Health Canada Santé Canada

Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2022-6564
Application: Application Subject to the Protection of Proprietary Interests in Pesticide Data (PPIP) Policy-Equivalency/Data Compensation
Product: Maxunitech Pinoxaden 100EC
Registration Number: 35184
Active ingredient (a.i.): Pinoxaden
PMRA Document Number: 3554747

Purpose of Application

The purpose of this application was to register the end-use product Maxunitech Pinoxaden 100EC, based on a registered precedent product.

Chemistry Assessment

Maxunitech Pinoxaden 100EC is formulated as an emulsifiable concentrate containing pinoxaden at a concentration of 100 g/L. This end-use product has a density of 1.0144 g/mL and a pH of 3.96 (1% solution). The required chemistry data for Maxunitech Pinoxaden 100EC have been provided, reviewed and found to be acceptable.

Health Assessments

Maxunitech Pinoxaden 100EC was of low acute toxicity via the oral, dermal, and inhalation routes of exposure. It was minimally irritating to the eye and skin, and was not a skin sensitizer.

The use pattern of Maxunitech Pinoxaden 100EC is comparable to the registered use pattern of the precedent product. Therefore, potential exposures for mixers, loaders, applicators, bystanders and postapplication workers are not expected to exceed the current exposures to the registered products containing 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 and safener cloquintocet-mexyl were submitted or were required to support the registration of Maxunitech Pinoxaden 100EC. Previously reviewed residue data were re-assessed in the framework of this application.

The use directions on the Maxunitech Pinoxaden 100EC label, including the target crops, method (ground or aerial), rates and timing of application, geographic restrictions, preharvest intervals, feeding restrictions, pre-grazing interval, and crop rotation restrictions are comparable to those on the labels of the precedent products.

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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 and cloquintocet-mexyl is not expected to increase with the registration of Maxunitech Pinoxaden 100EC 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 Maxunitech Pinoxaden 100EC label are within the currently registered use pattern for pinoxaden. Therefore, the risk is acceptable when Maxunitech Pinoxaden 100EC is used in accordance with the label, which includes statements to mitigate risks to the environment.

Value Assessment

The formulation of Maxunitech Pinoxaden 100EC was compared to that of the registered precedent products. Based on this comparison as well as efficacy and crop tolerance data generated in six small-scale field trials, it was concluded that these products are expected to perform similarly, both in terms of efficacy and crop tolerance. Therefore, the labelled uses and claims for Maxunitech Pinoxaden 100EC are supported since they are either included in the registration of the precedent products or were directly supported with performance data.

The availability of Maxunitech Pinoxaden 100 EC provides growers an additional option and increased flexibility to choose among pinoxaden herbicide products to manage common and economically important grass weeds in spring wheat (including durum) and barley based on product availability, personal preference and price point.

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 Maxunitech Pinoxaden 100EC.

References

PMRA Document Number	Reference
3419593	2022, Hamman 1, CAN AB wheat herb MaxPin_2022_Dec-3-2022, DACO: 10.2.3.3(B),10.3.2
3419594	2022, HS22ZZWS1 (ICMS)_Nov-21-2022, DACO: 10.2.3.3(B),10.3.2
3419595	2022, 22MA69C01_Dec-5-2022, DACO: 10.2.3.3(B),10.3.2
3419596	2022, Hamman 2, CAN AB barley herb MaxPin_2022_Dec-7-2022, DACO: 10.2.3.3(B),10.3.2
3419597	2022, HS22ZZBS1(ICMS)_Nov-21-2022, DACO: 10.2.3.3(B),10.3.2
3419598	2022, 22MA69C02_Nov-28-2022, DACO: 10.2.3.3(B),10.3.2
3419584	2022, Pinoxaden 100EC Oral423 Max202210, DACO: 4.6.1
3419585	2022, Pinoxaden 100EC Dermal402 Max202210, DACO: 4.6.2
3419586	2022, Pinoxaden 100EC Inhalation403 Max202210, DACO: 4.6.3
3419587	2022, Pinoxaden 100EC Eye405 Max202210, DACO: 4.6.4
3419588	2022, Pinoxaden 100EC Skin404 Max202210, DACO: 4.6.5
3419589	2022, Pinoxaden 100EC Sensitization406 Max202210, DACO: 4.6.6
3419572	2022, Pinoxaden 100 gL EC Storage stability&corrosion Max202210, DACO: 3.5.10,3.5.14 CBI
3419573	2022, Pinoxaden 100 gL EC Flash Point Max202209, DACO: 3.5.11 CBI
3419574	2022, Maxunitech Pinoxaden 100EC Formulating process, DACO: 3.2,3.2.1,3.2.2 CBI
3419577	2022, Pinoxaden 100 gL EC Method Validation Max202209, DACO: 3.4,3.4.1 CBI
3419578	2022, Pinoxaden 100 gL EC Appearance Max202210, DACO: 3.5.1,3.5.2,3.5.3 CBI
3419579	2022, Pinoxaden 100 gL EC Density Max202209, DACO: 3.5.6 CBI
3419580	2022, Pinoxaden 100 gL EC pH Max202209, DACO: 3.5.7 CBI
3419581	2022, Pinoxaden 100 gL EC Oxidation Reduction Max202210, DACO: 3.5.8 CBI
3419582	2022, Pinoxaden 100 gL EC Viscosity Max202209, DACO: 3.5.9 CBI
3448700	2023, Response to Deficiencies or Submission Number 2022-6564, Maxunitech Pinoxaden 100EC, Received March 21, 2023, DACO: 3.2.3 CBI
3564417	2024, Accelerated Storage Stability and Corrosion Characteristics of Cloquintocetmexyl Content in Pinoxaden 100 g/L EC, DACO: 3.5.10 CBI
3564418	2024, Validation of Analytical Method for determination of Cloquintocet-mexyl content in Pinoxaden 100 g/L EC, DACO: 3.4.1 CBI