



Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 2.5, 3.1, 3.11, 3.12, 3.4 Application

Application Number: 2010-2906
Application: New EP Product Chemistry-Guarantee, Identity and Proportion of Formulants and Formulation Type; New or Changes to Product Labels-Application Rate Increase, New Pests, New Site or Host and Application Method
Product: Metconazole 50 WDG Fungicide
Registration Number: 30401
Active ingredients (a.i.): Metconazole (GHA)
PMRA Document Number: 2136311

Purpose of Application

The purpose of this application was to register Metconazole 50 WDG Fungicide, a commercial end-use product containing metconazole as the technical grade active ingredient. Metconazole 50 WDG Fungicide is used as preventative control of certain fungal diseases in crop subgroup 20A (canola), crop subgroup 6C (dry beans, field peas, chickpea, and lentil), crop subgroup 1C (potato) and crop subgroup 13-07B (bushberry, including blueberry).

Chemistry Assessment

Metconazole 50 WDG Fungicide is formulated as water dispersible granules containing the active ingredient metconazole at a nominal concentration of 50.0%. This end-use product has a density of 0.52 – 0.53 g/cm³ and pH of 8 - 9 for a 1% solution in water. The end-use product contains the allergens sulfites and milk. The chemistry requirements for Metconazole 50 WDG Fungicide have been completed.

Health Assessments

Metconazole 50 WDG Fungicide is of slight acute toxicity to rats via the oral route (LD₅₀ = 1750 mg/kg). It was of low acute dermal (LD₅₀ > 5000 mg/kg) and inhalation (LC₅₀ > 2.27 mg/L) toxicity to rats. It is minimally irritating to the eyes and non-irritating to the skin of rabbits. It is not a dermal sensitizer in guinea pigs.

The use of Metconazole 50 WDG Fungicide on canola, legumes, potatoes and bushberries does not fit within the currently registered use pattern of metconazole. A health risk assessment was conducted for handlers, re-entry workers and bystanders exposure to metconazole and no unacceptable risks were identified. No risk of concern is expected when workers follow the label directions and wear the personal protective equipment identified on the label.

Residue data from crop field trials for metconazole in potatoes, canola, dry shelled peas, dry beans, chickpeas, lentils and blueberries were submitted to support the registration of Metconazole 50 WDG Fungicide. In addition, processing studies in treated canola seed and potatoes were also assessed to determine the potential for concentration of residues of metconazole into processed commodities.

Maximum Residue Limits

Based on maximum residues observed in crops treated according to label directions or at higher rates, maximum residue limits (MRLs) to cover combined residues of *cis*- and *trans*-metconazole in/on crops and processed commodities will be established as shown in Table 1. Combined residues of *cis*- and *trans*-metconazole 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 and Processing Data Used to Establish Maximum Residue Limits (MRLs)

Commodity	Application Method/ Total Application Rate (g a.i./ha)	PHI (days)	Residues (ppm)*		Experimental Processing Factor	Currently Established MRL	Recommended MRL
			Min.	Max.			
Canola Seed	136-142	42-62	<0.04	<0.07	Could not be determined since quantifiable residues were not observed in canola seed treated at an exaggerated rate	None	0.08 ppm for Crop subgroup 20A
Dry Beans	278-281	20-22	<0.04	<0.04	Not Applicable	None	0.15 ppm for Crop subgroup 6C
Dry Field Peas	274-327	20-22	<0.022	0.102	Not Applicable	None	
Highbush Blueberries	0.270-0.280	7	<0.10	0.24	Not Applicable	None	0.4 ppm for Crop subgroup 13-07B
Low Bush Blueberries	0.269-0.297	6-8	<0.12	0.33	Not Applicable	None	
Potatoes	551-570	1-2	<0.04	<0.04	Could not be determined since quantifiable residues were not observed in potato tubers treated at an exaggerated rate	None	0.04 ppm for Crop subgroup 1C

*combined residues of *cis*- and *trans*-metconazole.

Based on the anticipated dietary burden to livestock and the residue data provided, an MRL of 0.04 ppm in fat, meat and meat byproducts of poultry will be promulgated to cover combined residues of *cis*- and *trans*-metconazole in these commodities.

Environmental Assessment

The use of metconazole to control certain fungal diseases in canola, legume vegetables, potato, and bushberries does not fit within the currently registered use pattern of metconazole. There is an increase in the application rate, with the maximum single use rate at 140 g a.i./ha. Further, there is a maximum seasonal limit of 420 g a.i./ha per year imposed on potatoes.

The results of study data on biotransformation of metconazole in aerobic soil (at 10°C and 20°C) and on the dissipation of metconazole from Canadian terrestrial field sites (in Ontario and Saskatchewan) were incorporated into the environmental risk assessment. This information was combined with existing data previously evaluated and published in ERC2011-02 to determine the potential impacts on non-target organisms resulting from the use of metconazole on canola, legume vegetables, potato, and bushberries. The results of the environmental risk assessment indicated that the level of concern was exceeded for certain terrestrial organisms including non-target plants, birds, and small wild mammals (the latter two groups of organisms on a chronic basis only). The level of concern was exceeded for aquatic organisms including early life stages of freshwater fish, aquatic vascular plants, amphibians and marine mysid shrimp (the latter organism on a chronic basis only). Risk mitigation for these sensitive terrestrial and aquatic organisms includes precautionary label statements. In addition, risk mitigation for non-target aquatic organisms also includes spray buffer zones up to 30 m for ground application, and up to 70 m for aerial application. For the protection of terrestrial habitats, spray buffer zones of up to 2 m are required for ground application and up to 15 m for aerial application.

Value Assessment

The Metconazole 50 WDG Fungicide label includes claims for control of various fungal diseases in canola, legume vegetables, potato, and bushberries. A total of 57 trials conducted mostly in Canada or neighbouring states in the US were provided in support of fourteen claims. The trials were conducted between 2005 & 2009. Generally, experimental treatments were applied with little deviation from the use patterns for the various claims. Some trials from the US were not reviewed because they were deemed to be supplementary and did not affect the conclusions. All claims were supported, with the exception of mycosphaerella blight control on field peas and powdery mildew control on the entire bushberry subgroup. Overall, supported rates ranged from 87.5 to 140 g a.i./ha, with different maximum numbers of yearly applications, ranging from one to four, depending on the crop.

Conclusion

Following the review of the available data, MRLs of 0.08 ppm in/on crop subgroup 20A (rapeseed), 0.04 ppm in/on crop subgroup 1C (tuberous and corm vegetables), 0.15 ppm in/on crop subgroup 6C (dried shelled pea and bean except soybean), and 0.4 ppm in/on crop subgroup 13-07B (bushberries) are recommended to cover combined residues of *cis*- and *trans*-metconazole in/on these crops. In addition, an MRL of 0.04 ppm is recommended to cover combined residues of *cis*- and *trans*-metconazole in/on fat, meat and meat byproducts of poultry. Combined residues of *cis*- and *trans*-metconazole in these commodities at the established MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

The PMRA has completed an assessment of the available information for Metconazole 50 WDG Fungicide and has found the information sufficient to allow for conditional registration, with full registration being contingent upon conversion of the registration of Metconazole Fungicide Technical (Registration No. 29766) to full registration. In addition, Part 3 - storage stability and corrosion characteristic data (DACO 3.5.10 and 3.5.14) and Part 10 - efficacy data (DACO 10.2.3.3) are also required as conditions of registration.

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