



Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2023-5323
Application: Application Subject to the Protection of Proprietary Interests in Pesticide Data (PPIP) Policy - Equivalency/Data Compensation Assessment
Applicant: Lier Chemical Co., Ltd.
Product: LI'ER XPower Clopyralid 360 SN
Registration Number: 35352
Active ingredient (a.i.): Clopyralid (present as the monoethanolamine salt)
PMRA Document Number: 3640648

Purpose of Application

The purpose of this application was to register the commercial-class end-use product, LI'ER XPower Clopyralid 360 SN, based on a registered precedent product.

Chemistry Assessment

LI'ER XPower Clopyralid 360 SN is formulated as a solution containing clopyralid (present as monoethanolamine salt) at a concentration of 360 g/L. This end-use product has a density of 1.18 g/mL and pH of 7.03. The required chemistry data for LI'ER XPower Clopyralid 360 SN have been provided, reviewed and found to be acceptable.

Health Assessments

LI'ER XPower Clopyralid 360 SN is considered toxicologically equivalent to the precedent product; therefore, no toxicology data were required. LI'ER XPower Clopyralid 360 SN is considered to be of low acute toxicity via the oral and dermal routes of exposure, and of moderate acute toxicity via the inhalation route. LI'ER XPower Clopyralid 360 SN is considered to be minimally irritating to the eyes and skin, and not a potential dermal sensitizer.

The use pattern of LI'ER XPower Clopyralid 360 SN 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 clopyralid. No health risks of concern are expected for workers and bystanders when label directions, precautions and restrictions are followed.

No new residue data for clopyralid were submitted or were required to support the registration of LI'ER XPower Clopyralid 360 SN. Previously reviewed residue data were re-assessed in the framework of this application.

The use directions on the LI'ER XPower Clopyralid 360 SN label, including the target crops, method (ground), 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 clopyralid is not expected to increase with the registration of LI'ER XPower Clopyralid 360 SN and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The use on perennial and annual broadleaved weeds in labelled crops/non-crops is within the currently registered use pattern for clopyralid. Therefore, the risk is acceptable when LI'ER XPower Clopyralid 360 SN is used in accordance with the label, which includes statements to mitigate risks to the environment.

Value Assessment

The availability of LI'ER XPower Clopyralid 360 SN provides users with an alternative option to control perennial and annual broadleaf weeds in labelled crops/non-crops. Registration of a generic product may increase product competition in the marketplace, which may in turn reduce purchasing costs of similar products.

The formulation of LI'ER XPower Clopyralid 360 SN was compared to the formulations of the precedent product and agronomic equivalency was concluded. Therefore, all uses and claims found on the precedent product label are supported for inclusion on the LI'ER XPower Clopyralid 360 SN 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 LI'ER XPower Clopyralid 360 SN.

References

PMRA

Document

Number	Reference
3508072	2023, Color, physical state and odour, DACO: 3.5.1,3.5.2,3.5.3
3508074	2023, Container material and description, DACO: 3.5.5
3508075	2023, Density, DACO: 3.5.6
3508076	2023, pH, DACO: 3.5.7
3508077	2023, Oxidizing or reducing action, DACO: 3.5.8
3508078	2023, Viscosity, DACO: 3.5.9
3508079	2023, Storage stability and corrosion, DACO: 3.5.10,3.5.14
3508080	2023, Flash point, DACO: 3.5.11
3508081	2023, Explodability, DACO: 3.5.12
3508082	2023, Miscibility, DACO: 3.5.13
3508068	2023, Manufacturing process, DACO: 3.2.2 CBI
3508069	2023, Discussion of the formation of impurities of toxicological concern, DACO: 3.2.3
3508071	2023, Impurities of toxicological concern, DACO: 3.4.2
3533540	2023, Analytical method, DACO: 3.4.1

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