

US EPA ARCHIVE DOCUMENT

2-13-95

EFFICACY REVIEW

DATE: IN 7-18-94 OUT 2-13-95

FILE OR REG. NO. 4822-362

PETITION OR EXP. PERMIT NO. _____

DATE DIV. RECEIVED April 15, 1994

DATE OF SUBMISSION April 14, 1994

DATE SUBMISSION ACCEPTED _____

TYPE PRODUCT(S): (I,)D, H, F, N, R, S Repellent

DATA ACCESSION NO(S) 432556-01;D205570;S467783;Case#192727;AC:305

PRODUCT MGR. NO. 10-Brennis/Tavano

PRODUCT NAME(S) OFF! Lotion Formula II

COMPANY NAME S. C. Johnson & Son, Incorporated

SUBMISSION PURPOSE Provide performance data in support of claim for repellency of ticks (including those which cause Lyme disease) to be added to the product label.

| | | |
|------------------------|---|---------------|
| CHEMICAL & FORMULATION | <u>N,N-Diethyl-meta-toluamide</u> | <u>7.125%</u> |
| | <u>Related isomers</u> | <u>0.375%</u> |
| | <u>(0.4-12 fl. oz. of aqueous lotion of 1.0 Sp.Gr.)</u> | |

CONCLUSIONS & RECOMMENDATIONS The data presented in EPA Accession (MRID) Number 432556-01, having been obtained from a standard laboratory test meeting requirements of § 95-9(a)(2) and (3) on p. 263 and GLP requirements of 40 CFR 160 as well as the standard of § 95-9(b)(1)(iii) on p. 264 of the Product Performance Guidelines and the company-devised protocol for the method for testing insect repellents against ticks on human subjects in the laboratory and the alternate method for testing insect repellents against ticks on human subjects in the laboratory, are adequate to support the claim for repelling ticks from treated human skin, including those ticks which cause Lyme disease, for up to 2 hours following application according to label directions.

RL Vern L. McFarland, IRB

80301