

# ***Bacillus thuringiensis* Cry1Ab protein and the genetic material necessary for its production (pTDL004 or pTDL008) in Event T303-3 or T304-40 cotton plants (006525) Experimental Use Permit Fact Sheet**

**Proposed Active Ingredient Name:** *Bacillus thuringiensis* Cry1Ab protein and the genetic material necessary for its production (pTDL004 or pTDL008) in Event T303-3 or T304-40 cotton plants

**OPP Chemical Code:** 006525

## **Summary**

The plant-incorporated protectant *Bacillus thuringiensis* Cry1Ab protein and the genetic material necessary for its production (pTDL004 or pTDL008) in Events T303-3 and T304-40 cotton plants is designed to control lepidopteran pests of cotton including the cotton bollworm (*Helicoverpa zea*), tobacco budworm (*Heliothis virescens*), pink bollworm (*Pectinophora gossypiella*), fall armyworm (*Spodoptera frugiperda*), and beet armyworm (*Spodoptera exigua*). Four trial protocols have been proposed:

- Introgression (nurseries), evaluation (line trials) and seed increases.
- Evaluation of the insecticidal efficacy against cotton insect pests, under different degrees of insect pressure, in different growing environments and in different genetic backgrounds.
- Evaluation of the agronomic performance in different genetic backgrounds and in different growing regions.
- Generation of plant material and data to support future regulatory submissions in the United States and other countries.

## **I. Description of the Active Ingredient**

The proposed active ingredient is *Bacillus thuringiensis* Cry1Ab protein and the genetic material necessary for its production (pTDL004 or pTDL008) in Event T303-3 or T304-40 cotton plants. Events T303-3 and T304-40 were derived from *Agrobacterium tumefaciens*-mediated transformation of cotton variety Coker 315 with plasmid pTDL004 and plasmid pTDL008, respectively. The inserted

DNA contains the *cry1Ab* gene from *Bacillus thuringiensis* and the *bar* gene from *Streptomyces hygroscopicus* and regulatory sequences necessary for their expression in cotton. The *cry1Ab* gene sequence was modified for expression in plants. In each event, one copy of the *cry1Ab* gene was inserted into cotton.

The Cry1Ab protein encoded by the gene inserted into cotton is expected to have 617 amino acids and a molecular weight of approximately 69 kDa. The deduced amino acid sequence is identical to the *B.t.* protein except that it is truncated at the C-terminal end (the *B.t.* produced protein has a molecular weight of 130 kDa), and an alanine has been inserted at the N-terminal end. In addition, the deduced amino acid sequence of The Cry1Ab protein is identical to the amino acid sequence of the Cry1Ab protein in a previously registered PIP (Bt11, OPP chemical code 006444) with the exception of one amino acid at the C-terminus and two amino acids at the N-terminus. The PAT protein encoded by the *bar* gene is a homodimer of 183 amino acids and has an expected molecular weight of approximately 22 kDa. The PAT protein in events T303-3 and T304-40 is the same protein that is in a previously commercialized product, BCS LLCotton25.

The overall amino acid sequence of the Cry1Ab protein was compared with sequences of proteins in publicly available databases. No similarities with known allergens or mammalian toxins were observed based on a criterion of 35% identity over 80 amino acids. No similarities between the Cry1Ab protein and known allergens were identified based on 100% identity over an eight amino acid segment.

The current tolerance exemptions for Cry1Ab (40 CFR 180.1173) and PAT (40 CFR 180.1151) are applicable to the proteins produced in the Bayer's Events T303-3 and T304-40. The data submitted and cited are sufficient to support the product characterization and human health assessment of the EUP application.

The data submitted and cited are sufficient to support the environmental risk assessment of the EUP program. Due to the limited acreage and use of a crop-destruct procedure, no hazard is expected to the environment. There are no anticipated significant adverse effects of Cry1Ab proteins on the abundance of non-target beneficial organisms in any population in the field, whether they are pest parasites, pest predators, or pollinators.

## **II. Use Sites, Target Pests, and Application Methods**

- **Use Sites:** Cotton

- **Target Pests:** Lepidopteran pests of cotton including the cotton bollworm (*Helicoverpa zea*), tobacco budworm (*Heliothis virescens*), pink bollworm (*Pectinophora gossypiella*), fall armyworm (*Spodoptera frugiperda*), and beet armyworm (*Spodoptera exigua*)
- **Application Methods:** The product is a plant-incorporated protectant. Cotton plants are genetically-engineered to express the Cry1Ab insecticidal protein.

### **III. Regulatory Information**

Experimental Use Permit, 264-EUP-140 was issued from February 7, 2006 to January 31, 2007. It is authorized for 15 locations only in the states of Louisiana, Mississippi, North Carolina, Puerto Rico, South Carolina, and Texas. Planting under the EUP will not exceed 370 total acres.

Experimental Use Permit, 264-EUP-140, was extended from March 8, 2007 to May 1, 2008. It is authorized for 31 locations only in the states of Arizona, California, Georgia, Louisiana, Mississippi, North Carolina, South Carolina, and Texas. The EUP includes 84 acres of *Bacillus thuringiensis* Cry1Ab cotton and 201 acres of non-Bt plant-incorporated protectant border areas (285 total acres).

### **IV. Registrant Information**

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### **V. Additional Contact Information**

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