

## Evaluation Report for Category L, Subcategory 1.2 Application

**Application Number:** 2023-1276  
**Application:** Application Subject to the Protection of Proprietary Interests in Pesticide Data (PIIP) Policy-Equivalency/Data Compensation Assessment  
**Product:** Throne II Herbicide  
**Registration Number:** 35249  
**Active ingredient (a.i.):** Sulfentrazone  
**PMRA Document Number:** 3584116

### Purpose of Application

The purpose of this application was to register the end-use product Throne II Herbicide, based on a registered precedent product.

### Chemistry Assessment

Throne II Herbicide is formulated as a suspension containing sulfentrazone at a concentration of 480 g/L. This end-use product has a density of 1.290 g/mL and a pH of 5.49. The required chemistry data for Throne II Herbicide have been provided, reviewed and found to be acceptable.

### Health Assessments

Throne II Herbicide was considered to be toxicologically equivalent to the precedent product; therefore no toxicology data were required. Throne II Herbicide is considered to be of low acute toxicity by the oral, dermal, and inhalation routes. It is not considered to be a skin or eye irritant or a skin sensitizer.

The use pattern of Throne II Herbicide, containing sulfentrazone, 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 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 sulfentrazone were submitted or required to support the registration of Throne II Herbicide. Previously reviewed residue data were re-assessed in the framework of this application. The use directions on the Throne II Herbicide 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 or more restrictive than 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 sulfentrazone is not expected to increase with the registration of Throne II Herbicide and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

### **Environmental Assessment**

The use of Throne II Herbicide on terrestrial food and feed crops is within the currently registered use pattern for sulfentrazone. Therefore, the risk is acceptable when Throne II Herbicide is used in accordance with the label, which includes statements to mitigate risks to the environment.

### **Value Assessment**

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

The formulation of Throne II Herbicide was compared to the formulation of the precedent product. It was concluded that the performance of Throne II Herbicide was agronomically equivalent to the precedent product. Therefore, all labelled uses and claims for Throne II Herbicide are 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 Throne II Herbicide.

## References

<b>PMRA Document Number</b>	<b>Reference</b>
3449896	2017, Determination of Active Ingredient Content, Physical and Chemical Characteristics of SULFENTRAZONE 4SC (Sulfentrazone SC 39.6% W/W), DACO: 3.5 CBI
3449900	2021, Applicant Name and Address; Formulating Plant Name and Address; Product Data, 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
3449904	2021, Manufacturing Process of Sulfentrazone 39.6% SC, DACO: 3.2.1,3.2.2 CBI
3449910	2015, Determination of Active Ingredient Content, Physical and Chemical Characteristics of SULFENTRAZONE 4SC (Sulfentrazone SC 39.6% W/W), DACO: 3.5.1,3.5.10,3.5.14,3.5.2,3.5.3,3.5.4,3.5.6,3.5.7,3.5.8,3.5.9
3479488	2023, Formulation Process for Throne II Herbicide, DACO: 3.2 CBI

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