Memo to Registrants, Applicants and their Representatives

Re: DEET (N,N-diethyl-m-toluamide) Statement of Guarantee and Labelling Allowances

Purpose

The purpose of this memo is to communicate the Pest Management Regulatory Agency's (PMRA) policy with respect to standardizing the guarantee statement for DEET (N,N-diethyl-m-toluamide) on the Statement of Product Specification and the labels of pest control products containing this active ingredient.

Background

The manufacturing process for DEET (N,N-diethyl-m-toluamide) technical active ingredient typically results in a mixture of N,N-diethyl-m-toluamide, other related toluamides (e.g., ortho and para isomers) as well as impurities.

The re-evaluation of DEET published in Re-evaluation Decision Document RRD2002-01, Personal insect repellents containing DEET (N,N-diethyl-m-toluamide and related compounds) focussed N,N-diethyl-m-toluamide and its ortho and para isomers as those isomers are known to have repellent properties for blood-sucking arthropods. Following the re-evaluation, the PMRA expected registrants to separately identify and quantify DEET and active isomers on the Statement of Product Specification as N,N-diethyl-m-toluamide, N,N-diethyl-o-toluamide and N,N-diethyl-p-toluamide, and to express the label guarantee for both technical grade active ingredient and end-use products as a nominal concentration. The PMRA has been clarifying these expectations on an application-by-application basis and recognizes the need to communicate these requirements to all.

DEET Guarantee Declaration Requirement

The guarantee declaration on the Statement of Product Specification and label for products containing DEET must include the N,N-diethyl-m-toluamide and its ortho and para isomers represented to two decimal places. This information must be presented as follows:

a) Technical Grade Active Ingredient Products

Statement of Product Specification	DEET (meta isomer) N,N-DIETHYL-M-TOLUAMIDE						
Label	DEET plus related active toluamides (ortho and para isomers)95.28 %**						
	** DEET (N,N-DIETHYL-M-TOLUAMIDE)95.00 % Related active toluamides (ortho and para isomers)0.28 %						

b) Manufacturing Concentrates and End-use Products

Statement of Product Specification	DEET (N,N-DIETHYL-M-TOLUAMIDE) plus related active toluamides (ortho and para isomers) 95.00%
Label	DEET plus related active toluamides95.00%

c) Impregnated Materials

Impregnated materials include products such as moist towelettes that are impregnated with the active ingredient. The guarantee on the label of these products must be represented in terms of the solution used to impregnate the material and must follow the standard identified above for manufacturing concentrates and end-use products; therefore, the material must not be included in the guarantee statement on the label. However, as the last formulants record on the Statement of Product Specification, indicate the weight ratio percentage (% w/w) that the material would comprise in the formulation if it were included in the calculations (see example in Appendix I).

Implementation

The PMRA will implement this requirement as follows:

For registrations of existing technical grade active ingredients—currently registered technical grade active ingredients meet this requirement.

For registrations of existing manufacturing concentrates—within three months of release of this memo, the PMRA will require the registrants of manufacturing concentrates to file an application to amend the product label and Statement of Product Specification.

For registrations of existing end-use products—to minimize the burden on registrants and the PMRA, the PMRA will require that the Statement of Product Specification and label be updated to reflect this requirement when the next application is filed to amend the product register or at registration renewal, which ever occurs first (provided that the registered technical grade active ingredient or manufacturing concentrate used to formulate the product already meets this requirement).

For applications to register new products—the PMRA will require that the DEET guarantee on the Statement of Product Specification and label be consistent with this requirement (provided that the registered technical grade active ingredient or manufacturing concentrate used to formulate the proposed product already meets this requirement).

For More Information

Inquiries regarding the DEET statement of guarantee and labelling allowances or the implementation of these requirements should be directed to the PMRA's Pest Management Information Service.

Phone: 1 800 267-6315 (from within Canada) or (613) 736-3799 (from outside Canada)

Fax: (613) 736-3798

E-mail: pmra infoserv@hc-sc.gc.ca

APPENDIX I Sample Statement of Product Specification for Products Containing Impregnated Materials

12. Product Component	13. Supplier	14. %w/w	15. Certified Limits		16. Purpose in			
			a. Lower	b. Upper	Product			
DEET Technical (98.25%) Reg. No. xxxxx		25	N = 24.6		Active ingredient			
DEET (N,N-DIETHYL-M-TOLUAMIDE) plus related active toluamides (ortho and para isomers)			23.9	25.3				
Formulant Components								
Formulant A		75	N = 71.8 76.2		Solvent			
* % w/w of towelette (e.g., paper or 70% cotton 30% polyester blend) in product = 30%								
TOTAL % w/w (sum of column	100%							

^{*} The weight of an individual towelette should be included as part of the net contents on the application form.