



Evaluation Report for Category B, Subcategory 2.6 Application

Application Number: 2015-0470
Application: New End-Use Product Chemistry – New Combination of active ingredients
Product: Elixir Fungicide
Registration Number: 32271
Active ingredients (a.i.): Mancozeb, Chlorothalonil
PMRA Document Number : 2623205

Purpose of Application

The purpose of this submission was to register a new end-use product, Elixir Fungicide, containing a new combination of active ingredients, mancozeb and chlorothalonil, for the control of early and late blight in potatoes.

Chemistry Assessment

Elixir Fungicide is formulated as water dispersible granules containing mancozeb and chlorothalonil at nominal concentrations of 62.5 and 12.5 % respectively. This end-use product has a density of 0.66 – 0.75 g/mL and pH of 6.0 – 7.5. All the required chemistry data for Elixir Fungicide have been provided, reviewed and found to be acceptable.

Health Assessments

In rats, Elixir Fungicide is of low acute toxicity by the oral, dermal, and inhalation routes of exposure. The formulation is mildly irritating to the rabbit eye, but is not irritating to the rabbit skin. It is a potential skin sensitizer in guinea pigs.

The use on potatoes is not expected to result in an increase in occupational or bystander exposure over the registered use patterns for mancozeb and chlorothalonil. No health risks of concern are expected when workers follow label directions and wear personal protective equipment as stated on the label.

No new food residue chemistry data were submitted to support the registration of Elixir Fungicide containing 62.5% mancozeb and 12.5% chlorothalonil for aerial and ground foliar use on potatoes. The precedent products were considered to be biologically equivalent to Elixir Fungicide and the use pattern for each component of this end-use product falls within the currently registered use patterns for each of chlorothalonil and mancozeb on this crop. Based on this assessment, the dietary exposure to chlorothalonil and mancozeb is not expected to increase and 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 for the registration of Elixir Fungicide. The use pattern on potatoes is within what is currently registered for both active ingredients. Buffer zones were calculated based on the risk profile identified during the environmental risk assessment for the active ingredients chlorothalonil and mancozeb.

Value Assessment

Efficacy data were provided in support of the disease claims. Elixir Fungicide applied at 1.68 to 2.24 kg/ha provided suppression of early blight in four efficacy trials. However, since Elixir Fungicide will provide between 1050 – 1400 g mancozeb/ha, which is registered for control of early blight in precedent products, Elixir Fungicide is expected to provide the same level of control as these precedent products. In addition, the small amount of chlorothalonil added to the end-use product did provide a slight increase in control over mancozeb used alone. As for control of late blight, the end-use product provided a good level of control (average 77 to 86 % control with the low and high tested rate, respectively). In addition, both rates decreased tuber blight. The higher rate of Elixir Fungicide provided similar level of late blight control compared to commercial standards. The registration of Elixir Fungicide will provide an alternative product to potato growers to control early and late blight on potatoes.

Based on the value information provided a claim of control of early and late blight in potatoes was supported on the Elixir Fungicide label.

Conclusion

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

References

PMRA Document Number	Reference
2500657	2013, ELIXIR FUNGICIDE Product Identity, Composition and Analysis, DACO: 3.2.1, 3.2.2, 3.2.3, 3.3.1 CBI
2500658	2012, Validation of SOP DLA-288.1 version 0 "Chlorothalonil and Mancozeb; technical and formulations determination of active ingredients", DACO: 3.4.1
2554812	2012, Chromatograms for method DLA 288.1 for chlorothalonil from "Validation of SOP DLA-288.1 version 0 "Chlorothalonil and Mancozeb; technical and formulations determination of active ingredients"", DACO: 3.4.1 CBI
2573287	2011, Validation of SOP DLA-288.1 version 0 "Chlorothalonil and Mancozeb; technical and formulations determination of active ingredients", DACO: 3.4.1
2573288	2015, Deficiency Response for Elixir Fungicide, containing mancozeb and chlorothalonil, Submission Number: 2015-0470, DACO: 3.4.1

- 2500659 2010, Physical, chemical and technical properties of Chlorothalonil/mancozeb 12.5/62.5 WG (FFG01), including accelerated storage stability, DACO: 3.3.1, 3.4.2, 3.5.1, 3.5.10, 3.5.11, 3.5.12, 3.5.2, 3.5.3, 3.5.6, 3.5.7, 3.5.8
- 2554811 2014, Shelf-life of Chlorothalonil/mancozeb 12.5/62.5 WG (FFG01) for 2 years at ambient storage conditions in 1-kg PAPER/PE bags, DACO: 3.5.10, 3.5.14 CBI
- 2500660 2012. Acute oral toxicity study of chlorothalonil/mancozeb 12.5/62.5 WG (FFG01) in rats. Study Number: 401-1-01-4850; DACO 4.6.1
- 2500661 2012. Acute dermal toxicity study of chlorothalonil/mancozeb 12.5/62.5 WG (FFG01) in rats. Study Number: 403-1-01-4851; DACO 4.6.2
- 2500662 2012. Acute inhalation toxicity study of chlorothalonil/mancozeb 12.5/62.5 WG (FFG01) in rats. Study Number: 401-1-01-4852; DACO 4.6.3
- 2500663 2012. Acute eye irritation study of chlorothalonil/mancozeb 12.5/62.5 WG (FFG01) in rabbits. Study Number: 401-1-01-4854; DACO 4.6.4
- 2500664 2012. Acute dermal irritation study of chlorothalonil/mancozeb 12.5/62.5 WG (FFG01) in rabbits. Study Number: 401-1-01-4853; DACO 4.6.5
- 2500665 2012. Skin sensitization study of chlorothalonil/mancozeb 12.5/62.5 WG (FFG01) in guinea pigs [Guinea pig maximization test]. Study Number: 401-1-01-4855; DACO 4.6.6
- 2515730 2015, Value Summary for Elixir Fungicide, containing chlorothalonil and mancozeb, for use in potatoes for control of early and late blight., DACO: 10.1, 10.2.1, 10.2.2, 10.2.3, 10.2.4, 10.3, 10.3.2, 10.3.3, 10.4, 10.5.1, 10.5.2, 10.5.3, 10.5.4, 10.5.5

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