



U.S. ENVIRONMENTAL PROTECTION AGENCY
 Office of Pesticide Programs
 Biopesticides and Pollution Prevention Division (7511P)
 1200 Pennsylvania Ave., N.W.
 Washington, D.C. 20460

EPA Reg. Number:

67979-39

Date of Issuance:

2/18/2021

NOTICE OF PESTICIDE:

Registration
 Reregistration
 (under FIFRA, as amended)

Term of Issuance:

Unconditional

Name of Pesticide Product:

Bt11 × MIR604 × TC1507 × 5307 and
 Bt11 × MIR162 × MIR604 × TC1507
 × 5307 5% Refuge Seed Blend Corn

Name and Address of Registrant (include ZIP Code):

Syngenta Seeds, LLC – Field Crops – NAFTA
 9 Davis Drive, P.O. Box 12257
 Research Triangle Park, NC 27709

Note: Changes in labeling differing in 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 in commerce. 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 under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA or the Act).

Registration is in no way to be construed as an endorsement or recommendation of this product by the U.S. Environmental Protection Agency (EPA). In order to protect health and the environment, the Administrator, on his or her 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 the 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.

This product is unconditionally registered in accordance with FIFRA section 3(c)(5) provided that you:

1. The subject registration will automatically expire on midnight January 31, 2029.
2. Submit and/or cite all data required for registration or registration review of your product when the EPA requires all registrants of similar products to submit such data.

Signature of Approving Official:

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

Date:

2/18/2021

3. The subject registration will be limited to a seed mix of 80% *Bacillus thuringiensis* Cry1Ab, Vip3Aa20, mCry3A, Cry1F, and eCry3.1Ab proteins and the genetic material necessary for their production in Event Bt11 [OECD Unique ID. SYN-BT011-1], Event MIR162 [OECD Unique ID. SYN-IR162-4], Event MIR604 [OECD Unique ID. SYN-IR604-5], Event TC1507 [OECD Unique Identifier: DAS-01507-1], Event 5307 [OECD Unique Identifier: SYN- 05307-1] and 15% *Bacillus thuringiensis* Cry1Ab, mCry3A, Cry1F, and eCry3.1Ab proteins and the genetic material necessary for their production in Event Bt11 [OECD Unique ID. SYN-BT011-1], Event MIR604 [OECD Unique ID. SYN-IR604-5] Event TC1507 [OECD Unique Identifier: DAS-01507-1)], and Event 5307 [OECD Unique Identifier: SYN- 05307-1] corn seed blended with not less than 5% non-Bt corn seed.
4. This product may be grown only in the state of Kansas.
5. Make the following labeling change before you release this product for shipment:
 - Revise the EPA Registration Number to read, “EPA Reg. No. 67979-39.”
6. You must commit to do the following Insect Resistance Management (IRM) Program, consisting of the following elements:
 - Requirements for Syngenta Seeds, LLC-Field Crops-NAFTA (Syngenta) to implement an IPM-based stewardship program designed to reduce selection pressure for corn rootworm (CRW) resistance.
 - Requirements relating to a refuge assurance program for ensuring the correct refuge blend percentage.
 - Requirements for Syngenta to prepare and require Bt11 × MIR604 × TC1507 × 5307 and Bt11 × MIR162 × MIR604 × TC1507 × 5307 5% Refuge Seed Blend Corn users to sign grower agreements that impose binding contractual obligations on growers to comply with the growing requirements.
 - Requirements for Syngenta to develop, implement, and report to EPA on programs to educate growers about IRM for seed blends.
 - Requirements for Syngenta to develop, implement, and report to EPA on monitoring programs to evaluate whether there are statistically significant and biologically relevant changes in susceptibility to the Cry1Ab, Cry1F, and Vip3Aa20 proteins in the target insects.
 - Requirements for Syngenta to develop, and if triggered, to implement a remedial action plan that would contain measures Syngenta would take in the event that any field-relevant insect resistance to Cry1Ab, Cry1F, and Vip3Aa20 was detected, as well as to report on activity under the plan to EPA.
 - Requirements for Syngenta to investigate reports of unexpected CRW damage to Bt11 × MIR604 × TC1507 × 5307 and Bt11 × MIR162 × MIR604 × TC1507 × 5307 5% Refuge Seed Blend Corn from growers (“performance inquiries”) and sample CRW to determine if the insects are resistant to mCry3A, and eCry3.1Ab.

- Requirements for Syngenta to recommend CRW management options to growers in response to cases of unexpected CRW damage to Bt11 × MIR604 × TC1507 × 5307 and Bt11 × MIR162 × MIR604 × TC1507 × 5307 5% Refuge Seed Blend Corn.
- Requirements regarding mitigation and notification actions that Syngenta would take in the event that CRW resistance was detected.
- Requirements for Syngenta to make available to the Agency upon request records of the number of units of Bt11 × MIR604 × TC1507 × 5307 and Bt11 × MIR162 × MIR604 × TC1507 × 5307 5% Refuge Seed Blend Corn sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements for the previous growing season, within three months of the request.
- Requirements for Syngenta to submit reports on CRW IPM stewardship and resistance monitoring within the time frames specified in this registration notice.

a. Integrated Pest Management Stewardship Program (IPM)

- 1) Syngenta must implement an IPM-based stewardship program for Bt11 × MIR604 × TC1507 × 5307 and Bt11 × MIR162 × MIR604 × TC1507 × 5307 5% Refuge Seed Blend Corn. This program must be designed to reduce selection pressure for CRW resistance by encouraging growers to engage in a multi-year crop rotation strategy involving the use of one or more of the following: a non-CRW host crop (e.g., soybean), pyramided Bt corn Plant Incorporated Protectants (PIPs), other PIP corn products with different modes of action, and/or non-Bt or non-CRW protected *Bt* corn. As part of the stewardship program, Syngenta must update the technology use guide/grower guide and other grower educational materials to indicate that application of an insecticide to the soil surface, in furrows, and/or incorporated into the soil (referred to as “soil applied insecticide”, “soil insecticide” or “SAI”) with Bt11 × MIR604 × TC1507 × 5307 and Bt11 × MIR162 × MIR604 × TC1507 × 5307 5% Refuge Seed Blend Corn is not recommended for control of CRW except under limited circumstances and in consultation with extension, crop consultants or other local experts. Grower education materials should also state that SAIs should not be necessary for CRW control with pyramided CRW trait *Bt* corn product(s). As part of the stewardship program, Syngenta must promote the ABSTC/NCGA Best Management Practices (BMPs) for CRW control. Implementation of the IPM strategy can include:
 - Grower education initiatives or incentives;
 - Outreach to extension and consultant groups.
- 2) Syngenta must submit an annual report to EPA documenting activities conducted under the IPM stewardship program. This report must include an anonymous survey of grower practices, including adoption levels of the various crop rotation options (if employed) and other elements of the stewardship program. Syngenta may combine this product with other registered products to submit one annual report. The report must be submitted by January 31st each year.

b. Refuge requirements for Bt11 × MIR604 × TC1507 × 5307 and Bt11 × MIR162 × MIR604 × TC1507 × 5307 5% Refuge Seed Blend Corn:

Bt11 × MIR604 × TC1507 × 5307 and Bt11 × MIR162 × MIR604 × TC1507 × 5307 5% Refuge Seed Blend Corn contains a Lepidopteran and corn rootworm refuge that is “in the bag” and is automatically implemented when the grower plants the product. No additional refuge is required when planting this product. Foliar insecticide treatments for control of European corn borer, corn earworm, southwestern corn borer, fall armyworm, black cutworm, western bean cutworm, lesser corn stalk borer, southern corn stalk borer, common stalk borer and sugarcane borer may be applied only if economic thresholds are reached for one or more of these target pests.

Foliar insecticide treatments are also permitted for control of corn rootworm adults if economic thresholds are reached. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants).

c. Grower Agreements for Bt11 × MIR604 × TC1507 × 5307 and Bt11 × MIR162 × MIR604 × TC1507 × 5307 5% Refuge Seed Blend Corn

- 1) Persons purchasing Bt11 × MIR604 × TC1507 × 5307 and Bt11 × MIR162 × MIR604 × TC1507 × 5307 5% Refuge Seed Blend Corn must sign a grower agreement. The term grower agreement refers to any grower purchase contract, license agreement, or similar legal document.
- 2) The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.
- 3) Syngenta must integrate this registration into the current system used for its other Bt corn plant-incorporated protectants, which is reasonably likely to assure that persons purchasing Bt11 × MIR604 × TC1507 × 5307 and Bt11 × MIR162 × MIR604 × TC1507 × 5307 5% Refuge Seed Blend Corn will affirm annually that they are contractually bound to comply with the requirements of the IRM program.
- 4) If Syngenta wishes to change any part of the grower agreement or any specific stewardship documents referenced in the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, 30 days prior to implementing a proposed change, Syngenta must submit to EPA the text of such changes to ensure it is consistent with the terms and conditions of this registration.
- 5) Syngenta shall maintain records of all Bt11 × MIR604 × TC1507 × 5307 and Bt11 × MIR162 × MIR604 × TC1507 × 5307 5% Refuge Seed Blend Corn grower agreements for a period of three (3) years from December 31st of the year in which the agreement was signed.
- 6) Syngenta shall make available to the Agency upon request records of the number of units of Refuge Seed Blend Corn seed sold or shipped and not returned, and the Bt11 × MIR604 × TC1507 × 5307 and Bt11 × MIR162 × MIR604 × TC1507 × 5307 5% Refuge Seed Blend

Corn number of such units that were sold to persons who have signed grower agreements for the previous growing season, within three months of the request.

- 7) Syngenta must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license numbers of the growers, will be protected.

d. IRM Education Program for Bt11 × MIR604 × TC1507 × 5307 and Bt11 × MIR162 × MIR604 × TC1507 × 5307 5% Refuge Seed Blend Corn

- 1) Syngenta must implement and enhance a comprehensive, ongoing IRM education program designed to convey to Bt11 × MIR604 × TC1507 × 5307 and Bt11 × MIR162 × MIR604 × TC1507 × 5307 5% Refuge Seed Blend Corn users the importance of complying with the IRM program, as well as seed blend product performance expectations and guidance to growers on actions to take when unexpected damage occurs. The education program shall involve the use of multiple media (e.g., face-to-face meetings, mailing written materials, and electronic communications such as by Internet, radio, or television commercials). The program shall involve at least one (1) written communication annually to each Bt11 × MIR604 × TC1507 × 5307 and Bt11 × MIR162 × MIR604 × TC1507 × 5307 5% Refuge Seed Blend Corn user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. Syngenta shall coordinate its education programs with educational efforts of other registrants and organizations, such as the National Corn Growers Association and state extension programs.
- 2) Upon EPA request, Syngenta shall provide copies of grower education materials and information on grower education activities including any substantive changes to these materials and activities conducted either individually or as part of a report from the industry working group, Agricultural Biotechnology Stewardship Technical Committee (ABSTC). Syngenta is required to submit reports within three months of the Agency's request.

e. Insect Resistance Monitoring and Remedial Action Plans for Bt11 × MIR604 × TC1507 × 5307 and Bt11 × MIR162 × MIR604 × TC1507 × 5307 5% Refuge Seed Blend Corn

- 1) EPA is imposing the following conditions for the Cry1Ab, Cry1F and Vip3Aa20 toxins expressed in Bt11 × MIR604 × TC1507 × 5307 and Bt11 × MIR162 × MIR604 × TC1507 × 5307 5% Refuge Seed Blend Corn:

Syngenta will monitor for resistance to Bt11 × MIR604 × TC1507 × 5307 and Bt11 × MIR162 × MIR604 × TC1507 × 5307 5% Refuge Seed Blend Corn. The monitoring program shall consist of two approaches: (1) focused population sampling and laboratory testing; and (2) investigation of reports of less-than expected control of labeled insects. Should field-relevant resistance be confirmed, an appropriate remedial action plan will be implemented.

Focused Population Sampling

Syngenta shall annually sample and bioassay populations of the key target pests: *Ostrinia nubilalis* (European corn borer; ECB), *Diatraea grandiosella* (southwestern corn borer; SWCB), and *Helicoverpa zea* (corn earworm; CEW). Sampling for the target pests will be

focused in areas identified as those with the highest risk of resistance development (e.g., where lepidopteran-active Bt hybrids are planted on a high proportion of the corn acres, and where the insect species are regarded as key pests of corn). Bioassay methods must be appropriate for the goal of detecting field-relevant shifts in population response to Bt11 × MIR604 × TC1507 × 5307 and Bt11 × MIR162 × MIR604 × TC1507 × 5307 5% Refuge Seed Blend Corn and/or changes in resistance allele frequency in response to the use Bt11 × MIR604 × TC1507 × 5307 and Bt11 × MIR162 × MIR604 × TC1507 × 5307 5% Refuge Seed Blend Corn and, as far as possible, should be consistent across sampling years to enable comparisons with historical data.

The number of populations to be collected shall reflect the regional importance of the insect species as a pest, and specific collection regions will be identified for each pest. For ECB, a minimum of twelve (12) populations across the sampling region will be targeted for collection at each annual sampling. For SWCB, the target will be a minimum of six (6) populations. For CEW, the target will be a minimum of ten (10) populations. Pest populations should be collected from multiple corn-growing states reflective of different geographies and agronomic conditions. To obtain sufficient sensitivity to detect resistance alleles before they become common enough to cause measurable field damage, each population collection shall attempt to target 400 insect genomes (egg masses, larvae, mated females, and/or mixed- sex adults), but a successful population collection will contain a minimum of 100 genomes. It is recognized that it may not be possible to collect the target number of insect populations or genomes due to factors such as natural fluctuations in pest density, environmental conditions, and area-wide pest suppression.

The sampling program and geographic range of collections may be modified as appropriate based on changes in pest importance and for the adoption levels of Bt11 × MIR604 × TC1507 × 5307 and Bt11 × MIR162 × MIR604 × TC1507 × 5307 5% Refuge Seed Blend Corn. EPA shall be consulted prior to the implementation of such modifications.

Syngenta will report to EPA, on or before August 31st of each year, the results of the population sampling and bioassay monitoring program.

Any incidence of unusually low sensitivity to the Cry1Ab, Cry1F and Vip3Aa20 proteins in bioassays shall be investigated as soon as possible to understand any field relevance of such a finding. Such investigations shall proceed in a stepwise manner until the field relevance can be either confirmed or refuted, and results of these shall be reported to EPA annually on or before August 31st. The investigative steps will include the following:

1. Re-test progeny of the collected population to determine whether the unusual bioassay response is reproducible and heritable. If it is not reproducible and heritable, no further action is required.
2. If the unusual response is reproducible and heritable, progeny of insects that survive the diagnostic concentration will be tested using methods that are representative of exposure to Bt11 × MIR604 × TC1507 × 5307 and Bt11 × MIR162 × MIR604 × TC1507 × 5307 5% Refuge Seed Blend Corn under field conditions. If progeny do not survive to adulthood, any suspected resistance is not field relevant, and no further action is required.

3. If insects survive steps 1 and 2, resistance is confirmed, and further steps will be taken to evaluate the resistance. These steps may include the following:
 - Determining the nature of the resistance (i.e., recessive or dominant, and the level of functional dominance);
 - Estimating the resistance allele frequency in the original population;
 - Determining whether the resistance-allele frequency is increasing by analyzing field collections in subsequent years sampled from the same site where the resistance allele(s) was originally collected;
 - Determining the geographic distribution of the resistance allele by analyzing field collections in subsequent years from sites surrounding the site where the resistance allele(s) was originally collected.

Should field-relevant resistance be confirmed, and the resistance appears to be increasing or spreading, Syngenta will consult with EPA to develop and implement a case-specific remedial action plan.

Investigation of Reports of Unexpected Levels of Damage by the Target Pests

Syngenta will follow up on grower, extension specialist, or consultant reports of unexpected levels of damage by the lepidopteran pests listed on the pesticide label. Syngenta will instruct its customers to contact them if such incidents occur and provide guidance to growers on seed blend product performance expectations and actions to take when unexpected damage occurs. Syngenta will investigate all legitimate reports submitted to the company or the company's representatives.

If reports of unexpected levels of damage lead to the suspicion of resistance in any of the key target pests (ECB, SWCB, and CEW), Syngenta will implement the actions described below, based on the following definitions of suspected resistance and confirmed resistance.

Suspected Resistance

EPA defines suspected resistance to mean field reports of unexpected levels of insect-feeding damage for which:

- The corn in question has been confirmed to be lepidopteran-active Bt corn;
- The seed used had the proper percentage of corn expressing Bt protein;
- The relevant plant tissues are expressing the expected level of Bt protein; and

It has been ruled out that species not susceptible to the protein could be responsible for the damage, that no climatic or cultural reasons could be responsible for the damage, and that that there could be no other reasonable causes for the damage.

EPA does not interpret suspected resistance to mean grower reports of possible control failures or suspicious results from annual insect monitoring assays, nor does EPA intend that extensive field studies and testing be undertaken to confirm scientifically the presence of insects resistant to Bt11 × MIR604 × TC1507 × 5307 and Bt11 × MIR162 × MIR604 × TC1507 × 5307 5% Refuge Seed Blend Corn in commercial production fields before responsive measures are undertaken.

If resistance is suspected, Syngenta will instruct growers to do the following:

- Use alternative control measures in Bt11 × MIR604 × TC1507 × 5307 and Bt11 × MIR162 × MIR604 × TC1507 × 5307 5% Refuge Seed Blend Corn fields in the affected region to control the target pest during the immediate growing season.
- Destroy Bt11 × MIR604 × TC1507 × 5307 and Bt11 × MIR162 × MIR604 × TC1507 × 5307 5% Refuge Seed Blend Corn crop residues in the affected region within one (1) month after harvest with a technique appropriate for local production practices to minimize the possibility of resistant insects over-wintering and contributing to the next season's target pest population.

Additionally, if possible, and prior to the application of alternative control measures or destruction of crop residues, Syngenta will collect samples of the insect population in the affected fields for laboratory rearing and testing. Such rearing and testing shall be conducted as expeditiously as practical.

Confirmed Resistance

EPA defines confirmed resistance to mean, in the case of field reports of unexpected levels of damage from the key target pests, that all of the following criteria are met:

- There is >30% insect survival and commensurate insect feeding in a bioassay, initiated with neonate larvae, that uses methods that are representative of exposure to Bt corn hybrids under field conditions (ECB and SWCB only).
- In standardized laboratory bioassays using diagnostic concentrations of the Bt protein suited to the target pest in question, the pest exhibits resistance that has a genetic basis and the level of survivorship indicates that there may be a resistance allele frequency of ≥ 0.1 in the sampled population.
- In standardized laboratory bioassays, the LC_{50} exceeds the upper limit of the 95% confidence interval of the LC_{50} for susceptible populations surveyed both in the original baselines developed for this pest species and in previous years of field monitoring.

Response to Confirmed Resistance in a Key Target Pest as the Cause of Unexpected Levels of Damage in the Field

When field resistance is confirmed (as defined above), the following steps will be taken by Syngenta:

A report on results of resistance monitoring and investigations of damage reports must be submitted to EPA, on or before August 31st of each year, for the duration of the registration.

2) EPA is imposing the following conditions for the mCry3A, and eCry3.1Ab toxins expressed in Bt11 × MIR604 × TC1507 × 5307 and Bt11 × MIR162 × MIR604 × TC1507 × 5307 5% Refuge Seed Blend Corn:

- a) Investigation of Reports of Unexpected Levels of Damage (UXD) by Corn Rootworm (CRW): Performance Inquiries
 1. Syngenta is required to investigate "performance inquiries" (i.e., reports of unexpected CRW damage to Bt11 × MIR604 × TC1507 × 5307 and Bt11 × MIR162 × MIR604 × TC1507 × 5307 5% Refuge Seed Blend Corn) from growers. Fields (defined as a tract separated by permanent boundaries such as fences, permanent waterways, woodlands, crop lines not subject to change because of farming practices, or other similar features) with unexpected damage that meet both of the criteria below must be subjected to the follow-up actions in part 2) below:
 - a. The affected plants are confirmed to be Bt11 × MIR604 × TC1507 × 5307 and Bt11 × MIR162 × MIR604 × TC1507 × 5307 5% Refuge Seed Blend Corn plants (take leaf samples to determine the presence of the CRW- active Bt protein); and
 - b. Corn rootworm feeding caused root damage with a Node Injury Score (NIS) > 0.5 on at least 50% of plants surveyed in a transect sampling of the damaged site(s) within the field.
 2. Follow-up actions (performance inquiries). For Bt11 × MIR604 × TC1507 × 5307 and Bt11 × MIR162 × MIR604 × TC1507 × 5307 5% Refuge Seed Blend Corn fields meeting the criteria in part 1) above, Syngenta must take the following actions:
 - a. Collect at least 250 (ideally 500 or more) CRW adult individuals from the damaged site within the field in question. Collections may be extended to the whole field, if necessary to obtain sufficient CRW adult individuals. Collected populations must be subjected to the steps described for "investigation of populations of concern" in section e(2)(b) below.
 - If collections are unsuccessful, visit affected farm or field the following year (assuming the grower continues to be a customer and repurchases seed and does not rotate the field to a non-host crop) and attempt to collect CRW adults. If beetles are not present the subsequent year, see section e(2)(b)(3)(c) below.
 - b. Review with the grower their CRW management practices and provide CRW management recommendations including an assessment of corn fields with similar trait(s) adjacent to the affected corn field that are managed by the same grower.
 - c. Use of single trait products containing the CRW traits in Bt11 × MIR604 × TC1507 × 5307 and Bt11 × MIR162 × MIR604 × TC1507 × 5307 5% Refuge

Seed Blend Corn in fields with unexpected damage in previous years should be discouraged. Recommended management options include, but are not limited to, the following:

- Primary option: Rotation to non-host crop (e.g., soybean)
 - Secondary options:
 - Use of pyramided Bt corn products one or more different CRW PIP trait(s);
 - Use of different single-CRW PIP traits (i.e., an alternative CRW-active PIP);
 - Use of non-Bt or non-CRW protected corn.
 - Tertiary options:
 - If additional pest management need is determined beyond the secondary options listed above, use of the same pyramided Bt corn product is acceptable if it is very unlikely that both of the traits are affected (e.g., the affected field experienced UXD to one of the traits in the product in the previous year, the NIS is less than 1.0, there has been no continuous use of the second trait in the product in the affected field, and Syngenta has not been informed of resistance to the second trait in the county);
 - Additional corn rootworm control tools (e.g., soil applied insecticides, chemigation) should be considered.
- d. If field(s) with UXD is/are planted to a non-host crop (e.g., soybean) the following year, then the area will be considered “mitigated” (as discussed in section e(2)(b)(3)(d) below) even if subsequent bioassay results show that the population was resistant. No further action will be required by Syngenta for the UXD case.
3. Syngenta must submit an annual report to EPA detailing activities related to investigations of unexpected damage (UXD). This report will include the information from the most recent and previous corn growing seasons:
- a. Information from the most recent season:
 - The number of UXD reports investigated;
 - Location (by county and state);
 - CRW sampling (number and location of populations collected).
 - b. Information from the previous season:
 - The final disposition of UXD fields from the previous season (i.e., the management practices
 - employed in response to UXD if the grower continues to be a customer;
 - Results from bioassays conducted on CRW populations from UXD fields where the primary management option, rotation to non-host crop, was not used.
 - c. Grower information, such as farm addresses or other personally identifiable information, or other sensitive business/customer information must not be

included in this report. This report must be submitted by November 30th each year.

b) Investigation of Populations of Concern

1. Syngenta must conduct investigations of all CRW populations collected as part of the performance inquiry process in section e(2)(a) above. These investigations must include the use of an EPA-approved bioassay to determine if sampled CRW populations are resistant to any of the CRW PIP toxins in Bt11 × MIR604 × TC1507 × 5307 and Bt11 × MIR162 × MIR604 × TC1507 × 5307 5% Refuge Seed Blend Corn. Acceptable assays must be able to function as diagnostic tools capable of distinguishing resistant populations from susceptible ones. Unless previously approved, Syngenta must consult with EPA on their bioassay prior to its use.
2. A CRW population will be considered by EPA to be resistant to a CRW PIP toxin if the following criteria are met and additional collections and testing are not deemed to be necessary (based on part 3 below):
 - a. An initial performance inquiry investigation results in a finding of Unexpected Damage; and
 - b. Where green tissues are available and if plants are unusually stressed due to agronomic and/or environmental factors, Bt protein levels in affected plants are found to be within the documented range for that hybrid (if data are available); and
 - c. Either (A): On-plant bioassays of insect collections from the UXD fields result in the following two statistically relevant comparisons:
 - i. A statistically significant difference in measures of either mortality or sublethal effects (growth/development) between the field population and a relevant susceptible control population (i.e., one that responds as a typical susceptible field population) on Bt corn containing the single PIP and/or lack of a statistically significant difference in measures of mortality or sublethal effect between the field population and a resistant positive control population¹; and
 - ii. A lack of a statistically significant difference in the same measures of the field population raised on Bt corn containing the single PIP and non-Bt corn plants.

Or (B): Sublethal seedling bioassay of insect collections from the UXD fields result in two statistically relevant comparisons

- i. A statistically significant difference in measures of sublethal effects (growth/development) for populations on Bt corn containing the single PIP (normalized using non-Bt) seedlings between the field population and a relevant susceptible control population where available or historical field

¹ If a resistant positive control population is not available or accessible, Syngenta must consult with EPA prior to initiating bioassays and work to develop an appropriate resistant positive control population.

- populations and/or lack of a statistically significant difference in measures between the field population and a resistant positive control population¹; and
- ii. A lack of a statistically significant difference in the same measures of the field population raised on Bt corn seedlings containing the single PIP and non-Bt corn seedlings.

Or (C): Diet-based bioassays of insect collections from the UXD fields result in two statistically relevant comparisons:

- i. A statistically significant difference in measures of lethal or sublethal effects (growth/development) on diet containing the Bt protein (diagnostic concentration or concentration-response measures) between the field population and a relevant susceptible control population where available or historical field populations and/or lack of a statistically significant difference in measures between field population and a resistant positive control population¹; and
 - ii. Either a lack of a statistically significant difference in the same measures of the field population exposed to diet containing the Bt protein (diagnostic concentration) and diet not containing the Bt protein and/or lack of a statistically significant difference in measures between the field population and a resistant positive control population, or lack of a statistically significant concentration and/or lack of a statistically significant difference in concentration response between the field and a resistant positive control population¹.
3. Mitigation, as detailed in section e(2)(c) below, is required for any CRW population that meets EPA's resistance criteria above for any of the CRW traits in Bt11 × MIR604 × TC1507 × 5307 and Bt11 × MIR162 × MIR604 × TC1507 × 5307 5% Refuge Seed Blend Corn, unless the circumstances described below are applicable.
- a. To minimize the potential for incorrectly reaching a conclusion of resistance, another year of CRW adult collections and additional testing is needed to determine resistance if:
 - i. The results of the bioassays are inconclusive (e.g., the results of the statistical analysis are unclear because of low sample sizes) or
 - ii. Another reasonable explanation for the unexpected damage exists (e.g., high pest pressure and/or high plant stress).
 - b. In these cases, Syngenta and EPA will discuss and align on next steps before reaching any resistance conclusion.
 - c. If CRW collections are not possible in the current year or subsequent year due to successful management practices, then no further investigation is needed. The population would be considered "mitigated" meaning, in this case, that the population is suppressed or extirpated for the UXD field. However, EPA recommends that Syngenta continue to be vigilant in areas where CRW populations were successfully mitigated.

- d. If a UXD field receives non-host crop (e.g., soybean) rotation the following year as described in Section e(2)(a)(2) above, no additional mitigation is subsequently required.

c) Mitigation of CRW Populations Meeting EPA's Resistance Criteria

1. For any CRW population found to be resistant to one or more of the CRW traits Bt11 × MIR604 × TC1507 × 5307 and Bt11 × MIR162 × MIR604 × TC1507 × 5307 5% Refuge Seed Blend Corn under EPA's criteria described in section e(2)(b) above, Syngenta must take the following steps:
 - a. Syngenta must inform EPA of the results of the bioassays as soon as possible, but at least within 30 days if measures are triggered.
 - b. The mitigation action area (MAA) is defined as the growers' farming operation up to a ½ mile radius from the damaged site that produced the resistant population.
 - c. Within 30 days of informing EPA of the results of the bioassays, Syngenta must notify state extension agents and crop consultants who operate within the county in which resistance was identified. Information shared must include identification of the county in which resistance was detected and trait(s) affected.
 - d. Within the MAA, Syngenta must do the following:
 - i. Prior to finalizing the grower's seed order for the following season, inform the affected grower and other registrants that hold registrations containing the compromised trait(s). Syngenta must also inform neighboring growers if those growers are customers of Syngenta. Information shared must include identification of the county in which resistance was detected and trait(s) affected;
 - ii. Discontinue sales/planting of products containing the compromised trait(s) without additional/alternative (i.e. non-compromised) CRW traits until resistance has been demonstrated to have been mitigated. Other Bt registrants selling such products in the MAA are encouraged, but cannot be required, to follow suit;
 - iii. Syngenta must monitor the resistant population in the MAA, as long as grower remains a customer of the company, until mitigation has been demonstrated as described in part e. below unless otherwise agreed with EPA.
 - iv. Require any pyramids sold by Syngenta containing the compromised trait(s) be planted with a 20% refuge until resistance has been demonstrated to have been mitigated. Other Bt corn registrants selling such pyramided products in the MAA are encouraged, but cannot be required by this term of registration, to follow suit;
 - v. For Syngenta's affected customer's field(s), the mitigation goal is to control the resistant CRW population. Within the MAA Syngenta shall encourage the use of "Mitigation Practices" including:
 1. Primary option: Rotation to a non-host crop (e.g., soybean);

2. Secondary options:
 - a. Use of pyramided Bt corn products with different CRW PIP traits;
 - b. Only in the case that the resistance definition for one of the CRW traits in the Bt11 × MIR604 × TC1507 × 5307 and Bt11 × MIR162 × MIR604 × TC1507 × 5307 5% Refuge Seed Blend Corn is not met, continued use of the product with a 20% refuge;
 - c. Use of different single-CRW PIP traits (i.e., an alternative CRW-active PIP);
 - d. Use of non-Bt corn or non-CRW protected corn (with/without soil-applied insecticide);
 3. Tertiary options:
 - a. If additional pest management need is determined beyond the secondary options listed above, additional CRW control tools (e.g., soil insecticides, seed-applied insecticides, chemigation) should be used.
 - b. Use of foliar applications to control adults (when appropriate economic thresholds have been met) may be used in conjunction with one or more of the above;
- e. A resistant CRW population in the MAA will be considered mitigated if one of the following criteria are met:
- i. Corn fields within the MAA are rotated to a non-host crop (e.g. soybean) for one growing season.
 - ii. After implementation of mitigation practices (part d.v. above), resistance monitoring (sampling) is conducted but few CRW are found (i.e., <0.1 adults per plant) and environmental conditions (e.g., weather) are unlikely to be responsible for the lack of adult CRW presence. If environmental conditions are a factor, then monitoring should continue for another season.
 - iii. After implementation practices (part d.v. above), resistance monitoring (sampling) is conducted, CRW are found and collected, and bioassays (section e(2)(b)(2) above) show that the population susceptibility to the compromised trait(s) has returned to baseline levels.
- f. The mitigation actions in part d above can be lifted, and growers can resume the use Bt11 × MIR604 × TC1507 × 5307 and Bt11 × MIR162 × MIR604 × TC1507 × 5307 5% Refuge Seed Blend Corn as a primary tool for CRW management in the MAA, only when Syngenta demonstrates that successful mitigation as described in part e above has been achieved.
2. Based on further research to understand CRW resistance to Bt PIPs, EPA will consider refinements to the resistance mitigation program. Such research may include characterizing the genetics of resistance (e.g., number of genes, functional dominance, mechanism of resistance, and cross-resistance) and the biology of resistant insects (e.g., fitness in the presence and absence of the product), and other control tactics.

f. Seed Blend Refuge Assurance Program for Bt11 × MIR604 × TC1507 × 5307 and Bt11 × MIR162 × MIR604 × TC1507 × 5307 5% Refuge Seed Blend Corn

Syngenta must implement its EZ Refuge Corn Manufacturing System to ensure Bt11 × MIR604 × TC1507 × 5307 and Bt11 × MIR162 × MIR604 × TC1507 × 5307 5% Refuge Seed Blend Corn products are formulated with the appropriate rate of refuge seeds. The program must include the following four elements:

1. Trait purity check on seed lots prior to blending;
2. ISO 9000 Standard Operating Procedures for the blending process;
3. Calibration of blending equipment; and
4. Records and data retention records for seed blend products.
 - Calibration records - Syngenta will retain documentation for a specified period of time on the equipment calibration including the procedure, when it was conducted and the results.
 - Blend proportion records (weight and kernel based) - Syngenta will retain documentation for a specified period of time on the kernel per pound data of the components, the calculations to determine the proportions based on weight and the actual weights that are blended together to make up an Bt11 × MIR604 × TC1507 × 5307 and Bt11 × MIR162 × MIR604 × TC1507 × 5307 5% Refuge Seed Blend Corn product by seed lot.

All records must be maintained at the Syngenta blending facility and must be available for the EPA review upon request. All blending records must be maintained at the Syngenta blending facilities, third party contractors, and Syngenta licensees and must be available for EPA review upon request.

Should Syngenta or Syngenta's Licensees be notified by the USDA/AMS or State Seed Control Officials that your seed blend products have been found to have a lower percentage of the refuge component than is represented on the label, they must notify EPA within 30 days. This would constitute information reportable under FIFRA section 6(a)(2).

g. Annual Reporting Requirements for Bt11 × MIR604 × TC1507 × 5307 and Bt11 × MIR162 × MIR604 × TC1507 × 5307 5% Refuge Seed Blend Corn

The following annual reports must be submitted:

- 1) Insect Resistance Monitoring Results (Cry1Ab, Cry1F, and Vip3Aa20 only): results of monitoring and investigations of damage reports, on or before August 31st of each year.
- 2) IPM Stewardship Program (mCry3A and eCry3.1Ab only): Activities conducted under the IPM stewardship program, including an anonymous survey of grower practices, adoption levels of the various crop rotation options (if employed) and other elements of the stewardship program, on or before January 31st of each year.

- 3) Unexpected Damage Investigations (mCry3A and eCry3.1Ab only): Activities related to investigations of unexpected damage (UXD), including number and location of UXD cases, insect sampling, bioassays, and final disposition of UXD fields from the most recent and previous corn growing seasons, on or before November 30th of each year.

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 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. A stamped copy of the labeling is enclosed for your records. Please also note that the record for this product currently contains the following acceptable Confidential Statement of Formula (CSF):

- Basic CSF dated 02/16/2021

If you have any questions, please contact Stephanie Kelly of my team by phone at (202) 566-0890 or via email at kelly.stephanie@epa.gov.

Sincerely,



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

Enclosure

Plant-Incorporated Protectant Label

Bt11 × MIR604 × TC1507 × 5307 and Bt11 × MIR162 × MIR604 × TC1507 × 5307 5% Refuge Seed Blend Corn

ACCEPTED

02/18/2021

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 67979-39

Alternate Brand Name:

Agrisure Duracade 5122 and Agrisure Duracade 5222 Blend - E-Z Refuge

OECD Unique Identifier: SYN-BT011-1 × SYN-IR604-5 × DAS-01507-1 × SYN-05307-1
SYN-BT011-1 × SYN-IR162-4 × SYN-IR604-5 × DAS-1507-1 × SYN-05307-1

This product is effective in limiting corn leaf, stalk, ear, and root feeding damage caused by lepidopteran and corn rootworm pests.

15% component

Active Ingredients: Bt11 × MIR604 × TC1507 × 5307

Bacillus thuringiensis Cry1Ab protein and the genetic material necessary for its production (via elements of vector pZO1502) in Bt11 corn (SYN-BT011-1) ≤0.00460%*

Bacillus thuringiensis mCry3A protein and the genetic material necessary for its production (via elements of vector pZM26) in MIR604 corn (SYN-IR604-5) ≤0.00041%*

Bacillus thuringiensis Cry1F protein and the genetic material necessary for its production (via elements of vector PHP8999) in TC1507 corn (DAS-01507-1) ≤0.00103%*

Bacillus thuringiensis eCry3.1Ab protein and the genetic material necessary for its production (via elements of vector pSYN12274) in 5307 corn (SYN-05307-1) ≤0.00335%*

Other Ingredients:

Phosphinothricin acetyltransferase marker protein and the genetic material necessary for its production (via elements of vector pZO1502) in Bt11 corn (SYN-BT011-1) and (via elements of vector PHP8999) in TC1507 corn (DAS-01507-1) ≤0.00022%*

Phosphomannose isomerase marker protein and the genetic material necessary for its production (via elements of vector pZM26) in MIR604 corn (SYN-IR604-5) and (via elements of vector pSYN12274) in 5307 corn (SYN-05307-1) ≤0.00132%*

*Percent dry weight in whole plant

80% component

Active Ingredients: Bt11 × MIR162 × MIR604 × TC1507 × 5307

Bacillus thuringiensis Cry1Ab protein and the genetic material necessary for its production (via elements of vector pZO1502) in Bt11 corn (SYN-BT011-1) ≤0.00495%*

Bacillus thuringiensis Vip3Aa20 protein and the genetic material necessary for its production (via elements of vector pNOV1300) in MIR162 corn (SYN-IR162-4) ≤0.00431%*

<i>Bacillus thuringiensis</i> mCry3A protein and the genetic material necessary for its production (via elements of vector pZM26) in MIR604 corn (SYN-IR604-5)	≤0.00060%*
<i>Bacillus thuringiensis</i> Cry1F protein and the genetic material necessary for its production (via elements of vector PHP8999) in TC1507 corn (DAS-Ø15Ø7-1)	≤0.00122%*
<i>Bacillus thuringiensis</i> eCry3.1Ab protein and the genetic material necessary for its production (via elements of vector pSYN12274) in 5307 corn (SYN- Ø53Ø7-1)	≤0.00261%*
Other Ingredients: Phosphinothricin acetyltransferase marker protein and the genetic material necessary for its production (via elements of vector pZO1502) in Bt11 corn (SYN-BTØ11-1) and (via elements of vector PHP8999) in TC1507 corn (DAS-Ø15Ø7-1)	≤0.00020%*
Phosphomannose isomerase marker protein and the genetic material necessary for its production (via elements of vector pNOV1300) in MIR162 corn (SYN-IR162-4), (via elements of vector pZM26) in MIR604 corn (SYN-IR604-5), and (via elements of vector pSYN12274) in 5307 corn (SYN- Ø53Ø7-1)	≤0.00179%*

KEEP OUT OF REACH OF CHILDREN

CAUTION

NET CONTENTS _____

EPA Registration No. 67979-
EPA Establishment No. 66736-NC-01

Syngenta Seeds, LLC – Field Crops – NAFTA
9 Davis Drive
Research Triangle Park, NC 27709

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling.

This product is to be used only in the state of Kansas.

Seed bags and/or bag tags for corn hybrids that contain plant-incorporated protectants produced in the blended product consisting of 15% Bt11 × MIR604 × TC1507 × 5307 and 80% Bt11 × MIR162 × MIR604 × TC1507 × 5307 and 5% Refuge Seed Blend Corn (hereafter referred to as ‘The Blended Product’ must display the registration number and active ingredients, and stipulate that growers read the Syngenta Stewardship Guide (or equivalent guidance) prior to planting these hybrids. The refuge size requirement must be displayed on the bag or bag tag in both text and graphic format.

INSECTS CONTROLLED OR SUPPRESSED

Northern corn rootworm (*Diabrotica barberi*)
Western corn rootworm (*Diabrotica virgifera virgifera*)
Mexican corn rootworm (*Diabrotica virgifera zea*)
Black cutworm (*Agrotis ipsilon*)
Southern cornstalk borer (*Diatraea crambidoides*)
Southwestern corn borer (*Diatraea grandiosella*)
Sugarcane borer (*Diatraea saccharalis*)
Lesser cornstalk borer (*Elasmopalpus lignosellus*)
Dingy Cutworm (*Feltia jaculifera*)
Corn earworm (*Helicoverpa zea*)
European corn borer (*Ostrinia nubilalis*)
Common stalk borer (*Papaipema nebris*)
True armyworm (*Pseudaletia unipuncta*)
Beet armyworm (*Spodoptera exigua*)
Fall armyworm (*Spodoptera frugiperda*)
Western bean cutworm (*Striacosta albicosta*)

INSECT RESISTANCE MANAGEMENT

Each bag of The Blended Product contains a blend of 15% Bt11 × MIR604 × TC1507 × 5307 seed, 80% Bt11 × MIR162 × MIR604 × TC1507 × 5307 and 5% non-Bt refuge seed.

IRM Requirements for Corn-Growing Areas of the U.S.

Refuge seed is blended into each bag of Bt11 × MIR604 × TC1507 × 5307 and Bt11 × MIR162 × MIR604 × TC1507 × 5307 5% Refuge Seed Blend Corn. There is no requirement for growers to plant a separate structured refuge for managing resistance risk in corn-growing areas of the U.S. Corn-growing areas are those counties and states not defined as comprising the cotton-growing areas of the U.S. Read the Syngenta Stewardship Guide.

The following text and graphic indicating the supplemental refuge size requirement will appear on the blended product bags or bag tags.