Health Canada Santé Canada

Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2022-4486
Application: Application Subject to the Protection of Proprietary Interests in Pesticide Data (PPIP) policy - Equivalency/Data Compensation Assessment
Product: Kingpin Herbicide
Registration Number: 35070
Active ingredients (a.i.): Fluroxypyr (present as 1-methylheptyl ester) and pinoxaden
PMRA Document Number : **3511163**

Purpose of Application

The purpose of this application was to register a commercial class end-use product, Kingpin Herbicide, for the post-emergence control/suppression of annual broadleaf and grass weed species in labeled crops in the Prairie Provinces and the interior of British Columbia, based on a registered precedent product.

Chemistry Assessment

Kingpin Herbicide is formulated as an emulsifiable concentrate containing fluroxypyr (present as 1-methylheptyl ester) at a concentration of 87.5 g/L and pinoxaden at a concentration of 50 g/L. This end-use product has a density of 0.92792 g/mL and pH of 4.07. The required chemistry data for Kingpin Herbicide have been provided, reviewed and found to be acceptable.

Health Assessments

Kingpin Herbicide is considered toxicologically equivalent to the precedent product; therefore, no toxicology data were required. Kingpin Herbicide is considered to be of low acute toxicity via oral, inhalation, and dermal routes. Kingpin Herbicide is considered to be severely irritating to the eye, moderately irritating to the skin and is considered to be a dermal sensitizer.

The registered use pattern of Kingpin Herbicide is comparable to the registered use pattern of the precedent product. Therefore, potential exposure for mixers, loaders, applicators, bystanders and postapplication workers is not expected to exceed the current exposure to the registered products of fluroxypyr and pinoxaden. No health risks of concern are expected for workers and bystanders when label directions, precautions and restrictions are followed.

No new residue data for fluroxypyr or pinoxaden were submitted or were required to support the registration of Kingpin Herbicide. Previously reviewed residue data were re-assessed in the framework of this application. The use directions on the Kingpin Herbicide label, including the target crops, method (ground), rates and timing of application, geographic restriction, preharvest intervals, feeding restriction, and crop rotation restrictions are comparable to those on the label of the precedent product.

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Based on this assessment, residues are not expected to be greater than those from the currently registered uses and will be covered by the established maximum residue limits (MRLs). Consequently, dietary exposure to residues of fluroxypyr and pinoxaden is not expected to increase with the registration of Kingpin Herbicide and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The uses on the Kingpin Herbicide label are within the currently registered use pattern of pinoxaden and fluroxypyr. Therefore, risk to the environment is acceptable when Kingpin Herbicide is used in accordance with the label, which includes statements to mitigate risks to the environment.

Value Assessment

The availability of Kingpin Herbicide provides growers with an alternative option for the post-emergence control/suppression of annual broadleaf and grass weed species in labeled crops in the Prairie Provinces and the interior of British Columbia. Registration of a generic product may increase competition in the market, which may result in a reduction in the purchasing cost of similar products, thus lowering growers' overall input cost.

The formulation of Kingpin Herbicide was compared to the formulation of the precedent product. It was concluded that the differences in formulations would be unlikely to result in any significant impact on product performance, in regards to efficacy and crop tolerance. Therefore, all uses and claims found on the precedent product label are supported for inclusion on the Kingpin Herbicide label.

Conclusion

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

References

PMRA Document Number	Reference
3386564	2022, Additional Product Chemistry for Kingpin Herbicide - Parent, DACO: 3.1.1,3.1.2,3.1.3,3.1.4,3.5.15,3.5.4,3.5.5
3386570	2022, Kingpin Herbicide - Manufacturing Process, DACO: 3.2.1,3.2.2,3.2.3, 3.3.1 CBI
3386571	2022, Physical chemical studies of Pinoxaden 50 g/L + Fluroxypyr (Present like Methyl Heptyl ester) 87.5 g/L EC, DACO: 3.5.11,3.5.12,3.5.13,3.5.14, 3.5.6,3.5.8,3.5.9

3386572	2022, Accelerated Storage Stability Study of Pinoxaden 50 g/L + Fluroxypyr (Present like Methyl Heptyl ester) 87.5 g/L EC, DACO: 3.4.1,3.4.2,3.5.1, 3.5.10,3.5.2,3.5.3,3.5.7
3494999	2023, Clarification Response for Accelerated Storage Stability Study of Pinoxaden 50 g/L + Fluroxypyr (Present like Methyl Heptyl Ester) 87.5 g/L EC, DACO: 3.4.1