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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

Memorandum

JUL 12 2005

**Subject:** Primary Review of Application for Registration of Repel Insect Repellent 30LE. EPA File Symbol 305-AE. Active Ingredient: 30% Citriodiol (CAS # 129828-24-6, No PC Code assigned). DP# 316502. Decision # 355637. MRID 465095-01 and -02. CSF dated 03/17/2005.

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**To:** Tasha Gibbons, RAL  
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Biochemical Pesticides Branch

Action Requested

WPC Brand, Inc. requests registration of the product Repel Insect Repellent 30LE, EPA File Symbol 305-AE. It contains as its active ingredient 30% Citriodiol. This trade name is synonymous with Extract of Lemon Eucalyptus, which is acid modified Oil of Lemon Eucalyptus (PC Code 040503, CASRN 8000-48-4) and contains approximately 65% p-Menthane-3, 8-Diol (Chemical Code 0115500, CASRN 42822-86-6). The TGA1 was registered by WPC Brand as Citriodiol, EPA Reg. No. 305-59 on 12/20/2005. Repel Insect Repellent 30LE is ready-to-use-solution of the active ingredient in [REDACTED] with addition of [REDACTED]

Repel Insect Repellent 30LE is non aerosol pump spray repellent against mosquitoes, deer ticks and biting gnats for direct application on skin and clothing.

In support of the request the applicant submitted the product specific studies MRIDs 465095-01 and 465095-02. The applicant is citing toxicology data, analytical method and efficacy data for the registered products Citriodiol (TGA1, EPA Reg. No. 305-59) Repel Insect Repellent Lotion (EPA Reg. No. 305-56), Repel Essential Insect Repellent Pump Spray No. 305-57) and Repel Natural Insect Repellent Aerosol (EPA 305-LI, recently withdrawn). Also are submitted CSF dated 03/17/2005 and draft label.

**\*Inert ingredient information may be entitled to confidential treatment\***

Confidential Business Information

Internet Address (URL) • <http://www.epa.gov>

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## Conclusions and recommendations

1. The submitted studies describe adequately the composition of the product Repel Insect Repellent 30LE (EPA File Symbol 305-AE), the method of its manufacturing and its specific physical and chemical properties.
2. The citations of toxicity data, obtained for the TGAI (EPA Reg. No. 305-59), Repel Insect Repellent Lotion (EPA Reg. No. 305-56), Repel Essential Insect Repellent Pump Spray (EPA Reg. No. 305-57) and Repel Natural Insect Repellent Aerosol (EPA 305-LI, the application currently withdrawn) in order to meet the data requirements for registration of Repel Insect Repellent 30LE (EPA File Symbol 305-AE) are acceptable. Obviously Repel Insect Repellent 30LE will be less toxic in comparison with the above mentioned registered products, because it contains less or the same amount of the active ingredient (30 % compared with 30, 40 or 100%), less harmful inert ingredients (only from EPA's List 4B) and [REDACTED]
3. It is acceptable to cite the efficacy data for Repel Insect Repellent Lotion (EPA Reg. No. 305-56) to support the registration of Repel Insect Repellent 30LE (EPA File Symbol 305-AE), because the both products contain the same amount of the active ingredient and have similar composition.
4. It is acceptable to use the enforcement analytical method, developed for EPA Reg. No. 305-56 and used for 305-57 and 305-59 to support the registration of EPA File Symbol 305AE because this method determines the same active ingredient in products of similar type (lotion, ready-to-use solutions).

It is recommended:

- To find a better way to identify by chemical names, trade names and CASRNs the specific active ingredient, obtained through acid modification of the natural product 'Oil of Lemon Eucalyptus' and to use it in the CSF and on the label. The statement of ingredients on the label must be in strict compliance with the identification of the active ingredient in the CSF;
- To add in MRID 465095-02 the MSDSs for the ingredients in the formulation.

The application for registration of Repel Insect Repellent 30LE (EPA File Symbol 305-AE) is acceptable after resolving the above mentioned deficiencies.

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## Study Summaries

MRID 465095-01. Physical and Chemical Properties Determination. Repel Insect Repellent 30LE. pH, Odor, Color, Viscosity, Density (Specific Gravity), Physical State and Flash Point were determined on 5 separate lots of Repel Insect Repellent 30LE in compliance with GLP. Oxidation/Reduction and Explodability were addressed by estimation of the components in the formulation. The Storage Stability studies and the Corrosion Characteristics are pending. The raw data and the results were subject to Quality Assurance. The determination of the Physical & Chemical Characteristics is reliable.

MRID 465095-02. Product Identity & Disclosure of Ingredients and Analysis and Certification of Product Ingredients. Repel Insect Repellent 30LE

The Product Identity was revealed in the Confidential Statement of Formula. The Formulation Process is described in a Confidential Attachment with a table, containing the amounts of the ingredients used to prepare [REDACTED] batch and brief description of the formulation process.

There is no evidence of formation of impurities during the formulation process. No reaction with the packaging material during storage is taking place.

The application for registration will use the analytical method already registered for determination of the active ingredient in EPA 305-56,305-57 and 305-59. The applicant cites MRID 446239-01 as source of data about the analytical procedure.

Classification: acceptable, after resolving the difference between the CSF and the label's statement of ingredients and submitting the MSDSs of all the ingredients in the formulation.

cc: N. Simeonova to T. Gibbons, BPPD Subject File  
N. Simeonova, CM2. (703) 308-0291, 07/08/2005.

**\*Manufacturing process information may be entitled to confidential treatment\***



13544



# R135001

**Chemical:** Oil of eucalyptus

**PC Code:**  
040503

**HED File Code:** 41500 BPPD Tox/Chem

**Memo Date:** 7/12/2005

**File ID:** DPD316502

**Accession #:** 000-00-9001

**HED Records Reference Center**  
1/4/2007

