UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON D C 20460



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

AUG 1 0 2012

Sally Christopher Regulatory Analyst Registration and Regulatory Affairs Valent U S A Corp 1600 Riviera Ave Suite 200 Walnut Creek CA 94596 8025

Subject INOVATE Seed Protectant to add Soil borne Sclerotima to label

EPA Reg No 59639 176

Notification Application Dated June 29 2012

Dear Ms Christopher

The Agency has received your Application for Pesticide Notification under Pesticide Registration Notices (PRN) 98 10 dated June 29 2012 for the product Inovate Seed Protectant EPA Reg No 59639 176 The Registration Division (RD) has reviewed this request and finds that the actions requested fall within the scopes of PR Notice 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

Sincerely

Marianne Lewis

Insecticide Rodenticide Branch Registration Division (7505P) Office of Pesticide Programs June 29 2012



INOVATE[™] Seed Protectant EPA Reg No 59639-176 Active Ingredient Clothianidin/Metalaxyl/Ipconazole

Notification

Ms Venus Eagle
U S Environmental Protection Agency
Insecticide Rodenticide Branch
Registration Division (7505P)
1200 Pennsylvania Ave NW
Washington DC 20460

Dear Ms Eagle

Valent U S A Corporation would like to update our product label via Notification for *INOVATE* Seed Protectant (EPA Reg No 59639-176) which contains the active ingredients clothianidin metalaxyl and ipconazole. The update includes the following

The addition of soil borne for Sclerotinia see pages 7 and 9

Pleased find enclosed the following documents

- Pesticide application (Form 8570 1)
- Certification Statements consistent with the provisions of PR-Notice 98 10
- One (1) copy of the proposed label
- One (1) copy of the proposed label with redline additions/strike through

If you need any further information you can contact me at <u>sally christopher@valent com</u> or by phone at (925) 256 2710

Sincerely

Sally S Christopher Regulatory Analyst

Registrations and Regulatory Affairs

Sally S Clustopher

Valent US A Corporation

enclosures



NOTIFICATION AUG 1 0 2012

REDLINE COPY - NOTIFICATION

INOVATE™ Seed Protectant

A FUNGICIDE AND INSECTICIDE SEED TREATMENT PRODUCT PROVIDING SYSTEMIC SEED AND SEEDLING PROTECTION AGAINST LISTED EARLY SEASON SEEDLING DISEASES AND INSECTS OF SOYBEAN

Active Ingredients	By Wt
Clothianidin ¹	14 340%
Metalaxyl ²	1 153%
lpconazole ³	0 720%
Other Ingredients	<u>83 787%</u>
Total	100 00 %

 $^{^{1}(}E)$ 1 (2 chloro 1 3 thiazol 5 ylmethyl)-3 methyl 2 nitroguanidine 2 N (2 6-dimethylphenyl)-N (methoxyacetyl) DL alanınate

INOVATETM Seed Protectant contains 1 34 lbs Clothianidin per gallon 0 108 lbs Metalaxyl per gallon 0 0675 lbs Ipconazole per gallon

KEEP OUT OF REACH OF CHILDREN

CAUTION

SEE NEXT PAGE FOR PRECAUTIONARY STATEMENTS

NET CONTENTS

EPA Reg No 59639 176 **EPA Est No**

³2 [(4 chlorophenyl)methyl] 5 (1 methylethyl) 1 (1H 1 2 4 triazol 1 ylmethyl) cyclopentanol

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS & DOMESTIC ANIMALS CAUTION

Harmful if swallowed inhaled or absorbed through skin. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Avoid breathing vapor

FIRST AID				
If swallowed	 Call a poison control center or doctor immediately for treatment advice Have a person sip a glass of water if able to swallow Do not induce vomiting unless told to by a poison control center or doctor Do not give anything to an unconscious person 			
If in eyes	 Hold eye open and rinse slowly and gently with water for 15 to 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	 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	 Move person to fresh air If person is not breathing call 911 or ambulance then give artificial respiration preferably by mouth to mouth if possible Call a poison control center or doctor for further treatment advice 			
	NOTE TO PHYSICIAN			
Treatment is su	ipportive and symptomatic			

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 **800 892 0099** for emergency medical treatment information

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Some of the materials that are chemical resistant to this product are barrier laminate butyl rubber nitrile rubber neoprene rubber polyvinyl chloride and viton. If you want more options follow the instructions for category C on an EPA chemical resistance category selection chart.

All mixers, loaders, applicators and other handlers must wear. Long sleeved shirt and long pants shoes plus socks and chemical resistant gloves. Follow manufacturers 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.

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. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

This product is toxic to aquatic invertebrates. Do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water ma! Do not contaminate water when cleaning equipment or disposing of equipment washwaters. Do not apply where runoff is likely to occur. Runoff from treated areas may be hazardous to aquatic organism in neighboring areas. Apply this product only as specified on the label.

Treated seed exposed on soil surface maybe hazardous to birds. Cover or collect spilled seeds.

Metalaxyl has properties and characteristics associated with chemicals detected in ground water. This chemical may leach into ground water if used in areas where soils are permeable particularly where the water table is shallow. Therefore contain any product spills or equipment leaks and dispose of wastes according to the disposal instructions on this label.

Ipconazole may persist in soil and long term use in the same field may result in accumulation of active ingredient

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

For use only in commercial seed treatment equipment. Not for use in hopper box planter box slurry box or other on farm seed treatment applications. Do not apply this product in a way that will contact workers or other persons. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe. consult the State or Tribal 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

Exception Once the seeds are planted in soil the Worker Protection Standard under certain circumstances allows workers to enter the treated area without reserriction of there will be no worker contact with the soil subsurface or treated seed. 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 long sleeved shirt and long pants chemical resistant gloves such as barrier laminate butyl rubber nitrile rubber or Viton shoes plus socks

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.

ASSUMPTION OF RISK

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. Take of control of the target pests to this product. Such risks of crop injury, non-performance or other unintended consequences are unavoidable and may result because of such factors as weather, soil conditions disease moisture conditions irrigation practices cultural practices or the manner of use or application (or a combination of such factors) all of which are factors beyond the control of Va ent. The Buyer should be aware that these inherent unintended risks may reduce the harvested yield of the crop in all o 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 APPL CATION 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 specifically 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. To the extent consistent with applicable law AND 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

To the extent consistent with applicable law allowing such requirements 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

To the extent consistent with applicable law 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

COMMERCIAL TANK MIXES

NOTICE Commercial 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 commercial tank mix with this product

RESISTANCE MANAGEMENT

INOVATE Seed Protectant contains Clothianidin which is a neonicotinoid and a Group 4A insecticide. Insect biotypes with acquired resistance to Group 4A insecticides may eventually dominate the insect population if Group 4A insecticides are used repeatedly in the same field or in successive years as the primary method of control for targeted species. This may result in partial or total loss of control of those species by INOVATE. Seed Protectant or other Group 4A insecticides. Valent U.S.A. Corporation strives to maintain strong stewardship of this product by recommending that its use be coordinated in a planned resistance management strategy program established for the specific crop and area.

Contact your local extension specialist certified crop advisors and/or manufacturer fcr insecticide resistance management or IPM recommendations for the specific site and resistant pest problems

For further information or to report suspected resistance you may contact √alent U S A Corporation at 800 682 5368

PRECAUTIONS AND RESTRICTIONS

INOVATE Seed Protectant must be used only in accordance with specifications on this label utilizing commercial liquid or commercial slurry seed treatment equipment to secure proper application. Always mix product thoroughly before use. Not for use in hopper box, planter box, slurry box or other on farm seed treatment applications.

Regardless of type of application (seed treatment or foliar) do not apply more than 0 2 lbs of active ingredient clothianidin per acre per season

As stated by regulations specified in 40 CFR 153 155 all seed treated with *INOVATE* Seed Protectant must be colored with an EPA-approved dye or colorant to visually distinguish seed that is treated with a pesticide. It is mandatory that such dye or colorant be added into the slurry mixture containing *INOVATE* Seed Protectant prior to application through commercial seed treatment equipment. This regulation is necessary to prevent treated seed from accidental use as a food for man or feed for animals.

Seed Quality and Storage of Treated Seed

Seed treatments applied to low vigor or poor quality seed or to mechanically damaged seed may result in loss of seed germination or reduced seedling vigor. To verify seed safety, treat a small portion of seed with the desired slurry mixture (INOVATE Seed Protectant alone or in combination with other commercial seed treatment products) prior to treatment of an entire seed lot. Utilize standard seed germination methodologies to determine and verify seed safety. Proper storage conditions of treated seed are recommended. Due to seed quality and seed storage conditions beyond the control of Valent U.S.A. Corporation, no claims are made to guarantee the germination of carry over treated seed.

PRODUCT INFORMATION

INOVATE Seed Protectant (containing clothianidin metalaxyl and ipconazole) is a fungicide and insecticide seed treatment product offering both contact and systemic activity in providing broad-spectrum seed and seedling protection against seedling diseases soil insects and early season foliar insects of soybean. The fungicide components in INOVATE Seed Protectant are effective for control of Pythium Fusarium and Rhizoctonia solani. It is also effective against seed-borne Phomopsis seed borne and soil-borne. Sclerotinia and seed rot fungi such as Aspergillus and Penicillium.

Clothianidin the insecticide contained in *INOVATE* Seed Protectant provides protection against aphids bean leaf beetle grape colaspis leafhoppers pea leaf weevil seed corn maggot three cornered alfalfa hopper thrips white grubs and wireworm. Seed should be sound and well-cured before treatment

Accurate application of *INOVATE* Seed Protectant to seed is required for control of listed pests. Application to seed by commercial seed treatment equipment utilizing standard liquid or slurry treaters is necessary. Mix *INOVATE* Seed Protectant prior of application. Do not agitate or stir *INOVATE* Seed Protectant while treating seed. *INOVATE* Seed Protectant may be applied direct to soybean seed without adding water.

Tank Mix Information for Added Phytophthora Protection

INOVATE Seed Protectant provides control of Pythium and early protection against Phytophthora However if the target field has a history of high Phytophthora pressure INOVATE Seed Protectant may be tank mixed with a metalaxyl or mefenoxam containing product for increased protection against Phytophthora Consult your Valent U S A Corporation representative for information regarding additional rates of metalaxyl or mefenoxam for Phytophthora protection

Pre test tank mixtures with other seed treatment products to verify formulation compatibility and to assure proper physical compatibility of products. Be aware of limitations or cautions documented on labels of all products used in a seed treatment mixture.

SEED BAG TAG

The Federal Seed Act requires that the container of seed treated with INOVATE Seed Protectant must be labeled with the following statements

- This seed has been treated with INOVATE Seed Protectant which contains clothianidin metalaxyl and ipconazole
- Do not use treated seed for feed food or oil processing

In addition the U.S. Environmental Protection Agency requires the following statements on the container of seed treated with *INOVATE* Seed Protectant

- Regardless of the type of application (seed treatment or foliar) do not apply more than a total of 0 2 lb (90 7 gram) clothianidin (active ingredient) per acre per season (Based on the seed size of 3000 seeds/lb at the label rate the mg of clothianidin will be equal to 0 075 mg /seed)
- Store away from feeds and other foodstuffs
- Wear long sleeved shirt long pants and chemical resistant gloves such as Natural Rubber ≥ 14 mils Barrier Laminate Butyl Rubber Nitrile Rubber Neoprene Rubber or Viton when handling treated seed
- Dispose of all excess treated seed. Left over treated seed may be double sown around the headland or buried away from water sources in accordance with local requirements. Do not contaminate water bodies when disposing or clanting equipment washwaters.
- Dispose of seed packaging in accordance with local requirements
- The compound is toxic to birds and mammals. Treated clothianidin seeds exposed on soil surface may be hazardous to birds and mammals. Cover or collect seeds spilled during loading.
- Treated seeds must be planted at a minimum depth of 1 inch
- This compound is highly toxic to bees exposed directly (contact) Ensure that
 planting equipment is functioning properly in accordance with manufacturing
 recommendations to minimize seed coat abrasion during planting to reduce dust
 which can drift to blooming crops or weeds
- This product contains metalaxyl that is known to leach through soil into groundwater under certain conditions as result of agricultural use. Use of this product in areas where soils are permeable particularly where the water table is shallow may result in groundwater contamination.
- Do not graze or feed soybean forage and hay to livestock
- Areas planted with treated seed of soybean may be replanted immediately with bulb vegetables canola cereal grains (except rice) cotton corn (field pop and sweet) fruiting vegetables (including cucurbits) leafy vegetables (including brassica vegetables) rapeseed root and tuber vegetables and soybean. These areas may also be replanted after 30 days with dry beans grasses non grass animal feeds and rice. These areas may also be replanted after 8 months with sugarcane. Do not plant any other crop in the treated area for at least one year after these treated seeds are planted.
- After seeds have been planted do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours Exception Once seeds are planted and covered by soil or other planting media the Worker Protection Standard (WPS) allows workers to enter the treated area without restriction
- Do not re use bags from treated seed to handle food or feed products
- Do not use augers used for handling treated seed to move seed for feed food or oil processing

SOYBEAN				
Seed/Seedling Diseases	Insect Pests	INOVATE Seed Protectant Use Rates		
		fl oz/100 lbs seed	¹ mg active ingredient per seed	
Seed Rots (Including seed borne Phomopsis seed borne and soil borne Sclerotinia seed borne Fusarium Penicillium and Aspergillus) Damping Off and Seedling Blights (soil borne Pythium	Aphids Bean Leaf Beetle Grape Colaspis Leafhoppers Pea Leaf Weevil Seed Corn Maggot Three Cornered Alfalfa Hopper Thrips White Grubs Wireworm	4 74	Clothianidin 0 075 mg Metalaxyl 0 006 mg [pconazole 0 0028 mg	

- Foliar spray of clothianidin can be applied 45 days after planting INOVATE Seed Protectant treated soybean seeds for mid to late season foliar insects
- Regardless of type of application (seed treatment or foliar) do not apply more than a total of 0 2 lb (90 7 gram) active ingredient clothianidin per acre per season
- Do not graze or feed soybean forage and hay to livestock

mg active ingredient per seed is based on 3000 seeds per pound

STORAGE AND DISPOSAL

Do not contaminate water food or feed by storage and disposal

PESTICIDE STORAGE

Store in a dry place away from excessive heat
Do not store near food or feed
Store in original container only
To close package replace and tighten cap to form an airtight seal

PESTICIDE DISPOSAL

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

CONTAINER HANDLING

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. Fill the container 1/4 full with water Replace and tighten closures. Tip container on its side and roll it back and forth ensuring at least one complete revolution for 60 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip. It back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Orfer, for recycling, if available otherwise dispose of in a sanitary landfill or incineration.

[Use the following statement for all formulation types/all refillable container types] Refillable container Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times. Offer for recycling, if available, otherwise dispose of in a sanitary landfill or incineration.

RECYCLING

Once cleaned some agricultural plastic pesticide containers can be taken to a container collection site or picked up for recycling. To find the nearest site contact your chemical dealer or manufacturer or contact the Ag Container Recycling Council (ACRC) at 877 952 2272 (toll free) or www acrecycle org

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Manufactured For **Valent U S A Corporation** P O Box 8025 Walnut Creek CA 94596 8025 (800) 682 5368

Made in USA

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