

Evaluation Report for Category B, Subcategory B.2.1, B.2.3, B.2.4, B.3.1 Application

Application Number:	2013-2242
Application:	New End-Use Product with changes to guarantee, identity and
	proportion of formulants and application rate
Product:	ecoFOG-170 DPA
Registration Number:	31377
Active ingredients (a.i.):	Diphenylamine
PMRA Document Number : 2407798	

Purpose of Application

The purpose of this application was to register a new end-use product, ecoFOG-170 DPA containing diphenylamine, for post-harvest treatment by thermal fogging to reduce storage scald damage to apples. The product is based on the precedent product ecoFOG-100 (Registration Number 30410) with a new formulation and rate expansion.

Chemistry Assessment

ecoFOG-170 DPA is formulated as a solution containing diphenylamine at a nominal concentration of 17.0%. This end-use product has a density of 1.012 g/mL and pH of 5.34. The chemistry requirements for this product are complete.

Health Assessments

ecoFOG-170 DPA was of low acute oral, dermal, and inhalation toxicity in rats. It is moderately irritating to the eye and non-irritating to the skin in rabbits. It is not a dermal sensitizer in guinea pigs.

ecoFOG-170 DPA use on stored apples to control apple scald does not fit within the currently registered use pattern for diphenylamine since applicators can handle more diphenylamine in one day when treating stored apples as compared to other currently registered diphenylamine products. However, the potential exposure for mixers, loaders, applicators, postapplication reentry workers and bystanders is not expected to exceed the current exposure to registered products provided the label precautions are followed.

No new post-harvest residue trial data for diphenylamine were submitted in support of ecoFOG-170 DPA for use on stored apples. As the use directions and rates for ecoFOG-170 DPA are comparable to similar registered products, no impact on the magnitude of residues are expected. Accordingly, no increase in dietary exposure is anticipated. The use of ecoFOG-170 DPA will not pose risks of concern to any segment of the population, including infants, children, adults and seniors.



Environmental Assessment

ecoFOG-170 DPA is for indoor treatment and has similar uses to the registered precedent product ecoFOG-100. Therefore, the environmental exposure and risk are expected to limited and similar to the currently registered uses.

Value Assessment

Two trials conducted in South Africa (2007) and in Chile (2011) were submitted for review. Results demonstrated that 10% DPA applied as a thermo fogging treatment at 60 - 120 mL/1000 kg significantly reduced storage scald in different apple varieties. The efficacy of DPA was not affected when either applied as initial treatment after harvest, or re-application during the cold storage period.

For thermal fogging treatment, when different concentrations of guarantee appear in several enduse products, concentration of the spraying solutions varies according to the guarantee. Since ecoFOG-100 is currently registered for apple scald, the difference between ecoFOG-100 and ecoFOG-170 DPA for users is the fogging time to reach the required dosage. Use of ecoFOG-170 DPA cuts application time nearly in half and also reduces the amount of inert chemicals fogged into the storage facility by 48% as compared to ecoFOG-100 that is currently registered for fogging treatment on storage apples. However, like the precedent product ecoFOG-100, the proposed low rate of 20 mL/1000 kg was not tested, and reapplication at 50% of proposed rates was not confirmed in trials. Since ecoFOG-100 is registered with an outstanding registration condition, a similar condition is also applied to ecoFOG-170 DPA.

Based on the value evidence provided and current label of ecoFOG-100, the claim for using ecoFOG-170 DPA at 35 - 75 mL/1000 kg to reduce storage scald on apples is supported with conditions. Additional value information is required to confirm that the proposed low rate of 20 mL/1000 kg is efficacious on certain apple varieties, and to confirm that a second application at 50% of the initial application rate is appropriate.

Conclusion

The registration of ecoFOG-170 DPA for post-harvest treatment by thermal fogging to reduce storage scald damage to apples was approved with the same conditions as the precedent product ecoFOG-100.

References

PMRA Document Number	Reference
2295642	2011, ecoFog-170 DPA Product Identity, Manufacturing Process, Discussion of the Formation of Impurities, and Certified Limits, DACO: 3.2.1, 3.2.2, 3.2.3, 3.3.1, 3.4.1 CBI

2295644	2011, Physical and Chemical Characteristics: Color, Physical State, Odor, Oxidation/Reduction, Flammability, pH, Viscosity and Density/Relative Density,
2295646	DACO: 3.5.1, 3.5.11, 3.5.2, 3.5.3, 3.5.6, 3.5.7, 3.5.8, 3.5.9 CBI 2012, Storage Stability and Corrosive Characteristics - 12-Month Interim,
2273040	DACO: 3.5.10, 3.5.14 CBI
2295645	2013, Part 3 – Chemistry, DACO: 3.5.12, 3.5.13, 3.5.15, 3.5.4, 3.5.5 CBI
2295643	2011, Confidential Attachment: ecoFog-170 DPA Product Identity,
	Manufacturing Process, Discussion of the Formation of Impurities, and Certified
	Limits, DACO: 3.2.1, 3.2.2, 3.2.3, 3.3.1, 3.4.1 CBI
2321774	2013, Packaging BOM, DACO: 3.5.10, 3.5.14 CBI
2295639	2013, Part 3 - Chemistry, DACO: 3.1.1,3.1.2,3.1.3,3.1.4 CBI
2295648	2011, Acute Oral toxicity Up and Down Procedure in Rats, DACO: 4.6.1
2295649	2011, Acute Dermal Toxicity Study in Rats, DACO: 4.6.2
2295650	2011, Acute Inhalation Toxicity Study in Rats, DACO: 4.6.3
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2295652	2011, Primary Skin Irritation Study in Rabbits, DACO: 4.6.5
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2295668	2013, Resistance Management, DACO: 10.5.3
2295669	2007, The Effect of Thermofogging on the Control of Superficial Scald on
	Granny Smith Apples, DACO: 10.2.3.3
2295670	2011, Effect of DPA Reapplication by Thermofogging on Scald Control in
	Apples, DACO: 10.2.3.3

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