

Evaluation Report for Category B, Subcategory 3.11, 3.12 Application

Application Number: 2021-1209
Application: New or Changes to Product Labels - New Pests; New Site or Host
Product: APROVIA TOP
Registration Number: 31526
Active ingredients (a.i.): Benzovindiflupyr and Difenoconazole
PMRA Document Number: 3342050

Purpose of Application

The purpose of this application is to expand the use of the registered product APROVIA TOP to add the crops in Crop Subgroup (CSG) 1B (Root Vegetables, except sugar beet). Ginseng, which is in CSG 1B, was previously registered for use on the APROVIA TOP label.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

A toxicology assessment was not required for this application.

The occupational exposure and risk from the addition of the use on Root Vegetables (except sugar beet and ginseng) to the APROVIA TOP label was assessed. No health risks of concern are expected from the new use, provided that workers follow the label directions and wear the personal protective equipment identified on the label.

No new residue data for difenoconazole in CSG 1B were submitted. Previously reviewed residue data from field trials conducted in/on radishes and carrots were reassessed in the framework of this application. For benzovindiflupyr, residue data from field trials conducted in the United States, including growing regions representative of Canada, were submitted to support the use of APROVIA TOP on CSG 1B. Benzovindiflupyr was applied to radishes and carrots at the proposed rate, and harvested according to label directions. A processing study on carrots was also submitted and reviewed, and indicated that benzovindiflupyr residues did not concentrate in the processed commodities of carrots including juice.

Maximum Residue Limits

The recommendation for maximum residue limits (MRLs) for benzovindiflupyr was based upon the submitted field trial data, and the guidance provided in the [OECD MRL Calculator](#). MRLs to cover residues of benzovindiflupyr in/on crops are proposed as shown in Table 1. Residues in processed commodities not listed in Table 1 are covered under the proposed MRLs for the raw agricultural commodities (RACs).

Table 1 Summary of Field Trial Data Used to Support Maximum Residue Limits (MRLs)

TABLE 1. Summary of Field Trial Data Used to Support Maximum Residue Limits (MRLs)					
Commodity	Application Method/ Total Application Rate (g a.i./ha)	PHI (days)	Residues (ppm)		Recommended MRL (ppm)
			LAFT	HAFT	
Radish Root	Foliar/ 297.7-305.4	7-8	0.0322	0.235	0.6 [CSG 1B; Root Vegetable, except sugar beet and ginseng root]
Carrot Root			0.0261	0.128	
Radish Leaves			0.354	1.22	
Ginseng Root	Foliar/ 300-311	15-21	0.0336	0.145	0.3

LAFT = Lowest Average Field Trial; HAFT = Highest Average Field Trial

Following the review of all available data, MRLs as proposed in Table 1 are recommended to cover residues of benzovindiflupyr. Dietary risks from exposure to residues in these crop commodities at the proposed MRLs were shown to be acceptable for the general population and all subpopulations, including infants, children, adults and seniors. Thus the foods that contain residues as listed in Table 1 are considered safe to eat.

Environmental Assessment

The use pattern for root vegetables is within the registered use pattern of APROVIA TOP, therefore the previous risk assessment is adequate for the new uses. The product label includes all the required environmental precautions, directions for use and spray buffer zone information

which adequately mitigate risks to the environment. Risk from use of APROVIA TOP is acceptable from the environmental perspective when used according to label directions.

Value Assessment

The results from seven efficacy trial reports and scientific rationales support the use of APROVIA TOP to manage alternaria leaf blight and powdery mildew on labeled root vegetables, as well as the use of APROVIA TOP to manage cercospora leaf spot and alternaria leaf blight on carrots. The registration of APROVIA TOP for these claims will provide growers with an alternative product to manage important root vegetable diseases.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to support the addition of the use of APROVIA TOP on the crops in Crop Subgroup 1B (Root Vegetables, except sugar beet).

References

PMRA Document Number	Reference
3212775	2021, DACO 10 Value Summary: Efficacy and Crop Response for Control of <i>Alternaria dauci</i> and <i>Cercospora carotae</i> in carrots and <i>Alternaria brassicae</i> and <i>Erysiphe polygoni</i> in CG 1B: Root Vegetables (except sugar beet and ginseng) with Aprovia Top, DACO: 10.1, 10.3.1, 10.3.2
3212777	2010, A7402 - Efficacy against <i>Alternaria</i> and <i>Erysiphe</i> on Carrots, DACO: 10.2.3.3
3212778	2010, A7402T (difenoconazole 250EC) - Efficacy against <i>Alternaria</i> and <i>Erysiphe</i> on Carrots, DACO: 10.2.3.3
3212779	2016, F741 E 32016BR_CP_Efficacy Trials_Carrots_Fusha+DFZ_Season 2015/16_Field, DACO: 10.2.3.3
3212780	2019, Evaluation of fungicides for control of foliar blights of carrots, 2019., DACO: 10.2.3.3
3212781	2019, Evaluate Aprovia for control of <i>Cercospora</i> and <i>Alternaria</i> leaf blight in carrot, DACO: 10.2.3.3
3212782	2019, Evaluate Aprovia for control of <i>Cercospora</i> and <i>Alternaria</i> leaf blight in carrot, DACO: 10.2.3.3
3212783	2010, Evaluate Hambra for Control of Leaf Blight in Carrot, DACO: 10.2.3.3
3212813	2020, Benzovindiflupyr EC (A15457K) - Magnitude of the Residues in Carrot and Radish (Crop Group 1B) Raw Agricultural and Processed Commodities USA 2019, DACO: 7.4.1, 7.4.2, 7.4.5

© Her Majesty the Queen in Right of Canada, as represented by the Minister of Health Canada, 2022

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.