

Evaluation Report for Category B, Subcategory 2.3, 2.4 Application

Application Number: 2015-3147
Application: New EP Product Chemistry-Identity and Proportion of Formulants
Product: Prodex SC Fungicide
Registration Number: 32490
Active ingredients (a.i.): iprodione
PMRA Document Number: 2666566

Purpose of Application

The purpose of this application was to register a new commercial end-use product, Prodex SC Fungicide (guarantee 240 g/L iprodione), intended for the control of major diseases on canola and alfalfa grown for seed production.

Chemistry Assessment

Prodex SC Fungicide is formulated as a suspension concentrate containing iprodione at a nominal concentration of 240 g/L. This end-use product has a relative density of 1.086 – 1.091 and pH of 6.0. The required chemistry data for Prodex SC Fungicide have been provided, reviewed and found to be acceptable.

Health Assessments

Prodex SC Fungicide is considered toxicologically equivalent to the precedent. Consequently, no toxicological data were submitted or required.

The use of Prodex SC Fungicide is not expected to result in potential occupational, residential, or bystander exposure greater than that from the currently 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.

No new food residue data were submitted. The use pattern of Prodex SC Fungicide was determined to be identical to that of the registered precedent product. Therefore, previously reviewed data was reassessed in the context of the current application and confirmed that the use of Prodex SC Fungicide is not expected to result in increased iprodione residues in or on the treated crops. Therefore, the use of Prodex SC Fungicide will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The differences in the formulation of Prodex SC Fungicide compared to a registered precedent product are not expected to impact the environmental risk assessment the new end-use product. Therefore, when used according to the label directions, Prodex SC Fungicide is not expected to pose risks of concern to the environment.

Value Assessment

The formulation of Prodex SC Fungicide was compared to the formulations of a precedent product to confirm chemical and biological equivalence. The application rates for Prodex SC Fungicide are the same as those of the precedent product and the differences in formulations are not expected to affect efficacy.

Based on the formulation comparison between Prodex SC Fungicide and the precedent product, the products are expected to be biologically similar. Extrapolation of registered uses from the precedent product label to Prodex SC Fungicide label was therefore supported.

Conclusion

The PMRA has reviewed the information provided in support of Prodex SC Fungicide and found it to be sufficient for the registration this product.

References

PMRA Document Number	Reference
2550747	2015, Additional Product Chemistry for Sharda Iprodione 240 SC Fungicide, DACO: 3.1.1,3.1.2,3.1.3,3.1.4,3.5.12,3.5.13,3.5.15
2550748	2015, Additional Product Chemistry for Sharda Iprodione 240 SC Fungicide, DACO: 3.1.1,3.1.2,3.1.3,3.1.4,3.5.12,3.5.13,3.5.15 CBI
2550758	2015, Iprodione 24 % SC: Determination of the Physico-Chemical Properties, DACO: 3.5.1,3.5.10,3.5.11,3.5.2,3.5.3,3.5.6,3.5.7,3.5.8,3.5.9,3.7
2550759	2015, Iprodione 24 % SC: Determination of the Physico-Chemical Properties, DACO: 3.5.1,3.5.10,3.5.11,3.5.2,3.5.3,3.5.6,3.5.7,3.5.8,3.5.9,3.7
2550760	2015, Iprodione 24 % SC: Validation of the Analytical Method for the Determination of the Active Ingredient Content, DACO: 3.4.1,3.4.2
2550761	2015, Iprodione 24 % SC: Determination of the Accelerated Storage Stability and Corrosion Characteristics, DACO: 3.5.10,3.5.14
2550762	2015, Description of Process Formulation to Iprodione 240 g/L SC, DACO: 3.2.1,3.2.2,3.2.3,3.3.1 CBI
2550763	2011, SDS for [CBI REMOVED],DACO: 3.2.1 CBI
2550764	2010, SDS for [CBI REMOVED],DACO: 3.2.1 CBI
2550765	2011, SDS for [CBI REMOVED],DACO: 3.2.1 CBI
2550766	2013, SDS for [CBI REMOVED],DACO: 3.2.1 CBI
2550767	2013, SDS for [CBI REMOVED],DACO: 3.2.1 CBI
2550768	2015, SDS for [CBI REMOVED], DACO: 3.2.1 CBI
2550752	2015, Scientific Rationale for Value for Sharda Iprodione 240 SC Fungicide. DACO: 10.1

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