

Evaluation Report for Category B, Subcategory 3.6, 3.7 Application

Application Number: 2021-0455

Application: Changes to Product Labels – Pre-Harvest and Pre-Grazing Interval

Product: MODDUS **Registration Number:** 33930

Active ingredient (a.i.): Trinexapac-ethyl PMRA Document Number: 3331330

Purpose of Application

The purpose of this application was to amend the product label of MODDUS to add a preharvest/pregrazing interval (PHI/PGI) for cereal forage (wheat, barley and oats) of 30 days and thereby remove the grazing restriction for forage. Additional minor amendments were also implemented to improve the label.

Chemistry, Environmental and Value Assessments

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

Health Assessments

Submitted freezer storage stability data for trinexapac-ethyl were reviewed to support the amendments to remove the grazing/feeding restriction on wheat and oat forage and to add a preharvest/pregrazing interval of 30 days for wheat, oat and barley forage on the registered MODDUS product label, containing 11.3% trinexapac-ethyl (w/v). In addition, previously reviewed wheat and barley residue trial data were re-assessed in the context of the current application. A comparison of the submitted label with the registered label demonstrated that other than the indicated revisions to the restrictions on forage, all other parameters of the use directions remain unchanged; there are no other amendments to the currently registered use patterns of trinexapac-ethyl on wheat, barley and oats. As such, no additional residue data are required to support the amendments to the product label. Therefore, the revisions to grazing/harvesting of cereal forage on the MODDUS label will not pose unacceptable health risks of concern to any segment of the population, including infants, children, adults and seniors provided that the label directions are followed.

Toxicology and occupational exposure assessments were not required for this application.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided and has found it sufficient to support the amendments to the label for MODDUS.



References

PMRA References

Document Number

3196281 2020, Trinexapac-ethyl (CGA163935) - Storage Stability of Residues of

Trinexapac acid (CGA179500) in Crop Matrices Stored Frozen for up to 26

Months, DACO: 7.3

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