US ERA ARCHIVE DOCUMENT

EFFICACY REVIEW

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

| FILE OR REG. NO. 4822-373 |
|--|
| PETITION OR EXP. PERMIT NO. |
| DATE DIV. RECEIVEDApril 15, 1994 |
| DATE OF SUBMISSIONApril 14, 1994 |
| DATE SUBMISSION ACCEPTED |
| TYPE PRODUCT(S): (I,)D, H, F, N, R, S Repellent |
| DATA ACCESSION NO(S). 432556-01;D205571;S467819;Case#030571;AC:305 |
| PRODUCT MGR. NO. 10-Brennis/Tavano |
| PRODUCT NAME(S) OFF! Skintastic 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 N.N-Diethyl-meta-toluamide 7.125% Related isomers 0.375% (0.4-12 fl. oz. of aqueous lotion of 1.0 Sp.Gr.) |

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

