Regulatory Note

REG2000-07

Personal Insect Repellent and Sunscreen Combinations

This regulatory note is to formally announce that the Pest Management Regulatory Agency (PMRA) will not accept new applications to register combination personal insect repellent and sunscreen products pending the completion of the ongoing re-evaluation of personal insect repellents containing oil of citronella, N,N-diethyl-m-toluamide (DEET (DTU)), oil of lavender, di-*n*-propyl isocinchomeronate (MGK Repellent 326 (MGD)) and N-octyl bicycloheptene dicarboximide (MGK Synergist 264 (MGK)).

As part of this re-evaluation process, the Agency has been reconsidering the acceptability of combination products containing both personal insect repellents and sunscreens. With respect to these combination products, the findings to date indicate that the information currently available can no longer be regarded as sufficient to enable a determination of their safety, merit and value. In particular, a contradiction exists for the recommended application rate for such products: sunscreens are to be applied liberally and often during exposure to the sun, whereas insect repellents are pesticides and should be used judiciously and sparingly. If the product is used according to sunscreen recommendations, the resulting pesticidal exposure may represent an unacceptable risk. If used according to pesticidal recommendations, the necessary sun protection would not be obtained.

According to current practice, and because of the contradiction that exists with regard to these combination products, no new products or uses will be considered for any of these combination products pending the completion of the re-evaluation of all personal insect repellents, expected in December 2000. All submissions currently with the PMRA that meet these criteria (new product or use of combination personal insect repellent and sunscreen) will be closed.

Depending on the outcome of the re-evaluation, information requirements and acceptability criteria for these products may be established in the future. Appropriate changes for products currently registered that are subject to the re-evaluation will be effected upon completion of that process.

(publié aussi en français)

July 18, 2000

This document is published by the Submission Management and Information Division, Pest Management Regulatory Agency. For further information, please contact:

Publications Coordinator
Pest Management Regulatory Agency
Health Canada
2250 Riverside Drive
A.L. 6606D1
Ottawa, Ontario
K1A 0K9

Internet: pmra_publications@hc-sc.gc.ca www.hc-sc.gc.ca/pmra-arla/

nformation Somico

Information Service:

1-800-267-6315 or (613) 736-3799

Facsimile: (613) 736-3798

