

US EPA ARCHIVE DOCUMENT

INFORMATION WHICH MAY REVEAL A MANUFACTURING PROCESS IS NOT INCLUDED

Memorandum

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Date: March 17, 1981

Subject: EPA File Symbol: 41167-R SOLVIT BRAND PROPOXUR IMPREGINATED LACQUAR
Caswell #508

From: B. T. Backus
IRB/TSS

To: Mr. Jay Ellenberger
Product Manager 12

Applicant: International Chemetals Group
P.O. Box 6354
5800 Fairfield Ave.
Fort Wayne, IN 46807

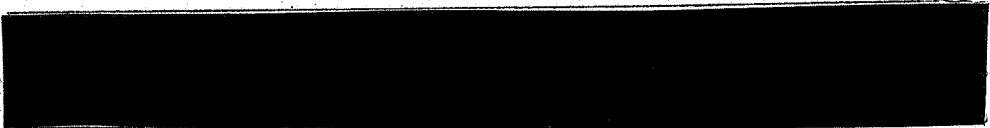
Active Ingredients (label declaration):

Propoxur (Baygon).....	4.2%
Methanol.....	3.0%
Inert Ingredients:.....	92.8%

Background:

The proposed product is a propoxur (Baygon)-impregnated lacquer. This reviewer has found it impossible to determine whether this application is for material which is being used in the manufacture of propoxur-impregnated paper, the paper itself, or (most likely) whether the applicant is of the opinion that one registration number would cover both products.

Comments and Recommendations:

1. 
2. The submitted toxicity studies will be adequate and acceptable once it has been determined precisely how much propoxur is in this product (and was in the material which was tested).
3. The submitted label is for "SOLVIT BRAND PROPOXUR IMPREGINATED LACQUAR." If this material is being proposed for use in the manufacture of propoxur (baygon) impregnated shelf-paper, labeling should specify something like: "For industrial use only in the manufacture of insecticidal propoxur-impregnated shelf-paper." Use directions would be given recommending the appropriate rate(s) at which the product is to be applied in the manufacturing process.

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4. The wording under PRECAUTIONARY STATEMENTS appears to refer to the propoxur-impregnated paper, rather than the manufacturing-use product.
5. Separate registration(s) would be required for end-use propoxur-impregnated paper(s) with insecticidal claims.
6. Precautionary labeling indicates that food, food utensils, linens, toweling, clothing etc. could not be stored on the impregnated paper. It would be appropriate to specify precisely what could be stored on it.

Labeling:

The following remarks are tentative. Any labeling which is submitted incorporating these revisions should be in draft form.

1. The appropriate signal word on the lacquer is CAUTION.
2. The statement under the heading PRECAUTIONARY STATEMENTS and the subheading HAZARDS TO HUMANS AND DOMESTIC ANIMALS should be something like:

CAUTION: Harmful if swallowed or absorbed through skin. Avoid contact with eyes, skin or clothing. Avoid contamination of food and feedstuffs.

3. The statement under the subheading ENVIRONMENTAL HAZARD should be something like:

This pesticide is toxic to fish and wildlife. Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes.

4. There should be a STATEMENT OF PRACTICAL TREATMENT (preferably under that heading) something like:

If Swallowed: Drink a glass or two of water and induce vomiting by touching finger to back of throat. Get medical attention.

If in eyes: Flush with plenty of water. If irritation persists, get medical attention.

If on skin: Wash off with soap and water.

5. There should be a NOTE TO PHYSICIAN indicating that this material is a cholinesterase inhibitor and atropine is antidotal.
6. Labeling should specify that any propoxur-treated paper which is marketed with insecticidal claims would require registration with the Environmental Protection Agency.

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Review:

The following studies were conducted on material identified as "Baygon Impregnated Shelf Lining Chemistry," an off-white chalky liquid of pH 7.75. No further information is provided as to composition. Studies were conducted at Hallowell Laboratories, 151 E. Tenth Ave., Conshohocken, PA 19428, and were received at EPA on 10-20-80.

1. Acute Dermal Toxicity Study of Baygon Impregnated Shelf Lining Chemistry on New Zealand Albino Rabbits (Acute Dermal LD50 - rabbit). Study No. 80-D-069, dated 28 May 1980. Acc. 244584³

Procedure: 5M, 5F NZ white rabbits, half with abraded skin, half with intact, received a 24-hr occluded dermal exposure to a dosage level of 2 g/kg, with subsequent 14-day observation, sacrifice and gross necropsy.

Results: No mortalities. Nine animals gained weight; one had an insignificant weight loss. Edema and/or erythema observed in 4 animals on day 1. Gross necropsies revealed nothing significant. Dermal LD50 above 2 g/kg.

Study Classification: Core Minimum Data (if accurate composition of test material is submitted)-animals only exposed to 2 g/kg dosage level; no symptomatology or lack of it reported.

Product Classification: Tox. Cat. III

2. Primary Dermal Irritation Study of Baygon Impregnated Shelf-Lining Chemistry on NZ Albino Rabbits (Primary Dermal Irritation - rabbit). Study No. 80-S-071, dated 18 April 1980. Acc. 244582.

Procedure: 0.5 mls test material was applied at each of 4 sites (2 intact, 2 abraded) on each of 6 NZ albino rabbits, with 24-hr occluded exposure.

Results: Some erythema (max. score=2) and edema (max. score=2) at 24 hrs. Abraded sites showed considerably more irritation than intact sites. All scores zero at 72 hrs. PDIS=0.85.

Study Classification: Core Guidelines Data (if accurate composition of test material is submitted)

Product Classification: Tox. Cat. IV

3. Primary Eye Irritation Study of Baygon Impregnated Shelf Lining Chemistry on New Zealand Albino Rabbits (Primary eye irritation - rabbit). Study No. 80-E-070, dated 14 May 1980. Acc. 244581.

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Procedure: 0.1 mls was instilled in one eye of each of 9 rabbits. Six eyes remained unwashed, 3 were flushed with lukewarm water starting at about 25 seconds post-instillation.

Results: No corneal involvement noted. Some conjunctival irritation in 5/6 unwashed eyes on days 1-2, still present in only 1/6 unwashed eyes on day 3. All scores zero at 4 and 7 days. All scores zero in washed eyes.

Study Classification: Core Guidelines Data (if accurate composition of test material is submitted).

Product Classification: Tox. Cat. III

4. Acute Oral Toxicity Study of Baygon Impregnated Shelf Lining Chemistry in Sprague-Dawley Rats (Acute Oral LD50-rat). Study No. 80-0-068, dated 8 May, 1980. Acc. 244580.

Procedure: 5M, 5F SD rats received, via intubation, a dosage level of 5 g/kg of test material with 14-day observation, sacrifice and gross necropsy.

Results: No mortalities. All subjects exhibited tonic convulsions, salivation and tremors at 1 hr, but were normal at 3 hrs and subsequently. All gained weight. Necropsies were unremarkable. Oral LD50 above 5 g/kg.

Study Classification: Core Minimum Data (if accurate composition of test material is submitted)

Product Classification: Tox. Cat. IV (recommendation though is for Tox. Cat. III labeling (rat oral LD50 for technical baygon is 83 mg/kg; for a 2 to 3% product expected oral LD50 would be between 2767 and 4150 mg/kg).

5. Determination of Acute Inhalation Toxicity of Baygon Impregnated Shelf Lining Chemistry in Sprague-Dawley Rats (Acute inhalation LC50 - rat). Study No. 80-1-072, dated 2 July 1980. Acc. 244584.

Procedure: 5M, 5F SD rats, 275-347 gms, were exposed to a nominal concentration of 9.02 ml/l of the test material for 4 hrs, with subsequent 14-day observation, sacrifice and gross necropsy. Mass median diam.=2.9um; geometric deviation=1.8um.

Results: No mortalities. Animals remained huddled and inactive during exposure. Slight nasal discharge was noted during first hr, but had disappeared by end of first day. Necropsies were unremarkable.

Study Classification: Core Supplementary Data (no actual concentration measurements made; test material was pre-filtered through glass wool "to remove excessively large particles which tended to clog the spray nozzle."). This may have affected composition and/or concentration rats were exposed to.

Byron T. Backus 3/17/81
Byron T. Backus
IRB/TSS

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Propoxur Toxicology Reviews

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Pages _____ through _____ are not included in this copy.

The material not included contains the following type of information:

- Identity of product inert ingredients
- Identity of product impurities
- Description of the product manufacturing process
- Description of product quality control procedures
- Identity of the source of product ingredients
- Sales or other commercial/financial information
- A draft product label
- The product confidential statement of formula
- Information about a pending registration action
- The document is a duplicate of page(s) _____

Propoxur Toxicology Reviews

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