



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

JUN 5 1985

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

TO: William Miller, PM # 16
Insecticide-Rodenticide Branch
Registration Division TS-767C

THRU: R. Bruce Jaeger, Section Head
Rev. Sec. # 1/Toxicology Branch
Hazard Evaluation Division TS-769C

FROM: D. Ritter, Toxicologist
Rev. Sec. # 1/Toxicology Branch
Hazard Evaluation Division TS-769C

Handwritten: MY 6/5/85
Handwritten: WJB
Handwritten: JLR 6-5-85

Subject: EPA Reg. No. 4758-RLG - Holiday Non-Aerosol Flea Spray (d-Limonene and linalool as active ingredients and piperonyl butoxide as synergist).

Registrant: Pet Chemicals, Inc., Miami Springs, FL.

Caswell #: 526/526A

Potomac #: P588

Action Requested:

In his March 20, 1985 letter, Mr. James M. Carpenter of Pet Chemicals Inc. requested that EPA provide a listing of additional toxicity data requirements to support an expanded usage pattern for the end use formulation (EP). Our records show that the added uses include application to carpets, rugs and upholstered furniture. These uses will be incorporated into those originally proposed on pets and pet bedding.

Our Response:

Proposed protocols for conducting these studies may be found in the Pesticide Assessment Guidelines, Subdivision F, published by NTIS in October, 1982 (EPA-540/9-82-025).

The required [R] toxicity data for these uses are listed in 40 CFR §158.135 (FR Vol 49, # 207, 10/24/84) under "Indoor" use patterns. They are:

1. Acute oral-rat on EP and TGAI
2. Acute dermal on EP and TGAI
3. Acute inhalation-rat on EP and TGAI
4. Primary eye irritation-rabbit on EP
5. Primary dermal irritation on EP
6. Dermal sensitization on EP
7. Gene mutation on TGAI

The registrant must provide the full complement of these acute toxicological tests prior to our further consideration for registration of this product. Alternatively, he may request a waiver of any or all data requirements, but he must provide an acceptable rationale for such waivers.

See the B. Dementi review of 11/5/84 of this proposal.

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INERT CLEARANCE SHORT REVIEW FORM

Action No.: 4758-RLN/-RU0

TO: William Miller, PM # 16

Chemical: d-limonene and linalool

Caswell #: 526-526A CAS-RN d-limonene 5989-27-5; linalool 78-70-6 Potomac # 588

Sponsor: PET Chemicals, Inc., Miami Springs, FL

Action Requested: Specify subacute and chronic studies that would be required for registration of both the technical grade products and consumer products containing these substances as active ingredients.

Use: d-limonene as the active ingredient in a flea and tick aerosol spray and linalool similarly as the active ingredient of a pump spray, both for use on cats and dogs.

Limitations: d-limonene at 5.0% of aerosol spray; linalool at 0.925% of pump spray.

Recommendation: No sub-acute or chronic studies will be required for the proposed uses of the two chemicals in pet sprays, or for registration of the technical grade materials.

Other Clearances: Limonene(d-, l- and dl-) and linalool are generally recognized as safe (GRAS) under 21 CFR 182.60(synthetic flavoring substances and adjuvants).

Bases for the Recommendation: The GRAS status of the two compounds as indicated above in concert with the low order of toxicity for both as revealed by studies cited in RTECS.

RPAR Status: Not in RPAR.

New Data: None.

Data Gaps: None.

Comments: None.

Reviewer Brian D. Smith, Ph.D.

Date 11/2/84

Section Head David R. Smith

Date 11-5-84

Ref for WBS
11/05/84