Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.6 Application

Application Number: 2019-5868
Application: New End Use Product; New combination of Technical Grade Active Ingredients
Product: Prominex Herbicide
Registration Number: 34021
Active ingredients (a.i.): Clopyralid, present as acid, or as salts
Fluroxypyr, present as 1-methylheptyl ester, and
Halauxifen, present as methyl ester
PMRA Document Number: 3189559

Purpose of Application

The purpose of this application was to register a new herbicide end-use product for application to spring wheat (including durum), winter wheat and barley, for the control of broadleaved weeds, based on precedents.

Chemistry Assessment

Prominex Herbicide is formulated as an emulsifiable concentrate containing halauxifen, present as methyl ester at a concentration of 4.7 g/L, fluroxypyr, present as 1-methylheptyl ester at a concentration of 122.2 g/L and clopyralid (present as the monoethanolamine salt) at a concentration of 97.8 g/L. This end-use product has a density of 1.0781 g/mL and pH of 4.85. The required chemistry data for Prominex Herbicide have been provided, reviewed and found to be acceptable.

Health Assessments

Prominex Herbicide is of low acute oral, dermal and inhalation toxicity in rats. It is mildly irritating to the eyes and moderately irritating skin of rabbits. It is not a dermal sensitizer in mice.

The registration of Prominex Herbicide, containing halauxifen, fluroxypyr and clopyralid for application to spring wheat (including durum), winter wheat and barley, for the control of perennial broadleaved weeds can be supported from an occupational exposure perspective as it fits within the registered use pattern for all three active ingredients. The fluroxypyr mixer/loader/applicator risk assessment for aerial application was updated. The potential exposure for mixers, loaders, applicators, postapplication workers and bystanders is not expected to result in health risks of concern when label directions, precautions and restrictions are followed.

No new residue data to support the new combination of active ingredients for the Prominex Herbicide label were submitted for clopyralid, fluroxypyr, and halauxifen-methyl in wheat and barley. Previously reviewed residue data from field trials conducted in/on

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wheat and barley were reassessed in the framework of this petition. Based on this assessment, residues of clopyralid, fluroxypyr, and halauxifen-methyl in/on treated wheat and barley commodities are not expected to increase and will be covered under the established maximum residue limits. Consequently, the dietary exposure to residues of clopyralid, fluroxypyr, and halauxifen-methyl is not expected to increase and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

A scientific review of the available information indicatesthat the environmental risks associated with the use of Prominex Herbicide, containing the active ingredients clopyralid, fluroxypyr, and halauxifen, are acceptable when used according to the label directions.

Value Assessment

The registration of Prominex Herbicide will provide farmers with another option for post-emergent control of certain broadleaf weeds in wheat and barley.

Value information submitted for review consisted of precedent registrations and data from field trials conducted in the Canadian Prairies in 2019. This information demonstrated that Prominex Herbicide provides consistent control of weeds labelled for a co-formulation of halauxifen and fluroxypyr plus the additional control of Canada thistle. Wheat and barley as host crops exhibit adequate margins of crop tolerance to Prominex Herbicide applied as per the label instructions.

Rotational crops supported for registration are based on the most restrictive registrations of the precedent products.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to support the registration of Prominex Herbicide.

References

PMRA Document Number	Reference
3043096	2019, Group A-Product Identity and Composition, Description of Materials Used to Produce the Product, Description of Formulation Process, Discussion of Formation of Impurities, Certified Limits, and Enforcement Analytical Method for GF-4030, an End Use Product Containing Clopyralid-olamine, Fluroxypyr-meptyl and Halauxifen-methyl, DACO: 3.1,3.2,3.2.1,3.2.2,3.2.3,3.3.1,3.4.1 CBI
3043097	2019, Analytical Method and Validation for the Determination of Clopyralid-olamine, Fluroxypyr-meptyl, Halauxifen-methyl, [CBI] in GF-4030 Formulation, DACO: 3.4.1 CBI

3043098 2019, Group B Determination of Color, Physical State, Odor, Oxidizing and Reducing Action,
Flammability, pH, Viscosity, and Density of GF-4030, an End Use Product Containing Clopyralid-Olamine, [CBI], Halauxifen-Methyl, Fluroxypyr-Meptyl, DACO: 3.5.1,3.5.11,3.5.2,3.5.3,3.5.4,3.5.6,3.5.7,3.5.8,3.5.9 CBI
3043099 2019, GF-4030 Two Week Accelerated Storage Stability and Packaging Corrosion Characteristics in Vented F-HDPE and Vented EVOH, DACO: 3.5.10 CBI
3043100 2018, Determination of Explosive Properties of GF-4030, DACO: 3.5.12 CBI
3043101 2019, Acute Oral Toxicity Study of GF-4030 in Rats, DACO: 4.6.1
3043102 2019, Acute Dermal Waiver, DACO: 4.6.2
3043103 2019, GF-4030: Inhalation Median Lethal Concentration (LC50) Study in Rats, DACO: 4.6.3
3043104 2019, Acute Eye Irritation Study of GF-4030 in Rabbits, DACO: 4.6.4
3043105 2019, Acute Dermal Irritation Study of GF-4030 in Rabbits, DACO: 4.6.5
3043106 2019, Skin Sensitization Study of GF-4030 by Local Lymph Node Assay in Mice, DACO: 4.6.6
3180436 2020, DAS Deficiency Response, GF-4030 Herbicide, 2019-5868, DACO: 6.3,7.4.1
3180437 2012, Residue Summary of XDE-729 in/on Wheat, Barley and Oat Crop Commodities across Studies from Australia, Canada, New Zealand and United States, DACO: 7.4.1
3180438 Victoria L. Taylor, Ian Cummins, Melissa Brazier-Hicks, Robert Edwards, 2013, Environmental and Experimental Botany Article: Protective responses induced by herbicide safeners in wheat, Envir. Exp. Bot. 88:93-99. DACO: 7.4.1
3180440 2005, EPA: Human Health Risk Assessment for [CBI Removed] for Uses on Wheat and Barley, DACO: 7.4.1
3180441 2005, EPA Memo: [CBI Removed] on Wheat and Barley. Data Submitted to Satisfy Conditional Registration Requirements for Use on Wheat, Revise Wheat Tolerances, and to Add Use on Barley. Summary of Analytical Chemistry and Residue Data. DACO: 7.4.1
3180442 unknown, 1995, UK Department for EFRA, Evaluation on [CBI Removed], DACO: 7.4.1
3043094 2019, Individual field efficacy and phyto trials (16 Trials), DACO: 10.2.3.2(B).