Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Re-evaluation Note REV2006-09

Pimaricin

The purpose of this Re-evaluation Note is to notify registrants, pesticide regulatory officials and the Canadian public that Health Canada's Pest Management Regulatory Agency (PMRA) has re-evaluated the active ingredient pimaricin and its associated use as a milk preservative for milk samples used in analytical testing laboratories.

The PMRA has determined that there is low risk associated with using pimaricin as a milk sample preservative. Therefore, pimaricin is acceptable for continued registration, and no additional mitigation measures are required.

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6605C
Ottawa, Ontario
K1A 0K9

Internet: pmra_publications@hc-sc.gc.ca
www.pmra-arla.gc.ca
Information Service:
1 800 267-6315 or 613 736-3799
Facsimile: 613 736-3758

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1.0 Background

The Pest Management Regulatory Agency (PMRA) is re-evaluating all pesticides, both active ingredients and formulated end-use products, that were registered prior to 31 December 1994 to ensure that their continued acceptability is examined using current scientific approaches. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

2.0 Re-evaluation of Pimaricin

Pimaricin, an antibiotic derived from *Streptomyces natalensis*, is registered for use as a preservative for milk samples used only in analytical testing laboratories. It was first registered in Canada in 1992. There is currently one technical grade active ingredient and one end-use product registered. In the end-use product, Brotab "10" Milk Preservative, pimaricin is present in combination with bronopol, another active ingredient that the PMRA is re-evaluating. Proposed Acceptability for Continuing Registration document PACR2005-06, *Re-evaluation of Bronopol*, dated 24 August 2005 presents the proposed regulatory decision for this active ingredient.

Brotab "10" Milk Preservative is a commercial class product that is packaged in the form of tablets. One tablet, containing 0.3 mg pimaricin, is dispensed into a milk sample container for each 50 mL milk sample to be preserved. Manufacturers of containers used for milk samples and laboratories or testing facilities can dispense the tablets into milk samples using either automatic dispensers or a hand-held dispenser pack. According to label directions, rubber gloves must be worn when handling the product.

No dietary exposure to pimaricin is expected as a result of its use pattern as a pest control product. Pimaricin-treated milk samples are never consumed; they are for laboratory use only. Minimal exposure to the environment is expected because only small amounts of pimaricin are used and disposed of.

Pimaricin, also known as natamycin, is also used as a food additive to control the growth of yeasts and moulds on the surface of cheese and other non-sterile products, such as meat and sausages. In addition, natamycin is used topically in veterinary medicine to treat mycotic infections, such as ringworm, in cattle and horses as well as in human medicine for topical treatment of corneal fungal infections and the prevention of such infections in people who wear contact lenses.

With respect to the use of natamycin as a food additive, the World Health Organization estimated dietary intake of pimaricin as a result of consuming cheese and/or meat products to be acceptable. In Canada, maximum levels of use have been established in Division 16 of the Food and Drug Regulations for natamycin applied to the surface of cheese (20 ppm) and for grated or shredded cheese (10 ppm).

3.0 Regulatory Decision

Pimaricin, when used as a pest control product, is expected to result in minimal exposure to handlers because the end-use product is dispensed in a tablet form using a closed system (i.e., automatic dispenser or hand-held dispenser pack) and contains a small amount of pimaricin (i.e., each tablet contains 0.3 mg). No dietary exposure of pimaricin is expected from the registered use pattern. In addition, it has been established in Canada that pimaricin can be used safely as a food additive on cheese at a concentration up to 20 ppm. Exposure to the environment is considered to be minimal. The available information on pimaricin is considered adequate to support a re-evaluation decision. The PMRA has determined there is low risk associated with using pimaricin as a milk sample preservative. Therefore, pimaricin is acceptable for continued registration, and no additional mitigation measures are required. This concludes the re-evaluation of pimaricin.