

Evaluation Report for Category B, Subcategory 5.0 Application

Application Number: 2012-0242
Application: B.5.0 (New MRL for previously assessed TGAI)
Product: Spirotetramat Technical Insecticide
Registration Number: 28952
Active ingredients (a.i.): spirotetramat
PMRA Document Number: 2292893

Purpose of Application

The purpose of this application was to establish import maximum residue limits (MRLs) for spirotetramat (Spirotetramat Technical, EPA Reg. No. 264-1049; Movento, EPA-Reg. No. 264-1050; and ULTOR, EPA Reg. No. 264-1065) on Banana/Plantain, Pineapple, Pomegranate, Watercress, Coffee, Taro leaves, and Crop Group 10 (revised).

Chemistry, Environmental and Value Assessments

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

Health Assessments

To support the import MRLs in/on Banana/Plantain, Watercress, Coffee, Pineapple, Pomegranate, Taro leaves, and Crop Group 10 (revised), residue data from supervised residue trials conducted in the United States were assessed, in which the requested crops/representative crops were treated with spirotetramat and harvested according to label directions. In addition, processing studies in treated **coffee and pineapple** were reviewed to determine the potential for concentration of residues of **spirotetramat and its metabolites (expressed as parent equivalents)** into **roasted coffee beans, instant coffee, and pineapple juice**.

Maximum Residue Limit (MRL)

The recommendation for import MRLs for spirotetramat and its metabolites (expressed as parent equivalents) in/on bananas, plantains, watercress, coffee, pineapples, pomegranates, and taro leaves were based on the OECD MRL Calculator and guidance provided by the OECD MRL Calculator Statistical White Paper. Based on the residue data and the MRL statistical methodology, import MRLs to cover residues of spirotetramat and its metabolites (all expressed as parent equivalents) in/on bananas, plantains, watercress, coffee, pineapples, pomegranates, and taro leaves will be established as shown in Table 1. Residues of spirotetramat and its metabolites (expressed as parent equivalents) in processed commodities not listed in Table 1 are covered under established MRLs for the raw agricultural commodities (RACs).

Table 1. Summary of Field Trial Data Used to Establish Import Maximum Residue Limits (MRLs) for Spirotetramat

Commodity	Application Method/ Total Application Rate (g a.i./ha)	PHI (days)	Residues (ppm)		Currently Established MRL (ppm)	Recommended MRL (ppm)
			Min	Max		
Watercress	Foliar & Chemigation/ 425 – 443	3	<0.29	<0.71	None	2.0 ppm
Coffee	Foliar/ 536 – 555	13 – 14	<0.05	0.0079	None	0.20 ppm
Pineapple	Foliar/ 351 – 359	1	<0.053	<0.111	None	0.30 ppm
Banana	Foliar/ 1.40 – 1.45 kg a.i./ha	1	<0.51	<2.1	None	4.0 ppm
Pomegranate	Foliar/ 349 – 356	1	<0.070	<0.199	None	0.50 ppm
Processed Food						
Fraction		HAFT (ppm)	Concentration Factor	Currently Established MRL (ppm)	Recommended MRL (ppm)	
Instant Coffee		0.072	4.4x	None	0.50 ppm	
Based upon the maximum theoretical concentration factor and residues from the highest average coffee field trial, residues would be expected to reach 0.32 ppm in instant coffee. Since the limit of quantitation (LOQ) for the analytical method in instant coffee is 0.50 ppm, a MRL of 0.50 ppm is recommended to cover residues of spirotetramat and its metabolites (expressed as parent equivalents) in/on instant coffee.						

The import MRL of 0.60 ppm currently established in/on citrus fruits (Crop Group 10) will be extended to the commodities in the revised citrus fruits crop group. The MRL of 9.0 currently established in/on leafy vegetables (Crop Group 4) will be extended to taro leaves.

Conclusions

Following the review of all available data, it was determined that MRLs of 9.0 ppm (taro leaves), 0.60 ppm (Crop Group 10, revised), 2.0 ppm (watercress), 4.0 ppm (bananas and plantains), 0.30 ppm (pineapples), 0.50 ppm (pomegranates), 0.20 ppm (green coffee beans), and 0.50 ppm (instant coffee), for residues of spirotetramat and its metabolites (all expressed as parent equivalents) in/on these crops are considered adequate to cover residues of spirotetramat and its metabolites (all expressed as parent equivalents) in/on these commodities as a result of these new uses. Residues of spirotetramat and its metabolites (all expressed as parent equivalents) in these commodities at the established and proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

References

PMRA Document Number	Reference
2148590	2011, Spirotetramat: Magnitude of the residue on Banana, DACO: 7.2.1,7.2.5,7.3,7.4.1,7.4.2
2148591	2011, Spirotetramat: Magnitude of the residue on Pomegranate, DACO: 7.2.1,7.2.5,7.4.1,7.4.2
2148592	2011, Spirotetramat: Magnitude of the residue on Pineapple, DACO: 7.2.1,7.2.5,7.4.1,7.4.2
2148597	2011, Spirotetramat: Magnitude of the residue on coffee, DACO: 7.2.1,7.2.5,7.3,7.4.1,7.4.2
2148598	2010, Spirotetramat: Magnitude of the residue on Watercress, DACO: 7.2.1,7.2.5,7.4.1,7.4.2

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