



Evaluation Report for Category B, Subcategory 3.1 Application

Application Number: 2008-2627
Application: B.3.1 (New or Changes to Product Labels- Application Rate Increase)
Product: Rhapsody ASO
Registration Number: 28627
Active ingredients (a.i.): *Bacillus subtilis* strain QST 713 (BSA)
PMRA Document Number 1759372

Background

Rhapsody ASO (Reg. No. 28627) is a registered commercial class product containing *Bacillus subtilis* strain QST 713 as its active ingredient. Rhapsody ASO is currently registered for the suppression of powdery mildew, Botrytis blight, leaf spot, anthracnose, and Botrytis lesion on a number of ornamental plants grown indoors, outdoors, in greenhouses and nurseries.

Purpose of Application

The Ontario Ministry of Agriculture, Food and Rural Affairs, with the support of Agraquest Inc., submitted an application to expand the label of Rhapsody ASO to include a wide variety of diseases on various crops including cucurbits, fruiting and leafy vegetables, brassica vegetables, ornamentals and turf.

Chemistry Assessment

A chemistry assessment was not required as this application did not involve a change in the product chemistry.

Health Assessments

The active ingredient in Rhapsody ASO, *B. subtilis* strain QST 713, is also found in other registered end-use products including Serenade MAX (Reg. No. 28549), Serenade ASO (Reg. No. 28626), Serenade Garden Concentrate (Reg. No. 28628), and Serenade Garden RTU (Reg. No. 28629). These products are registered for use on many of the food crops or similar food crops as those listed above.

For food crops listed on the Rhapsody ASO label, the proposed application rates of the active ingredient are similar to those listed on the Serenade Garden Concentrate label (rates for Serenade MAX, Serenade ASO, and Serenade Garden RTU are in units that are incompatible for comparison purposes). A maximum residue limit (MRL) was not required for *B. subtilis* strain QST 713 as human health and safety studies did not warrants its establishment. Therefore, differences in rates are not considered to be a significant concern.

The proposed turf use, however, presents an additional means of non-occupational exposure. Although none of the registered end-use products containing *B. subtilis* strain QST713 include turf uses, Serenade Garden Concentrate and Serenade Garden RTU are domestic products intended for residential uses which pose comparable exposure concerns. Furthermore, human health and safety data do not indicate a cause for concern. *Bacillus subtilis* strain QST713 was found to be of low toxicity via the dermal route and slightly irritating to the skin. Dermal toxicity and dermal irritation studies were conducted on Serenade AS, an alternate end-use formulation that was considered an acceptable substitute. Serenade AS was found to be of low toxicity via the dermal route, slightly irritating to the skin, minimally/slightly irritating to the eye and not a dermal sensitizer (although sensitization could occur via other routes of exposure). The toxicology data are sufficient to conclude that the risks associated with Rhapsody ASO due to non-occupational exposure are negligible.

The proposed label expansion for Rhapsody ASO will pose no additional human health and safety concerns.

Environmental Assessment

The non-target studies and published literature submitted in support of the original *B. subtilis* strain QST 713 submission were determined to be sufficiently complete to permit a decision on registration. Data to address environmental fate and behaviour were not required due to the absence of significant toxicological effects in non-target organisms in Tier 1 testing. Environmental effects studies demonstrated that the currently registered uses of products containing *B. subtilis* strain QST 713 do not post a significant hazard to birds, terrestrial arthropods (including honey bees), freshwater fish, aquatic invertebrates and algae. The remaining groups of non-target organisms, mammals, earthworms and other soil macroorganisms, microorganisms and terrestrial plants, were satisfactorily assessed based on studies and reports in the published literature or studies submitted for human health and safety testing or efficacy testing.

The active ingredient in Rhapsody ASO, *B. subtilis* strain QST 713, is also found in other registered end-use products including Serenade Garden Concentrate (Reg. No. 28628) which is registered for use on many of the food crops or similar food crops as those on the Rhapsody ASO label. For food crops listed on the Rhapsody ASO label, the proposed application rates of the active ingredient are similar to those listed on the Serenade Garden Concentrate label.

The environmental risks, as a result of the proposed label expansion for Rhapsody ASO, are expected to be minimal. There are no additional environmental safety concerns posed by the proposed label expansion of Rhapsody ASO.

Value Assessment

In all, 28 crop-disease combinations were proposed as claims for registration including five tank mixes with conventional products for use on lawns, sod, and turf. The majority of proposed rates fell within the registered rate of 1.0-2.0 L/100 L of water. The application rates for the turf-related claims, however, were 125 to 250 mL/100 m². The methods of application for the new uses are generally the same as what is already registered on the RHAPSODY label (i.e. foliar applications) with the exception of a proposed soil drench for ornamental plants. A total of 39

trials conducted in Canada, the US and southern parts of Europe were submitted in support of the various claims. In many instances, support was derived from comparable claims previously registered on the SERENADE ASO and SERENADE MAX label. The full evaluation of this submission has resulted in 13 supported claims, five conditionally supported claims and ten unsupported claims. Data requirements for conditionally accepted claims are provided.

Conclusion

The PMRA has completed the assessment of available data and has found the information sufficient to support the expansion of the Rhapsody ASO label to include various fungal diseases on cucurbit vegetables, leafy vegetables, brassica crops, fruiting vegetables, greenhouse and outdoor ornamentals and turf. Data required for the conditionally supported use claims are:

Two confirmatory trials for each of the following claims:

- suppression of black spot (caused by *Marssonina rosae*) on roses,
- suppression of powdery mildew (caused by *Erysiphe cichoracearum*) on crop group 4 crops, leafy vegetables,
- suppression of bacterial spot (caused by *Xanthomonas campestris*) on crop group 8 crops, fruiting vegetables,
- suppression of brown patch (caused by *Rhizoctonia solani*) on turf, sod, lawns, golf courses, and seed production grasses,
- suppression of anthracnose (caused by *Colletotrichum graminicola*) on turf, sod, lawns, golf courses, and seed production grasses.

References

- PMRA # 1615505 2008. Efficacy data summary table for Rhapsody ASO. DACO 10.2.3.1.
PMRA # 1615506 2008. Efficacy data summary for bridging rationale ASO to MAX. DACO 10.2.3.1.
PMRA # 1615505 2008. Draft supplemental label Rhapsody ASO. DACO 10.2.3.1.

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