

Evaluation Report for Category B, Subcategories B.2.3, B.2.4 (Identity/Proportion of Formulants) Application

Application Number: 2005-1010
Application: Evaluation Report for Category B, subcategories B.2.3, B.2.4,
(Identity/Proportion of Formulants)
Product: Garlon EC Manufacturing Concentrate
Registration Number: 28432
Active ingredients (a.i.): Triclopyr
PMRA Document Number: 1364324

Purpose of Application

The purpose of this submission is to register a new Manufacturing Concentrate, Garlon EC Manufacturing Concentrate, with an altered formulation from that of Garlon Manufacturing Concentrate (PCP# 23447), and a Master/Initial Product Status. Garlon Manufacturing Concentrate and Garlon EC Manufacturing Concentrate have the same use pattern: For manufacturing or reformulating only. For specific details of uses, application rates and methods, precautions, restrictions, and personal protective equipment, refer to product label.

Chemistry Assessment

Garlon EC Manufacturing Concentrate is formulated as an emulsifiable concentrate containing triclopyr, present as butoxyethyl ester, at a nominal concentration of 480 g/L. This end-use product has a density of 1.1116 g/mL and a pH of 3.36 for a 1% solution. With the exception of the storage stability study that is currently in progress, the chemistry requirements for Garlon EC Manufacturing Concentrate are complete.

Health Assessment

The data for an identical product was reviewed to support Garlon EC Manufacturing Concentrate. The results indicate that Garlon EC Manufacturing Concentrate is of low acute toxicity by the dermal ($LD_{50} > 5000$ mg/kg bw) and by oral routes ($LD_{50} = 3200$ mg/kg bw) in rats. It is of low toxicity via inhalation with an LC_{50} greater than 5.05 mg/L in rats. Garlon EC Manufacturing Concentrate is a moderate irritant to the skin of rabbits. It is mildly irritating to rabbit eyes. This product is a dermal sensitizer in guinea pigs.

To support the new Manufacturing Concentrate, Garlon EC Manufacturing Concentrate, no new residue data were submitted. Following the comparison of the new formulation to the original formulation of Garlon Manufacturing Concentrate (PCP# 23447), there is no indication that any formulants will have an impact on the magnitude of the residues of triclopyr when the new manufacturing concentrate will be used to produce end use products. Therefore, no increase in dietary exposure is anticipated.

The personal protective equipment recommended on the label (Where frequent inhalation of spray mist cannot be avoided, occupational exposure to pesticides can be reduced by use of an air-purifying respirator equipped with an organic-vapour-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH approved respirator with an organic vapour (OV) cartridge or canister with any N, R, P or HE prefilter. When handling concentrate, wear goggles or faceshield, chemical resistant gloves (nitrile or neoprene), clean coveralls over long-sleeved shirt and long pants, impermeable head covering and chemical resistant boots (rubber) during all mixing/loading activities.) is considered adequate to address acute and short term risk associated with Triclopyr.

Environmental Assessment

No environmental studies were required to support registration of Garlon 4 EC Manufacturing Concentrate, since it has the same active concentration and use pattern as Garlon 4 Manufacturing Concentrate but different formulants. Manufacturing concentrates are not released directly into the environment but in any case, the formulants in Garlon 4 EC Manufacturing Concentrate were determined to be of equal or decreased risk to the environment than those found in Garlon 4 Manufacturing Concentrate, therefore no additional impact to the environment is expected from use of Garlon 4 EC Manufacturing Concentrate.

Value Assessment

A value assessment is not required for a manufacturing concentrate.

Conclusions

The Agency has completed an assessment of available information for Garlon EC Manufacturing Concentrate and has found the information sufficient to allow for conditional registration, with registration being contingent upon fulfilling the following requirements:

Reference List

PMRA 1047051. Determination of color, physical state, odor, oxidizing and reducing action, flammability, explodability, pH, viscosity and density of GF-1529, an end use product containing triclopyr BEE. Dow AgroSciences LLC. Laboratory Study ID FAPC043368. Study report date: 10-Nov-2004. 17 pp. DACO 3.5.

- PMRA 1047052. Accelerated storage stability study of GF-1529: a triclopyr butoxyethyl ester emulsifiable concentrate formulation, in glass for 2 weeks at 54°C. Dow AgroSciences LLC Laboratory Study ID FOR-05-010. Study report date: 03-Jun-2005. 19 pp. DACO 3.5.10.
- PMRA 1047050. Group A - Product identity, composition, and analysis for GF-1529; an end use product containing triclopyr butoxyethyl ester. Dow AgroSciences LLC. Laboratory Study ID NAFST-04-882. Study report date: 20-Dec-2004. 70 pp.
- PMRA 1303474. Pest Management Regulatory Agency (2006). Re-evaluation Decision Document. RRD2006-02.
<http://www.pma-arla.gc.ca/english/pdf/rrd/rrd2006-02-e.pdf> pp 5.

ISSN: 1911-8082

© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2007

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.