

Public Information and Records Integrity Branch, Information Resources and Services Division at the address provided, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding holidays. It is suggested that persons interested in reviewing the application file, telephone this office at (703-305-5805) to ensure that the file is available on the date of intended visit.

Authority: 7 U.S.C. 136.

List of Subjects

Environmental protection, Pesticides and pest, Product registration.

Dated: August 26, 1997.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

[FR Doc. 97-23685 Filed 9-9-97; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

[OPP-30394A; FRL-5726-6]

Monsanto Company; Approval of a Pesticide Product Conditional Registration

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces Agency approval of an application submitted by Monsanto Company to conditionally register the product YieldGard for a changed use pattern pursuant to the provisions of section 3(c)(7)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

FOR FURTHER INFORMATION CONTACT: By mail: Michael Mendelsohn, Regulatory Action Leader, Biopesticides and Pollution Prevention Division (7501W), Office of Pesticide Programs, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Westfield Building North Tower, CS #1, Environmental Protection Agency, 2800 Crystal Drive, Arlington, VA 22202, 703-308-8715; e-mail: mendelsohn.mike@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

Electronic Availability: Electronic copies of this document and the Fact Sheet are available from the EPA home page at the Environmental Sub-Set entry for this document under "Regulations" (<http://www.epa.gov/fedrgstr/>).

EPA issued a notice, published in the **Federal Register** of November 1, 1995

(60 FR 55574; FRL-4979-7), which announced that Monsanto Company 700 Chesterfield Parkway North St. Louis, MO 63198, had submitted an application to register the product *Bacillus thuringiensis* subsp. *kurstaki* (B.t.k.) Insect Control Protein (EPA File Symbol 524-UIO).

The product was announced as containing the plant pesticide active ingredient *Bacillus thuringiensis* subsp. *kurstaki* delta-endotoxin as produced in corn by a cryIA(b) gene and its controlling sequences, an active ingredient not included in any previously registered product. Subsequent to this, the Agency approved a seed increase registration for this active ingredient on May 28, 1996, under EPA Registration No. 524-492.

The full commercial use application from Monsanto was approved on December 20, 1996, as YieldGard (formerly *Bacillus thuringiensis* subsp. *kurstaki* (B.t.k.) Insect Control Protein) for use on field corn (EPA Registration Number 524-489), the chemical was amended to read "*Bacillus thuringiensis* CryIA(b) delta endotoxin and the genetic material necessary for its production in corn at 0.023-0.029 percent."

This registration was conditionally granted to allow additional use of the active ingredient for food and feed in field corn in accordance with FIFRA section 3(c)(7)(B). This use is conditional upon data development in the area resistance management research and *Collembola* and *Daphnia magna* toxicity testing and limited by resistance management and expiration provisions of the registration.

A conditional registration may be granted under section 3(c)(7)(B) of FIFRA for a product involving a changed use pattern where certain data are lacking, on condition that such data are received as specified by EPA and the applicant has submitted satisfactory data pertaining to the proposed additional use and the amended registration would not significantly increase the risk of any unreasonable adverse effect.

The Agency has considered the available data on the risks associated with the proposed use of *Bacillus thuringiensis* CryIA(b) delta endotoxin and the genetic material necessary for its production in corn, and information on social, economic, and environmental benefits to be derived from such use. Based on these reviews, the Agency was able to make basic health and safety determinations which show that use of *Bacillus thuringiensis* CryIA(b) delta endotoxin and the genetic material

necessary for its production in corn consistent with the terms and conditions of registration during the period of conditional registration will not cause any unreasonable adverse effect on the environment.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(B). This registration will automatically expire on midnight April 1, 2001. EPA will reevaluate the effectiveness of Monsanto's resistance management plan before April 1, 2001, and decide whether to convert the registrations to a non-expiring registrations. If the conditions are not complied with the registration will be subject to cancellation in accordance with FIFRA section 6(e).

More detailed information on this conditional registration is contained in an EPA Pesticide Fact Sheet on Monsanto's *Bacillus thuringiensis* CryIA(b) delta-endotoxin and the genetic material necessary for its production in corn.

A copy of the fact sheet, which provides a summary description of the chemical, use patterns and formulations, science findings, and the Agency's regulatory position and rationale, may be obtained from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161.

In accordance with section 3(c)(2) of FIFRA, a copy of the approved label, the list of data references, the data and other scientific information used to support registration, except for material specifically protected by section 10 of FIFRA, are available for public inspection in the Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Rm. 1132, CM #2, Arlington, VA 22202 (703-305-5805). Requests for data must be made in accordance with the provisions of the Freedom of Information Act and must be addressed to the Freedom of Information Office (A-101), 401 M St., SW., Washington, D.C. 20460. Such requests should: (1) Identify the product name and registration number and (2) specify the data or information desired.

Authority: 7 U.S.C. 136.

List of Subjects

Environmental protection, Pesticides and pests, Product registration.

Dated: August 26, 1997.

Janet L. Andersen,

Director, Biopesticides and Pollution
Prevention Division, Office of Pesticide
Programs.

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ENVIRONMENTAL PROTECTION AGENCY

[OPP-30394B; FRL-5740-4]

Novartis Seeds; Approval of a Pesticide Product Conditional Registration

AGENCY: Environmental Protection
Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces Agency approval of an application to conditionally register the product Northrup King Insect Resistant Corn containing a new plant pesticide active ingredient not included in any previously registered product pursuant to the provisions of section 3(c)(7)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended and the subsequent amendment of this product for a changed use pattern pursuant to section 3(c)(7)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

FOR FURTHER INFORMATION CONTACT: By mail: Michael Mendelsohn, Regulatory Action Leader, Biopesticides and Pollution Prevention Division (7501W), Office of Pesticide Programs, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Westfield Building North Tower, CS #1, Environmental Protection Agency, 2800 Crystal Drive, Arlington, VA 22202, 703-308-8715; e-mail: mendelsohn.mike@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

Electronic Availability: Electronic copies of this document and the Fact Sheet are available from the EPA home page at the Environmental Sub-Set entry for this document under "Regulations" (<http://www.epa.gov/fedrgstr/>).

EPA issued a notice, published in the **Federal Register** of November 1, 1995 (60 FR 55574; FRL-4979-7), which announced that Northrup King Company, 7500 Olson Memorial Highway, Golden Valley, MN 55427, submitted an application to register the transgenic plant pesticide product Northrup King Insect Resistant Corn (EPA File Symbol 67979-R). The Northrup King Co., has changed and is now known as Novartis Seeds, P.O. Box 12257, Research Triangle Park, NC

27709-2257. This product contained the plant pesticide active ingredient *Bacillus thuringiensis* subsp. *kurstaki* delta-endotoxin as produced in corn by a CryIA(b) gene and its controlling sequences, an active ingredient not included in any previously registered product.

The application from Northrup King (now known as Novartis Seeds) was approved on May 14, 1996, as Northrup King Insect Resistant Corn for seed propagation only (EPA Registration Number 67979-1) the chemical was amended to read "*Bacillus thuringiensis* delta endotoxin as produced by a CryIA(b) gene and its controlling sequences as found on plasmid vector pZO1502 at 0.00475-0.0006 percent."

A conditional registration may be granted under section 3(c)(7)(C) of FIFRA for new active ingredients where certain data are lacking, on condition that such data are received by the end of the conditional registration period and do not meet or exceed the risk criteria set forth in 40 CFR 154.7; that use of the pesticide during the conditional registration period will not cause unreasonable adverse effects; and that use of the pesticide is in the public interest.

The Agency has considered the available data on the risks associated with the proposed use of *Bacillus thuringiensis* delta endotoxin as produced by a CryIA(b) gene and its controlling sequences as found on plasmid vector pZO1502, and information on social, economic, and environmental benefits to be derived from such use. Specifically, the Agency has considered the nature and its pattern of use, application methods and rates, and level and extent of potential exposure. Based on these reviews, the Agency was able to make basic health and safety determinations which show that use of *Bacillus thuringiensis* delta endotoxin as produced by a CryIA(b) gene and its controlling sequences as found on plasmid vector pZO1502 during the period of conditional registration will not cause any unreasonable adverse effect on the environment, and that use of the pesticide is in the public interest.

This product was conditionally registered in accordance with FIFRA section 3(c)(7)(C). The registration was originally to expire in May 1997. However, as outlined further in this document, this product was amended pursuant to section 3(c)(7)(B) of FIFRA to allow commercial use and thus, the expiration date was extended to April 1, 2001. EPA will reevaluate the effectiveness of Novartis Seeds resistance management plan before

April 1, 2001, and decide whether to convert the registration to a non-expiring registration. If the conditions are not complied with the registration will be subject to cancellation in accordance with FIFRA section 6(e).

Consistent with section 3(c)(7)(C), the Agency has determined that this conditional registration was in the public interest. Use of the pesticide is of significance to the user community, and appropriate labeling, use directions, and other measures have been taken to ensure that use of the pesticides will not result in unreasonable adverse effects to man and the environment.

The product was amended on August 5, 1996 to include in the already registered uses a new use for commercial use in field corn.

This registration was conditionally amended to allow additional use of the active ingredient for food and feed in field corn in accordance with FIFRA section 3(c)(7)(B). This use is conditional upon data development in the area resistance management research and *Collembole* and *Daphnia magna* toxicity testing and limited by resistance management and expiration provisions of the registration.

A conditional registration may be granted under section 3(c)(7)(B) of FIFRA for a product involving a changed use pattern where data are lacking, on condition that such data are received as specified by EPA and the applicant has submitted satisfactory data pertaining to the proposed additional use and the amended registration would not significantly increase the risk of any unreasonable adverse effect.

More detailed information on this conditional registration is contained in an EPA Pesticide Fact Sheet on *Bacillus thuringiensis* delta endotoxin as produced by a CryIA(b) gene and its controlling sequences as found on plasmid vector pZO1502.

A copy of the fact sheet, which provides a summary description of the chemical, use patterns and formulations, science findings, and the Agency's regulatory position and rationale, may be obtained from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161.

In accordance with section 3(c)(2) of FIFRA, a copy of the approved label, the list of data references, the data and other scientific information used to support registration, except for material specifically protected by section 10 of FIFRA, are available for public inspection in the Public Information and Records Integrity Branch, Information Resources and Services