Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 4.6 Application

Application Number: 2014-3528
Application: Submission to fulfill requirements of registration on a product with full registration
Product: Initium SC Fungicide (formerly called BAS 650 00 F Fungicide)
Registration Number: 30322
Active ingredients (a.i.): Ametoctradin
PMRA Document Number (English PDF): **2494175**

Background

Initium SC Fungicide (Registration Number 30322; guarantee 200 g/L ametoctradin) was first registered for use in Canada in 2012. At the time of registration some additional confirmatory data were requested as requirements of full registration.

Purpose of Application

The purpose of this application was to fulfill the requirements of registration for Initium SC Fungicide for the claim of suppression of phytophthora blight caused by *Phytophthora capsici* in cucurbit vegetables and fruiting vegetables, the claim of control of downy mildew caused by *Pseudoperonospora humuli* in hops, as well as providing additional confirmatory residue data for green onion and hops.

No information was submitted to support aerial application; therefore the requirements for aerial application are still outstanding.

Chemistry and Environmental Assessments

Chemistry and environmental assessments were not required for this application.

Health Assessments

A toxicology assessment was not required for this application.

Submitted ametoctradin residue data on green onions and hops were reviewed and adequately addressed the requirements of full registration of Initium SC Fungicide. Ametoctradin was

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applied to green onions and hops at the label rates, and crops were harvested according to the label directions. Previously reviewed residue data from field trials conducted on green onions and hops were also re-assessed in the framework of these submissions.

The recommendation for maximum residue limits (MRLs) for ametoctradin was based upon the previously and newly submitted field trial data for each crop, as well as the guidance provided in the OECD MRL Calculator. For green onions (and all commodities of crop subgroup 3-07B), the currently established MRL of 20 ppm is considered adequate to cover residues of ametoctradin in/on the raw agricultural commodities. For hops, a revised MRL of 60 ppm is proposed for promulgation 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.

TABLE 1. Summary of Newly Submitted Field Trial Data Used to Support Maximum Residue Limit(s) (MRLs)

Commodity	Application Method/ Total Application Rate (g a.i./ha)	PHI[1] (days)	Residues (ppm)		Experimental Processing Factor	Currently Established MRL (ppm)	Recommended MRL (ppm)
			LAFT[2]	HAFT[3]			
Green onions (whole plants without roots)	Foliar broadcast/ 900 - 934	0	2.28	3.46	Not required	20	None
Hops (dried)	Foliar broadcast/ 907 - 914	6 - 8	9.26	28.70	Not required	10	60

[1] PHI = preharvest interval
[2] LAFT = Lowest Average Field Trial
[3] HAFT = Highest Average Field Trial

Following the review of all available data, a revised MRL of 60 ppm is recommended to cover residues of ametoctradin in/on hops (dried). For green onions and all commodities of crop subgroup 3-07B, the currently established MRL of 20 ppm is adequate. Residues of ametoctradin in these crop commodities at the proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Value Assessment

Value information was submitted in the form of efficacy trials data (four trials) to confirm the claims of suppression of phytophthora blight in cucurbit and fruiting vegetables. Data demonstrated in all trials that ametoctradin provided suppression of phytophthora blight in cucurbit and fruiting vegetables. Efficacy data from four trials were submitted to confirm the claim of control of downy mildew cause by *Pseudoperonospora humuli* in hops. The data submitted were sufficient to support the claim of control of downy mildew in hops.

There are ten priorities listed in the Canadian Grower Priority Database for phytophthora blight in cucurbit and fruiting vegetables and four priorities for downy mildew in hops. This indicates that these diseases are of concern for cucurbit vegetable, fruiting vegetable and hop production. Confirming the requirements of registration of this product provides continued use of this product as an alternative with a unique mode of action, thus supporting resistance management when used in rotation with other products.

Conclusion

The PMRA has completed a review of all available information and found it sufficient to address the requirements of registration for Initium SC Fungicide for the claim of suppression of phytophthora blight caused by *Phytophthora capsici* in cucurbit vegetables and fruiting vegetables, the claim of control of downy mildew caused by *Pseudoperonospora humuli* in hops, as well as residue data for green onion and hops. A revised MRL of 60 ppm is recommended to cover residues of ametoctradin in/on hops (dried). For green onions and all commodities of crop subgroup 3-07B, the currently established MRL of 20 ppm is adequate.

The requirement for additional aerial application information is still outstanding.

References

List of Studies/Information Submitted By Registrant

PMRA Document Number	Reference
2451891	2014, DACO 7.4.1 Crop Field Trials Response to PMRA Conditions for full registration: Request for Additional Trial Data for Green Onion and Hops, DACO: 7.4.1
2451892	2013, Magnitude of the residues of BAS 650 F (Ametoctradin) and BAS 550 F (Dimethomorph) in green onion following applications of BAS 651 00 F: Report of the magnitude of the residue of BAS 650 F (Ametoctradin) and BAS 550 F (Dimethomorph), DACO: 7.4.1
2451894	2008, Study on the residue behaviour of BAS 650 F and BAS 550 F in bulb and spring onion after treatment with BAS 651 00 F under field conditions in Northern and Southern Europe during 2006, DACO: 7.4.1
2451895	2013, Magnitude of BAS 650 F residues in hops after applications of BAS 651 00 F, DACO: 7.4.1
2451896	2010, Determination of residues of BAS 650 F and Dimethomorph in hops after two applications of BAS 651 00 F in Germany, DACO: 7.4.1
2451897	2011, Determination of residues of BAS 550 F (Dimethomorph) and BAS 650 F (Ametoctradin) in hops after two applications of BAS 651 00 F in Germany, DACO: 7.4.1

2451898	2011, Determination of residues of BAS 650 F and Dimethomorph in hops and its processed products after three applications of BAS 651 00 F in Germany, DACO: 7.4.1
2505355 2505363	2015, Cover Email for response to PMRA, DACO: 7.4.1
2451890	2014, BASF response to Conditions of Registration BAS 650 00 F Fungicide, containing Ametoctradin, EP Submission Number: 2010-0963 and Zampro Fungicide, containing Ametoctradin, EP Submission Number: 2010-0960, DACO: 10.2.3.3

Other References

2014. Lizotte, E. Downy mildew of hops already reported in Michigan for 2014, Michigan State University extension.

2001. Gevens, A.J. et al. Vegetable Diseases Caused by Phytophthora capsici in Florida. University of Florida.

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