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

AUG - 4 1995

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

DECISION MEMORANDUM

SUBJECT: New Chemicals: Consideration of Unconditional Registration for the New Chemicals Dioctyl sodium sulfosuccinate and Undecylenic acid for use on dogs and cats to control fleas.

FROM: Steve Johnson, Director
Registration Division

TO: Dan Barolo, Director
Office of Pesticide Programs

This memorandum recommends that you concur on the unconditional registration of the end-use pesticide product DEFLEA PET SHAMPOO CONCENTRATE which contains the new chemicals Dioctyl sodium sulfosuccinate and Undecylenic acid because this product meets the criteria for FIFRA Section 3 (c) (5) and is thus eligible for unconditional registration. The applicable data requirements as put forth in 40 CFR Parts 150 to 189 have been adequately addressed for Section 3 (c) (5) registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for this product.

The Registration Division reviewed all toxicology data within the division and therefore has not sought the concurrence of the Health Effects Division or the Environmental Fate and Effects Division.

BACKGROUND

DEFLEA PET SHAMPOO CONCENTRATE containing Dioctyl sodium sulfosuccinate and Undecylenic acid was previously registered. The registrant did not pay maintenance fees and, as a result, the product was cancelled in 1987. In addition, no registrant committed to support either active ingredient for reregistration. Because the registrant continued to market the old product, EPA Region 4 has been pursuing enforcement action against the registrant for several years. It is our understanding that the enforcement case could be resolved after OPP reaches a decision on registration.

The registrant applied for a new registration on October 31, 1990. He sought and we granted data waivers because the two active ingredients are used in over the counter human health products as follows:

Active Ingredient	Amount of Active Ingredient	Human Health Product
Dioctyl sodium sulfosuccinate	50-100 mg/day	Colace Stool Softener Correctol Laxative Doxidan Laxative Gentle Laxative Surfak Stool Softener
Undecylenic acid	20-25%	Desenex Foot Powder

SUMMARY AND STATUS OF DATA REQUIREMENTS

In letters dated July 5, 1994 and November 14, 1994, EPA set forth the data requirements which would apply to this product. The requirements were: submit a complete and correct confidential statement of formula; submit the 6 acute toxicology studies; submit material safety data sheets for the inert ingredients; and list the pH of the undiluted product. Efficacy data would be required after registration because an identical product was previously registered and because testimonials had been submitted.

I. Product Chemistry

The active ingredients are not registered; therefore this product is an integrated formulation. The registrant submitted Material Safety Data Sheets for all ingredients. The inerts are cleared for use in nonfood products.

II. Toxicology

As noted, all toxicology requirements were waived except for acute toxicity. The acute tox studies were submitted, reviewed and found acceptable. The acute tox profile is:

Acute tox study	Classification
Acute oral	Category IV
Acute dermal	Category III
Acute inhalation	Category III
Eye irritation	Category III

Acute tox study	Classification
Dermal irritation	Category IV
Dermal Sensitization	Not a sensitizer

The signal word is caution; the label has been amended as appropriate.

III. Residue Chemistry, Ecological Effects, and Environmental Fate data.

All data have been waived or are not required for registration.

IV. Efficacy Data

The registrant submitted and the agency found acceptable data to support label claims about control of fleas. No data were submitted to support label claims about effectiveness against ticks and lice. Since the Agency told the registrant in a letter dated July 5, 1994 that efficacy data could be submitted after registration, we are preparing a Data Call-in Notice (DCI) to obtain the tick and lice efficacy data. This should be issued within the next month.

In the meanwhile, we are allowing the tick and lice claim on the label, because, as mentioned above, the product was previously registered for this use.

REGULATORY STATUS

- Each of the data requirements applicable to the conventional pest control agent that were not waived have been addressed and found to be adequate to support the registration of this chemical for the proposed indoor nonfood use pattern.

- There is a regulatory action pending against this product. An administrative law judge has the action under review. If the registration is issued, the enforcement action could be closed.

- A DCI for tick and lice efficacy data is being prepared and should be issued with the next month.

RECOMMENDATION

I recommend that you concur with the unconditional registration under FIFRA Section 3(c)(5) of the proposed manufacturing-use and end-use products containing the new chemical active ingredients Dioctyl sodium sulfosuccinate and

Undecylenic acid for the following reason: The toxicology data base is adequate to support the Section 3 registration of the product for the proposed indoor nonfood use pattern.

Concur: _____

Nonconcur: _____

Date: August 4, 1995

Attachment: Acute tox review
Proposed product label