

Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2024-0042
Application: Application Subject to the Protection of Proprietary Interests in Pesticide Data (PIIP) Policy - Equivalency/Data Compensation Assessment
Applicant: Sharda Cropchem Limited
Product: Mishri Herbicide
Registration Number: 35536
Active ingredients (a.i.): Rimsulfuron and mesotrione
PMRA Document Number: 3687856

Purpose of Application

The purpose of this application was to register Mishri Herbicide for use on field corn, based on a precedent product.

Chemistry Assessment

Mishri Herbicide is formulated as a wettable granule containing mesotrione at a concentration of 41.38 % and rimsulfuron at a concentration of 4.31 %. This end-use product has a density of 0.56 – 0.60 g/mL and pH of 6.69. The required chemistry data for Mishri Herbicide have been provided, reviewed and found to be acceptable.

Health Assessments

Mishri Herbicide was considered toxicologically equivalent to the precedent product; therefore, no toxicology data were required. Based on the toxicological profile of the precedent product, Mishri Herbicide is considered to be of low acute toxicity to rats via the oral, dermal, and inhalation routes. It is considered minimally irritating to the eye and non-irritating to the skin. It is not considered to be a potential skin sensitizer.

The use pattern of Mishri 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 these active ingredients. No health risks of concern are expected for workers and bystanders when label directions, precautions and restrictions are followed.

No new residue data for mesotrione or rimsulfuron were submitted or are required to support the registration of Mishri Herbicide. Previously reviewed residue data were re-assessed in the framework of this application.

The use directions on the Mishri Herbicide label, including the target crops, timing and number of applications, application methods and rates, spray volumes, pre-harvest intervals, grazing and feeding restrictions, geographical restrictions, rotational crop restrictions, as well as any other use direction, restriction, or limitation are comparable to those on the label of the precedent end-use product.

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 limit (MRLs). Consequently, dietary exposure to residues of mesotrione and rimsulfuron is not expected to increase with the registration of the new end-use product Mishri Herbicide and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The use of Mishri Herbicide on field corn is within the currently registered use pattern for rimsulfuron and mesotrione. Therefore, the environmental risk is acceptable when Mishri Herbicide is used in accordance with the label, which includes statements to mitigate risks to the environment.

Value Assessment

The availability of Mishri Herbicide as a selective pre-emergence or early post-emergent herbicide provides Eastern Canadian growers with an alternative option to control annual broadleaf weeds and annual grass weeds as well as quackgrass in field corn. Registration of a generic product may increase competition in the marketplace, which may result in a reduction in purchasing cost of similar products, thus lowering growers' overall input costs.

Value information from replicated field trials demonstrated that the performance, in terms of efficacy and crop tolerance, of Mishri Herbicide can be expected to be agronomically comparable to that of the precedent product. Therefore, all labelled uses and claims found on the precedent product label are supported for inclusion on the Mishri Herbicide label.

Conclusion

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

References

PMRA

Document

Number	Reference
3541650	2022, Accelerated Storage Stability Test of Rimsulfuron 4.31 % + Mesotrione 41.38 % WG, DACO: 3.4.1, 3.5.1, 3.5.10, 3.5.14, 3.5.2, 3.5.3, 3.5.7
3541651	2022, Physico-Chemical Properties of Rimsulfuron 4.31 % + Mesotrione 41.38 % WG, DACO: 3.5.11, 3.5.12, 3.5.13, 3.5.6, 3.5.8
3685355	2025, Manufacturing Process - Mesotrione 41.38% and Rimsulfuron 4.31% w/w WG, DACO: 3.2.1, 3.2.2, 3.2.3, 3.3.1, 3.7 CBI
3541633	2023, Value Summary for Mishri Herbicide, DACO: 10.1, 10.2.1, 10.2.2, 10.2.3.1, 10.2.3.3(B), 10.3.1, 10.4,10.5
3541652	2023, Establish Biological Equivalency of Mishri Herbicide, DACO: 10.2.3.3(B), 10.3.2(A)
3541653	2023, Sharda Rimsulfuron and Mesotrione in Corn Ontario Site 1 Pre, DACO: 10.2.3.3(B), 10.3.2(A)
3541654	2023, Sharda Rimsulfuron and Mesotrione in Corn Ontario Site 2 Post, DACO: 10.2.3.3(B), 10.3.2(A)

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