

Evaluation Report for Category B, Subcategory 3.12 Application

Application Number: 2019-2359
Application: B.3.12: New or Changes to Product Labels-New Site or Host
Product: Velum Prime
Registration Number: 32108
Active ingredients (a.i.): Fluopyram
PMRA Document Number: 3143819

Purpose of Application

The purpose of this application was to add pest claims and crop claims to the label of Velum Prime.

Chemistry Assessment

Chemistry assessment was not required for this application.

Health Assessments

The occupational exposure and risk from the addition of the use on Brassica (cole) leafy vegetables, crop group 8-09 (fruiting vegetables), crop group 9 (cucurbit vegetables), crop group 11-09 (pome fruit), 12-09 (stone fruit), crop subgroup 13-07A (caneberries) and ginseng to the Velum Prime label was assessed. No risks of concern are expected from the new use, provided workers follow the label directions and wear the personal protective equipment identified on the label.

No new residue data for fluopyram in Brassica (Cole) Leafy Vegetables, Fruiting Vegetables, Cucurbit Vegetables, Pome Fruits, Stone Fruits, Chokecherry, and Caneberries were submitted to support the use expansion of this active on the Velum Prime label. Previously reviewed residue data were re-assessed in the framework of this application. Based on this assessment, residues of fluopyram in/on treated Brassica (Cole) Leafy Vegetables, Fruiting Vegetables, Cucurbit Vegetables, Pome Fruits, Stone Fruits, Chokecherry, and Caneberry commodities are not expected to increase and will be covered under the established maximum residue limits for fluopyram. Consequently, the dietary exposure to residues of fluopyram is not expected to increase with the addition of Brassica (Cole) Leafy Vegetables, Fruiting Vegetables, Cucurbit Vegetables, Pome Fruits, Stone Fruits, Chokecherry, and Caneberries and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

After a scientific review of the available information, PMRA has concluded that the environmental risks associated with the uses of Velum Prime are acceptable when used according to the label directions.

Value Assessment

Scientific rationales and efficacy data from field and greenhouse trials conducted in Canada, the USA, Mexico, Brazil, India, Italy, the Philippines and Spain were provided in support of the use claims. Overall, Velum Prime at the tested rates demonstrated its effectiveness against certain plant parasitic nematodes at the level of suppression on cucumber, broccoli, melon, Brussels sprouts, tomato, apple, raspberry, cherry and ginseng. Velum Prime also suppressed powdery mildew on cucumber as shown in the efficacy trials. The value of Velum Prime on the use claims was confirmed from both rationales and efficacy data.

The registration of these new uses will provide Canadian growers with a new active ingredient to manage nematode infestation on Brassica (cole) leafy vegetables, cucurbit vegetables, fruiting vegetables, pome fruits, stone fruits, caneberries, chokecherry and ginseng. It also provides Canadian growers a new product to manage listed fungal diseases on Brassica (cole) leafy vegetables, cucurbit vegetables and fruiting vegetables.

Conclusion

PMRA has reviewed the information provided to support the addition pest claims and crop claims to the label of Velum Prime. Based on the results of this review, the addition pest claims and crop claims to the label of Velum Prime are acceptable for registration.

References

- 2997271 2019, Value Assessment of Velum Prime for Suppression of Powdery Mildew and Nematodes in Crop Group 5 Brassica (Cole) Leafy Vegetables and Crop Group 9 Cucurbit Vegetables, DACO: 10,10.1,10.2.1,10.2.2,10.2.3,10.2.3.1,10.3,10.3.1,10.3.2(A), 10.5,10.5.1,10.5.2,10.5.3
- 2997272 2019, Value Assessment of Velum Prime - Label expansion to include suppression of nematodes and early blight on Crop Group 8-09: Fruiting Vegetables, DACO: 10,10.1, 10.2.1,10.2.2,10.2.3,10.2.3.1,10.3,10.3.1,10.3.2(A),10.5,10.5.1,10.5.2,10.5.3
- 2997273 2019, Value Assessment of Velum Prime - Label expansion to include suppression of nematodes on Ginseng; Crop Group 11-09: Pome Fruits; Crop Group 12-09 Stone Fruits; and Crop Subgroup 13-07A: Caneberries, DACO: 10,10.1,10.2.1,10.2.2,10.2.3, 10.2.3.1,10.3,10.3.1,10.3.2(A),10.5,10.5.1,10.5.2,10.5.3
- 2997274 2019, CBI Reference Document: Value Assessment of Velum Prime for Suppression of Powdery Mildew and Nematodes in Crop Group 5 Brassica (Cole) Leafy Vegetables and Crop Group 9 Cucurbit Vegetables, DACO: 10,10.1,10.2.1,10.2.2,10.2.3,10.2.3.1, 10.3,10.3.1,10.3.2(A),10.5,10.5.1,10.5.2,10.5.3 CBI
- 2997278 2019, Field Trial reports: Value Assessment of Velum Prime for Suppression of Powdery Mildew and Nematodes in Crop Group 5 Brassica (Cole) Leafy Vegetables and Crop Group 9 Cucurbit Vegetables, DACO: 10.2.3,10.2.3.3,10.2.3.3(D)
- 2997279 2019, Field Trial reports: Value Assessment of Velum Prime - Label expansion to include suppression of nematodes and early blight on Crop Group 8-09: Fruiting Vegetables, DACO: 10.2.3,10.2.3.3,10.2.3.3(D)
- 2997280 2019, Field Trial reports: Value Assessment of Velum Prime - Label expansion to include suppression of nematodes on Ginseng; Crop Group 11-09: Pome Fruits; Crop Group 12-09 Stone Fruits; and Crop Subgroup 13-07A: Caneberries, DACO: 10.2.3,10.2.3.3,10.2.3.3(D)
- 2997283 2016, Fluopyram: Rationale characterizing new uses in sugar beets, onion, caneberry, bushberry, hops, tobacco, corn (field, pop and sweet), wheat and sorghum, DACO: 7.1,7.4.1

© Her Majesty the Queen in Right of Canada, as represented by the Minister of Health Canada, 2020

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 Health Canada, Ottawa, Ontario K1A 0K9.