Health Canada Santé Canada

Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2021-1551
Application: Submissions subject to Protection of Proprietary Interests in Pesticide Data policy-Equivalency/Data Compensation Assessment
Product: Joust Fungicide
Registration Number: 34800
Active ingredient (a.i.): Prothioconazole
PMRA Document Number : 3429654

Purpose of Application

The purpose of this application was to register Joust Fungicide, based on a registered precedent product, to manage common and economically important fungal diseases of certain grain, oilseed, pulse, cucurbit vegetable, bushberry and low-growing berry crops as well as soybean, sunflower/safflower, sugar beet, flax, crambe and borage crops grown in the field.

Chemistry Assessment

Joust Fungicide is formulated as an emulsifiable concentrate containing prothioconazole at a concentration of 250 g/L. This end-use product has a density of 0.984-1.014 g/mL and pH of 4.85-5.70. The required chemistry data for Joust Fungicide have been provided, reviewed and found to be acceptable.

Health Assessments

Joust Fungicide is considered to be of low acute toxicity in rats by the oral route and dermal routes. It is considered to be slightly acutely toxic by the inhalation route. It is considered corrosive to the eyes and skin, and is not considered to be a dermal sensitizer.

The use pattern of Joust Fungicide is similar to the registered use pattern of the precedent product. Therefore, potential exposure for mixers, loaders, applicators, bystanders and postapplication workers is not expected to exceed the current exposures to the registered product of this active ingredient. No health risks of concern are expected for workers and bystanders when label directions, precautions and restrictions are followed.

No new residue data for prothioconazole were submitted or are required to support the registration of Joust Fungicide. Previously reviewed residue data were re-assessed in the framework of this application. The use directions on the Joust Fungicide label, including the target crops, method (ground), rates and timing of application, geographic restrictions, preharvest intervals, feeding restrictions, and crop rotation restrictions are comparable to

those on the label of the precedent end-use product. Based on this assessment, residues are not expected to be greater than those from the currently registered uses and will be covered by the established maximum residue limits. Consequently, dietary exposure to residues of prothioconazole is not expected to increase with the registration of Joust Fungicide, and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

A scientific review of the available information has concluded that the environmental risks associated with the use of Joust Fungicide are acceptable when the product is used according to the label directions.

Value Assessment

The efficacy and crop safety of Joust Fungicide with and without the addition of an adjuvant was compared to that of the applicant-cited precedent product in field bridging trials. Based on this comparison, it was concluded that these products are expected to perform similarly, both in terms of efficacy and crop tolerance. Therefore, all uses and claims included in the registration of the precedent product are acceptable for Joust Fungicide.

The availability of Joust Fungicide will provide Canadian growers with an additional product to manage common and economically important fungal diseases of certain grain, oilseed, pulse, cucurbit vegetable, bushberry and low-growing berry crops as well as soybean, sunflower/safflower, sugar beet, flax, crambe and borage crops grown in the field.

Conclusion

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

References

PMRA Document Number	Reference
3219837	2021, Joust Fungicide Supplementary Chemistry Information, DACO: 3.1.1,3.1.2,3.1.3,3.1.4,3.3.1,3.5.12,3.5.13,3.5.15,3.5.4,3.5.5 CBI
3219838	2021, Technical Package Prothioconazole 250EC NUL3391 Global Formulation, DACO: 3.2,3.2.1,3.2.2 CBI
3219839	2021, Final Report for: Method Validation of NUL3391, DACO: 3.4.1
3219840	2020, Prothio 250EC: Physical and Chemical Characteristics, DACO: 3.5.1,3.5.11,3.5.2,3.5.3,3.5.6,3.5.7,3.5.8,3.5.9
3219841	2021, Final Report for: Accelerated Storage Stability and Corrosion Characteristics of NUL3391, DACO: 3.5.10,3.5.14
3219842	2021, A Rationale Based on Trial Data to Support the Equivalence of Joust Fungicide to the Precedent Product PROLINE 480 SC Foliar Fungicide, DACO: 10.1,10.2.1,10.2.2,10.2.3.1,10.3.1
3219843	2021, Joust Trials_Spreadsheet, DACO: 10.1,10.2.3.3(D),10.3.2(B)
3219844	2021, Joust Trials_Barley, DACO: 10.2.3.3(D),10.3.2(B)
3219845	2021, Joust Trials_Canola, DACO: 10.2.3.3(D),10.3.2(B)
3219846	2021, Joust Trials_Lentils, DACO: 10.2.3.3(D),10.3.2(B)
3219847	2021, Joust Trials_Peas, DACO: 10.2.3.3(D),10.3.2(B)
3219848	2021, Joust Trials_Wheat 2019, DACO: 10.2.3.3(D),10.3.2(B)
3219849	2021, Joust Trials_Wheat 2020, DACO: 10.2.3.3(D),10.3.2(B)