

Evaluation Report for Category B, Subcategory 3.12, 3.6 Applications

Application Number: 2013-0051

Application: B.3.12: New Site or Host

B.3.6: New PHI

Product: Oberon Flowable Insecticide-Miticide

Registration Number: 28905

Active ingredients (a.i.): Spiromesifen PMRA Document Number: 2635059

Purpose of Application

The purpose of this application was to add one pest (mint bud mite), specific crop groups and reduce the pre-harvest interval (PHI) of fruiting vegetables from 7 days to 1day.

Chemistry Assessment

Chemistry assessment was not required for this application.

Health Assessments

Occupational exposures from the use expansion of Oberon Flowable Insecticide-Miticide to popcorn and sweet corn, wheat and sorghum, leafy and legume vegetables, low-growing berries, and mint are acceptable. No unacceptable risk is expected when workers follow the label directions and wear the personal protective equipment identified on the label. The reduction of the pre-harvest interval (PHI) of fruiting vegetables from 7 days to 1day is acceptable.

New residue data from field trials conducted in the United States were submitted to support the domestic use of Oberon Flowable Insecticide in/on wheat, sorghum, dry peas, celery, mint, sweet corn, popcorn, tomatoes and bell and non-bell peppers. Previously reviewed residue data from field trials conducted in/on strawberries, dry beans, succulent-shelled beans or edible-podded beans were reassessed in the framework of this petition. Spiromesifen was applied at the registered and exaggerated rates, and harvested according to label directions. In addition, processing studies in treated wheat, sorghum and mint were reviewed to determine the potential for concentration of residues of spiromesifen into processed commodities.

Maximum Residue Limits

The recommendation for maximum residue limits (MRLs) for spiromesifen was based upon the submitted field trial data, and the guidance provided in the <u>OECD MRL Calculator</u>. MRLs to cover total residues of spiromesifen in/on various 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)

	(MIKLS)						
	Application Method/ Total Application Rate (g ai/ha)	PHI (days)	Residues (ppm)		Experiment	Currently	
Commodity			Min	Max	al Processing Factor	Establishe d MRL (ppm)	Recommended MRL (ppm)
Celery	Foliar / 446-461	7	0.025	4.24	NA	None	8.0
Tomato	Foliar / 445-459		0.038	0.451	NA	0.45	0.5 (CSG 8- 09A)
Bell Pepper	Foliar / 436-453	1	< 0.02	0.17	NA	0.45	0.9 (CCC 9
Non-bell pepper	Foliar / 438-441		0.03	0.34	NA	0.45	0.8 (CSG 8- 09B)
Strawberry	Foliar / 843-863	2-4	0.23	1.64	NA	2.0	2.0^{1}
Dry shelled peas	Foliar / 631-676	9-11	<0.02	0.06	NA	None	0.002
Dry shelled beans	Foliar / 634-726	9-10	<0.02	< 0.02	NA	0.02	-0.08^2
Sweet corn (K+CWHR)	Foliar / 291-305	28-30	<0.02	<0.02	NA	None	0.02
Popcorn grain	Foliar / 303-303	28-29	< 0.02	< 0.02	NA	None	0.02
Sorghum grain	Foliar / 297-309	28-30	0.02	0.678	NA	None	0.9
Wheat grain	Foliar / 295-309	28-30	<0.02	0.053	4.9 (bran) 3.8 (germ)	0.03	0.06 0.15 (bran) 0.15 (germ)
Mint tops	Foliar / 842-869	6-8	1.72	10.97	NA	None	20
Head lettuce	Foliar / 451-465	6-9	0.156	4.65	NA	12	
Leaf lettuce	Foliar / 451-466	7-8	0.507	9.99	NA	12	
Spinach	Foliar / 449-476	6-9	0.236	8.65	NA	12	20^{3}
Mustard greens	Foliar / 448-453	6-8	0.628	10.026	NA	12	
Broccoli	Foliar / 445-462	7-10	< 0.02	0.713	NA	2	4 ⁴
Cabbage	Foliar / 451-466	6-9	< 0.02	1.91	NA	2	

¹Previously established under S2006-5550/5544. The strawberry MRL will be extended to the whole CSG 13-07G. ²This MRL is to replace the current established MRL of 0.02 ppm on dry shelled beans. The new proposed MRL is to be extended to all crops within CSG 6C. ³This MRL is to replace the current established MRL on CSG 4A. The new proposed MRL is to be extended to all crops within CG 4-13. ⁴This MRL is to replace the current established MRLs on CSG 5A and 5B. The new proposed MRL is to be extended to all crops within CG 5-13.

Based on the dietary burden and residue data, MRLs of 0.03 ppm in meat of cattle, goats, hogs, horses and sheep, 0.03 ppm in fat of hogs, 0.15 ppm in meat by-products of cattle, goats, hogs, horses and sheep and 0.02 ppm in milk to cover total residues of spiromesifen are also proposed.

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

Environmental assessment was not required for this assessment.

Value Assessment

Three field trials conducted in Wisconsin in 2007-2009 demonstrated control of bud mite on mint with application of 600-880 mL Oberon Flowable Insecticide-Miticide per hectare. All other new use claims were supported based on uses already registered for the same pests on similar crops, with confirmatory data from 10 field trials against two-spotted spider mites on beans and soybean.

Conclusion

The PMRA has reviewed the information provided in support of the addition bud mite on mint, specific crop groups and reducing the pre-harvest interval (PHI) of fruiting vegetables from 7 days to 1day. Based on the results of this review, the addition of bud mite on mint, the crop groups and reducing the pre-harvest interval (PHI) of fruiting vegetables from 7 days to 1day is acceptable.

References

PMRA# 2264851	2012, Oberon Flowable Insecticide-Miticide: Data to support mite
	and whitefly control on additional crops, DACO: 10.1, 10.2.2,
	10.2.3.1, 10.2.3.2, 10.2.3.3, 10.2.3.4, 10.3.1, 10.3.2, 10.3.3, 10.5.1,
	1052 1053 1054

PMRA# 2264852 2012, Efficacy trial summary tables, DACO: 10.2.3.3

PMRA # 2115788 2011. Agricultural Reentry Task Force (ARTF). 2008. Data Submitted by the ARTF to Support Revision of Agricultural Transfer Coefficients.

PMRA Number	Reference
2363991	2013, Spiromesifen: Frozen Storage Recovery Study on Bell Pepper, DACO 7.3
1296173	2002, BSN 2060 240 SC - magnitude of the residue on strawberries, DACO:
	7.4.1,7.4.2
2264888	2008, Oberon 240 SC - Magnitude of the residue in/on popcorn, DACO: 7.4.1
2264894	2008, Oberon 240 SC - Magnitude of the residue in/on sweet corn - IR-4 minor use
	submission in support of tolerances for spiromesifen in or on sweet corn, sweet
	corn forage, and sweet corn stover, DACO: 7.4.1,7.4.2
2264889	2007, Oberon 240 SC - Magnitude of the residue in/on tomato, DACO: 7.4.1

2264891	2009, Spiromesifen - Magnitude of the residue on pepper (Bell & non-bell),
	DACO: 7.4.1
2264892	2007, Spiromesifen: Magnitude of the residue on bean (dry shelled, succulent
	shelled, edible podded), DACO: 7.4.1,7.4.2
2264896	2009, Spiromesifen: Magnitude of the residue on pea (dry), DACO: 7.4.1,7.4.2
2264895	2009, Oberon 240 SC - Magnitude of the Residue in/on celery (crop subgroup 4B),
	DACO: 7.4.1,7.4.2
2264897	2009, Spiromesifen: Magnitude of the residue on mint, DACO: 7.4.1,7.4.2
2264898	2009, Oberon 2 SC - Magnitude of the residue in/on wheat, DACO: 7.4.1,7.4.2
2264903	2009, Oberon 2 SC - Magnitude of the residue in/on wheat processed commodities
	and aspirated grain fractions, DACO: 7.4.5
2264899	2009, Oberon 2 SC - Magnitude of the residue in/on sorghum, DACO: 7.4.1,7.4.2
2264902	2009, Oberon 2 SC - Magnitude of the residue in/on sorghum aspirated grain
	fractions, DACO: 7.4.5
1296283	2002, Request for waiver of poultry feeding study and residue analytical method
	for BSN 2060, DACO: 7.5
1296238	2002, BSN 2060 - A 28 - day dairy cattle feeding study, DACO: 7.4.6,7.5

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