

Evaluation Report for Category B, Subcategory 3.13 Application

Application Number: 2009-0232
Application: Changes to Product Labels-Precautions
Product: Helix Liquid Seed Treatment
Registration Number: 26637
Active ingredients (a.i.): Difenoconazole, Fludioxonil, Metalaxyl-M (Mefenoxam), Thiamethoxam (DFZ, FLD, MFN, THE)
PMRA Document Number: 1803548

Purpose of Application

The purpose of this application was to amend the precautionary statements on the label of Helix Liquid Seed Treatment to remove the use of respiratory PPE and headgear during treatment, clean-up and repair activities, and the requirement for chemical resistant gloves for forklift drivers. Syngenta also requested the removal for the formal requirement to uphold the Product Stewardship Program as a condition of registration.

Chemistry, Environmental and Value Assessments

Chemistry, environmental and value assessments were not required for this application.

Health Assessments

A toxicology assessment was not required for this application as there was no change to the product formulation.

The personal protective equipment for Helix Liquid Seed Treatment has been amended according to the assessment for the conversion of Helix Liquid Seed Treatment (Reg. No. 26637) to full registration. Exposure for commercial seed treatment facility workers, and post-application handlers and planters of treated seeds are acceptable when workers wear the listed personal protective equipment and follow the precautions and directions on the labels.

Conclusion

The PMRA has conducted a review of the available information for Helix Liquid Seed Treatment and has found the information sufficient to amend the precautionary statements on the label to remove the use of respiratory PPE and headgear during treatment, clean-up and repair activities. However, chemical resistant gloves for forklift drivers remain a requirement for use. Further, the formal requirement for the Product Stewardship Program is no longer a condition of registration.

References

List of Studies/Information Submitted by Registrant

<u>PMRA #</u>	<u>Title</u>
1706653	2008, Thiamethoxam/Difenoconazole/Metalaxyl-M/Fludioxonil FS (A11642A, A11642B, A12608B, A12608D) - Occupational Exposure Risk Assessment for the Refinement of Personal Protective Equipment During Commercial Application of HELIX or HELIX XTra Seed Treatment to Canola and Mustard Seed, DACO: 5.3

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