



Evaluation Report for Category B, Subcategory 3.1 Application

Application Number: 2008-2629
Application: B.3.1 (New or Changes to Product Labels – Application Rate)
Product: Serenade ASO
Registration Number: 28626
Active ingredients (a.i.): *Bacillus subtilis* strain QST 713
PMRA Document Number: 1759380

Background

Serenade ASO is a registered (Reg. No. 28626) commercial grade end-use product containing *Bacillus subtilis* QST 713 Technical Powder (Reg. No. 28548) as its technical grade active ingredient (TGAI). Serenade ASO is registered as a preventative biofungicide on a wide range of food crops and is applied using standard ground spray equipment.

Purpose of Application

The Ontario Ministry of Agriculture, Food and Rural Affairs, with the support of Agraquest Inc. has submitted an application to expand the label of Serenade ASO to include a wide variety of diseases on berries, brassica vegetables, soybean, bulb vegetables, peanut, root and tuber vegetables, leafy vegetables, cucurbit vegetables, fruiting vegetables, pome fruits and canola.

Chemistry Assessment

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

Health Assessments

The acute toxicity and infectivity studies submitted in support of *B. subtilis* strain QST 713 and the acute toxicity studies submitted in support of Serenade ASO were determined to be sufficiently complete to permit registration (infectivity testing is not required for end-use products). *Bacillus subtilis* QST 713 Technical Powder was of low toxicity in the rat when administered via the oral, pulmonary, intravenous and dermal routes and was not pathogenic or infective via the oral, pulmonary and intravenous routes. The estimated clearance time from the lung and associated lymph nodes after pulmonary exposure was 108 days. Slight dermal irritation and minimal eye irritation were observed with the technical product. Human health and safety studies submitted in support of Serenade ASO were conducted with Serenade AS which was considered an acceptable substitute. Serenade ASO was found to be non-toxic via the oral, pulmonary and dermal routes. Serenade ASO is expected to be slightly irritating to the skin and non- to minimally irritating to the eyes.

The proposed rates are consistent with the already registered rates for Serenade ASO. Based on the acute toxicity and infectivity studies, increased dietary exposure as a result of expanding the use of *B. subtilis* strain QST 713 to other crops is not expected to pose a significant risk. The post-harvest application of Serenade ASO to potatoes is acceptable as a post-harvest interval was not required for Serenade ASO.

Pulmonary, dermal and ocular routes were identified as potential routes of exposure to mixer/loaders, handlers and early-entry workers. While submitted persistence in the lungs and associated lymph nodes after exposure via the pulmonary route has been noted, inhalation exposure is not a concern as commercial users are required to wear NIOSH respirators. To minimize risk to workers, use of appropriate PPE is stipulated on the Serenade ASO label. No additional health concerns are posed by the proposed aerial application of Serenade ASO.

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

Environmental Assessment

At the time of registration of *Bacillus subtilis* strain QST 713 Technical Powder, environmental effects studies were submitted to address the risks to non-target organisms. Those studies showed that the registered uses of products containing *B. subtilis* strain QST 713 would not pose a significant hazard to birds, terrestrial arthropods (including honeybees), freshwater fish, aquatic invertebrates and algae. The remaining groups of non-target organisms, mammals, earthworms and other soil macroorganisms, microorganisms and terrestrial plants were assessed based on studies and reports in the published literature or studies submitted for human health and safety testing or efficacy testing and the risks were found to be of no concern.

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

Value Assessment

In total, 34 crop-disease combinations were proposed as claims for registration. The majority of proposed rates fell within the registered rate of 4 to 12 L/ha. The methods of application for the new uses are generally the same as what is already registered on the Serenade MAX label (i.e. foliar applications) with the exception of a proposed aerial application for canola. A total of 33 trials conducted in the US, Canada, South America and Europe were submitted in support of the various claims. The full evaluation of this submission has resulted in 19 supported claims, eight conditionally supported claims and 7 unsupported claims. Data requirements for conditionally accepted claims are provided. Several crops and crop groups were added to the Serenade ASO label such as soybean, peanut, crop group 1: root tuber vegetables, crop group 3: bulb vegetables, potato, spinach, crop group 12: stone fruits, crop group 4: leafy vegetables, and canola for ground and aerial applications.

Conclusion

The PMRA has completed the assessment of this application and can support the expansion of the Serenade ASO label to include various fungal diseases on berries, brassica vegetables, soybean, bulb vegetables, peanut, root and tuber vegetables, leafy vegetables, cucurbit vegetables, fruiting vegetables, pome fruits and canola. Data required for the conditionally supported use claims are:

Two confirmatory trials for each of the following claims:

- suppression of bacterial blight (*Pseudomonas syringae*) on Crop Group 13: berries
- Suppression of powdery mildew (*Erysiphe cichoracearum*) on Crop Group 4: leafy vegetables
- suppression of bacterial spot (*Xanthomonas campestris*) on tomato and pepper
- suppression of white rust (*Albugo occidentalis*) on spinach
- suppression of brown rot (*Monilinia* spp.) on Crop Group 12: Stone Fruits
- suppression of Sclerotinia stem rot (*Sclerotinia sclerotiorum*) on canola by ground application
- suppression of Sclerotinia stem rot (*Sclerotinia sclerotiorum*) on canola by aerial application
- suppression of silver scurf (*Helminthosporium solani*) on potatoes

References

- PMRA # 1615655. 2008. Efficacy data summary table for Serenade MAX. DACO 10.2.3.1.
- PMRA # 1615656. 2008. Efficacy data summary for bridging rationale ASO to MAX. DACO 10.2.3.1.

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