Health Canada Santé Canada

Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2022-6350
Application: Application Subject to the Protection of Proprietary Interests in Pesticide Data (PPIP) Policy - Equivalency/Data Compensation Assessment
Product: NAPRO
Registration Number: 35315
Active ingredient (a.i.): Napropamide
PMRA Document Number: 3538209

Purpose of Application

The purpose of this application was to register the commercial class end-use product, NAPRO, based on a registered precedent product.

Chemistry Assessment

NAPRO is formulated as a suspension containing napropamide at a concentration of 240 g/L. This end-use product has a density of 1.075 g/mL and pH of 7.10. The required chemistry data for NAPRO have been provided, reviewed and found to be acceptable.

Health Assessments

NAPRO is considered toxicologically comparable to the precedent product; therefore, no toxicology data were required. NAPRO is considered to be of low acute toxicity via the oral, dermal and inhalation routes of exposure. It is considered to be mildly irritating to the eyes and non-irritating to the skin and is not considered to be a dermal sensitizer.

The registered use pattern of NAPRO is comparable to the registered use pattern of the precedent product. Therefore, potential exposure for mixers, loaders, applicators, bystanders, postapplication workers and adults, youth and children entering treated residential settings, are not expected to exceed the current exposure to the registered products of napropamide. No health risks of concern are expected for workers, bystanders, adults, youth and children when label directions, precautions and restrictions are followed.

No new residue data for napropamide were submitted or were required to support the registration of NAPRO. Previously reviewed residue data were re-assessed in the framework of this application. The use directions on the NAPRO label, including the target crops, method, rates and timing of application, geographic restrictions 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 napropamide is not expected to increase with the registration of NAPRO 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 NAPRO label are within the currently registered and approved uses of napropamide. No additional risk is expected when NAPRO is used in accordance with the label, which includes statements to mitigate risks to the environment.

Value Assessment

Registration of generic products may increase product competition in the marketplace, which may in turn reduce purchasing costs of similar products.

The formulation of NAPRO was compared to the formulation of the precedent product. The differences between the formulations were considered minor, which are unlikely to result in any significant impact on product performance, in terms of efficacy and/or crop tolerance. Therefore, all uses and claims found on the precedent product label are supported for inclusion on the NAPRO 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 NAPRO.

References

PMRA Document Number	Reference
3413959	2022, Applicants Name & Address; Formulating Plant Name & Address; Product Data, DACO: 3.1.1,3.1.2,3.1.3,3.1.4,3.2.3,3.3.1,3.5.13,3.5.15,3.5.5
3413962	2022, Physicochemical Properties of Napropamide 240g/L SC, DACO: 3.5.11,3.5.12,3.5.13,3.5.14,3.5.6,3.5.8,3.5.9
3413963	2022, Accelerated Storage Stability Test by Heating at 54 +- 2C of Napropamide 240g/L SC, DACO: 3.5.1,3.5.10,3.5.14,3.5.2,3.5.3,3.5.7
3413970	2022, Manufacturing process to Napropamide 240g/L SC, DACO: 3.2.1,3.2.2 CBI