



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

April 3, 2009

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Doina Bujor, Regulatory Manager
Valent BioSciences Corporation
870 Technology Way
Libertyville, IL 60048

RE: Product Name: VECTOBAC AS
EPA Reg. No: 73049-11
Application for Label Notification Dated February 4, 2009 to Update Storage and
Disposal Language per PR Notice 2007-4

Dear Ms. Bujor:

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under Pesticide Registration Notice (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 Ms. Diana Hudson at (703) 308-8713 or email at hudson.diana@epa.gov.

Sincerely,

Sheryl K. Reilly

Sheryl K. Reilly, Ph.D., Chief
Microbial Pesticides Branch
Biopesticides and Pollution Prevention
Division (7511P)



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 73049-11	2. EPA Product Manager Sheryl Reilly	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) VectoBac AS	PM# 92	
5. Name and Address of Applicant (Include ZIP Code) Valent BioSciences Corporation 870 Technology Way Libertyville, IL 60048 <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: <input checked="" type="checkbox"/> EPA Reg. No. _____ Product Name _____	

Section - II

NOTIFICATION

<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.

Date Reviewed: 4/3/09
Reviewed By: D. Hudson

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

Notification of label per PR Notice 2007-4. This notification is consistent with the guidance in PR Notice 2007-4 and requirements of EPA's regulations at 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. (see next page)

Section - III

1. Material This Product Will Be Packaged In:

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

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name Doina Bujor	Title Regulatory Manager	Telephone No. (Include Area Code) 847-968-4724
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Certification

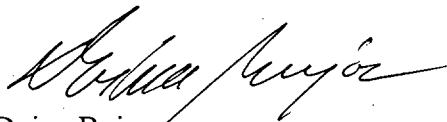
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature 	3. Title Regulatory Manager	6. Date Application Received (Stamped)
4. Typed Name Doina Bujor	5. Date Feb 4, 2009	

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Notification of Storage and Disposal Statement (PR Notice 2007-4) for VectoBac® AS,
EPA Reg. No. 73049-11 (continuation from the previous page)

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 the amended label is not consistent with the requirements of 40 CFR §§152.46, 56.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and may be subject to enforcement action and penalties under section 12 and 14 of FIFRA.



Doina Bujor
Regulatory Manager

February 4, 2009



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February 4, 2009

Sheryl Reilly
Biopesticides & Pollution Prevention Division
Document Processing Desk (NOTIF)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501
703-308-8269

RE: VectoBac® AS (EPA Reg. No. 73049-11) Notification

Dear Ms. Reilly:

Valent BioSciences Corporation is submitting the present notification for VectoBac® As (Alternate Brand Name Gnatrol™) (EPA Reg. No. 73049-11) in accordance with PR Notice 2007-4. The changes made to the label are to the Storage and Disposal statement.

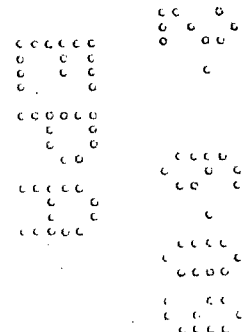
Present submission consists of:

- Application for Registration (EPA form 8570-1)
- One copy of the red-lined label
- One copy of the clean label.

Please contact me if you have any questions at 847-968-4724 or by e-mail at doina.bujor@valent.com.

Sincerely,

Doina Bujor
Regulatory Manager



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NOTIFICATION

**VECTOBAC® AS
BIOLOGICAL LARVICIDE
AQUEOUS SUSPENSION**

Date Reviewed: 4-3-09

Reviewed By: D. Hudson

Active Ingredient:

Bacillus thuringiensis, subspecies *israelensis*, strain 65-52, fermentation solids, spores,
and insecticidal toxins.....6.38%
Other Ingredients.....93.62%
Total.....100.00%

Potency: 600 International Toxic Units (ITU) per milligram (Equivalent to 2.19 billion ITU per gallon; 0.576 billion ITU per liter)

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

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

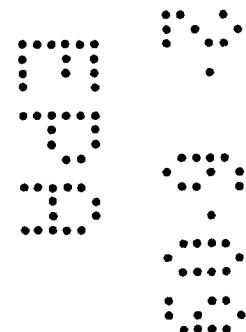
See side panel for additional precautionary statements and first aid statements.

Valent BioSciences Corporation
870 Technology Way, Suite 100
Libertyville, IL 60048

EPA Reg. No. 73049-11
EPA Establishment No. 33762-IA-1

Lot No. _____

Net Contents:



FIRST AID	
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.
If in eyes	<ul style="list-style-type: none"> • Hold eyes 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.
HOTLINE 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.	

PRECAUTIONARY STATEMENTS
HAZARD TO HUMANS (AND DOMESTIC ANIMALS)
CAUTION

Harmful if absorbed through the skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling. Remove and wash contaminated clothing before reuse.

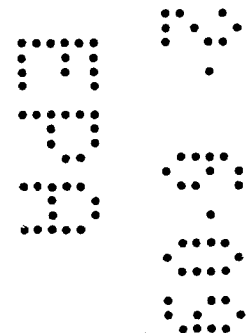
Personal Protective Equipment

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.

Mixers/loaders and applicators not in enclosed cabs or aircraft must wear a dust/mist 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.



User Safety Recommendations

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco products or using the toilet.
- 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.

ENVIRONMENTAL HAZARDS

Do not contaminate water when cleaning equipment or disposing of equipment washwaters. Do not apply directly to treated finished drinking water reservoirs or drinking water receptacles intended for human consumption.

PHYSICAL OR CHEMICAL HAZARDS

Diluted or undiluted VectoBac AS can cause corrosion if left in prolonged contact with aluminum spray system components. Rinse spray system with plenty of clean water after use. Care should be taken to prevent contact with aluminum aircraft surfaces, structural components and control systems. In case of contact, rinse with plenty of water. Inspect aluminum aircraft components regularly for signs of corrosion.

STORAGE AND DISPOSAL

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

Storage: Store in a cool [59° - 86° F (15° - 30° C)], dry place.

Pesticide Disposal: Wastes resulting from use of this product may be disposed of on site or at an approved waste disposal facility.

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 ¼ 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. Once cleaned, some agricultural plastic pesticide containers can be taken to a container collection site or picked up for recycling. If recycling is not available puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

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.

Keep unprotected person out of the treated areas until sprays have dried.

AGRICULTURAL USE SITE 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 agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

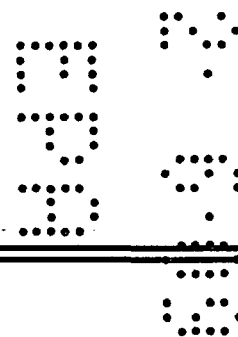
Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements 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 intervals. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

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

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.

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

- Coveralls
- Waterproof gloves
- Shoes plus socks.



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CHEMIGATION

Do not apply this product through any irrigation system unless labeling on chemigation is followed.

APPLICATION DIRECTIONS

(Fungus Gnat Control)

<u>Fungus Gnat Habitat</u>	<u>Suggested Range Rate</u>
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Ornamental and nursery plantings in greenhouse or potting soil mixtures.	Light infestation: 16-32 oz/100 gallons* applied as a soil drench
Vegetable plants such as the following: Tomatoes, leafy and cole crops, cucumbers, peppers and eggplants.	Heavy infestation: 64-128 oz/100 gallons** applied as a soil drench

* 16-32 oz/100 gallons = 1 - 2 tsp/gallon.

** 64-128 oz/100 gallons - 4 - 8 tsp/gallon.

Apply VectoBac AS with adequate water by soil drench to sufficiently wet the soil surface above and under benches where larvae are found. Areas under benches should be treated at high rates as this is one of the primary breeding areas. Reapply as needed. In situations where all life forms (eggs, larvae, pupae and adults) are present, such as with existing infestations, make three (3) weekly applications at the suggested rate range for heavy infestations. Regular follow-up applications using the suggested light infestation rates, will establish a long term maintenance program.

VectoBac AS is a larvicide and will not control adult gnats, therefore, applications must be timed for a stage of development when larvae are present in the soil.

Fungus gnat larvae generally respond to VectoBac AS treatment within 24 hours following application.

VectoBac AS is not known to be phytotoxic to ornamental plant species. However, since all ornamental plant species have not been evaluated, sensitivity to VectoBac AS should be checked on several plants prior to wide scale usage.

PRECAUTIONS

Important: VectoBac AS should not be injected in combination with fertilizers or fungicides containing copper or chlorine, as this may neutralize the active ingredients. (Chlorine levels in potable water supplies should not present a problem with VectoBac AS performance).

Do not apply soil drenches to plants under stress, or follow application with excessive amounts of water.

For best results, apply drenches toward the end of irrigation period.

(Mosquito and Blackfly Control)
Suggested Rate Range*

Mosquito Habitat

(Such as the following examples):

Irrigation ditches, roadside ditches, flood water, standing ponds, woodland pools, snow melt pools, pastures, catch basins, storm water retention areas, tidal water, salt marshes and rice fields.

VectoBac AS

0.5-2 pts/acre

Polluted water

(such as sewage lagoons, animal waste lagoons).

2 pts/acre

*Use higher range in polluted water when late 3rd and early 4th instar larvae predominate, mosquito populations are high, water is heavily polluted, and/or algae are abundant.

Suggested Rate Range

Blackflies Habitat

VectoBac AS

Streams

Stream water** (=ppm) for
1 minute exposure time.

1 - 50 mg/liter

Stream water** (=ppm) for
10 minute exposure time.

0.1 - 5 mg/liter

**Use higher rate range when stream contains high concentration of organic materials, algae, or dense aquatic vegetation.

Ground and Aerial Application

VectoBac AS may be applied in conventional ground or aerial application equipment with quantities of water sufficient to provide uniform coverage of the target area. The amount of water needed per acre will depend on the weather, spray equipment, and mosquito habitat characteristics. Do not mix more VectoBac AS than can be used in a 72-hour period.

For most ground equipment, apply in 5 - 100 gallons per acre using hand-pump, airblast, mist blower, etc., spray equipment.

For aerial application, VectoBac may be applied either undiluted or diluted with water. For undiluted applications, apply 0.5 to 2.0 pts/acre of VectoBac AS through fixed wing or helicopter aircraft equipped with either conventional boom and nozzle systems or rotary atomizers.

For diluted applications, fill the mix tank or plane hopper with the desired quantity of water. Start the mechanical or hydraulic agitation to provide moderate circulation before adding the VectoBac AS. VectoBac AS suspends readily in water and will stay suspended over normal application periods. Brief recirculation may be necessary if the spray mixture has sat for several hours or longer. **AVOID CONTINUOUS AGITATION OF THE SPRAY MIXTURE DURING SPRAYING.**

Rinse and flush spray equipment thoroughly following each use.

For blackfly aerial applications, VectoBac AS can be applied undiluted via fixed wing of helicopter aircraft equipped with either conventional nozzle systems or open pipes. Rate of application will be determined by the stream discharge and the required amount of VectoBac AS necessary to maintain a 1 - 50 ppm concentration in the stream water. VectoBac AS can also be applied diluted with similar spray equipment. Do not mix more product than can be used in a 72-hour period.

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

SMALL QUANTITY DILUTION RATES Gallons Spray Solution/Acre (Ounces needed per Gallons of Spray)

VectoBac AS Rate in Pints per Acre	10 Gal/A	25 Gal/A	50 Gal/A
0.5	.8	.33	.16
1.0	1.6	.66	.32
2.0	3.2	1.30	.64

CHEMIGATION

VectoBac AS can be applied by injection into drip or overhead (sprinkler) irrigation systems.

Apply this product only through: sprinkler including solid set; flood (basin); or drip (trickle) irrigation systems. Do not apply this product through any other type of irrigation system.

Crop injury, lack of effectiveness, or illegal pesticide residues in the crop can result from non-uniform distribution of treated water.

If you have questions about calibration, you should contact State Extension Service Specialist, equipment manufacturers or other experts.

Do not connect irrigation system used for pesticide application to a public water system unless the pesticide label-prescribed safety devices for public water systems are in place.

A person knowledgeable of the chemigation system and responsible for its operation, or under the supervision of the responsible person, shall shut the system down and make necessary adjustments should the need arise.

RICE-FLOOD (BASIN) CHEMIGATION

Systems using gravity flow pesticide dispensing systems must meter the pesticide into the water at the head of the field and downstream of a hydraulic discontinuity such as a drop structure or weir box to decrease potential for water source contamination from backflow if water flow stops.

VectoBac AS is metered or dripped into the rice floodwater at application stations positioned at the point of introduction (levee cut) of water into each rice field or pan. Two pints of VectoBac AS are diluted in water to a final volume in 5 gallons. The diluted solution is contained in a 5 gallon container and metered or dispersed into the irrigation water using a constant flow device at the rate of 80 ml per minute.

Introduction of the solution should begin when 1/3 to 1/2 of the pan or field is covered with floodwater. Delivery of the solution should continue for a period of approximately 4 1/2 hours. Floodwater depth should not exceed 10-12 inches to prevent excessive dilution of VectoBac AS which could result in reduced larval kill. Agitation is not required during the period in which the VectoBac AS solution is being dispersed.

Application of VectoBac AS into rice floodwater is not permitted using a pressurized water and pesticide injection system.

Greenhouse - Drip (Trickle) and Sprinkler Chemigation

Public water system means a system for the provision to the public of piped water for human consumption if such system has at least 15 service connections or regularly serves an average of at least 25 individuals daily at least 60 days out of the year.

Chemigation systems connected to public water systems must contain a functional reduced pressure zone, backflow preventor (RPZ) or the functional equivalent in the water supply line upstream from the point of the pesticide introduction. As an option to the RPZ, the water from the public water system should be discharged into a reservoir tank prior to pesticide introduction. There shall be a complete physical break (air gap) between the outlet end of the fill pipe and the top or overflow rim of the reservoir tank of at least twice the inside diameter of the fill pipe.

The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.

The pesticide injection pipeline must also contain functional, normally closed solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.

The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops, or in cases where there is no water pump, when the water pressure decreases to the point where pesticide distribution is adversely affected. Systems must use a water pump, such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials compatible with pesticides and capable of being fitted with a system interlock.

The system must contain a functional check valve, vacuum relief valve and low pressure drain, appropriately located on the irrigation pipeline to prevent water source contamination from backflow.

The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure to the point where pesticide distribution is adversely affected.

If VectoBac AS needs to be diluted prior to injection, material may be mixed separately and then put into the injector. Agitation may be necessary if materials are kept more than one day. VectoBac AS may be applied continuously.

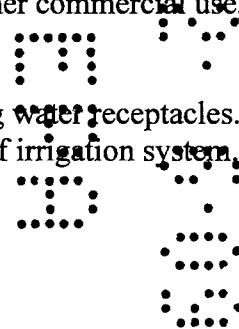
Where supply tanks are used for continuous application, fill the supply tank with the desired quantity of water. Start mechanical or hydraulic agitation to provide moderate circulation before adding VectoBac AS. VectoBac AS suspends readily in water and will stay suspended over normal application periods. Avoid continuous agitation of spray mixture during spraying. Brief recirculation may be necessary if the spray mixture has sat for several hours.

NON-AGRICULTURAL USE SITE 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 agency responsible for pesticide regulation.

For use on plants intended for aesthetic purposes and being grown in interior landscapes and indoor ornamental gardens. Not for use on plants being grown for sale or other commercial use, or for commercial seed production, or for research purposes.

Do not apply directly to treated finished drinking water reservoirs or drinking water receptacles. Do not apply this product to the non-agricultural use sites through any type of irrigation system.



APPLICATION DIRECTIONS (Fungus Gnat Control)

<u>Fungus Gnat Habitat</u>	<u>Suggested Rate Range</u>
----------------------------	-----------------------------

Indoor ornamental and plant
scape use.

Light Infestation:
16-32 oz/100 gallons*
applied as a soil drench.

Heavy infestation:
64-128 oz/100 gallons**
applied as a soil drench.

*16-32 oz/100 gallons = 1-2 tsp/gallon

**64-128 oz/100 gallons = 4-8 tsp/gallon

Apply VectoBac AS with adequate water by soil drench to sufficiently wet the soil surface. Reapply as needed. In situations where all life forms (eggs, larvae, pupae and adults) are present, such as with existing infestations, make (3) weekly applications at the suggested rate range for heavy infestations. Regular follow-up using suggested light infestation rates will establish a long term maintenance program.

VectoBac AS is a larvicide and will not control adult gnats, therefore, applications must be timed for a stage of development when larvae are present in the soil.

Fungus gnat larvae generally respond to VectoBac AS treatment within 24 hours following application.

VectoBac AS is not known to be phytotoxic to ornamental species. However, since all ornamental plant species have not been evaluated, sensitivity to VectoBac AS should be checked on several plants prior to wide scale usage.

NOTICE TO USER

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 risk of use, storage or handling not in strict accordance with accompanying directions.

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