

100-909

06/06/2000

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U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505C)
401 "M" St., S.W.
Washington, D.C. 20460

EPA Reg. Number:

100-909

Date of Issuance:
JUN 6 2000

Date of Expiration:
12/31/2000

NOTICE OF PESTICIDE:

Registration
 Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

Clodinafop-propargyl
Technical

Name and Address of Registrant (include ZIP Code):

Novartis Crop Protection, Inc.
P.O. Box 18300
Greensboro, NC 27419-8300

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.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(C) provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product when the Agency requires all registrants of similar products to submit such data.
2. Submit data to fulfill the following guideline requirements as specified in the Health Effects Division's May 15, 2000 risk assessment of Clodinafop-propargyl on wheat (copy enclosed). These data must be submitted by June 1, 2003. Refer to the review for detailed information concerning the nature of the deficiencies and the information/data that must be submitted:
 - (a) Acute Neurotoxicity Study in Rats (OPPTS 870.6200)
 - (b) Subchronic Neurotoxicity Study in Rats (OPPTS 870.6200)
 - (c) Developmental Neurotoxicity Study in Rats (OPPTS 870.6300)
 - (d) In vitro Cytogenetic Assay (OPPTS 870.5375)
 - (e) Nature of the Residue in Plants (OPPTS 860.1300)
 - (f) Residue Analytical Methods (OPPTS 860.1340)
 - (g) Storage Stability Data (OPPTS 860.1380)
 - (h) Magnitude of the Residue in Plants (OPPTS 860.1500)

Signature of Approving Official:

Date:

JUN 6 2000

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Additional deficiencies were noted in HED's review. These deficiencies either have already been adequately addressed (Proposed Uses/Guideline 860.1200); are not being required at this time (Nature of the Residue in Livestock/Guideline 860.1300); or are reserved pending review of the data required above (Magnitude of the Residue in Processed Food/Guideline 860.1520). The data pertaining to the Nature of the Residue in Livestock are not being required at this time, since the Agency has concluded that tolerances in animal commodities are not required in connection with the use of clodinafop-propargyl on wheat. If it is determined in the future that animal commodity tolerances are needed, you must fulfill this guideline requirement (860.1300) at that time. Finally, as noted in HED's review, if you wish to amend the label to include shorter rotational crop intervals, you must submit a new Confined Rotational Crop study (Guideline 860.1850) in support of the amendment. Pending the results of the new study, a Field Accumulation Study (Guideline 860.1900) may also be required.

3. Submit data to fulfill the following guideline requirements as specified in the Environmental Fate and Effects Division's January 27, 2000 risk assessment of Clodinafop-propargyl on wheat (previously sent to Novartis). These data must be submitted by June 1, 2003. Refer to the review for detailed information concerning the nature of the deficiencies and the information/data that must be submitted:

- (a) Hydrolysis (Guideline 161-1) - **Clodinafop-propargyl**
- (b) Photolysis in Water (Guideline 161-2) - **Clodinafop-propargyl**
- (c) Anaerobic Soil Metabolism (Guideline 162-2) - **Clodinafop-propargyl and the metabolites CGA-193469 and CGA-302371**
- (d) Adsorption/Desorption (Guideline 163-1) - **Clodinafop-propargyl and the metabolites CGA-193469 and CGA-302371**
- (e) Field Dissipation (Guideline 164-1) - **Clodinafop-propargyl**
- (f) Aerobic Soil Metabolism (Guideline 162-1) - **Clodinafop-propargyl and the metabolites CGA-193469 and CGA-302371**
- (g) Avian Reproduction (Guideline 71-4) - **Clodinafop-propargyl**
- (h) Seedling Emergence/Vegetative Vigor (Guideline 123-1(a) and 123-1(b)) - **the metabolite CGA-193469**

4. Submit adequate analytical methods for enforcement of the tolerances on wheat. EPA acknowledges that you have submitted enforcement methods which use both normal and reverse phase liquid chromatography with UV detection (HPLC-UV). These methods are currently being validated by the Analytical Chemistry Branch laboratories, BEAD (7503C), Office of Pesticide Programs. We will notify you of the lab's conclusions as soon as they are available.

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5. Comply with the terms of the agreement regarding the maximum amount of clodinafop-propargyl to be sold under this conditional registration as outlined in the correspondence, dated May 26, 2000, from Ms. Karen S. Stumpf of Novartis to Mr. Donald Stubbs, chief of the Herbicide Branch. As agreed in the May 26th letter, Novartis may sell a maximum of 168,900 pounds of clodinafop-propargyl active ingredient during 2000.

6. Submit one copy of the final printed label for the record before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

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

Joanne I. Miller
Product Manager (23)
Herbicide Branch
Registration Division (7505C)

Enclosures

RD:STANTON:PM Team 23:Rm. 239:CM-2:305-5218:Clodinafop Disk:100-ONO.REG

CONCURRENCES

SYMBOL ▶	7505C							
SURNAME ▶	S. Stanton							
DATE ▶	May 26, 2000							

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**ACCEPTED
with COMMENTS
In EPA Letter Dated**

Import Label

JUN 6 2000

**Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.
100-909**

Clodinafop-propargyl Technical

_____ Pounds
Net Weight

For Formulation Only Into Herbicides For Weed Control in Certain Crops

Active Ingredient:	
Clodinafop-propargyl: (CAS No. 105512-06-9).....	97.5%
Other Ingredients:	2.5%
Total:	100.0%

Product of United Kingdom

KEEP OUT OF REACH OF CHILDREN.

CAUTION

Precautionary Statements

Hazards to Humans and Domestic Animals

Causes eye irritation. Harmful if swallowed or absorbed through skin. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Avoid contact with eyes, skin, or clothing. Wash thoroughly with soap and water after handling.

Statement of Practical Treatment

If in eyes: Flush eyes with plenty of water. Call a physician if irritation persists.

If on skin: Wash with plenty of soap and water. Get medical attention.

If swallowed: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

Note to Physician: If ingested, induce emesis or lavage stomach. Treat symptomatically.

Environmental Hazards

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.

EPA Reg. No. 100-909

Product ID. 53941

EPA Est. 70992-GBR-001

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DIRECTIONS FOR USE AND CONDITIONS OF SALE AND WARRANTY

IMPORTANT: Read the entire **Directions for Use** and the **Conditions of Sale and Warranty** before using this product. If terms are not acceptable, return the unopened product container at once.

Conditions of Sale and Warranty

The **Directions for Use** of this product reflect the opinion of experts based on field use and tests. The directions are believed to be reliable and should be followed carefully. However, it is impossible to eliminate all risks inherently associated with use of this product. Crop injury, ineffectiveness, or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application all of which are beyond the control of Novartis Crop Protection, Inc. or the Seller. All such risks shall be assumed by the Buyer.

Novartis warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes referred to in the **Directions for Use** subject to the inherent risks referred to above. **Novartis makes no other express or implied warranty of Fitness or Merchantability or any other express or implied warranty. In no case shall Novartis or the Seller be liable for consequential, special, or indirect damages resulting from the use or handling of this product.** Novartis and the Seller offer this product, and the Buyer and user accept it, subject to the foregoing **Conditions of Sale and Warranty**, which may be varied only by agreement in writing signed by a duly authorized representative of Novartis.

No end use of this product other than formulation is intended or implied by the above Conditions of Sale and Warranty.

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DIRECTIONS FOR USE

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

This product is to be used only for formulation into herbicides for use on wheat.

Note to Formulators

Formulators are responsible for providing data to support registration of products formulated from Clodinafop-propargyl Technical.

Storage and Disposal

Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited.

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

Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

For minor spills, etc., follow all precautions indicated on this label and clean up immediately. Take special care to avoid contamination of equipment and facilities during cleanup procedures and disposal of wastes. In the event of a major spill, fire, or other emergency, call 1-800-888-8372, day or night.

Imported by
Novartis Crop Protection, Inc.
Greensboro, North Carolina 27419
www.cp.us.novartis.com

NCP 909A-L1 0500

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