Health Canada Santé Canada

Evaluation Report for Category B Subcategory 2.6 Application

Application Number: 2007-5861
Application: New End Use Product – New Combination of TGIAs
Product: Cruiser Maxx Cereals Seed Treatment
Registration Number: 29127
Active ingredients (a.i.): Difenoconazole, Metalaxyl-M and Thiamethoxam
PMRA Document Number: 1693548

Purpose of Application

The purpose of this application is to register the new end-use product, Cruiser Maxx Cereals Seed Treatment. This end-use product is to be used as a commercial seed treatment for the control of certain insect pests as well as seed and soil borne diseases of cereal crops.
The use pattern of Cruiser Maxx Cereals Seed Treatment falls within the currently registered use pattern for the active ingredients found in this end-use product.

Value Assessment

Cruiser MAXX Cereals Seed Treatment is a pre-mix formulation comprised of two registered commercial seed treatment products, Cruiser 350FS Seed Treatment Insecticide (active ingredient: thiamethoxam) and Dividend XL RTA Fungicide (active ingredients: difenoconazole and metalaxyl-m). Cruiser 350FS Insecticide and Dividend XL RTA Fungicide are currently registered as tank-mix partners. The pest claims for Cruiser Maxx Cereals Seed Treatment include the same disease and wireworm claims currently registered on Cruiser 350FS Seed Treatment Insecticide and Dividend XL RTA Fungicide. The value of Cruiser MAXX Cereals Seed Treatment is to save growers the labour of tank-mixing. Various tank-mixes have also been proposed to address certain insect and disease claims on the current Cruiser 350FS and Dividend XL RTA labels.

A tank-mix with Dividend XL RTA Fungicide was proposed on the Cruiser Maxx Cereals Seed Treatment label to increase the rate of active ingredients to address conditions of high disease pressure or to control seed-borne Septoria diseases. Since Dividend XL RTA Fungicide is currently registered as a tank-mix option with both Cruiser 350FS and Cruiser 5FS Insecticides, no disease control antagonism or phytotoxicity is expected with Cruiser Maxx Cereals Seed Treatment applied alone or with the tank-mix of Cruiser Maxx Cereals Seed Treatment with Dividend XL RTA. All disease claims are supported as proposed.

Canada

The claim of wireworm suppression on wheat and barley is acceptable for Cruiser Maxx Cereals Seed Treatment at 325 mL product per 100 kg of seed. The claim of European chaffer control is acceptable for the tank-mix with the insecticide products, Cruiser 350FS or Cruiser 5FS at 30 g thiamethoxam per 100 kg seed. The claim of wireworm control is acceptable for the tank-mix when Cruiser 350FS or Cruiser 5FS are applied at 20-30 g thiamethoxam per 100 kg seed. Cruiser 350FS and Cruiser 5FS are currently registered for tank-mixing with fungicides which contain the active ingredients in Cruiser Maxx Cereals Seed Treatment at the same rates, therefore, no adverse effects or loss of insecticidal efficacy are expected.

Tank-mix options with Charter Seed Treatment Fungicide (active ingredient: triticonazole), Raxil 250FL Flowable Fungicide (active ingredient: tebuconazole) or Baytan 30 Flowable Fungicide (active ingredient: triadimenol) to control true loose smut (*Ustilago nuda*) on barley were proposed on the Cruiser Maxx Cereals Seed Treatment label. Although Charter Seed Treatment Fungicide, Raxil 250FL 250FL Flowable Fungicide and Baytan 30 Flowable Fungicide are registered as tank-mixes with Dividend XL RTA on barley, they are not registered to be used in combination with Cruiser 350FS. Therefore, these tankmix options have been removed from the Cruiser Maxx Cereals Seed Treatment label.

Chemistry Assessment

Cruiser Maxx Cereals Seed Treatment is formulated as a solution containing the active ingredients difenoconazole, at a nominal concentration of 3.36%, thiamethoxam, at a nominal concentration of 2.80 %, and metalaxyl-M (and S isomer) at a nominal concentration of 0.56%. Cruiser Maxx Cereals Seed Treatment has a density of 1.16 g/mL and pH of 7.0. The chemistry requirements for Cruiser Maxx Cereals Seed Treatment are complete.

Health Assessments

Cruiser Maxx Cereals Seed Treatment is of low acute toxicity to rats via the oral (LD_{50} >5000 mg/kg), dermal (LD_{50} >5000 mg/kg), and inhalation routes (LC_{50} >2.00 mg/L). It is minimally irritating to the eye and non-irritating to the skin of rabbits. It is not a dermal sensitizer in guinea pigs

The proposed use of Cruiser Maxx Cereals Seed Treatment on wheat, barley, buckwheat, millet, rye, sorghum and triticale falls within the registered use pattern for the active ingredients found in this end-use product. No unacceptable risk is expected when workers follow the label directions and wear the personal protective equipment identified on the label. The use of this product will not pose an unacceptable risk to any segment of the population including infants, children, adults, and seniors.

Environmental Assessment

No environmental studies were required to support registration of Cruiser Maxx Cereals Seed Treatment. The addition of buckwheat, millet, oats, rye, sorghum, and triticale at 30 g thiamethoxam/100 kg seed to the Cruiser 350FS Seed Treatment label has been approved from the viewpoint of environmental protection (PMRA #1504840). The remaining crops and application rates are already on the Cruiser 350FS Seed Treatment and Dividend XL RTA

Fungicide labels. Therefore, no additional impact to the environment is expected from use of Cruiser Maxx Cereals Seed Treatment.

One scientific study related to the active ingredients found in Cruiser Maxx Cereals Seed Treatment was submitted in accordance with the Incident Reporting provisions of the PCPA 2002 reporting requirements (PMRA #1470091). The canola seed treatment study investigated the effects of HELIX XTra seed treatment (Reg. No. 26638) at (24.6g difenoconazole, 7.80g metalaxyl-m, 403.5g thiamethoxam, 2.70g fludioxonil)/100 kg seed which is equivalent to (1.8g difenoconazole, 0.57g metalaxyl-m, 29.4g thiamethoxam, 0.20g fludioxonil)/ha at a seeding rate of 7.28 kg seed/ha. The insecticide thiamethoxam is the active ingredient of concern to honeybees, while the fungicidal active ingredients are not hazardous to honeybees. The study reported there were no observable effects on bee foraging activity, brood pattern, egg laying or mortality, and no evidence of repellency, loss of coordination or disorientation. The detections of thiamethoxam in the pollen, honey, and bees prove that the bees were obtaining pollen and nectar from the HELIX-treated crop without any observable adverse effects.

For buckwheat and millet crops that rely on bee pollination (wheat, barley, sorghum, rye, triticale and oats rely on self-pollination and/or wind pollination), the rate of application of thiamethoxam is 10.6g ai/100 kg seed which is equivalent to a rate of 21.2g ai/ha based on a conservative seeding rate of 200 kg seed/ha. More realistic environmental exposure rates would be 8.6g ai/ha for buckwheat (81 kg seed/ha) and 2.9g ai/ha for millet (27 kg seed/ha). Considering the field study on canola seed treatment (PMRA #1470091), seed treatments equivalent to rates as high as 30 g thiamethoxam/ha on crops that are reliant on bee pollination are not expected to result in observable adverse effects on honeybee colonies. Therefore, the proposed uses of Cruiser Maxx Cereals Seed Treatment are not expected to adversely affect honeybee colonies.

Conclusion

Cruiser Maxx Cereals Seed Treatment is acceptable for full registration

References

Chemistry

1461823 2007, CRUISER MAXX CEREALS (A15424B): Starting Materials, DACO: 3.2.1 CBI

1461824 2007, CRUISER MAXX CEREALS (A15424B): Manufacturing Process, DACO: 3.2.2 CBI

1461825 2007, CRUISER MAXX CEREALS (A15424B): Discussion of Formation of Impurities, DACO: 3.2.3 CBI

1461828 2007, CRUISER MAXX CEREALS (A15424B): Enforcement Analytical Method SF-216/1, PC-07-053, DACO: 3.4.1 CBI

1461829 2007, CRUISER MAXX CEREALS (A15424B): Chemical and Physical Properties, T001111-07, DACO: 3.5, 3.5.1, 3.5.10, 3.5.11, 3.5.12, 3.5.13, 3.5.14, 3.5.15, 3.5.2, 3.5.3, 3.5.4, 3.5.5, 3.5.6, 3.5.7, 3.5.8, 3.5.9

1616405 2008, A15424B - Content of Active Ingredient(s) after Storage for 1 Year and Corrosion Characteristics after Storage for 1 Year in Non-Fluorinated HDPE at 20 Degrees Celsius, T001113-07, DACO: 3.5.10, 3.5.14

Health

PMRA 1461831. 2007, Difenoconazole / Thiamethoxam / Mefenoxam FS (A15424B) – Acute Oral Toxicity Up-and-Down Procedure in Rats.

PMRA 1461832. 2007, Difenoconazole / Thiamethoxam / Mefenoxam FS (A15424B) – Acute Dermal Toxicity in Rats.

PMRA 1461833. 2007, Difenoconazole / Thiamethoxam / Mefenoxam FS (A15424B) – Acute Inhalation Toxicity in Rats.

PMRA 1461834. 2007, Difenoconazole / Thiamethoxam / Mefenoxam FS (A15424C) – Primary Eye Irritation in Rabbits.

PMRA 1461835. 2007, Difenoconazole / Thiamethoxam / Mefenoxam FS (A15424C) – Primary Skin Irritation in Rabbits.

PMRA 1461836. 2007, Difenoconazole / Thiamethoxam / Mefenoxam FS (A15424C) – Dermal Sensitization Test – Buehler Method

Environment

1470091 2007, Two field trials to determine the effects of HELIX seed treatment on honeybees foraging on canola flowers, CER 03214/99, DACO: 9.2.4.3

1504840 2007, Environmental evaluation of Cruiser 350FS Seed Treatment, User requested minor use label expansion to include oats, rye, triticale, buckwheat, perl millet, proso millet and sorghum for the control of wireworms

ISSN: 1911-8082