

5481-8976

09/14/2012

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D C 20460



OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

SEP 14 2012

Kaila Moran
Regulatory Consultant
AMVAC
4695 MacArthur Court, Suite 1250
Newport Beach, CA 92660

Subject Orthene 15 Granular
 EPA Reg No 5481-8976
 Notification Application Dated July 12, 2012
 Minor label revisions and updating Storage and Disposal Instructions

Dear Ms Moran

The Agency has received your Application for Pesticide Notification under Pesticide Registration Notices (PRN) 2007-4 and 98-10, dated July 12, 2012 for the subject product, EPA Reg No 5481-8972. The Registration Division (RD) has reviewed this request and finds that the actions requested fall within the scopes of PR Notices 2007-4 and 98-10. The label submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions, please call me directly at (703) 308-8043 or email lewis.marianne@epa.gov

Sincerely,

A handwritten signature in black ink that reads "Marianne Lewis".

Marianne Lewis
Insecticide-Rodenticide Branch
Registration Division (7505P)
Office of Pesticide Programs



United States
 Environmental Protection Agency
 Washington DC 20460

- Registration
- Amendment
- Other

OPP Identifier Number

2/8

Application for Pesticide - Section I

1 Company/Product Number 5481-8976	2 EPA Product Manager	3 Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4 Company/Product (Name) Orthene 15 Granular	PM#	
5 Name and Address of Applicant (Include Zip Code) Amvac Chemical Corporation 4695 MacArthur Court Suite 1250 Newport Beach CA 92660 <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) Notification of Minor Label Revisions and Storage and Disposal Statements
 Notification of label change per PR Notice 2007 4 This notification is consistent with the guidance in PR Notice 2007 4 and the 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 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 §§ 156 10 156 140 156 144 156 146 and 156 156 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
 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			
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 checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If Yes No per Unit Packaging wt container	If Yes No per Package wt container
3 Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4 Size(s) Retail Container	5 Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6 Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithographed <input checked="" 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 Kaila Moran	Title Regulatory Consultant	Telephone No (Include Area Code) (562) 607-2146
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		8 Date Application Received (Stamped)
2 Signature 	3 Title Regulatory Consultant	
4 Typed Name Kaila Moran	5 Date 17 Jul 2008	



July 12 2012

Ms Julie Chao
Document Processing Desk
Office of Pesticide Programs (Notif)
U S Environmental Protection Agency
One Potomac Yard
2777 S Crystal Drive
Arlington VA 22202

Subject Notification of Minor Label Revisions and Storage and Disposal Language Per PR Notice 2007-4
Orthene Tobacco Insect Spray (EPA Reg No 5481-8972)
Orthene 15 Granular (EPA Reg No 5481-8976)
Orthene Turf & Container Grown Nursery Stock 15G (EPA Reg No 5481-8977)

Dear Julie

This is submitted in response to the EPA letters dated May 31 2012 as well as our phone conversation June 8 2012 As you mentioned on the phone the Container Disposal Statements updated per the PR Notice 2007-4 are acceptable However you requested revising the language throughout the label with regards to using the word general when referring to mandatory (non-optional) use directions I have made the requested label changes as suggested as well as included REDLINE labels to highlight the revisions I have also revised the applications to with the updated certification under PR 98-10

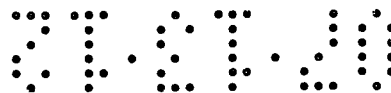
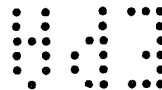
In support of this request, enclosed please find the following

- Application for each Pesticide Registration (EPA Form 8570-1)
- ^{two} ~~two~~ copies of each label with a redline copy showing changes (Ref No 8972-20120509r1, 8976-20120509r1 8977-20120508r1)
- Copies of the May 31, 2012 letters for reference

It is my understanding that this satisfies the requirements of the Agency s PR Notice and will require no further action If you have any questions or require additional information, please do not hesitate to contact me at 562-607-2146 or email kailam@amvac-chemical.com Thank you for your attention to this matter

Best regards

Kaila Moran
Regulatory Consultant



ORTHENE® 15 GRANULAR

Soil Applied Insecticide

Active Ingredient

*Acephate

Inert Ingredients

Total

*O,S-Dimethyl acetylphosphoramidothioate

By Weight

15.0%

85.0%

100.0%

U S Patent Nos 5 298 501 5 369,100 5 352 674

NOTIFICATION

SEP 14 2012

KEEP OUT OF REACH OF CHILDREN
CAUTION

FIRST AID	
Acephate is an organophosphate, cholinesterase inhibitor	
If swallowed	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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 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 inhaled	<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
EMERGENCY INFORMATION	
Have the product container or label with you when calling a poison control center or doctor or going for treatment FOR THE FOLLOWING EMERGENCIES PHONE 24 HOURS A DAY	
Transportation CHEMTREC	1 800 424 9300
Other AMVAC	1 323 264 3910
NOTE TO PHYSICIAN	
Acephate is a cholinesterase inhibitor If signs of cholinesterase inhibition appear atropine is antidotal 2 PAM (PROTOPAM) is also antidotal and may be used in conjunction with atropine but should not be used alone	

SEE SIDE/BACK PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS AND DIRECTIONS FOR USE

EPA Reg No 5481-8976

EPA Est No

Net Contents

As Marked on Container



4100 E Washington Blvd

Los Angeles CA 90023 U S A

1 323 264 3910

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS & DOMESTIC ANIMALS**CAUTION**

Harmful if swallowed or absorbed through skin Causes moderate eye irritation Avoid contact with skin eyes or clothing

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 and Neoprene ≥ 14 mils
- Shoes plus socks

See Engineering Controls for additional requirements

ENGINEERING CONTROLS

When handlers use closed systems or enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170 2430(d)(6)] the handler PPE requirements may be reduced or modified as specified in the WPS

Follow manufacturer s instructions for cleaning/maintaining PPE If there are 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

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 Soil incorporate (disc) any surface material present in turn-rows immediately after application to limit exposure of birds to surface granules

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

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
- Shoes plus socks

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.

DIRECTIONS

CROP	PESTS CONTROLLED	RATE OF ORTHENE 15 GRANULAR PER ACRE	FURTHER USE INSTRUCTIONS
Cotton	Aphids Cutworms Thrips	5 to 6 2/3 lbs (0.75 to 1.0 lb ai/A)	<p>Apply with in furrow granular application equipment at planting. Minimize surface application by ensuring adequate application depth (2" minimum) and immediate coverage of furrows with soil. Calibrate and adjust application equipment to insure proper rate and accurate placement. Soil incorporate (disc) any surface material present in turn rows immediately after application. Use the higher end of the rate range in areas which historically experience prolonged early season insect pressure due to factors such as adjacent alternate hosts, i.e. maturing cereal grains, weedy underbrush, etc. Cotton treated with the lower end of the rate range may display more visible feeding symptoms and require subsequent foliar application(s) of insecticide to control prolonged infestations of early season insects.</p> <p>Do not apply more than 4 lbs of ai/A per crop cycle. This includes the use of ORTHENE 15 Granular as an in furrow at planting treatment, all ORTHENE[®] foliar spray, liquid in furrow application, hopper box and seed treatment uses.</p>

CALIBRATION GUIDE
Use Rate Lbs /A (lbs ai/A)
Row Ft (rf) to Collect 1 oz ORTHENE 15 Granular

ROW SPACING	5 lbs /A (0.75)	5 1/2 lbs /A (0.83)	6 lbs /A (0.9)	6 2/3 lbs /A (1.0)
30	218 rf	198 rf	182 rf	163 rf
36	182 rf	165 rf	151 rf	136 rf
38"	172 rf	156 rf	143 rf	129 rf
40	163 rf	149 rf	136 rf	123 rf

When applied to soil in which adequate moisture for germination and normal seedling growth is maintained either by irrigation or rainfall the active ingredient in ORTHENE 15 Granular is quickly absorbed by the roots and translocated in the xylem throughout the entire plant. Insufficient moisture after application will result in a lack of insect control.

STORAGE AND DISPOSAL
<p>Do not contaminate water, food or feed by storage, disposal or cleaning of equipment</p> <p>PESTICIDE STORAGE Keep pesticide in original container Store in cool dry place. Protect from excessive heat. Do not contaminate food or foodstuffs. 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 1-323-264-3910 Open dumping is prohibited.</p> <p>PESTICIDE DISPOSAL Wastes resulting from use of this product may be disposed of on site or at an approved waste disposal facility.</p> <p>CONTAINER DISPOSAL Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment. Do not reuse container. Dispose of empty bag in a sanitary landfill or by incineration, or if allowed by State and local authorities, by burning. If burned, stay out of smoke.</p>

LIMITED WARRANTY AND DISCLAIMER

The manufacturer warrants (a) that this product conforms to the chemical description on the label (b) that this product is reasonably fit for the purposes set forth in the directions for use, subject to the inherent risks referred to herein when it is used in accordance with such directions and (c) that the directions, warnings and other statements on this label are based upon responsible experts' evaluations of reasonable tests of effectiveness of toxicity to laboratory animals and to plants and residues on food crops and upon reports of field experience. Tests have not been made on all varieties of food crops and plants or in all states or under all conditions.

THERE ARE NO EXPRESS WARRANTIES OTHER THAN THOSE SET FORTH HEREIN TO THE EXTENT CONSISTENT WITH APPLICABLE LAW. THE MANUFACTURER (NEITHER MAKES NOR INTENDS, NOR DOES IT AUTHORIZE ANY AGENT OR REPRESENTATIVE, TO MAKE ANY OTHER WARRANTIES, EXPRESS OR IMPLIED, AND IT EXPRESSLY

EXCLUDES AND DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY OF FITNESS FOR A PARTICULAR PURPOSE, OR ANY WARRANTY OF QUALITY OR PERFORMANCE THIS WARRANTY DOES NOT EXTEND TO, AND THE BUYER SHALL BE SOLELY RESPONSIBLE FOR, ANY AND ALL LOSS OR DAMAGE WHICH RESULTS FROM THE USE OF THIS PRODUCT IN ANY MANNER WHICH IS INCONSISTENT WITH THE LABEL DIRECTIONS, WARNINGS OR CAUTIONS

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW BUYER'S EXCLUSIVE REMEDY AND MANUFACTURER'S OR SELLER'S EXCLUSIVE LIABILITY FOR ANY AND ALL CLAIMS, LOSSES, DAMAGES, OR INJURIES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER OR NOT BASED IN CONTRACT, NEGLIGENCE, STRICT LIABILITY IN TORT OR OTHERWISE, SHALL BE LIMITED, AT THE MANUFACTURER'S OPTION, TO REPLACEMENT OF, OR THE REPAYMENT OF THE PURCHASE PRICE FOR, THE QUANTITY OF PRODUCT WITH RESPECT TO WHICH DAMAGES ARE CLAIMED TO THE EXTENT CONSISTENT WITH APPLICABLE LAW MANUFACTURER OR SELLER SHALL NOT BE LIABLE FOR SPECIAL, INDIRECT OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT

AMVAC offers this product and Buyer accepts it, subject to the foregoing Limited Warranty which may be varied only by agreement in writing signed by an authorized representative of AMVAC

Orthene is a registered trademark of OMS Investments Inc

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Los Angeles, CA 90023 U S A
1-323-264-3910

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