

Evaluation Report for Category B, Subcategory 3.5, 3.12 Application

Application Number: 2018-6222
Application: B.3.5: New Rotational Crops/Plantback Interval
B.3.12: New Site or Host
Product: BYI 02960 200SL Insecticide
Registration Number: 33696
Active ingredients (a.i.): Flupyradifurone
PMRA Document Number : 3083763

Purpose of Application

The purpose of this application was to register end-use product BYI 02960 200SL Insecticide.

Chemistry Assessment

Chemistry assessment was not required for this application.

Health Assessments

BYI 02960 200SL Insecticide is considered to be of low acute toxicity via the oral, dermal and inhalation routes in rats, non-irritating to the skin or rabbits, minimally irritating to the eyes of rabbits, and a potential dermal sensitizer, as determined by a local lymph node assay conducted in mice.

The use of the end-use product BYI 02960 200SL Insecticide is not expected to result in risks of concern when workers follow label directions and wear personal protective equipment as stated on the label.

Residue data from field trials conducted in Canada and the United States were submitted to support the domestic use of flupyradifurone on potatoes (crop subgroup 1C), strawberries (crop subgroup 13-07G) and rapeseeds (crop subgroup 20A). Flupyradifurone was applied to potatoes and strawberries at 1-fold GAP and to canola at 5.6-6.4 fold GAP. Crops were harvested according to label directions. In addition, a processing study in treated sugar beets was reviewed and processing studies in potato, soybean and cottonseed were also reassessed to determine the potential for concentration of residues of flupyradifurone into processed commodities.

Maximum Residue Limits

The recommendation for maximum residue limits (MRLs) for flupyradifurone was based upon the submitted field trial data, and the guidance provided in the [OECD MRL Calculator](#). MRLs to cover residues of flupyradifurone 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 and Processing Data Used to Support Maximum Residue Limits (MRLs)

Commodity	Application Method/ Total Application Rate (g a.i./ha)	PHI (days)	Residues (ppm)		Experimental Processing Factor	Currently Established MRL (ppm)	Recommended MRL (ppm)
			LAFT	HAFT			
Tuberous and Corm Vegetables (Crop Subgroup 1C)							
Potato	Soil/ 399-423	51-108	<0.010	0.011	N/A	0.05	N/A
Low Growing Berries (Crop Subgroup 13-07G)							
Strawberries	Foliar/ 410-420	0	0.222	0.998	N/A	1.5	N/A
	Soil/ 400-410	1	0.019	0.671			
Rapeseeds (Crop Subgroup 20A)							
Canola	Seed + Foliar/ 254-289	60-170	<0.010	0.024	N/A	N/A	0.03

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

Based on the dietary burden and residue data, MRLs of 0.1 ppm in fat and 0.07 ppm in milk to cover residues of flupyradifurone are also proposed to replace the current MRLs of 0.06 ppm for each animal commodity.

Following the review of all available data, MRLs as proposed in Table 1 and those proposed for fat and milk are recommended to cover residues of flupyradifurone. Residues in these crop/livestock commodities at the proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

No additional risk to the environment is expected from the registration of the end-use product, BYI 02960 200SL Insecticide. The use pattern of BYI 02960 200SL Insecticide fits within the registered use pattern for flupyradifurone. The product label contains the required environmental hazard statements and directions for use.

Value Assessment

Most of the uses of BYI 02960 200SL Insecticide were supported based on extrapolation from the same use claims on labels of the registrant's similar registered products. The additional uses were supported based on submitted efficacy data from five field trials for aphids on potato and four field trials for flea beetles on canola, combined with rationales to include Crop Subgroup 13-07G (Low Growing Berries, except cranberry and lowbush blueberry) and the other crops in Crop Subgroups 1C (Tuberous and Corm Vegetables) and 20A (Rapeseeds). BYI 02960 200SL Insecticide provides a new active ingredient for soil application on Crop Subgroups 1C and 13-07G and a new mode of action for foliar application on Crop Subgroup 20A.

Conclusion

The PMRA has reviewed the information provided in support of the end use product, BYI 02960 200SL Insecticide. Based on the results of this review, the end use product BYI 02960 200SL Insecticide is acceptable for registration.

References

PMRA#	Reference
2938046	2018, Sivanto 200 SL (flupyradifurone) - Magnitude of the residue in strawberry (low growing berry subgroup, crop subgroup 13-07G), bridging trials, DACO: 7.4.1,7.4.2
2938047	2018, Sivanto 200 SL (Flupyradifurone) - Magnitude of the residue in potatoes (Tuberous and corm vegetables, crop subgroup 1C), DACO: 7.4.1,7.4.2
2938048	2018, BYI 02960 200 SL and BYI 02960 480 FS - Magnitude of the residue in/on canola, DACO: 7.4.1,7.4.2
2938079	2018, Flupyradifurone Request for six-month plant-back interval to sugar beet following the application at the maximum seasonal application rate to primary crops, DACO: 7.4.4
2938082	2012, Processing study - Determination of the residues of BYI 02960 in/on beet, sugar and processed fractions (body, washed; washings; pulp; raw juice; thin juice; cake, lime; thick juice; molasses; raw sugar; white sugar; pulp, extracted, wet; press liquor; pulp, extracted, pressed; pulp, extracted, dry; pulp, extracted, ensiled; and refined sugar) after spraying and incorporation of BYI 02960 SL 200 in the field in Germany, DACO: 7.4.5
2938083	2018, Flupyradifurone - Extrapolation of soybean and cotton processing data to canola processed commodities, DACO: 7.4.5
2938008	2018, Value Assessment of Sivanto Prime Insecticide (flupyradifurone) for control of flea beetles in Crop SubGroup 20A: Rapeseeds, DACO: 10.1, 10.2.3.1, 10.2.3.3, 10.3.1, 10.3.2, 10.5, 10.5.1, 10.5.2, 10.5.3, 10.5.4
2938010	2018, Value Assessment of soil use-patterns in Crop SubGroup 1-C and Crop SubGroup 13-07G with Sivanto Prime Insecticide (flupyradifurone), DACO: 10.1, 10.2.3.1, 10.2.3.3, 10.3.1, 10.3.2, 10.5.1, 10.5.2, 10.5.3, 10.5.4
2938015	2018, Value Assessment of Sivanto Prime Insecticide (flupyradifurone) for control of flea beetles in Crop SubGroup 20A: Rapeseeds: Compilation of trial reports, DACO: 10.2.3.3
2938016	2018, Value Assessment of soil use-patterns in Crop SubGroup 1-C and Crop SubGroup 13-07G with Sivanto Prime Insecticide (flupyradifurone): Compilation of trial reports, DACO: 10.2.3.3

ISSN: 1911-8082

© 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.