Product Safety Assessment

POWERCORE™

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Names

- Bt Corn
- Bt Proteins
- Bacillus thuringiensis proteins
- Cry1A.105
- Cry1F
- Cry2Ab2
- POWERCORE
- PowerCore
- TC1507
- NK603
- MON 89034
- MON 89034 x TC1507 x NK603
- MON-89Ø34-3 x DAS-Ø15Ø7-1x MON-ØØ6Ø3-6
- 5-enol-pyruvylshikimate-3-phosphate synthase (CP4 EPSPS)
- Phosphinothricin Acetyltransferase (PAT)
- OECD Identifier: MON-89Ø34-3 x DAS-Ø15Ø7-1 x MON-ØØ6Ø3-6

Product Overview

- POWERCORE™ is a transgenic corn technology developed through a research and development collaboration between Dow AgroSciences and Monsanto. POWERCORE seed corn trait package provides multiple modes of action for above-ground insect control to control leaf, stalk and ear-feeding insects, and herbicide tolerance.
- Combining multiple modes of action reduces the likelihood of targeted insect populations developing resistance and allows corn growers, in some geographies, to reduce the size of their non-Bt corn refuge, based on the insect populations.
- POWERCORE expresses three insect-control proteins (Cry1A.105, Cry2Ab2, and Cry1F) derived from proteins produced by the soil bacterium Bacillus thuringiensis (Bt). The expression of the insect-control proteins provides three modes of action for control of above-ground Lepidoptera pests. For information on what insects are controlled by these traits, see Product Description.
- POWERCORE is highly effective against some of the most devastating corn insect pests which are capable of significantly reducing productivity. POWERCORE controls Spodoptera frugiperda, Helicoverpa zea, Diatreaa saccharalis, Agrotis ipsilon, and Elasmopalpus lignosellus, and several other lepidopteran pests of corn. This trait package provides broad spectrum and robust insect control using multiple modes of action from multiple genes -- the first three-Bt gene combination available in Brazil and Argentina. POWERCORE is also commercialized in Canada, Colombia, Paraguay, Uruguay, and USA.
POWERCORE also contains two herbicide tolerance traits—5-enol-pyruvylshikimate-3-phosphate synthase (CP4 EPSPS) obtained from the soil bacterium *Agrobacterium* sp., and phosphinothricin acetyltransferase (PAT), obtained from the soil bacterium *Streptomyces viridochromogenes*. Corn plants expressing these traits can be sprayed post emergence with glyphosate herbicides (e.g., Roundup® herbicide) and/or glufosinate-ammonium herbicides (LibertyLink herbicide), allowing for broad spectrum weed control without herbicide damage to the corn plant. Benefits to the farmer are convenient and effective weed control that ultimately enhances yield potential for the corn. For more information about these traits, see Product Description.

On the basis of rigorous testing, regulatory agencies concluded that POWERCORE corn hybrids are equivalent to non-transgenic corn. Exposure to the proteins in POWERCORE occurs primarily through ingestion. The *Bt* proteins and the herbicide tolerance enzymes are derived from common soil organisms. Extensive safety data were provided previously by Dow AgroSciences LLC and Monsanto Technology LLC to CTNBio, the U.S. Department of Agriculture (USDA), Environmental Protection Agency (EPA), Food and Drug Administration (FDA), and the regulatory systems of other countries on the individual traits contained in POWERCORE. The POWERCORE product has been reviewed by the CTNBio (Brazil), SENASA and CONABIA (Argentina), the U.S. EPA, and numerous importing countries. Margins of exposure previously determined for the proteins in the individual events (MON 89034, TC1507, and NK603) were applicable for the risk assessment of these proteins combined in POWERCORE. There is no indication of synergistic or antagonistic interactions among the components, and there has been no indication of unreasonable adverse effects to the environment. For further details, see Exposure Potential and Health Information.

**Manufacture of Product: Plant Transformation Process**

Plant biotechnology can be defined as a precise process in which scientific techniques (e.g., genetic modifications) are used to develop useful and beneficial plants with desirable “traits.” A trait refers to a characteristic that is associated with the plant, including agronomic qualities and resistance to insects, herbicides, and plant pathogens. The genes responsible for the desired traits are identified, and then the desired genes are transferred into plant cells by plant transformation. A trait may come originally from the plant itself (corn, in this case) or from a very specific gene of another organism, such as a bacterium.

DNA is the “genetic backbone” found in all microorganisms, plants, animals, and humans. Organisms that carry DNA introduced via genetic transformation are referred to as transgenic, and the introduced DNA is termed a transgene.

POWERCORE™ contains three independent corn transformation events carrying specific genes; MON 89034 (cry1A.105, cry2Ab2), TC1507 (cry1F, pat), and NK603 (cp4 epsps), that are combined together through plant breeding so that all five genes are present in the same plant.

The first step in creating the transformation events in POWERCORE™ corn was the identification and isolation of DNA segments responsible for the expression of the desired insecticidal proteins (Cry1A.105, Cry1F, and Cry2Ab2,) and herbicide tolerance proteins (PAT and CP4 EPSPS). The isolated DNA fragments were then chemically re-synthesized to create the final transgene, including plant-preferred DNA sequences that optimize expression of the proteins in the plant.

The transgenes were inserted into plant tissue through a process known as transformation. The three transformation events that comprise POWERCORE were created through one of two means of transformation; *Agrobacterium*-mediated transformation or microparticle bombardment. *Agrobacterium* is a naturally occurring soil bacterium that can transfer and integrate selected DNA segments into plant cells, allowing for the expression of the desired traits.
DNA in a stable fashion into the corn plant. In Agrobacterium mediated transformation, immature corn embryos (or cells) are incubated on artificial media with special strains of *Agrobacterium* that transferred the desired DNA into the corn plant cells. In microparticle bombardment, the DNA is “shot” at high speed to embed the transgene DNA in the corn embryo cells. The embryos are then allowed to grow and express the inserted genes in the transformed plant. Each unique DNA insertion or transformation is called an “event,” and many events were created and tested in the plants using a process called “event sorting” to identify the optimal protein expression.

Using traditional plant breeding techniques, POWERCORE is produced by crossing each of the three individual transformation events (MON 89034, TC1507, and NK603) to create plants that contain the combined Cry1A.105, Cry2Ab2, Cry1F, PAT, and CP4 EPSPS proteins.

Numerous tests and checks are in place to ensure the quality of the genetically modified seed and, ultimately, the generations of seed formed afterward. POWERCORE corn was extensively tested for the stability of the traits through several growing cycles, for safety to animals, humans, and the environment, and for nutritional value.

Following this rigorous testing and approvals by regulatory agencies globally, the genetically modified material is sold to farmers to grow for human and animal consumption.

**Product Description**

The product that is purchased is seed corn with POWERCORE™ traits. The protection against insects and herbicides is achieved by genetically modifying the corn to include five genes that express proteins, making the corn plants resistant to the larval stages of multiple insect pests of corn and tolerant to certain herbicides. The expression of the proteins Cry1A.105, Cry2Ab2, Cry1F, CP4 EPSPS, and PAT by the genes cry1A.105, cry2Ab2, cry1F, cp4 epsps, and pat, respectively, allows the plants to produce the proteins derived from the naturally occurring soil bacteria from which the genes were isolated. All of the *Bt* proteins (the Cry proteins) are expressed during all growth stages of the corn plant, protecting POWERCORE™ corn hybrids from insects from the time of plant emergence from the soil through ear formation, with more than one protein expressed for control of the insect pests. The herbicide-tolerant proteins (CP4 ESPS and PAT) expressed in POWERCORE corn hybrids enable the plants to tolerate two non-selective herbicides, which provide farmers with more weed control options.

Following is background information about *Bacillus thuringiensis*, and each protein and its effects.

**Bacillus thuringiensis (Bt)**—All of the insect-control proteins expressed in POWERCORE corn hybrids were obtained from the common soil bacterium *Bacillus thuringiensis*, often referred to as *Bt*. *Bt* naturally forms crystalline proteins (Cry proteins) that are toxic to some insects. Cry proteins are highly selective; with toxicity only against certain groups and/or species of insects (i.e. different Cry proteins are effective against different groups and/or species of insects).

*Bt* was first discovered in 1901 by the Japanese biologist S. Ishiwatari as the source of disease that was killing large populations of silkworms. *Bt* was first used as an insecticide in 1920, and spray formulations containing either *Bt* bacteria or *Bt* proteins have been used for more than 40 years.®

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years for crop protection, including their use in organic farming operations. The development and use of EPA-approved Bt insecticides as alternatives to synthetic chemical insecticides increased significantly during the 1980s.

Beginning in the 1980s, the genes responsible for making Bt proteins were isolated and transferred into corn plants. Bt proteins were commercially approved as plant-incorporated protectants in transgenic corn and cotton seed in the mid-1990s. Compared with conventional Bt spray formulations, transgenic plants expressing Bt proteins provide much more effective insect protection throughout the growing season. Several different Bt genes have been used to genetically modify corn, cotton, and potatoes, as well as other transgenic crops currently in development.

Bt proteins must be ingested to kill the insect. A susceptible immature insect (larva) eats the protein, which then binds to a specific receptor in the larva’s gut. Binding initiates a cascade of effects in the larva that ultimately leads to death.

Each type of Bt protein expressed in a plant binds to a specific receptor in the insect’s gut. Different Bt proteins targeting the same insect species will bind in different places in the insect’s gut. If a target insect population were to develop resistance to one Bt protein, it is likely that the other Bt protein(s) targeting the same insect species would remain effective.

Cry1A.105, Cry2Ab2—These two Bt proteins, which are also expressed products such as Genuity™ VT Triple PRO corn hybrids, protect the corn from lepidopteran insects that feed on above-ground portions of the plant—leaves, stalks, ears. The insects targeted by these proteins are the corn earworm (Helicoverpa zea), European corn borer (Ostrinia nubilalis), fall armyworm (Spodoptera frugiperda), sugarcane borer (Diatraea saccharalis), and southwestern corn borer (Diatraea grandiosella). Corn borers are considered to be the second most important complex of insect pests in North America, second only to the corn rootworm complex. The fall armyworm causes injury to corn leaves (particularly on late-planted corn) and corn ears. The fall armyworm is the most important insect pest of corn in South America.

Cry1F—This Bt protein, which is expressed in corn hybrids with Herculex® I Insect Protection and Herculex XTRA Insect Protection, protects the corn from lepidopteran insects that feed on above-ground portions of the plant—leaves, stalks, ears—all season long. The insect targeted by these proteins are the black cutworm (Agrotis ipsilon), European corn borer (Ostrinia nubilalis), fall armyworm (Spodoptera frugiperda), lesser cornstalk borer (Elasmopalpus lignosellus), southern corn stalk borer (Diatraea cramboides), southwestern corn borer (Diatraea grandiosella), sugarcane borer (Diatraea saccharalis), and western bean cutworm (Striacosta albicosta). The protein also provides suppression of corn earworm injury. The black cutworm is an occasionally destructive pest that feeds on corn seedlings shortly after emergence, severely reducing corn populations when infestations are significant. The western bean cutworm is an increasingly threatening insect pest whose range has expanded rapidly eastward in the United States from the Great Plains to New York (for the first time in 2009) within the past decade. It feeds on the ears, reducing yields because of its destruction of kernels and because damaged ears are open for infection ear rot organisms. The Cry1F protein provides excellent control of major lepidopteran pests from early in the season (black cutworm) to late in the season (ear-feeding insects such as fall armyworm and western bean cutworm).

CP4 EPSPS—5-Enol-pyruvylshikimate-3-phosphate synthase (CP4 EPSPS) is the protein expressed in Roundup Ready® Corn 2 hybrids, imparting tolerance to glyphosate-based herbicides. Glyphosate-based herbicides, such as Durango® and Roundup®, are non-selective, providing control of a broad spectrum of weeds. Glyphosate-based herbicides kill non-tolerant plants (e.g., weeds) by inhibiting the enzyme EPSPS. EPSPS interferes with the development of aromatic amino acids in plants, resulting in reduced plant growth. POWERCORE corn can be sprayed with glyphosate-based herbicides to control weeds with no resulting crop loss.
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**PAT**–Phosphinothricin acetyltransferase (PAT) is the protein expressed in Herculex® corn hybrids with LibertyLink® technology, making them tolerant to over-the-top applications of glufosinate herbicides, such as LibertyLink. PAT is an enzyme isolated from the common soil bacterium *Streptomyces viridochromogenes*. POWERCORE™ corn can be sprayed with glufosinate-based herbicides to control weeds with no resulting crop loss.

Glufosinate-ammonium, developed from the same bacterium as PAT, lowers glutamine levels of non-tolerant corn plants. The reduction of glutamine results in increased concentrations of ammonia, disrupting the cell membrane, halting photosynthesis, and resulting in necrosis. Eventually the plant, preferably a weed, dies. PAT is essentially the antidote to the herbicide, allowing the plant to detoxify the active ingredient in this particular herbicide.

**Product Uses**

POWERCORE™ corn hybrids are used to produce high-quality corn with greater efficiency for higher yields and less loss due to feeding damage of key corn lepidopteran insect pests. Growing POWERCORE corn hybrids reduces the need for insecticide applications.

**Exposure Potential**

The *Bt* and herbicide tolerance proteins are derived from common, non-pathogenic soil bacteria, so environmental exposure presents no issues unique to POWERCORE and these proteins. The potential for external exposure to genetically modified corn seed and plants is greatest for farmers who plant the seed, grow the plants, and harvest the crop. Because harvested corn with POWERCORE traits is equivalent to corn without them, standard farm workplace procedures and precautions should be followed. See **Health Information**.

Internal exposure to the proteins expressed in POWERCORE occurs mainly through ingestion of corn-derived foods. Consumers and animals are already consuming processed corn products that contain the Cry1A.105, Cry1F, Cry2Ab2, PAT, and CP4 EPSPS proteins. None of the proteins is associated with toxicity or allergenicity and numerous studies have demonstrated the safety of these proteins for human and animal consumption. See **Health Information**.

**Health Information**

On the basis of rigorous testing, regulatory agencies concluded that corn with POWERCORE™ traits is equivalent to non-transgenic corn. The POWERCORE traits have full food, feed, and environmental approval by regulatory agencies in Argentina, Brazil, Canada, Colombia, Paraguay, United States, and Uruguay, as well as food and feed approvals in global corn import countries. A complete list of regulatory approvals is found at biotradestatus.com.

POWERCORE™ is not known to pose risks to human health. All of the proteins expressed in POWERCORE are derived from naturally-occurring soil bacteria and are not considered as

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pathogens for humans or animals. Moreover, none of the proteins expressed in POWERCORE™ has biochemical characteristics or homology (relevant similarities) with known food allergens or toxins, indicating that POWERCORE is highly unlikely to pose any risk of toxic or allergic reaction.

Studies conducted on the nutrient composition profiles of grain and whole plant forage confirmed that POWERCORE corn hybrids and conventional non-transgenic corn hybrids are compositionally equivalent, including nutrients and anti-nutrients.

The three individual transformation events that comprise the POWERCORE product have individually passed regulatory safety assessments globally and are available commercially as individual traits. In combining the three individual events into POWERCORE™ by traditional breeding, no further modifications were made to the DNA or transgenes. Studies demonstrated that there are no synergistic or antagonistic interactions among the events, and protein expression levels in POWERCORE are similar to those in the individual events. Therefore the individual safety assessments of the proteins and traits in POWERCORE also apply to the POWERCORE product. Those assessments included investigating toxicity in mice; where healthy mice demonstrated lack of acute toxicity after ingesting a dose of protein many thousand times the estimated dietary intake of humans. Broiler chicken feeding studies were also conducted with grain harvested from each of the individual transformation event corn hybrids. No differences in nutritional quality or growth of the broilers were observed between those animals that consumed the transgenic corn and those that were fed conventional corn.

**Seed Treatments**

Agricultural seeds, including corn with POWERCORE™ traits, may be treated with an insecticide and/or a fungicide. These seed treatments as used in conventional crops can present certain health risks, which are associated with the seed treatments and not the POWERCORE traits.

For more information, farmers should consult the appropriate Safety Data Sheet and/or label or tag for seed treatment hazard information, and wear all recommended personal protective equipment.

**Environmental Information**

Before a biotechnology product can be introduced to the market, approval by appropriate governmental agencies is required. Using the criteria established by these agencies, Dow AgroSciences conducts extensive, validated tests for its biotechnology products. For the approval of corn with the POWERCORE traits, extensive safety data were provided to the EPA as part of the registration application and to the regulatory agencies of other countries.

POWERCORE corn produces minute quantities of the Cry1A.105, Cry1F, Cry2Ab2, CP4 EPSPS, and PAT proteins, which are contained in the plant and plant parts such as pollen, roots, and leaves. All of the transgenic proteins degrade rapidly in the soil, minimizing the potential for run-off or exposure to soil-dwelling non-target organisms.

Each of the events (MON 89034, TC1507, and NK603) that comprise POWERCORE has been previously tested extensively, as required by the EPA and USDA as Herculex®, YieldGard™

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products. A number of non-target organisms were tested as part of the registration process for these products, and no adverse effects were observed. Some of the organisms tested include honeybees, earthworms, lady beetles, springtails, green lacewings, and monarch butterfly caterpillars. Additionally, no adverse effects were identified for birds or fish, and the product does not pose a threat to endangered species.

The protein expression levels in POWERCORE are comparable to the protein levels in the individual events that comprise it. Consequently, margins of exposure previously determined for the proteins in the individual events (MON 89034, TC1507, and NK603) were applicable for the risk assessment of these proteins combined in POWERCORE. There is no indication of synergistic effects, and no indication of adverse effects to the environment.

Another important environmental consideration with a biotechnology product is how cross-pollination will affect the environment. Gene exchange between corn with POWERCORE traits and other cultivated corn varieties can occur. The exchange is similar to that which occurs naturally between cultivated corn varieties (both transgenic and non-transgenic). In Argentina, Brazil, Canada and U.S., where cultivation of POWERCORE is approved, there is no plant species closely related to corn in the wild, so gene flow to other species does not occur. There is no selective advantage for corn hybrids with POWERCORE™ traits in the natural environment.

There is a potential for target pest populations to adapt over time to the insect-control proteins in POWERCORE, which could potentially lead to reduced efficacy. However, POWERCORE hybrids produce multiple Bt proteins to control key pests (i.e., gene pyramiding). POWERCORE can thereby control insects that may develop resistance to one of the expressed Bt proteins. Consequently, the target insects are much less likely to develop resistance to the trait combination than to individual traits.

Dow AgroSciences promotes use of an insect resistance management plan with a refuge to mitigate the risk of target insect pests developing resistance to the insect-control proteins.

**Regulatory Information**

Regulations may exist that govern the manufacture, sale, transportation, use, and/or disposal of corn with POWERCORE™ traits, especially if the seed is treated with an insecticide or fungicide. These regulations may vary by city, state, country, or geographic region. Please review the Product Use Guide for POWERCORE. For more information, farmers should consult the appropriate Safety Data Sheet and/or label or tag for seed treatment hazard information, and wear all recommended personal protective equipment.

**Additional Information**

- Dow AgroSciences website ([http://www.dowagro.com](http://www.dowagro.com))
- Biotechnology Industry Organization “Commercial Status of Certain Agricultural Biotechnology Products” ([www.biотradestatus.com](http://www.biотradestatus.com))
References
Food and Feed safety assessment of maize event MON 89034 x TC1507 x NK603. SENASA
(http://www.senasa.gov.ar/Archivos/File/File6093-MON89034xTC1507xNK603_english.pdf)

Notice of Pesticide Registration. MON 89034 x TCI 507 Insect-Protected
Herbicide-Tolerant Corn. U.S. Environmental Protection Agency (EPA) (the plant-incorporated
protectant proteins are regulated by EPA)
(http://www3.epa.gov/pesticides/chem_search/ppls/068467-00012-20131114.pdf)
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