Re-evaluation Note

Santé

Canada

REV2013-11

Re-evaluation Project Plan for Quinclorac

(publié aussi en français)

20 November 2013

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6604-E2
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca healthcanada.gc.ca/pmra Facsimile: 613-736-3758 Information Service:

Information Service: 1-800-267-6315 or 613-736-3799 pmra.infoserv@hc-sc.gc.ca



ISSN: 1925-0630 (print) 1925-0649 (online)

Catalogue number: H113-5/2013-11E (print version)

H113-5/2013-11E-PDF (PDF version)

© Her Majesty the Queen in Right of Canada, represented by the Minister of Health Canada, 2013

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.

In Canada, quinclorac is under re-evaluation by Health Canada's Pest Management Regulatory Agency (PMRA). The PMRA's pesticide re-evaluation program considers potential risks as well as the value of pesticide products to ensure they continue to meet standards of modern science and current policy established to protect human health and the environment. Under the authority of Section 16 of the *Pest Control Products Act*, the registrants of quinclorac were notified of the initiation of the re-evaluation of quinclorac. Following this, the registrant of quinclorac technical grade active ingredient in Canada indicated their intention to support all uses included on the labels of commercial products in Canada. This Re-evaluation Note outlines a project plan and timeline for review, as well as summarizes the anticipated areas of focus related to the re-evaluation of quinclorac.

Quinclorac is an herbicide that has been registered in Canada since 1997. Quinclorac is currently registered for selective post-emergence control of green foxtail, cleavers, volunteer flax, barnyard grass; suppression of annual and perennial sow thistle in spring and durum wheat, spring barley and canary seed in the prairie provinces and Peace River region of British Columbia only (Use-Site Category 7, 13 and 14). Registered quinclorac end-use products are formulated as wettable granules or water dispersible granules in water soluble packaging, to be applied by ground equipment only.

The project plan discussed below outlines the anticipated areas of focus and risk assessments required to complete the re-evaluation of quinclorac. Should additional information become available during the re-evaluation period that affects the regulatory status of quinclorac, the Agency will reconsider the areas of focus and risk assessments required. Currently, a proposed re-evaluation decision for quinclorac is anticipated to be published in 2015.

Re-evaluation Project Plan

Human Health Risk Assessment

The toxicology database for quinclorac was considered complete at the time of initial registration and no major updates have been made since then. Data generated since the time of the original submission (for example, additional acute toxicity studies, immunotoxicity, short-term inhalation and neurotoxicity studies) that may impact the hazard assessment, will be evaluated. Verification of the points of departure used for risk assessment will be undertaken and areas not addressed in the original evaluation (for example, establishment of an acute reference dose, application of the PCPA factor) will be reviewed. Recent scientific literature and incident reports will also be incorporated into the re-evaluation.

Dietary exposure and risk assessments previously conducted to support currently registered uses will be verified to ensure they meet current science standards and policies. This includes the incorporation of revisions to toxicological reference doses if applicable, drinking water estimated environmental concentrations, food consumption data and the use of available residue data from pesticide residue surveillance programs conducted by the Canadian Food Inspection Agency and the United States Department of Agriculture.

The occupational exposure and risk assessments will be revised to reflect the currently available scientific data and approaches, as well as revised toxicological points of departure, if applicable. In the absence of chemical-specific data, standard defaults will be used in the occupational exposure and risk assessment.

Environmental Risk Assessment

Environmental risk assessments will be updated, where appropriate, using current methodologies, available scientific data and relevant scientific literature.

Environmental risk mitigation measures will be reviewed to ensure consistency with current label requirements.

Buffer zones for the protection of sensitive terrestrial and aquatic habitats will be calculated based on current practices and taking into consideration currently registered uses.

The Toxic Substances Management Policy (TSMP) will be taken into consideration.

Environmental fate will be reviewed to determine drinking water and environmental EECs for risk assessment purposes.

Value

The value of quinclorac will be considered. The viability of alternatives will be examined if risks of concern are identified.

Data Requirements

Additional data requirements related to toxicology and environmental assessment have been identified for quinclorac and were requested from technical registrants (Appendix I).

Anticipated Timeline for Re-evaluation

A proposed re-evaluation decision for quinclorac is anticipated to be published for consultation in 2015.

Additional Information

PMRA documents can be found in the Pesticides and Pest Management section of Health Canada's website: healthcanada.gc.ca/pmra. PMRA documents are also available through the Pest Management Information Service. Phone: 1-800-267-6315 within Canada or 1-613-736-3799 outside Canada (long distance charges apply); fax: 613-736-3798; e-mail: pmra.infoserv@hc-sc.gc.ca.

Appendix I Data Requirements for the Re-evaluation of Quinclorac

Human Health

DACO 4.2.1	Acute Oral
DACO 4.2.2	Acute Dermal
DACO 4.2.3	Acute Inhalation
DACO 4.2.4	Primary Eye Irritation
DACO 4.2.5	Primary Dermal Irritation
DACO 4.2.6	Dermal Sensitization
DACO 4.3.7	Short-term Inhalation (21/28 day)
DACO 4.5.7	Genotoxicity
DACO 4.8	Other Studies – Neurotoxicity and Immunotoxicity

Environment

DACO 8.2.4.6	Special Studies – Groundwater
DACO 9.3.3	Daphnia sp. Chronic (Life-Cycle)
DACO 9.5.3.1	Fish, Early Life Cycle Toxicity Test