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Registration Decision

RD2015-23

d-Limonene

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Registration Decision for d-Limonene

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act*, and Regulations, is granting full registration for the sale and use of d-Limonene Technical, MotherEarth Botanical Crawling Insect Killer and ProCitra-DL Botanical Crawling Insect Killer, containing the technical grade active ingredient d-limonene, to control cockroaches, spiders, crickets, millipedes, centipedes, flour beetles, cluster flies, ticks, fleas, bed bugs and Asian lady beetles on contact.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document¹ Proposed Registration Decision PRD2010-21, *d-Limonene*. This Registration Decision² describes this stage of the PMRA's regulatory process for d-limonene, summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2010-21. This decision is consistent with the proposed registration decision stated in PRD2010-21.

For more details on the information presented in this Registration Decision, please refer to the PRD2010-21, which contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable³ if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value⁴ when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

¹ "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

² "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

³ "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

⁴ "Value" as defined by subsection 2(1) of *Pest Control Products Act* "...the product's actual or potential contribution to pest management, taking into account its conditions or conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What is d-Limonene?

d-Limonene is a chemical compound found in citrus fruits. Direct contact with d-limonene kills certain insects and arthropods.

Health Considerations

Can Approved Use of d-Limonene Affect Human Health?

d-Limonene is unlikely to affect human health when used according to label directions.

Exposure to d-limonene may occur when applying the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

The technical grade active ingredient, d-limonene, is of low acute toxicity by the oral and dermal routes, slightly irritating to eyes, and moderately irritating to skin. Due to the irritative nature of d-limonene, inhalation exposure may cause respiratory irritation. There is potential for skin sensitization to occur when skin is repeatedly exposed to d-limonene. Due to the irritative and sensitizing nature of d-limonene, hazard statements alerting users are required on the product labels. Based on the available toxicological information, there is no evidence to suggest that d-limonene is carcinogenic to humans, neurotoxic, genotoxic, teratogenic, or a reproductive toxicant.

Residues in Water and Food

Dietary risks from food and water are not of concern.

End-use products containing d-limonene are not applied directly to food or feed crops; therefore, residues on food are expected to be negligible.

Risks from Handling MotherEarth Botanical Crawling Insect Killer and ProCitra-DL Botanical Crawling Insect Killer

Risks are not of concern when MotherEarth Botanical Crawling Insect Killer and ProCitra-DL Botanical Crawling Insect Killer are used according to label directions, which include protective measures.

As the end-use products are ready-to-use cans, exposure to applicators, domestic users and bystanders is minimal and likely mainly to be from spot treatments when individuals may be exposed via the inhalation route from spray drift or volatile vapours. Dermal exposure is also possible via direct contact with spray drift or with freshly sprayed surfaces.

Significant risks to humans from occupational/residential exposures are not anticipated due to the low toxicity of the formulations and additional precautionary measures on the product labels that are aimed at mitigating exposure, including restrictions on entry to freshly-treated sites and the wearing of personal protective equipment for commercial applicators.

Exposure is expected to be brief, and not likely to result in unacceptable risks to commercial applicators, other workers, domestic users, or bystanders if the end-use products are used according to label directions, including mitigative measures.

Environmental Considerations

What Happens When d-Limonene Is Introduced Into the Environment?

d-Limonene is a highly volatile insoluble terepene that naturally occurs in fruits, vegetables, meats and spices. It is used as an additive in a variety of foods and beverages.

d-Limonene Technical is highly volatile and insoluble in water, therefore it is not expected to leach into ground water or be persistent in water or soil. Non-target organisms could be exposed by consumption of contaminated food items, such as insects. However, d-limonene is also registered by the United States Environmental Protection Agency as a mammal repellent, therefore, contaminated food items are not likely to be consumed by mammals. The exposure of non-target terrestrial organisms to d-limonene under the operational conditions of these products is considered to be negligible.

The use of ProCitra-DL Botanical Crawling Insect Killer and MotherEarth Botanical Crawling Insect Killer is not expected to pose a risk to non-target organisms.

Value Considerations

What Is the Value of MotherEarth Botanical Crawling Insect Killer and ProCitra-DL Botanical Crawling Insect Killer?

MotherEarth Botanical Crawling Insect Killer and ProCitra-DL Botanical Crawling Insect Killer are products that are for commercial and domestic use respectively. Both products contain 10% d-limonene that kills cockroaches, spiders, crickets, millipedes, centipedes, flour beetles, cluster

flies, ticks, fleas, bed bugs and Asian lady beetles on contact. These products provide users with an alternative to conventional pest control products. d-Limonene represents a new mode of action for use against labelled pests and therefore provides an additional tool for resistance management in integrated pest management programs.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of MotherEarth Botanical Crawling Insect Killer and ProCitra-DL Botanical Crawling Insect Killer to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

The signal words “POTENTIAL SKIN SENSITIZER” and “WARNING- SKIN IRRITANT” on the principal display panels and the precautionary statements “Potential skin sensitizer”, “Causes skin and mucous membrane irritation”, and “Do not get in eyes, on skin or on clothing” on the secondary display panels are required of both the technical label and the end-use product labels.

The commercial label for MotherEarth Botanical Crawling Insect Killer directs applicators to not apply the product to classrooms when in use, to remove patients before using in nursing homes and hospitals, and not to apply to institutions (including libraries, sport facilities, etc.) in the vicinity of people. The label also recommends that after application in nursing homes and hospitals, the rooms be ventilated for 30 minutes before returning the patients. Furthermore, the label instructs applicators to not remain in the treated area, ventilate the area after treatment is completed, not contaminate water, food, or food stuffs, cover or remove exposed food in the treatment area, remove all pets and birds, and cover fish tanks or remove before spraying. The inclusion of the following precautionary statements are also required: “Indoor application of the product should be performed only when commercial facilities are not in operation.”; “Vacate indoor areas during application.”; and “When applying and during clean-up, applicators and related workers are required to wear long pants, a long-sleeved shirt, shoes plus socks, goggles or face shield, and chemical-resistant gloves. Wear a NIOSH approved respirator with an organic vapour cartridge or canister with any R or P prefilter when working in enclosed or confined spaces or when exposure to vapour or spray mist is expected.”

The label for the domestic product, ProCitra-DL Botanical Crawling Insect Killer, includes the precautionary statements: “Apply only in well-ventilated areas.”; and “For spot treatment, apply close to the surface and do not spray in the air.” The following additional precautionary statements are also required: “Avoid breathing vapours or spray mists.”; “Do not enter or allow re-entry of people/children/pets to treated areas until surfaces are dry and the areas are thoroughly ventilated.”; “Do not apply in the immediate vicinity of people or pets.”; and “Do not remain in freshly treated area, and ventilate the area thoroughly after the treatment is completed.”

Other Information

The relevant test data on which the decision is based (as referenced in PRD2010-21) are available for public inspection, upon application, in the PMRA’s Reading Room (located in Ottawa). For more information, please contact the PMRA’s Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection⁵ regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada’s website (Request a Reconsideration of Decision, healthcanada.gc.ca/pmra) or contact the PMRA’s Pest Management Information Service.

⁵ As per subsection 35(1) of the *Pest Control Products Act*.