

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 3.10 Application

Application Number: 2018-6007
Application: New End-Use Product, Product Chemistry – Guarantee, Identify of Formulants and Proportion of Formulants, Changes to Product Labels – Tank Mixes
Product: Kasumin 4L Bactericide
Registration Number: 33630
Active ingredient (a.i.): Kasugamycin (present as hydrochloride hydrate)
PMRA Document Number: 3056219

Purpose of Application

The purpose of this application was to register Kasumin 4L Bactericide for use on terrestrial and greenhouse food crops.

Chemistry Assessment

Kasumin 4L Bactericide is formulated as a liquid containing kasugamycin (present as hydrochloride hydrate) at a concentration of 4.00 %. This end-use product has a density of 1.0273g/mL and pH of 4.25. The required chemistry data for Kasumin 4L Bactericide have been provided, reviewed and found to be acceptable.

Health Assessments

Kasumin 4L Bactericide is of low acute toxicity by the oral, dermal, and inhalation routes. Kasumin 4L Bactericide is minimally irritating to the skin and mildly irritating to eyes, and is a potential skin sensitizer.

The use of Kasumin 4L Bactericide is not expected to result in occupational and bystander exposures to kasugamycin which are greater than those from the precedent product. Risks have been shown to be acceptable when workers follow label directions and wear personal protective equipment as stated on the label. Post-application risks to workers have been shown to be acceptable.

No residue data were submitted in support of the registration of Kasumin 4L Bactericide. The use pattern of the end-use product was determined to be equivalent to that of the registered precedent product. Therefore, the previously reviewed data were reassessed in the framework of the current application and it was confirmed that the use of Kasumin 4L Bactericide is not expected to result in an increase in the magnitude of kasugamycin residues in/on the treated crops.

Therefore, the registration of Kasumin 4L Bactericide will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The use patterns for Kasumin 4L Bactericide fall within those currently registered for the active ingredient. No additional risk to the environment is expected from the registration of Kasumin 4L Bactericide that cannot be mitigated through labelling.

Value Assessment

Value information was submitted as data generated in field trials in which a treatment of Kasumin 4L Bactericide was directly compared to that of the precedent product. The two products were applied at the same labeled rate on an active ingredient basis, and their efficacy against fire blight in apple and bacterial spot of tomato was compared. The submitted data and a comparison of the two product formulations demonstrated that the two products are biologically equivalent and that, therefore, the extrapolation of all claims from the precedent product to the Kasumin 4L Bactericide label is supported, including use on Fruiting Vegetables (Crop Group 8) in the field or greenhouse, pome fruit crops (Crop Group 11-09), walnut, caneberries (Crop Subgroup 13-07 A), saskatoon berries and cherries (Subgroup 12-09A) for the control or suppression of several bacterial diseases.

Registration of this product will facilitate product transport and storage as well as reduce the number of units handled by growers.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the available information and has found it sufficient to support the registration of Kasumin 4L Bactericide.

References

PMRA Document Number	References
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2934603	2017, Method Validation for F1781 AB Fungicide, DACO: 3.4.1
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2934611	2018, F1781 ab Fungicide: Local Lymph Node Assay (LLNA) in Mice, DACO: 4.6.6
2934612	2018, Cross Reference for Exposure for Kasumin 4L Bactericide - Bridging from the Precedent Product, Kasumin 2L Bactericide (Reg. No. 30591), DACO: 5.2,7.1
2934597	2016, Evaluation of F1781aa, F1781ab and ARY-0627-002 for control of fire blight on McIntosh apples, 2016, DACO: 10.2.3.3
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2934599	2018, General Efficacy of Formulations of F1483aa on Fruiting Vegetable for Control of Bacterial Diseases, DACO: 10.2.3.3
2934600	2018, Tables for Summary of Value for Kasumin 4L Bactericide, DACO: 10.2.3.3,10.3.1

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