



Re-evaluation Note

REV2005-05

Update on the Re-evaluation of Citronella Oil and Related Active Compounds for Use as Personal Insect Repellents

This document provides an update on the re-evaluation of citronella oil and related active compounds for use as personal insect repellents. This is a follow up to Health Canada's Pest Management Regulatory Agency's (PMRA) proposed decision for these products, published for consultation on 17 September 2004 in Proposed Acceptability for Continuing Registration document [PACR2004-36](#), *Re-evaluation of Citronella Oil and Related Active Compounds for Use as Personal Insect Repellents*.

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1.0 Background

Citronella-based insect repellents applied directly to the skin are being re-evaluated by Health Canada's Pest Management Regulatory Agency (PMRA) as part of the current program to re-assess all pesticides registered prior to 1995. Under this program, products are assessed to determine if they meet modern safety standards, including new approaches to risk assessments that place specific emphasis on exposure to children. This re-evaluation does not apply to other uses of citronella, such as in candles, as a food additive or as a scenting agent in cosmetics.

The active ingredient in any pesticide, whether a naturally occurring chemical or a synthetic chemical, must meet the same "safety" standard. It is the responsibility of those wanting to market a pesticide to provide evidence of safety according the stringent standards. A natural source of a chemical does not equate to safety. Many powerful toxins are naturally occurring chemicals derived from plants, animals or minerals.

Insect repellents are often applied directly to the skin, over a relatively large area of the body, which leads to high exposures. Because citronella-based products repel insects for approximately 30 minutes to 2 hours, repeated applications can lead to even greater exposures. The limited data available for the re-evaluation of citronella-based insect repellents has brought a number of concerns to light. While no immediate health risks were identified with the use of these products, the PMRA did not have adequate safety data to support their continued registration. As a result, the PMRA was unable to conclude that the use of citronella-based personal insect repellents continues to be acceptable and proposed to phase out this use unless further data and information were provided.

Details of the scientific rationale for the proposed decision are included in PACR2004-36, *Re-Evaluation of Citronella Oil and Related Active Compounds for Use as Personal Insect Repellents*, available on the PMRA's website. As part of the PMRA's re-evaluation process, interested parties were given until 21 January 2005 to provide further information or comments prior to finalization of the re-evaluation decision. Manufacturers were also asked to commit to generating the data required to address the uncertainties identified during the re-evaluation. Additional information to refine the risk assessment was not provided nor was there a commitment to generate the required data. However, the PMRA received comments relating to the perceived safety of citronella oil based on its natural source, its history of use and limited record of reported adverse effects.

2.0 Independent Review of the Basis for the Proposed Decision

To address the differences between the outcome of the PMRA's standard risk assessment and the perceived safety of citronella oil, the PMRA will convene an independent scientific panel to review the basis for the decision proposed in PACR2004-36, *Re-evaluation of Citronella Oil and Related Active Compounds for Use as Personal Insect Repellents*, prior to finalizing its decision. The scientific review will ensure that the PMRA has explored all scientifically based options in reaching its decision.

3.0 Next Steps

The independent scientific panel will review the basis for the decision proposed in PACR2004-36, *Re-evaluation of Citronella Oil and Related Active Compounds for Use as Personal Insect Repellents*. The scientific review panel's findings and recommendations will be considered before the PMRA proceeds with the publication of a decision concerning the citronella oil and relative active compounds for use as personal insect repellents.

During this period, citronella-based insect repellents may remain on the market. However, the PMRA will not accept any application for new personal insect repellents containing active compounds identified in PACR 2004-36.