

US EPA ARCHIVE DOCUMENT

CONFIDENTIAL

COPY

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 #.: 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 (98.88%)	25.2830	30.00000	25.2800	25.2830	Active

Inert ingredient information not included.

These 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 IS MISSING

CONFIDENTIAL BUSINESS INFORMATION

Recommendations:

1. The following label modifications are acceptable for all three registrations based upon the data cited:
 - a. General "up to 8 hour repellency" claim against mosquitoes.
 - b. Claims against "mosquitoes that may transmit/carry/vector West Nile virus."
2. Modify or Remove the following claims:
 - a. **4822-397**
 - i. New – acceptable for 6 months from data of first manufacture.
 - ii. LONG LASTING PROTECTION – Modify to read "up to 8 hours protection."
 - iii. "Provide protection against mosquitoes" – Correct typographical errors.
 - iv. Repels mosquitoes that may carry diseases – Remove all instances; claims must be specific and supported by data.
 - v. Repels mosquitoes that may carry (St. Louis)(*Eastern equine*)(Western equine) (*Lacrosse*)(*Japanese*)(*Cache Valley*)(*Venezuelan equine*)(Murray Valley) encephalitis (for up to 8 hours) – Remove the diseases listed in bold and italicized. They have not been identified to occur in the U.S. or suitable vectors have not been tested. Submit or cite data in support of these claims.
 - vi. Repels ticks that may carry (Lyme disease)(Rocky Mountain Spotted Fever)(Tick Paralysis)(Ehrlichiosis)(*European Tick Borne Encephalitis*)(Powassan Encephalitis) – Remove the diseases listed in bold and italicized. They have not been identified to occur in the U.S.
 - vii. Repels black flies that may carry Onchocerciasis. Remove, per the review of K. Sweeney.
 - viii. Remove the marketing claim "Proven shield"... This statement implies complete protection.
 - b. **4822-399**
 - i. New – acceptable for 6 months from data of first manufacture.
 - ii. LONG LASTING PROTECTION – Modify to read up to 8 hours protection; modify all occurrences.
 - iii. "...the #1 (trusted) brand of insect repellents" – Remove all references; this is a comparative claim.
 - iv. Repels mosquitoes that may carry diseases – Remove all instances; claims must be specific and supported by data.
 - v. Repels mosquitoes that may carry (St. Louis)(*Eastern equine*)(Western equine) (*Lacrosse*)(*Japanese*)(*Cache Valley*)(*Venezuelan equine*)(Murray Valley) encephalitis (for up to 8 hours) – Remove the diseases listed in bold and italicized. They have not been identified to occur in the U.S. or suitable vectors have not been tested. Submit or cite data in support of these claims.

CONFIDENTIAL BUSINESS INFORMATION

- vi. Repels mosquitoes that may carry (*Ross River Fever*)(*Barmah Forest Disease*)(*Dengue Fever*)(*Yellow Fever*)(*Rift Valley Fever*) (for up to 8 hours) – Remove the diseases listed in bold and italicized. They have not been identified to occur in the U.S.
 - vii. Repels ticks that may carry (Lyme disease)(Rocky Mountain Spotted Fever)(Tick Paralysis)(Ehrlichiosis)(*European Tick Borne Encephalitis*)(Powassan Encephalitis) – Remove the diseases listed in bold and italicized. They have not been identified to occur in the U.S.
 - viii. Repels black flies that may carry Onchocerciasis. Remove, per the review of K. Sweeney.
 - ix. Remove the marketing claim “Proven shield...” This statement implies complete protection; remove all occurrences.
 - x. Remove the marketing claim “Proven protection...” This statement implies complete protection; remove all occurrences.
 - xi. Claims for sweat resistance have not been supported. Remove all claims related to sweat resistance. Submit or cited data to support such claims.
- c. 4822-258
- i. (LONG) LASTING PROTECTION – Modify to read up to 8 hours protection; modify all occurrences.
 - ii. (New) Pleasant Scent – Remove this statement contradicts the two subsequent statements “Unscented” and “Fragrance Free”. The CSF lists no fragrance.
 - iii. Remove the marketing claim “Proven shield”... This statement implies complete protection; remove all occurrences.
 - iv. Remove the marketing claim “Proven protection”... This statement implies complete protection; remove all occurrences.
 - v. Repels mosquitoes that may carry diseases – Remove all instances; claims must be specific and supported by data.
 - vi. Claims for perspiration resistance have not been supported. Remove all claims related to perspiration resistance. Submit or cited data to support such claims.
 - vii. Remove all occurrences and permutations of: “... West Nile Virus... Prevention/Protection/Center”
 - viii. Repels mosquitoes that may carry (St. Louis)(*Eastern equine*)(Western equine) (*Lacrosse*)(*Japanese*)(*Cache Valley*)(*Venezuelan equine*)(*Murray Valley*) encephalitis (for up to 8 hours) – Remove the diseases listed in bold and italicized. They have not been identified to occur in the U.S. or suitable vectors have not been tested. Submit or cite data in support of these claims.
 - ix. Repels mosquitoes that may carry (*Ross River Fever*)(*Barmah Forest Disease*)(*Dengue Fever*)(*Yellow Fever*)(*Rift Valley Fever*) (for up to 8 hours) – Remove the diseases listed in bold

CONFIDENTIAL BUSINESS INFORMATION

- and italicized. They have not been identified to occur in the U.S.
- x. Repels ticks that may carry (Lyme disease)(Rocky Mountain Spotted Fever)(Tick Paralysis)(Ehrlichiosis)(***European Tick Borne Encephalitis***)(Powassan Encephalitis) – Remove the diseases listed in bold and italicized. They have not been identified to occur in the U.S.
 - xi. Repels black flies that may carry Onchocerciasis. Remove, per the review of K. Sweeney.
 - xii. Modify the statement “(Enjoy) up to 8 hours...(including ticks that cause Lyme disease)...” – The tick claims may read “...ticks that may carry/transmit Lyme disease”.
 - xiii. Remove the marketing claim “Proven shield”... This statement implies complete protection.

Enclosure
004822-00397,-00399,-00258-ER