Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.6 Application

Application Number: 2021-3334
Application: New End-use Product (Product Chemistry) – New Combination of Technical Grade Active Ingredients
Product: Viatude Fungicide
Registration Number: 34672
Active ingredients (a.i.): Prothioconazole and picoxystrobin
PMRA Document Number: 3409117

Purpose of Application

The purpose of this application was to register a commercial end-use product containing the active ingredients picoxystrobin and prothioconazole for the control of sclerotinia stem rot (white mould) on canola and the suppression of sclerotinia rot (white mould) on soybeans.

Chemistry Assessment

Viatude Fungicide is formulated as suspension containing picoxystrobin at a concentration of 187.5 g/L and prothioconazole at a concentration of 62.5 g/L. This end-use product has a density of 1.09-1.18 g/mL and pH of 5.8-6.8. The required chemistry data for Viatude Fungicide have been provided, reviewed and found to be acceptable.

Health Assessments

Viatude Fungicide is of low toxicity via the oral, dermal and inhalation routes of exposure. It is non-irritating to the eyes, slightly irritating to the skin and it is not a skin sensitizer.

The use of Viatude Fungicide on canola and soybeans to control or suppress sclerotinia rot (white mould) is not expected to result in potential occupational or bystander exposure over the registered use of prothioconazole and picoxystrobin. No risks of concern are expected when workers follow label directions and wear personal protective equipment as stated on the label.

No new residue data for prothioconazole or picoxystrobin in canola or soybeans were submitted or required to support the registration of Viatude Fungicide. Previously reviewed residue data from field trials and processing studies for prothioconazole and picoxystrobin conducted in/on canola and soybeans were re-assessed in the framework of this application. Dietary risks from exposure to residues of prothioconazole and picoxystrobin in these crop commodities at the established maximum residue limits (MRLs) were shown to be acceptable for the general population and all subpopulations, including infants, children, adults and seniors.

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Environmental Assessment

The registration of Viatude Fungicide for the control of labelled diseases on soybeans and canola, will not pose any additional risks to the environment. The required environmental precautions statements and required spray buffer zones to mitigate risks to the environment are included in the label. When used according to label directions, the environmental risks are acceptable for Viatude Fungicide.

Value Assessment

Efficacy data from nine field trials conducted in Canada in 2019 and 2020 were submitted in support of the use claims on the Viatude Fungicide label. Efficacy of Viatude Fungicide against *Sclerotinia* infection on canola and soybean demonstrated an acceptable level of disease control or suppression under adequate disease pressure in field trials. The performance of Viatude Fungicide was equal to or slightly better than the labelled use on the commercial standards tested in the efficacy trials.

The supporting evidence confirmed the value of Viatude Fungicide for control of sclerotinia stem rot on canola, and for suppression of sclerotinia rot on soybean. The registration of Viatude Fungicide will provide Canadian growers with a new product to manage these important diseases on canola and soybean.

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 Viatude Fungicide.

References

PMRA Document Number	Reference
3309499	2022, DACO 3.2 Formulation Process, DACO: 3.2
3309500	2021, DACO 3.5 GF-4630 Physical Properties Final, DACO: 3.5
3252001	2021, Product Identity and Composition, Description of Materials Used to Produce the Product, Description of Formulation Process, Discussion of Formation of Impurities, Certified Limits, and Enforcement Analytical Method for GF-4630, an End Use Product Containing Picoxystrobin and Prothioconazole, DACO: 3.4.1,3.4.2
3252003	2021, 201642 GF-4630 US 2 Week Stability Final, DACO: 3.5.10
3251997	2021, Efficacy and Safety of GF-4630_10Mar2021-Final, DACO: 10.1
3251998	2021, Appendix 1 - Canola, Efficacy of Acapela + Prothioconazole on the canola disease *Sclerotinia sclerotiorum* (Sclerotinia, SCLESC), DACO: 10.2.3.3
3251999	2021, Appendix 2 - Soybean, Efficacy of Acapela + Prothioconazole on the soybean disease *Sclerotinia sclerotiorum* (Sclerotinia, SCLESC), DACO: 10.2.3.3
3251988	2021, Acute oral toxicity study of GF-4630 in rats, DACO: 4.6.1
3251990	2020, GF-4630: Inhalation Median Lethal Concentration (LC50) Study in Rats, DACO: 4.6.3
3251991	2021, Acute eye irritation study of GF-4630 in rabbits, DACO: 4.6.4
3251992	2020, GF-4630 EpiOcularTM eye irritation test (EIT) for identifying chemicals not requiring classification and labelling for eye irritation or serious eye damage, DACO: 4.6.4
3251989	2021, Acute dermal irritation study of GF-4630 in rabbits, DACO: 4.6.5
3251993	2020, GF-4630: Skin Irritation Test (SIT) using the Epiderm™ Skin Model, DACO: 4.6.5
3251995	2021, Skin sensitization study of GF-4630 by local lymph node assay in mice, DACO: 4.6.6