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U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs Registration Division (7505P) Ariel Rios Building 1200 Pennsylvania Ave., NW Washington, D.C. 20460 EPA Reg. Number:

59639-27

Date of Issuance:

JUN 20 2007

NOTICE OF PESTICIDE:

_ Registration

x Reregistration (under FIFRA, as amended)

Term of Issuance:

Name of Pesticide Product:

Orthene Tobacco Insect Spray

Name and Address of Registrant (include ZIP Code):

Valent U.S.A. Corporation

1600 Riviera Avenue, Suite 200

PO Box 8025

Walnut Creek, CA 94596

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number:

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.

Based on your response to the Reregistration Eligibility Decision (RED) for Acephate, EPA has reregistered the product listed above. This action is taken under the authority of section 4(g)(2)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. Reregistration under this section does not eliminate the need for continual reassessment of pesticides. EPA may require submission of data at any time to maintain the registration of your product.

Generic data requirements that have been identified in the RED as confirmatory data for the active ingredient contained in the subject product will continue to be tracked and assessed in the Agency's continual reassessment of pesticides.

The labeling for the subject product submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable provided you submit one (1) copy of the final printed label incorporating the following corrections before you release the product for shipment. Products shipped after 12 months from the date of this Notice must bear the new revised label.

- 1. Remove the PPE for use of low pressure hand wand application equipment (page 2) This is in direct conflict with the restriction against the use of such equipment appearing on page 6.
- 2. Correct the text in the engineering controls PPE for mixers/loaders (page 3) from "__ and must be provided and must have immediately available for use in an emergency __ " to read as follows: "__ and must be provided, must have immediately available and must use in an

Signature of Approving Official:

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emergency	7	

- 3. Reinstate the following statement as the last sentence in the User Safety Recommendation box as it appears in the acephte RED and on the previously submitted label: As soon as possible, wash thoroughly and change into clean clothing.
- 4. For clarity, relocate the listed chemical resistant materials now appearing in the PPE for mixers, loaders, applicators and other handlers (page 2) to the first sentence under the PPE heading; i.e. "Some Materials that are chemical resistant to this product are: ___."
- 5. Correct the warranty statements under "Prompt Notice of Claim" as specified below. Refer to the enclosed examples of warranty statements.
- a. Add the phrase "to the extent consistent with applicable law allows such requirements" to the beginning of the sentence "Valent must be provided notice as soon as Buyer has reason to believe it may have a claim, but in no event later than twenty-one days from date of planting, or ____."
- b. Add the phrase "to the extent consistent with applicable law" to the beginning of the sentence "If Buyer does not notify Valent of any claims, in such period, it shall be barred from obtaining any remedy."
- 6. Remove the Non-Agricultural Requirements box and its contents (page 4). There are no non-agricultural uses on the label.
- 7. Make the corrections described below to the tobacco use directions (pages 6 and 7).
- a. Relocate the use restriction "Do not apply using low-pressure hand wand equipment." From the General Information heading to the General Use Precautions section. As there are no other statements under the General Information heading, the heading can be removed all together.
- b. Reinstate the statement prohibiting use of the product though any type of irrigation system as it appears on the registered label for the product.
- c. Either expand the text in the maximum seasonal application precautions to include the float bed use as it appears on the registered label or replace it with the text "This includes all methods of application."
- d. Correct the ant claim from "ants (including imported fire ants and harvester ants)" to read as follows: ants (excluding carpenter and harvester).
- e. The use directions must either be revised to reflect the amount of product contained in the individual water soluble packets or the appropriate equivalency tables added similar to those appearing on your other acephate water soluble container products. The directions for the use of a smaller amount than that contained in one individual packet is not

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appropriate for products required to be contained in water soluble packaging such as the subject product. Such packages are not meant to be opened. The inappropriate directions include the use of "1 oz /5 gals. water" and "1 tbsp. in 1 gallon water" It may also include the directions for use of 1/3 lb. and 2/3 lb. of product, depending on the size of the water soluble packets other than the 1.0 lb container size specified on the submitted label.

8. Since the uses appearing on the subject label are now those uses for which water soluble packaging is required, the label must bear the special handling precautions and instructions for use of water soluble packages as they appear on your registered acephate water soluble packaged products. For the record, the attached page from your product registered under EPA Reg. No. 59639-26 bearing these precautions and instructions is enclosed as reference for the addition of the special handling precautions and instructions.

A stamped copy of the label is enclosed for your records.

The Agency has completed the cumulative assessment for the organophosphate pesticides (OPs) and finalized the Interim Reregistration Eligibility Decisions (IREDs) for the OP pesticides. The assessment and supporting documents may be found on the Agency's web site at www.epa.gov/pesticides/cumulative and in the docket (EPA-HQ-OPP-2006-0618).

> Meredith F. Laws, Chief Insecticide-Rodenticide Branch Registration Division (7504P)

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Enclosures:

Stamped label

Examples of warranty statements

Page 8 from Orthene 75S label, EPA Reg. No. 59639-26



ACCEPTED
with COMENTS
in EPA Letter Dated:
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
As amended, for the pesticide
Registered under EPA Reg. No.

ORTHENE® Tobacco Insect Spray

[Insecticide in a Water Soluble Packet]

Active Ingredient	By Wt.
*Acephate	
Other Ingredients	
Total	
,	

*O,S-Dimethyl acetylphosphoramidothiate

KEEP OUT OF REACH OF CHILDREN

CAUTION

SEE NEXT PAGE FOR ADDITIONAL PRECAUTIONARY STATEMENTS.

NET WEIGHT 1 POUND

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS & DOMESTIC ANIMALS CAUTION

Harmful if swallowed

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If swallowed:

- Call a 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 in eyes:

- Hold eyelid open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue
- 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 by mouth-to-mouth, if possible.
- Call a poison control center or doctor for further treatment advice.

If on skin or clothing:

- 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.

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 **1-800-892-0099** for emergency medical treatment information.

NOTE TO PHYSICIANS

This material contains a cholinesterase inhibitor. Measurement of blood cholinesterase activity may be useful in monitoring exposure but decisions regarding treatment will usually need to be made before test results are available. If signs of cholinesterase inhibition appear, atropine sulfate is antidotal. 2-PAM (PROTOPAM) is also antidotal and may be used in conjunction with atropine but should not be used alone.

PERSONAL PROTECTIVE EQUIPMENT (PPE):

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category A on an EPA chemical-resistance category selection chart.

Mixers, Loaders, Applicators and Other Handlers must wear: Long sleeved shirt and long pants, chemical-resistant gloves such as Butyl rubber ≥ 14 mils, Nitrile rubber ≥ 14 mils or Neoprene ≥ 14 mils and socks plus shoes.

In addition, Applicators using low pressure hand wand application equipment must wear: A NIOSH-approved dust mist filtering respirator with MSHA/NIOSH approved number prefix TC-21C or a NIOSH-approved respirator with any N, R, P or HE filter.

See Engineering Controls for additional requirements.

Engineering Controls: Water soluble packets, when used correctly, qualify as a closed mixing/loading system under the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(4)]. Mixers and loaders using water soluble packets must wear: the personal protective equipment required above for Mixer/Loaders, and must be provided and must have immediately available for use in an emergency (such as a broken package, spill or equipment breakdown) the following PPE: coveralls, chemical-resistant footwear and a NIOSH approved dust mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or a NIOSH approved respirator with any N,R, P or HE filter.

Pilots must use an enclosed cockpit in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(6)].

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry. As soon as possible, wash thoroughly and change into clean clothing.

The use of human flaggers is prohibited.

USER SAFETY RECOMMENDATIONS

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco 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.

ENVIRONMENTAL HAZARDS:

This pesticide is toxic to birds. 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 contaminate water when cleaning equipment or disposing of equipment washwaters. Cover or soil-incorporate spills.

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

This product and its degradate is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds while bees are actively visiting the treatment area.

DIRECTIONS FOR USE

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

READ ENTIRE LABEL. USE STRICTLY IN ACCORDANCE WITH PRECAUTIONARY STATEMENTS AND DIRECTIONS, AND WITH APPLICABLE STATE AND FEDERAL REGULATIONS.

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. 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 interval. 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 24 hours.

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, chemical resistant gloves made of any waterproof material and shoes plus socks.

NON-AGRICULTURAL USE REQUIREMENTS

The requirements in this box apply to uses of this product 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.

Do not enter or allow others to enter until sprays have dried.

DISCLAIMER, RISKS OF USING THIS PRODUCT, LIMITED WARRANTY AND LIMITATION OF LIABILITY

IMPORTANT: Read the entire Label including this Disclaimer, Risks of Using this Product, Limited Warranty, and Limitation of Liability before using this product. If the terms are not acceptable THEN DO NOT USE THE PRODUCT; rather, return the unopened product within 15 days of purchase for a refund of the purchase price.

RISKS OF USING THIS PRODUCT

The Buyer and User (referred to collectively herein as "Buyer") of this product should be aware that there are inherent unintended risks associated with the use of this product which are impossible to eliminate. These risks include, but are not limited to, injury to plants and crops to which this product is applied, lack of control of the target pests or weeds, resistance of the target pest or weeds to this product, injury caused by drift, and injury to rotational crops caused by carryover in the soil. Such risks of crop injury, non-performance, resistance or other unintended consequences are unavoidable and may result because of such factors as weather, soil conditions, disease, moisture conditions, irrigation practices, condition of the crop at the time of application, presence of other materials either applied in the tank mix with this product or prior to application of this product, cultural practices or the manner of use or application, (or a combination of such factors) all of which are factors beyond the control of Valent. The Buyer should be aware that these inherent unintended risks may reduce the harvested yield of the crop in all or a portion of the treated acreage, or otherwise affect the crop such that additional care, treatment and expense are required to take the crop to harvest. If the Buyer chooses not to accept these risks, THEN THIS PRODUCT SHOULD NOT BE APPLIED. By applying this product Buyer acknowledges and accepts these inherent unintended risks AND TO THE FULLEST EXTENT ALLOWED BY LAW, AGREES THAT ALL SUCH RISKS ASSOCIATED WITH THE APPLICATION AND USE ARE ASSUMED BY THE BUYER.

Valent shall not be responsible for losses or damages (including, but not limited to, loss of yield, increased expenses of farming the crop or such incidental, consequential or special damages that may be claimed) resulting from use of this product in any manner not set forth on the label. Buyer assumes all risks associated with the use of this product in any manner or under conditions not specially directed or approved on the label.

LIMITED WARRANTY

Valent warrants only that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the label, under average use conditions, when used strictly in accordance with the label and subject to the Risks of Using This Product as described above. EXCEPT AS SET FORTH ABOVE, VALENT MAKES NO OTHER WARRANTIES, EITHER EXPRESSED OR IMPLIED. No agent or representative of Valent or Seller is authorized to make or create any other express or implied warranty.

LIMITATION OF LIABILITY

To the fullest extent allowed by law, Valent or Seller is not liable for any incidental, consequential, indirect or special damages resulting from the use or handling of this product. The limitation includes, but is not limited to, loss of yield on all or any portion of the treated acreage, increased care, treatment or other expenses required to take the crop to harvest, increased finance charges or altered finance ratings, emotional or mental distress and/or exemplary damages. TO THE FULLEST EXTENT ALLOWED BY LAW, THE EXCLUSIVE REMEDY OF THE BUYER, AND THE EXCLUSIVE MAXIMUM LIABILITY OF VALENT OR 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 THIS PRODUCT OR, AT THE ELECTION OF VALENT OR SELLER, THE REPLACEMENT OF THE PRODUCT.

PROMPT NOTICE OF CLAIM

Valent must be provided notice as soon as Buyer has reason to believe it may have a claim, but in no event later than twenty-one days from date of planting, or twenty-one days from the date of application, whichever is latter, so that an immediate inspection of the affected property and growing crops can be made.

If Buyer does not notify Valent of any claims, in such period, it shall be barred from obtaining any remedy.

NO AMENDMENTS

Valent and Seller offer this product, and Buyer accepts it, subject to the foregoing **Disclaimer**, **Risks of Using This Product**, **Limited Warranty** and **Limitation of Liability**, which may not be modified by any oral or written agreement.

TANK MIXES

NOTICE: Tank mixing or use of this product with any other product which is not specifically and expressly authorized by the label shall be the exclusive risk of user, applicator and/or application advisor.

Read and follow the entire label of each product to be used in the tank mix with this product.

TOBACCO

GENERAL INFORMATION

Do not apply using low-pressure hand wand equipment.

GENERAL USE PRECAUTIONS

Do not apply more than 5 1/3 lbs./A (4 lbs. ai) ORTHENE Tobacco Insect Spray per crop cycle. This includes
the use of ORTHENE in transplant water, plant bed, soil and foliar applications.

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APPLICATION METHOD	PESTS CONTROLLED	RATES OF ORTHENE TOBACCO INSECT SPRAY PER ACRE	REMARKS	DAYS TO HARVEST
SOIL MOUND TREATMENT	Ants (including Imported Fire Ants and Harvester Ants)	Drench Method: 1 oz/5 gals. water	Mix 1 oz. in 5 gals. of water. Apply 1 gal. of mix to each mound area by sprinkling the mound until it is wet and treat a 4 ft. diameter circle around the mound. For best results apply the material in the early moming or late afternoon when the ants are most active. Applications made under prolonged hot and dry conditions may be ineffective due to the location of the ants deep within the nest.	3
USE PRECAUTIONS: Treat a maximum of 13 mode Do not treat more than once PLANT BED FOLIAGE: Apply at the	e per crop cycle. Cutworm Flea Beetle	1 lb.	Apply evenly to ensure thorough coverage.	
equivalent of 1 Tbsp. in 1 gal. water per every 1,000 sq. ft. of bed	Green Peach Aphid Tobacco Aphid	·	For repeat applications use a minimum spray interval of 7 days.	
TRANSPLANT Apply in a minimum of 100 gals. of transplant water per acre	Cutworm Flea Beetle Green Peach Aphid Potato Tuberworm Tobacco Aphid Tobacco Thrip	1 lb.	Make transplant-water applications using mechanical transplant equipment only. Using such equipment, the insecticide/water mixture is mechanically applied directly into the soil along with the transplanted plants.	
			Provides control for approximately 3 to 4 weeks after transplanting.	
HEE DRECALITIONS			For control late in the season, apply foliar sprays of ORTHENE Tobacco Insect Spray.	

USE PRECAUTIONS:

 Do not apply more than 1 lb. ORTHENE Tobacco Insect Spray per acre as a transplant-water application as some phytotoxicity may occur.

continued

Directions for Use - (continued)

APPLICATION METHOD	PESTS CONTROLLED	RATES OF ORTHENE TOBACCO INSECT SPRAY PER ACRE	REMARKS	DAYS TO HARVEST
FOLIAR	Grasshopper	1/3 to 2/3 lb.	For repeat applications use a minimum spray interval of 3 days for application rates up to and including 2/3 lb./A and a minimum of 7 days for rates exceeding 2/3 lb./A	3
By Ground: 10 to 50 gals./A of spray By Air: Minimum of 3 gals./A of spray	Flea Beetle Green Peach Aphid Hornworm Tobacco Thrips	2/3 lb.		
	Stinkbugs Tobacco Aphid Vegetable Weevils	2/3 to 1 lb.		
•	Budworm Cabbage Looper Cutworm Japanese Beetle	1 lb.		

STORAGE AND DISPOSAL

PESTICIDE STORAGE

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

Keep pesticide in original container.

Do not put concentrate or dilute into food or drink containers.

Store in cool, dry place.

Protect from excessive heat.

Do not store or transport near feed or food

For help with any spill, leak, fire or exposure involving this material, call day or night 800-892-0099.

PESTICIDE DISPOSAL

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

CONTAINER DISPOSAL

Completely empty canister into application equipment. Do not reuse container. Dispose of empty canister 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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ORTHENE® - Reg. TM of OMS Investments, Inc. for acephate insecticide

Manufactured for Valent U.S.A. Corporation P. O. Box 8025 Walnut Creek, CA 94596-8025 www.valent.com

Made in U.S.A.

EPA Reg. No. 59639-27 EPA Est.