

US EPA ARCHIVE DOCUMENT

# Registration Review Linalool

Case 6058

Biopesticides and Pollution Prevention Division

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Docket No. EPA-HQ-OPP-2006-0356

Opened April 11, 2007

Closed June 3, 2007

# Background

- Registered 1985
- Technical Registrant: Wellmark International (transferred from Pet Chemicals)

# Background

- Use and Usage Information
  - Residential Uses only;
  - Directed pet treatment (shampoos, dips, sprays and powders);
  - Indoor area treatments (sprays and foggers);
  - Outdoor Area Repellents (fragrance generators and Candles);
  - Less than 250,000 lbs. sold annually

# Product Information

- Registered Products
  - 16 section 3 registrations
    - Linalool Only:
      - 5 products
        - » - 1 technical
        - » - 1 MUP
        - » - 3 EUPs (Outdoor Repellents)
      - Multiple Active Ingredients:
        - 11 products
        - Indoor area sprays and directed pet use

# Risk Assessment

- Human Health Risk Assessment (1984)
  - Sub-acute and chronic studies cited from public literature;
  - No Additional studies due to low toxicity;
  - Generally recognized as Safe (GRAS);
    - Synthetic flavoring substances and adjuvants
  - No additional sub-acute or chronic studies were required due to low toxicity / GRAS status.

# Risk Assessment

- Ecological Risk Assessment
  - 1984
    - Based on low toxicity and low exposure, EPA determined that Technical and End-Use products (pet and indoors uses only) posed minimal risk to non-target organisms. No data required.
  - 1999/2002
    - Again based on low toxicity and minimal exposure, EPA determined that new uses (out-door area repellents) present extremely low risk to non-target organisms. Endangered species designation of “No Effect”.

# Incident Report

- OPP Incident Data System (IDS) included minor human and domestic animal incidents;
- All products reported in data base were multiple A.I.;
- Agency analyzed reports and determined no clear linkage to linalool;
- Agency will consider any comments or additional data in response to docket.



# Anticipated Risk Assessment and Data Needs

- **Human Health:** Occupational and residential risks are minimal to non-existent.
  - Data and/or revised risk assessment not needed;
  - Agency will consider any public comments submitted in response to docket.

# Anticipated Risk Assessment and Data Needs

- **Ecological:** Adequate data and use patterns (indoors, pets and outdoors in candles and fragrance generators) preclude need for another risk assessment unless other information is submitted to the docket.
  - Extremely low exposure to non-target organisms therefore an ESA NE to listed species determination has been made;
  - Extremely low or no exposure to aquatic sites or drinking water;
  - Agency will consider any public comments submitted in response to docket.

# Conclusion

- For currently registered uses:
  - No further health data;
  - No further ecological effects data;
  - Meets criteria for “Easy off” RR;
  - Adverse comments not expected.

# Documents Submitted to the Docket

Document Title	Source (author, database, etc.)	Document Date
Federal Register Notice Announcing the Opening of the Docket	Federal Register	April 2007
Summary Document	Steve Morrill	April 2007
Recommendation for Registration and Fact Sheet	William Miller	6/5/19/85
HED DER	HED	10/22/83
EEB DER	EEB	3/14/85
BPPD Memo	Russell Jones	11/5/98
Endangered Species NAE Determination	Russell Jones	03/14/07
Linalool Incident Summary Memo	Rodger Gardner	3/28/07

# Timeline

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	FY 2008 1 <sup>st</sup> Quarter
Close Public Comment Period	FY 2008 2 <sup>nd</sup> Quarter
Final Decision	FY 2008 2 <sup>nd</sup> Quarter
Total (years)	1