



Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2022-4582
Application: Application Subject to the Protection of Proprietary Interests in Pesticide Data (PIIP) policy - Equivalency/Data Compensation Assessment
Product: OUTSHINE ALL IN
Registration Number: 35082
Active ingredients (a.i.): Fluroxypyr (present as 1-methylheptyl ester), florasulam, and MCPA (present as 2-ethylhexyl ester)
PMRA Document Number: 3513892

Purpose of Application

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

Chemistry Assessment

OUTSHINE ALL IN is formulated as an emulsifiable concentrate containing florasulam at a concentration of 2.5 g/L, fluroxypyr (present as 1-methylheptyl ester) at 100 g/L and MCPA (present as 2-ethylhexyl ester) at 350 g/L. This end-use product has a density of 1.053 g/mL and a pH of 3.80. The required chemistry data for OUTSHINE ALL IN have been provided, reviewed and found to be acceptable.

Health Assessments

OUTSHINE ALL IN is of slight acute toxicity via the oral route, and of low acute toxicity via the dermal and inhalation routes. It is minimally irritating to the eye and mildly irritating to the skin and is a skin sensitizer.

The use pattern of OUTSHINE ALL IN containing florasulam, fluroxypyr and MCPA 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 florasulam, fluroxypyr and MCPA were submitted or were required to support the registration of OUTSHINE ALL IN. Previously reviewed residue data were re-assessed in the framework of this application.

The use directions on the OUTSHINE ALL IN label, including the target crops and sites, method (ground only), rates and timing of application, geographic restrictions, preharvest intervals, feeding restrictions, and crop rotation restrictions are comparable to those on the label of the precedent 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 limits (MRLs). Consequently, dietary exposure to residues of florasulam, fluroxypyr and MCPA is not expected to increase with the registration of OUTSHINE ALL IN and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The use pattern of OUTSHINE ALL IN is within the registered use pattern of florasulam, fluroxypyr (present as a 1-methylheptyl ester), and MCPA (present as esters). Therefore, unacceptable risks to the environment are not anticipated when OUTSHINE ALL IN is used in accordance with the label directions.

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 OUTSHINE ALL IN was compared to the formulation of the precedent product. The differences among the formulations were considered minor, and are unlikely to result in any significant impact on product performance, in terms of efficacy and/or crop tolerance. Data from replicated field trials corroborated the conclusion from the formulation comparison. Therefore, all uses and claims found on the precedent product label are supported for inclusion on the OUTSHINE ALL IN 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 OUTSHINE ALL IN.

References

PMRA

Document

| Number | Reference |
|---------|--|
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| 3387888 | 2022, Outshine All In: Acute Inhalation Toxicity in Rats, DACO 4.6.3 |
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| 3387890 | 2022, Outshine All In: Primary Skin Irritation in Rabbits, DACO 4.6.5 |
| 3387891 | 2022, Outshine All In: Local Lymph Node Assay (LLNA) in Mice, DACO 4.6.6 |
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