

Evaluation Report for Category B, Subcategory 2.2 Application

Application Number: 2020-1340
Application: Changes to EP Product Chemistry - Form of Technical Grade Active Ingredient
Product: Rhapsody ASO
Registration Number: 28627
Active ingredient (a.i.): *Bacillus subtilis* (strain QST 713)
PMRA Document Number: 3167376

Purpose of Application

The purpose of this application was to update the registration of the end-use product (EP) Rhapsody ASO to reflect the use of the newly registered technical grade active ingredient (TGAI) QST 713 Technical 1.

Product Characterization and Analysis

The description of the formulation process for the registered EP, Rhapsody ASO, was updated to reflect the use of a newly registered technical grade active ingredient (TGAI), QST 713 Technical 1.

Health Assessments

Rhapsody ASO produced using QST 713 Technical 1 is considered to be biologically equivalent to that produced using the existing registered TGAI. As the human health and safety database for the active ingredient, *Bacillus subtilis* strain QST 713, and Rhapsody ASO is considered complete, no additional information is required.

Maximum Residue Limit

Bacillus subtilis strain QST 713 is currently registered in Canada for food uses. The Pest Management Regulatory Agency (PMRA) has determined that specification of a maximum residue limit (MRL) under the *Pest Control Products Act* (PCPA) is not required for *B. subtilis* strain QST 713 (see ERC2007-06, *Evaluation Report - Bacillus subtilis strain QST 713, Serenade MAX, Serenade ASO, Rhapsody ASO, Serenade Garden Concentrate, Serenade Garden Ready To Use*).

Environmental Assessment

Rhapsody ASO produced using QST 713 Technical 1 is considered to be biologically equivalent to that produced using the existing registered TGAI. As the environmental toxicology database for the active ingredient, *Bacillus subtilis* strain QST 713, and Rhapsody ASO is considered complete, no additional information is required.

Value Assessment

A value assessment was not required for this application.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to update the registration of Rhapsody ASO.

References

PMRA Document Number	Reference
3110368	2020, Manufacturing process for Serenade ASO for Canada, DACO: M2.8 CBI
3110369	2015, Material accountability of Serenade ASO - (<i>B. subtilis</i> QST713 SC) - 5 batch analysis, DACO: M2.10.1,M2.10.2,M2.9.2 CBI
3110370	2015, Determination of the total spore number in different biological formulations based on bacterial spores, DACO: M2.10.1,M2.9.2 CBI

© Her Majesty the Queen in Right of Canada, as represented by the Minister of Health Canada, 2021

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of Health Canada, Ottawa, Ontario K1A 0K9.