100-1205

6/5/2006

Page 17 18

Date of Issuance:



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (H7505C)
1200 Pennsylvania Avenue N W

1200 Pennsylvania Avenue, N.W. Washington, D.C. 20460

NOTICE	OF	PESTIC	DE:

X Registration
Reregistration

100-1205	JUN	ე	2006
Term of Issuance: Conditional	<u> </u>		
Name of Pesticide Produc Prevel D	t:		

EPA Reg. Number:

(Under FIFRA as amended)

Name and Address of Registrant (include ZIP Code):

Syngenta Corp Protection, Inc.

P.O. Box 18300

Greensboro, NC 27419

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is <u>conditionally</u> registered in accordance with FIFRA sec. 3(c)(7)(A), since you agreed in your letter dated October 27, 2004 that:

- 1. You will submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.
- 2. You will make the following label changes before you release the product for shipment:
 - a) Revise the EPA Registration Number to read "EPA Reg. No. 100-1205"."
 - b) As this product has not been assessed for exposure to residential applicators and is intended only for use by commercial/professional applicators, the size of the package in which this product is to be sold is limited to containers in sizes of 5 gallons and greater. In addition this product is only to be marketed through distribution and sales channels which supply commercial and professional cleaning and remediation businesses. This product is not to marketed through retail consumer outlets such as Big Box Stores, grocery stores, home improvement outlets such as Lowe's and Home Depot as well as consumer internet outlets.. If you wish to change the container sizes used for this product, such changes must be done via amendment as an additional risk assessment for residential users may be warranted.

Wander ADV Juct Manager (13), RD/IB (75050	$\begin{array}{c c} Date \\ O \\ U \end{array}$	ne 5, 2006

- c) Add the statements "For Use By Commercial/Professional Applicators Only" and "Not for application by homeowners" immediately following the signal word "CAUTION" on page 1, 6 and 13.
- d) On pages 1 and 13, replace "Prevel Carpet Spray is a broad-spectrum treatment, which effectively controls and/or inhibits aids in the control of/or inhibits dust mites, mold and mildews in carpets and rugs" with "Prevel Carpet Spray is a broad-spectrum treatment, which aids in the control of dust mites and inhibits mold and mildews in carpets and rugs". The submitted laboratory assay demonstrated the potential for the product to aid in the control of dust mites but field testing data is required to support claims greater than "aids". Likewise there was no information or directions demonstrating the product controls mold/mildews already present. Therefore only preventative claims are permitted. Refer to the enclosed efficacy review for more information in this regard.
- e) On page 8 the product refers to the use of a Prevel Precision Applicator, yet there is information as to the rate at which the product is being used with this applicator. We do not know how much water is mixed with the product. Either submit complete information for the label or delete the use of the applicator. Note that the application rate must not exceed 227 ppm azoxystrobin. This is the maximum rate used in the occupational/residential exposure assessment conducted by Antimicrobial Division for EPA Reg. No. 100-1197.
- f) On page 9, there is a rate chart for applications not using a Prevel Precision Applicator. This chart indicates that the azoxystrobin in this product is being used at a much higher rate than was previously approved for Reg. No. 100-1197. We previously approved and conducted a risk assessment on 100-1197 at 229 ppm. It is proposed that this product be used at 1875 ppm. The risk assessment will not support this higher rate. Therefore revise the rate in the chart to be consistent with the risk assessment or delete this equipment from the label.
- g) Delete the following claims: "molds can trigger asthma and allergy episodes", "...mold may produce allergens" and "Allergens can trigger asthma and allergic reactions" throughout the labeling. Medical claims are not acceptable.
- h) Delete "Optional" on page 6 in direction 4 referring to the use of the bonnet method in homes. This is not an option.
- i) Revise page 8 and 10 by correcting the section beginning: "Dry carpets within 24 hours to prevent conditions ..." to read: "... or other methods of ventilation should be used..."

- j) On page 11, move "In case of spill on floor or paved surfaces, mop and remove to chemical waste storage area until proper disposal can be made if product cannot be used according to the label." From the Pesticide Storage section to the Pesticide Disposal section.
- k) Add storage and disposal language to the non-detachable container label.
- 1) On page 11, either delete or revise Optional Proposed test as follows:
 - a. Either delete "Effective against house dust mites", "Kills dust mites" or change to, "Aids in control of house dust mites".
 - b. Delete, "Stops (new) (pre-adult) (hatching) dust mites from developing", "Effectively breaks dust mites like cycle", "Kill dust mites on contact", "Inhibits mold germination, growth and sporulation". There was no data submitted in support of these claims.
- m) Based on the acute toxicity studies submitted, you may delete "Harmful if absorbed through the skin or inhaled" and "Avoid contact with skin" and "If inhaled" first aid statements. Also under Precautionary Statements move the statements beginning, "Do not allow people (other than applicator ... etc" and "People and pets may enter" to the Directions for Use section of the label.
- n) Revise the first sentence under General Information on page 6 to read, "Prevel aids in the control of dust mites and inhibits molds and mildews that contribute to Etc".
- o) Delete "It is Syngenta's and seller's intention that in no event shall syngenta or seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product." From the Warranty statement. This statement is overly broad and implies buyer has no legal right to recover damages from manufacturer and is unacceptable under statutory and regulatory standards. We recommend revising it to read "It is Syngentas's and Seller's intention that to the extent allowable under State law,.... etc."
- 3. You must agree to submit or cite corroborative product performance data that are obtained from field studies within 12 months of the Notice of Registration. If new studies are to be submitted, the Agency encourages the submission of protocols for review prior to study initiation. Note that the rates of application used in the study must not exceed the maximum rate approved for risk assessment purpose. See comment f above.
- 4. Please submit an one year storage stability study for the proposed product along with a corrosion characteristics study. We recommend that observation be made at 0, 3, 6, 9 and 12 months intervals in the storage stability study.

4 8 18

If you have any questions regarding this action, please contact BeWanda Alexander of my team at (703) 305-7460.

Prevel™ D

Dust Mite and Mold Carpet and Rug Spray

Prevel Carpet Spray is a broad-spectrum treatment, which effectively controls and/or inhibits dust mites, molds and mildews in carpets and rugs.

Molds and mildews can be associated with carpet and rug odor, staining and discoloration. Mites and molds can trigger asthma and allergy episodes. This product is not intended to protect users or others against bacteria, including food-borne or disease-causing bacteria. This product is not for use in food/feed handling areas.

Active Ingredients:

Active ingredients.	
Azoxystrobin ¹	4.0%
Permethrin ²	4.0%
Other Ingredients:	92.0%
Total:	100.0%

¹CAS No. 131860-33-8 ²CAS No. 52645-53-1

Contains 0.7 lbs. of active ingredient per gallon.

KEEP OUT OF REACH OF CHILDREN.

CAUTION

See additional precautionary statements and directions for use in booklet.

EPA Reg. No. 100-XXXX

EPA Est. XXXX

Product of XXXXX

Formulated in the USA

SCP XXXXM(Prevel D draft b)

Net Contents

ACCEPTED
with COMMENTS
In EPA Letter Dated
JUN 5 2006

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

	FIRST AID	
If in eyes	 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.	
If swallowed	Call poison control center or doctor 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	Take off contaminated clothing.	
clothing	Rinse skin immediately with plenty of water for 15-20 minutes.	
	Call a poison control center or doctor for treatment advice.	
If inhaled	Move person to fresh air.	
	If person is not breathing, call 911 or an ambulance, then give	
artificial respiration, preferably mouth-to-mouth if possible.		
	Call a poison control center or doctor for further treatment advice.	
Have the produ	ct container or label with you when calling a poison control center or	
doctor, or going	for treatment.	
•	HOTLINE NUMBER	
For	24-Hour Medical Emergency Assistance (Human or Animal)	
or Chemical Emergency Assistance (Spill, Leak, Fire, or Accident)		
	Call	
	1-800-888-8372	

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION

Causes moderate eye irritation. Harmful if swallowed, absorbed through the skin or inhaled. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

Do not allow people (other than the applicator) or pets on treatment area during application.

People and pets may enter treated area after carpet has dried.

7 7 18

Environmental Hazards

This product is toxic to fish and aquatic invertebrates. Do not apply directly to water. Do not contaminate water (i.e. lakes, streams and other natural bodies of water) when disposing of equipment washwater.

8 7 18

Environmental Hazards

This product is toxic to fish and aquatic invertebrates. Drift may adversely affect aquatic invertebrates and fish. Cover fish tanks if broadcast sprayer is used. Do not apply directly to water. Do not contaminate water (i.e. lakes, streams and other natural bodies of water) when disposing of equipment washwater.

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

SYNGENTA warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, when used in accordance with directions under normal use conditions. This warranty does not extend to the use of this product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or SYNGENTA, and Buyer and User assume the risk of any such use. SYNGENTA MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

IT IS SYNGENTA'S AND SELLER'S INTENTION THAT in no event shall SYNGENTA or Seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product. THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SYNGENTA AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF SYNGENTA OR SELLER, THE REPLACEMENT OF THE PRODUCT.

SYNGENTA and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of SYNGENTA.

DIRECTIONS FOR USE

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

GENERAL INFORMATION

Prevel controls and/or inhibits dust mites and controls and/or inhibits molds and mildews that contribute to odor, staining and discoloration to carpet and rugs. It provides an invisible barrier to control dust mites and inhibit the fungal organisms associated with mold and mildew. Dust mites and molds can produce allergens, which may trigger asthma or allergy episodes.

This product is intended for commercial service providers only. This product is not intended for application by homeowners.

For commercial use by professional service providers in homes, offices, automobiles and institutions such as schools, public buildings, daycare centers, hospitals, churches, motels, and correctional facilities.

Do not use this product for reformulation.

Remediation of moldy carpet is not recommended, moldy carpet and padding should be removed and discarded.

Prior to application of Prevel

- Thoroughly vacuum carpets or rugs.
- 2. Vacuum cleaner bag or contents should be discarded in an outdoor trash container prior to spray treatment.
- 3. Clean carpet or rug using either hot-water extraction (steam) or bonnet cleaning to remove existing loose dirt.
- 4. (Optional) Note: Bonnet method should not be used in residences.
- 5. Spot test an inconspicuous area with the prepared spray solution to ensure dyes will not bleed or that staining will not occur. Apply diluted product and then rub with a clean, white cloth. If color transfers to the cloth or the color on the carpet changes, this product should not be used.

GENERAL PRECAUTIONS AND RESTRICTIONS

Recommended for use on washable synthetic fibers, but not recommended for use on wool carpets or wool rugs.

-7-{Label language for all Prevel D labels}

Apply Prevel *prior* to any additional after-care products (i.e. stain protectors, fire retardants, deodorizing agents, etc.).

Carpet pile can be groomed or set with a carpet pilator, rake or stiff brush after application is made.

Do not allow people (other than applicator) or pets in treatment area during application.

People and pets may enter treated area after carpet has dried.

Do not apply to classrooms when in use.

Do not apply when occupants are present in the immediate area in institutions such as libraries, sport facilities, etc.

Do not use product with fogging equipment.

Apply at least once per year to prevent recurrence of dust mites, and/or molds and mildews. Do not apply product more than 2 times per year.

NOT for use in areas where food/feed items are present.

APPLICATION PROCEDURES FOR APPLICATIONS USING A PREVEL PRECISION APPLICATOR (PPA)

DIRECTIONS FOR BROADCAST APPLICATION

Remove cap on container. Insert container into machine port, as indicated on equipment. Container will quick connect to application device. Fill water port with clean tap water. Open Prevel flow control valve. Product will be mixed within the machine immediately prior to application.

Adjust machine for correct pile depth. Position the PPA machine in the area to be treated and pull the trigger to begin application. PPA is self-propelled and designed to deliver 1 gal. of solution per 800 sq. ft. Release the trigger to halt forward motion and to stop spraying. After desired area has been treated, flush machine with clean water by turning off the product flow control valve and squeezing trigger to run fresh water through applicator. Clean-out should be conducted at edge of wall or on a spare piece of carpet. Remove Prevel container from machine and close cap prior to storing unused product.

DO NOT REFILL CONTAINER.

IMPORTANT: Rinse machine after use to ensure proper maintenance. Do not leave mixed product in lines; flush any mixed product from system.

A fan may be used to assist in drying carpets and rugs.

Dry carpets within 24 hours. To assist the drying process after cleaning and application of this product, use of fans, dehumidifiers, heaters or other methods of ventilation may be used.

APPLICATION PROCEDURES FOR APPLICATIONS NOT USING A PREVEL PRECISION APPLICATOR (PPA)

Calibration

Before mixing Prevel and filling any equipment tank, calibrate equipment using plain water to ensure a flow rate of 1 gal. of Prevel solution per 800 sq. ft. area of rugs and/or carpets.

Mixing and Spraying

Preparation of spray solution: Prepare a solution by adding the required amount of Prevel to ½ the final volume of water in the spray tank, mix thoroughly, and add the remaining ½ volume of water to the container. Prepare no more mixture than is necessary for the immediate use. Refer to **Spray Preparation Table**.

Spray Preparation Table			
Desired amount of Solution	Prevei (fl. oz.)	Water (fl. oz.)	Treatment Area (ft. ²)
1 qt.	1.5	31.0	200 ft. ²
2 qt. (1/2 gal.)	3.0	61.0	400 ft. ²
3 qt.	4.5	92.0	600 ft. ²
1 gal.	6.0	122.0	800 ft. ²
1 ¼ gal.	7.5	153.0	1000 ft. ²
1 ½ gal.	9.0	183.0	1200 ft. ²
1 ¾ gal.	10.5	214.0	1400 ft. ²
2 gal.	12.0	244.0	1600 ft. ²
2 1/4 gal.	13.5	275.0	1800 ft. ²
2 ½ gal.	15.0	305.0	2000 ft. ²

Broadcast treatment using commercial carpet-cleaning equipment (e.g., carpet steamers, rotary jet extraction cleaners, pressure sprayers)

After mixing in tank, evenly apply Prevel over the treatment area at a rate of 1 gal. solution per 800 sq. ft. area.

Do not apply more than 1 gal. of Prevel spray solution per 800 sq. ft. Do not soak, or allow dripping or run-off to occur. If it does occur, blot dry with disposable cloth or sponge and discard as directed in **Disposal** section of label.

Note: It is important to obtain uniform coverage. Uneven applications may result in unacceptable performance.

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-10-

{Label language for Non-Prevel Precision Applicator (PPA) labels}

Use all of Prevel mixture within 2 hours of preparation. Flush out spray equipment with water to prevent clogging. Application equipment must be cleaned within 2 hours of treatment's completion.

Dry carpets within 24 hours. To assist the drying process after cleaning and application of this product, use of fans, dehumidifiers, heaters or other methods of ventilation may be used.

STORAGE AND DISPOSAL

Prohibitions

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

Pesticide Storage

Store upright in original containers only in a cool, dry place. Do not store product below 32° F. Store in a secure area inaccessible to children and pets and away from food or feed.

In case of spill on floor or hard surfaces, soak up with sand, earth, synthetic adsorbent, or disposable towel. In case of spill on carpet, blot up spill with disposal towel. Dispose of on site or at an approved waste disposal facility.

Pesticide Disposal

Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

Never place unused product down any indoor or outdoor drain.

Plastic Container Disposal

Do not reuse container. Puncture and dispose of in a sanitary landfill, or by other procedures allowed by state and local authorities.

CONTAINER IS NOT SAFE FOR FOOD, FEED, OR DRINKING WATER.

Optional Proposed Text (Note: The final production label may include some or all of the optional proposed text.)

- · Allow carpet and rugs to dry before re-entry or use
- Leaves no residue to promote resoiling. Does not affect stain resistance properties of carpet.
- · Effective against house dust mites
- Unique combination of ingredients

-12-{Label language for all Prevel D labels}

- Kills dust mites
- Stops {new} {pre-adult} {hatching} dust mites from developing
- · Effectively breaks dust mites life cycle
- Kills dust mites on contact
- Inhibits mold germination, growth and sporulation
- No lingering odor, no stains, no sticky mess
- Dust mites and molds may produce allergens
- Allergens can trigger asthma and allergic reactions.
- Safe to pets (fish-tanks should be covered prior to applications).

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For non-emergency (e.g. current product information) call Syngenta Crop Protection at 1-800-334-9481.

Syngenta Crop Protection, Inc. Greensboro, North Carolina 27409 www.syngenta-us.com

SCP XXXXM(Prevel D draft b)

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{Label language for all Prevel D labels}

(Non-detachable Container Label)

Prevel™ D

Dust Mite and Mold Carpet and Rug Spray

Prevel Carpet Spray is a broad-spectrum treatment, which effectively controls and/or inhibits dust mites, molds and mildews in carpets and rugs.

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Active Ingredients: Azoxystrobin ¹	4.0%
Permethrin ²	4.0%
Other Ingredients:	92.0%
Total:	100.0%

¹CAS No. 131860-33-8 ²CAS No. 52645-53-1

Contains 0.7 lbs. of active ingredient per gallon.

KEEP OUT OF REACH OF CHILDREN.

CAUTION

See additional precautionary statements and directions for use in booklet.

EPA Reg. No. 100-XXXX

EPA Est. XXXX

SCP XXXXM(Prevel D draft b)

Net Contents

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION

Causes moderate eye irritation. Harmful if swallowed, absorbed through the skin or inhaled. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

Refer to FIRST AID, Environmental Hazards, Physical and Chemical Hazards, Storage and Disposal sections in booklet.

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Syngenta Crop Protection, Inc. Greensboro, North Carolina 27409 www.syngenta-us.com

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