

Evaluation Report for Category B, Subcategory B.1.3 Application

Application Number: 2009-3329
Application: B.1.3 - Changes to chemistry specifications
Product: Technical Active Ingredient Funginex (Triforine)
Registration Number: 20333
Active ingredients (a.i.): Triforine
PMRA Document Number English PDF: 2008759

Purpose of Application

Summit Agro (USA) Corporation has submitted an application to update the specifications of the technical active ingredient so that they are aligned with global specifications.

Chemistry Assessment

The chemistry requirements for Technical Active Ingredient Funginex (Triforine) have been completed.

Health Assessments

The request to change the specifications of Technical Active Ingredient Funginex (Triforine) is not expected to alter the residues in food and feed crops treated with end-use products containing Triforine. Therefore, no increase in dietary exposure to Triforine is anticipated.

Toxicological Assessment

The new specifications for the Technical Active Ingredient Funginex (Triforine) are considered to be similar to that of the currently registered active ingredient; therefore no additional toxicological data were required.

Environmental and Value Assessment

The environmental and value assessment were not required for this evaluation report.

Conclusion

The PMRA has conducted a review of the available information for this application and has concluded that the change in specifications of Technical Active Ingredient Funginex (Triforine) is acceptable for full registration.

References

PMRA #	Reference
1301011	2006, Product Chemistry DACO 2.1 to 2.9 for Triforine, DACO: 2.1,2.2,2.3,2.3.1,2.4,2.5,2.6,2.7,2.8,2.9
1301013	1999, Production Process Information for Technical Triforine, DACO: 2.11.1,2.11.2,2.11.3 CBI
1301018	2006, Five (5) Batches Analyses of SC-581211 (Triforine), DACO: 2.11.4,2.12.1,2.13.1,2.13.2,2.13.3 CBI
1388457	1996, Method of Analysis CFS-DPA M7/3/N. High Performance Liquid Chromatographic Method to Assay for Minor Components in the Technical Grade of Triforine (CL 902224), DACO: 2.13.1 CBI
1796683	Discussion of Formation of Impurities, and Certified Limits, DACO: 2.11.4

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