Center for Environmental Risk Assessment

GM Crop Database

Database Product Description

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MON-ØØ81Ø-6 (MON810)

Host Organism / Variety	*Zea mays L.* L. (Maize) Yieldgard®
Trait	Resistance to European corn borer (*Ostrinia nubilalis*).
Trait Introduction	Microparticle bombardment of plant cells or tissue
Proposed Use	Production of *Z. mays* for human consumption (wet mill or dry mill or seed oil), and meal and silage for livestock feed. These materials will not be grown outside the normal production area for corn.
Company Information	Monsanto Company Chesterfield Village Research Center (MO) 700 Chesterfield Parkway North St. Louis MO USA

Summary of Regulatory Approvals

Country	Environment	Food and/or Feed	Food	Feed	Marketing
Argentina	1998		1998	1998	
Australia			2000		
Brazil	2007	2007			
Canada	1997		1997	1997	
China		2004			
Colombia		2003			
European Union	1998	1998			1998
Japan	1996		1997	1997	
Korea			2002	2004	
Mexico		2002			
Philippines	2002		2002	2002	
South Africa	1997		1997	1997	
Switzerland			2000	2000	
Taiwan			2002		
United States	1995	1996			
Uruguay	2003	2003			

Click on the country name for country-specific contact and regulatory information.

Notes

Netherlands	Food and feed use notification.
United Kingdom	Food use notification.
European Union	Notified as an existing product on 12 July 2004.

Introduction

Maize line MON 810 (trade name YieldGard) was developed through a specific genetic modification to be resistant to attack by European corn borer (ECB; *Ostrinia nubilalis*), a major insect pest of maize in agriculture. The novel variety produces a truncated version of the insecticidal protein, Cry1Ab, derived from *Bacillus thuringiensis*. Delta-endotoxins, such as the Cry1Ab protein expressed in MON 810, act by selectively binding to specific sites localized on the brush border midgut epithelium of susceptible insect species. Following binding, cation-specific pores are formed that disrupt midgut ion flow and thereby cause paralysis and death. Cry1Ab is insecticidal only to lepidopteran insects, and its specificity of action is directly attributable to the presence of specific binding sites in the target insects. There are no binding sites for delta-endotoxins of *B. thuringiensis* on the surface of mammalian intestinal cells, therefore, livestock animals and humans are not susceptible to these proteins.

Summary of Introduced Genetic Elements

Code	Name	Type	Promoter, other	Terminator	Copies	Form
cry1Ab	Cry1Ab delta-endotoxin (*Btk* HD-1) *(Bacillus thuringiensis subsp. kurstaki (Btk))*	IR	enhanced CaMV 35S, maize HSP70 intron NULL	None. Lost through 3' truncation during integration	1	Truncated

Characteristics of *Zea mays* L. (Maize)

Center of Origin	Reproduction	Toxins	Allergenicity
Mesoamerican region, now Mexico and Central America	Cross-pollination via wind-borne pollen is limited, pollen viability is about 30 minutes. Hybridization reported with teosinte species and rarely with members of the genus Tripsacum.	No endogenous toxins or significant levels of antinutritional factors.	Although some reported cases of maize allergy, protein(s) responsible have not been identified.

Donor Organism Characteristics

Latin Name	Gene	Pathogenicity
Bacillus thuringiensis subsp. *kurstaki*	*cry1Ab*	While target insects are susceptible to oral doses of *Bt* proteins, no evidence of toxic effects in laboratory mammals or birds given up to 10 µg protein/g body weight.

Modification Method

Maize line MON 810 was produced by biolistic transformation of maize genotype Hi-II with a mixture of plasmid DNAs, PV-ZMBK07 and PV-ZMGT10. The PV-ZMBK07 plasmid contained the *cry1Ab* gene and PV-ZMGT10 plasmid contained the CP4 EPSPS and *gox* genes. Both plasmids contained the *nptII* gene under the control of a bacterial promoter required for selection of bacteria containing either plasmid, and an origin of replication from a pUC plasmid (ori-pUC) required for replication of the plasmids in bacteria.

Characteristics of the Modification

The Introduced DNA

Southern blot analysis of MON810 genomic DNA indicated the incorporation of a single copy of the truncated *cry1Ab* gene, together with the enhanced CaMV 35S (E35S) promoter and hsp70 leader sequences. The NOS 3' termination signal, present in plasmid PV-ZMBK07, was not

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Product Related Info

Documents

1. Maize biology document
2. Product summary prepared by Monsanto
3. Key food and feed nutrients and antinutrients of maize

Figures

1. Concentration of Cry1Ab protein in various tissues
2. Fatty acid analysis
3. Plasmid construct used in transformation
4. Proximate analysis of forage

Synopsis

> Overview of all products in database

integrated into the host genome but was lost through a 3' truncation of the gene cassette. The native Cry1Ab protein (HD-1) has a molecular weight of 131 kD while the inserted, plant expressed *cry1Ab* gene codes for a truncated protein with a molecular weight of 91 kD, as confirmed by Western blot analysis of MON810 tissue extracts.

Evidence was provided that no plasmid backbone sequences from the plasmid PV-ZMGT10 were integrated into the MON810 genome. Further Southern blot analysis indicated that the genes for glyphosate tolerance (CP4 EPSPS) and antibiotic resistance (*neo*) were not transferred to line MON 810 and the absence of the CP4 EPSPS and *gox* gene products was also confirmed by Western blotting. The CP4 EPSPS and GOX protein encoding genes were presumed to have been inserted into the initial transformant at a separate genetic loci from the *cry1Ab* gene and then subsequently lost through segregation during the crossing events leading to line MON810.

Genetic Stability of the Introduced Trait
Segregation and stability data were consistent with a single site of insertion of the *cry1Ab* gene into the MON810 genome. The stability of the insertion was demonstrated through multiple generations of crossing. MON810 was derived from the third generation of backcrossing and stable integration of the single insert was demonstrated through all three generations by Southern Blot analysis.

Expressed Material
The synthetic *cry1Ab* gene was linked to a strong constitutive promoter and modified for maximum expression in corn. The amino acid sequence of the toxin expressed in the modified corn was found to be identical to that occurring naturally, and equivalent to that produced for use as the biopesticide that is widely used by the organic food industry. Average protein expression, as measured in samples obtained from field trials at six locations, was 9.35 µg/g (fresh weight) in leaves and 0.31 µg/g (f.w.) in seeds. The concentration of expressed toxin, as determined from a single sample obtained from one site, was 4.15 µg/g (f.w.) in the whole plant and 0.09 µg/g (f.w.) in pollen. Protein expression ranged from 7.93 to 10.34 µg/g (f.w.) in leaves, from 0.19 to 0.39 µg/g (f.w.) in grain, and from 3.65 to 4.65 µg/g (f.w.) in the whole plant. Protein expression declined over the growing season as indicated by the Cry1Ab protein concentrations in leaves assayed over the growing season.

The Cry1Ab protein was shown to degrade readily in the environment. The plant expressed protein had DT50 and DT90 values (time to degrade to 50% and 90 % of the original bioactivity) of 2 and 15 days respectively.

Environmental Safety Considerations

Outcrossing
Since pollen production and viability were unchanged by the genetic modification resulting in MON810, pollen dispersal by wind and outcropping frequency should be no different than for other maize varieties. Gene exchange between MON810 maize and other cultivated maize varieties will be similar to that which occurs naturally between cultivated maize varieties at the present time. In Canada and the United States, where there are no plant species closely-related to maize in the wild, the risk of gene flow to other species appears remote.

Maize (*Zea mays* ssp. mays) freely hybridizes with annual teosinte (*Zea mays* ssp. mexicana) when in close proximity. These wild maize relatives are native to Central America and are not present in Canada and the United States, except for special plantings. Tripsacum, another genus related to Zea, contains sixteen species, of which twelve are native to Mexico and Guatemala. *Tripsacum floridanum* (Florida gamagrass) is native to the southern tip of Florida. Outcrossing with Tripsacum species is not known to occur in the wild and it is only with extreme difficulty that maize can be crossed with Tripsacum.

Weediness Potential
No competitive advantage was conferred to MON810, other than that conferred by resistance to European Corn Borer. Resistance to ECB will not, in itself, render maize weedy or invasive of natural habitats since none of the reproductive or growth characteristics were modified. Cultivated maize is unlikely to establish in non-cropped habitats and there have been no reports of maize surviving as a weed. *Zea mays* is not invasive and is a weak competitor with very limited seed dispersal.

Secondary and Non-Target Adverse Effects
The history of use and literature suggest that the bacterial *Bt* protein is not toxic to humans, other vertebrates, and beneficial insects. The insecticidally active core of the *Bt* protein expressed in MON810 maize (Cry1Ab) was shown to be equivalent to the original microbial protein. This protein is active only against specific lepidopteran insects and no lepidopteran species are listed as threatened or endangered species in Canada or the United States.

Maize inbreds and hybrids expressing the Cry1Ab protein were compared to their non-transformed counterpart for relative abundance of beneficial arthropods. Field studies demonstrated that Cry1Ab had neither a direct nor an indirect effect on the beneficial arthropod populations. Specific feeding trials were also carried out with a number of non-target species, including honey bee larvae and adults, green lacewing, parasitic hymenopterans, ladybird beetles, daphnia (aquatic invertebrates), earthworm, and collembola (soil dwelling invertebrates). In all cases there were no observable adverse effects. In summary, it was determined that when compared with currently commercialized maize varieties, MON810 maize did not present an increased risk to or impact on interacting organisms, including humans, with the exception of specific lepidopteran insect species.

Impact on Biodiversity
MON810 has no novel phenotypic characteristics that would extend its use beyond the current geographic range of maize production. Since the risk of outcrossing with wild relatives in North America is remote, it was determined that risk of transferring genetic traits from MON810 maize to species in unmanaged environments was insignificant.

Other Considerations
In order to prolong the effectiveness of plant-expressed *Bt* toxins, and the microbial spray formulations of these same toxins, regulatory authorities in Canada and United States have required developers to implement specific Insect Resistant Management (IRM) Programs. These programs are mandatory for all transgenic *Bt*-expressing plants, including MON810 maize, and require that growers plant a certain percentage of their acreage to non-transgenic varieties in order to reduce the potential for selecting *Bt*-resistant insect populations. Details on the specific design and requirements of individual IRM programs are published by the relevant regulatory authority.

Food and/or Feed Safety Considerations

Dietary Exposure
Little whole kernel or processed maize is directly consumed by humans in comparison to maize-based food ingredients. Maize is a raw material for the manufacture of starch, the majority of which is converted to a variety of sweetener and fermentation products, including high fructose syrup and ethanol. Maize oil is commercially processed from the germ. These materials are components of many foods including bakery and dairy goods, and the human food uses of grain from MON810 are not expected to be different from the uses of non-transgenic field maize varieties. As such, the dietary exposure to humans of grain from insect resistant hybrids will not be different from that for other commercially available field maize varieties.

Nutritional Data
Data on fatty acid profiles, protein content, amino acid composition, crude fibre, ash, phytate, and moisture content were provided for samples of MON810 grown in field trials in various

locations in the United States and Europe. Comparisons of these parameters between MON810 and a non-transgenic control maize line did not reveal any biologically significant differences.

The observed variations in nutritional composition were judged to arise from normal variability rather than as a result of the inserted novel traits. As a percentage of dry weight, the component analyses for line MON810, are approximately: protein 13.1%; fat 3.0%; moisture 12.4%; calories 408 Kcal/100g; ash 1.6%; and carbohydrate 82.4%.

Toxicity

The trypsin-resistant Cry1Ab protein core expressed in insect-protected MON810 was identical to the same form of the protein contained in microbial *Bt* spray formulations that have been safely used in agriculture for more than 30 years. The low potential for toxicity of plant-expressed Cry1Ab protein was further demonstrated by a lack of amino acid sequence homology with known protein toxins, rapid digestion in simulated gastric juices, and lack of toxicity in feeding studies with laboratory animals.

An acute oral toxicity study was done to assess the potential mammalian toxicity of Cry1Ab protein purified from *Escherichia coli* transformed with the same *cry1Ab* gene used to produce MON810. Bacterial expressed protein was used in these studies because insufficient amounts could be purified from plant tissue. Data demonstrating the molecular equivalence of bacterial and plant-expressed Cry1Ab protein were provided.

The Cry1Ab core protein was administered to groups of ten male and female CD-1 mice in doses up to 4000 mg/kg body weight. These doses were well above the level of expression found in insect-protected maize plants and represented a 200-1000 fold excess over the level of exposure that would be predicted based on consumption of MON810 grain. As a control, equivalent groups of mice were administered either 4000 mg/kg bovine serum albumin or 66.66 mg/kg sodium carbonate solution (vehicle control).

Clinical observations were performed and body weights and food consumption were determined. One female mouse belonging to the vehicle control died during the test — on day 1. The death of the control female was considered a result of the intubation procedure. As there were no deaths in other treated mice, or at higher exposure levels, the death was not considered to be treatment related. Mice were observed up to 9 days after dosing and no treatment related effects on body weight, food consumption, survival, or gross pathology upon necropsy were observed for mice administered the Cry1Ab test protein.

Allergenicity

The Cry1Ab protein was evaluated for potential allergenicity by examining: (1) physiochemical characteristics; (2) amino acid sequence homology to known protein allergens; (3) digestibility; and (4) history of safe use of microbial insecticides containing this protein. Although the molecular weight of the Cry1Ab trypsin-resistant core protein, 63 kDa, was within the size range of known protein allergens, unlike many of these allergens it was not glycosylated. A search for amino acid sequence homology between the Cry1Ab protein and the amino acid sequences of 219 known allergens, using a database assembled from the public domain databases GenBank, EMBL, Pir and SwissProt, did not reveal any significant matches.

Maize products are an important alternative to wheat flour for individuals afflicted with celiac disease, an immune mediated food intolerance for which wheat gliadins have been implicated as the causal agent. In light of the importance of maize products to these individuals, a sequence similarity search was conducted and no amino acid sequence homologies between the Cry1Ab protein and gliadins were detected.

The digestibility of Cry1Ab protein was determined experimentally using *in vitro* mammalian digestion models. Purified Cry1Ab trypsin-resistant core protein (63 kDa) was added to simulated gastric and intestinal fluids and incubated at 37ºC. The degradation of the protein in the digestion fluid was assessed over time by Western blot analysis and insect bioassay. In simulated gastric fluid, more than 90% of the Cry1Ab protein was degraded after 2 minutes incubation, while in simulated intestinal fluid the trypsin-resistant Cry1Ab core protein was not further degraded after more than 19 hrs incubation. This latter result was expected as serine proteases, such as trypsin, are the predominant proteolytic components of intestinal fluid.

The source of the *cry1Ab* gene has a long history of use on food crops as a biopesticide and no evidence of adverse effects. This fact, combined with the lack of amino acid sequence homology between Cry1Ab protein and known allergens, and the rapid degradation of Cry1Ab protein in acidic gastric fluids, were sufficient to provide a reasonable certainty of lack of allergenic potential.

Links to Further Information

Assessing the impact of Cry1Ab-expressing corn pollen on monarch butterfly larvae in field studies PDF [PDF Size: 129748 bytes]
Diane E. Stanley-Horn , Galen P. Dively, Richard L. Hellmich, Heather R. Mattila, Mark K. Sears, Robyn Rose , Laura C. H. Jesse, John E. Losey, John J. Obrycki, and Les Lewis. (2001). *Proc. Natl. Acad. Sci. USA Early Edition*.

Australia New Zealand Food Authority PDF [PDF Size: 243139 bytes]
Final Risk Analysis Report A346: Food produced from insect-protected corn line MON810

Canadian Food Inspection Agency, Plant Biotechnology Office PDF [PDF Size: 170534 bytes]
Decision Document 97-19: Determination of the Safety of Monsanto Canada Inc.'s YieldgardTM Insect Resistant Corn (Zea mays L.) Line MON810

Comissão Técnica Nacional de Biossegurança - CTNBio PDF [PDF Size: 369629 bytes]
Parecer Técnico nº 1.100/2007: Liberação comercial de nilho geneticamente modifcado MON810

European Commission Scientific Committee on Plants PDF [PDF Size: 153232 bytes]
Opinion of the Scientific Committee on Plants Regarding the Genetically Modified, Insect Resistant Maize Lines Notified by the Monsanto Company (NOTIFICATION C/F/95/12/02)

European Commission: Community Register of GM Food and Feed PDF [PDF Size: 12813 bytes]
Notification of the placing on the Community Register of MON-ØØ81Ø-6.

European Food Safety Authority PDF [PDF Size: 399635 bytes]
Scientific Opinion: Applications (EFSA-GMO-RX-MON810) for renewal of authorisation for the continued marketing of (1) existing food and food ingredients produced from genetically modified insect resistant maize MON810; (2) feed consisting of and/or containing maize MON810, including the use of seed for cultivation; and of (3) food and feed additives, and feed materials produced from maize MON810, all under Regulation (EC) No 1829/2003 from Monsanto.

Impact of Bt corn pollen on monarch butterfly populations: A risk assessment PDF [PDF Size: 166577 bytes]
Mark K. Sears, Richard L. Hellmich, Diane E. Stanley-Horn, Karen S. Oberhauser, John M. Pleasants, Heather R. Mattila, Blair D. Siegfried, and Galen P. Dively (2001). *Proc. Natl. Acad. Sci. USA Early Edition*

Japanese Biosafety Clearing House, Ministry of Environment PDF [PDF Size: 156206 bytes]
Outline of the biological diversity risk assessment report: Type 1 use approval for MON810

Monsanto Company PDF [PDF Size: 106701 bytes]
Product safety description

Office of Food Biotechnology, Health Canada [PDF Size: 11200 bytes]
NOVEL FOOD INFORMATION - FOOD BIOTECHNOLOGY INSECT RESISTANT CORN, MON 810

PNAS Early Edition (June 2000) [PDF Size: 95323 bytes]
C. L. Wraight, A. R. Zangerl, M. J. Carroll, and M. R. Berenbaum. (2000). Absence of toxicity of Bacillus thuringiensis pollen to black swallowtails under field conditions.

THE COMMISSION OF THE EUROPEAN COMMUNITIES [PDF Size: 36277 bytes]
98/294/EC: Commission Decision of 22 April 1998 concerning the placing on the market of genetically modified maize (Zea mays L. line MON 810), pursuant to Council Directive 90/220/EEC (Text with EEA relevance)

U.S.Department of Agriculture, Animal and Plant Health Inspection Service [PDF Size: 1505444 bytes]
Monsanto Co. Petition for Determination of Non-regulated Status of Additional Yieldgard Corn Lines MON 809 and 810

US Environmental Protection Agency [PDF Size: 280302 bytes]
Biopesticide Fact Sheet: *Bacillus thuringiensis* Cry1Ab Delta-Endotoxin and the Genetic Material Necessary for Its Production in Corn [MON 810]

US Food and Drug Administration [PDF Size: 418873 bytes]
Memorandum to file concerning insect-protected maize lines MON810, 809.

References

Benefits

Betz, F.S., Hammond, B.G. & Fuchs, R.L. (2000). Safety and advantages of *Bacillus thuringiensis*-protected plants to control insect pests. *Regulatory Toxicology* **32**, 156-173.

Digestive Fate

Artim, L., Charlton, S., Dana, G., Glenn, K., Hunst, P., Jennings, J., Shilito, R. and Song, P. (2004). Sensitive PCR analysis of animal tissue samples for fragments of endogenous and transgenic DNA. *Journal of Agricultural and Food Chemistry* **52**: 6129-6135.

Jennings, J.C., Albee, L.D., Kolwyck, D.C., Surber, J.B., Taylor, M.L., Hartnell, G.F., Lirette, R.P. and Glenn, K.C. (2003). Attempts to detect transgenic and endogenous plant DNA and transgenic protein in muscle from broilers fed YieldGard Corn Borer Corn. *Poultry Science* **82**(3): 371-380.
[PDF Size: 2361395 bytes]

Sung, H., Min, D., Kim, D., Li, D., Kim, H., Upadhaya, S. and Ha, J. (2006). Influence of transgenic corn on the in vitro rumen microbial fermentation. *Asian-Australasian Journal of Animal Sciences* **19**(12): 1761-1768.

Efficacy

Buntin,G.D. (2008). Corn expressing Cry1Ab or Cry1F endotoxin for fall armyworm and corn earworm (Lepidoptera: noctuidae) management in field corn for grain production. *Florida Entomologist* **91**(4): 523-530.
[PDF Size: 69713 bytes]

Hubert, J., Kudlikova-Krizkova, I., Stejskal, V. (2008). Effect of Mon 810 Bt transgenic maize diet on stored-product moths (Lepidoptera: Pyralidae). *Crop Protection* **27**(3-5): 489-496.

Novillo, C., Fernandez-Anero, F. and Costa, J. (2003). Performance of insect-protected corn varieties derived from Bt line Mon 810, genetically protected from corn borers. *Boletin de Sanidad Vegetal, Plagas* **29**(3): 427-439.

Singh, R., Channappa, R.K., Deeba, F., Nagaraj, N.J., Sukavaneaswaran, M.K. and Manjunath, T.M. (2005). Tolerance of Bt corn (MON 810) to maize stem borer, *Chilo partellus* (Lepidoptera: Pyralidae). *Plant Cell Rep.* **24**(9). 556-560.

Storer, N.P., Van Duyn, J.W. and Kennedy, G.G. (2001). Life history traits of *Helicoverpa zea* (Lepidoptera: Noctuidae) on non-Bt and Bt transgenic corn hybrids in eastern North Carolina. *J Econ Entomol* **94**(5): 1268-1279.

Environmental Fate

Dubelman, S., Ayden, B., Bader, B., Brown, C., Jiang, C. and Vlachos, D. (2005). Cry1Ab protein does not persist in soil after 3 years of sustained Bt corn use. *Environmental Entomology* **34**(4): 915-921.

Feeding Studies

Hammond, B.G., Dudek, R., Lemen, J.K. and Nemeth, M.A. (2006). Results of a 90-day safety assurance study with rats fed grain from corn borer-protected corn. *Food Chem. Toxicol.* **44**(7): 1092-1099.

Nutritional Equivalence

Donkin, SS; Velez, JC; Totten, AK; Stanisiewski, EP; and Hartnell, GF. (2003). Effects of feeding silage and grain from glyphosate-tolerant or insect-protected corn hybrids on feed intake, ruminal digestion, and milk production in dairy cattle. *J. Dairy Sci.* **86**: 1780–1788.
[PDF Size: 68520 bytes]

Piva, G., Morlacchini, M., Pietri, A., Piva, A. and Casadei, G. (2001). Performance of weaned piglets fed insect-protected - MON 810 - or near isogenic corn. *Journal Animal Science* **79**. Suppl. 1: 106. Abstract 441.

Piva, G., Morlacchini, M., Pietri, A., Rossi, F. and Prandini, A. (2001). Growth performance of broilers fed insect - protected (MON 810) or near isogenic control corn. *Poultry Science* **79**. Abstract 1324(Suppl 1): 320.

Potential Non-Target Organism Effects

Daly, T. and Buntin, C.D. (2005). Effect of *Bacillus thuringiensis* transgenic corn for Lepidopteran control on nontarget arthropods. *Environmental Entomology* **34**(5): 1292-1301.

Oliveira, A.P., Pampulha, M.E. and Bennett, J.P. (2008). A two-year field study with transgenic *Bacillus thuringiensis* maize: effects on soil microorganisms. *Sci. Total Environ.* **405**: 351-357.

Toschki, A., Hothorn, L.A. and Ross-Nickoll, M. (2007). Effects of cultivation of genetically modified Bt maize on epigeic arthropods (Araneae; Carabidae). *Environ. Entomol.* **36**(4): 967-981.

Regulatory Policy

Ricroch, A., Berge, J. and Kuntz, M. (2009). Is the German suspension of MON810 maize cultivation scientifically justified. *Transgenic Research* June 2009. 12 pages. DOI: 10.1007/s11248-009-9297-5.

[PDF Size: 263072 bytes]

Safety Assessment

Sanders, P.R., Lee, T.C., Groth, M., Astwood, J.D. & Fuchs, R.L. (1998). Safety assessment of insect-protected corn. In: Biotechnology and Safety Assessment 2nd ed. John A. Thomas ed., Taylor and Francis, pp241-256.

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