Health Canada Santé Canada

Evaluation Report for Category B, Subcategory B.2 & B.3 Application

Application Number: 2010-3649
Application: Changes EP Product Chemistry-Guarantee and Formulation Type Changes to Product Labels-Precautions, Application Timing, Application Method, and Re-Entry Interval
Product: Decco No Scald DPA Aerosol
Registration Number: 30231
Active ingredients (a.i.): Diphenylamine
PMRA Document Number: **2011077**

Purpose of Application

The purpose of this application was to register a new end-use product, Decco No Scald DPA Aerosol. The product essentially is a repack of the technical active ingredient (Diphenylamine Technical, Registration number 29636) with application directions as an aerosol.

Chemistry Assessment

Decco No Scald DPA Aerosol is a solid containing the active ingredient diphenylamine at a nominal concentration of 99.8%. This product has a density of 1.177 g/cm^3 and pH of 6.4 (1% aqueous solution). The product chemistry requirements for Decco No Scald Aerosol have been completed.

Health Assessments

A toxicological assessment was not required for this application.

The use of Decco No Scald DPA Aerosol should not result in unacceptable exposure to the active ingredient, diphenylamine. No unacceptable risk is expected when workers follow the label directions and wear the personal protective equipment identified on the label.

Residue data for diphenylamine in apples from trials conducted in the United States (US) were reviewed to support the use of Decco No Scald DPA Aerosol on apples post-harvest.

Canada

Maximum Residue Limit(s)

Based on the maximum residues observed in/on apples, the maximum residue limit (MRL) 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). The MRL currently established for diphenylamine on apples (5.0 ppm) is adequate to cover this use.

TABLE 1. Summary of Field Trial and Processing Data Used

Commodity	Application Method/ Total Application Rate	Collection Time	Residues (ppm)		Mean Experimental Processing Factor	Currently Established MRL	Recommended MRL
			Min	Max			
Apples	Post-harvest (Thermal Fogger)/ 7 g a.i./ metric tonne	20 hours after treatment	0.425	1.99	Residues of diphenylamine did not concentrate in apple juice.	5.0	None

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

No additional environmental data were required to register Decco No Scald DPA Aerosol. Environmental label statements may undergo revision based on the re-evaluation of diphenylamine.

Value Assessment

Two studies were submitted for review. However, product efficacy could not be assessed since CO_2 injury level was too low and significant difference among treatments was noted. In addition, an untreated control was not tested to evaluate the severity of scald on the apples. Some information could be retained from the efficacy studies, in one study there was some concern regarding DPA damage (phytotoxicity) using the aerosol application and in the other study, a loss in efficacy to reduce CO_2 injury was measured when the DPA treatment was applied later than 4 days after harvest.

A history record of 59 storage rooms in Michigan treated with Decco No Scald DPA Aerosol in 2009, as well as three letters of support from pomology specialists, were submitted by the applicant. Several cultivars more or less sensitive to scald were treated with rates ranging from 5.8 to 9.0 g DPA per Tonne of apples. The scald pressure was estimated to be low in the 2009 season. Decco US Post-Harvest Inc. has not received any report of skin damage or scald in any of the treated fruit as mentioned by the support letters from the researchers in Michigan. According to the post-harvest specialists, Decco No Scald DPA Aerosol is effective at controlling scald on apple fruit. In addition other benefits in using DPA aerosol versus drench application were mentioned in the letters of support from the specialists with the main advantage being the elimination of fungicide treatments to prevent rot diseases caused by the presence of spores and organic contaminants in the drench material.

In an effort to harmonize Canadian and US application rates, the applicant has agreed to a rate range comparable to the US depending on the susceptibility of the apple variety to scald. In addition, regarding the application timing concerns, the applicant agreed to reduce the maximum application window from 15 to 10 days after harvest. The applicant stated that it can take 5 to 10 days to fill the apple storage room and when a partially filled room is treated with DPA it can not be treated again when it is full. Therefore for practicality, the PMRA agrees with the applicant that the 10 days maximum application window is necessary. Furthermore, there is no mention of product failure in the letters of support from Michigan and New York when used according to the United States registered use pattern.

Based on the applicant's rationale and credible use history that was provided, the use of Decco No Scald DPA Aerosol to reduce scald on apples at rates of 4.0 to 7.0 g of product/Tonne depending on the susceptibility of the apple variety and applied within 10 days after harvest can be supported.

Conclusion

The PMRA has completed an assessment of the available information and is able to support the registration of Decco No Scald DPA Aerosol.

References

PMRA No.	Title
1945204	2010, Applicant name and address, DACO: 3.1.1
1945205	2010, Establishing Certified Limits, DACO: 3.3.1
1945206	2008, Diphenylamine / Thiabendazole: Magnitude of Residue on Fumigated Apples, DACO: 3.4.1
1945207	2010, Oxidation Reduction, DACO: 3.5.8
1945208	2010, Flammability, DACO: 3.5.11
1945209	2010, Explodability, DACO: 3.5.12
1945210	2010, Miscibility, DACO: 3.5.13
1945211	2010, Corrosion Characteristic, DACO: 3.5.14
1945212	2010, Dielectric Breakdown Voltage, DACO: 3.5.15
2008523	2011, Decco No Scald DPA Aerosol Storage Stabilty & Crossion Charectrestic, DACO: 3.5.10,3.5.14
1945202	2010, Efficacy Trials with DPA and 1-MCP. OMAFRA Study prepared for Ceraxagria, Unpublished DACO: 10.2, 10.2.3.1, 10.2.3.2, 10.3, 10.3.1, 10.3.2
1945203	Efficacy Data with DPA (published): Fawbush, F. et al. 2007. External carbon dioxide injury and 1-methylcyclopropene (1-MCP) in the 'Empire' apple. Postharvest Biology and Technology 48: 92-98. DACO: 10.2.3
2009505	2011, History record of Michigan treated storage rooms with DECCO NO SCALD DPA AEROSOL and letters of support from pomology specialists.
1754147	2009, Diphenylamine / Thiabendazole: Magnitude of the Residue on Fumigated Apples, DACO: 7.2.1,7.4.1
1441731	US EPA, 1998, Reregistration Eligibility Decision (RED) Diphenylamine, DACO: 12.5

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