Re-evaluation Note REV2013-16

Re-evaluation Project Plan for Cyromazine

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In Canada, cyromazine 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 registrant of cyromazine was notified of the initiation of the re-evaluation of cyromazine. Following this, the registrant of cyromazine technical grade active ingredient in Canada indicated their intention to support all uses included on the labels of commercial class 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 cyromazine.

Cyromazine is a systemic insecticide that has been registered in Canada since 1996. Cyromazine is currently registered for use in greenhouse ornamentals, mushrooms and vegetables (Use-Site Categories 5, 6, 10, 13 and 14). Registered cyromazine end-use products are formulated as wettable powders, for foliar or drench application.

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

Re-evaluation Project Plan

Human Health Risk Assessment

The toxicology database for cyromazine was considered complete at the time of initial registration. Data generated since the time of the original submission or previously unavailable (for example, acute neurotoxicity and additional acute toxicity, metabolism and genotoxicity studies), but that may impact the hazard assessment, will be evaluated. Verification of the points of departure in the toxicology studies as well as those used for risk assessment will be undertaken. Areas not addressed in the original evaluation (for example, establishment of an acute reference dose, long-term occupational endpoints, application of the *Pest Control Products Act* factor) will be reviewed. The toxicity of relevant metabolites will be re-assessed. 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 of cyromazine will be re-evaluated to ensure they meet current science standards and policies. This includes the incorporation of revisions to toxicological reference doses and residue definitions, if applicable. Revised drinking water estimated environmental concentrations, usage information, food consumption data and available residue data from pesticide residue surveillance programs conducted by the Canadian Food Inspection Agency and the United States Department of Agriculture will also be considered.

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. Since there are no registered residential uses for cyromazine, a residential risk assessment is not required. In the absence of chemical-specific data, standard defaults will be used in the occupational exposure and risk assessment. Therefore, available dermal absorption data are being requested to conduct refined mixer/loader/applicator and postapplication worker assessments, as well as use description to evaluate exposure from dry bulb planting and the use in mushroom houses.

Environmental Risk Assessment

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

Submitted water monitoring studies conducted in high use areas of Ontario and Quebec will be reviewed and results incorporated into the risk assessment and mitigation measures.

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

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 will be taken into consideration.

Value

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

Data Requirements

Additional data requirements related to toxicology, occupational, residential and bystander exposure, and environment assessments have been identified for cyromazine and were requested from the technical registrant (Appendix I).

Anticipated Timeline for Re-evaluation

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

Additional Information

PMRA documents can be found on the Pesticides and Pest Management portion of Health Canada's website at 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 Cyromazine

Toxicology

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 4.4.5 Other Long-term Studies
DACO 4.5.4 Genotoxicity: Bacterial Reverse Mutation Assay
DACO 4.5.5 Genotoxicity: In vitro Mammalian Cell Assay
DACO 4.5.9 Metabolism/Toxicokinetics in Mammals (laboratory animals)
DACO 4.5.12 Acute Neurotoxicity

Occupational, residential and bystander exposure

DACO 5.2 Use Description/Scenario (Application and Post Application)
DACO 5.8 Dermal Absorption *(in vivo)*

Environment

DACO 9.4.4 An estuarine/marine mollusk shell deposition study
DACO 9.4.5 A chronic estuarine/marine crustacean (mysid shrimp)