

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

Application Number: 2015-1635

Application: New / Changes EP or MA Product Chemistry-Guarantee

New / Changes EP or MA Product Chemistry-Identity of Formulants

New / Changes EP or MA Product Chemistry-Proportion of
Formulants

Product: Prodex TZ Fungicide

Registration Number: 32491

Active ingredients (a.i.): Iprodione

PMRA Document Number : 2680244

Purpose of Application

The purpose of this application was to register a new fungicide product containing iprodione to control diseases on canola and alfalfa. This application is based on a precedent product under the Protection of Proprietary Data Program (PPIP).

Chemistry Assessment

Prodex TZ Fungicide is formulated as a suspension containing iprodione at a nominal concentration of 500 g/L. This end-use product has a density of 1.16 g/mL and pH of 4.0 – 6.0. The required chemistry data for Prodex TZ Fungicide have been provided, reviewed and found to be acceptable.

Health Assessments

The end use product, Prodex TZ Fungicide, is toxicologically equivalent to the cited precedent product. Subsequently, no toxicological data were reviewed or are required.

No new residue data were submitted in support of the registration of Prodex TZ Fungicide. The use pattern of the end-use product was determined to be identical to that of the currently registered product. Therefore, the previously reviewed data was reassessed in the framework of the current submissions and confirmed that the use of Prodex TZ Fungicide is not expected to result in an increase in the magnitude of iprodione residues in/on the treated crops. Therefore, the use of Prodex TZ Fungicide will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

The use of the new end-use product Prodex TZ Fungicide is not expected to result in potential occupational, residential or bystander exposure over the registered use of iprodione. No risks of concern are expected when workers follow label directions and wear personal protective equipment as stated on the label.

Environmental Assessment

As the use pattern and rate are comparable to registered uses of iprodione, an additional environmental review was not required for Prodex TZ Fungicide.

Value Assessment

The formulation of Prodex TZ Fungicide was compared to the formulations of the precedent product to assess for biological equivalence. The differences in the formulations are not expected to affect efficacy. The application rates, in terms of active ingredient delivered, are the same as the precedent product. Extrapolation of registered uses from the precedent product label to the Prodex TZ Fungicide label was supported.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to support the registration of the new end-use product Prodex TZ Fungicide.

References

Studies/Information Provided by Applicant/Registrant:

PMRA Document Number	Reference
2527766	2008, MSDS [CBI removed], DACO: 3.2.1 CBI
2527764	2010, MSDS [CBI removed], DACO: 3.2.1 CBI
2527761	2011, MSDS [CBI removed], DACO: 3.2.1 CBI
2527760	2011, MSDS [CBI removed], DACO: 3.2.1 CBI
2527772	2012, Flash Point on the sample Iprodione 50% SC, DACO: 3.5.11
2527769	2012, Iprodione 50% SC: Determination of the Colour, Odour and Physical State, DACO: 3.5.1,3.5.2,3.5.3
2527780	2012, Iprodione 50% SC: Determination of the Low Temperature Stability, DACO: 3.7
2527781	2012, Iprodione 50% SC: Determination of the Low Temperature Stability, DACO: 3.7
2527774	2012, Iprodione 50% SC: Determination of the Relative Density, DACO: 3.5.6
2527776	2012, Iprodione 50% SC: Determination of the Viscosity, DACO: 3.5.9
2527775	2012, Iprodione 50% SC: Determination of the pH Value and Acidity or Alkalinity, DACO: 3.5.7
2527770	2013, Iprodione 50% SC: Determination of the Accelerated Storage Stability and Corrosion Characteristics, DACO: 3.5.10,3.5.14
2527773	2013, Iprodione 50% SC: Determination of the Oxidizing Properties and Explosive Properties, DACO: 3.5.12,3.5.8
2527768	2013, Iprodione 50% SC: Validation of the Analytical Method for the Determination of the Active Ingredient Content, DACO: 3.3.1,3.4.1,3.4.2

2527762	2013, MSDS [CBI removed], DACO: 3.2.1 CBI
2527763	2013, MSDS [CBI removed], DACO: 3.2.1 CBI
2527771	2014, Iprodione 50% SC: Two Years Storage Stability and Corrosion Characteristics, DACO: 3.5.10,3.5.14
2527784	2015, Additional Product Chemistry for Prodex TZ Fungicide , DACO: 3.1.1,3.1.2,3.1.3,3.1.4,3.5.12,3.5.13,3.5.4,3.5.5
2527785	2015, Additional Product Chemistry for Prodex TZ Fungicide , DACO: 3.1.1,3.1.2,3.1.3,3.1.4,3.5.12,3.5.13,3.5.4,3.5.5 CBI
2527767	2015, Description of Process Formulation to Iprodione500 g/L SC, DACO: 3.2.1,3.2.2,3.2.3,3.3.1 CBI
2527765	2015, MSDS [CBI removed], DACO: 3.2.1
2626260	2016, Description of Process Formulation to Iprodione500 g/L SC, DACO: 3.2.1,3.2.2,3.3.1 CBI
2626764	2016, Description of Process Formulation to Iprodione500 g/L SC, DACO: 3.2.1,3.2.2,3.3.1 CBI
2628208	2016, Description of Process Formulation to Iprodione500 g/L SC, DACO: 3.2.1,3.2.2,3.3.1 CBI

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