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Systems Integration Group, Inc.

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100-903

5/19/99

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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

EPA Reg. Number:

100-903

Date of Issuance:

MAY 19 1999

NOTICE OF PESTICIDE:

x Registration
Reregistration

(under FIFRA, as amended)

Term of Issuance: Conditionally
until May 1, 2002

Name of Pesticide Product:

Denim™ Insecticide

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), since you have agreed to:

1. Submit the data listed below, conducted in accordance with the 40 CFR Part 158 test guidelines referred to below:

Table with 3 columns: Guideline Reference No., Title of Study, Date Due. Rows include 72b (Estuarine/Marine Invertebrate Life-Cycle Study, May 1, 2001) and 171-4 (Residue Analytical Method, Awaiting Agency Validation).

2. Submit and/or cite all data required for registration/ reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.

Signature of Approving Official:

Date:

MAY 19 1999

CONCURRENCES

Table for tracking approvals with columns for SYMBOL, SURNAME, and DATE. Includes handwritten entries for 'LCA' and '5/19/99'.

3. You will submit production information (pounds or gallons produced) for this product for the fiscal year in which the use(s) on head and stem brassica are conditionally registered, in accordance with FIFRA Section 29. The fiscal year begins October 1 and ends September 30. The production information will be submitted to the Agency no later than November 15, following the end of the preceding fiscal year.

This information should be submitted to:

U.S. Environmental Protection Agency
Office of Pesticide Programs (7504C)
Document Processing Desk (RSB)
401 M Street, SW
Washington, DC 20460

4. Make the following label change before you release the product for shipment:

a. Add the phrase "EPA Registration Number 100-903 " to the label.

b. Revise the Container Disposal statement to read as follows:

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.

c. Revise the Pesticide Disposal Statement to read as follows:

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

d. Revise the Hazards to Human and Domestic Animals to read as follows:

Corrosive. Cause irreversible eye damage. Do not get in eyes or on clothing. Wear protective eyewear goggles or face shields. Harmful if swallowed or absorbed through skin. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse. Prolonged or frequently repeated exposure may cause allergic skin reactions in some individuals.

e. Revise the first paragraph of the Environmental Hazards statements to read as follows:

This pesticide is toxic to fish, birds, mammals, and 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 mark. Do not contaminate water when cleaning equipment or disposing of equipment washwaters or rinsate.

- f. Add the section "Recommendations to Avoid Spray Drift" before the Resistance Management section and add the following statements:

OBSERVE THE FOLLOWING PRECAUTIONS WHEN SPRAYING IN THE VICINITY OF AQUATIC AREAS SUCH AS LAKES; RESERVOIRS; RIVERS; PERMANENT STREAMS; MARSHES OR NATURAL PONDS; ESTUARIES AND COMMERCIAL FISH FARM PONDS

Do not apply by ground within 25 feet of lakes; reservoirs; rivers; permanent streams; marshes or natural ponds; estuaries and commercial fish farm ponds.

Make ground application when wind velocity favors on-target product deposition (approximately 3 to 10 mph). Do not apply when wind velocity exceeds 10 mph. Avoid applications when wind gusts approach 10 mph.

Risk of exposure to sensitive aquatic areas can be reduced by avoiding applications when wind direction is toward the aquatic area.

Do not cultivate within 25 feet of the aquatic area as to allow growth of a vegetative filter strip.

Low humidity and high temperatures increases the evaporation rate of spray droplets and therefore the likelihood of spray drift to aquatic areas. Avoid spraying during conditions of low humidity and/or high temperature.

Do not make ground applications during temperature inversions. Inversions are characterized by stable air and increasing temperatures with height above the ground. Mist or fog may indicate the presence of an inversion in humid areas. The applicator may detect the presence of an inversion by producing smoke and observing a smoke layer near the ground surface.

- g. Under the Statement of Practical Treatment section, place the IF IN EYES statements before the IF SWALLOWED statements. Also revise the IF IN EYES statement to read: "Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention."

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- h. Revise the IF SWALLOWED statement to read as follows: Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person. Drink promptly a large quantity of milk, eggwhites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol.

Items (g) and (h) above are based upon review of the acute toxicity data submitted in support of registration. If you have incident data or use information that recommends First Aid statements different than the above, submit this for our consideration.

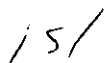
- i. Under Agricultural Use Requirements change the REI to 48hrs based upon a toxicity category I classification for eye irritation.
- j. Delete "cole crops" under the crop/site table and replace with cavalo broccolo or head and stem brassica, since the tolerance is established for "head and stem brassica" only. Is this product only for use cavalo broccolo.

3. Submit two copies of the revised final printed label for the record. Refer to the A-79 enclosure for a further description of final printed labeling.

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.

Sincerely yours,



George T. LaRocca
Product Manager 13
Insecticide Branch
Registration Division

Enclosure

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RESTRICTED USE PESTICIDE
Toxic to Fish, Mammals, and Aquatic Organisms

For Retail Sale to and use only by Certified Applicators or
Persons under their direct supervision and only for
those uses covered by the Certified Applicator's certification

Denim™

INSECTICIDE

For Use on cavalo broccolo

Active Ingredient:

Emamectin benzoate: (CAS No. 137512-74-4)	2.15%*
Other Ingredients:	97.85%
Total:	100.00%

*1 gallon contains 0.16 pound emamectin benzoate

KEEP OUT OF REACH OF CHILDREN.

DANGER/PELIGRO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

See back label for additional Precautionary Statements and Statement of Practical Treatment.

EPA Est. No. 39578-TX-001

EPA Reg. No. 100-903

1 GALLON

For Lot Number see bottom of bottle.

NCP 903A-L1A 0199

ACCEPTED
with COMMENTS
in EPA Letter Dated

MAY 19 1999

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
registered, for the pesticide
registered under EPA Reg. No.
100-903

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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.

DIRECTIONS FOR USE

It is a violation of Federal (U.S.A.) law to use this product in a manner inconsistent with its labeling. 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 that are not covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of ~~12~~ ⁴⁸ 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 over short-sleeved shirt and short pants
- chemical-resistant gloves, such as barrier laminate, nitrile rubber, neoprene rubber, or Viton
- chemical-resistant footwear plus socks
- protective eyewear
- chemical-resistant headgear for overhead exposure

Cavalo broccolo: Denim is an emulsifiable concentrate that will control the following lepidopteran insects when applied according to the **Directions for Use:**

Crops/Pests	fl. oz./acre	lb. ai/acre
Cole Crops Beet Armyworm Cabbage Looper Cabbage Webworm Corn Earworm Cross-Striped Cabbageworm Diamondback Moth Fall Armyworm Imported Cabbageworm Soybean Looper	6-12	0.0075-0.015

Mix with water and apply by ground equipment as a foliar spray. Apply thoroughly to ensure good upper and lower leaf coverage. Thorough coverage is essential for good insect control on crops. Use 6 fl. oz./acre for low to moderate infestations and 12 fl. oz./acre for severe infestations. Apply when larvae are first observed and repeat applications as necessary to maintain control.

Resistance Management: Because of the inherent risks of resistance development to any product, it is strongly advised that Denim be used in a sound resistance management program which includes rotation with other products with different modes of action.

Use Restrictions

- Do not exceed 72 fl. oz. Denim per acre on a given crop during its full cropping season.
- Do not apply within 7 days of harvest.
- Do not apply at less than 7-day intervals.
- Do not apply this product through any type of irrigation system.
- Do not apply by aircraft.
- Do not graze livestock in treated areas.

NOTES

Denim may be used without a wetting agent. When necessary to improve the wetting of foliage and to smooth out spray deposits, a non-ionic surfactant is recommended.

Denim has been tested for phytotoxicity and has a wide margin of safety on a variety of crops. However, since all combinations and sequences of pesticide sprays, nutritionals, surfactants, and adjuvants have not been fully evaluated, it is recommended not to tank mix Denim with these products, except as directed, until greater experience is gained.

STORAGE AND DISPOSAL

Storage: Store in a tightly closed original container in a cool, dry place.

Prohibitions: Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Do not reuse empty container.

Pesticide Disposal: Pesticide spray mixture or rinsate that cannot be used or chemically reprocessed should be disposed of in a landfill approved for pesticides or buried in a safe place away from water supplies. Improper disposal of excess pesticide spray mixture or rinsate is a violation of Federal (U.S.A.) law. If these wastes cannot be disposed of by the use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal: Triple rinse (or equivalent) and dispose in an or landfill approved for pesticide containers.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

DANGER

Corrosive, causes eye damage. Do not get in eyes. Harmful if swallowed, inhaled, or absorbed through the skin. Avoid breathing spray mist. Avoid contact with the skin. Prolonged or frequently repeated exposure may cause allergic skin reactions in some individuals.

Personal Protective Equipment

Some materials that are chemical-resistant to this product are listed

below. If you want more options, follow the instructions for category E on an EPA chemical-resistance category selection chart. Applicators and other handlers must wear coveralls worn over short-sleeved shirt and short pants, chemical-resistant gloves, (such as barrier laminate, nitrile rubber, neoprene rubber, or Viton), chemical-resistant footwear plus socks, and protective eyewear. Wear chemical-resistant headgear for overhead exposure. Wear chemical-resistant apron when cleaning equipment, mixing, or loading. Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them. 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. When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticide [40 CFR 170 240(d)94-6], the handler PPE requirements may be reduced or modified as specified in the WPS.

User Safety Recommendations

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet
- Remove clothes immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Statement of Practical Treatment

If inhaled: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.

If swallowed: Call a physician or Poison Control Center immediately. Drink one or two glasses of water and induce vomiting by gently touching the back of the throat with finger. Repeat until vomit fluid is clear. Do not induce vomiting or give anything by mouth to an unconscious person.

If on skin: Remove contaminated clothing and wash affected areas with soap and water. Get medical attention if irritation persists.

If in eyes: Flush eyes with plenty of water. Call a physician immediately.

Recommendations for Medical Treatment for Emamectin Benzoate
Acute Toxicity: Early signs of intoxication include mydriasis (dilated

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pupils), ataxia (unsteadiness), and muscle tremors. Toxicity following accidental ingestion of the concentrate can be minimized by inducing vomiting within one-half hour of exposure. If toxicity from exposure has progressed to cause severe vomiting, the extent of resultant fluid and electrolyte imbalance should be gauged. Appropriate supportive parenteral fluid replacement therapy should be given, along with other required supportive measures (such as maintenance of blood pressure levels) as indicated by clinical signs, symptoms, and measurements.

In severe cases, observations should continue for at least several days until clinical condition is stable and normal. Since emamectin benzoate is believed to enhance GABA activity in animals, it is probably wise to avoid drugs that enhance GABA activity (barbiturates, benzodiazepines, valproic acid) in patients with potentially toxic emamectin benzoate exposure.

For 24-hour emergency information, call the 1-800-888-8372.

Environmental Hazards

This pesticide is toxic to fish and wildlife. Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not apply when weather conditions favor drift from target areas. Do not contaminate water when disposing of equipment, wash water, rinsate, or runoff.

This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow drift to blooming crops or weeds if bees are visiting the treatment area.

Physical/Chemical Hazards

Do not use or store near heat or open flame.

U.S. Pat. 4,874,749 and 4,427,663

Denim™ trademark of Novartis

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Novartis Crop Protection, Inc.
Greensboro, North Carolina 27419
NCP 903A-L1A 0199

[QUARK/DENIM/DENIM] - ccg - 2/12/99