



Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2021-5948
Application: Submissions Subject to Protection of Proprietary Interests in Pesticide Data (PIIP) Policy – Equivalency/Data Compensation Assessment
Product: Obex Seed Treatment Fungicide
Registration Number: 34858
Active ingredients (a.i.): Metalaxyl and Trifloxystrobin
PMRA Document Number: 3442457

Purpose of Application

The purpose of this application was to register Obex Seed Treatment Fungicide, an end-use product that controls labelled seed- and soil-borne diseases on beans(succulent, snap, and dry), chickpeas, peas (dry and field), lentils, and soybeans, based on a registered precedent product.

Chemistry Assessment

Obex Seed Treatment Fungicide is formulated as a suspension containing trifloxystrobin and metalaxyl at a concentration of 13.5 g/L and 10.8 g/L, respectively. This end-use product has a density of 1.021 g/mL and pH of 6.8 (1% solution). The required chemistry data for Obex Seed Treatment Fungicide have been provided, reviewed and found to be acceptable.

Health Assessments

Obex Seed Treatment Fungicide is considered toxicologically equivalent to the precedent product; therefore, no toxicology data were required. It is considered to be of low acute toxicity via the oral, dermal, and inhalation routes. This product is considered to be minimally irritating to the eyes and skin, and is not considered to be a potential dermal sensitizer.

The registered use pattern of Obex Seed Treatment Fungicide is identical 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 exposure to the registered products of these active ingredients. No health risks of concern are expected for workers and bystanders when label directions, precautions and restrictions are followed.

No new residue data for trifloxystrobin and metalaxyl were submitted or required to support the registration of Obex Seed Treatment Fungicide. Previously reviewed residue data were re-assessed in the framework of this application.

The use directions on the Obex Seed Treatment Fungicide label, including the target crops, method (seed), rates and timing of application, feeding restrictions, and crop rotation restrictions are comparable to those on the label of the precedent 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 (MRLs). Consequently, dietary exposure to residues of trifloxystrobin and metalaxyl are not expected to increase with the registration of Obex Seed Treatment Fungicide and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The use pattern for Obex Seed Treatment Fungicide is within the registered use pattern of trifloxystrobin and metalaxyl, therefore, no additional risk is expected from the use of Obex Seed Treatment Fungicide.

The label includes all the required environmental precautions and directions for use information, which adequately mitigate risks to the environment.

Risk from use of Obex Seed Treatment Fungicide is acceptable from the environmental perspective when used according to label directions.

Value Assessment

Obex Seed Treatment Fungicide was compared to the precedent product. 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 on the precedent product label are acceptable for Obex Seed Treatment Fungicide.

The availability of Obex Seed Treatment Fungicide will provide Canadian growers with an additional product to manage common and economically important seed and seedling diseases in beans, chickpea, pea, lentil and soybean.

Conclusion

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

References

PMRA Document Number	Reference
3286428	2021, Physico-chemical Properties of Trifloxystrobin 13.5 g/L + Metalaxyl 10.8 g/L FS, DACO: 3.4.1,3.5.1,3.5.10,3.5.11,3.5.12,3.5.14,3.5.2,3.5.3,3.5.6,3.5.7,3.5.8,3.5.9 CBI
3286418	2021, Applicant Name and Address; Manufacturer Name and Address and Product Identification, DACO: 3.1.1,3.1.2,3.1.3,3.1.4,3.2.3,3.3.1,3.5.13,3.5.15,3.5.5
3425834	2022, Revised Formulation Process, DACO: 3.2.2 CBI

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