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524-478

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION,  
PESTICIDES AND TOXIC  
SUBSTANCES

OCT 31 1995

Russell P. Schneider, Ph.D.  
Agricultural Regulation Director  
Monsanto Company  
700 14th St. N.W. Suite 1100  
Washington, D.C. 20005

Dear Dr. Schneider:

Subject: Application to Amend Your Seed Increase/Plant  
Propagation Registration to Allow Its Additional Use in  
Commercial Cotton. EPA Reg. No.: 524-478

This registration is conditionally amended to allow the  
additional use of the product for food and feed in cotton in  
accordance with FIFRA § 3(c)(7)(B) provided that you:

- 1) Submit/cite all data required for registration of your  
product under FIFRA § 3(c)(5) when the Agency requires all  
registrants of similar products to submit such data.
- 2) Submit production information (pounds or gallons  
produced) for this product for the fiscal year in which the use  
of commercial cotton is conditionally registered, in accordance  
with FIFRA § 29. The fiscal year begins October 1 and ends  
September 30. Production information will be submitted to the  
Agency no later than November 15, following the end of the  
preceding fiscal year.
- 3) This registration will automatically expire on midnight  
January 1, 2001. EPA will reevaluate the effectiveness of  
Monsanto's resistance management plan before January 1, 2001, and  
decide whether to convert the registration to a non-expiring  
(and/or unconditional) registration.

CONCURRENCES

SYMBOL	750/W						
SURNAME	HUTTON						
DATE	10/31/95						

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2. The pesticide product may be used only for seed production for seed increase and breeding nurseries as specified in the terms and conditions of this registration and on the labeling.

3. Monsanto shall enter into a written agreement with each of its cooperators that requires the cooperator to comply with all the terms and conditions of this registration. "Cooperator" means any person who has been granted permission from Monsanto to use the pesticide product on property owned or controlled by that person.

4. Monsanto shall be liable under the Federal Insecticide, Fungicide, and Rodenticide Act for any action of a cooperator that does not comply with the terms and conditions of this registration.

5. Plants that contain the pesticide product may be grown on no more than a total of 36,850 acres. Plants that contain the pesticide product may only be grown in the states of: Arizona, Arkansas, Mississippi, Puerto Rico, California, South Carolina and Texas. The maximum acres grown in each State shall be:

Summary by State and Maximum Number of Acres Proposed for Seed Increase and Breeding Nurseries of Insect Resistant Cotton

Seed Increase Acres

<u>State</u>	<u>Total Acres</u>
Arizona	23,500
Arkansas	2,500
Mississippi	10,500
<u>Territory</u>	<u>Total Acres</u>
Puerto Rico	30

Total Seed Increase Acres 36,530

Breeding Nursery Acres

<u>State</u>	<u>Total Acres</u>
Arizona	110
California	15
Mississippi	100
South Carolina	30
Texas	30
<u>Territory</u>	<u>Total Acres</u>
Puerto Rico	35

Total Breeding Nurseries Acres 320

Total United States Acres 36,850

"Seed Increase" means to increase the seed quantities of cotton cultivars containing the pesticide product. "Breeding Nursery" means transferring the pesticide product, through breeding, to cotton varieties not containing the pesticide product.

6. The registration of this pesticide product will automatically expire on midnight of March 15, 1996, unless EPA extends the registration.

7. Any area with a plant that contains the pesticide product must be isolated by one of the following methods:

- a. Any such area may be surrounded by a border that is at least 1320 feet (one-quarter of a mile) wide and free of any cotton plant;
- b. Any breeding nursery acres or any seed increase acres that are 10 acres or more may be surrounded by a border that is at least 76 feet wide and that contains 24 border rows of cotton plants that do not contain the pesticide product; or
- c. Any breeding nursery acres or any seed increase acres that are less than 10 acres may be surrounded by a border that is at least 39 feet wide and contains 12 border rows of cotton plants that do not contain the pesticide product.

8. No plants or plant propagation materials that contain the pesticide product may be sold or distributed, except that such plants and materials may be distributed between Monsanto and its cooperators, and may be distributed for storage under Monsanto's control; and any lint that is obtained from the seed cotton at ginning may sold and distributed.

9. All sites are to be monitored for 12 months for germinating seed which must be subsequently destroyed by mechanical cultivation, by hand, or by herbicide application.

10. All plant propagation materials produced by Monsanto and its cooperators that contain the pesticide product must be either destroyed or securely stored for future plantings, research, or used for additional plant propagation material pursuant to the conditions of this registration.

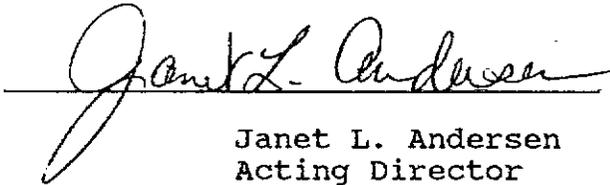
11. After this registration has expired, no plants or plant propagation materials that contain the pesticide product may be planted, grown, or harvested.

12. Equipment used for planting and harvesting must be carefully cleaned of seed cotton that contains these pesticide product ~~as the plot site.~~ *before further use JEA* Seed from all plots must be harvested or destroyed.

13. Paragraphs 8, 9, 10, 11, and 12 apply to any plants or plant propagative materials in border rows.

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14. After the registration expires, no plants or plant propagation materials that contain the pesticide product may be planted, grown, or harvested.



Janet L. Andersen  
Acting Director  
Biopesticides and Pollution  
Prevention Division

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RECEIVED  
OCT 27 1995

**PLANT PESTICIDE ACTIVE INGREDIENT**

***Bacillus thuringiensis* subsp. *kurstaki*  
Insect Control Protein**

Pure form of the Plant Pesticide, *Bacillus thuringiensis* subsp. *kurstaki* control protein as expressed in cotton cells.

**Active Ingredient:**

*Bacillus thuringiensis* subsp. *kurstaki* CryIA(c) delta endotoxin protein and the genetic material necessary for its production. . . . . 0.001 - 0.006%\*

**Inert:**

Substances produced by marker genes and their controlling sequences in cotton . . . . . 0.001 - 0.003%

\*Percentage of total protein on a dry weight basis.

Keep Out of Reach of Children

**CAUTION**

Keep out of lakes, ponds, or streams. Do not contaminate water by cleaning of equipment or disposal of wastes.

EPA REGISTRATION NUMBER 524-478

Monsanto Company  
700 Chesterfield Parkway North  
St. Louis, Missouri 63198

**Directions for Use:**

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

In Florida do not plant south of Tampa, (Florida Route 60). Not for commercial sale or use in Hawaii. Test plots or breeding nurseries established in Hawaii must be surrounded by either 12 border rows of non-transgenic cotton if the plot size is less than 10 acres or 24 border rows if the plot is over 10 acres, and must not be planted within 1/4 mile of *Gossypium tomentosum*

Cotton has been transformed to express the *Bacillus thuringiensis* subsp. *kurstaki* (*B.t.k.*) delta endotoxin protein for the control of the following lepidopteran cotton insect pests:

Cotton bollworm  
Tobacco budworm  
Pink bollworm

*Helicoverpa zea*  
*Heliothis virescens*  
*Pectinophora gossypiella*

**ACCEPTED  
with COMMENTS  
in EPA Letter Dated**

OCT 31 1995  
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act  
as amended, for the pesticide  
registered under EPA Reg. No.  
524-478

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