

US EPA ARCHIVE DOCUMENT

CONFIDENTIAL

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PRODUCT PERFORMANCE / EFFICACY REVIEW

Mark Suarez, Entomologist - IB

Mark Suarez
1 August 2005

DATE: 22 July 2005

EPA REG. NUMBER: 4822-397
4822-399
4822-258

PRODUCT NAME: 4822-397, Unscented Deep Woods Off!
Insect Repellent
4822-399, Unscented Deep Woods Off!
Insect Repellent II
4822-258, Off! Towelette Insect Repellent

REGISTRANT: S.C. Johnson & Son, Inc.

PM: Richard Gebken, PM10
REVIEWER: Joe Tavano

DECISION NO.: 354049 [4822-397]
354050 [4822-399]
354052 [4822-258]

DP BARCODE: 315517 [4822-397]
315515 [4822-399]
315513 [4822-258]

ACTION: R34

ACTIVE INGREDIENT(S): [4822-397]
08031, Diethyl toluamide.....30.0%
[4822-399 & 4822-258]
08031, Diethyl toluamide.....25.0%

TYPE: Topical Insect Repellent

OPPTS GUIDELINE(S): 810.1000
810.3000
810.3300

MRID: 45922801

GLP ?: Yes.

SITES: Outdoor Premise

PESTS: Mosquitoes that may carry/transmit WNV

CONFIDENTIAL BUSINESS INFORMATION

STUDY APPLICATION RATE: 1.0 g/ 600 cm²

LABEL APPLICATION RATE: Typically; understood to be approximately 1.0 g/ 600 cm²

STUDY SUMMARIES:

The registered formulations, for which label amendments have been requested, are compared to the test formulation below (Table 1). The formulations were determined to be similar enough to consider the efficacy data cited as proof of efficaciousness for the subject formulations.

Ingredient (%)	Formulation				Function in Formula
	Test [4822-167]	4822-397	4822-399	4822-258	
DEET	25.2830	30.00000	25.2800	25.2830	Active
[REDACTED]					
TOTAL	100.0	100.0	100.0	100.0	

The data were previously reviewed by Kevin Sweeney on 2 June 2004. The data, collected from a field trial, were found to support an 8 hour repellency claim and claims related to mosquitoes that may transmit West Nile Virus. A myriad of extraneous label claims were not supported – mainly because potential protection can not be claimed against general or unrecognized threats.

ENTOMOLOGIST'S COMMENTS AND RECOMMENDATIONS:

As per the review of Kevin Sweeney on 2 June 2004 and subsequent review of the data provided in the subject formulation submissions the following recommendations are provided. It is recommended that any label approvals supersede all previous versions.

The label for EPA Reg. # 4822-167 is not consistent with current labeling policy and should be submitted for review. The claims in question are the same as those listed below for EPA Reg. # 4822-397.

Inert ingredient information may be entitled to confidential treatment