Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.6, 3.4 and 3.12 Application

Application Number: 2015-1253
Application: New End-Use Product Chemistry – New combination of technical grade active ingredients, new site or host and application method
Product: Metlock CT Fungicide
Registration Number: 32371
Active ingredients (a.i.): Metconazole
PMRA Document Number : **2556674**

Purpose of Application

The purpose of this application was to register a new commercial/on farm seed treatment product, Metlock CT Fungicide (guarantee 46.5 g/L metalaxyl and 23.2 g/L metconazole), to control seed and seedling diseases of cereals and corn.

Chemistry Assessment

Metlock CT Fungicide is formulated as a solution containing metconazole and metalaxyl at nominal concentrations of 23.2 and 46.5 g/L respectively. This end-use product has a density of 1.03 g/mL and pH of 8.67. The chemistry requirements for Metlock CT Fungicide are complete.

Health Assessments

Metlock CT Fungicide is of low acute toxicity in rats by the oral, dermal and inhalation routes of exposure. It was minimally irritating to the eyes and non-irritating to the skin of rabbits. It was not a dermal sensitizer in mice.

The requested seed treatment uses of metalaxyl in Metlock CT Fungicide on cereals are already registered. Existing MRLs for metalaxyl are adequate to cover all uses of Metlock CT Fungicide.

New residue data for metconazole in barley were submitted to support the registration of the seed treatment end-use product Metlock CT Fungicide, containing metconazole and metalaxyl, for use on various cereal grain seeds. In addition, previously reviewed metconazole residue data from field trials conducted in/on corn and wheat were reassessed in the framework of this petition.

The recommendation for maximum residue limits (MRLs) for metconazole was based upon the previously and newly submitted field trial data, and the guidance provided in OECD MRL Calculator, as shown in Table 1 below. 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 Metconazole Field Trial and Processing Data Used to Support MRLs

Commodity	Application Method/ Total Application Rate (g a.i./100 kg seed)	Days after planting	Total *cis*- and *trans*-Metconazole Residues (ppm)		Experimental Processing Factor	Currently Established MRL (ppm)	Recommended MRL (ppm)
			LAFT[1]	HAFT[1]			
Corn	Seed treatment (Radiotracer) 1.7 - 3.1	169-189	<0.005	<0.005	No quantifiable residues observed when treated at exaggerated rates	0.04	0.04[3] (Buckwheat, Pearl millet, Proso millet, Teosinte)
Wheat	Seed treatment 1.6 - 1.8	102-286	<0.02	<0.02		0.15[2]	
Barley	Seed treatment 2.6 - 3.0	77-118	<0.01	<0.01		2.5[2]	

[1] LAFT = Lowest Average Field Trial; HAFT = Highest Average Field Trial
[2] Based on residues observed following foliar treatment.
[3] Based on the limit of quantitation (LOQ) of the enforcement method.

Following the review of all available data, MRLs as proposed in Table 1 are recommended to cover residues of metconazole in/on buckwheat, pearl millet, proso millet and teosinte. Existing MRLs for metconazole in/on barley, wheat, oats, rye, triticale and corn (popcorn grain, sweet corn kernels plus cob with husks removed and field corn) are adequate to cover all other uses of Metlock CT Fungicide. Residues in these crops at the proposed MRLs will not pose an unacceptable health risk to any segment of the population, including infants, children, adults and seniors.

The registration of the seed treatment product Metlock CT Fungicide for use on various cereal grains, corn and teosinte fits within the existing use pattern for metalaxyl, but not for metconazole. As such, occupational exposure and risk assessments were conducted for commercial and on-farm treaters, as well as planters of treated seeds, and all uses can be supported. No health risks of concern are expected from the use of Metlock CT Fungicide provided that the recommended label amendments are made, and that workers wear the appropriate personal protective equipment and follow all label directions.

Environmental Assessment

As the rates for Metlock CT Fungicide on the new cereal crops are the same as the rate currently registered for wheat through other products, there is no change to the risk profile and this application is supported from an environmental perspective.

Value Assessment

Certain disease claims on the label have been reviewed previously under other submissions for related products. The rates of metalaxyl and metconazole for wheat are the same as those registered for use against the same pathogens and diseases on the other related seed treatment labels. The extrapolation of seed and seedling claims for *Fusarium* spp., *Rhizoctonia solani*, smuts, and common root rot was supported based on previously reviewed value information. The

rates for teosinte were extrapolated from corn as these crops are closely related.

Pythium claims could not be extrapolated from previously reviewed value information for corn, barley, oats, or the other cereal grains; however, metalaxyl and metalaxyl-m are registered on the majority of these crops in other products that contain these active ingredients as the sole component and in combination with other fungicides and/or insecticides. The rates of metalaxyl for cereals and corn in Metlock CT Fungicide are deemed acceptable as they are comparable to the registered rates. The extrapolation of the claim to corn, barley, oats, rye, triticale, millet (pearl, proso), and buckwheat was supported. Since teosinte is related to corn and is affected by the same pathogens, the claim was also extrapolated to this crop.

Metlock CT Fungicide provides early protection of seedlings against multiple soil-borne pathogens with a single application at low rates compared to foliar products. The registration of metconazole for these uses provides an initial seed treatment product to control *Fusarium* spp. on teosinte. Metconazole is also a new mode of action fungicide to control *Rhizoctonia solani* on sugarbeet, millet, and teosinte and to control *Fusarium* spp. on sugarbeet.

Conclusion

The PMRA has reviewed all information submitted in support of Metlock CT Fungicide and found it sufficient to grant registration for all uses.

MRLs as proposed in Table 1 are recommended to cover residues of metconazole in/on buckwheat, pearl millet, proso millet and teosinte. Existing MRLs for metconazole and metalaxyl are adequate to cover all other uses of Metlock CT Fungicide.

References

PMRA Document Number	Reference
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2518382	2012, Metlock CT Fungicide: Product Identity, Composition, and Analysis, DACO: 3.2.1, 3.2.2, 3.2.3, 3.3.1, 3.4.1
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2518389	2012, V-10305 0.58 DC: Primary Eye Irritation Study in Rabbits, DACO: 4.6.4
2518390	2012, V-10305 0.58 DC: Primary Skin Irritation Study in Rabbits, DACO: 4.6.5
2518391	2012, V-10305 0.58 DC: Local Lymph Node Assay (LLNA) in Mice, DACO: 4.6.6
2518398	2014, Cross Reference to Residue Summary for Metlock CT Fungicide, DACO: 7.1, 7.8
2518454	2015, Food and Feed Residue Summary for Metlock Fungicide on Cereal Grains and Sugarbeet, DACO: 7.1
2518456	2015, Clothianidin and Metconazole: Magnitude of the Residue of Metconazole and Clothianidin on Barley, DACO: 7.2.1, 7.2.2, 7.3, 7.4.1, 7.4.5
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2524599	2014, Amended: Summary of Occupational Risk Assessments for the Seed Treatment Use of Metlock CT Fungicide On Barley, Corn, and Wheat Seed, DACO: 5.1
2524600	2014, Amended: Use Description and Exposure Scenarios for Barley, Wheat, and Corn Seed Treatment with Metlock CT Fungicide, DACO: 5.2
2524601	2014, Amended: Mixer/Loader/Applicator Passive Dosimetry Study in Support of Commercial and On Farm Seed Treatment of Barley, Corn, and Wheat Seed with Metlock CT Fungicide, DACO: 5.4
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