

Evaluation Report for Category B, Subcategory 3.10, 3.11, 3.12 Application

Application Number: 2017-1297
Application: B.3.10: New Tank Mixes
B.3.11: New Pests
B.3.12: New Host
Product: Sirocco
Registration Number: 31091
Active ingredients (a.i.): Potassium Bicarbonate
PMRA Document Number : 2855696

Purpose of Application

The purpose of this application was to add to the Sirocco label, Reg. # 31091 the following amendments: (1) the addition of a new claim: suppression of *Botrytis cinerea* on grapes, (2) the addition of a new crop and associated claim: suppression of apple scab (*Venturia inaequalis*) on apple trees and (3) the addition of a tank-mix with Buran (garlic powder) for use on apples.

Chemistry Assessment

Chemistry assessment was not required for this application.

Health Assessment

Potential exposure to potassium bicarbonate may occur by applying the end use product, entering treated sites, or consuming food and water. PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). As such, sex is taken into account in the risk assessment. Registration is only supported for uses that are determined as having no health risks of concern.

Toxicology studies in laboratory animals describe potential health effects resulting from various levels of exposure to a chemical and identify dose levels at which no effects are observed.

Sirocco is of low acute oral, dermal and inhalation toxicity. Sirocco is moderately irritating to the skin, and mildly irritating to the eyes, but is not a dermal sensitizer.

Occupational exposure to individuals handling Sirocco is not expected to result in unacceptable risk when the product is used according to label directions. Precautionary and hygiene statements on the product label aimed at mitigating worker exposure are considered adequate to protect individuals from any unnecessary risk due to occupational exposure.

Bystander exposure is not expected to result in health risks of concern when

the product is used according to label directions.

Residential and non-occupational exposure is not expected to result in health risks of concern when the product is used according to label directions.

Maximum Residue Limit

The Food and Drug Act prohibits the sale of adulterated food; that is, food containing a pesticide residue that exceeds the established maximum residue limits (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in or on certain foods. Food containing a pesticide residue that is at or below the established MRL does not pose an unacceptable health risk.

The uses for Sirocco on apples and grapes will not result in an increase in dietary risks from food or drinking water. Consequently, the specification of an MRL for potassium bicarbonate under the PCPA is not required.

Environmental Assessment

The use of Sirocco on apples and grapes will not result in any additional environmental impact or risk of concern relative to the existing registered uses. Environmental concerns have been mitigated through adequate statements on the product label.

Value Assessment

Based on efficacy data from two trials on grapes and six trials on apples, the claims and uses were supported.

Grey mold is one of the most serious diseases in grapes. This disease leads to quality and yield lost in Canada and more solutions are highly requested by producers, especially from growers using low risk pesticides. Sirocco is a low risk pesticide that can be used up to the day of harvest.

Conclusion

PMRA has conducted a critical review of the information provided in support of (1) the addition of a new claim: suppression of *Botrytis cinerea* on grapes, (2) the addition of a new crop and associated claim: suppression of apple scab (*Venturia inaequalis*) on apple trees and (3) the addition of a tank-mix with Buran (garlic powder) for use on apples to the Sirocco label, Reg. # 31091. Based on the results of this review, these amendments are acceptable for registration.

References

i) List of Studies Conducted by Registrant

| | |
|---------|--|
| 2741196 | 2017, Evaluation of reduced rates of Sirocco(R) and Buran(R) alone and combined on the control of Botrytis on Grapevine, DACO: 10.2.3.3 |
| 2741197 | Philion, V and Joubert, V., 2014, MISE AU POINT SUR LUTILISATION DU BICARBONATE DE POTASSIUM POUR LUTTER CONTRE LA TAVELURE DU POMMIER, DACO: 10.2.3.3 |
| 2741198 | Philion, V and Joubert, V., 2015, Evaluation of fungicides for different spray timings, rates, and spray volumes to control apple scab, 2015, DACO: 10.2.3.3 |

ISSN: 1911-8082

© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2018

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.