

Evaluation Report for Category B, Subcategory 5.0 Application

Application Number: 2009-0872
Application: New MRL for previously assessed TGAI
Product: Spirotetramat Technical Insecticide
Registration Number: 28952
Active ingredients (a.i.): Spirotetramat
PMRA Document Number (English PDF): 1844492

Purpose of Application

The purpose of this application is to establish import maximum residue limits (MRLs) for the technical grade active ingredient spirotetramat on cotton, kiwifruit, and various tropical fruits. This application is a joint review between the United States, Canada, and Austria.

Health Assessments

To support the establishment of import MRLs on cotton, kiwifruit, and various tropical fruits, residue data for spirotetramat were evaluated for cotton undelinted seed, avocado, guava, lychee, papaya, mango, and kiwifruit. Following review of all available data, the following MRLs are being proposed: 0.30 ppm for cotton undelinted seed; 13 ppm for lychee (also extended to longan, Spanish lime, rambutan, pulasan); 0.60 ppm for avocado (also extended to black sapote, canistel, mamey sapote, sapodilla, star apple, white sapote); 0.35 ppm for papaya; 2.5 ppm for guava (also extended to feijoa, jaboticaba, wax jambu, starfruit, passion fruit, acerola); 0.30 ppm for mango; and 0.20 ppm for kiwifruit.

Based on the maximum residues observed in crops treated according to foreign label directions, the MRLs to cover residues of spirotetramat and related metabolites in/on crops will be established as shown in Table 1. Residues of spirotetramat in processed commodities not listed in Table 1 are covered under established MRLs for the raw agricultural commodities (RACs).

It is noted that because tropical fruit field trials were conducted at exaggerated rates (according to US GAP), PMRA is requesting confirmatory trials from the applicant in order to determine the relationship between residues resulting from the labelled use pattern and the submitted field trials. The import MRLs for tropical fruits will therefore be reassessed once these confirmatory studies have been submitted.

TABLE 1. Summary of Field Trial Data Used to Establish Maximum Residue Limit(s) (MRLs)						
Commodity	Application Method/Total Application Rate (g a.i./ha)	PHI (days)	Total Spirotetramat Residues ¹ (ppm)		Experimental Processing Factor	Recommended MRL (ppm)
			Min	Max		
Cotton – undelinted seed	Broadcast foliar/ 176-181	18-22	<0.05 5	0.28	Cottonseed Oil 0.02	0.30
Lychee, extended to Longan, Spanish lime, Rambutan, Pulasan	Broadcast foliar/ 852-865	1	0.26	5.16	--	13
Avocado, extended to Black sapote, Canistel, Mamey sapote, Sapodilla, Star apple	Broadcast foliar/ 857-874, 1.02 kg a.i./ha/season	1	<0.05 5	0.33	--	0.60
Papaya	Broadcast foliar/ 858-876	1	0.10	0.21	--	0.35
Guava, extended to Feijoa, Jaboticaba, Wax jambu, Starfruit, Passion fruit, Acerola	Broadcast foliar/ 876-886	3	0.22	0.82	--	2.5
Mango (Australia)	Broadcast foliar/ 9.68 g a.i./100L	13-14	<0.11	0.25	--	0.30
Kiwifruit (New Zealand)	Broadcast foliar/192	NA	<0.17	<0.1 7	--	0.20

¹ Total residues of spirotetramat, BYI08330-enol, BYI08330-ketohydroxy, BYI08330-mono-hydroxy, and BYI08330-enol-glucoside, expressed in parent equivalents.

Following the review of all available data, the MRLs for the crops noted in Table 1 above are recommended to cover residues of spirotetramat and related metabolites. Residues of spirotetramat in these crop commodities at the established MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Chemistry, Environmental and Value Assessment

Chemistry, environmental and value assessments were not required for this application.

Conclusion

The PMRA has completed an assessment of available information for Spirotetramat Technical Insecticide and has found the information sufficient to support the addition of import MRLs on cotton, kiwifruit, and various tropical fruits.

References

PMRA Document Number	Reference
1721295	2009, Spirotetramat 150 OD and 240 SC - Magnitude of the residue in/on cotton, DACO: 7.4.1,7.4.2,7.4.6,IIIA 8.3.1
1721307	2009, Spirotetramat 150 OD and 240 SC - Magnitude of the residue in/on tropical fruit (except grapefruit) - US import tolerance, DACO: 7.4.1,7.4.2,7.4.6,IIIA 8.3.1
1721315	2008, Determination of residues of BYI-08330 (spirotetramat) in mango following three applications of BYI-08330 240 SC at 7.2, 9.6 or 14.4 g a.i./100 L or two applications of BYI-08330 150 OD at 9.6 g a.i./100 L as a foliar spray, DACO: 7.4.1,7.4.2,7.4.6,
1721321	2007, Determination of spirotetramat and metabolite residues in kiwifruit, DACO: 7.4.1,7.4.2,7.4.6,IIIA 8.3.1
1721322	2008, Spirotetramat 150 OD - Magnitude of the residue in/on cotton processed commodities, DACO: 7.4.5,8.4.1,IIIA 8.5.1

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