



Evaluation Report for Category B, Subcategory 2.6 Application

Application Number: 2007-6217
Application: New End-Use Product – New combination of TGAI's
Product: A15424B Seed Treatment
Registration Number: 29192
Active ingredients (a.i.): Difenoconazole, Metalaxyl-m, Thiamethoxam
PMRA Document Number: 1692980

Purpose of Application

The purpose of this application is to register the new end-use product, A15424B Seed Treatment. This end-use product is to be used on-farm as a seed treatment for the control of certain insect pests as well as seed and soil borne diseases of cereal crops.

The use pattern of A15424B Seed Treatment falls within the currently registered use pattern for the active ingredients found in this end-use product.

Value Assessment

Fungicide

A15424B Seed Treatment is a pre-mix formulation comprised of two registered commercial seed treatment products, Cruiser 350FS 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 A15424B Seed Treatment include the same disease and wireworm claims currently registered for the tank-mix of Cruiser 350FS Insecticide and Dividend XL RTA Fungicide. The value of A15424B Seed Treatment is to save growers the labour of tank-mixing. Two tank-mixes were also proposed on the A15424B Seed Treatment label to address certain disease claims on the current Dividend XL RTA label.

A tank-mix with Dividend XL RTA Fungicide was proposed 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 partner with Cruiser 350FS, no antagonism or phytotoxicity is expected with the premix or with subsequent mixing of the premix with Dividend XL RTA. All disease claims are supported as proposed.

The claim of wireworm suppression on wheat and barley is acceptable for A15424B Seed Treatment at a rate of 325 mL product per 100 kg of seed. Cruiser 350FS is currently registered for tank mixing with fungicides which contain active ingredients in A15424B TM 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 was proposed on the A15424B Seed Treatment label. Although Charter, Raxil 250FL and Baytan 30 fungicides 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 A15424B Seed Treatment label.

Insecticides

A tank-mix of thiamethoxam, difenoconazole and metalaxyl-M is currently registered for use on wheat and barley for suppression of wireworm, therefore, no antagonism or phytotoxicity is expected with A15424B Seed Treatment application on wheat and barley. The use of A15424B Seed Treatment is supported for wireworm suppression on wheat and barley at a rate of 325 mL product per 100 kg of seed.

Chemistry Assessment

A15424B 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%. A15424B Seed Treatment has a density of 1.16 g/mL and pH of 7.0. The chemistry requirements for A15424B Seed Treatment are complete.

Health Assessments

A15424B 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 A15424B 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 proposed use of A15424B 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. Therefore, the use of A15424B Seed Treatment 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 A15424B 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 A15424B Seed Treatment.

One scientific study related to this product 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 fungicide 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 A15424B Seed Treatment are not expected to adversely affect honeybee colonies.

Conclusion

A15424B Seed Treatment is acceptable for full registration.

References

Chemistry Assessment

- 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
- 1616408 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 Assessment

1461831. 2007, Difenoconazole / Thiamethoxam / Mefenoxam FS (A15424B) – Acute Oral Toxicity Up-and-Down Procedure in Rats.
1461832. 2007, Difenoconazole / Thiamethoxam / Mefenoxam FS (A15424B) – Acute Dermal Toxicity in Rats.
1461833. 2007, Difenoconazole / Thiamethoxam / Mefenoxam FS (A15424B) – Acute Inhalation Toxicity in Rats.
1461834. 2007, Difenoconazole / Thiamethoxam / Mefenoxam FS (A15424C) – Primary Eye Irritation in Rabbits.
1461835. 2007, Difenoconazole / Thiamethoxam / Mefenoxam FS (A15424C) – Primary Skin Irritation in Rabbits.
1461836. 2007, Difenoconazole / Thiamethoxam / Mefenoxam FS (A15424C) – Dermal Sensitization Test – Buehler Method.

Environmental Assessment

- 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, pearl millet, proso millet and sorghum for the control of wireworms

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