

US EPA ARCHIVE DOCUMENT



R.E.D. FACTS

Pesticide Reregistration

Oil of Citronella

All pesticides sold or distributed in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides which were first registered before November 1, 1984, be reregistered to ensure that they meet today's more stringent standards.

In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers, describing the human health and environmental effects of each pesticide. The Agency develops any mitigation measures or regulatory controls needed to effectively reduce each pesticide's risks. EPA then reregisters pesticides that can be used without posing unreasonable risks to human health or the environment.

When a pesticide is eligible for reregistration, EPA explains the basis for its decision in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 3105, oil of citronella.

Use Profile

Oil of citronella is a biopesticide (biochemical) with a non-toxic mode of action. It is registered as an insect repellent/feeding depressant and as an animal repellent. Oil of citronella is the volatile oil obtained from the steam distillation of freshly cut or partially dried grasses, (*Cymbopogon nardus* (Rendal) and *Cymbopogon winterianus* (Jowitt)). Two varieties of citronella oil exist commercially -- "Ceylon type" (derived from *C. nardus*) and "Java type" (derived from *C. winterianus*).

Formulation Types Registered:

Liquid-ready to use, impregnated material, pelleted/tableted, impregnated collar/tag.

Methods and Rates of Application:

Oil of citronella may be applied by hand-held sprayer, cloth wipe-on, candles, cartridge, rub-on, scent-post application, sprinkle by hand, and flea collar.

Use practice limitations:

End-use products formulated from "Ceylon type" oil with use directions for dermal applications:

"CAUTION: For external use only. Avoid contact with eyes. Discontinue if irritation or rash appears. Prolonged or frequent repeated skin contact may cause allergic reactions in some individuals. Use on children under 6 months only with the advice of a physician."

End-use products formulated from "Java type" oil containing sunscreen ingredients with use directions for dermal applications:

"CAUTION: For external use only. Avoid contact with eyes. Discontinue if irritation or rash appears. Use on children under 6 months of age only with the advice of a physician."

Regulatory History

The insect repellent, oil of citronella was initially registered in the United States in 1948 as McKesson's[®] oil of citronella (EPA Reg. No. 385-32) for human applications (body, hair, clothing, and footwear while being worn) to repel gnats (adult) and mosquitoes (adult). Oil of citronella is a biochemical pesticide which has a non-toxic mode of action. It is registered as an insect repellent (feeding inhibitor) and as an animal repellent.

On February 28, 1996, the Agency issued a rule exempting certain pesticides, including oil of citronella, from regulation under FIFRA. In order to be eligible for this exemption (under FIFRA Section 25(b)), the oil of citronella products must meet all of the criteria listed below:

1. The product must only contain inert ingredients listed in the most current List 4A. [This list is updated periodically and is published in the Federal Register. The most current list may be obtained by writing to the Registration Support Branch (4A Inert List), Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW, Washington, DC 20460].
2. The product must bear a label identifying the name and percentage (by weight) of each active ingredient and the name of each inert ingredient.

3. The product must not bear claims either to control or mitigate microorganisms that pose a threat to human health, including but not limited to, disease transmitting bacteria or viruses, or claims to control insects, rodents carrying specific diseases, including, but not limited to, ticks that carry Lyme disease.
4. The product must not include any false and misleading labeling statements, including those listed in 40 CFR 156.10 (a)(5)(i) through (viii).

Citronella products that do not meet the criteria listed above, must comply with the provisions of reregistration set forth in this RED.

During Phase 4 of Reregistration, the database for oil of citronella was evaluated and determined to be inadequate in satisfying certain requirements for biochemical pesticides. The following were identified as outstanding data gaps and a DCI was issued in September 1992:

<u>Guideline No.</u>	<u>Study</u>
<u>Product Chemistry:</u>	
151B-10	Product Identity
151B-11	Manufacturing Process
151B-12	Discussion of formation of unintentional ingredients
151B-13	Analysis of samples
151B-15	Certification of limits
151B-16	Analytical methods
151B-17(a-p)	Physical/Chemical properties

Mammalian Toxicity:

152B-10	Acute oral toxicity
152B-11	Acute dermal toxicity
152B-12	Acute inhalation toxicity
152B-13	Primary eye irritation
152B-14	Primary dermal irritation
152B-15	Dermal sensitization
152B-16	Hypersensitivity
152B-17	Mutagenicity battery
152B-18	Immunotoxicity
152B-21	90-Day dermal - rat

152B-22	90-Day inhalation -rat
152B-23	Teratogenicity

Human Health Assessment Toxicity

In studies using laboratory animals, oil of citronella generally has been shown to be of low acute toxicity. The acute oral toxicity for oil of citronella derived from "Ceylon type" ($LD_{50} > 5000$ mg/kg) places it in Toxicity Category IV, while the acute oral toxicity for oil of citronella derived from "Java type" ($LD_{50} > 4380$ mg/kg) is in Toxicity Category III. The dermal toxicity for oil of citronella ($LD_{50} > 2000$ mg/kg -- both "Ceylon type" and "Java type") is in Toxicity Category III. Acute inhalation ($LC_{50} > 5000$ mg/kg -- "Ceylon type" and $LC_{50} > 3.1$ mg/l -- "Java type") is in Toxicity Category IV. Eye irritation ("Ceylon type" - irritation cleared in 72 hrs. and "Java type" - irritation cleared within 7 days or less) is in Toxicity Category III. Dermal irritation is in Toxicity Category III (Refer to Section III for additional information). Oil of citronella derived from "Ceylon type" oil is a weak dermal sensitizer while citronella oil derived from "Java type" is a non-sensitizer.

[NOTE: For acute oral, dietary, mammalian/avian/aquatic toxicity:

Category I = very highly or highly toxic

Category II = moderately toxic

Category III = slightly toxic

Category IV = practically non-toxic]

Environmental Assessment

Based on a review of all available ecological data, exposure information, and oil of citronella's non-toxic mode of action, the Agency expects that the currently registered uses of oil of citronella will pose minimal risk to nontarget wildlife and fish.

Environmental fate studies for biochemicals are not imposed unless adverse effects are anticipated. The Agency will not, at this time, impose any environmental fate data requirements for currently registered uses of oil of citronella.

Product Labeling Changes Required

The Agency has reexamined the toxicological data base for oil of citronella and concluded that the current precautionary labeling for certain products must be upgraded. EPA is requiring that a revised Confidential Statement of Formula (CSF) and specific product labeling pertaining to

dermal sensitization and maintenance of effectiveness (efficacy) be submitted for reregistration. Refer to Section V.

Regulatory Conclusion

The Agency has determine that, based on available data, the use of currently registered products containing oil of citronella in accordance with their approved labeling will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all currently registered uses of these products are eligible for reregistration.

Oil of citronella products will be reregistered once the required revised Confidential Statements of Formula, and revised product labeling pertaining to dermal sensitization and maintenance of effectiveness are received and accepted by EPA.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for oil of Citronella during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To obtain a copy of the RED document or to submit written comments, please contact the Pesticide Docket, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

Electronic copies of the RED and this fact sheet can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet on EPA's gopher server, *GOPHER.EPA.GOV*, or using ftp on *FTP.EPA.GOV*, or using WWW (World Wide Web) on *WWW.EPA.GOV*.

Printed copies of the RED and fact sheet can be obtained from EPA's National Center for Environmental Publications and Information (EPA/NCEPI), PO Box 42419, Cincinnati, OH 45242-0419, telephone 513-489-8190, fax 513-489-8695.

Following the comment period, the oil of citronella RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 703-487-4650.

For more information about EPA's pesticide reregistration program, the oil of citronella RED, or reregistration of individual products containing oil of citronella, please contact the Special Review and Reregistration Division (7508W), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticides Telecommunications Network (NPTN). Call toll-

free 1-800-858-7378, between 9:30 am and 7:30 pm Eastern Standard Time, Monday through Friday.