

US EPA ARCHIVE DOCUMENT

Docket Number: EPA-HQ-EPA-2006-0356
www.regulations.gov

Linalool Summary Document
Registration Review: Initial Docket
April 2007

US EPA ARCHIVE DOCUMENT

TABLE OF CONTENTS

	Page #
I. Preliminary Work Plan (PWP)	3
Introduction	3
Anticipated Risk Assessment and Data Needs	3
Incidences	4
Efficacy and Label Claims	4
Timeline	4
Guidance for Comments	5
Next Steps	5
II. Fact Sheet	6
Background Information	6
Use Information	6
Recent Actions	6
Ecological Risk Assessment Status	6
Human Health Risk Assessment Status	7
Incidents	7
Labels and Products	7

Docket Number: EPA-HQ-EPA-2006-0356

www.regulations.gov

I. PRELIMINARY WORK PLAN

Introduction:

The Food Quality Protection Act of 1996 mandated the continuous review of existing pesticides. All pesticides distributed or sold in the United States must generally be **registered** by EPA, based on scientific data showing that they will not cause unreasonable risks to human health, workers, or the environment when used as directed on product labeling. The new registration review program is intended to make sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects. Changes in science, public policy, and pesticide use practices will occur over time. Through the new registration review program, the Agency periodically reevaluates pesticides to make sure that as change occurs, products in the marketplace can be used safely. Information on this program is provided at: http://www.epa.gov/oppsrd1/registration_review/.

The Agency has begun to implement the new Registration Review program pursuant to FIFRA Section 3(g) and intends to review each registered pesticide approximately every 15 years to determine whether it continues to meet the FIFRA standard for registration. The public phase of registration review begins when the initial docket is opened for each case. The docket is the Agency's opportunity to state clearly what it knows about the pesticide and what additional risk analyses and data or information it believes are needed to make a registration review decision. Linalool is among the first chemicals going through the registration review process and is the first biochemical pesticide going through the registration review.

Anticipated Risk Assessment and Data Needs:

Ecological: Registered Linalool products are used indoors, on pets or outdoors in candles or electronic fragrance generating devices. Based on use patterns and low exposure levels, the Agency does not anticipate the need for new data or the need to conduct another ecological risk assessment. However, EPA will review any public comments made in response to this docket and, if necessary, will reevaluate the need to conduct another environmental risk assessment.

As part of its environmental risk assessment of linalool, EPA considered any effects from the use of Linalool on non-target species. Since Linalool products registered for outdoor use (candles and fragrance generators) only affect (repel) biting insects and indoor uses preclude any exposure to other non-targets, EPA has determined that there is no exposure to non-target organisms and therefore has made a no adverse effects (NAE) determination in regards to the Endangered Species Act (ESA).

Linalool uses preclude any exposure to aquatic sites and/or drinking water and therefore no assessment is needed for these unless any other data are submitted to the docket.

Docket Number: EPA-HQ-EPA-2006-0356

www.regulations.gov

Human Health: The Agency does not anticipate the need for new data or the need for a new human health assessment. Occupational and residential risks are minimal to non-existent. However, EPA will review any public comments submitted in response to this docket and determine if new data are required for the assessment of Linalool.

Incidents:

The National Pesticides Information Center (NPIC) database included reports of minor human and domestic animal incidents for products containing Linalool. The Agency reviewed the incident reports and determined that there was not a clear indication that Linalool was the only possible cause of adverse effects noted, nor was there any evidence from the reports that misuses of products containing Linalool occurred. The Agency will consider any additional incidents data or comments submitted in response to this docket.

Efficacy and Label Claims

The Agency requires and reviews efficacy data for products making labeling claims to control public health pests. A preliminary screen of labels for products containing Linalool (as the sole active ingredient) indicates that efficacy data on file with the Agency may not support certain claims to repel mosquitos. The Agency is currently working with the registrant of these products to address this issue. If the issue is not resolved prior the publication of the final registration review decision, registrants will be required to resolve any outstanding efficacy/labeling concerns when submitting product labels in response to the final decision.

Timeline:

EPA has created the following estimated timeline for the completion of the Linalool Registration Review case. This schedule is subject to revision should there be a need for a Data Call-in during the registration review process or should other issues arise.

Activities	Estimated Month/Year
Open Public Comment Period for Linalool Docket	April 2007
Close Public Comment Period	June 2007
Develop Final Work Plan (FWP)	August 2007
Open Public Comment Period for Proposed Reg. Review Decision	November
Close Public Comment Period	January 2008
Final Decision	March 2008
Total (years)	1

Docket Number: EPA-HQ-EPA-2006-0356

www.regulations.gov

Guidance for Commenters:

The public is invited to comment on EPA's preliminary registration review work plan. Stakeholders are specifically asked to provide any additional information regarding use and/or usage information and any incident data not already reported to the agency. In addition, the agency welcomes any comments regarding EPA's risk assessments and its decision not to conduct further risk assessments. The Agency will carefully consider all comments as well as any additional information or data provided prior to issuing a final work plan for the Linalool case.

Next Steps:

After the comment period closes, the Agency will prepare a Final Work Plan for this pesticide.

Docket Number: EPA-HQ-EPA-2006-0356

www.regulations.gov

II. LINALOOL FACT SHEET

Background Information:

- Registration review case number: 6058
- PC Code: 128838 CAS#: 78-70-6
- Technical registrant: Wellmark International
- First approved for use in a registered product in 1985
- Not subject to reregistration (no Reregistration Eligibility Decision [RED])
- Not subject to Tolerance Reassessment (no food uses)
- Registration Review Lead: Steve Morrill: morrill.stephen@epa.gov
- Biopesticides and Pollution Prevention Division Regulatory Action Leader: Todd Petersen: Petersen.todd@epa.gov

Use Information:

- Linalool is used directly on dogs and cats (shampoos, dips and sprays) and as an area treatment on indoor sites (sprays, powders and foggers) to repel fleas, mites, spiders and ticks.
- Linalool is also used outdoors in electronic fragrance generators or scented candles to repel mosquitoes.
- Uses are primarily residential.
- There are sixteen section 3 registrations.

Recent Actions:

There have been no recent significant regulatory activities regarding Linalool products, (i.e. tolerance related actions, changes of use patterns, submission of toxicology studies or incident reports).

Ecological Risk Assessment Status:

- A risk assessment for Linalool was conducted prior to initial registration of Linalool Technical and end use product (1985). EPA determined that there is very little potential for exposure to the environment during manufacture of Linalool under normal conditions. Further, EPA determined that proposed end uses (indoor only for these initial registrations) would pose minimal hazards to non-target organisms. The assessment stated that additional data and a reassessment might be needed if outdoor uses are added in future registration actions (see below).
- Applications for registration of products with outdoor uses were submitted in 1999 and 2002. EPA revised its risk assessment and determined that the products (repellents contained in candles or fragrance generating devices) would present no direct exposure to birds, fish, aquatic invertebrates or plants.

The Agency does not anticipate the need to conduct another ecological risk assessment, including an endangered species assessment, for Linalool. Registered Linalool products are used indoors, on pets or outdoors in candles or electronic fragrance generating devices. Since Linalool only affects (repels) biting insects in its outdoor use in candles and fragrance generators, and indoor uses preclude any exposure to other non-targets, EPA has determined that there is no exposure or risk to non-target organisms, habitats or water.

Human Health Risk Assessment Status:

- Sub-acute and chronic studies were cited from public literature and no new studies were required for the initial registration of Linalool Technical and its end-use product (dog and cat shampoo) in 1985. Linalool is generally recognized as safe (GRAS) under 21 CFR 182.60.
- During the registration of the product Mosquito Cognito in 1999, the registrant demonstrated that even if the maximum possible amount of Linalool contained in Mosquito Cognito was ingested orally or absorbed dermally, the exposure would still be far below the oral or dermal LD 50.

The Agency does not anticipate that another human health assessment will be needed for Linalool because residential and occupational risks are minimal to non-existent. No tolerances have been established or proposed for Linalool as there are no current or proposed food uses.

Incidents:

The National Pesticides Information Center (NPIC) database included reports of minor human and domestic animal incidents for products containing Linalool. The Agency reviewed the incident reports and determined that there was no clear indication that Linalool was the only possible cause of adverse effects noted, nor was there any evidence from the reports that misuses of products containing Linalool occurred.

Labels and Products:

The following registered products have Linalool as their sole active ingredient:

Linalool Technical (92.5% a.i.)	EPA Reg. No. 2724-762
Holiday Concentrated Dog & Cat Shampoo (3.7% a.i.)	EPA Reg. No. 2724-766
Mosquitol-L (95.54% a.i.)	EPA Reg. No. 52991-13
Mosquito Cognito (95.54% a.i.)	EPA Reg. No. 70909-2
Conceal Candle (3.5%)	EPA Reg. No. 70909-5

Docket Number: EPA-HQ-EPA-2006-0356

www.regulations.gov

The following products have Linalool in combination with conventional pesticide active ingredients:

Holiday Pet Spray	EPA Reg. No. 2724-618
Hill's Holiday Flea Stop	
Pump Spray for Dogs & Cats	EPA Reg. No. 2724-763
Holiday Non-Aerosol Flea Spray	EPA Reg. No. 2724-764
Pest Control Products Demize E.C.	EPA Reg. No. 2724-769
Flea Stop Linatoc Dip	EPA Reg. No. 2724-770
Permalool Home & Carpet Spray	EPA Reg. No. 2724-771
Permalool Plus Fogger	EPA Reg. No. 2724-772
Permalool Plus Home and Carpet Spray	EPA Reg. No. 2724-773
Permalool Plus Inverted Carpet Spray	EPA Reg. No. 2724-774
Linalool Mousse	EPA Reg. No. 2724-776
Linalool Plus Carpet Powder	EPA Reg. No. 2724-777
Metam KLR 54%	EPA Reg. No. 45728-27

Labels for the above products can be obtained from the Pesticide Product Label System (PPLS) website: <http://oaspub.epa.gov/pestlabl/ppls.home>.