

Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2023-1431

Application: Application Subject to Protection of Proprietary Interests in

Pesticide Data (PPIP) Policy – Equivalency/Data Compensation

Assessment

Applicant: Northern Cropscience Inc.

Product: Nirvana GA200

Registration Number: 35290

Active ingredient (a.i.): Glufosinate-ammonium

PMRA Document Number: 3607520

Purpose of Application

The purpose of this application was to register the end-use product, Nirvana GA200, based on a registered precedent product.

Chemistry Assessment

Nirvana GA200 is formulated as a liquid containing glufosinate-ammonium at a concentration of 200 g/L. This end-use product has a density of 1.0772 g/mL and a pH of 4.45. The required chemistry data for Nirvana GA200 have been provided, reviewed and found to be acceptable.

Health Assessments

Nirvana GA200 was considered toxicologically equivalent to the precedent product; therefore, no toxicology data were required or submitted. Nirvana GA200 is considered to be of slight acute toxicity via the oral and dermal routes, of low acute toxicity via the inhalation route of exposure, as well as moderately irritating to the eyes and slightly irritating to the skin, and is not considered to be a dermal sensitizer.

The use pattern of Nirvana 200GA, 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 glufosinate-ammonium were submitted or are required to support the registration of Nirvana GA200. Previously reviewed residue data were re-assessed in the framework of this application.



The use directions on the Nirvana GA200 label, including the target crops, methods (ground), rates and timing of application, preharvest intervals, feeding restrictions, and crop rotation 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 glufosinate-ammonium is not expected to increase with the registration of Nirvana GA200 and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

There are no environmental concerns with the registration of the EP Nirvana GA200.

Value Assessment

The availability of Nirvana GA200 provides growers with an alternative option to control or suppress broadleaf and grass weeds in glufosinate-ammonium tolerant field corn, glufosinate-ammonium tolerant soybeans in Canada and glufosinate-ammonium tolerant canola in Eastern Canada and British Columbia. 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 Nirvana GA200 was compared to the formulation of the registered precedent product, and it was concluded that Nirvana GA200 was agronomically equivalent. Therefore, all labelled uses and claims for Nirvana GA200 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 Nirvana GA200.

References

PMRA	
Document	
Number	Reference
3453074	2022, DACO Extras, DACO: 3.1.1,3.1.3,3.1.4,3.5.12,3.5.15,3.5.4,3.5.5,3.5.8
3453082	2014, Flash point of Glufosinate-ammonium 200 G/L SL, DACO: 3.5.11
3453083	2014, Miscibility in water and organic solvents of Glufosinate-ammonium
	200 GIL SL, DACO: 3.5.13
3453085	2014, Physical State, Appearance, Color, and Odor of Glufosinate-
	ammonium 200 Gil SL, DACO: 3.5.1,3.5.2,3.5.3
3453086	2014, Determination of the density of Glufosainate-ammonium 200 G/L SL,
	DACO: 3.5.6
3453087	2014, Determination of the pH value of an aqueous solution of Glufosinate-
	ammonium 200 G/L SL, DACO: 3.5.7
3453088	2014, Viscosity of Glufosinate-ammonium 200 G/L SL, DACO: 3.5.9
3484449	2020, Accelerated Storage Stability and Corrosion Characteristics of
	Glufosinate-ammonium 200 g/L SL, DACO: 3.5.10,3.5.14
3484450	2023, Manufacture Process for Glufosinate-ammonium 200g/L SL, DACO:
	3.2.1,3.2.2,3.2.3,3.3.1 CBI
3587337	2024, Deficiency Response for Nirvana GA200, 2023-1431, DACO:
	3.2.2,3.5.1,3.5.10,3.5.3 CBI

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