

Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2021-3031
Application: Submissions Subject to Protection of Proprietary Interests in Pesticide Data (PIIP) Policy – Equivalency/Data Compensation Assessment
Product: Ace 50 Herbicide
Registration Number: 34668
Active ingredient (a.i.): Pinoxaden
PMRA Document Number : 3380446

Purpose of Application

The purpose of this application was to register Ace 50 Herbicide, a new end-use product that selectively controls wild oats, green foxtail, yellow foxtail, barnyard grass, volunteer oats, volunteer canary seed and proso millet in Spring Wheat and Barley, based on a registered precedent product.

Chemistry Assessment

Ace 50 Herbicide is formulated as an emulsifiable concentrate containing pinoxaden at a concentration of 50 g/L. This end-use product has a density of 0.9408 g/mL and pH of 4.63 (1% solution). The required chemistry data for Ace 50 Herbicide have been provided, reviewed and found to be acceptable.

Health Assessments

Ace 50 Herbicide was considered toxicologically equivalent to the precedent product; therefore, no toxicology data were required. Ace 50 Herbicide is considered to be of low acute toxicity via the oral, dermal, and inhalation routes. Ace 50 Herbicide is considered to be mildly irritating to the eyes, severely irritating to the skin, and not a potential dermal sensitizer.

Ace 50 Herbicide is comparable to the registered use pattern of the precedent product. Therefore, potential exposure for mixers, loaders, applicators, bystanders and post application workers is not expected to exceed the current exposure to the registered products of this active ingredient. No health risks of concern are expected for workers and bystanders when label directions, precautions and restrictions are followed.

No new residue data for pinoxaden were submitted or are required to support the registration of Ace 50 Herbicide. As the current request does not represent an expansion of use for pinoxaden, previously reviewed residue data are acceptable to support this

application.

The use directions on the Ace 50 Herbicide label, including the target crops, method (ground or air), rates and timing of application, geographic restrictions, pre-harvest intervals, feeding restrictions, and crop rotation restrictions 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 limits (MRLs). Consequently, dietary exposure to residues of pinoxaden is not expected to increase with the registration of Ace 50 Herbicide and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

There are potentially additional risks to the environment associated with the use of Ace 50 Herbicide compared to its precedent product. The required environmental precautions and spray buffer zones to mitigate these additional risks are included on the label. When used according to these label directions, the environmental risks are acceptable for the use of Ace 50 Herbicide.

Value Assessment

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

The agronomic equivalence between Ace 50 Herbicide and the cited precedent product can be established based on data that demonstrated comparable levels of control for labelled weeds as well as comparable crop safety to spring wheat and spring barley. Therefore, all uses and claims found on the precedent product label are supported for inclusion on the Ace 50 Herbicide label.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to support the registration of Ace 50 Herbicide.

References

PMRA Document Number	Reference
3248194	2021, Applicant's Name and Office Address, Formulating Plant and address, Identity for Pinoxaden 50 EC, 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
3248196	2021, Manufacturing Process of Pinoxaden EC, DACO: 3.2.2 CBI
3369164	2022, Manufacturing Process of Pinoxaden 50 EC, DACO: 3.2.2 CBI

PMRA Document Number	Reference
3358039	2022, Clarification Response for Pinoxaden 50EC Herbicide, DACO: 3.2.2,3.2.3,3.5,3.5.12,3.5.5 CBI
3248189	2020, Accelerated Storage Stability of Pinoxaden 50 g/L + Cloquintocet-Mexyl 12.5 G/L EC, DACO: 3.4.1,3.5.10,3.5.14 CBI
3248184	2020, Determination of Physical State, Color and Odor of Pinoxaden 50 g/L + Cloquintocet-Mexyl 12.5 g/L EC, DACO: 3.5.1,3.5.2,3.5.3 CBI
3248190	2020, Determination of Flash Point of Pinoxaden 50 g/L + cloquintocet-mexyl 12.5 g/L EC, DACO: 3.5.11 CBI
3248191	2020, Determination of Miscibility of Pinoxaden 50 g/L + cloquintocet-mexyl 12.5 g/L EC, DACO: 3.5.13 CBI
3248192	2020, Determination of Corrosive Characteristics of Pinoxaden 50 g/L + Cloquintocet-Mexyl 12.5 g/L EC, DACO: 3.5.14 CBI
3248185	2020, Determination of Density of Pinoxaden 50 g/L + cloquintocet-mexyl 12.5 g/L EC, DACO: 3.5.6 CBI
3248186	2020, Determination of pH of Pinoxaden 50 g/L + cloquintocet-mexyl 12.5 g/L EC, DACO: 3.5.7 CBI
3248187	2020, Determination of Oxidation / Reduction (Chemical Incompatibility) of Pinoxaden 50 g/L + cloquintocet-mexyl 12.5 g/L EC, DACO: 3.5.8 CBI
3248188	2020, Determination of Viscosity of Pinoxaden 50 g/L + cloquintocet-mexyl 12.5 g/L EC, DACO: 3.5.9 CBI
3268154	2020, Operational Trial for Pinoxaden 50EC (Trial ID: HCER20AC1A), DACO: 10.2.3.4(B)
3268155	2021, DACO 10 Pinoxaden, DACO: 10.1, 10.2.1, 10.2.2, 10.2.3.1, 10.2.3.3, 10.3.1, 10.4, 10.5
3268158	2020, Operational Trial for Pinoxaden 50EC (Trial ID: HCER20AC1B), DACO: 10.2.3.4(B)
3268159	2020, Operational Trial for Pinoxaden 50EC (Trial ID: HCER20AC1C), DACO: 10.2.3.4(B)
3268160	2020, Operational Trial for Pinoxaden 50EC (Trial ID: HCER20AC1D), DACO: 10.2.3.4(B)
3268161	2020, Operational Trial for Pinoxaden 50EC (Trial ID: HCER20AC1E), DACO: 10.2.3.4(B)
3268162	2020, Operational Trial for Pinoxaden 50EC (Trial ID: HCER20AC1F), DACO: 10.2.3.4(B)

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