

524-522

6-14-2002

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U.S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs  
Biopesticides and Pollution Prevention Division (7511C)  
1200 Pennsylvania Avenue NW  
Washington, DC 20460

EPA Reg. Number:  
24-  
542-522

Date of Issuance:  
JUN 14 2002

NOTICE OF PESTICIDE:

Registration  
 Reregistration  
(under FIFRA, as amended)

Term of Issuance: Conditional

Name of Pesticide Product:  
Bollgard II Cotton

Name and Address of Registrant (include ZIP Code):

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

Note: Changes in labeling different substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label for commercial use. 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.

The registration application referred to above, submitted in connection with registration under § 3(c)(7)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable provided that you do the following terms and conditions.

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 for this product to Mr. Owen Beeder of Registration Division (7505C) for the fiscal year in which this product 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 is registered under FIFRA § 3(c)(7)(C) because of the outstanding avian oral toxicity using higher levels of the Cry2Ab2 protein, and ladybeetle larval data. These data must be submitted within the specified timeframes:

6 Months from the date of this seed increase registration

Signature of Approving Official:

(See second page for signature)

Date:

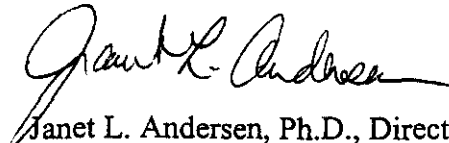
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- 4. This registration will automatically expire on midnight 30 June, 2003. EPA will reevaluate the avian oral toxicity data and ladybeetle larval data as well as any and all other relevant data before 30 June, 2003 on whether to amend and/or convert this seed increase registration to a non-expiring registration. An acceptable insect resistance management plan and heat stability study must be submitted. Further, EPA is requiring a confirmatory soil degradation study with a more sensitive indicator insect before EPA can decide on a full commercial registration.
- 5. The seed may only be planted in the following states on acreage not to exceed the maximum specified for each location:
  - Arizona - 8,000 acres**
  - Mississippi - 11,700 acres**
  - Louisiana - 300 acres**
- 6. No plants or plant propagation materials that contain the plant-incorporated protectant 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.
- 7. The plant-incorporated protectant may be used only for seed production as specified in the terms and conditions of this registration and on the labeling.
- 8. After the registration expires, no plants or plant propagation materials that contain the plant-incorporated protectant may be planted, grown or harvested..
- 9. Equipment used for planting and harvesting must be carefully cleaned of seed that contains this plant-incorporated protectant at the plot site. Seed from all plots must be harvested or destroyed. Any seed or plant material that contains the plant-incorporated protectant must be either destroyed, securely stored for future plantings or research or used to produce additional seed pursuant to this registration.
- 10. Submit five (5) copies of the revised final printed labeling before you release the product for shipment. 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,



Janet L. Andersen, Ph.D., Director  
 Biopesticides and Pollution Prevention Division

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**Bollgard® II Cotton**  
*Bacillus thuringiensis* subsp. *kurstaki*  
**Insect Control Protein**

**Active Ingredients:**

*Bacillus thuringiensis* Cry2Ab2 protein and the genetic material  
necessary for its production in cotton .....0.01 - 0.02% \*

*Bacillus thuringiensis* Cry1Ac protein and the genetic material  
necessary for its production in cotton .....0.001 - 0.006%\*

**Other Ingredients:**

Substances produced by marker genes and their controlling sequences  
in cotton. .... 0.016 - 0.073%\*

\* Percentage of whole plant on a dry weight basis

**PRECAUTIONARY STATEMENT**

**CAUTION**

**KEEP OUT OF REACH OF CHILDREN**

Net (Contents) \_\_\_\_\_

EPA Registration Number <sup>524</sup>542-  
EPA Establishment Number 524-MO-002

**ACCEPTED  
with COMMENTS  
in EPA Letter Dated**

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

**JUN 14 2002**  
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act  
as amended, for the pesticide  
registered under EPA Reg. No.  
524-522

**DIRECTIONS FOR USE**

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

This seed may only be planted for seed production purposes. All Bollgard II cottonseed used for seed production by Monsanto and its seed partners must be accompanied by a copy of this label. Prior to planting, growers are instructed to read the terms of their seed production contract and their regulatory compliance packets for information on agronomic procedures, restrictions, and record keeping requirements.

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Bollgard II cotton has been transformed to express the *Bacillus thuringiensis* Cry2Ab2 delta-endotoxin protein for the control or suppression of the following cotton lepidopteran insect pests:

Tobacco Budworm	<i>Heliothis virescens</i>
Pink Bollworm	<i>Pectinophora gossypiella</i>
Cotton Bollworm	<i>Helicoverpa zea</i>
Cabbage Looper	<i>Trichoplusia ni</i>
Saltmarsh Caterpillar	<i>Estigmene acrea</i>
Cotton Leaf Perforator	<i>Bucculatrix thurbeiella</i>
Soybean Looper	<i>Pseudoplusia includens</i>
Beet Armyworm	<i>Spodoptera exigua</i>
Fall Armyworm	<i>Spodoptera frugiperda</i>
Yellowstriped Armyworm	<i>Spodoptera ornithogolli</i>

No plants or plant propagation materials that contain the Cry2Ab2 pesticidal protein may be sold or distributed commercially except that such plants and materials may be distributed between Monsanto and its seed partners, and for storage under controlled conditions. This seed and any plant materials produced from it may not be released into commerce or used for food or feed until all federal regulatory approvals have been granted.

The federal registration for Bollgard II cottonseed production will automatically expire on June 30, 2003. After this registration has expired, no further Bollgard II cottonseed may be planted for seed production purposes.

This seed may only be planted in the following states on acreage not to exceed the maximum specified for each location:

**Approved States for Bollgard II cotton**

State	Acreage
Arizona	8,000
Mississippi	11,700
Louisiana	300

**Insect Resistance Management**

The insect resistance management will be conducted according to the current refuge conditions for insect resistance management of Bollgard® cotton (EPA Reg. No. 524-478).

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## CONTAINMENT

### **Pollen Containment**

Bollgard II cotton plants will be separated from receptive cotton plants outside the transgenic area according to USDA APHIS field trial performance standards described in 7CFR340. A distance adequate to prevent mechanical mixture is necessary, as is standard practice for production of breeder or certified cottonseed.

### **Equipment**

After planting is completed and before the planter leaves the field, the planter will be thoroughly cleaned out to prevent mixing with other cottonseed.

- 1) Small amounts of seed cleaned out of the planter may be allowed to fall into the field and to germinate along with the test crop.
- 2) Significant quantities of seed cleaned out from the planter will be securely packaged and returned to Monsanto Company or seed company partner or disposed of according to seed disposal guidelines below.

### **Transporting Plant Materials**

Bollgard II cottonseed will be transported in closed containers and double packaged to avoid unintentional release.

### **Monitoring**

The site will be monitored for a period of twelve (12) months to ensure that no cotton regrowth or volunteers occur.

### **Control Of Volunteer Cotton**

In compliance with USDA-APHIS performance standards, each field production area will be monitored for volunteers and all volunteers will be destroyed. Volunteers will be minimized by growing transgenic material in defined areas in the field and by performing termination procedures outlined above. The use of stakes or markers to define the area where the transgenic plants are grown may be used to identify volunteers for later elimination.

## STORAGE AND DISPOSAL

### **Storage of Bollgard II cottonseed**

Bollgard II cottonseed will be stored in a secure location. All Bollgard II cottonseed bags will be color coded, marked, tagged, or otherwise distinguished to allow immediate recognition.

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**Disposal of Leftover Planting Bollgard II Cottonseed**

Seed unused for planting will be either:

- 1) Destroyed by incineration, autoclaving or burying in the test field, or
- 2) Returned to Monsanto Company or seed company partner.

**Destruction**

After harvest, all edible portions of the crop will be destroyed except for the cottonseed. The seed will be saved to be used for commercial planting upon receipt of necessary regulator approvals and small samples of the seed may be sent to Monsanto or seed company laboratories for further analysis. Methods standard for the area will be employed (bush-hog; shred and disk, *etc.*), in compliance with any local plow down regulations. Waste plant materials may be plowed under, burned in the field (subject to burning ordinances), or otherwise devitalized.

*Bollgard* is a trademark of Monsanto Company.

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Questions? Contact Monsanto Company at 1-800-332-3111 (1-800-768-6387)