

U. S. Regulatory Agency Activity Summary

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Product Information Summary:

Database Record Number:	9
Unique Identifier:	MON-ØØ531-6
Reviewed Uses within the U.S.:	Planting, food, and feed
Product :	Cotton/Gossypium hirsutum
Tradename(s):	Bollgard Cotton
Event:	531
Trait Category:	Insect Resistance, Lepidopteran Resistance
Trait Description:	Lepidopteran resistant; Cry1Ac; from Bacillus thuringiensis (Bt)

Regulatory Agency Review Summary:



USDA Animal and Plant Health Inspection Service: 94-308-01p

Status: Granted petition for non-regulated status

Determination: http://www.aphis.usda.gov/brs/aphisdocs2/94_30801p_com.pdf



DHHS Food and Drug Administration: 13

Status: Consultation Completed

Response Letter:

<http://www.fda.gov/Food/Biotechnology/Submissions/ucm161121.htm>

Summary Memo:

<http://www.fda.gov/Food/Biotechnology/Submissions/ucm161140.htm>



Environmental Protection Agency:

Registration Number: 524-478

Registration Status: Current

Expiration Date: 9/30/2006

Assessment Summary:

http://www.epa.gov/pesticides/biopesticides/pips/bt_brad.htm

Registration Label: <http://oaspub.epa.gov/pestlabl/ppls.getimage?imgid=103943>

Registration Label 2: <http://oaspub.epa.gov/pestlabl/ppls.getimage?imgid=148663>

Labels can be updated by EPA or the registrant at any time, therefore this link might not reflect the most current information. Go to <http://oaspub.epa.gov/pestlabl/ppls.home> to search for the latest label by the registration number.

Tolerance(s)

Tolerance No: 180.1155**More Info at::** <http://www.epa.gov/docs/fedrgstr/EPA-PEST/1997/April/Day-11/p9376.htm>A small blue rectangular button with the text "Help..." in white.

Product uses are described in the database as: "food," "feed," or "planting". For each product, the database lists only those uses for which the product has completed all relevant procedures required or recommended by the regulatory agencies. Note that not all of the products in the database have completed reviews for all uses. For example, the database includes products that have completed reviews for food and/or feed uses, but have not completed reviews necessary for planting. In circumstances in which a use has been withdrawn by an agency, that use will no longer be listed.

"Food" use means that a product:

- Has completed an FDA review for consumption by humans; and
- If the product is a plant that contains a plant-incorporated protectant (PIP), the PIP has completed EPA reviews.

"Feed" use means that a product:

- Has completed an FDA review for consumption by animals; and
- If the product is a plant that contains a plant-incorporated protectant (PIP), the PIP has completed EPA reviews.

"Planting" use means that a product:

- Has completed USDA-APHIS review for cultivation in the United States; and
- If the product is a plant that contains a plant-incorporated protectant (PIP), the PIP has completed EPA reviews.

Particular restrictions or conditions associated with "planting" may be specified by EPA and/or USDA-APHIS. These conditions can be found in the agency decision documents. To access agency documents for a specific product, click on the links to agency documents provided on this U.S. Regulatory Agency Activity Summary Page. It is the responsibility of the user to ascertain whether the use of a product is subject to conditions.

U.S. Government documents that pertain to a product can be accessed through links established with this U.S. Government database to provide online access to public information. While the U.S. Government makes every effort to ensure that this U.S. Government website remains current and accurate and provides access to the final version of the pertinent documents, we cannot guarantee that it is so. For example, there may be some delay in posting modifications made after a document has been posted on a website. Please contact the relevant agency(s) prior to acting on information provided either in this U.S. Government database or at U.S. Government agency websites to ensure you have the most up-to-date information. Reference in this U.S. Government website to any specific commercial products, process, service, manufacturer, or company does not constitute its endorsement or recommendation by the U.S. Government.