

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 3.12 Application

Application Number: 2018-1597
Application: New End-Use Product Chemistry – Guarantee, Identity and Proportion of Formulants
New End-Use Product Label – New Site or Host
Product: RANCONA CTS Fungicide
Registration Number: 33606
Active ingredients (a.i.): Ipconazole, Metalaxyl
PMRA Document Number: 3052256

Purpose of Application

The purpose of this application was to register a new end-use product (EP), RANCONA CTS Fungicide, for use as a seed treatment on cereal grains (wheat, barley, oats, rye and triticale) and legume vegetables (soybean, dried shelled pea and bean, succulent and edible-podded pea and bean, lentil and chickpea).

Chemistry Assessment

RANCONA CTS Fungicide is formulated as a solution containing ipconazole at a concentration of 25 g/L and metalaxyl at a concentration of 20 g/L. This EP has a density of 1.03 g/mL and pH of 5.6 – 7.6. The required chemistry data for the EP have been provided, reviewed and found to be acceptable.

Health Assessments

RANCONA CTS Fungicide is of low acute oral, dermal and inhalation toxicity in rats. It is minimally irritating to the eyes and non-irritating to the skin of the rabbit. The EP is not a skin sensitizer in the guinea pig.

A human health evaluation was performed for commercial treaters and planters and on-farm treaters and planters that may be exposed to RANCONA CTS Fungicide. Use of the new product should not result in risks of concern when workers follow the label directions and wear the personal protective equipment identified on the label.

No new residue data were submitted in support of the registration of RANCONA CTS Fungicide. The use pattern of the EP was determined to be within that of the registered products. Therefore, the previously reviewed data were reassessed in the framework of the current submission and it was confirmed that the use of RANCONA CTS Fungicide is not expected to result in an increase in the magnitude of ipconazole and metalaxyl residues in/on the treated crops.

Therefore, the registration of RANCONA CTS Fungicide will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

RANCONA CTS Fungicide is not expected to increase the environmental exposure relative to the registered precedent product. Environmental concerns have been mitigated through adequate statements on the product label.

Value Assessment

Scientific rationales and efficacy data from 27 trials conducted in Canada and the USA were provided in support of the use claims. Overall, RANCONA CTS Fungicide at the tested rates demonstrated its effectiveness against the proposed diseases at the level of control or suppression on wheat, barley, soybean and navy bean. The value of RANCONA CTS Fungicide on the use claims was confirmed by the efficacy data. In addition, the value of the EP has also been established previously as all the uses are currently registered on several similar RANCONA products.

The registration of RANCONA CTS Fungicide provides an additional seed treatment product against target seed and seedling diseases on cereal grains (wheat, barley, oats, rye and triticale) and legume vegetables (soybean, dried shelled pea and bean, succulent and edible-podded pea and bean, lentil and chickpea).

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found it sufficient to support the registration of RANCONA CTS Fungicide.

References

PMRA

Document Number

Reference

2874805	2018, DACO 3.1.4 Other Names, DACO: 3.1.4
2874806	2011, Product Identity and Composition, Description of Materials, Method Used to Produce the Product, Description of the Formulation Process and Discussion of the Formation of Impurities for Rancona Dimension Pro, DACO: 3.2.1,3.2.2,3.2.3
2874807	2011, Description of Starting Materials, DACO: 3.2.1,3.2.2,3.2.3 CBI
2874808	2018, Certified Limits of Rancona CTS Fungicide, DACO: 3.3.1
2874809	2018, Establishing Certified Limits, DACO: 3.3.1 CBI
2874810	2012, Validation of an Analytical Method for the Determination of Ipconazole and Metalaxyl in Formulated Products, DACO: 3.4.1
2874811	2018, Enforcement Analytical Method for the Formulated Product, Rancona CTS Fungicide (UBI 6957.01), DACO: 3.4.1
2874813	2011, The Physical and Chemical Characteristics of Dimension Undyed, DACO: 3.5.1,3.5.2,3.5.3,3.5.6,3.5.7,3.5.9
2874814	2011, Determination of the Shelf Life (0, 3, 6, 12 and 24 months at ambient temperature) of Ipconazole/Metalaxyl 25/20 ME in High Density Polyethylene Containers with Evaluation of Pack Stability, Physical State, Colour and Odour, Weight Change, Emulsion Stability, pH Determination and Analysis of Active Ingredient Content, DACO: 3.5.10,3.5.14
2874815	2013, Determination of the Shelf Life (36 Months at Ambient) of Ipconazole/Metalaxyl 25/20 ME in 1 Litre High Density Polyethylene Containers with Evaluation of Pack Stability, Physical State, Colour, Odour, Weight Change, Emulsion Stability, pH Determination, and Analysis of Active Ingredient Content, DACO: 3.5.10,3.5.14
2874816	2018, Flammability of Rancona CTS Fungicide, DACO: 3.5.11
2874817	2018, Explodability of Rancona CTS Fungicide, DACO: 3.5.12
2874818	2018, Miscibility of Rancona CTS Fungicide, DACO: 3.5.13
2874819	2018, Dielectric Breakdown Voltage of Rancona CTS Fungicide, DACO: 3.5.15
2874820	2018, DACO 3.5.4 Formulation Type , DACO: 3.5.4
2874821	2018, DACO 3.5.5 Container Material and Description , DACO: 3.5.5
2874822	2018, Oxidizing or Reducing Action of Rancona CTS Fungicide, DACO: 3.5.8
3020925	2019, the Storage Stability and Corrosion Characteristics of RANCONA CTS Fungicide (Ubi6957-02) in Stainless Steel Drums Over 1 Year DACO: 3.5.10, 3.5.14
2874823	2009, UBI 6953 (dyed) ipconazole /metalaxyl 25/20 g/L ME: Acute Oral Toxicity in Rat - Fixed Dose Method, DACO: 4.6.1
2874824	2009, UBI 6957:01 (undyed) Ipconazole/metalaxyl 25/20 g/L ME: Acute Dermal Toxicity (Limit Test) in the Rat, DACO: 4.6.2
2874825	2009, UBI 6953 (dyed) Ipconazole/metalaxyl 25/20 g/L ME: Acute Inhalation Toxicity (Nose Only) Study in the Rat, DACO: 4.6.3
2874826	2012, UBI 6953 (dyed) Ipconazole/metalaxyl 25/20 g/L ME: Primary Eye Irritation Study in Rabbits, DACO: 4.6.4

- 2874827 2012, UBI 6953 (dyed) Ipconazole/metalaxyl 25/20 g/L ME: Primary Skin Irritation Study in Rabbits, DACO: 4.6.5
- 2874828 2009, UBI 6953 (dyed) Ipconazole/metalaxyl 25/20 g/L ME:Skin Sensitization in the Guinea Pig - Magnusson and Kligman Maximisation Method: Amended Final Report, DACO: 4.6.6
- 2874800 2018, Efficacy and Seed Safety of Rancona CTS Fungicide Seed Treatment Applied to Cereal Grains (Barley, Wheat, Oats, Rye and Triticale) and Crop Group 6 Legume Vegetables (Soybeans, Dried Shelled & Succulent/Edible-Podded Peas and Beans), DACO:10.1,10.2,10.2.1,10.2.2,10.2.3,10.2.4,10.3,10.4, 10.5

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