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

JUN 1 1993

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

911524
040505

MEMORANDUM

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: Considerations in Support of Cedarwood Oil as a Candidate for Reduced Data Requirements and Reregistration Eligibility

FROM: Charles Frick CF 5/27/93
Registration Section
Chemical Coordination Branch
Health Effects Division (H7509C)

TO: Jay Ellenberger, Chief
Accelerated Reregistration Branch
Special Review and Reregistration Branch (H7508W)

THROUGH: Esther Saito, Chief Esther Saito 5/28/93
Chemical Coordination Branch
Health Effects Division (H7509C)

Penelope Fenner-Crisp, Director
Health Effects Division (H7509C) 6/1/93

The Agency believes there is a category of pesticide active ingredients for which the Agency can define a reduced set of data requirements when determining eligibility for reregistration. Specifically, for the Health Effects Division (HED), products in this category would be candidates for exemption from the toxicology, human exposure and residue chemistry data requirements for the active ingredient as presently set forth in CFR 40 part 158.

Cedarwood oil (case No. 3150) has been identified by SRRD as a candidate for screening to determine whether the conditions set forth in the guidelines for reduced data requirements are met.

CONCLUSION

- HED does not require additional toxicology or exposure data for the reregistration of cedarwood oil.
- Cedarwood oil, when used in products according to label instructions, are not expected to present a human health risk.

Recycled/Recyclable
Printed with Soy/Canola Ink on paper that contains at least 50% recycled fiber

BACKGROUND

In the Phase IV Review (13 April 1993) of cedarwood oil, HED recommended that this active ingredient be nominated as a Reduced Data Set candidate. Based on the available information, no toxicology or exposure data were required for reregistration.

Cedarwood oil was presented for discussion by the SRRD "reduced data requirement" screening committee on 19 April 1993 and 17 May 1993. According to SRRD, no 6(a)(2) data or incident reports have been submitted to the Agency. Based on the available information, the committee concluded that cedarwood oil would met the conditions in Group I (#1 and #3), Group II and Group III (#1 and #2); see attachment.

DISCUSSION

Cedarwood oil is a mixture of organic components. As a pesticide, it repels insect pests by a non-toxic mode of action. The alcohols and terpenes of cedarwood oil are considered GRAS as set forth in 21 CRF 172.515 (synthetic flavoring substances and adjuvants).

There have been some studies performed on cedarwood dust as well as the constituents of cedarwood oil. According to a recent

survey of the literature, pulmonary effects and liver effects have been noted in laboratory animals (1,2). These effects are hypothesized to be related to the occupational hazards associated with saw mill workers chronically exposed to environments high in cedarwood dust. (The registrants did not provide any data or literature on potential adverse effects.)

There are three types of pesticide products containing cedarwood oil as the active ingredient. They are: solid cedarwood blocks, materials impregnated with cedarwood oil, and ready-to-use liquids that may be applied by hand spray. The cedarwood oil is 2 to 8% as a natural component in the wood blocks. Impregnated materials (such as flea collars) contain 1% cedarwood oil. Liquids for use as a flea spray are formulated with approximately 0.5% cedarwood oil.

The cedarwood oil is naturally contained in the wood; it cannot easily be separated from the wood or wood products.

Human health risk is not expected as consumers using such cedarwood products or the impregnated material are unlikely to be exposed to significant amounts of the dust or the cedarwood oil, either by the inhalation or the dermal route.

There is a potential for inhalation and dermal exposure from use of the liquids. However, the acute toxicity testing of the end-

use products would allow appropriate labeling to address potential exposure concerns.

REFERENCES

The following citations were provided by Compact Cambridge: PoLTox I: 1988 - 1991.

1. Ayars GH; Altman LC; Frazier CE; Chi EY; (1989) The Toxicity of Constituents of Cedar and Pine Woods to Pulmonary Epithelium. Published by Journal Allergy Clin Immunol; VOL 83, ISS 3, P610.

2. Gordon WP; Forte AJ; McMurtry RJ; Nelson SD (1982) Hepatotoxicity and Pulmonary Toxicity of Pennyroyal Oil and its Constituent Terpenes in the Mouse. Published by Toxicol Appl Pharmacol; VOL 65, ISS 4, P413-24.

13544

R060849

Chemical:	**Oils, Cedarwood; Cedarwood oil**
PC Code:	**911524; 040505**
HED File Code	**11000 Chemistry Reviews**
Memo Date:	**06/01/93 12:00:00 AM**
File ID:	**00000000**
Accession Number:	**412-04-0141**

HED Records Reference Center
04/22/2004