

US EPA ARCHIVE DOCUMENT

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TYPE PRODUCT(S): (I), D, H, F, N, R, S RepellentDATA ACCESSION NO(S). 416198-01; D156932; S279120; Case #192727; Action Code: 160PRODUCT MGR. NO. 17-HuttonPRODUCT NAME(S) OFF! Lotion Formula IICOMPANY NAME S. C. Johnson & Son, IncorporatedSUBMISSION PURPOSE Provide performance data in support of effectiveness and duration claims of repellency against mosquitoes biting flies and sand flies on human skin.CHEMICAL & FORMULATION N,N-Diethyl-meta-toluamide 7.125%Other isomers 0.375%(8.3 lbs. per gallon aqueous ready-to-use liquid [cream])

CONCLUSIONS & RECOMMENDATIONS The data presented in EPA Accession (MRID) Number 416198-01, having been obtained from laboratory and field testing conducted according to protocols which meet the essential requirements of § 95-9 on pp. 262-4 and especially § 95-9(a)(1)-(3) on p. 263 and the standards for § 95-9(b)(1)(iv) and (v) on p. 264 of the Product Performance Guidelines, are adequate to support the claims for repellency against mosquitoes and biting flies for up to 2 hours when the subject product is applied to human skin according to label directions. Test No. 1 demonstrates laboratory efficacy of the subject product against yellow fever mosquito and stable fly, as well as equivalency to a 7.0% aerosol applied at the same rate of deet a. i. Tests No. 2, 3, 4 and 5 demonstrate effectiveness of the equivalent aerosol against stable fly and mosquitoes in 1 laboratory and 3 field tests. Test No. 6 demonstrates field efficacy of the subject product in repelling sand flies and complies with § 95-9(b)(1)(v) by limiting label claims for duration to the period for which data were submitted. As to claims for repelling ticks and fleas, these are acceptable on the basis of the subject product's equivalence in protection to a 7.0% aerosol, of which there are 10 active registrations, according to REFS. Some or all of these carry repellency claims for ticks and fleas, although the subject registrant is not represented by such a registered product at present. The identity of the product designated "Sample 6205E123" in Test Nos. 1 and 6 and that designated "Sample 6205E123-2a" in Test Nos. 3, 4 and 5 is not disclosed as to complete formulation or proprietorship. Providing toxicology data in MRID Nos. 415162-02, -03, -04, -05 and -06 are adequate to fulfill requirements of § 95-9(a)(4) on p. 263, we have no objection to this product or its labeling.

RL Verrill, L. McFarland, IRB