

Evaluation Report for Category B, Subcategory B.2.3, B.2.4, B.3.10, B.3.12 Application

Application Number:	2015-2650
Application:	New End-Use Product Chemistry-Identity and Proportion of
	Formulants; New Product Labels-Tank Mixes and New Site or
	Host
Product:	GF-3335 Herbicide
Registration Number:	32412
Active ingredients (a.i.):	2,4-D, present as choline salt
PMRA Document Number:	2663994

Purpose of Application

The purpose of this application was to register a new end-use product, GF-3335 Herbicide, containing 2,4-D, for use as a post emergent herbicide for the management of broadleaf weeds in cereals, soybeans, berries, asparagus, established pastures, rangeland, turf, stubble land, roadsides, uncropped land and woody growth.

Chemistry Assessment

GF-3335 Herbicide is formulated as a solution containing 2,4-D, present as choline salt, at a nominal concentration of 454 g/L. This end-use product has a density of 1.1934 g/mL at 20°C and a pH of 5.27. The required chemistry data for GF-3335 Herbicide have been provided, reviewed and found to be acceptable.

Health Assessments

The acute toxicity of GF-3335 Herbicide is moderate via the oral route and low via the dermal and inhalation routes of exposure in rats. It is moderately irritating to the eyes and mildly irritating to the skin of rabbits. It is a skin sensitizer in mice.

The use of the new end-use product GF-3335 Herbicide on EnlistTM field corn, EnlistTM soybeans, wheat, barley, rye, corn, strawberries, raspberries, asparagus, cranberries, established pastures, rangeland, turf, stubble land, roadsides, uncropped land and for the control of woody growth is not expected to result in potential occupational or bystander exposure over the registered use of 2,4-D (present as choline salt). No health risks of concern are expected when workers follow label directions and wear personal protective equipment as stated on the label.



No new residue data for 2,4-D were submitted to support the registration of the new end use product GF-3335 Herbicide. Previously reviewed residue data from field trials conducted in/on various crops were reassessed in the framework of this application. No changes are expected in the magnitude of residues in food and feed crops. Hence, no increase in the dietary exposure is anticipated.

Environmental Assessment

GF-3335 Herbicide has similar application rates as a currently registered 2,4-D product. On this basis, no significant increase in environmental exposure to 2,4-D is expected with the spraying of GF-3335 Herbicide at the labeled application rates, thus, no additional environmental precautions are required for this product.

Value Assessment

The label for GF-3335 Herbicide includes uses and claims registered for three cited precedent products containing 2,4-D present as the choline salt or the dimethylamine salt plus the tank mix with glyphosate herbicide for use on Enlist field corn and Enlist soybeans. The registration of GF-3335 Herbicide provides users a greater flexibility to access and employ 2,4-D present as the choline salt for control of broadleaf weeds.

The formulation of GF-3335 Herbicide was compared to the formulations of the cited precedent products. It was concluded that the differences among the formulations are unlikely to result in any impact on the product performance, in terms of efficacy and crop tolerance, when applied at similar rates of active ingredient per hectare. Data from field research trials corroborated the conclusion from the formulation comparison.

Furthermore, data from field trials previously submitted in support of the registrations of GF-2654 TC Herbicide, GF-2654 TSOY Herbicide, Enlist Duo Herbicide, and GF-2726 TSOY Herbicide are applicable to GF-3335 Herbicide. The data demonstrated that (1) the product performance of 2,4-D present as the choline salt was comparable to that of 2,4-D present as the dimethylamine salt and (2) the product performance of 2,4-D present as the choline salt co-formulated with glyphosate was comparable to that of the registered tank mix of 2,4-D presented as dimethylamine salt or 2-thylhexyl ester plus glyphosate.

Based on the weight of evidence, the registration of GF-3335 Herbicide for control of broadleaf weeds in listed crops, including Enlist corn and Enlist soybeans, is deemed to have value.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided in support of GF-3335 Herbicide and has found it to be sufficient to support a full registration of the product.

References

PMRA	Reference
Document	
Number	
2545095	2015, Product Identification, GF-3335 Herbicide, DACO: 3.1.1,3.1.2,3.1.3,3.1.4 CBI
2545096	2014, Group A-Product Identity and Composition, Description of Materials Used to Produce the Product, Description of Formulation Process, Discussion of Formation of Impurities, Certified Limits, and Enforcement Analytical Method for GF-3335, an End Use Product Containing 2,4-D Choline Salt, DACO: 3.2.1.3.2.2.3.2.3.3.1.3.4.1.3.4.2 CBI
2545098	2014, Group B-Physical/Chemical Properties for GF-3335, A Liquid End Use Product Containing 2,4-D Choline Salt, DACO: 3.5 CBI
2545099	2014, Group B - Determination of Color, Odor, Physical State, Oxidizing and Reducing Action, Flammability, Explodability, pH, Viscosity, and Density of GF- 3335, an End Use Product Containing 2,4-D Choline Salt, DACO: 3.5.1,3.5.11,3.5.12,3.5.2,3.5.3,3.5.4,3.5.5,3.5.6,3.5.7,3.5.8,3.5.9 CBI
2545100	2015, GF-3335 Herbicide, Storage Stability Data, DACO: 3.5.10 CBI
2545101	2015, GF-3335 Herbicide, Miscibility, DACO: 3.5.13 CBI
2545102	2015, GF-3335 Herbicide, Corrosion Characteristics, DACO: 3.5.14 CBI
2545103	2015, GF-3335 Herbicide, Dielectric Breakdown Voltage, DACO: 3.5.15 CBI
2578494	2015, GF-3335: Determination of One Year Ambient Shelf-life in HDPE, DACO: 3.5.10,3.5.14 CBI
2545105	2014, Acute Oral Up and Down Procedure in Rats, GF-3335 Herbicide, DACO: 4.6.1
2545106	2014, ACUTE DERMAL TOXICITY STUDY OF GF-3335 IN RATS, DACO: 4.6.2
2545107	2014, ACUTE INHALATION TOXICITY STUDY OF GF-3335 IN RATS, DACO: 4.6.3
2545111	2014, ACUTE EYE IRRITATION STUDY OF GF-3335 IN RABBITS, DACO: 4.6.4
2545113	2014, ACUTE DERMAL IRRITATION STUDY OF GF-3335 IN RABBITS, DACO: 4.6.5
2545114	2014, Skin Sensitisation Study of GF-3335 by Local Lymph Node Assay in Mice, DACO: 4.6.6
2545115	Exposure (Occupational and/or Bystander) Summaries, DACO: 5.1 & 5.2.
2545092	2015, Appendix 1-Enlist corn, DACO: 10.2.3.3 and 10.3
2545093	2015, Appendix 2-Enlist soybean, DACO: 10.2.3.3 and 10.3

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