Health Canada Santé Canada

Evaluation Report for Category B, Subcategory B.5.0 Application

Application Number: 2011-6058
Application: New maximum residue limit for a previously assessed technical grade active ingredient (TGAI)
Product: Spiromesifen Technical Insecticide - Miticide
Registration Number: 28589
Active ingredients (a.i.): Spiromesifen
PMRA Document Number: **2323899**

Purpose of Application

The purpose of this submission was to establish a maximum residue limit (MRL) for the active ingredient Spiromesifen on tea imported from India and Japan.

Health Assessments

To support the establishment of an import maximum residue limit (MRL) on dried tea leaves, residue data from field trials conducted in India and Japan were reviewed. In addition, processing studies were reviewed to determine the potential for concentration of residues of spiromesifen into tea processed commodities.

Maximum Residue Limit

Based on the maximum residues observed in tea treated according to label directions, a maximum residue limit (MRL) to cover residues of 60 ppm in/on dried tea leaves will be proposed as shown in Table 1. Residues of spiromesifen in processed commodities not listed in Table 1 are covered under proposed MRL.

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TABLE 1. Summary of Field Trial and Processing Data Used to Support the Maximum Residue Limit (MRL)

Commodity	Application Method/ Total Application Rate (g a.i./ha)	PHI[1] (days)	Residues[2] (ppm)		Experimental Processing Factor	Currently Established MRL	Recommended MRL
			Min	Max			
Fresh tea leaves	Foliar/600 g a.i./ha	7	0.64	9.99	3.26 (black tea)	None	60 ppm
Crude green tea leaves	Foliar/600 g a.i./ha	7	6.32	21.07	None		
Crude green tea leaves	Foliar/600 g a.i./ha	7	6.16	21.75	None		

[1] Plant harvest interval (PHI)
[2] Total residues of spiromesifen and the -enol metabolite (converted to parent equivalents)

Chemistry, Environmental and Value Assessments

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

Conclusion

Following review of the application, an MRL of 60 ppm is recommended to cover total residues of spiromesifen in/on dried tea leaves imported from India and Japan. Total residues of spiromesifen in this imported crop commodity at the proposed MRL will not pose an unacceptable risk to any segment of the population.

References

PMRA Document Number	Reference
2140763	2004, Summary of residue of Danigetter SC in green tea official, DACO: 7.1,7.4.1,7.4.2
2140764	2004, Residue of Danigetter SC in green tea and hot water Inhouse, DACO: 7.1,7.4.1,7.4.2,7.4.5
2140765	2007, Independent laboratory validation of Bayer CropScience analytical method 01038 for the determination of residues of BSN 2060 and its metabolite BSN2060-enol in/on plant material by LC/MS/MS, DACO: 7.2.3
2140767	2004, Danigetter SC green tea inhouse 1, DACO: 7.2.1,7.4.1,7.4.2
2140768	2004, Danigetter SC tea hot water inhouse 2, DACO: 7.2.1,7.4.1,7.4.2,7.4.5
2140769	2004, Agrochemical residue analysis results report - Spiromesifen (BCI-033) flowable, DACO: 7.2.1,7.4.1,7.4.2
2140773	2011, Analytical method 01038 for the determination of residues of BSN 2060 and its metabolite BSN2060-enol in/on plant matrices by HPLC-MS/MS, DACO: 7.2.1
2140774	2011, Magnitude of residue of Spiromesifen in/on tea following application of Spiromesifen SC 240C G, DACO: 7.2.5,7.4.1,7.4.2

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