

Evaluation Report for Category B, Subcategory 2.6 Application

Application Number: 2006-0569
Application: Category B, subcategory 2.6 (new end-use product formulation)
Product: Frontline XL Herbicide
Registration Number: 28804
Active ingredients (a.i.): Florasulam at 4 g a.i./L in combination with MCPA 2-ethylhexyl ester at 280 g a.e./L.
PMRA Document Number: 1694515

Background

Florasulam technical grade active ingredient (PCP 26890) was first registered in 2001, while MCPA 2-ethylhexyl technical grade active ingredient (PCP 27784) was first registered in 2004. Both technical grade active ingredients are currently registered in the tank mix of Frontline A SC Herbicide (PCP # 27029, 50 g a.i./L of florasulam) and Frontline B EC Herbicide (PCP # 27030, 500 g a.e./L of MCPA) for the control of a wide spectrum of broadleaf weeds on barley, oats, and spring wheat (including durum). The tank mix of Frontline A SC Herbicide and Frontline B EC Herbicide, herein referred to as Frontline A + B, is sold for use in the prairie provinces and Peace river region of British Columbia only.

Purpose of Application

The purpose of this application was to register a new commercial pre-mix formulation, Frontline XL Herbicide, to replace the currently registered tank mix of Frontline A + B. The proposed end-use product controls a wide spectrum of broadleaf weeds on barley, oats, and spring wheat (including durum) and is to be sold for use in the prairie provinces and Peace river region of British Columbia only.

Chemistry Assessment

Frontline XL Herbicide, is formulated as a suspension containing florasulam at a nominal concentration of 4 g a.i./L and MCPA (present as 2-ethylhexyl ester) at a nominal concentration of 280 g a.e./L. It also contains 1,2-benzisothiazoline-3-one at 0.02% as a preservative. This end-use product has a density of 1.0336 g/mL and pH of 3.47. With the exceptions of the storage stability and corrosion characteristics studies that are currently in progress, the chemistry requirements for Frontline XL Herbicide are complete.

Health Assessments

Frontline XL Herbicide is of low acute toxicity through the oral ($LD_{50} = 3129$ mg/kg bw [95% C.I. 1750 - 5000 mg/kg bw] in females), dermal ($LD_{50} > 5000$ mg/kg bw in both males and females) and inhalation ($LC_{50} > 5.64$ mg/L in both males and females) routes in the rat. It is minimally irritating to the eyes (MIS [1hr] of 6/110 and an MAS [24, 48 and 78 hr] of 1.6/110) and mildly irritating to the skin (MAS [24, 48 and 78 hr] of 1.33/8 in both males and females) of the rabbit. Frontline XL Herbicide is considered to be a potential skin sensitizer.

A review of the proposed Frontline XL Herbicide label and the currently registered Frontline A + B tank mix labels finds that the proposed crops and the rates of application are identical on both the proposed and currently registered labels. Therefore, it can be concluded that the new pre-mix formulation will not result in residues in/on food or feed items that exceed those that occur from currently registered tank mix products.

Residues of MCPA 2-ethylhexyl ester and florasulam on treated crops grown and utilized for food and feed resulting from the use of the proposed Frontline XL Herbicide formulation are expected to be covered by the established maximum residue limit (MRL) for MCPA 2-ethylhexyl ester and florasulam.

The Frontline XL Herbicide formulation fits within the use pattern, including host crops, application rates and timings, and application equipment. The personal protective equipment recommended on the label (impervious gloves, coveralls and chemical worker's goggles) is considered adequate to address the associated risk. No increase in potential exposure to mixer/loader/applicator or post-application workers is anticipated.

Environmental Assessment

An environmental assessment was not required since the proposed use site category, seasonal rates and application methods are the same as those currently registered on the tank mix of Frontline A + B. Buffer zones of 5 metres for the protection of freshwater habitats and 30 metres for the protection of terrestrial habitats have already been established for this use pattern and are specified on both the proposed and registered labels. Therefore, additional environmental data were not required to support the proposed new pre-mix formulation of Frontline XL Herbicide. The label statements on the proposed label reflected the approved text on the registered labels.

Value Assessment

To support the registration of Frontline XL Herbicide, the applicant submitted data from 58 trials conducted in 1999 and 2005 across 25 locations in the prairie provinces. Forty-one trials compared the alone treatment of Frontline XL Herbicide to the tank mix of Frontline A + B. Two formulations of Frontline XL Herbicide were tested. In 1999, the applicant tested a formulation developed to deliver 5g a.i./ha florasulam / 420g a.e./ha MCPA. In 2005, the applicant tested a new formulation (the currently proposed formulation) developed to deliver 5g a.i./ha florasulam / 350g a.e./ha MCPA; this formulation would then allow for the addition of 70 g a.e./ha MCPA to Frontline XL Herbicide for optimum control of pigweed and hempnettle. These two formulations of Frontline XL Herbicide were shown to be equivalent, and therefore both were used to support the product registration.

The following is a list of Frontline XL Herbicide and Frontline A + B tank mix rates that were tested:

- Frontline XL Herbicide - 5g a.i./ha florasulam / 350g a.e./ha MCPA
- Frontline A+B tank mix - 5g a.i./ha florasulam + 350g a.e./ha MCPA

- Frontline XL Herbicide - 5g a.i./ha florasulam / 420g a.e./ha MCPA
- Frontline XL Herbicide + MCPA ester - 5g a.i./ha florasulam / 350g a.e./ha MCPA + 70g a.e./ha MCPA

- Frontline A + B tank mix - 5g a.i./ha florasulam + 420g a.e./ha MCPA

The efficacy against 16 broadleaf weeds was assessed, and the data indicated Frontline XL Herbicide provided control comparable to that seen with the registered tank mix for all weeds at all the rates tested. Crop tolerance was evaluated on cereal crops from all major crop classes; wheat - Hard Red Spring (HRS), Canadian Prairie Spring (CPS), and Durum (TRZDU); and barley - two-row; six-row; and hullless. Crop tolerance to Frontline XL Herbicide was comparable to the registered tank mix for all crops tested.

In addition, the efficacy and crop tolerance of Frontline XL Herbicide (5g a.i./ha florasulam / 350g a.e./ha MCPA + 70g a.e./ha MCPA) versus Frontline A + B (5g a.i./ha florasulam + 420g a.e./ha MCPA) when tankmixed with either Assert (imazamethabenz 500g a.i./ha), Horizon (clodinfop-propargyl 56g a.i./ha), Puma Super (fenoxaprop-p-ethyl 92g a.i./ha) or Everest Solupak 70 DF (flucarbazone 30g a.i./ha) was evaluated in 17 trials. Wild oat control and crop tolerance of spring wheat was comparable between Frontline XL Herbicide Frontline A + B when tankmixed with Assert, Horizon, Puma Super, or Everest.

Conclusion

The PMRA has completed an evaluation of Frontline XL Herbicide and has determined that it is eligible for full registration.

References

PMRA Document Number	Title
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1138054	2006, Applicant Name and Address; Formulating plant Name and Address, DACO: 3.1.1
1138055	2006, Control Product Specification Form, DACO: 3.3.2
1138056	2006, Group A - Product Identity, Composition and Analysis for GF-1727, a Suspension Emulsion End-Use Product Containing Florasulam and MCPA 2-Ethylhexyl Ester, NAFST-06-014, DACO: 3.2.1,3.2.2,3.2.3,3.3.1,3.4.1
1138057	2005, Determination of Colour, Odour, Oxidizing and Reducing Action, Flammability, Explodability, pH, Viscosity and Density of GF-1727, an End-Use Product Containing Florasulam and MCPA 2-EHE, FAPC-052-011, DACO: 3.5.1,3.5.11,3.5.12,3.5.13,3.5.14,3.5.15,3
1138058	2006, Formulation Type, DACO: 3.5.4
1138059	2006, Container Material & Description, DACO: 3.5.5
1138060	2006, Storage Stability, DACO: 3.5.10
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1138063	2005, Acute Oral Toxicity Up and Down Procedure in Rats, Product Safety Laboratories, DACO: 4.6.1
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1138067	2005, GF-1727: Acute Liquid Aerosol Inhalation Toxicity Study in F433/DUCRL Rats, The Dow Chemical Company, DACO: 4.6.3
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- 1138073 2005, GF-1727: Local Lymph Node Assay in BALB/cAnNCrI Mice, The Dow Chemical Company, DACO: 4.6.6
- 1138075 2006, Exposure - Summaries and Use Description Scenario, DACO: 5.1, 5.2
- 1138076 2006, GF-1727, Frontline Premix, DACO: 5.2
- 1138078 2006, Frontline XL Herbicide - Small Scale Trials (Field), DACO: 10.2.3.1
- 1138079 2005, EF-1343 (DE-570) + MCPA Ester Tank-Mix vs DE-570/MCPA Ester Preformulated Mixtures EF-1473/GF-1727 - Master Weed Summary, DACO: 10.2.3.1
- 1138169 2005, EF-1343 (DE-570) + MCPA Ester Tank Mix vs. DE-570/MCPA Ester Preformulated Mixtures GF-1727/EF-1473 - Master Adverse Effect Summary - Spring Barley, DACO: 10.3.1
- 1138170 2005, EF-1343 (DE-570) + MCPA Ester Tank Mix vs. DE-570/MCPA Ester Preformulated Mixtures GF-1727/EF-1473 - Master Adverse Effect Summary - Durum Wheat, DACO: 10.3.1
- 1138171 2005, EF-1343 (DE-570) + MCPA Ester Tank Mix vs. DE-570/MCPA Ester Preformulated Mixtures GF-1727/EF-1473 - Master Adverse Effect Summary - Spring Wheat, DACO: 10.3.1
- 1138179 2005, DE-570/MCPA Ester (GF-1727) + MCPA Ester + Assert for Control of Wild Oat (AVEFA) - Master Weed Control Summary, DACO: 10.2.3.1
- 1138182 2006, Assert Tankmix with EF-1343 + MCPA Ester Tank mix vs. DE-570/MCPA Ester Preformulated Mixture GF-1727 - Master Adverse Effect Summary, DACO: 10.3.1
- 1138184 2005, DE-570/MCPA Ester (GF-1727) + MCPA Ester + Everest for Control of Wild Oat (AVEFA) - Master Weed Control Summary, DACO: 10.2.3.1
- 1138192 2006, Everest Tabkmix with EF-1343 + MCPA Ester Tank-mix vs. DE-570/MCPA Ester Preformulated Mixture GF-1727 - Master Adverse Effect Summary - Spring Wheat, DACO: 10.3.1

- 1138195 2005, DE-570/MCPA Ester (GF-1727) + MCPA Ester + Horizon for Control of Wild Oat (AVEFA) - Master Weed Control Summary, DACO: 10.2.3.1
- 1138203 2006, Horizon Tankmix with EF-1343 + MCPA Tankmix vs. DE-570/MCPA Ester Preformulated Mixture GF-1727 - Master Adverse Effect Summary, DACO: 10.3.1
- 1138207 2005, DE-570/MCPA Ester (GF-1727) + MCPA Ester + Puma Super for Control of Wild Oat (AVEFA) - Master Weed Control Summary, DACO: 10.2.3.1
- 1138215 2006, Puma Super Tankmix with EF-1343 + MCPA Ester Tankmix vs. DE-570/MCPA Ester Preformulated Mixture GF-1727 - Master Adverse Effect Summary, DACO: 10.3.1

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