

85493-2

05-03-2011

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAY 03 2011

Ann M. Tillman
Agent for Repellex USA, Inc.
Pyxis Regulatory Consulting, Inc.
4110 136th St. NW
Gig Harbor, WA 98332

Subject: Repellex Systemic Tablet, EPA Reg. No: 85493-2
Application for Label Amendment via Notification dated April 4, 2011

Dear Ms. Tillman:

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under PRN 98-10 dated above. A preliminary screen of this request has been conducted for its applicability under PRN 98-10 and it has been determined that the action(s) requested falls within the scope of PRN 98-10. Our records have been duly noted, and the label submitted with this application has been stamped "Notification, received and reviewed" and will be placed accordingly in our records.

Questions concerning this action should be directed to John Fournier at (703) 308-0169 or email at fournier.john@epa.gov.

Sincerely,

Linda Hollis

Linda Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division (7511P)

CONCURRENCES

SYMBOL	▶ 7511P						
SURNAME	▶ Fournier						
DATE	▶ 3 May 11						

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Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060, Approval expires 2-28-95



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 85493-2	2. EPA Product Manager L. Hollis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Repellex USA, Inc./85493-2	PM# 91	
5. Name and Address of Applicant (Include ZIP Code) Repellex USA, Inc. c/o Pyxis Regulatory Consulting, Inc. 4140 136th St. NW Gig Harbor, WA 98332 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of label notification per PRN 98-10 to add graphics which present the same use directions already approved by EPA in narrative form. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Ann M. Tillman	Title Agent	Telephone No. (Include Area Code) 253-853-7369
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Agent	
4. Typed Name Ann M. Tillman	5. Date 4/4/2011	

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Master Label
Sub-label #1 Commercial Use and Sub-Label #2 Residential Use

REPELLEX® SYSTEMIC TABLET

Repels Deer, Rabbits, Voles, Moles, Gophers, Groundhogs, Feral Hogs, Dogs and Cats
 from Ornamental Plants

ACTIVE INGREDIENT:

Capsaicin and Related Capsaicinoids 0.3%

OTHER INGREDIENTS: 99.7%

TOTAL: 100.0%

Contains 0.213 grams of active ingredient per tablet

KEEP OUT OF REACH OF CHILDREN
CAUTION

FIRST AID	
IN THE CASE OF ACCIDENTAL...	IMMEDIATELY...
Inhalation	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.
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 the National Pesticide Information Center at 1-800-858-7378 for emergency medical treatment information.	
NOTE TO PHYSICIAN	
No specific antidote is available. Treat the patient symptomatically.	

See back panel of label for additional PRECAUTIONARY STATEMENTS.

NOTIFICATION

EPA Reg. No. 85493-2

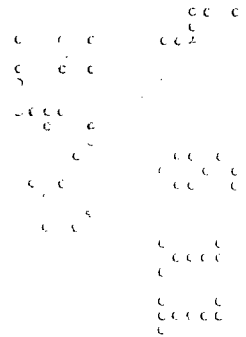
EPA Est. No. 85493-MI-001

Manufactured By:
 Repellex USA, Inc.
 PO Box 396
 Niles, MI 49120

Date Reviewed: MAY 03 2011

Reviewed By: John Fournier, BPPD

NET WEIGHT:
 Batch Code/Lot Number: _____



Sub-label #1 Commercial Use

**[Optional text:
Systemic Repellent
Protects Ornamentals
Last Up to One Year
Rainproof**

This product is a systemic animal repellent. Its exclusive formula protects ornamental plants, flowers, trees, and shrubs all season long with a single application.

One Easy Application

Easy-to-Use

Absorbs into Plant Roots

New! Exclusive Technology

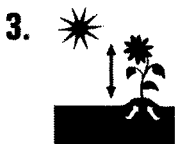
Repels Deer, Rabbits, Moles, Voles, Gphers, Groundhogs, Feral Hogs, Dogs & Cats from Ornamental Plants

No Mixing

No Spraying

The easy-to-use tablets are pre-measured and require no mixing or spraying. Just place tablets into the soil, water in and walk away.

How it Works



Last all season]

REPELLEX® SYSTEMIC TABLET

**Repels Deer, Rabbits, Voles, Moles, Gophers, Groundhogs, Feral Hogs, Dogs and Cats
from Ornamental Plants
For Commercial Use**

ACTIVE INGREDIENT:

Capsaicin and Related Capsaicinoids.....0.3%

OTHER INGREDIENTS:99.7%

TOTAL:100.0%

Contains 0.213 grams of active ingredient per tablet

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KEEP OUT OF REACH OF CHILDREN CAUTION

FIRST AID	
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Inhalation	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.
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NOTE TO PHYSICIAN	
No specific antidote is available. Treat the patient symptomatically.	

See back panel of label for additional PRECAUTIONARY STATEMENTS.

EPA Reg. No. 85493-2

EPA Est. No. 85493-MI-001

Manufactured By:

Repellex USA, Inc.
PO Box 396
Niles, MI 49120

NET WEIGHT:

Batch Code/Lot Number: _____

PRECAUTIONARY STATEMENTS 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.

ENVIRONMENTAL HAZARDS

This product may be toxic to aquatic organisms. For terrestrial uses: Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not apply to or allow runoff to reach lakes, streams or ponds. Do not contaminate water when disposing of equipment washwaters or rinsate. Tablets exposed on the soil surface may be hazardous to fish and aquatic invertebrates. Cover or collect tablets spilled during loading.

DIRECTIONS FOR USE

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

This product is a systemic animal repellent. Its exclusive formula protects ornamental plants, flowers, trees, and shrubs all season long with a single application. The easy-to-use tablets are pre-measured and require no mixing or spraying. Just place tablets into the soil, water in, and walk away! Growing beautiful, strong plants has never been easier.

How it Works: Water dissolves this product in soil, where it is absorbed by roots and moves up through the plant. Once absorbed, rain or watering cannot wash off this internal protection. Even new growth is

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protected against animal browsing for the entire growing season. For complete results, the repellent must distribute throughout the plant. Depending on the size and health of the plant, this may take one week to one month (for very large plants). To protect plants during uptake, treat with a foliar spray such as Repellex® Deer & Rabbit Repellent.

RESTRICTIONS

- NOT INTENDED FOR USE ON FOOD OR FEED CROPS.
- AVOID CONTACT OF PESTICIDE WITH ROOTS, FOLIAGE, STEMS, AND FRUIT OF ALL CROPS INTENDED FOR CONSUMPTION BECAUSE UNPLEASANT TASTE WILL RESULT.

APPLICATION RATES

When to Use: Apply when planting. For established plants, use any time after new growth appears. Do not apply when plant is dormant or when soil is waterlogged or frozen. These conditions inhibit uptake into the plant. Apply once every growing season.

Note: Application to plants heavily browsed may not prevent their eventual loss due to existing damage and stress. For best results, use this product as part of a regular maintenance program before problems start.

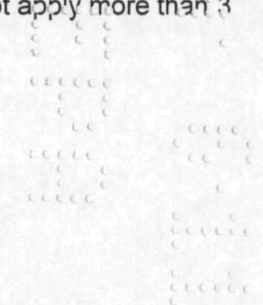
Where to Use: Use on ornamental plants, flowers, trees, and shrubs to deter animals (deer, rabbits, voles, moles, gophers, groundhogs, feral hogs, dogs and cats) from feeding on all parts of plants. Does not protect against birds or insects.

How to Apply: Place tablets in soil or growing medium of plant. Position 2-3 inches away from root crown, and push 1-3 inches below the soil surface. When more than one tablet is applied at once, evenly space them around the plant. Activate the application with irrigation or natural rainfall. Do not over water. For containerized plants, use enough water to wet the potting soil thoroughly without causing water to flush out from the bottom of the container.

How Much to Apply: Measure the height and width of the plant to the nearest foot (12"). Apply 1 tablet per every foot of plant height and width (height + width). For large tree forms, measure the crown only, not including the height of the trunk. Apply once every growing season.

		Plant Width (ft)					
		1ft	2ft	3ft	4ft	5ft	6ft
Plant Height (ft)	1ft	2	3	4	5	6	7
	2ft	3	4	5	6	7	8
	3ft	4	5	6	7	8	9
	4ft	5	6	7	8	9	10
	5ft	6	7	8	9	10	11
	6ft	7	8	9	10	11	12

Note: If plant is very fast-growing, more than doubling in size during a single growing season, additional applications may be required. Repeat application after plant doubles in size. Do not apply more than 3 times per year.



STORAGE AND DISPOSAL

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

Pesticide Storage: Keep container closed to prevent spills and contamination. Keep away from excess heat and open flames.

Container Disposal: Nonrefillable Container (flexible-bag-all weights in outer box): Liner bag: Nonrefillable container. Do not reuse or refill this container. Completely empty liner 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 liner in a sanitary landfill."

Container Disposal – Outer Box: Nonrefillable container. Do not reuse or refill this container. When completely empty offer for recycling if available or dispose of box in a sanitary landfill. **Nonrefillable Container (rigid-fifty lbs or less):** Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. 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. If recycling is not available, puncture or dispose of in a sanitary landfill or incineration or if allowed by state and local authorities, by burning. If burned stay out of smoke.

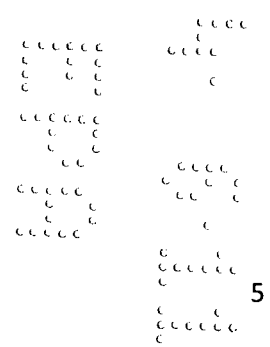
WARRANTY STATEMENT

Terms of sale or use: Buyer assumes all risks of use, storage or handling of this product not in accordance with directions. REPELLEX® makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Except as so warranted, the product is sold as is.

To the fullest extent permitted by State Law: The manufacturer shall not be liable for the buyer's and user's use and/or handling and or storage for this material, when such use and/or handling and/or storage is contrary to labeling directions. Follow directions carefully. Timing and method of application, weather and crop conditions, mixture with other chemicals not specifically recommended and other influencing factors in the use of this product are beyond the control of the seller and are assumed by the buyer and user at their own risk.

REPELLEX®'s directions for the use of this product are based upon tests believed to be reliable. The use of this product being beyond the control of the manufacturer, no guarantee, expressed or implied, is made as to the effects of such or the results to be obtained if not used in accordance with label directions or established safe practice.

Damages: Buyers or users exclusive remedy for damages for breach of warrantee or negligence shall be limited to direct damages not exceeding the purchase price paid and shall not include incidental or consequential damages.



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**Master Label
Sub-label #2 Residential Use**

**[Optional text:
Systemic Repellent
Protects Ornamentals
Last Up to One Year
Rainproof**

This product is a systemic animal repellent. Its exclusive formula protects ornamental plants, flowers, trees, and shrubs all season long with a single application.

One Easy Application

Easy-to-Use

Absorbs into Plant Roots

New! Exclusive Technology

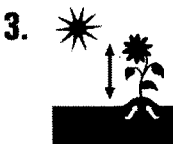
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How it Works



Last all season]

REPELLEX® SYSTEMIC TABLET

**Repels Deer, Rabbits, Voles, Moles, Gophers, Groundhogs, Feral Hogs, Dogs and Cats
from Ornamental Plants
For Residential Use**

ACTIVE INGREDIENT:

Capsaicin and Related Capsaicinoids 0.3%

OTHER INGREDIENTS: 99.7%

TOTAL: 100.0%

Contains 0.213 grams of active ingredient per tablet

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KEEP OUT OF REACH OF CHILDREN CAUTION

FIRST AID	
IN THE CASE OF ACCIDENTAL...	IMMEDIATELY...
Inhalation	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.
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 the National Pesticide Information Center at 1-800-858-7378 for emergency medical treatment information.	
NOTE TO PHYSICIAN	
No specific antidote is available. Treat the patient symptomatically.	

See back panel of label for additional PRECAUTIONARY STATEMENTS.

EPA Reg. No. 85493-2

EPA Est. No. 85493-MI-001

Manufactured By:
Repellex USA, Inc.
PO Box 396
Niles, MI 49120

NET WEIGHT:
Batch Code/Lot Number: _____

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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.

ENVIRONMENTAL HAZARDS

This product may be toxic to aquatic organisms. To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Tablets exposed on the soil surface may be hazardous to fish and aquatic invertebrates. Cover or collect tablets spilled during application.

DIRECTIONS FOR USE

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

This product is a systemic animal repellent. Its exclusive formula protects ornamental plants, flowers, trees, and shrubs all season long with a single application. The easy-to-use tablets are pre-measured and require no mixing or spraying. Just place tablets into the soil, water in, and walk away! Growing beautiful, strong plants has never been easier.

How it Works: Water dissolves this product in soil, where it is absorbed by roots and moves up through the plant. Once absorbed, rain or watering cannot wash off this internal protection. Even new growth is protected against animal browsing for the entire growing season. For complete results, the repellent must distribute throughout the plant. Depending on the size and health of the plant, this may take one week to one month (for very large plants). To protect plants during uptake, treat with a foliar spray such as Repellex® Deer & Rabbit Repellent.

RESTRICTIONS

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- AVOID CONTACT OF PESTICIDE WITH ROOTS, FOLIAGE, STEMS, AND FRUIT OF ALL CROPS INTENDED FOR CONSUMPTION BECAUSE UNPLEASANT TASTE WILL RESULT.

APPLICATION RATES

When to Use: Apply when planting. For established plants, use any time after new growth appears. Do not apply when plant is dormant or when soil is waterlogged or frozen. These conditions inhibit uptake into the plant. Apply once every growing season.

Note: Application to plants heavily browsed may not prevent their eventual loss due to existing damage and stress. For best results, use this product as part of a regular maintenance program before problems start.

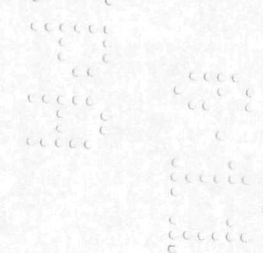
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	4ft	5	6	7	8	9	10
	5ft	6	7	8	9	10	11
	6ft	7	8	9	10	11	12

Note: If plant is very fast-growing, more than doubling in size during a single growing season, additional applications may be required. Repeat application after plant doubles in size. Do not apply more than 5 times per year.



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STORAGE AND DISPOSAL

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

Pesticide Storage: Store in original container in a cool, dry place, out of reach of children, preferably in a locked storage cabinet. Keep container closed to prevent spills and contamination. Keep away from excess heat and open flames.

Pesticide Disposal and Container Handling: Nonrefillable container. Do not reuse or refill this container. If empty, place in trash or offer for recycling, if available. If partly filled, call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

WARRANTY STATEMENT

Terms of sale or use: Buyer assumes all risks of use, storage or handling of this product not in accordance with directions. REPELLEX® makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Except as so warranted, the product is sold as is.

To the fullest extent permitted by State Law: The manufacturer shall not be liable for the buyer's and user's use and/or handling and or storage for this material, when such use and/or handling and/or storage is contrary to labeling directions. Follow directions carefully. Timing and method of application, weather and crop conditions, mixture with other chemicals not specifically recommended and other influencing factors in the use of this product are beyond the control of the seller and are assumed by the buyer and user at their own risk.

REPELLEX®'s directions for the use of this product are based upon tests believed to be reliable. The use of this product being beyond the control of the manufacturer, no guarantee, expressed or implied, is made as to the effects of such or the results to be obtained if not used in accordance with label directions or established safe practice.

Damages: Buyers or users exclusive remedy for damages for breach of warrantee or negligence shall be limited to direct damages not exceeding the purchase price paid and shall not include incidental or consequential damages.