

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 3.4, 3.13 Application

Application Number: 2010-0412
Application: B.2.1 (Product chemistry – guarantee)
B.2.3 (Product chemistry – identity of formulants)
B.2.4 (Product chemistry – proportion of formulants)
B.3.4 (Product label – application method)
B.3.13 (Product label – precautions)
Product: ecoFOG-100
Registration Number: 30410
Active ingredients (a.i.): diphenylamine (DPA)
PMRA Document Number 2145607

Purpose of Application

The purpose of this application was to register a new end-use product, ecoFOG-100 (guarantee: 10% diphenylamine), based on the precedent product, Shield DPA 15% Super Refined (Registration number 18983, guarantee: 15.0% diphenylamine). EcoFOG-100 is used in stored food and feed (USC 12).

Chemistry Assessment

EcoFOG-100 is formulated as a solution containing diphenylamine at a nominal concentration of 10.0%. This end-use product has a density of 1.0235 g/mL and a pH of 9.01. The chemistry requirements for ecoFOG-100 are complete.

Health Assessments

EcoFOG-100 is of low acute toxicity by the oral, dermal, and inhalation routes in rats. EcoFOG-100 is minimally irritating to the eye and it is not a dermal irritant in rabbits. This end-use product is not a dermal sensitizer in guinea pigs.

The use on apples should not result in an increase in potential dermal (reentry) exposure over other currently registered uses of the active ingredient since the application rate, number of applications and frequency of application are within the currently registered use pattern.

Inhalation exposure may increase during and after application of ecoFOG-100 as a result of the thermal fogging process. The risk to workers and bystanders is not of concern provided that all label directions are followed.

Residue data for diphenylamine in apples from post-harvest trials were reviewed to support the use of ecoFOG-100 on apples.

Maximum Residue Limit(s)

Based on the maximum residues observed in/on apples treated according to the accepted use directions, the maximum residue limit (MRL) of 5.0 ppm currently established for diphenylamine on apples is adequate to cover this use. Residues in processed commodities not listed in Table 1 are covered under the established MRL for the raw agricultural commodity (RAC).

TABLE 1. Summary of Field Trial and Processing Data Used

Commodity	Application Method/ Application Rate	Collection Time (Days after last application)	Residues (ppm)		Mean Experimental Processing Factor	Currently Established MRL	Recommended MRL
			Min	Max			
Apples	Post-harvest (Thermal Fogger)/ 13.9 ppm (1 st application)	Day 1	0.736	2.69	Residues of diphenylamine did not concentrate in apple juice.	5.0	None
		Day 7	0.802	2.37			
		Day 47	0.621	1.35			
		Day 90	0.194	1.12			
	Post-harvest (Thermal Fogger)/ 13.9 + 13.6 ppm (1 st + 2 nd application)	Day 1	1.27	2.49			
		Day 7	1.37	4.1			
		Day 45	0.716	2.55			
		Day 90	0.549	2.18			

Following the review of all available data, the established MRL of 5.0 ppm for diphenylamine in apples will cover residues of diphenylamine. Residues of diphenylamine at the established MRL will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

An environmental assessment was not conducted as no additional environmental data were required for registration of the new end-use product, ecoFOG-100. Label statements were amended in accordance with current practice.

Value Assessment

Results from two scientific papers published in 1988 and in 2007 were submitted for review. Trials were conducted in South Africa and in France. The results show that diphenylamine applied at 125 ml product per 1000 kg was as effective in controlling scald on a susceptible

apple variety as the currently registered drench treatment. A second application is supported under prolonged storage periods. Application at 60 ml per 1000 kg was efficacious in storage, but less efficacious after apples were removed from storage. Although not be suitable for apple varieties susceptible to scald, this rate is deemed appropriate for more tolerant varieties. The proposed low rate of 35 ml per 1000 kg was not tested in trials. More data are required to support this rate and to determine if a second application at 50% of the first application rate would be appropriate. Data requirements have been provided to the applicant.

Based on the submitted evidence, the following claim is supported: To reduce scald on apples, apply ecoFOG-100 by thermal fogging at the rate of 60 - 125 ml product (6.0 - 12.5 g a.i.)/1000 kg. Use the lower application rate on less susceptible varieties. The treatment must be applied to fruit within 15 days after harvesting. Consult with pomology specialists for diphenylamine application rate recommendations within the labelled range for specific apple varieties. A second treatment may be applied at a rate of between 50% and 100% of the initial dosage between the second and third months during periods of prolonged storage.

Conclusion

The PMRA has completed an assessment of the available information and is able to support the full registration of ecoFOG-100, based on the precedent product, Shield DPA 15% Super Refined (Registration number 18983), for use in stored food and feed (USC 12).

References

PMRA No.	Title
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