

Evaluation Report for Category B, Subcategory 3.1 Application

Application Number:	2022-2939
Application:	Changes to Product Labels-Application Rate Increase or Decrease
Product:	MODDUS
Registration Number:	33930
Active ingredient (a.i.):	Trinexapac-ethyl
PMRA Document Numbe	r: 3505242

Purpose of Application

The purpose of this application was to amend the label of MODDUS to include the option of applying a higher rate to spring wheat, including durum, than the currently registered rate for these crops.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

A toxicology assessment was not required for this application.

The occupational exposure and risk from the increased application rates on the MODDUS label to spring wheat (including durum) to match the maximum rates used on winter wheat and barley was assessed. Although this change represents an expansion of the use pattern for spring wheat (including durum), the previously conducted quantitative risk assessments on file for mixers, loaders, applicators and post-application workers are adequate to cover the new use pattern and no updates were required. No health risks of concern are expected from the new use, provided that workers follow the label directions and wear the personal protective equipment identified on the label.

No new residue data for trinexapac-ethyl in wheat were submitted to support the increased application rate of this active on the MODDUS label. Previously reviewed residue data from field trials conducted in/on wheat were reassessed in the framework of this application. In addition, a processing study in treated wheat was reassessed to determine the potential for concentration of residues of trinexapac-ethyl in processed commodities.



Based on this assessment, residues are expected to be covered by the established maximum residue limits (MRLs) on wheat and wheat bran as the MRLs were based on residue data generated at a rate of 125 g a.i./ha (which is equivalent to the increased rate). Dietary risks from exposure to residues of trinexapac-ethyl were shown to be acceptable at the increased application rate of MODDUS and will not pose health risks of concern to any segment of the population, including infants, children, adults, and seniors.

Environmental Assessment

After a scientific review of the available information, it has been concluded that the environmental risks associated with an increase in application rate of MODDUS to spring wheat (including durum), are acceptable when the product is used according to the label directions.

Value Assessment

Value information was submitted in the form of rationales and performance data generated in four field studies conducted on spring wheat in the U.S. in which products similar to MODDUS were tested. While these products were applied at slightly different rates on an active ingredient basis than labelled for MODDUS, the data demonstrated that MODDUS applied once at 1.03 L product/ha or as a split application of 0.52 L product/ha can be expected to reduce wheat height to a greater extent than when applied once at 0.83 L product/ha. In the two trials in which lodging was severe, a single application of the higher tested rate resulted in greater lodging reduction than the lower one. Rationales were used to bridge differences between tested and MODDUS-labelled application rates and timings and to extrapolate the higher single and split application rate supported for spring wheat to include durum wheat.

The option to apply MODDUS at a higher rate of 1.03 L product/ha on spring wheat, including durum, allows growers to more effectively manage lodging of cultivars known to be more lodging prone and/or in intensively managed fields, e.g., high seeding and fertility rates that result in taller crops.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable to support the increased application rate for MODDUS on spring wheat, including durum.

References

PMRA	
Document	
Number	Reference
3367480	2022, DACO 10 VALUE SUMMARY - Moddus Plant Growth regulator: amending
	the use rate in spring wheat, DACO: 10.1,10.2.2,10.2.3.1,10.2.4,10.3.1,10.3.2,
	10.3.3,10.4,10.5.1,10.5.3,10.5.4,10.5.5
3367482	2007, Trinexapac-ethyl: Variety trials under normal/high nitrogen levels, DACO:
	10.2.3.3
3367483	2011, Palisade: University exposure program for use in cereals, DACO: 10.2.3.3
3367484	2008, Trinexapac-ethyl: Evaluate for lodging control in barley and INTENSIVE
	wheat, DACO: 10.2.3.3
3367485	2016, Evaluation of Palisade EC timing to improve standability and yield in HRSW,
	DACO: 10.2.3.3
3398060	2022, Response to PMRA - Moddus 33930 2022-2939 2022-10-12, DACO: 10.1
3398061	2022, Appendix 1 - Moddus 33930 2022-2939 2022-10-12, DACO: 10.1
3398062	2022, Appendix 2 - Moddus 33930 2022-2939 2022-10-12, DACO: 10.1

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