

Evaluation Report for Category B, Subcategory 3.11, 3.12 Application

Application Number: 2009-3793

Application: New product label: New pests, new site or host

Product: Jazz

Registration Number: 29725

Active ingredient (a.i.): *Bacillus subtilis* strain QST 713

PMRA Document Number: 1891991

Purpose of Application

The purpose of this application was to register a new end-use product, Jazz, containing *Bacillus subtilis* strain QST 713 for suppression of green mould (*Trichoderma harzianum*) in mushroom crops. The application was based on the precedent product, Serenade Max (Registration Number 28549).

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessment

Human health and safety data supporting the registration of Serenade Max are sufficient to support the new end-use product, Jazz.

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 10^8 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, a similar formulation 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. Serenade Max was found to be slightly irritating via the dermal route and non- to minimally irritating to the eye. Serenade Max was determined to be a sensitizing agent in a hypersensitivity study.

Although the proposed rate for Jazz applications to mushrooms is ten times higher than the maximum rates approved for Serenade Max. The human health and safety studies do not indicate a concern with the higher rate. Moreover, there is no maximum residue limit established for *B. subtilis* strain QST 713 or its end-use products.

Serenade Max is currently registered for use on field crops whereas mushrooms are 

grown in specialized facilities. Rhapsody ASO (Registration Number 28627), another end-use product containing *B. subtilis* strain QST 713, is registered for use in greenhouses where the exposure scenario may be similar to that of mushroom growing rooms. Additionally, the personal protective equipment (PPE) proposed on the label for Jazz include a long-sleeved shirt, long pants, shoes plus socks, water-proof gloves and a NIOSH approved respirator with any N-95, R-95, P-95 or HE filter for biological products when handling, and during all clean-up and repair activities. These PPE requirements are consistent with those listed on the Canadian labels for Serenade Max and Rhapsody ASO.

Environmental Assessment

Environmental toxicology data supporting the registration of Serenade Max are sufficient to support the new end-use product, Jazz. No studies were submitted to address the environmental fate and behaviour of *B. subtilis* strain QST 713. Environmental fate data (Tier II/III) were not required, due to the absence of significant toxicological effects in non-target organisms in Tier I testing.

Environmental effects studies were submitted to address risks of *B. subtilis* strain QST 713 to non-target organisms. Those studies showed that the proposed uses of products containing *B. subtilis* strain QST 713 would not pose 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 assessed based on studies and reports in the published literature or studies submitted for human health and safety testing or efficacy testing. In published scientific literature, adverse effects attributed to *B. subtilis* were reported in mammals, terrestrial insects and non-arthropod invertebrates. These reports, however, were few in number despite this microorganism's ubiquitous nature in the environment and, in most cases, the implication of select strains of *B. subtilis* was not thoroughly investigated.

The biological properties of this microorganism suggest that spores of this MPCA could survive in aquatic ecosystems. However, no harm to aquatic organisms is expected based on the absence of disease or other adverse effects in aquatic organisms. Similarly, no harm to terrestrial organisms is expected based on the number of adverse effects reported in published literature and the results of the ecotoxicology tests submitted.

Although the proposed rate for Jazz applications to mushrooms is ten times higher than the maximum rates approved for Serenade Max. Despite the higher rate, environmental exposure is expected to be minimized due to the fact that mushrooms are grown in specialized indoor facilities and that spent mushroom substrate is steam pasteurized prior to disposal.

Value Assessment

Three trials from Pennsylvania conducted in 2007-2008 were submitted for evaluation. Jazz mixed with the spawn and the supplement provided decreasing levels of protection throughout the harvest period, but still adequately suppressed green mould under severe disease pressure. In all trials, mushroom yield was significantly higher when Jazz was mixed with 1) the spawn or 2) both spawn and supplement. Moreover, these treatments were statistically comparable to the non inoculated untreated check. However, no trials tested the Jazz application to the supplement alone. Furthermore, one drench application to the surface of mushroom beds did not significantly increase yield compared to the inoculated untreated check and resulted in a significantly lower yield than the spawn treatment.

Based on these results, the use of Jazz for suppression of green mould on white button mushrooms is supported, when mixed at 0.3/0.6 kg/4-6 kg gypsum, limestone or chalk/100 kg spawn grains/100 m². The use of Jazz applied alone as a supplement coating or as drench applications to the growing beds cannot be supported given the lack of efficacy data. A second Jazz application as a supplement coating, following

the Jazz treatment to the spawn grains, is supported at 0.3-0.6 kg/4-6 kg gypsum, limestone or chalk/100 kg supplement/100 m². Taking into consideration the lack of conclusive efficacy data for support of the drench treatments, but also the potential benefit of additional drench applications for season-long suppression of this disease, a third Jazz application as a drench to the growing beds before the first flush is conditionally supported at 0.3-0.6 kg/75 L water/100 m². Additional efficacy data is required to fully support this claim. Tank mix and compatibility claims were not supported with efficacy data.

Conclusion

The PMRA conducted an evaluation of the subject application and found the information sufficient to support conditional registration of the end-use product, Jazz. Additional efficacy data are required by April 30, 2011 to fulfill the terms and conditions for conditional registration.

References

Information	submitted	by	Registrant:
PMRA Reference: 2009, Value - Jazz: suppression of green mould on mushroom, Data Numbering Code: M10.1, M10.3.1, M10.3.2, M10.4.2, M10.4.3	Document	Number:	1804142
PMRA Reference: Individual Summary Reports, Data Numbering Code: M10.2	Document	Number:	1804143
PMRA Reference: 2009, Summary Table, Data Numbering Code: M10.2	Document	Number:	1804144
PMRA Reference: 2008, Agaricus 0714 - Serenade Trial II, Final Report, Data Numbering Code: M10.2.2	Document	Number:	1804145
PMRA Reference: 2007, Evaluation of bioshields for control of <i>Trichoderma</i> green mold disease of <i>Agaricus Bisporus</i> crop 0703, Data Numbering Code: M10.2.2	Document	Number:	1804147
PMRA Reference: 2007, Evaluation of biorational fungicides for the control of dry bubble and green mold diseases on mushrooms, Data Numbering Code: M10.2.2	Document	Number:	1804149

Additional information considered:

ERC2007-06 Evaluation Report: *Bacillus subtilis* strain QST 713, Serenade MAX, Serenade ASO, Rhapsody ASO, Serenade Garden Concentrate, Serenade Garden Ready To Use.
ISBN : 1911-8082

Catalogue number: xxxxxxxxxxx (xxxxxxxx)

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