Bacillus thuringiensis Cry1F /Cry1Ac Construct 281/3006 Insecticidal Crystal Protein as expressed in cotton (006445 & 006481) Fact Sheet

OPP Chemical Code: 006481 & 006445

Summary

On September 29, 2004, the Agency issued a section 3 registration for a new cotton plant-incorporated protectant (PIP). The trade name for this new PIP is WideStrike Cotton. Dow AgroSciences is the registrant. This new cotton PIP contains two crystal proteins, Cry1F and Cry1Ac which both target lepidopteran pests.

I. Description of the Active Ingredient

Dow AgroSciences (DAS) transformed Acala cotton line GC510 with plasmids pAGM281 and pMYC3006. Cotton event 281-24-236 (Cry1F) resulted in the insertion from pAGM281 of one intact copy of cry1F and one intact copy of pat (plant selectable marker gene, phosphinothricin acetyltransferase). Cotton event 3006-210-23 (Cry1Ac) resulted in the insertion from pMYC3006 of one intact copy of Cry1Ac and one intact copy of Pat. These two Acala cotton lines, Event 281-24-236 (Cry1F) and Event 3006-210-23 (Cry1Ac) were separately backcrossed three times with cotton line PSC355 followed by one generation of self-pollination to yield the BC3F1generation. The two BC3F1 events were then intercrossed and self-pollinated to the F3 generation, forming cottonseed designated 281-24-236/3006-210-23, which designated as WideStrike® (MXB-13).

II. Use Sites, Target Pests, and Application Methods

- **Use sites:** Cotton
- **Target pests:** Cotton bollworm, tobacco budworm, pink bollworm saltmarsh caterpillar, cotton leaf perforator, soybean looper, beet armyworm, fall armyworm, yellowstriped armyworm and European corn borer
- **Application methods:** Plant-incorporated Protectant

III. Assessing Risks to Human Health

The health effects assessment concludes that there is a reasonable certainty that no harm will result from exposure to Cry1F and Cry1Ac. For purposes of the dietary risk assessment, the maximum levels of expression in cottonseed (cotton processed fraction) were 0.46 and 3.1 ng protein/mg tissue fresh weight for Cry1Ac and Cry1F proteins in the pyramided Cry1F/Cry1Ac/PAT product, respectively, based on the expression data.

IV. Assessing Risks to the Environment

The Agency has conducted an environmental hazard assessment of the MXB-13 transgenic cotton line containing pyramided PIPs (Cry1F/Cry1Ac). The assessment includes effects on wildlife, gene flow to related wild plants, development of weediness, fate of Cry1F/Cry1Ac proteins in the environment and effects on endangered species. The assessment is based on data submitted to the Agency during the developmental stages of the transgenic cotton lines. Additional data were submitted for registration.

Based on the evaluation of the submitted limit dose testing data and information on the general biology of Bt Cry proteins, no unreasonable adverse effects on the flora and fauna of the cotton agroecosystems are expected from the cultivation of MXB-13 transgenic cotton. Specific data are cited relating to aquatic and terrestrial wildlife, Cry protein fate in soils, potential effects on soil biota and field census data examining the effects on non-target foliar insects, and endangered or threatened species hazard assessment, particularly Lepidoptera listed by the United States Fish and Wildlife Service (USFWS). The submitted studies examined the effects of the Cry1F and Cry1Ac proteins separately and in combination to detect any possible synergistic effects. No synergistic effects or increase in non-target host range as a result of stacking were seen.

V. Regulatory Information

Dow AgroSciences has developed WideStrike cotton plants that contain two protein, Cry1F and Cry1Ac. Unlike a "stacked" product, which produces pesticides effective against different pests, this "pyramided" product produces pesticides effective against the same type of lepidopteran pests. The Cry1F and Cry1Ac insect control proteins are derived from the common soil microbes Bacillus thuringiensis var. kurstaki Cry1Ac (synpro) and Bacillus thuringiensis var. aizawai Cry1F (synpro). DowAgro Sciences petitioned the Agency for a full commercial section 3 registration on November 13, 2002.

In the Federal Register of August 10, 2004, EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act, (FFDCA), 21 U.S.C. 346a(d), as amended by the Food Quality Protection Act (FQPA) (Public Law 104-170) announcing the filing of pesticide tolerance petition, petition number 3F6785, by Dow AgroSciences for WideStrike cotton. This notice included a summary of the petition prepared by the petitioner Dow AgroSciences. The only comments received in response to the notice of filing were from the National Cotton Council supporting this petition. The petition was for an exemption from the requirement of a temporary tolerance for residues of Cry1F and Cry1Ac when used as PIP in the food and feed commodities of field cotton seed, cotton oil, cotton meal, cotton hay, cotton hulls, cotton forage, and cotton gin by- products. The temporary tolerance exemption was issued by the Agency on April 30, 2003. This temporary tolerance exemption expired May 1, 2004; however, an extension of the temporary tolerance exemption was issued by the Agency which expired May 1, 2005. A permanent tolerance exemption was issued by the Agency on for Cry1Ac on March 31, 2004. In the Federal Register dated August 10, 2004 a notice of filing of pesticide tolerance petition, petition number 3F6785, by Dow AgroSciences for Widestrike cotton. This petition was an exemption from the requirement of a tolerance for residues of Cry1F when used as a PIP in the food and feed commodities of field cotton, seed, cotton oil, cotton meal, cotton hay, cotton hulls, cotton forage, and cotton gin by-products. The permanent tolerance was published on September 30, 2004.

VI. Registrant Information

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VII. Additional Contact Information:

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