Health Canada Santé Canada

Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2020-2861
Application: Submissions Subject to Protection of Proprietary Interests in Pesticide Data (PPIP) Policy – Equivalency/Data Compensation Assessment
Product: Advantage Glufosinate Plus
Registration Number: 34802
Active ingredients (a.i.): Glufosinate-ammonium, Quinclorac, present as dimethylamine salt
PMRA Document Number : 3334155

Purpose of Application

The purpose of this application was to register a new herbicide, Advantage Glufosinate Plus, containing a new combination of active ingredients, glufosinate-ammonium and quinclorac (present as dimethylamine salt), for control of labelled weeds in canola varieties and hybrids that are specifically tolerant to glufosinate-ammonium, based on precedent products.

Chemistry Assessment

Advantage Glufosinate Plus is formulated as a solution containing glufosinate-ammonium at 146 g/L and quinclorac at 15 g/L, present as dimethylamine salt. This end-use product (EP) has a density of 1.05 g/mL and pH of 7.142. The required chemistry data for Advantage Glufosinate Plus have been provided, reviewed and found to be acceptable.

Health Assessments

Advantage Glufosinate Plus is of low acute toxicity via the oral, dermal, and inhalation routes. It is minimally irritating to the eyes and not irritating to the skin. Advantage Glufosinate Plus is not a potential dermal sensitizer.

Advantage Glufosinate Plus, containing glufosinate-ammonium and quinclorac, present as the dimethylamine salt, can be supported from an occupational exposure perspective given that the use pattern for the co-formulants in the new EP fits within the registered use pattern for each active ingredient alone. 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 or quinclorac (present as dimethylamine salt) in glufosinate-ammonium tolerant canola (i.e., LibertyLink) were submitted to support the registration of Advantage Glufosinate Plus. Previously reviewed residue data from field trials conducted in/on canola were reassessed in the framework of this application. In addition, processing studies in treated canola were also reassessed to determine the

potential for concentration of residues of glufosinate-ammonium and quinclorac (present as dimethylamine salt) into processed commodities. Based on this assessment, residues are not expected to be greater than that for the currently registered uses and will be covered by the established MRLs. Consequently, dietary exposure to residues of glufosinate-ammonium and quinclorac (present as dimethylamine salt) is not expected to increase with the registration of Advantage Glufosinate Plus and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The registration of a new combination of active ingredients in a new end-use product, Advantage Glufosinate Plus, to control labelled weeds in canola does not result in an increased risk to the environment. The risks associated with the use of the product are acceptable from the viewpoint of environmental protection when label instructions, which include environmental precautions and directions for use, are followed.

Value Assessment

The registration of Advantage Glufosinate Plus provides farmers with a useful solution to control a broad spectrum of grassy and broadleaf weeds, including cleavers at up to the 3 whorls stage, in canola that are specially developed to be tolerant to glufosinate-ammonium.

Value information submitted for review consisted of scientific rationales, precedent registrations, and data from replicated field trials. This information collectively demonstrated that (1) the application of Advantage Glufosinate Plus could provide acceptable control of the labelled weeds as well as control of cleavers at up to the 3 whorls and (2) glufosinate-ammonium tolerant canola could exhibit an adequate margin of tolerance to Advantage Glufosinate Plus when applied as per the label instructions.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to support the registration of Advantage Glufosinate Plus.

References

PMRA Document Number	Reference
3135623	2019, Validation of Analytical Method for Determination of Active Ingredients Content of Agent 5268-057 FD Trial, DACO: 3.4.1 CBI
3135624	2020, Product Chemistry Testing and Accelerated Stability/Corrosion Characteristics Testing of Agent 5268-058 FD TRL, DACO: 3.5 CBI
3160453	2020, DACO 3.0 for Advantage Glufosinate PLUS, DACO: 3.0 CBI

3160454	2020, Technical Information for Quinclorac and Glufosinate Ammonium SL, DACO: 3.2.1,3.2.2 CBI
3160455	2020, CSF for Glufosinate Ammonium (146g/L) Quinclorac Acid (DMA Salt) (15g/L) SL, DACO: 3.2.1,3.3.1 CBI
3135626	2019, Acute Oral Toxicity Study of Agent 5268-057 FD TRL in Rats, DACO: 4.6.1
3135627	2019, Acute Dermal Toxicity Study of Agent 5268-057 FD TRL in Rats, DACO: 4.6.2
3135628	2019, Acute Inhalation Toxicity Study of Agent 5268-057 FD TRL in Rats, DACO: 4.6.3
3135629	2019, Acute Eye Irritation Study of Agent 5268-057 FD TRL in Rabbits, DACO: 4.6.4
3135630	2019, Acute Dermal Irritation Study of Agent 5268-057 FD TRL in Rabbits, DACO: 4.6.5
3135631	2019, Skin Sensitisation Study of Agent 5268-057 FD TRL in Guinea Pigs, DACO: 4.6.6
3135610	2020, Advantage Glufosinate Plus - New premix, DACO: 10.1
3135612	2017, PRTox17MNT102, Trial report, DACO: 10.2.3.3.
3135613	2018, PRTox18MNT101, Trial report, DACO: 10.2.3.3.
3135614	2018, PRTox18MNT101a, Trial report, DACO: 10.2.3.3.
3135615	2018, PRTox18MNT102a, Trial report, DACO: 10.2.3.3.