Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, and 3.12 Application

Application Number: 2007-7518
Application: Category B, Subcategory 2.1 (Changes in Guarentee), 2.3 (Changes in Identity of Formulants), 2.4 (Changes in Proportion of Formulants), and 3.12 (New Site or Host).
Product: Express Pro Herbicide
Registration Number: 29212
Active ingredients (a.i.): Tribenuron-methyl (MEX) and metsulfuron-methyl (MEM)
PMRA Document Number: 1701477

Purpose of Application

The purpose of this application was to register a new end use product (EUP), Express Pro Herbicide, that is a physical blend of two previously registered manufactured use products (MUPs), Express 50 SG MUP (Reg. No. 28176) and Metsulfuron-methyl MUP Herbicide (Reg. No. 26677). Express Pro Herbicide was proposed for pre-seed control of certain broadleaf weeds and grasses in spring wheat, durum wheat, winter wheat, spring barley, oats and summer-fallow.

Chemistry Assessment

Express Pro Herbicide is formulated as a wettable granule containing tribenuron-methyl and metsulfuron-methyl at nominal concentrations of 42.9% and 8.6%, respectively. This end-use product has a pour density of 0.5 - 0.6 g/cm^3 and pH of 5-8.9. The chemistry requirements for Express Pro Herbicide are complete.

Health Assessments

No toxicology data specific to the new blend herbicide was required as each blend component is a currently registered product for which data has already been assessed. A combined toxicity profile can be estimated based on the prior acute toxicity testing of the component manufactured use products. Express Pro Herbicide is of low acute toxicity via the oral and dermal routes of exposure. It is slightly toxic via the inhalation route of exposure. It is mildly irritating to rabbit eyes and is not irritating to the rabbit skin. The formulation is considered to be a potential dermal sensitizer.

No new data for food residues were submitted to support the registration of Express Pro Herbicide. Data on file support the use of tribenuron-methyl and metsulfuron-methyl in/on wheat (spring, winter and durum) and barley. No data were available to support the application of

Express Pro Herbicide on oats. The proposed use of Express Pro Herbicide will not result in the residues of tribenuron-methyl and metsulfuron-methyl exceeding their established MRLs on wheat and barley. Therefore, the dietary exposure is not expected to increase and will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

The use of the new end-use product Express Pro Herbicide should not result in an increase in potential occupational or bystander exposure over the registered uses of active ingredients tribenuron methyl and metsulfuron methyl. No unacceptable risk is expected when workers follow label directions and wear personal protective equipment on the label.

Environmental Assessment

An environmental assessment of Express Pro Herbicide for use in Western Canada, was not required since the use pattern (application rates, number of applications and use areas) is the same as that currently registered, thus, there will be no increase in environmental exposure. Environmental concerns have been mitigated through adequate statements on the product label but may undergo revision based upon the re-evaluation of tribenuron-methyl.

Value Assessment

Efficacy data from 21 field trials conducted in the Prairie Provinces in 2006 and 2007 were considered to be acceptable for review. Weed control was visually assessed following an application of Express Pro Herbicide in combination with Roundup WeatherMax or Touchdown iQ for 17 weed species on two to three occasions through the field season. The registered treatment of Express SG MUP in combination with the same glyphosate herbicide was arranged side-by-side for direct efficacy comparison. It was concluded from these field trials that the treatment of Express Pro Herbicide in combination with glyphosate herbicide provided comparable weed control with Express SG MUP in combination with the same glyphosate herbicide. In addition, the treatment of Express Pro Herbicide in combination with glyphosate herbicide increased residual control of several weed species as provided by the metsulfuron-methyl component.

Crop safety data from six dedicated crop tolerance trials and rotational crop safety data from 18 trials were submitted for review. In these trials, only the metsulfuron-methyl component of the treatment of Express Pro Herbicide + glyphosate herbicide was assessed. The applicant submitted scientific rationales to support the use of crop tolerance data generated with the metsulfuron-methyl component at 1.5 (1 x) and 3.0 (2 x) g a.i./ha to support the treatment of Express Pro Herbicide in combination with a glyphosate herbicide. The rationales were considered to be acceptable from a value standpoint.

Crop tolerance, expressed as percent crop injury, and final yield, expressed as percent of an untreated weed-free check, were reported in these trials. It was concluded from dedicated crop tolerance trials that the crop tolerance of spring wheat, durum wheat, spring barley, and oats to pre-seeding application of Express Pro Herbicide in combination with a listed glyphosate herbicide was acceptable. It was concluded from rotational crop tolerance trials that fields treated with Express Pro Herbicide in combination with a listed glyphosate herbicide can be

seeded to canola, field peas, lentils, and flax following a minimum of 10 months after application.

Overall, the registration of Express Pro Herbicide and its use pattern (applied with a glyphosate herbicide) can be supported.

Conclusion

The PMRA has completed an assessment of available information for Express Pro Herbicide and has found the information sufficient to support a full registration of all uses except oats.

References

PMRA Identification Number	Reference
1486772	Express Pro Herbicide - Efficacy, crop tolerance, and re-cropping data to support use on summer-fallow and pre-seed application to cereals. E.I. du Pont Canada Company. DACO. 10.2.3.3, 10.3.2, and 10.3.3. September 28, 2007. pp. 906.
857087	2004, Tribenuron Methyl 50SG Water Soluble Granular Herbicide Formulation: Laboratory Study of Physical and Chemical Properties, Dupont-11674, DACO: 3.5 CBI
1604081	1999, Summary Report of Physical and Chemical Characteristics of End-Use Product Metsulfuron Methyl 60% Herbicide Formulation, DuPont-2489, DACO: 3.5, 3.5.1, 3.5.2, 3.5.3, 3.5.6, 3.5.7
1604083	2000, Storage Stability and Corrosion Characteristics of End-Use Product Metsulfuron Methyl 60% Herbicide Formulation, DuPont-2490, DACO: 3.5.10, 3.5.14
857083	2003, Product Identity and Composition of End-Use Product Tribenuron Methyl 50SG, Dupont-12816, DACO: 3.2, 3.3.1 CBI
1604076	2001, Product Identity and Composition of End-Use Product Metsulfuron Methyl 60 WG (Paste Extruded Granule) CONFIDENTIAL ATTACHMENT, DuPont-4548 RV1, DACO: 3.2, 3.2.1, 3.2.2, 3.2.3, 3.3.1 CBI
832431	2004, Validation of the HPLC/UV analytical method to verify the certified true limits of thifensulfuron methyl (DPX M6316), tribenuron methyl(DPX-L5300), and metsullfuron methyl(DPX T-6376) in WG and SG blended end-use products, DuPont-12950 RV 1, DACO: 3.4.1
1604084	2008, DACO 3.5.4, 3.5.5, 3.5.4,3.5.5
1604082	1999, Explosive Properties, Flammability of Solids and Auto-Flammability of Metsulfuron Methyl 60% Water Dispersible Granular Herbicide Formulation, DuPOnt-2488, DACO: 3.5.11, 3.5.12
857099	Tribenuron methyl 50SG Soluble Granules Herbicide Formulation: Laboratory Study of Explosive and Oxidizing Properties, Flammability and Relative Self-ignition Temperature. DACO: 3.5.11, 3.5.12

1486784	2007, EXPRESS Pro Herbicide - DACO 3.1 - 3.2, DACO: 3.1, 3.1.1, 3.1.2, 3.1.3, 3.1.4, 3.2, 3.2.1, 3.2.2, 3.2.3 CBI
1604076	2001, Product Identity and Composition of End-Use Product Metsulfuron Methyl 60 WG (Paste Extruded Granule) CONFIDENTIAL ATTACHMENT, DuPont-4548 RV1, DACO: 3.2, 3.2.1, 3.2.2, 3.2.3, 3.3.1
1604077	1998, Manufacturing Process for Formulated Product,, DACO: 3.2.2 CBI

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