

IRB/TSS Precautionary Labeling Review

11/25/86

TO: PM-16 12

SUBJECT: 707-ENG
Kelthane Technical
Rohm and Haas Company
Philadelphia, PA 19105

In TSS: 11-25-86 (Expedite)
Record #: 185989
Action #: 161

FORMULATION: Technical Kelthane.

Active Ingredient:
Dicofol.....89%
Inert Ingredients.....11%
(Impurities in this technical dicofol contain [REDACTED])

BACKGROUND: Team 12 has submitted primary eye irritation and primary dermal irritation studies for TSS review.

SUBMITTED DATA: Studies were done in Toxicology Department of Rohm and Haas Company; R and H Technical Report No. 85R-0004, date 1-16-85. Testing was done on Kelthane Technical Purified Miticide (96.2% dicofol [REDACTED])

1. Primary Dermal Irritation: Six New Zealand White rabbits received 4 hour occluded dermal exposure to 0.5g on one intact skin patch per rabbit. Test substance was described as a solid, which was warmed to 70°C to liquify before application was made. Observations were made at 1, 24, 72 hours and on day 7. Mild to moderate erythema and mild to severe edema were observed on all test sites. Edema cleared and erythema was improving by day 7; no further observations were reported.

PDIS = 4.6.

Study Classification = Core minimum data.

Product Classification = Toxicity category III.

2. Primary Eye Irritation: Nine New Zealand White rabbits received 0.1 ml of prepared solution in one eye of each rabbit. Test substance was prepared as a 5% solution in etahnol. Fluorescein scan was used pre-test. Observations were made at 24, 48, 72 hours and on day 7. There was no corneal involvement.

INFORMATION WHICH MAY REVEAL FORMULATION IMPURITIES IS NOT INCLUDED

All irritation cleared within 7 days.
Study Classification: Supplementary data.

COMMENTS:

1. The primary eye irritation was classified as supplementary data because study was done on a 5% solution of the technical, which will not indicate irritation potential of the undiluted technical. Guidelines require that a solid test substance should be ground into a fine dust or powder, and it should not be moistened before it is placed in the eye. If it not possible to grind the test substance into a fine powder, then it should be liquified by heating, and then cooled to room temperature, as was done for the dermal irritation study. Also, an illustrated guide to explain grading of ocular responses should be submitted.

2. The primary dermal irritation study is acceptable as core minimum data, and we have the following toxicity information on Technical Kelthane:

<u>Exposure Route</u>	<u>Toxicity Category</u>
Acute Oral Toxicity	III
Acute Dermal Toxicity	III
Primary Dermal Irritation	III

3. Precautionary labeling will be reviewed when acute toxicity profile will be complete.

4. Note to team: Proposed label is quite similar to presently registered Technical Kelthane label, and considering the similarity between old and new technicals, a conditional registration can be granted provided remaining acute studies are run within a certain time and label is revised as needed at that time. Although the acute toxicity profile is incomplete at this time, this reviewer feels that products formulated from the new technical will not pose a greater threat to the public health and environment than did products formulated from the old technical.

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