

Evaluation Report for Category B, Subcategory 1.3 Application

Application Number: 2018-0609
Application: Changes TGAI Prod Chemistry-Specifications
Product: *Bacillus firmus* strain GB126 Technical Nematicide
Registration Number: 30278
Active ingredients (a.i.): *Bacillus firmus* strain I-1582
PMRA Document Number : 2910691

Purpose of Application

The purpose of this application was to update the current manufacturing process for the Technical Grade Active Ingredient *Bacillus firmus* strain GB126 Technical Nematicide.

Product Characterization and Analysis

Information and data were provided to support a new manufacturing process for *Bacillus firmus* GB126 Technical Nematicide. The described manufacturing and quality control processes, and representative batch data were adequate to demonstrate that the TGAI manufactured by the new process is equivalent to the previously registered product. No additional information or data are required to complete the Product Characterization and Analysis database for *Bacillus firmus* GB126 Technical Nematicide.

Health Assessment

The change in the manufacturing process for *Bacillus firmus* GB126 Technical Nematicide (TGAI) does not pose any additional health risk of concern.

Environmental and Value Assessments

Environmental and value assessments were not required for this application.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided in support of the manufacturing process, and has found the information sufficient to continue to support the registration of *Bacillus firmus* strain GB126 Technical Nematicide.

References

Product Characterization

Information submitted by the Applicant

2436031	2014, Origin, Derivation, And Identification Of MPCA(S), DACO: M2.10.2,M2.10.3,M2.8 CBI
2860758	2018, Analysis For Microbial Contaminants, DACO: M2.10.2,M2.8 CBI
2877651	Bayer Response To PMRA Clarification Request Sub. No. 2018-0609, DACO M2.8, M2.10
2877652	2018, Manufacturing Methods And Quality Assurance, DACO: M2.8 CBI
2877653	2018, Analysis For Microbial Contaminants, DACO: M2.10.1,M2.10.2 CBI
2894604	Bayer Response To PMRA Clarification Request Sub. No. 2018-0609 DACO M2.8
2894605	2012, Active Ingredient Or MPCA, DACO: M2.10.1 CBI

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