

Evaluation Report for Category B, Subcategory 3.12 Application

Application Number: 2014-5497
Application: New or Changes to Product Labels-New Site or Host
Product: Isofetamid 400SC Fungicide
Registration Number: 31555
Active ingredients (a.i.): Isofetamid
PMRA Document Number: 2718719

Purpose of Application

The purpose of this application was to amend the Isofetamid 400SC Fungicide end-use product by adding new crops to the label.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

The risks for mixers, loaders, applicators, post-application re-entry workers and bystanders from exposures to Isofetamid 400SC Fungicide from treatments of legume vegetables, berries and small fruit crops, apples and stone fruits are not of concern. Risks to the public entering treated pick-your-own facilities to pick highbush blueberries, raspberries, cherries, peaches, plums, or apples are not of concern. No risks of concern are expected when workers follow the label directions and precautions, and wear the personal protective equipment stated on the label.

New residue data for isofetamid in raspberry, blueberry, kiwifruit, cherry (sweet and tart), peach, plum, apple, beans and peas (both dry and succulent) were submitted to support the use expansion of the Isofetamid 400SC Fungicide. Residue data from field trials conducted in Canada and the United States were submitted to support the domestic use of Isofetamid 400SC Fungicide on these crops. In addition, a processing study in treated apples and plums was reviewed to determine the potential for concentration of residues of isofetamid into processed commodities.

Maximum Residue Limit(s)

The recommendation for maximum residue limits (MRLs) for isofetamid was based upon the submitted field trial data, and the guidance provided in the [OECD MRL Calculator](#). MRLs to cover residues of isofetamid in/on crops and processed commodities 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 Limit(s) (MRLs)

Commodity	Application Method/ Total Application Rate (g ai/ha)	PHI (days)	Residues (ppm)		Experimental Processing Factor	Currently Established MRL (ppm)	Recommended MRL (ppm)
			LAFT	HAFT			
Blueberries	1774-1957	6-8	0.184	3.59	-	-	4.0: CSG 13-07A (Caneberries)
Raspberries	1904-1954	6-7	0.202	1.59	-	-	5.0: CSG 13-07B (Bushberries)
Kiwifruits	1921-1957	7	<0.01	3.8	-	-	10 for CSG 13-07E (Small Fruits Vine Climbing, Except Grape)
Cherries (sweet and tart)	1063-1102	0-1	0.310	2.52	-	-	4.0: CSGs 12-09A (Cherries) and 12-09B (Peaches)
Peaches	1074-1130	1	0.240	1.70	-	-	
Plums	1080-1106	1	0.030	0.360	Prune: 4.0	-	0.8: CSG 12-09C (Plums) 1.5: Dried prune plums
Apples	1901-2905	18-21	0.020	0.380	Juice: 0.3 Pomace: 3.8	-	0.6: Apples
Snap beans (edible- podded)	974-1034	5-7	0.031	0.325	-	-	0.6: CSG 6A (Edible- Podded Legume Vegetables, except pigeon pea and pea (<i>Pisum</i> spp.), including dwarf pea, edible- podded pea, snow pea, sugar snap pea)
Green peas (succulent shelled)	970-1004	2-17	<0.01	0.025	-	-	0.04: CSG 6B (Succulent Shelled Pea and Bean)
Lima beans (succulent shelled)	986-1009	14	<0.01	<0.01	-	-	
Dry pea seeds	966-1009	21-42	<0.01	0.025	-	-	0.04: CSG 6C (Dried Shelled Pea and Bean (except soybean))
Dry bean and dry lima bean seeds	811-1034	23-57	<0.01	0.036	-	-	

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

Based on the dietary burden and residue data, MRLs of 0.01 ppm in milk, fat meat and meat by-products of cattle, goats, hogs, horses and sheep, to cover residues of isofetamid are also proposed.

Following the review of all available data, MRLs as proposed in Table 1 are recommended to cover residues of isofetamid. 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

Isofetamid 400SC Fungicide is already registered for the same use site category (USC) as the new uses. The new uses have lower maximum single and seasonal application rates than the current registered uses. No additional data was required for the environmental assessment of Isofetamid 400SC Fungicide, and no additional environmental risk is expected from the use of this product. Environmental concerns are mitigated with the environmental label statements.

Value Assessment

A combination of efficacy data and scientific rationales were provided in support of the proposed label expansion. The same use pattern is sought in the USA, therefore, registration in Canada will bring the same technology to Canadian growers as their USA counterparts. Isofetamid 400SC Fungicide adds another mode of action for pest management where resistance has developed to fungicides of other modes of action.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided in support of the product, Isofetamid 400SC Fungicide, and has found the information sufficient to add new crops to the product label.

References

PMRA Document Number	Reference
2573327	2010, Evaluate IKF-5411 for control of Sclerotinia sclerotiorum on dry beans, DACO: 10.2.3.3(D)
2573328	2010, Evaluation of IKF-5411 against apple scab and other apple diseases, DACO: 10.2.3.3(D)
2573329	2011, Evaluation of IKF-5411 against white mold in dry beans, DACO: 10.2.3.3(D)
2573331	2011, Evaluation of IKF-5411 against white mold in dry beans, DACO: 10.2.3.3(D)
2573332	2011, Evaluation of IKF-5411 against white mold in dry beans - simulated aerial application, DACO: 10.2.3.3(D)
2573335	2011, Evaluation of IKF-5411 against blossom blight on peach, DACO: 10.2.3.3(D)
2573340	2011, Evaluation of IKF-5411 against fruit brown rot on nectarine and peach, DACO: 10.2.3.3(D)
2573344	2012, Evaluation of IKF-5411 against brown rot blossom blight and shot hole on apricots, DACO: 10.2.3.3(D)
2573346	2012, Evaluation of IKF-5411 against post harvest brown rot and Rhizopus on peach, DACO: 10.2.3.3(D)
2573347	2012, Evaluation of IKF-5411 against brown rot on peach, DACO: 10.2.3.3(D)
2573353	2014, Evaluation of IKF-5411 against apple scab on apples, DACO: 10.2.3.3(D)
2573354	2013, Evaluation of IKF-5411 against postharvest brown rot, Rhizopus rot and Gilbertella rot on peach, DACO: 10.2.3.3(D)
2573355	2013, Evaluation of IKF-5411 against brown rot on peach, DACO: 10.2.3.3(D)
2573357	2014, Evaluation of IKF-5411 against diseases on apples, DACO: 10.2.3.3(D)
2573311	2015, Use Description/Scenario (Application and Post Application) for Isofetamid 400SC Agricultural Fungicide Label Expansion to Crop Group 6, Legume Vegetables (succulent or dried), Crop Group 11-10, Pome fruit, Crop Group 12-12, Stone Fruit and the remainder of Crop Group 13-07, Berry and small fruit, except for subgroup 13-07C, DACO: 5.2.
2273744	2012, IKF-5411: In Vivo Dermal Absorption Study in the Male Rat, DACO: 5.8
2273746	2012, Dislodgeable Foliar Residue Study IKF-5411 on Apples - USA in 2012, DACO: 5.9(A)
2273747	2013, Dislodgeable Foliar Residue Study IKF-5411 on Grapes USA in 2012, DACO: 5.9(A)
2273748	2013, Dislodgeable Foliar Residue Study IKF-5411 on Beans - USA in 2012, DACO: 5.9(A)

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