

Evaluation Report for Category B, Subcategory 2.1, 2.4, 2.6, 3.10, 3.11 Application

Application Number: 2005-0498

Application: Category B, subcategories: B2.1 (guarantee for EP or MA), B2.4

(proportion of formulant in EP or MA), B2.6 (new combination of active ingredients), B3.10 (addition of tank mix), B3.11 (addition

of pests)

Product: Lumax SE Selective Herbicide

Registration Number: 28891

Active ingredients (a.i.): Atrazine at 120 g a.i./L

Mesotrione at 32 g a.i./L S-Metolachlor at 320 g a.i./L

PMRA Document Number: 1546176

Purpose of Application

The purpose of this application is to register Lumax SE Selective Herbicide, a new formulated end-use product which contains the active ingredients atrazine, mesotrione and s-metolachlor, for pre- emergent control of various grasses and broadleaf weeds on field corn, seed corn and sweet corn in Eastern Canada only. Lumax SE Selective Herbicide can also be used for post-emergent application in field corn for control of annual grasses and broadleaf weeds. Lumax SE Selective Herbicide may be tankmixed with Glyphosate (Touchdown iQ (Reg. No. 27192), Roundup Transorb (Reg. No. 25455) or Roundup Weathermax (Reg. No. 27487) for surface preplant application in field corn. The requested use pattern of Lumax SE Selective Herbicide is within the currently registered use pattern for all active ingredients.

Chemistry Assessment

Lumax SE Selective Herbicide is a solution containing three active ingredients, atrazine, s-metolachlor and mesotrione at nominal concentrations of 120 g/L, 320 g/L and 32 g/L respectively. This product has a density of 1.09 g/mL and pH of 2-5. The chemistry requirements for Lumax SE Selective Herbicide have been completed.

Health Assessments

The Lumax SE Selective Herbicide basic formulation is of low acute toxicity by oral (LD $_{50}$ = 2730 mg/kg) and dermal routes (LD $_{50}$ > 5000 mg/kg) in rats. It is of low toxicity via inhalation with an LC $_{50}$ greater than 2.05 mg/L in rats. The Lumax SE Selective Herbicide basic formulation is slightly irritating to rabbit eyes. It is also mildly irritating to the skin of rabbits. This product is a dermal sensitizer.

Lumax SE Selective Herbicide alternate formulation is of low acute toxicity by oral ($LD_{50} = 3129 \text{ mg/kg}$) and dermal routes ($LD_{50} > 5000 \text{ mg/kg}$) in rats. It is of low toxicity via inhalation with an LC_{50} greater than 2.42 mg/L in rats. Lumax SE Selective Herbicide alternate formulation is mildly irritating to rabbit eyes. It is also mildly irritating to the skin of rabbits. This product is not a dermal sensitizer.

The active ingredients in the Lumax SE Selective Herbicide (s-metolachlor, atrazine and mesotrione) are in other end-use products which are currently registered for weed control in corn using similar application methods, therefore, a new occupational exposure assessment is not required. The application rates of s-metolachlor, mesotrione and atrazine in Lumax SE Selective Herbicide are within the currently registered rate range. Therefore, exposure to mixer/loader/applicators and post application workers for the Lumax SE Selective Herbicide use pattern should not be greater than that for end -use products currently registered use in corn.

Residues of mesotrione, atrazine and s-metolachlor on treated crops grown and utilized for food and feed resulting from the use of Lumax SE Selective Herbicide in combination with a glyphosate tank mix partner (Touchdown iQ, Roundup Transorb or Roundup Weathermax) are expected to be covered by the established maximum residue limits (MRLs) for mesotrione (0.01 ppm), atrazine (0.1 ppm as per subsection B.15.002(1)), s-metolachor (0.1 ppm) and glyphosate (0.1 ppm). Since the use directions, including the use rate, for Lumax SE Selective Herbicide are the same or lower than the mesotrione, s-metolachlor and atrazine registered rates for use on corn, no increase in dietary exposure is anticipated.

Environmental Assessment

An environmental assessment was not required as the application rate, number of applications, frequency of application, and tankmix partners are within the currently registered use pattern the active ingredients for field corn, seed corn, and sweet corn. There are no environmental concerns with the use of the Lumax SE Selective Herbicide which are not mitigated by the label statements.

Value Assessment

Value data were submitted to establish the efficacy of Lumax SE Selective Herbicide on broadleaf and grassy weeds and to establish the crop safety of this end-use product on field, seed and sweet corn.

Efficacy data were submitted from 67 trials conducted in 2002, 2003 and 2004 at 27 different locations in Ontario and Québec. The data provided support the claim of control of American nightshade, Eastern black nightshade, common chickweed, lady's thumb, lamb's quarter, redroot pigweed, velvetleaf, wild buckwheat, wild mustard, barnyard grass, smooth crabgrass, hairy crabgrass, fall panicum, green foxtail, yellow foxtail, giant foxtail and witchgrass with a surface pre-plant, pre-emergence or early post-emergence application.

Crop phytotoxicity data were available from 88 trials conducted in 2002, 2003 and 2004 at 35 different locations in Ontario and Québec. Sixty-six (66) of these trials evaluated visual crop phytotoxicity in weed efficacy trials. Twenty-two (22) of the trials were dedicated crop tolerance trials to assess the crop safety on field, seed and sweet corn to an application of Lumax SE Selective Herbicide. The data provided support the use of Lumax SE Selective Herbicide as a surface pre-plant, pre-emergence or early post-emergence application in field corn and the use of Lumax SE Selective Herbicide as a pre-emergence application in seed and sweet corn.

A waiver for rotational re-cropping was provided by the applicant. The following rotational crops are acceptable to appear on the Lumax SE Selective Herbicide label: field corn, seed corn, sweet corn: no restriction; winter wheat: 4.5 months; spring wheat: 10 months; soybeans, white beans, alfalfa: 11 months; and all other crops: bioassay.

Conclusion

The PMRA has completed an evaluation of the subject application. As a result of the evaluation, the PMRA is proposing conditional registration for the subject product based on the conditional registration of the active ingredient mesotrione.

References

A. LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT

PMRA Document Number	Reference
1.0	Chemistry Assessment
1028386	2005, Lumax (A12854L) Certification of Limits, DACO: 3.3.1 CBI
1028389	2005, Lumax (A12854F) Product Information, DACO: 3.1 CBI
1028390	2005, Lumax (A12854L) Product Information, DACO: 3.1 CBI
1028391	2005, Lumax (A12854F) Starting Materials, N/S, MRID: N/S, DACO: 3.2.1 CBI
1028392	2005, Lumax (A12854L) Starting Materials, DACO: 3.2.1 CBI
1028393	2005, Lumax (A12854F) Manufacturing Process, DACO: 3.2.2 CBI
1028394	2005, Lumax (A12854L) Manufacturing Process, DACO: 3.2.2 CBI
1028395	2005, Lumax (A12854F) Discussion of Formation of Impurities, MRID: N/S, DACO: 3.2.3 CBI
1028396	2005, Lumax (A12854L) Discussion of Formation of Impurities, MRID: N/S, DACO: 3.2.3 CBI

1028397	2005, Lumax (A12854F) Certification of Limits, DACO: 3.3.1 CBI
1028398	2005, Lumax (A12854F) Analytical Method AF 1460/2, DACO: 3.4.1 CBI
1028399	2005, Lumax (A12854L) Analytical Method - Note to the Reviewer, DACO: 3.4.1 CBI
1028400	2005, Lumax (A12854F) Analytical Method AF 1460/2, MRID: N/S, DACO: 3.4.1 CBI
1028401	2005, Lumax (A12854F) Chemical and Physical Properties, DACO: 3.5 CBI
1028402	2005, Lumax (A12854L) Chemical and Physical Properties, DACO: 3.5 CBI
1028403	2001, Physical Characteristics (Color, Physical State and Odor) of G-30027/ CGA 77102/Mesotrione 3.9SE (A12854F), 2458-01, DACO: 3.5.1 CBI
1028404	2001, Physical Characteristics (Viscosity and Density) of G-30027/ CGA 77102/Mesotrione 3.9SE (A12854F), 2460-01, DACO: 3.5.6 CBI
1028405	2003, A12854L: Density, T001958-03, DACO: 3.5.6 CBI
1028406	2001, Physical Characteristics (pH and Flammability) of G-30027/ CGA 77102/Mesotrione 3.9SE (A12854F), 2459-1, MRID: N/S, DACO: 3.5.7 CBI
1028407	2004, Oxidising Properties - A12798L, HT03/361, DACO: 3.5.8 CBI
1028408	2003, Chemical Stability of G-30027/CGA 77102/Mesotrione 3.9SE (A12854F) in Non- fluorinated High Density Polyethylene (HDPE) Packaging at Ambient Temperature, 2463-01, DACO: 3.5.10 CBI
1028409	2003, Chemical Stability of G-30027/CGA 77102/Mesotrione 3.9SE (A12854F) in Stainless Steel Packaging at Ambient Temperature, 2462-01, DACO: 3.5.10 CBI
1028410	2004, A12854L: Chemical Reanalysis of Batch FL031443, T016293-04, DACO: 3.5.10 CBI
1028411	2002, Chemical Characteristics of G-30027/CGA 77102/Mesotrione 3.9SE
1028422	(A12854F), 2457-01, DACO: 3.5.14 CBI 2003, A12854L:pH, T001957-03, DACO: 3.5.7 CBI
1034726	Lumax (A12854F) Specification Sheet Final Product, DACO: 3.3.2 CBI
1034727	Lumax (A12854L) Specification Sheet Final Product, N/S, DACO: 3.3.2 CBI
2.0	Impact on Human and Animal Health

1028412	2004, Lumax SE Herbicide - Summary of Acute Toxicology Studies (A12854F and A12854L), N/S, MRID: N/S, DACO: 4.6
1028413	2002, Summary of A12854F variant - Summary of Acute Toxicology Studies with G-30027/CGA-77102/Mesotrione 3.9SE, 2662-01, DACO: 4.6
1028414	2004, Summary of A12854L variant - Summary of Acute Toxicology Studies with Atrazine/S-metolachlor/Mesotrione SE (A12854L), T011355-04, MRID: N/S, DACO: 4.6
1028415	2001, Summary of A12854F variant - G-30027/CGA-77102/Mesotrione 3.9SE-F (A12854F): Acute Oral Toxicity in the Rat, 2678-01, DACO: 4.6.1
1028416	2004, Atrazine/S-Metolachlor/Mesotrione 3.9SE (A12854L):Acute Oral Toxicity Up and Down Procedure in Rats, 1194-03, DACO: 4.6.1
1028417	2002, G-30027/CGA-77102/Mesotrione 3.9SE-F (A12854F): Acute Dermal Toxicity Study in the Rat, 2679-01, DACO: 4.6.2
1028418	2004, Atrazine/S-Metolachlor/Mesotrione SE (A12854L): Acute Dermal Toxicity Study in the Rat, CR3642, DACO: 4.6.2
1028419	2002, G-30027/CGA-77102/Mesotrione 3.9SE-F: Acute Inhalation Toxicity Study in the Rat, 2430-01, DACO: 4.6.3
1028420	2004, Atrazine/S-Metolachlor/Mesotrione SE (A12854L): 4-Hour Acute Inhalation Toxicity Study in Rats, HR2449, DACO: 4.6.3
1028421	2002, G-30027/CGA-77102/Mesotrione 3.9SE-F (A12854F): Eye Irritation Study in the Rabbit, 2680-01, DACO: 4.6.4
1028423	2003, G30027/CGA77102/Mesotrione SE (A12854L): Eye Irritation Study in the Rabbit, FB6043, DACO: 4.6.4
1028424	2002, G-30027/CGA-77102/Mesotrione 3.9SE-F (A12854F): Skin Irritation Study the Rabbit, 2681-01, DACO: 4.6.5
1028425	2003, G-30027/CGA-77102/Mesotrione SE (A12854L): Skin Irritation Study in the Rabbit, EB 5037, DACO: 4.6.5
1028426	2002, G30027/CGA77102/Mesotrione SE (A12854F): Skin Sensitization Study in the Guinea Pig, 2682-01, DACO: 4.6.6
1028427	2004, Atrazine/S-Metolachlor/Mesotrione 3.9SE (A12854L):Skin Sensitization Study in the Guinea Pig, GG7784, DACO: 4.6.6
1028571	2005, S-Metolachlor, Atrazine, Benoxacor and Mesotrione - Residue Levels on

	Field Corn (Forage, Grain and Fodder) and Sweet Corn (K+CWHR and Forage) from Trials Conducted with Primextra or with Pre-Formulated Products in Canada, CER0908/02, DACO: 7.4.1
1028644	2005, S-Metolachlor, Atrazine, Benoxacor and Mesotrione - Residue Levels on Field Corn (Forage, Grain and Fodder) and Sweet Corn (K+CWHR and Forage) from Trials Conducted with Primextra or with Pre-Formulated Products in Canada, CER0908/02, MRID: N/S, DAC
1028645	2005, S-Metolachlor, Atrazine, Benoxacor and Mesotrione - Residue Levels on Field Corn (Forage, Grain and Fodder) and Sweet Corn (K+CWHR and Forage) from Trials Conducted with Primextra or with Pre-Formulated Products in Canada, CER0908/02, MRID: N/S, DAC
1028646	2005, S-Metolachlor, Atrazine, Benoxacor and Mesotrione - Residue Levels on Field Corn (Forage, Grain and Fodder) and Sweet Corn (K+CWHR and Forage) from Trials Conducted with Primextra or with Pre-Formulated Products in Canada, CER0908/02, DACO: 7.4.1
1028647	2005, S-Metolachlor, Atrazine, Benoxacor and Mesotrione - Residue Levels on Field Corn (Forage, Grain and Fodder) and Sweet Corn (K+CWHR and Forage) from Trials Conducted with Primextra or with Pre-Formulated Products in Canada, CER0908/02, DACO: 7.4.1
1028648	2005, S-Metolachlor, Atrazine, Benoxacor and Mesotrione - Residue Levels on
1020010	Field Corn (Forage, Grain and Fodder) and Sweet Corn (K+CWHR and Forage) from Trials Conducted with Primextra or with Pre-Formulated Products in Canada, CER0908/02, DACO: 7.4.1
3.0	Field Corn (Forage, Grain and Fodder) and Sweet Corn (K+CWHR and Forage) from Trials Conducted with Primextra or with Pre-Formulated Products in
	Field Corn (Forage, Grain and Fodder) and Sweet Corn (K+CWHR and Forage) from Trials Conducted with Primextra or with Pre-Formulated Products in Canada, CER0908/02, DACO: 7.4.1
3.0	Field Corn (Forage, Grain and Fodder) and Sweet Corn (K+CWHR and Forage) from Trials Conducted with Primextra or with Pre-Formulated Products in Canada, CER0908/02, DACO: 7.4.1 Value Assessment
3.0 1028287	Field Corn (Forage, Grain and Fodder) and Sweet Corn (K+CWHR and Forage) from Trials Conducted with Primextra or with Pre-Formulated Products in Canada, CER0908/02, DACO: 7.4.1 Value Assessment 10.2.3.1 Efficacy Summary Table (Excel), DACO: 10.2.3.1
3.0 1028287 1028586	Field Corn (Forage, Grain and Fodder) and Sweet Corn (K+CWHR and Forage) from Trials Conducted with Primextra or with Pre-Formulated Products in Canada, CER0908/02, DACO: 7.4.1 Value Assessment 10.2.3.1 Efficacy Summary Table (Excel), DACO: 10.2.3.1 2005, Lumax SE - Value Summary, DACO: 10.1
3.0 1028287 1028586 1028587	Field Corn (Forage, Grain and Fodder) and Sweet Corn (K+CWHR and Forage) from Trials Conducted with Primextra or with Pre-Formulated Products in Canada, CER0908/02, DACO: 7.4.1 Value Assessment 10.2.3.1 Efficacy Summary Table (Excel), DACO: 10.2.3.1 2005, Lumax SE - Value Summary, DACO: 10.1 2005, Lumax SE - Summary of Efficacy Trials, DACO: 10.2.3.1
3.0 1028287 1028586 1028587 1028588	Field Corn (Forage, Grain and Fodder) and Sweet Corn (K+CWHR and Forage) from Trials Conducted with Primextra or with Pre-Formulated Products in Canada, CER0908/02, DACO: 7.4.1 Value Assessment 10.2.3.1 Efficacy Summary Table (Excel), DACO: 10.2.3.1 2005, Lumax SE - Value Summary, DACO: 10.1 2005, Lumax SE - Summary of Efficacy Trials, DACO: 10.2.3.1 2005, Lumax SE Surface Preplant Efficacy Trial Abstracts, DACO: 10.2.3.3 Lumax SE Surface Preemergent/Early Postemergent Efficacy Trial Abstracts,
3.0 1028287 1028586 1028587 1028588 1028590	Field Corn (Forage, Grain and Fodder) and Sweet Corn (K+CWHR and Forage) from Trials Conducted with Primextra or with Pre-Formulated Products in Canada, CER0908/02, DACO: 7.4.1 Value Assessment 10.2.3.1 Efficacy Summary Table (Excel), DACO: 10.2.3.1 2005, Lumax SE - Value Summary, DACO: 10.1 2005, Lumax SE - Summary of Efficacy Trials, DACO: 10.2.3.1 2005, Lumax SE Surface Preplant Efficacy Trial Abstracts, DACO: 10.2.3.3 Lumax SE Surface Preemergent/Early Postemergent Efficacy Trial Abstracts, DACO: 10.2.3.3

Lumax SE - Sweet Corn Early Postemergence Tolerance Trials, DACO: 10.3.2
 2005, Agriculture and Agri-Food Canada, Lumax SE - Seed Corn Early Postemergence Tolerance Trials, DACO: 10.3.2
 2005, Lumax SE Damage to Rotational Crops - Note to the Reviewer, DACO: 10.3.3

B. ADDITIONAL INFORMATION CONSIDERED

i) Published Information

DACO: 10.3.2

Re-evaluation of Atrazine (PACR2003-13). Appendix IV, Mitigation Measures.

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