



Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2020-0190
Application: Submissions Subject to Protection of Proprietary Interests in Pesticide Data Policy - Equivalency/ Data Compensation Assessment
Product: Lixar Pro Fungicide
Registration Number: 34270
Active ingredients (a.i.): Metalaxyl, Prothioconazole, Tebuconazole
PMRA Document Number: 3221756

Purpose of Application

The purpose of this application was to register a new seed treatment fungicide, Lixar Pro Fungicide, for use as a seed and seedling protection against certain seed-borne and soil-borne diseases on barley, wheat, oats, rye and triticale, based on a precedent.

Chemistry Assessment

Lixar Pro Fungicide is formulated as a suspension containing prothioconazole at a concentration of 15.4 g/L, tebuconazole at a concentration of 3.0 g/L, and metalaxyl at a concentration of 6.2 g/L. This end-use product has a density of 1.029 g/mL (20 °C) and pH of 6.4–7. The required chemistry data for Lixar Pro Fungicide have been provided, reviewed and found to be acceptable.

Health Assessments

Lixar Pro Fungicide was considered toxicologically equivalent to the precedent product; therefore, no toxicology data were required. Lixar Pro Fungicide is considered to be of low acute toxicity by the oral, dermal and inhalation routes of exposure. It is considered to be corrosive to the eye and non-irritating to the skin of rabbits. It is not considered to be a dermal sensitizer in guinea pigs.

The use of Lixar Pro Fungicide to control various seed- and soil-borne diseases in various crops is not expected to result in potential occupational or bystander exposure over the registered use of tebuconazole, prothioconazole and metalaxyl. No health 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 tebuconazole, prothioconazole, or metalaxyl were submitted or are required to support the registration of Lixar Pro Fungicide. Previously reviewed residue data were re-assessed in the framework of this petition. The use directions on the Lixar Pro Fungicide label, including the seed types, method (seed treatment) and rate, are identical to the precedent end-use product.

Based on this assessment, residues are not expected to be greater than those for the currently registered uses and will be covered by the established MRLs. Consequently, dietary exposure to residues of tebuconazole, prothioconazole, or metalaxyl is not expected to increase with the registration of Lixar Pro Fungicide and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

When used in accordance with label directions, the environmental risks associated with the registration of Lixar Pro Fungicide are acceptable.

Value Assessment

Lixar Pro Fungicide was concluded to be biologically equivalent to the cited registered precedent product based on a comparison of their formulations. As differences in the formulations are unlikely to result in any significant impact on product performance, in terms of either efficacy or crop tolerance, the registered use pattern of the precedent product is supported for Lixar Pro Fungicide.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided and has found it sufficient to support the registration of Lixar Pro Fungicide.

References

PMRA Document Number	References
3079687	2018, Metalaxyl 6.2g/L + Tebuconazole 3.0g/L + Prothioconazole 15.4g/L FS Addendum No 1 to Study Report Method validation for the determination of the active substances content and relevant impurities of metalazyle and prothioconazole, DACO: 3.4.1,3.4.2
3079689	2018, Metalaxyl 6.2g/L + Tebuconazole 3.0g/L + Prothioconazole 15.4g/L FS Method validation for the determination of the active substances content and relevant impurities of metalazyle and prothioconazole, DACO: 3.4.1,3.4.2
3079690	2018, Metalaxyl 6.2g/L + Tebuconazole 3.0g/L + Prothioconazole 15.4g/L FS Part I: Determination of flash point, auto-ignition temperature and oxidizing properties, DACO: 3.5.11,3.5.8,3.7
3079699	2020, Manufacturing Description- Lixar Pro Fungicide, DACO: 3.2.1,3.2.2,3.2.3,3.5.4
3079701	2018, Metalaxyl 6.2g/L + Tebuconazole 3.0g/L + Prothioconazole 15.4g/L FS Part I: Determination of physiochemical properties of the initial preparation and after accelerated storage, DACO: 3.5.1,3.5.10,3.5.2,3.5.3,3.5.5,3.5.6,3.5.7,3.5.9,3.7

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