Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.3, 2.4 Application

Application Number: 2015-1495
Application: New EP/Product Chemistry-Identity and Proportion of Formulants
Product: MPower Fluroxypyr 180 g/L Herbicide
Registration Number: 32952
Active ingredient (a.i.): Fluroxypyr (present as 1-methylheptyl ester)
PMRA Document Number: 2758287

Purpose of Application

The purpose of this submission was to register a new end-use product, MPower Fluroxypyr 180 g/L Herbicide, containing a new source of the active ingredient fluroxypyr, present as 1-methylheptyl ester, based on a precedent product.

Chemistry Assessment

MPower Fluroxypyr 180 g/L Herbicide is formulated as an emulsifiable concentrate containing fluroxypyr (present as 1-methylheptyl ester) at a nominal concentration of 180 g/L. This end-use product has a density of 0.98 g/mL and pH of 3.5-4.5. The required chemistry data for MPower Fluroxypyr 180 g/L Herbicide have been provided, reviewed and found to be acceptable.

Health Assessments

MPower Fluroxypyr 180 g/L Herbicide is considered toxicologically equivalent to the registered precedent product. No toxicological data were submitted or required.

The use of MPower Fluroxypyr 180 g/L Herbicide to control annual broadleaf weeds in spring wheat, durum wheat and spring barley not underseeded with legumes, and on seedling and established tall fescue and forage grasses grown for seed in the Prairie Provinces and the interior of British Columbia is not expected to result in potential occupational or bystander exposure over the registered uses of fluroxypyr. No health risks of concern are expected when workers follow label directions and wear personal protective equipment as stated on the label.

No residue chemistry data were submitted for fluroxypyr to support the registration of MPower Fluroxypyr 180 g/L Herbicide. No additional data are required to support this registration request given that MPower Fluroxypyr 180 g/L Herbicide is considered to be toxicologically and agronomically equivalent to the precedent end-use product, and that all crops and their respective use directions and restrictions are identical to those on the precedent end-use product label. As such, the current petition does not represent an expansion of use for fluroxypyr. Dietary exposure to fluroxypyr is not expected to increase and will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

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Environmental Assessment

The use of MPower Fluroxypyr 180 g/L Herbicide is not expected to increase the environmental exposure to fluroxypyr relative to the registered precedent product. Therefore, no additional risk of concern is expected. Environmental concerns have been mitigated through adequate statements on the label.

The technical grade active ingredient in the new end-use product MPower Fluroxypyr 180 g/L Herbicide has been shown to contain contaminants which have been identified in the federal government's *Toxic Substances Management Policy* (TSMP, 1995) as Track 1 substances. When compared to other registered sources, the use of the proposed new source is not expected to result in an increase in the release of Track 1 contaminants. PMRA's strategy to manage Track 1 contaminants in pest control products is captured in DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*.

Value Assessment

The formulation of MPower Fluroxypyr 180 g/L Herbicide was compared to the formulation of the precedent product. It was concluded that differences in the formulations were unlikely to result in any significant impact on product performance, in terms of efficacy and crop tolerance.

The availability of MPower Fluroxypyr 180 g/L Herbicide would provide users an alternative option to manage broadleaf weeds in small grain cereals in the Canadian Prairies and Peace River Region of British Columbia. Registration of a generic product may increase product competition in the marketplace, thereby potentially reducing purchasing costs of similar 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 the end-use product MPower Fluroxypyr 180 g/L Herbicide.

References

PMRA Document Number	Reference
2524658	2014, Product Chemistry Testing of Fluroxypyr-Meptyl 180 g/L EC, DACO: 3.5.1,3.5.2,3.5.3,3.5.6,3.5.7,3.5.8,3.5.9 CBI
2615846	2015, Combined Storage Stability/Corrosion Characteristics Testing of Fluroxypyr-Meptyl 180 g/L EC, DACO: 3.5.10,3.5.14 CBI
2524659	2015, MPower Fluroxypyr 180 g/L Herbicide: Physical and Chemical Properties and Waiver Requests, DACO: 3.5.10,3.5.11,3.5.12,3.5.13,3.5.14,3.5.15,3.5.4,3.5.5 CBI
2524657	2015, Product Identity and Composition, Description of the Materials Used, Description of the Formulation Process, Discussion of the Formation of Impurities, Certified Limits, and Enforcement Analytical Method for MPower Fluroxypyr 180 g/L Herbicide, DACO: 3.2,3.2.1,3.2.2,3.3.1,3.4 CBI
2615844	2016, Determination of Flash Point of Fluroxypyr Meptyl 180 g/l EC (As Acid), DACO: 3.5.11 CBI
2615845	2016, Validation of Enforcement Method for the Determination of Fluroxypyr-Meptyl 180 g/L EC and 333 g/L EC Formulations, DACO: 3.4.1 CBI

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