Health Canada Santé Canada

MANA LADDER 240 EC
Evaluation Report for Category B, Subcategory B.2.3, B.2.4, B.3.1 & B.3.10 Application (Identity of formulants, Proportion of formulants, Application rate increase, Tank Mixes)

Application Number: 2007-8623
Application: Category B, subcategory B.2.3 (Identity of formulants), B.2.4 (Proportion of formulants), B.3.1 (Application rate increase), B.3.10 (Tank Mixes)
Product: MANA LADDER 240 EC
Registration Number: 29268
Active ingredients (a.i.): clodinafop-propargyl
PMRA Document Number : 1827898

Purpose of Application

The purpose of this application was to register MANA LADDER 240 EC, an end-use product containing the active ingredient, clodinafop-propargyl, for the control of annual grass weeds in spring wheat and durum wheat. The product is intended for post-emergence application at 55 or 96 g ai/ha. MANA LADDER 240 EC is intended for application alone or in tank mixtures with certain other herbicides for broad spectrum weed control.

Background

The requested use pattern of this product is similar to that of Horizon 240EC Herbicide (Reg. No. 24067). For specific details of uses, application rates and methods, precautions, restrictions, and personal protective equipment requirements, refer to the product label.

Chemistry Assessment

MANA LADDER 240 EC is formulated as an emulsifiable concentrate containing clodinafop-propargyl at a nominal concentration of 240 g/L. This end-use product has a density of 1.080 g/mL and pH of 4-6. With the exception of an analytical method and the storage stability study, which are conditions of registration, the chemistry requirements for MANA LADDER 240 EC are complete.

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Health Assessments

MANA LADDER 240 EC is of low toxicity to rats via the oral (LD_{50} = 2000 mg/kg) and dermal (LD_{50} > 2000 mg/kg) routes and is slightly toxic via the inhalation route (LC_{50} >1.05 mg/L). It is moderately irritating to the eye and mildly irritating to the skin of rabbits. It is not a dermal sensitizer in guinea pigs (Maximization method).

No new residue data were submitted for the present submission. As the proposed application rate for MANA LADDER 240 EC is identical to the registered one for Horizon 240 EC Herbicide, and the TGAI used in this new EP is determined to be chemically equivalent to the registered TGAI, no impact on the magnitude of residues is expected. Consequently, no increase in dietary exposure to any segment of the population is anticipated.

The proposed use of MANA LADDER 240 EC should not result in unacceptable exposure to the active ingredient, clodinafop-propargyl. No unacceptable risk is expected when workers follow the label directions and wear the personal protective equipment identified on the label.

Environmental Assessment

No new environmental data were submitted to support the new end-use product MANA LADDER 240 EC (clodinafop-propargyl at 240 g/L). When comparing the new product to the registered precedent Horizon 240 EC Herbicide (registration No. 24067), no additional environmental risk is expected from the use of this product. Additional environmental data were not required to support this new formulation. Environmental concerns are mitigated on the existing label and no increase in environmental risk is anticipated.

Value Assessment

Value data were submitted to establish whether MANA LADDER 240 EC was agronomically equivalent to Horizon 240EC Herbicide.

Efficacy data for weed control were submitted from 30 field trials conducted in 2006 or 2007 in Alberta, Saskatchewan or Manitoba. The level of weed control in treatments of MANA LADDER 240 EC applied alone or in tank mixture with broadleaf herbicides was similar to that in treatments of the same rate of Horizon 240EC Herbicide applied alone or in combination with the same tank mix partner products. Crop tolerance data were available from 24 field trials where MANA LADDER 240 EC was applied alone or in tank mixture with a broadleaf herbicide. These trials were conducted in 2006 or 2007 in Alberta, Saskatchewan or Manitoba on spring wheat (17 trials) and durum wheat (7 trials). In all trials, the tolerance of spring wheat or durum wheat to an application of MANA LADDER 240 EC was compared to that of spring wheat or durum wheat treated with the same rate of the registered precedent product, Horizon 240EC Herbicide. Injury to spring wheat or durum wheat treated with MANA LADDER 240 EC alone or in tank mix combination with other labeled herbicides was low and similar to the level of injury observed in treatments of Horizon 240EC Herbicide applied alone or in tank mix combination with the same partner herbicide products. Crop tolerance was confirmed with grain yield data collected in 22 of the 24 trials.

Two trials examining tank mixes of MANA LADDER 240 EC and Horizon 240 EC Herbicide with Decis Flowable Insecticide or Matador 240EC Insecticide were submitted for review. The proposed use patterns and application rates of each tank mix partner are the same as those registered. One trial each on durum wheat and spring wheat was conducted to determine the efficacy against lesser migratory grasshoppers of each insecticide, either alone or in a tank mix with MANA Clodinafop-Propargyl 240 EC. The data show that tank mixing with MANA LADDER 240 EC does not reduce the efficacy of either insecticide. No phytotoxicity was observed in either trial. From a value and sustainability perspective, the tank mixes of Decis Flowable Insecticide or Matador 240EC Insecticide with MANA LADDER 240 ECare acceptable.

Three trials examining tank mixes of MANA LADDER 240EC and Horizon 240 EC Herbicide with Tilt 250E Fungicide were submitted for review. One trial was not reviewed because disease pressure was too low to make a meaningful assessment of the tank-mix. The other two trials were conducted in Manitoba in 2006. Evidence shows that there is no loss of fungicide efficacy when Tilt 250E is tank mixed with either MANA LADDER 240 EC or Horizon 240 EC Herbicides. The level of efficacy against diseases on spring or durum wheat was equivalent between a tank-mix of Tilt 250E with MANA LADDER 240 EC and a tank-mix with Horizon 240 EC.

Conclusion

The Agency has completed an assessment of available information for MANA LADDER 240 EC and has found the information sufficient to allow for conditional registration, with registration being contingent upon fulfilling the following data requirements:

PART 3 **CHEMISTRY REQUIREMENTS FOR THE REGISTRATION OF MANUFACTURING CONCENTRATES AND END-USE PRODUCTS FORMULATED FROM REGISTERED TECHNICAL GRADE OF ACTIVE INGREDIENTS OR INTEGRATED SYSTEM PRODUCTS**

DACO:	3.4.1
Title:	Enforcement Analytical Method
Deficiency:	When asked to provide a validated analytical method capable of separating stereoisomers in the EP, the applicant provided a validated analytical method capable of separating stereoisomers in the TGAI.
Required DATA:	**The applicant must provide a validated analytical method capable of separating the stereoisomers of the active in the EP.**

DACO:	3.5.10
Title:	Storage Stability Data
Deficiency:	The study did not include a test to monitor for the stability of clodinafop-propargyl towards chiral inversion.
Required DATA:	**The applicant must provide data from a storage stability study which includes a test to monitor for the stability of clodinafop-propargyl towards chiral inversion.**

References

A. LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT

PMRA# 1515261 Reference: 2007, Excel Summaries-Spriung Wheat DACO: 10.2.3.1,10.3.1

PMRA# 1515262 Reference: 2007, Excel Summaries-Durum Wheat DACO: 10.2.3.1,10.3.1

PMRA# 1515263 Reference: 2006, Effect of Clodinafop-propargyl on Weed Control and Crop Tolerance in Durum Wheat DACO: 10.2.3.3,10.3.2

PMRA# 1515264 Reference: 2006, Efficacy of MANA Clodinafop 240 g/L vs. Horizon 240 EC on Weeds in Wheat DACO: 10.2.3.3,10.3.2

PMRA# 1515265 Reference: 2006, Evaluate the efficacy and determine the phyto potential for MANA clodinafop 240 g/L versus Horizon 240 EC on weeds in wheat (Durum)
DACO: 10.2.3.3,10.3.2

PMRA# 1515267 Reference: 2006, Control of Persian darnel, wild oats, green foxtail and broadleaved weeds in Durum wheat with MANA-Clodinafop vs. Horizon in tank mixes
DACO: 10.2.3.3,10.3.2

PMRA# 1515270 Reference: 2006, Control of Persian darnel, wild oats, green foxtail and broadleaved weeds in Durum wheat with MANA-Clodinafop vs. Horizon in tank mixes
DACO: 10.2.3.3,10.3.2

PMRA# 1515271 Reference: 2006, Effect of Fungicide on Clodinafop-propargyl Performance in Weed Control, Disease Control and Crop Tolerance in Spring and Durum Wheat
DACO: 10.2.3.3,10.3.2

PMRA# 1515272 Reference: 2006, Control of wild oats and green foxtail in durum wheat with MANA-clodinafop tank mixed with the fungicide Bumper: Analysis of Variance Summary Table
DACO: 10.2.3.3,10.3.2

PMRA# 1515273 Reference: 2006, Control of wild oats and green foxtail in durum wheat with MANA-clodinafop tank mixed with the fungicide Bumper DACO: 10.2.3.3,10.3.2

PMRA# 1515275 Reference: 2006, Effect of Insecticide on Clodinafop-propargyl Performance in Weed Control and Crop Tolerance in Spring and Durum Wheat DACO: 10.2.3.3,10.3.2

PMRA# 1515276 Reference: 2006, Labeling of Mana-clodinafop 240 g/L with insecticides
DACO: 10.2.3.3,10.3.2

PMRA# 1515277 Reference: 2006, Effect of Fungicide on Clodinafop-propargyls Performance in Weed Control, Disease Control and Crop Tolerance in Spring and Durum Wheat
DACO: 10.2.3.3,10.3.2

PMRA# 1515278 Reference: 2006, Labeling of Mana-clodinafop 240 g/L with insecticides DACO: 10.2.3.3,10.3.2

PMRA# 1515279 Reference: 2006, Effect of insecticide on Clodinafo-propargyls performance in weed control and crop tolerance in spring and durum wheat DACO: 10.2.3.3,10.3.2

PMRA# 1515280 Reference: 2006, Control of wild oats, green foxtail and grasshoppers in HRS wheat with MANA-clodinafop tank mixed with the insecticide Matador or Decis, DACO: 10.2.3.3,10.3.2

PMRA# 1515281 Reference: 2006, Control of wild oats, green foxtail and grasshoppers in HRS wheat with MANA-clodinafop tank mixed with the insecticide Matador or Decis-Summary DACO: 10.2.3.3,10.3.2

PMRA# 1515283 Reference: 2006, Efficacy of MANA Clodinafop 240 g/L vs. Horizon 240 EC on Weeds in Wheat DACO: 10.2.3.3,10.3.2

PMRA# 1515284 Reference: 2006, Efficacy of MANA Clodinafop 240 g/L vs. Horizon 240 EC on Weeds in Wheat DACO: 10.2.3.3,10.3.2

PMRA# 1515286 Reference: 2006, Evaluate the efficacy and determine the phyto potential for MANA clodinafop 240 g/L versus Horizon 240 EC on weeds in wheat (Spring Wheat)
DACO: 10.2.3.3,10.3.2

PMRA# 1515287 Reference: 2006, Control of Persian darnel, wild oats, green foxtail and broadleaved weeds in HRS wheat with MANA-Clodinafop vs. Horizon in tank mixes DACO: 10.2.3.3,10.3.2

PMRA# 1515288 Reference: 2006, Control of Persian darnel, wild oats, green foxtail and broadleaved weeds in spring wheat – Summary DACO: 10.2.3.3,10.3.2

PMRA# 1515289 Reference: 2006, Effect of Clodinafop-propargyl on weed control and crop tolerance in spring wheat DACO: 10.2.3.3,10.3.2

PMRA# 1515290 Reference: 2006, Effect of Clodinafop-propargyl on weed control and crop tolerance in spring wheat DACO: 10.2.3.3,10.3.2

PMRA# 1515291 Reference: 2006, Evaluation of MANA Clodinafop with different surfactants in wheat DACO: 10.2.3.3,10.3.2

PMRA# 1515292 Reference: 2006, Efficacy of MANA Clodinafop 240 g/L vs. Horizon with different COCs on wheat DACO: 10.2.3.3,10.3.2

PMRA# 1515293 Reference: 2006, Control of wild oats and green foxtail in HRS wheat with MANA-clodinafop 240 with several COC¿¿¿s DACO: 10.2.3.3,10.3.2

PMRA# 1515294 Reference: 2006, Control of wild oats and green foxtail in HRS wheat with MANA-clodinafop 240 with several COC¿¿¿s-Summary DACO: 10.2.3.3,10.3.2

PMRA# 1515296 Reference: 2007, Evaluate the efficacy and determine the phyto potential for MANA clodinafop 240 g/L versus Horizon 240 EC on weeds in wheat DACO: 10.2.3.3,10.3.2

PMRA# 1515298 Reference: 2007, 2007-CLODIN-02 DACO: 10.2.3.3,10.3.2

PMRA# 1515299 Reference: 2007, Efficacy/ phyto evaluation on grass weeds in wheat
DACO: 10.2.3.3,10.3.2

PMRA# 1515300 Reference: 2007, Control of Persian darnel, wild oats, green foxtail and broadleaved weeds in HRS wheat with MANA-Clodinafop vs. Horizon in tank mixes
DACO: 10.2.3.3,10.3.2

PMRA# 1515301 Reference: 2007, Control of Persian darnel, wild oats, green foxtail and broadleaved weeds in HRS wheat with MANA-Clodinafop vs. Horizon in tank mixes
DACO: 10.2.3.3,10.3.2

PMRA# 1515303 Reference: 2007, Efficacy Evaluation Of Mana Clodinafop 240 Ec Versus Horizon 240 Ec In Wheat DACO: 10.2.3.3,10.3.2

PMRA# 1515304 Reference: 2007, Efficacy Evaluation Of Mana Clodinafop 240 Ec Versus Horizon 240 Ec In Wheat DACO: 10.2.3.3,10.3.2

PMRA# 1515305 Reference: 2007, Evaluate the efficacy and determine the phyto potential for MANA clodinafop 240g/L versus Horizon 240 EC on weeds in wheat DACO: 10.2.3.3,10.3.2

PMRA# 1515306 Reference: 2007, Control of Persian darnel, wild oats, green foxtail and broadleaved weeds in durum wheat with MANA-Clodinafop vs. Horizon in tank mixes DACO: 10.2.3.3,10.3.2

PMRA# 1515307 Reference: 2007, Control of Persian darnel, wild oats, green foxtail and broadleaved weeds in durum wheat with MANA-Clodinafop vs. Horizon in tank mixes DACO: 10.2.3.3,10.3.2

PMRA# 1515309 Reference: 2007, Evaluate the efficacy and determine the phyto potential for MANA clodinafop 240 g/L versus Horizon 240 EC on weeds in wheat. DACO: 10.2.3.3,10.3.2

PMRA# 1515310 Reference: 2007, Evaluate the efficacy and phyto potential for Clodinafop 240 g/L, Horizon 240 EC with different COCs on wheat. DACO: 10.2.3.3,10.3.2

PMRA# 1515311 Reference: 2007, Evaluate the efficacy and determine the phyto potential for MANA clodinafop 240 g/L versus Horizon 240 EC on weeds in wheat. DACO: 10.2.3.3,10.3.2

PMRA# 1515312 Reference: 2007, Product Identification DACO: 3.1.1,3.1.2,3.1.3,3.1.4 CBI

PMRA# 1515313 Reference: 2007, CLODINAFO-PROPARGYL 240 EC - Composition and Preparation DACO: 3.2.1,3.2.2 CBI

PMRA# 1515314 Reference: 2007, Waiver for Not Submitting Impurity Data for MANA Clodinafop-propargyl 240 ECWaiver for Not Submitting Impurity Data for MANA Clodinafop-propargyl 240 EC DACO: 3.2.3,3.4.2 CBI

PMRA# 1515315 Reference: 2007, CLODINAFOP-PROPARGYL 240 EC - Chemical Composition DACO: 3.3.1 CBI

PMRA# 1515316 Reference: 2007, Addendum to final report - Clodinafop-propargyl 240 EC - Storage Stability and Shelf Life Specification of Clodinafop-propargyl 240 EC Stored at 54oC for 14 Days DACO: 3.4.1,3.5.1,3.5.10,3.5.11,3.5.2,3.5.

PMRA# 1515317 Reference: 2006, Determination of Storage Stability and Shelf Life Specification of Clodinafop-propargyl 240 EC Stored at 54oC for 14 Days
DACO: 3.4.1,3.5.1,3.5.10,3.5.11,3.5.2,3.5.3,3.5.6,3.5.7,3.5.9 CBI

PMRA# 1515318 Reference: 2006, Determination of the auto-ignition temperature of Clodinafop-propargyl 240 EC DACO: 3.5.11 CBI

PMRA# 1515319 Reference: 2006, Expert statement on the explosive properties of Clodinafop-propargyl 240 EC DACO: 3.5.12 CBI

PMRA# 1515320 Reference: 2007, DACO 3.5.13 Waiver in Lieu of a Miscibility Study
DACO: 3.5.13 CBI

PMRA# 1515321 Reference: 2007, Waiver for Not Submitting Dielectric Breakdown Voltage Data for MANA Clodinafop-propargyl 240 EC DACO: 3.5.15

PMRA# 1515322 Reference: 2007, Clodinafop-Propargyl 240 EC - Data on packing DACO: 3.5.5 CBI

PMRA# 1515323 Reference: 2007, Clodinafop-Propargyl 240 EC – Formulation DACO: 3.5.5

PMRA# 1515324 Reference: 2006, Expert statement on the oxidizing properties of Clodinafop-propargyl 240 EC DACO: 3.5.14,3.5.8 CBI

PMRA# 1515325 Reference: 2006, Acute Oral Toxicity Study of Clodinafop-propargyl 240 EC in Rats DACO: 4.6.1

PMRA# 1515326 Reference: 2006, Acute Dermal Toxicity of Clodinafop-propargyl 240 EC in CD Rats DACO: 4.6.2

PMRA# 1515327 Reference: 2006, Acute Inhalation Toxicity Study of Clodinafop-propargyl 240 EC in Rats DACO: 4.6.3

PMRA# 1515328 Reference: 2006, Acute Eye Irritation/Corrosion Test of Clodinafop-propargyl 240 EC in Rabbits DACO: 4.6.4

PMRA# 1515329 Reference: 2006, Acute Dermal Irritation/Corrosion Test (Patch Test) of Clodinafop-propargyl 240 EC in Rabbits DACO: 4.6.5

PMRA# 1515330 Reference: 2007, Clodinafop-propargyl 240EC: Skin Sensitisation in the Guinea Pig – Magnusson and Kligman Maximisation Method DACO: 4.6.6

PMRA# 1515331 Reference: 2007, Dossier for the Evaluation of the Active Substance Clodinafop-propargyl and the Representative Formulation Clodinafop-propargyl 240 EC
DACO: 5.2

PMRA# 1682364 Reference: 2008, Clodinafop-Chemistry-2.13.1-FAO WHO standards
DACO: 3.3.1

PMRA# 1682365 Reference: 2007, Chemistry-3.2.1-3.2.2-pages 2-3 DACO: 3.3.1 CBI

PMRA# 1682366 Reference: 2008, Clodianfop-Propargyl Technical-Five Lot Analysis of Optical Isomers in Active Ingredient After 2 Years of Storage at Room Temperature
DACO: 3.4.1,3.5.10,3.5.14 CBI

PMRA# 1682367 Reference: 2008, Clodinafop-propargyl 240EC-Determination of Storage Stability and Shelf Life Specification for Two Years DACO: 3.4.1,3.5.10,3.5.14 CBI

PMRA# 1687052 Reference: 2008, Applicant and Chemistry Information
DACO: 2.1,2.2,2.3,2.3.1,2.4,2.5,2.6,2.7,2.8,2.9

PMRA# 1687053 Reference: 2006, [CBI REMOVED] Technical Product Chemistry Data for Registration DACO: 2.11.1,2.11.2,2.11.3,2.11.4 CBI

PMRA# 1687056 Reference: 2006, [CBI REMOVED] Technical- 5-Lots analysis and Method Validation DACO: 2.12.1,2.13.1,2.13.2,2.13.3,2.13.4 CBI

PMRA# 1687057 Reference: 2007, Physical and Chemical Characteristics: Color, Physical State, Odor, Stability to Normal and Elevated Temperature ¿¿¿ Metals and Metal Ions, pH and bulk Density DACO: 2.14.1,2.14.13,2.14.2,2.14.3,2.14.6

PMRA# 1687058 Reference: 2008, [CBI REMOVED]
DACO: 2.14.10,2.14.11,2.14.4,2.14.7,2.14.8,2.14.9

PMRA# 1687059 Reference: 2008, Chemistry Part 2 Chemical and Physical Properties
DACO: 2.14.10,2.14.11,2.14.14,2.14.4,2.14.7,2.14.8,2.14.9

PMRA# 1687060 Reference: 2008, [CBI REMOVED] IR and Mass Spectra DACO: 2.14.12 CBI

PMRA# 1800787 Reference: 2008, [CBI REMOVED] UV Visible Spectrum DACO: 2.14.12

PMRA# 1800801 Reference: 2009, [CBI REMOVED] Technical- 5-Lots analysis and Method Validation DACO: 2.13.1 CBI

PMRA# 1800802 Reference: 2008, Determination of Storage Stability and Shelf Life Specification of Clodinafop-propargyl 240 EC Stored at Ambient Temperature for 2 Years DACO: 3.5.10,3.5.14

PMRA# 1800803 Reference: 2008, Determination of Storage Stability and Shelf Life Specification of Clodinafop-propargyl 240 EC Stored at Ambient Temperature for 2 Years DACO: 3.5.10,3.5.14

PMRA# 1800804 Reference: 2008, Chemistry-2.14.12-uv visible-17sept2009 DACO: 2.14.12

PMRA# 1812481 Reference: 2009, Chemistry-2.13.1-[CBI REMOVED]-revised page 93-13oct2009 DACO: 2.13.1 CBI

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