



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 27, 2015

Michael Weeks
Registration Manager
Bayer CropScience L.P.
2 T.W. Alexander Drive
Research Triangle Park, N.C. 27709

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling Amendment –
Product Name: T304-40 x GHB119 x COT102
EPA Registration Number: 264-1179
Application Date: July 15, 2015
OPP Decision Number: 507469

Dear Mr. Weeks:

On July 15, 2015, Bayer CropScience L.P. submitted an application to amend the subject registration. Revisions were proposed to:

- Change the name of the product to T304-40 x GHB119 x COT102;
- Add an alternate brand name “TwinLink® Plus”;
- Remove restrictions on growing the subject product in ten counties in Texas: Dallam, Sherman, Hansford, Ochiltree, Lipscomb, Hartley, Moore, Hutchinson, Roberts, and Carson;
- To the product label, add the specific structured refuge requirements for Arizona, California, New Mexico, and fourteen Texas Trans-Pecos counties of Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler.

The proposed revisions to the subject product registration and label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, are acceptable. You continue to be subject to all other existing terms and conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling reflecting the new product name is enclosed for your records. This labeling supersedes all previously accepted labeling. In accordance with 40 CFR § 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. “To distribute or sell” is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR § 152.3.

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Should you wish to add/retain a reference to your company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the U.S. Environmental Protection Agency (EPA). If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the EPA find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6.

If you have any questions, please contact Kenneth Haymes, Ph.D. of my team by phone at (703) 347-0398 or via email at haymes.kenneth@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'Alan Reynolds', with a long horizontal flourish extending to the right.

Alan Reynolds, Team Leader
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs

Enclosure: Stamped Label

Plant-Incorporated Protectant Label

T304-40 x GHB119 x COT102
Insect-Protected, Herbicide Tolerant Cotton
(Alternate Brand Name: TwinLink® Plus)
(OECD Unique Identifier: BCS-GH004-7 x BCS-GH005-8 x
SYN-IR102-7)

Active Ingredients:

Bacillus thuringiensis Cry1Ab protein and the genetic material (from plasmid pTDL008) necessary for its production in Event T304-40 x GHB119 x COT102 cotton.....0.000071 - 0.001055%*

Bacillus thuringiensis Cry2Ae protein and the genetic material (from plasmid pTEM12) necessary for its production in Event T304-40 x GHB119 x COT102 cotton..... 0.005543 - 0.013779%

Bacillus thuringiensis Vip3Aa19 protein and the genetic material (from plasmid pCOT1) necessary for its production in Event T304-40 x GHB119 x COT102 cotton..... 0.002957 - 0.011624%

Inert Ingredients:

Substance produced by a herbicide tolerance gene and its controlling sequences (from plasmids pTDL008 and pTEM12) necessary for its production in Event T304-40 x GHB119 x COT102 cotton.....0.028049 - 0.065381%

Substance produced by a marker gene and its controlling sequences (from plasmid pCOT1) necessary for its production in Event T304-40 x GHB119 x COT102.....< 0.000045%

*Percentage protein on a dry weight basis as expressed in whole cotton plants.

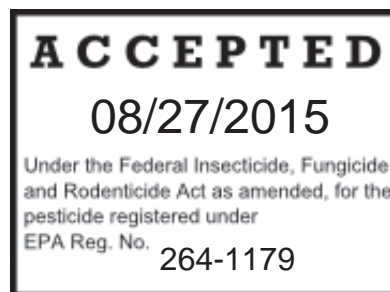
KEEP OUT OF REACH OF CHILDREN CAUTION

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EPA ESTABLISHMENT NUMBER: 000264-TX-004

Bayer CropScience LP 2
T.W. Alexander Dr.
Research Triangle Park, NC 27709



DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Information regarding commercial production must be included in the Trait Technology Use Manual.

T304-40 x GHB119 x COT102 protects cotton plants from damage caused by certain lepidopteran cotton pests.

CROP	PESTS
Cotton	Cotton Bollworm (<i>Helicoverpa zea</i>) Tobacco Budworm (<i>Heliothis virescens</i>) Pink Bollworm (<i>Pectinophora gossypiella</i>) Fall Armyworm (<i>Spodoptera frugiperda</i>) Beet Armyworm (<i>Spodoptera exigua</i>) Other lepidopteran insects in cotton

The following information regarding commercial production must be included in the Trait Technology Use Manual:

- a) No commercial planting of this product is permitted south of Route 60 (near Tampa) in Florida.
- b) Commercial planting of this product is prohibited in Hawaii, Puerto Rico and the U.S. Virgin Islands.

The following information regarding test plots and seed production must occur on bags of T304-40 x GHB119 x COT102 seed intended for these purposes:

- a) Test plots or breeding nurseries, regardless of plot size, established in Hawaii must not be planted within 3 miles of *Gossypium tomentosum*.
- b) Experimental plots and breeding nurseries of T304-40 x GHB119 x COT102 cotton are prohibited on the U.S. Virgin Islands, and
- c) Test plots or breeding nurseries, regardless of the plot size, established on the island of Puerto Rico must not be planted within 3 miles of feral cotton plants.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Storage: Store in a cool, dry place inaccessible to children.

Pesticide disposal: Any seed not used must be returned to the seed provider.

Container disposal: Do not reuse the bag. Ensure that the bag is completely empty of seeds prior to destroying.

INSECT RESISTANCE MANAGEMENT

Growers of T304-40 x GHB119 x COT102 Cotton in the states of Arizona, California, and New Mexico and in the following Texas counties: Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler must employ one of the following structured refuge options:

1) External, Unsprayed Refuge

Ensure that at least 5 acres of non-*Bt* cotton (refuge cotton) is planted for every 95 acres of T304-40 x GHB119 x COT102 Cotton. The size of the refuge must be at least 150 feet wide, but preferably 300 feet wide. This refuge may not be treated with sterile insects, pheromone, or any insecticide (except listed below) labeled for the control of tobacco budworm, cotton bollworm, or pink bollworm. At the pre-squaring cotton stage only, the refuge may be treated with any lepidopteran insecticide to control foliage feeding caterpillars. The refuge may be treated with acephate or methyl parathion at rates which will not control tobacco budworm or the cotton bollworm (equal to or less than 0.5 lbs active ingredient per acre). The variety of cotton planted in the refuge must be comparable to T304-40 x GHB119 x COT102 Cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, termination, and management of other pests) similarly to T304-40 x GHB119 x COT102 Cotton. Ensure that a non-*Bt* cotton refuge is maintained within at least ½ linear mile (preferably adjacent to or within ¼ mile or closer) from the *Bt* cotton fields.

2) External, Sprayed Refuge

Ensure that at least 20 acres of non-*Bt* cotton are planted as a refuge for every 80 acres of T304-40 x GHB119 x COT102 Cotton (total of 100 A). The variety of cotton planted in the refuge must be comparable to *Bt* cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, termination, and management of other pests) similarly to T304-40 x GHB119 x COT102 Cotton. The non-*Bt* cotton may be treated with sterile insects, insecticides (excluding foliar *Bt. kurstaki* products), or pheromones labeled for control of the tobacco budworm, cotton bollworm, or pink bollworm. Ensure that a non-*Bt* refuge is maintained within at least 1 linear mile (preferably within ½ mile or closer) from the *Bt* cotton fields.

3) Embedded Refuge Options (for pink bollworm only)

Refuge cotton must be planted as at least one single non-*Bt* cotton row for every six to ten rows of T304-40 x GHB119 x COT102 Cotton. The refuge may be treated with sterile insects, any insecticide (excluding foliar *Bt. kurstaki* products), or pheromone labeled for the control of pink bollworm whenever the entire field is treated. The in-field refuge rows may not be treated independently of the surrounding *Bt* cotton field in which it is embedded. The refuge must be managed (fertilizer, weed control, etc.) identically to the T304-40 x GHB119 x COT102 Cotton. There is no field unit option.