Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4 Application

Application Number: 2015-0448
Application: B.2.1 - New Guarantee
B.2.3 - New Change in Formulants
B.2.4 - New Proportion of Formulants
Product: Votivo 240 FS Nematicide
Registration Number: 31996
Active ingredients (a.i.): *Bacillus firmus* strain I-1582
PMRA Document Number : 2568679

Purpose of Application

The purpose of this application was to register a new formulation of Votivo 240 FS Nematicide. The use pattern for the new formulation product, Votivo 240 FS is the same as the currently registered product, Votivo 247 FS.

Chemistry Assessment

The product characterization information and data for Votivo 240 FS Nematicide were deemed adequate to assess their potential human health and environmental risks. The product was characterized and its specifications were supported by the analyses of a sufficient number of batches. Sufficient information was provided to support a shelf life of 6 months when stored at room temperature.

Health Assessments

Acute toxicity and irritation studies were submitted in support of Votivo 240 FS Nematicide. Votivo 240 FS Nematicide was of low acute oral toxicity (LD_{50} > 2000 mg/kg bw), low acute inhalation toxicity (LC_{50} > 3.83 mg/L) and low acute dermal toxicity (LD_{50} > 2000 mg/kg bw) in rats. In irritation studies, Votivo 240 FS Nematicide was minimally irritating to the eye and not irritating to the skin. Votivo 240 FS Nematicide was not a dermal sensitizer in mice, however, PMRA considers all microbial pest control agents (MPCA) as potential sensitizers since most microorganisms contain substances that could elicit a positive reaction in test animals. Consequently, the statements, “POTENTIAL SENSITIZER” and “May cause sensitization.” are required on the principal display panel and on the secondary display panel of the label under the “PRECAUTIONS” section, respectively. In addition, the microbial pest control agent (MPCA) was previously not found to be pathogenic in acute oral, pulmonary and intravenous infectivity testing.

The label statements for Votivo 240 FS Nematicide, coupled with the end-use product’s low potential for toxicity and infectivity, are considered adequate to address any potential risk due to exposure of the mixer, loader, applicator, and bystanders.

Based on the seed treatment use of Votivo 240 FS Nematicide, the likelihood of bacteria to remain as residues on the corn and soybeans at harvest is very low. Furthermore, since *Bacillus firmus* strains are common in nature, a seed treatment use 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 *Bacillus firmus* strain I-1582, and when *Bacillus firmus* strain I-1582 was administered orally to rats, there was no significant toxicity and no signs of disease were observed.

For the same reasons, no risks are expected from exposure to this microorganism via drinking water. The Votivo 240 FS Nematicide label instructs users not to contaminate irrigation or drinking water supplies or aquatic habitats through equipment cleaning or waste disposal, and municipal treatment of drinking water is expected to further remove the transfer of residues to drinking water.

Maximum Residue Limit

The specification of a maximum residue limit is not required for *Bacillus firmus* strain I-1582.

Incident Reports

As of August 17 2015, no human, domestic animal or environment incident reports involving *Bacillus firmus* strain I-1582 had been submitted to the PMRA.

Environmental Assessment

The environmental fate studies, non-target studies, scientific rationales and supporting published scientific literature previously submitted in support of *B. firmus* strain I-1582 were determined to be sufficiently complete. The use of Votivo 240 FS Nematicide as seed treatment is not expected to pose an unacceptable risk to birds, mammals, arthropods, fish and plants.

Value Assessment

The difference in formulation should not have a significant impact on the efficacy of Votivo 240 FS compared to the currently registered product Votivo 247 FS since both formulations will provide the same amount of active ingredient per seed and will be delivered with the same type of formulation, i.e. a suspension formulation. This new formulation applied at the accepted rates and timing will most likely provide the same level of control against the accepted pests on the crops. It was also demonstrated that this new formulation will not adversely affect the host crops.

Therefore, this new formulation of Votivo, Votivo 240 FS Nematicide, is supported for the same claims and use pattern as registered on the Votivo 247 FS Nematicide. On corn, the new formulation of Votivo 240 FS Nematicide will partially suppress needle nematodes (*Longidorus* spp.), root lesion nematodes (*Pratylenchus* spp.), and root knot nematodes (*Meloidogyne* spp.). On soybean, Votivo 240 FS Nematicide will partially suppress soybean cyst nematode (*Heterodera glycines*), root lesion nematodes (*Pratylenchus* spp.), and root knot nematodes (*Meloidogyne spp*.).

Conclusion

The PMRA has conducted a critical review of the information provided in support of the subject product. Based on the results of this review, Votivo 240 FS Nematicide is acceptable for full registration.

References

1972956 2006, Product identity of Chancellor, DACO: M2.7.1, M2.7.2, M2.8 CBI

1972957 2010, Product chemistry of Bafi SDN (MUP) (supersedes MRID numbers 48050201 and 47963601), DACO: M2.10.1, M2.10.2, M2.12, M2.7.1, M2.7.2, M2.8, M2.9.3 CBI

1972958 2010, Product chemistry of Bafi SDN (MUP) - Supplement to MRID 48110301 and MRID 48110401, DACO: M2.10.1, M2.10.2, M2.12, M2.7.1, M2.7.2, M2.8, M2.9.3 CBI

2500199 2012, Biological Stability Counts of VOTiVO 240 FS, DACO: M2.10.1

2500200 2014, *Bacillus firmus* I-1582 FS 240 - One batch analysis for microbial contaminants, DACO: M2.10.2 CBI

2500201 2014, Microbial contamination control of *Bacillus firmus* TK, DACO: M2.10.2 CBI

2500202 2014, Storage stability at elevated temperature and cold stability of *Bacillus firmus* I-1582 FS 240 (240 g/L) - Packaging material: HDPE - Final report (18 weeks), DACO: M2.11

2500203 2014, Storage stability at elevated temperature and corrosion characteristics of *Bacillus firmus* I-1582 FS 240 (240 g/L) - Packaging material: HDPE - Final report (8 weeks), DACO: M2.11

2500204 2014, Safety-relevant data of *Bacillus firmus* I-1582 FS 240 (240 g/L), DACO: M2.12

2500208 2014, Formulation process of Votivo 240 FS, DACO: M2.8 CBI

2500209 2014, *Bacillus firmus* I-1582 FS 240: Validation of method BM000112KQ1 (Biological stability counts of votivo 240 FS), DACO: M2.10.1, M2.8

2500210 2014, The certified limits of Votivo 240 FS, DACO: M2.9.1 CBI

2500211 2014, The characterization of *Bacillus firmus* I-1582 FS 240, batch number 2014-000270, DACO: M2.9.2

2500212 2014, Physical, chemical and technical properties of *Bacillus firmus* I-1582 FS 240 (240 g/L), DACO: M2.12, M2.9.2

2500196 2015, VALUE SUMMARY: VALUE ASSESSMENT of Votivo 240 FS Nematicide Data to Support a Formulation Change DACO: M10.1