



## Evaluation Report for Category L, Subcategory 1.2 Application

**Application Number:** 2022-0840  
**Application:** Submissions subject to Protection of Proprietary Interests in Pesticide Data policy-Equivalency/Data Compensation Assessment  
**Product:** Bentazon 480  
**Registration Number:** 34988  
**Active ingredient (a.i.):** Bentazon (present as sodium salt)  
**PMRA Document Number:** 3469781

### Purpose of Application

The purpose of this application was to register a new end-use product, Bentazon 480, for post-emergence broadleaf weed control in several agricultural field crops and turf, based on a precedent product.

### Chemistry Assessment

Bentazon 480 is formulated as a solution containing bentazon (present as the sodium salt) at a concentration of 480 g/L. This end-use product has a density of 1.16 – 1.22 g/mL and pH of 6.5 – 9.5. The required chemistry data for Bentazon 480 have been provided, reviewed and found to be acceptable.

### Health Assessments

Bentazon 480 was considered toxicologically equivalent to the precedent product; therefore, no toxicology data were required. Bentazon 480 is considered to be slightly acutely toxic by the oral route, and is considered to be of low acute toxicity by the dermal and inhalation routes. It is considered to be severely irritating to the eyes, mildly irritating to the skin of rabbits, and a dermal sensitizer.

The use pattern of Bentazon 480 is comparable to the registered use pattern of the precedent product. *Therefore, potential exposures for mixers, loaders, applicators, bystanders, postapplication workers and 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 are required to support the registration of Bentazon 480. Previously reviewed residue data were re-assessed to support this application.

The use directions on the Bentazon 480 label, including the target crops, method (ground), rates and timing of application, geographic restrictions, preharvest intervals, and grazing 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 bentazon is not expected to increase with the registration of Bentazon 480 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 Bentazon 480 label are within the currently registered use pattern of the active ingredient bentazon, present as sodium salt. Therefore, no additional risk is expected when Bentazon 480 is used in accordance with the label, which includes statements to mitigate risks to the environment.

### **Value Assessment**

The availability of Bentazon 480 provides growers with an alternative option to manage weeds in certain crops in Canada. 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 Bentazon 480 was compared to the formulation of a cited precedent product. It was concluded that differences in the formulations would be unlikely to result in any significant impact on product performance, in terms of both efficacy and crop tolerance. Therefore, all uses and claims registered on the precedent product label are supported for inclusion on the Bentazon 480 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 Bentazon 480.

## References

<b>PMRA Document Number</b>	<b>Reference</b>
3326078	2020, Certificate of Composition [CBI Removed], DACO: 3.2.1 CBI
3326079	2021, Formulation Process and Flow Chart of Bentazone 480G/L SL [CBI Removed]), DACO: 3.2.1,3.2.2 CBI
3326080	2021, Formulation Blank Chromatogram [CBI Removed], DACO: 3.4.1,3.5.10 CBI
3326090	2022, Recipe Statement [CBI Removed], DACO: 3.2.1 CBI
3326091	2020, Purity Determination of the Test Item Bentazone 480 G/L SL and Analytical Method Validation for the Active Ingredient Bentazone [CBI Removed]), DACO: 3.4.1,3.5.10
3326092	2020, Determination of Physical State, Appearance, Color and Odor of the Test Item Bentazone 480 g/L SL [CBI Removed], DACO: 3.5.1,3.5.2,3.5.3
3326093	2020, Determination of the PH Value of an Aqueous Solution of the Test Item Bentazone 480 g/L SL [CBI Removed], DACO: 3.5.7
3326094	2020, Determination of the Density of the Test Item Bentazone 480 g/L SL [CBI Removed]), DACO: 3.5.6
3326095	2020, Determination of the Viscosity of the Test Item Bentazone 480 g/L SL [CBI Removed]), DACO: 3.5.9
3326096	2020, Determination of Accelerated Storage Stability and Corrosion Characteristics of the Test Item Bentazone 480 g/L SL [CBI Removed], DACO: 3.4.1,3.5.10,3.5.14
3326097	2020, Determination Of Oxidation/Reduction: Chemical Incompatibility Of The Test Item Bentazone 480 g/L SL [CBI Removed], DACO: 3.5.8
3465143	2023, Formulation Process and Flow Chart of Bentazone 480G/L SL [CBI Removed], DACO: 3.2.2 CBI
3465144	2023, Composition Statement of Bentazone 480g/L SL [CBI Removed], DACO: 3.2.1 CBI
3465146	2023, Manufacture process of BENTAZONE 480g/L SL [CBI Removed], DACO: 3.2.2 CBI
3465147	2022, Recipe Statement [CBI Removed], DACO: 3.2.1 CBI

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