



Evaluation Report for Category B, Subcategory 3.1 Application

Application Number: 2008-2628
Application: B.3.1 (New or Changes to Product Labels – Application Rate Increase)
Product: Serenade Max
Registration Number: 28549
Active ingredients (a.i.): *Bacillus subtilis* strain QST 713 (BSA)
PMRA Document Number : 1759375

Background

Serenade MAX (Reg. No. 28549) is a registered commercial class product containing *Bacillus subtilis* strain QST 713 as its active ingredient. Serenade MAX is currently registered as a 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 MAX to include a wide variety of diseases on a wide variety of crops including leafy vegetables, berries, brassica vegetables, cucurbit vegetables, soybean, peanut, root and tuber vegetables, leafy vegetables, stone fruits and canola for ground and aerial application.

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 MAX 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 MAX were conducted with Serenade WP, which was considered an acceptable substitute. Serenade MAX was found to be non-toxic via the oral and dermal routes. An acute inhalation study was submitted for Serenade MAX, however, the actual concentration of the product in the test was not measured and this study was, therefore, considered acceptable but supplemental. A replacement study was waived as the

particle size of the wettable powder poses a low risk of inhalation exposure and the nature of the formulants in the product are not of concern. In addition, any risk is mitigated by the use of standard personal protective equipment (PPE). Serenade MAX was found to be slightly irritating via the dermal route and non- to minimally irritating to the eye.

The proposed use rates are consistent with those already registered for Serenade MAX. 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. 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 MAX label. No additional health concerns are posed by the proposed aerial application of Serenade MAX.

The proposed label expansion for Serenade MAX 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 acceptable.

The proposed use rates are consistent with those already registered for Serenade MAX. The environmental risks, as a result of the proposed label expansion for Serenade MAX, are expected to be minimal. There are no additional environmental safety concerns posed by the proposed label expansion of Serenade MAX.

Value Assessment

In total, 26 crop-disease combinations were proposed as claims for registration. The majority of proposed rates fell within the registered rate of 1.0-3.0 kg/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 13 supported claims, six 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 MAX label such as soybean, peanut, crop group 1: root tuber vegetables, potato, spinach, crop group 12: stone fruits, crop group 4: leafy vegetables, radish, turnip and rutabaga, and canola for ground and aerial applications.

Conclusion

The PMRA has evaluated all available information and has found it to be sufficient to support the expansion of the Serenade MAX label to include various fungal diseases on soybean, peanut, root and tuber vegetables, leafy vegetables, stone 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 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

References

- PMRA # 1615585 2008. Efficacy data summary table for Serenade MAX. DACO 10.2.3.1.
PMRA # 1615586 2008. Efficacy data summary for bridging rationale ASO to MAX. DACO 10.2.3.1

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