarget wildlife, or in tamper-resistant bait stations. These stations must be resistant to destruction by dogs and by children under six (6) years of age, and must be used in a manner that prevents such children from reaching into bait compartments and obtaining bait. If bait can be shaken from bait stations when they are lifted, units must be secured or otherwise immobilized. Even stronger bait stations are needed in areas open to hoofed livestock, raccoons, bears or other potentially destructive animals, or in areas prone to vandalism.
3. Dispose of product container and unused, spoiled or unconsumed bait as specified on this label.

USE RESTRICTIONS: This product may only be used to control norway rats, roof rats, and house mice in and around homes, and in industrial, commercial, and public buildings. This product may also be used in transport vehicles (ships, trains, aircraft) and in and around related port or terminal buildings. This product may be used in alleys. Do not use in sewers.

Do not place bait in areas where there is a possibility of contaminating food or surfaces that come in direct contact with food. Do not broadcast bait. Wear water-proof gloves if you handle bait or dead animals.

SELECTION OF TREATMENT AREAS: Determine where rats and mice will most likely find an opening and consume the bait. Generally, these areas are along walls, by gnawed openings or rub marks, in or beside burrows, in corners and concealed places, between floors and walls, or in locations where signs of rodents have been seen. Protect bait from rain or snow. Remove as much alternative food as possible.

BAITING:

Language based on container size:	
For package of 4, 0.75 oz. packs	This product contains enough bait (3 oz.) to kill 4 to 6 rats.
For package of 2, 0.75 oz. packs	This package contains enough bait (1.5 oz.) to kill 1 to 3 rats.

APPLICATION DIRECTIONS:

Norway Rats and Roof Rats: Use 2 to 8 [place packs][bait packs][bait bags] per placement. Make placements at intervals of approximately 15 to 30 feet at appropriate locations in infected area. Adjust the amount of bait provided according to the level of rat feeding expected at each placement location.

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MASTER LABEL – OUTER CONTAINER BACK PANEL (Page 3 of 4)
[Rat and Mouse Control – Placepacks Not Sold Separately]

House Mice: Use 1 [place pack][bait pack][bait bag] per typical placement. Space placements at intervals of 8 to 12 feet in appropriate locations in infested areas. Up to 2 [place packs][bait packs][bait bags] may be placed at points of extremely high house mouse activity.

Baiting Strategy (Rats and Mice): Highest bait consumption is expected to occur on the first day or two after treatment begins. After several days, inspect the placement and replenish bait at sites where there is evidence of heavy feeding or where there is continued evidence of rodent activity. Normally, the volume of bait consumed will be significantly less with bromethalin baits than with anticoagulant baits. Although one night's feeding will usually provide a lethal dose, maintain bait for at least one week to provide all rodents a chance to feed on the bait. Continue baiting until all signs of feeding have ceased.

Follow-Up: Replace contaminated or spoiled bait immediately. Using waterproof gloves, collect and properly dispose of all dead animals and leftover bait. To discourage reinfestation, limit sources of rodent food, water and harborage and rodent-proof structures as much as possible. If reinfestation does occur, repeat treatment. When a continuous source of infestation is present, establish permanent bait stations and replenish bait as needed.

STORAGE AND DISPOSAL: [Household Labels]

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

STORAGE: Store in original container in a cool, dry place inaccessible to children and pets.

DISPOSAL: If empty: Do not reuse this container. Place in trash or offer for recycling if available.

Partly Filled Containers and Spoiled and Unconsumed Bait: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

STORAGE AND DISPOSAL: [Non-Household Labels]

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

STORAGE: Store only in original container in a cool, dry place inaccessible to children, and pets.

Keep containers closed and away from other chemicals.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product, and spoiled and unconsumed bait, may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Dispose of empty container in a sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

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MASTER LABEL – OUTER CONTAINER BACK PANEL (Page 4 of 4)
[Rat and Mouse Control – Placepacks Not Sold Separately]

Note: Seller warrants that this product complies with the specifications expressed in this label. To the extent consistent with applicable law, Seller makes no other warranties, and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and fitness for the intended purpose. To the extent consistent with applicable law, Seller's liability or default, breach or failure under this label shall be limited to the amount of the purchase price. To the extent consistent with applicable law, Seller shall have no liability for consequential damages.

Manufactured For:
Woodstream Corporation
69 N. Locust St
Lititz, PA 17543
For Information Call: 1-800-800-1819

EPA Reg. No. 47629-13

EPA Est. No. 47629-PA-01

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MASTER LABEL – PLACEPACK FRONT PANEL (Page 1 of 1)
[Rat and Mouse Control – Placepacks Not Sold Separately]

BROMETHALIN 0.01% PELLET

ACTIVE INGREDIENT:	BY WT.
Bromethalin.....	0.01%
OTHER INGREDIENTS:.....	99.99%
TOTAL:	100.000%

KEEP OUT OF REACH OF CHILDREN CAUTION

STOP! Read entire label, including precautions, use directions, and storage and disposal text prior to using this product.

For First Aid Treatment advice, call a poison control center, doctor, or 1-800-222-1222

It is illegal to sell these placepacks [bait packs][bait bags] individually.

Do not open placepacks [bait packs][bait bags]. Rats and mice will chew through the wrapper.

Manufactured For:
Woodstream Corporation
69 N. Locust St
Lititz, PA 17543-0327
For Information Call: 1-800-800-1819

EPA Reg. No. 47629-13

EPA Est. No. 47629-PA-01

NET CONTENTS: 0.75 oz

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MASTER LABEL – OPTIONAL CLAIMS (Page 1 of 1)

[Rat and Mouse Control – Placepacks Not Sold Separately]

[Additional - Optional Marketing/Advertising Claims]

- Mouse and Rat Poison Pack
- Palatable bait formulation
- Palatable formulation
- Contains Bromethalin
- 0.01% Bromethalin pellets
- Formulated for Norway rat, roof rat, and house mice control
- Demonstrated control of norway rats, roof rats, and house mice
- [Controls][Kills] norway rats, roof rats, and house mice
- [Controls][Kills] anticoagulant resistant rats & mice
- [Kills][Controls] rats & mice in and around the home
- [Kills][Controls] rats & mice both inside and outside the home
- Can be used Indoors or Outdoors for control of Rats & Mice
- For Indoor and Outdoor Rat & Mouse Control
- For indoor and outdoor use.
- Ready to use

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MASTER LABEL – PLACEPACK FRONT PANEL (Page 1 of 1)
[House Mouse Control Only – 0.75 oz. Placepacks Sold Separately]

BROMETHALIN 0.01% PELLET

[Optional Logos/Marketing Claims]

- Kills House Mice
- House Mice usually consume a lethal dose in a single night’s feeding, but it may take two or more days from the time of bait consumption for these rodents to die. Rodents cease feeding after consuming a toxic dose. This product is effective against anticoagulant-resistant house mice.
- Kills Mice
- Indoor/Outdoor
- For use in Attics, Kitchens, Basements, Garages
- Can be used in Attics, Kitchens, Basements, Garages
- No-Touch™ Design
- Drop N’ Kill™ No-Touch Bait Bag [Bait Pack] [Place Pack]
- Place N’ Kill™ No-Touch Bait Bags [Bait Packs] [Place Packs]

ACTIVE INGREDIENT:	BY WT.
Bromethalin.....	0.01%
OTHER INGREDIENTS:	<u>99.99%</u>
TOTAL:	100.000%

KEEP OUT OF REACH OF CHILDREN

CAUTION: (See side [back] panel for additional precautionary statements)

NET CONTENTS: 0.75 oz.

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MASTER LABEL – PLACEPACK BACK PANEL (Page 1 of 3)
[House Mouse Control Only – 0.75 oz. Placepacks Sold Separately]

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION: Harmful if swallowed. Wash thoroughly with soap and water after handling, and before eating, drinking, chewing gum, or using tobacco.

FIRST AID	
Have label with you when obtaining treatment advice.	
If swallowed:	<ul style="list-style-type: none"> - Call a poison control center, doctor or 1-800-222-1212 immediately for treatment advice. - Have person sip a glass of water if able to swallow. - Do not induce vomiting unless told to do so by the poison control center or doctor. - Do not give anything by mouth to an unconscious person.
If on skin or clothing:	<ul style="list-style-type: none"> - Take off contaminated clothing. - Rinse skin immediately with plenty of water for 15-20 minutes. - Call a poison control center or doctor for treatment advice.
NOTE TO PHYSICIAN OR VETERINARIAN	
This is not an anticoagulant rodenticide. If ingested, limit absorption by either emesis or gastric lavage. Sublethal symptoms, if present, would be the result of cerebral edema and should be treated accordingly through administration of an osmotic diuretic and corticosteroid.	

ENVIRONMENTAL HAZARDS

This product is toxic to fish, birds and other wildlife. Do not apply this product directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark.

DIRECTIONS FOR USE

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

READ THIS LABEL! Read this entire label and follow all use directions and use precautions. Use only for the sites, pests, and application methods described on this label.

IMPORTANT: Do not expose children, pets, or nontarget animals to rodenticides. To help prevent accidents:

1. Store product not in use out of reach of children and pets.

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MASTER LABEL – PLACEPACK BACK PANEL (Page 2 of 3)
[House Mouse Control Only – 0.75 oz. Placepacks Sold Separately]

2. Apply bait in locations out of reach of children, pets, domestic animals and nontarget wildlife, or in tamper-resistant bait stations. These stations must be resistant to destruction by dogs and by children under six (6) years of age, and must be used in a manner that prevents such children from reaching into bait compartments and obtaining bait. If bait can be shaken from bait stations when they are lifted, units must be secured or otherwise immobilized. Even stronger bait stations are needed in areas open to hooved livestock, raccoons, bears or other potentially destructive animals, or in areas prone to vandalism.
3. Dispose of product container and unused, spoiled or unconsumed bait as specified on this label.

USE RESTRICTIONS: This product may only be used to control house mice in and around homes, and in industrial, commercial, and public buildings. This product may also be used in transport vehicles (ships, trains, aircraft) and in and around related port or terminal buildings. This product may be used in alleys. Do not use in sewers.

Do not place bait in areas where there is a possibility of contaminating food or surfaces that come in direct contact with food. Do not broadcast bait. Wear water-proof gloves if you handle bait or dead animals.

SELECTION OF TREATMENT AREAS: Determine where mice will most likely find an opening and consume the bait. Generally, these areas are along walls, by gnawed openings or rub marks, in or beside burrows, in corners and concealed places, between floors and walls, or in locations where signs of rodents have been seen. Protect bait from rain or snow. Remove as much alternative food as possible.

BAITING:

House Mice: Use 1 [place pack][bait pack][bait bag] per typical placement. Place single [place pack][bait pack][bait bag] at point of highest activity. If more [place packs][bait packs][bait bags] are purchased, space placements at intervals of 8 to 12 feet in appropriate locations in infested areas. Up to 2 [place packs][bait packs][bait bags] may be placed at points of extremely high house mouse activity.

Baiting Strategy (Mice): Highest bait consumption is expected to occur on the first day or two after treatment begins. After several days, inspect the placement and replenish bait at sites where there is evidence of heavy feeding or where there is continued evidence of rodent activity. Normally, the volume of bait consumed will be significantly less with bromethalin baits than with anticoagulant baits. Although one night's feeding will usually provide a lethal dose, maintain bait for at least one week to provide all rodents a chance to feed on the bait. Continue baiting until all signs of feeding have ceased.

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MASTER LABEL – PLACEPACK BACK PANEL (Page 3 of 3)
[House Mouse Control Only – 0.75 oz. Placepacks Sold Separately]

Follow-Up: Replace contaminated or spoiled bait immediately. Using water-proof gloves, collect and properly dispose of all dead animals and leftover bait. To discourage reinfestation, limit sources of rodent food, water and harborage and rodent-proof structures as much as possible. If reinfestation does occur, repeat treatment. When a continuous source of infestation is present, establish permanent bait stations and replenish bait as needed.

STORAGE AND DISPOSAL: [Household Labels]

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

STORAGE: Store in original container in a cool, dry place inaccessible to children and pets.

DISPOSAL: If empty: Do not reuse this container. Place in trash or offer for recycling if available.

Partly Filled Containers and Spoiled and Unconsumed Bait: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

STORAGE AND DISPOSAL: [Non-Household Labels]

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

STORAGE: Store only in original container in a cool, dry place inaccessible to children, and pets. Keep containers closed and away from other chemicals.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product, and spoiled and unconsumed bait, may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Dispose of empty container in a sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Note: Seller warrants that this product complies with the specifications expressed in this label. To the extent consistent with applicable law, Seller makes no other warranties, and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and fitness for the intended purpose. To the extent consistent with applicable law, Seller’s liability or default, breach or failure under this label shall be limited to the amount of the purchase price. To the extent consistent with applicable law, Seller shall have no liability for consequential damages.

Manufactured For:
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69 N. Locust St
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For Information Call: 1-800-800-1819

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MASTER LABEL – OPTIONAL CLAIMS (Page 1 of 1)

[House Mouse Control Only – 0.75 oz. Placepacks Sold Separately]

[Additional - Optional Marketing/Advertising Claims]

- Mouse Poison Pack
- Palatable bait formulation
- Palatable formulation
- Contains Bromethalin
- 0.01% Bromethalin pellets
- Formulated for house mice control
- Demonstrated control of house mice
- [Controls][Kills] house mice
- [Controls][Kills] anticoagulant resistant mice
- [Kills][Controls] mice in and around the home
- [Kills][Controls] mice both inside and outside the home
- Can be used Indoors or Outdoors for control of Mice
- For Indoor and Outdoor Mouse Control
- For indoor and outdoor use.
- Ready to use