

## Evaluation Report for Category B, Subcategory 2.6 Application

**Application Number:** 2012-1486  
**Application:** B.2.6 (Product Chemistry – New combination of TGAIs)  
**Product:** Poncho Votivo  
**Registration Number:** 31029  
**Active ingredients (a.i.):** *Bacillus firmus* I-1582 (BCL) and Clothianidin (COD)  
**PMRA Document Number:** 2316184

### Purpose of Application

The purpose of this application was to register the end-use product, Poncho Votivo, containing clothianidin and *Bacillus firmus* I-1582 for use on corn (including field, pop, seed and sweet).

### Chemistry Assessment

Poncho Votivo is formulated as a suspension containing clothianidin at a concentration of 508 g/L and *Bacillus firmus* strain I-1582 at a concentration of 8.0% (containing a minimum of  $2 \times 10^9$  CFU/mL). This end-use product has a density of 1.26 - 1.30 g/mL and pH of 6.54. The data submitted to address the proposed new end-use product formulation is acceptable. The required chemistry data for Poncho Votivo have been provided, reviewed and found to be acceptable.

Data from an acceptable number of batches were provided to support the *Bacillus firmus* strain I-1582 product guarantee and storage stability.

### Health Assessments

Poncho Votivo is of slight acute toxicity via the oral route ( $LD_{50} = 2000$  mg/kg bw), and of low acute toxicity via the dermal ( $LD_{50} > 5000$  mg/kg bw) and inhalation ( $LC_{50} > 2.03$  mg/L) routes of exposure in rats. It is non-irritating to the eyes (MAS = 0) and slightly irritating to the skin (MAS = 0.67) of rabbits. It is not a dermal sensitizer in mice.

*Bacillus firmus* strain I-1582, the microbial active for Poncho Votivo is of low toxicity and is not pathogenic by the oral and pulmonary route, and is not a dermal irritant. There was also no evidence of pathogenicity from *B. firmus* strain I-1582 via the intravenous route of exposure. Although *B. firmus* strain I-1582 spores and Votivo 240 FS Nematicide were mild ocular irritants, Poncho Votivo was considered only slightly irritating to the eye (MIS = 9.33/110, MAS = 0) such that no precautionary statements are required. *Bacillus firmus* strain I-1582 is considered to be a potential sensitizing agent.

A human exposure and health risk assessment were completed for Poncho Votivo, containing clothianidin guaranteed at 40.3% to support the registration as a seed treatment on corn. Exposure in commercial facilities and during the planting of corn treated with Poncho Votivo is not expected to increase from the currently registered products providing the product is used according to label directions. Worker exposure to Poncho Votivo in commercial facilities and during the planting of treated soybeans is not expected to result in unacceptable risks when the product is used according to label directions.

It is not expected that the occupational exposure to *Bacillus firmus* strain I-1582 from the use of Poncho Votivo will be of concern on the basis of the low toxicity/pathogenicity profile for *B. firmus* strain I-1582, and on the assumption that the precautionary labelling instructions aimed at minimizing worker exposure are adhered to by users. Also, it is not expected that bystander exposure, including exposure to infants and children, will pose an undue risk on the basis of the low toxicity/pathogenicity profile for *B. firmus* strain I-1582 and the related end-use formulation.

Poncho Votivo, is used on corn (field, pop, seed, and sweet). Previously reviewed residue data from field trials conducted in/on corn were reassessed in the framework of this application.

Based on the seed treatment use of Poncho Votivo and with *B. firmus* strains being common in nature, the likelihood of bacteria to remain as residues on the corn at harvest is very low, and is not expected to significantly increase the natural environmental background levels of this microorganism. No adverse effects have been attributed to dietary exposure from natural populations of *B. firmus* strain I-1582, and when *B. firmus* strain I-1582 was administered orally to rats, there was no significant toxicity, and no signs of disease were observed. The PMRA does not require crop residue data on crops grown from seeds treated with *B. firmus* strain I-1582, and the establishment of a maximum residue limit is not required for *B. firmus* strain I-1582.

**Maximum Residue Limit (MRL)**

An MRL of 0.01 ppm is already established in Canada for corn (field, pop, sweet). Residues of clothianidin in processed commodities are covered under MRLs for the raw agricultural commodity (RACs). Residues of clothianidin in corn (field, pop, sweet) at the established MRL, following seed treatment, will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

**Table 1 Summary of Field Trial and Processing Data Used to Establish Maximum Residue Limits (MRL).**

Commodity	Application Method/Total Application Rate	PHI (days)	Residues (ppm)		Experimental Processing Factor	Currently Established MRL	Recommended MRL
			Min	Max			
Corn	Seed treatment/ 2 mg a.i./seed	119-159	<0.01	<0.01	None	0.01	Not applicable

## **Environmental Assessment**

Registration of Poncho Votivo, containing *Bacillus firmus* Strain I-1582 and clothianidin is considered acceptable from an environmental perspective. The environmental label statements were updated to reflect the risk mitigation measures in the recent re-evaluation decisions RVD2019-05 (Clothianidin and Its Associated End-use Products: Pollinator Re-evaluation) and SRD2021-03 (Special Review Decision: Clothianidin Risk to Aquatic Invertebrates).

The microbial active *Bacillus firmus* strain I-1582 in Poncho Votivo does not pose an unacceptable risk to the terrestrial or aquatic environments.

## **Value Assessment**

Trials and rationales supported the use of Poncho Votivo for seed treatment of corn to control corn flea beetle, black cutworm, seed corn maggot, wireworms and white grubs at 80 mL Poncho Votivo/80,000 corn seeds. Tank mix recommendations with Allegiance FL, Poncho 600 FS, Trilex AL Concentrate, Trilex FS and Vortex FL were supported.

## **Conclusion**

The Pest Management Regulatory Agency has completed an assessment of the available information and is able to support the registration of Poncho Votivo, containing clothianidin and *Bacillus firmus* I-1582.

## References

### A. List of studies/Information submitted by registrant

PMRA No.	Reference
2182105	2011, Product Chemistry Data Poncho Votivo, DACO: 3.0,3.1,3.2,3.2.1,3.2.2,3.3.1,3.5,3.5.1,3.5.11,3.5.15,3.5.2,3.5.4,3.5.6,3.5.7,3.5.8,3.5.9 CBI
2240755	2011, The Storage Stability and Corrosion Characteristics of L1902 end-use product, DACO: 3.5.10,3.5.14 CBI
2182097	2011, Poncho/Votivo Acute Oral Toxicity Up And Down Procedure in Rats, DACO: 4.6.1
2182098	2012, Poncho/Votivo Acute Dermal Toxicity Study in Rats, DACO: 4.6.2
2182099	2012, Poncho/Votivo Acute Inhalation Toxicity Study in Rats, DACO: 4.6.3
2182100	2012, Poncho/Votivo Primary Eye Irritation Study in Rabbits, DACO: 4.6.4
2182101	2012, Poncho/Votivo Primary Skin Irritation Study in Rabbits, DACO: 4.6.5
2182102	2011, Poncho/Votivo Local Lymph Node Assay (LLNA) in Mice, DACO: 4.6.6
2182096	2012, Poncho 600FS Seed Treatment Insecticide on Soybean and Poncho Votivo on Soybean and Corn, DACO: 10.1,10.2,10.2.2,10.2.3,10.2.3.1,10.2.3.3(C),10.3,10.3.1,10.3.2(B)
2241937	2012, 10.2.3.1 Efficacy Summary Table EST-4. Nematode control on corn with Poncho VOTiVO seed treatment and a Poncho 600 + VOTiVO tank-mixture seed treatment., DACO: 10.2.3.1
2241938	2012, 10.2.3.1 Efficacy Summary Table EST-1. Soybean aphid control on soybean with Poncho 600 and Poncho VOTiVO seed treatments, DACO: 10.2.3.1
2241939	2012, 10.2.3.1 Efficacy Summary Table EST-2. Bean leaf beetle control on soybean with Poncho 600 and Poncho VOTiVO seed treatments, DACO: 10.2.3.1
2241940	2012, 10.2.3.1 Efficacy Summary Table EST-3. White grub control on soybean with Poncho 600 and Poncho VOTiVO seed treatments, DACO: 10.2.3.1
2241941	2012, 10.2.3.1 Efficacy Summary Table EST-5. Seed corn maggot control on soybean with Poncho VOTiVO and Poncho 600 seed treatments, DACO: 10.2.3.1
2241942	2012, 10.2.3.1 Efficacy Summary Table EST-6. Wireworm control on soybean with Poncho 600 seed treatment, DACO: 10.2.3.1
2241943	2012, 10.3 NSAEST-1. Non-safety adverse-effects with Poncho 600 FS and Poncho VOTiVO on soybean. Field Trials, 2011, DACO: 10.2.3.1
2241944	2012, 10.3 NSAEST-2. Non-safety adverse-effects with Poncho 600 FS and Poncho VOTiVO on soybean. Laboratory studies, 2011, DACO: 10.2.3.1
3342865	2020, PonchoVotivo FS 610 shelf life at various temperatures (BAS 496 00 I), DACO: 3.5.10 CBI
3358420	2022, Response to Clarifications required: Product Characterization and Analysis for Poncho Votivo 2012-1486, DACO: M2.0 CBI
3358421	2022, Additional information regarding the Manufacturing Process and Quality Assurance of Poncho Votivo, DACO: M2.8 CBI

3358422 2021, BIOLOGICAL STABILITY COUNTS OF PONCHO<sub>ii</sub>+VOTIVO<sub>ii</sub> FS  
(BAS 496 01 F), DACO: M2.8 CBI

3358423 2022, Certificates of Analysis for 5 Commercial Batches of Poncho Votivo,  
DACO: M2.8 CBI

3361295 2022, Response to Clarifications required: Product Characterization and Analysis  
for Poncho Votivo 2012-1486, DACO: M2.0 CBI

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