

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4 Application

Application Number:	2007-8837
Application:	B 2.1 – New Guarantee
	B 2.3 – New Identity of Formulants
	B 2.4 – New Proportion of Formulants
Product:	Garlon RTU Herbicide
Registration Number:	29334
Active ingredients (a.i.):	Triclopyr, present as Butoxethyl Ester
PMRA Document Number:	: 1755757

Purpose of Application

The purpose of this application is to register a new commercial herbicide, Garlon RTU Herbicide, based on the precedent product, Garlon 4 Herbicide (Reg. No. 21053). Garlon RTU Herbicide is for selective control of individual and undesirable woody plants in pastures and rangelands, lowbush blueberry site preparation, forest and woodland management areas, and in non-crop areas. The use for Garlon RTU Herbicide is a subset of the currently registered uses for Garlon 4 Herbicide.

Chemistry Assessment

Garlon RTU Herbicide is formulated as a solution containing the active ingredient triclopyr, present as butoxyethyl ester at 144 g/L. This end-use product has a density of 0.857 - 0.877 g/mL and pH of 5.2. The chemistry requirements for Garlon RTU Herbicide are complete.

Health Assessments

Garlon RTU Herbicide exhibits low acute oral (LD50 \bigcirc = 3200 mg/kg), dermal (LD50 \bigcirc \bigcirc > 5000 mg/kg) and inhalation (LC50 \bigcirc \bigcirc =>5.37mg/L) toxicity in the rat. It is minimally irritating to the eye (MAS = 2.67/110) and skin (MAS= 0.33/8.0) of the rabbit and is a dermal sensitizer in mice by the Local Lymph Node Assay.

The use of Garlon RTU Herbicide fits within the currently registered use pattern of the active ingredient triclopyr. The change in formulation and guarantee are not expected to result in an increase in occupational exposure. The active ingredient application rates, timings and methods are equivalent to the currently registered precedent product Garlon 4 Herbicide. No



unacceptable exposure is expected when workers follow label directions and wear the personal protective equipment identified on the label.

No new residue data were submitted to support the registration of Garlon RTU Herbicide. The food residue risk profile for Garlon RTU Herbicide is expected to be covered by that of the currently registered uses, as the use pattern is a subset of the uses of the registered product Garlon 4 Herbicide. In this context, the two products have identical use patterns in terms of rate of application and target areas. No increase in dietary exposure is anticipated. This new formulation of triclopyr will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

No new environmental data were submitted to support the formulation of Garlon RTU Herbicide. When comparing Garlon RTU Herbicide to the currently registered Garlon 4 Herbicide and Release Silvicultural Herbicide (Reg. No. 22093), no additional environmental risk is expected from the use of Garlon RTU Herbicide. Additional environmental data were not required to support Garlon RTU Herbicide. Environmental concerns are mitigated on the existing label and no increase in environmental risk is anticipated.

Value Assessment

The registration of Garlon RTU Herbicide can be supported from a value standpoint based on the following facts:

- Garlon RTU Herbicide has a similar formulation as that of Garlon 4 Herbicide.
- The listed use, basal bark application, on the Garlon RTU Herbicide label is a subset of the currently registered uses on the Garlon 4 Herbicide label. Garlon 4 Herbicide recommends a rate of 20 to 30 litres of the product in enough oil to make 100 L of spray mixture. The 30 litre rate is equivalent to the rate recommended on the Garlon RTU Herbicide label.
- The listed pest claims on the Garlon RTU Herbicide label are presently registered on the Garlon 4 Herbicide label.
- As Garlon RTU Herbicide is to be applied directly to individual target vegetation, crop safety is not a concern.

Conclusion

Garlon RTU Herbicide is acceptable for full registration.

References

Value PMRA #	
1524643:	Part 10 - Data waiver request for registration of Garlon RTU Herbicide. Dow AgroSciences DACO 10.2.3.3 and 10.3.2. December 6, 2007. pp. 1.
1524631.	Acute Oral Toxicity Up and Down Procedure in Rats. Eurofins Product Safety Laboratories. Dayton, NY USA. Laboratory report number: 22236. Study report date: 27-September-2007. Applicant Report Number: 070308. Unpublished. DACO 4.6.1.
1524633.	Acute Dermal Toxicity Study in Rats-Limit Test. Eurofins Product Safety Laboratories, Dayton, NY USA Laboratory report number: 22237. Study report date: 11-September-2007 Applicant Report Number: 070309. "Unpublished" DACO 4.6.2.
1524634.	Acute Inhalation Toxicity in Rats- Limit Test. Eurofins Product Safety Laboratories, Dayton, NY USA Laboratory report number. 22238 Study report date: 12-September-2007. Applicant Report Number 070322. Unpublished DACO 4.6.3.
1524636	Primary Eye Irritation Study in Rabbits. Eurofins Product Safety Laboratories, Dayton, NY, USA. Laboratory report number:. 22239. Study report date: 10- September-2007. Applicant Report Number: 070311.Unpubloished DACO 4.6.4.
152438.	Primary Skin Irritation Study in Rabbits. Eurofins Product Safety Laboratories, Dayton, NY, USA. Laboratory report number: 22240. Study report date: 11- September-2007. Applicant Report number 070310 Unpublished. DACO 4.6.5.
152440.	GF-2059 Local Lymph Node Assay in CBA/J Mice. Toxicology and Environmental Research and Consulting. The Dow Chemical Company. Midland, Michigan USA. Laboratory report number: 071121. Study report date: 24- September-2007, Unpublished. DACO 4.6.6.
1524621	2007, Description of starting materials, DACO: 3.2.1 CBI
1524622	2007, Analytical Method and Validation for the Determination of Triclopyr Butotyl in GF-2059 Formulation, DAS-AM-07-017, DACO: 3.4.1 CBI
1524623	2007, Determination of Colour, Physical State, Odour, Oxidizing and Reducing Action, Flammability, Thermal Explodability, pH, Viscosity, and Density of GF-2059, and End-Use Product Containing Triclopyr Butotyl., 07-059-G, DACO: 3.5.1, 3.5.11, 3.5 CBI

1524624	2007, Accelerated Storage Stability of GF-2059, 07-059-G, DACO: 3.5.10, 3.5.14 CBI
1524625	2007, Determination of Explodability of GF-2059, an End Use Product Containing Triclopyr BEE, FAPC073263, DACO: 3.5.12 CBI
1524627	2007, Miscibility - Garlon RTU Herbicide (GF-2059), DACO: 3.5.13 CBI
1524628	2007, Corrosion Characteristics - Garlon RTU Herbicide (GF-2059), DACO: 3.5.14 CBI
1524629	2007, Dielectric Breakdown Voltage - Garlon RTU Herbicide (GF-2059), DACO: 3.5.15 CBI
1671488	2007, Accelerated Storage Stability of GF-2059, NAFST-07-062, DACO: 3.5.10 CBI
1671489	2007, 3.5.10 Storage Stability - Long term storage stability study, DACO: 3.5.10
1671490	2007, 3.5.14 Corrosion Characteristics Garlon RTU, DACO: 3.5.14
1679856	2008, Revised SPSF - Garlon RTU GF2059, DACO: 0.1.6003,3.2.2 CBI
1679857	2008, Garlon RTU 2007-8837 FOR-07-059 (1 year SS for GF-2059), FOR-07-059, DACO: 3.5.10 CBI
1679858	2008, Corrosion characteristics Garlon RTU 2007-8837, DACO: 3.5.14

ISSN: 1911-8082

[®] Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2010

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 the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5. s gouvernementaux Canada, Ottawa, Ontario K1A 0S5.