Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 3.12, 3.13 Application

Application Number: 2008-4748
Application: B.3.12 (Changes to Product Labels-New Site or Host)
B.3.13 (Changes to Product Labels-Precautions)
Product: Cruiser Maxx Cereals Seed Treatment
Registration Number: 29192
Active ingredients (a.i.): Difenoconazole (DFZ), Metalaxyl-M (MFN), Thiamethoxam (THE)
PMRA Document Number English PDF: 1889837

Purpose of Application

The purpose of this application was to add a new use on oats to Cruiser Maxx Cereals Seed Treatment (Registration number 29192) and to remove the "closed system" requirement from the product label.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

A toxicology assessment was not required as there was no change to the product formulation.

Considering throughput, application rate, and dust-off potential, it is expected that overall worker dermal and inhalation exposures while treating oat seeds and handling treated oat seeds, will not increase relative to seeds already registered on the Cruiser Maxx Cereal Seed Treatment and Cruiser Maxx Cereal Commercial Seed Treatment products. Therefore, the addition of oats to the labels is acceptable.

The removal of the closed-transfer restriction from the Cruiser Maxx Cereal (commercial and on-farm) products is acceptable based on expected use scenarios compared to on-farm and commercial seed treatment worker exposure studies using open-pour mix/load operations, including labelled tank-mixes. The tank-mixes of both Cruiser Maxx Cereal Seed Treatment and Cruiser Maxx Cereal Commercial Seed Treatment products with Dividend XL RTA, and Cruiser Maxx Cereal Commercial Seed Treatment with Cruiser 5FS Seed Treatment or Cruiser 350FS Seed Treatment are acceptable when treating oat seed, and with open-pour mix/load operations.

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The use of a ‘quasi-closed’ type of product delivery system is considered acceptable when used with an open-pour mix and load product. The manual uncapping of the container and attachment of a DrumQuick spigot and hose for transferring the product for treatment is not likely to result in more exposure to workers than handling small size containers for an open-pour, mixing and loading scenario.
Following the review of all available data, it was determined that residues of thiamethoxam, difenoconazole, and metalaxyl-m in commodities of Crop Group 15 (cereal grains), are adequate to support the use expansion of Cruiser Maxx Cereals in/on oats as a seed treatment. Residues of thiamethoxam, difenoconazole, and metalaxyl-m in commodities of Crop Group 15 at the established MRLs of 0.02 ppm, 0.01 ppm, and 0.05 ppm, respectively, will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

No environmental data were provided by the applicant in support of this application. Since the proposed use pattern is included on the current end-use product label, an increased risk to the environment is not expected as a result of the addition of oats as a host crop.

Value Assessment

Cruiser Maxx Cereals Seed Treatment is registered for suppression of wireworm and for control or suppression of listed seed- and soil-borne diseases on wheat and barley at a rate of 325 mL product per 100 kg seed. As wheat and barley are two representative crops from Crop Group 15 (Cereal Grains), and the seed sizes of the crops in this group are similar, it is possible to extrapolate insecticidal efficacy of Cruiser Maxx Cereals Seed Treatment for suppression of wireworm at the registered rates for wheat and barley to oats. Cruiser Maxx Cereals Seed Treatment is considered equivalent to the tank mix of Cruiser 350FS Seed Treatment and Dividend XL RTA Seed Treatment which is registered on the Cruiser 350FS label for wheat and barley. The diseases listed on the Dividend XL RTA Fungicide label for oats are the same as those listed on the Cruiser Maxx Cereals Seed Treatment label for the same crop. Therefore, the claim for suppression of wireworm and control or suppression of listed diseases at a rate of 325 ml of product per 100 kg of seed is supported on the Cruiser Maxx Cereals Seed Treatment label.

Conclusion

The PMRA has assessed all available information and is able to support the addition of oats to Cruiser Maxx Cereals Seed Treatment (Registration number 29192) and the removal of the “closed system” requirement from the product label.

References

1826319 2009, Thiamethoxam/Difenoconazole/Metalaxyl-M/S FS (A15424B): Occupational Exposure Risk Assessment for Cruiser Maxx Cereals Seed Treatment on Oats. DACO 5.2, 5.3, 5.6

1826320 2009, Determination Of Operator Exposure During Typical Activities Associated With On-Farm Treatment Of Small Grain Cereal Seed Using Austral Plus Net (40 Gil Tefluthrin And 10 Gil Fludioxonil, As A Suspension Concentrate) At Farm Locations In France, 2007. DACO 5.4

1826322 2009, Thiamethoxam FS (CGA293343)- Estimated Dermal Absorption Values in Humans for Seed Treatment Formulations. DACO 5.8

1826323 2009, Thiamethoxam/Difenoconazole/Metalaxyl-M/S FS (A15424B): Dust-Off Measurements of Oats Treated with Cruiser Maxx Cereals Seed Treatment. DACO 5.14

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