

MEMORANDUM

October 4, 1983

TO: PM ~~8~~/7

SUBJECT: 432-667
Scourge Insecticide
Penick Corporation
Lyndhurst, NJ 07071

IN TSS: 8-19-83
AccNo: 250875
RN: 103308
OLTS: 14

FORMULATION: Resmethrin..... 18.00%
Piperonyl Butoxide..... 54.00
Aromatic Petroleum Solvent... 24.67
Mosquito fog pH 4.5

BACKGROUND

This product was accepted for registration on 12-26-83 under the cite-all method of support. The applicant has now submitted product specific acute toxicity data.

SUBMITTED DATA

Accession Number 250875. All data developed by MB Research Laboratories, Spinnerstown, PA. 18968.

1. Acute Oral LD50. MB 83-6700A. 5 Male and 5 Female white albino rats per group. Group housing. Dose by syringe and dosing needle. Results:

<u>Mg/Kg</u>	% Mortality:	<u>Males</u>	<u>Females</u>	<u>Overall</u>
1700		20	40	30
2500		40	40	40
3500		60	80	70
5000		100	60	80
Acute Oral LD50		2800	2600	2700
95% Confidence Limits		1900-4100	1700-4100	2000-3600

CORE MINIMUM DATA

TOXICITY CATEGORY III

2. Acute Dermal LD50. MB 83-6700B. 5 male and 5 female albino rabbits. Individual housing. Material applied to clipped sites but there were no abraded areas. All animals were dosed at 2000 mg/kg. No deaths occurred. 4 animals developed dermatological signs and 1 had liver and intestinal abnormalities upon necropsy. While the data are not adequate to determine the actual LD50, they are sufficient to classify the product.

CORE MINIMUM DATA

TOXICITY CATEGORY III

3. Primary Dermal Irritation. MB 83-6700C. 6 albino rabbits. 4 hour exposure. All sites clipped but none abraded. Individual housing. Researcher comments " appears to be corrosive". Results:

<u>Rabbit</u>	<u>Erythema and Eschar</u>		<u>Edema</u>	
	<u>24</u>	<u>72</u>	<u>24</u>	<u>72</u>
1	2	3	1	0
2	2	4	2	0
3	1	2	1	1
4	2	2	1	1
5	2	1	1	0
6	3	3	1	1
	<u>2.0</u>	<u>2.5</u>	<u>1.2</u>	<u>0.5</u>

PDIS: 3.1

CORE MINIMUM DATA

TOXICITY CATEGORY II (Note that this is based primarily upon the researchers' comments and the fact that the irritation increased to a level of 4 for erythema and eschar for rabbits 3,4,and 6 at day 7 rather than improving.) Note that additional data could result in reclassification of this product into toxicity category III.

3. Primary Eye Irritation. MB 83-6700 D. 6 albino rabbits, individually housed. 0.1 ml. per eye. None of the eyes were washed. Sodium flourescein scan pre-test. Researcher states "eye corrosive". Results:

<u>Rabbit</u>	<u>Corneal Opacity</u>						
	Day:	<u>1</u>	<u>3</u>	<u>7</u>	<u>14</u>	<u>21</u>	
1		x	x	x	x	x	Did not clear
2		x	x	x	x		Clear
3		x	x	x	Clear		
4		x	x	x	x	x	Did not clear
5		x	x	x	(Died from (presumably) eye injury)		
6		x	x	x	x	x	Did not clear

As can be seen, all treated eyes had corneal opacity and 4/6 did not clear in 21 days. Product appears to be corrosive.

CORE MINIMUM DATA

TOXICITY CATEGORY I

CONCLUSIONS

The data are acceptable to support continued registration of the subject product. The product falls into TOXICITY CATEGORY I as a result of the extreme ocular hazard demonstrated in the data. The product is in TOXICITY CATEGORY III for the oral and dermal routes of exposure and in TOXICITY CATEGORY II for skin irritation.

LABEL COMMENTS

The present labelling is unacceptable. The following label changes are necessary for continued registration.

1. The signal word must be changed from CAUTION to DANGER as a result of the findings of the eye irritation study.

2. Precautionary labelling should delete "avoid contact with skin, eyes, or clothing" and add the following:

"Corrosive. Causes irreversible eye damage and skin irritation. Wear (goggles, face shield, or safety glasses). Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse."

3. The statements of practical treatment should be revised by deleting the statement "if irritation persists " from the eye and skin statements.

Phil Hutton
TSS/IRB