

Evaluation Report for Category B, Subcategory 2.3 and 2.4 Application

Application Number: 2011-4781
Application: Changes to product chemistry: Identity and proportion of
formulants
Product: L1397 Seed Treatment Fungicide
Registration Number: 30102
Active ingredients (a.i.): Metalaxyl (MTA), Prothioconazole (PRB), and Tebuconazole
(TEU)
PMRA Document Number: 2151443

Background

L1397 Seed Treatment Fungicide (Registration Number 30102) is currently registered as a seed treatment fungicide for control or suppression of certain seed-borne and soil-borne diseases on barley, oats and wheat.

Purpose of Application

The purpose of this application was to replace the four currently registered formulations for L1397 Seed Treatment Fungicide with two new formulations.

Chemistry Assessment

L1397 Seed Treatment Fungicide is formulated as a suspension concentrate containing tebuconazole at 3.0 g/L, prothioconazole at 15.4 g/L, and metalaxyl at 6.2 g/L. The end-use product has a density of 1.046 g/mL and a pH of 8.27. With the exception of the storage stability and corrosion characteristics study, the chemistry requirements for L1397 Seed Treatment Fungicide are complete.

Health Assessments

L1397 Seed Treatment Fungicide is of low toxicity to rats via the oral ($LD_{50} > 2000$ mg/kg bw), dermal ($LD_{50} > 5000$ mg/kg bw), and inhalation routes ($LC_{50} > 2.55$ mg/L). It is corrosive to the eye and non-irritating to the skin of rabbits. It is not a dermal sensitizer in guinea pigs.

New residue data for metalaxyl, prothioconazole and tebuconazole were not submitted to support the request to replace the four approved formulations for the end-use product L1397 Seed Treatment Fungicide by the two new proposed formulations. The new formulations are not expected to alter the residues in food and feed crops treated with the end-use product. Therefore, the dietary exposure to metalaxyl, prothioconazole or tebuconazole is not anticipated to increase, and will not pose an unacceptable risk to any segment of the population, including infants,

children, adults and seniors.

The amendment to replace the four currently registered formulations of L1397 Seed Treatment Fungicide with two new formulations, without any change in guarantee of the three active ingredients, can be supported from an occupational exposure perspective. Updated risk assessments were performed for commercial and on-farm seed treatment workers handling tebuconazole, and there were no risks of concern identified. There were no changes to the registered PPE based on the change in label signal words. No unacceptable risk is expected when workers follow label directions and wear personal protective equipment as recommended on the label.

Environmental Assessment

No environmental risk assessment was required as the formulation changes will not result in higher environmental risk over the currently registered formulations.

Value Assessment

Based on the rationale provided and other available information, the formulations for L1397 Seed Treatment Fungicide are considered similar to the currently registered formulations. The efficacy of L1397 Seed Treatment Fungicide is unlikely to change due to the formulation changes.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the available information and is able to support the replacement of the four currently registered formulations with two new formulations for L1397 Seed Treatment Fungicide.

References

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- 2180513 2012, BCS response to questions from the PMRA (March 29, 2012) regarding the product chemistry for L1397 Seed Treatment Fungicide (Sub. No. 2011-4781), DACO: 3.2.2,3.5.10,3.5.14 CBI
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