Health Canada Santé Canada

Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2023-0553
Application: Application Subject to the Protection of Proprietary Interests in Pesticide Data (PPIP) Policy-Equivalency/Data Compensation Assessment
Product: ZS Bentazone SL
Registration Number: 35254
Active ingredient (a.i.): Bentazon (present as sodium salt)
PMRA Document Number: 3595734

Purpose of Application

The purpose of this application was to register the end-use product ZS Bentazone SL, based on a registered precedent product.

Chemistry Assessment

ZS Bentazone SL is formulated as a solution containing bentazon at a concentration of 480 g/L. This end-use product has a density of 1.19 g/mL and a pH of 6.96. The required chemistry data for ZS Bentazone SL have been provided, reviewed and found to be acceptable.

Health Assessments

ZS Bentazone SL is considered to be slightly acutely toxic by the oral route of exposure and of low acute toxicity by the dermal and inhalation routes of exposure. It is considered to be severely irritating to the eyes, moderately irritating to the skin, and a dermal sensitizer.

The use pattern of ZS Bentazone SL is comparable to the registered use pattern of the precedent product. Therefore, potential exposures for mixers, loaders, applicators, bystanders, postapplication workers, as well as adults, youth and children entering treated residential settings, are not expected to exceed the current exposures to the registered products of this active ingredient. 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 bentazon were submitted or were required to support the registration of ZS Bentazone SL. Previously reviewed residue data were re-assessed in the framework of this application.

The use directions on the ZS Bentazone SL label, including the target crops, methods (ground and aerial, for listed crops), rates, number and timing of application, preharvest intervals, and grazing restrictions, are comparable to those on the label of the precedent product.
Based on this assessment, bentazon 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 bentazon is not expected to increase with the registration of ZS Bentazone SL and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The registered uses of ZS Bentazone SL are within the currently registered use pattern for bentazon. Therefore, the risk is acceptable when ZS Bentazone SL is used in accordance with the label, which includes statements to mitigate risks to the environment.

Value Assessment

The availability of ZS Bentazone SL provides growers with an alternative option to control/suppress broadleaf weeds in labelled crops. Registration of a generic product may increase competition in the market, which may result in a reduction in the purchasing cost of similar products, thus lowering growers' overall input cost.

The formulation of ZS Bentazone SL was compared to the formulation of a registered precedent product. It was concluded that the performance of ZS Bentazone SL was agronomically equivalent to the precedent product. Therefore, all labelled uses and claims for ZS Bentazone SL were supported for inclusion since they are registered on the precedent product 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 ZS Bentazone SL.

References

PMRA Document Number	Reference
3434290	2020, Purity Determination of the Test Item Bentazone 480 g/L SL and Analytical Method Validation for the Active Ingredient Bentazone, DACO: 3.4,3.4.1
3434292	2020, Determination of Physical State, Appearance, Color and Odor of the Test Item Bentazone 480 g/L SL, DACO: 3.5,3.5.1,3.5.2,3.5.3,3.5.4
3434293	2020, Determination of Accelerated Storage Stability and Corrosion Characteristics of the Test Item Bentazone 480 g/L SL, DACO: 3.5.10,3.5.5
3434294	2020, Determination of the Density of the Test Item Bentazone 480 g/L SL, DACO: 3.5.6
3434295	2020, Determination of the pH Value of an Aqueous Solution of the Test Item Bentazone 480 g/L SL, DACO: 3.5.7
3434296	2020, Determination of Oxidation/Reduction: Chemical Incompatibility of the Test Item Bentazone 480 g/L SL, DACO: 3.5.8
3434297	2020, Determination of the Viscosity of the Test Item Bentazone 480 g/L SL, DACO: 3.5.9
3434298	2020, Determination of the Flash Point of the Test Item Bentazone 480 g/L SL, DACO: 3.5.11
3434299	2020, Determination of the Corrosivity of the Test Item Bentazone 480 g/L SL, DACO: 3.5.14
3434300	2023, ZS Bentazone 480 g/L SL Physical and Chemical Property Waiver Requests, DACO: 3.5.12,3.5.13,3.5.15,3.5.16,3.7
3488026	2023, Formulation Process and Flow Chart of Bentazone 480 g/L SL, DACO: 3.2 CBI