

## Evaluation Report for Category L, Subcategory 1.2 Application

**Application Number:** 2022-2258  
**Application:** Application Subject to Protection of Proprietary Interests in Pesticide Data (PIIP) Policy – Equivalency/Data Compensation Assessment  
**Product:** Predator Herbicide  
**Registration Number:** 35028  
**Active ingredient (a.i.):** Imazethapyr  
**PMRA Document Number:** 3502570

### Purpose of Application

The purpose of this application was to register the new end-use product, Predator Herbicide, based on registered precedent products.

### Chemistry Assessment

Predator Herbicide is formulated as a solution containing Imazethapyr at a concentration of 240 g/L. This end-use product has a density of 1.12 g/mL and pH of 6.00 (1% solution). The required chemistry data for Predator Herbicide have been provided, reviewed and found to be acceptable.

### Health Assessments

Predator Herbicide is considered toxicologically comparable to the precedent products; therefore no toxicology data were required. Predator Herbicide is considered to be of low acute toxicity via the oral, dermal and inhalation routes of exposure. It is not considered to be a skin or eye irritant. It is not considered to be a skin sensitizer.

The registered use pattern of Predator Herbicide is comparable to the registered use pattern of the precedent products. *Therefore, potential exposure for mixers, loaders, applicators, bystanders and postapplication workers is not expected to exceed the current exposure to the registered products of imazethapyr. No health risks of concern are expected for workers and bystanders when label directions, precautions and restrictions are followed.*

No new residue data for imazethapyr were submitted or were required to support the registration Predator Herbicide. Previously reviewed residue data were re-assessed in the framework of this application.

The use directions on the Predator 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 those on the labels of the precedent end-use products.

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 imazethapyr is not expected to increase with the registration of Predator 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 pattern for Predator Herbicide is within the use pattern of the registered precedent products, therefore, no additional risk is expected from the use of Predator Herbicide.

The label includes all the required environmental precautions, directions for use and spray buffer zones information, which adequately mitigate risks to the environment.

Risk from use of Predator Herbicide is acceptable from the environmental perspective when used according to label directions.

### **Value Assessment**

The availability of Predator Herbicide 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 Predator Herbicide was compared to the formulations of the registered precedent products. Although differences between the formulations were observed, the product performance, in terms of both efficacy and/or crop tolerance, of Predator Herbicide is expected to be comparable to that of the registered precedent products. Therefore, all uses and claims for the registered precedent products are supported for inclusion on the Predator Herbicide 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 Predator Herbicide.

## References

### PMRA

#### Document

#### Number

#### Reference

3359893	2022, AG36877 C 2SL Herbicide, Physical and Chemical Properties Product Chemistry, Group A: Product Identity and Composition, DACO: 3.2.1,3.2.2,3.2.3,3.3.1 CBI
3359894	2022, Final Report for: Storage Stability and Corrosion Characteristics of AG36877 2 SL, DACO: 3.4.1,3.5.10,3.5.14
3359895	2021, Physical and Chemical Characteristics of AG36877 2 SL, DACO: 3.5.1,3.5.2,3.5.3,3.5.6,3.5.7,3.5.8,3.5.9
3359896	2022, AG36877 2SLHerbicide, Physical and Chemical Properties Waiver Requests of Product Chemistry Data, DACO: 3.5.11,3.5.12,3.5.13,3.5.15,3.5.4
3473570	2023, Clarification Response for AG36877 C 2SL Herbicide, DACO: 3.2.1,3.2.2,3.4.1,3.5.10
3473571	2021, Method Validation of AG36877 2 SL, DACO: 3.4.1

© His Majesty the King in Right of Canada, as represented by the Minister of Health Canada, 2023

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of Health Canada, Ottawa, Ontario K1A 0K9.