

Evaluation Report for Category B, Subcategory 2.6 and 3.12 Application

Application Number: 2013-5117
Application: New end-use product chemistry - New combination of actives and new site or host
Product: A20682 Fungicide
Registration Number: 31564
Active ingredients (a.i.): Difenoconazole and Fludioxonil
PMRA Document Number : 2461983

Purpose of Application

The purpose of this application was to register a new end-use product, A20682 Fungicide (guarantee: 247 g/L difenoconazole and 142 g/L fludioxonil) for control of post-harvest storage diseases in pome fruit (Crop Group 11-09). This application was reviewed as part of a joint review with the U.S. EPA.

Chemistry Assessment

A20682 Fungicide is a suspension containing the active ingredients difenoconazole and fludioxonil at a nominal concentration of 247 g/L and 147 g/L, respectively. This product has a density of 1.17 g/mL and a pH of 7.8. The chemistry requirements for A20682 Fungicide have been fulfilled.

Health Assessments

A20682 Fungicide was of low acute oral, dermal and inhalation toxicity in rats. In rabbits, it was non-irritating to the skin and minimally irritating to the eyes. It was not a skin sensitizer in mice.

A20682 Fungicide for use on pome fruits to control various post-harvest diseases fits within the registered use pattern for fludioxonil but not for difenoconazole, as difenoconazole is not currently registered for post-harvest use. A chemical handler and post-application exposure quantitative risk assessment was completed for difenoconazole and no risks of concern were identified when the label precautions are followed and workers wear the required personal protective equipment.

Residue data resulting from post-harvest use were submitted to support the use of A20682 Fungicide, containing difenoconazole and fludioxonil, on pome fruits. Difenoconazole and fludioxonil were applied at the supported use pattern. Previously reviewed residue data for difenoconazole and fludioxonil were also reassessed in the framework of this application.

The use of A20682 Fungicide will not result in residues of fludioxonil exceeding the established maximum residue limit (MRL) in pome fruits. The recommendation for an MRL for difenoconazole was based upon the submitted field trial data, and the guidance provided in the

[OECD MRL Calculator](#). An MRL to cover residues of difenoconazole in/on crops and processed commodities is proposed as shown in Table 1. Residues in processed commodities not listed in Table 1 are covered under the proposed MRL for the raw agricultural commodities (RACs).

TABLE 1. Summary of Field Trial and Processing Data Used to Support Maximum Residue Limit(s) (MRLs)							
Commodity	Application Method/ Total Application Rate ² (g a.i./ha)	PTI ³ (days)	Residues (ppm)		Experimental Processing Factor	Currently Established MRL (ppm)	Recommended MRL ¹ (ppm)
			Min	Max			
Apples	Dip (P2): 0.30 g ai/L, or Drench (P3): 0.30-0.32 g ai/L,	0	0.467	2.61	n/a	1.0	5.0 [Pome Fruit (CG 11-09)]
Pears	or Spray (P4): 12.5 g ai/ 10,000 kg fruits, or Dip + Spray (P5): P2+P4		0.381	1.62	n/a	1.0	

¹ The recommended MRL will replace the current established MRL of 1.0 ppm for CG 11-09.

² The rate reflects post-harvest applications only. However, residues reported represent both foliar and post-harvest treatments. At each trial, the treated plot received five foliar broadcast applications at total rates of 383-393 g ai/ha for apples and 375-390 g ai/ha for pears.

³ PTI=post-harvest treatment interval

Following the review of all available data, an MRL as proposed in Table 1 is recommended to cover residues of difenoconazole. Residues of difenoconazole and fludioxonil in these crop commodities at the proposed/established MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

As limited environmental exposure is anticipated with post-harvest spraying of A20682 Fungicide on pome fruit, the risk to the environment is expected to be negligible.

Value Assessment

Submitted information consisted of data from 12 field trials conducted in New York, Virginia and California in 2011 and 2012 in which the efficacy of treatments of fludioxonil (Scholar SC Fungicide, containing 230 g/L, EPA Registration Number 100-1242), difenaconazole (Thesis Fungicide, containing 360 g/L, EPA Registration Number 100-1386), and/or mixtures of fludioxonil plus difenoconazole were evaluated for control of one or more post-harvest diseases in apples and pears. Fruit were wound-inoculated with the specific pathogens for which the efficacy of fungicide treatments for control of the relevant diseases was to be evaluated. Efficacy was assessed as percent disease incidence. Information in the form of a rationale was submitted to support efficacy claims against *Alternaria* side rot and surface mold.

The submitted information was concluded to be adequate to support claims of control of *Alternaria* rot (side rot) and surface mold (*Alternaria alternata*), bitter rot (*Colletotrichum acutatum*), blue mold (*Penicillium expansum*), bull's-eye rot (*Neofabraea perennans*), grey mold (*Botrytis cinerea*), and white rot (*Botryosphaeria dothidea*) when A20682 Fungicide is applied according to label directions. These claims were extrapolated to other crops within the pome

crop group.

A20682 Fungicide, when applied according to label directions, can be expected to reduce losses due to post-harvest decay from several diseases that occur in pome fruit during short or long term storage and/or distribution and marketing at the retail level. Both active ingredients are fungicidally active on at least a subset of diseases, including *Alternaria* side rot and surface mold, blue mold, and white rot. In addition to the product's expected benefit in mitigating the development of resistance, A20682 Fungicide offers broader spectrum post-harvest disease control than currently registered alternatives. As A20682 Fungicide was jointly reviewed by the PMRA and the U.S. EPA, product launch is anticipated at about the same time in Canada and the U.S., thereby fostering the international competitiveness of the Canadian pome fruit subsector as well as maximizing fruit quality for the domestic market.

Conclusion

The PMRA has completed a review of all information available for A20682 Fungicide and has found the information sufficient to support a full registration.

References

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2347743	2013, Difenconazole Fludioxonil SC (A20682A) - Acute Inhalation Toxicity in Rats, DACO: 4.6.3,IIIA 7.1.3
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2347745	2013, Difenconazole Fludioxonil SC (A20682A) - Primary Eye Irritation in Rabbits, DACO: 4.6.4,IIIA 7.1.5
2347749	2013, Difenconazole Fludioxonil SC (A20682A) - Local Lymph Node Assay (LLNA) in Mice, DACO: 4.6.6,IIIA 7.1.6

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