

ISS/IRB PRECAUTIONARY LABELING REVIEW

08-15-86

PM: 16

04787-00005  
Fyfanon Technical  
Cheminova c/o Trans Chemic Industries  
Secaucus, NJ 07094

In: 06-19-86  
Accn: 263072,73  
RN: 17 5780  
AC: 400  
DLTS: RL

FORMULATION:

Malathion.....97.400%

Technical

INTRODUCTION

Application for registration. Note previous Beltsville tests for the acute oral toxicity of this product.

3-23-73	3050 F	12-4-73	700 M
8-27-75	2900 M	06-22-77	>2120 M

(male average is 1907)

USES

Technical

SUBMITTED DATA

A. Accession 263073 (Identity Data) and 263072 (Tox). Huntingdon Research Centre Ltd, Cambridgeshire, England. Only the acute toxicity data are reviewed here. The product appears to be adequately identified.

1. Acute Oral Toxicity. HRC 851341D/chv 33/AC. 5 male and 5 female sprague-dawley derived albino rats, group housed/sex. Administration by gavage. 14 day observation period. Signs include piloerection, lethargy, abnormal posture, salivation. Necropsies unremarkable. Results:

Dose, Mg/Kg	Percent Mortality:	Males	Females
2000		0	0
3200		0	0
5000		60	20
8000		80	100
LD 50		5400	5700 ?
95% Confidence Limits		4100-6900	4300-7800

Core Minimum Data- These data are adequate to classify the product but differ markedly from previous EPA test results. Published test results indicate that the acute oral toxicity of malathion should be between 1000-2000 mg/kg.

#### TOXICITY CATEGORY III

2. Acute dermal toxicity. HRC 851330D/CHV 34/AC. 5 M and 5 F Sprague Dawley derived rats, group housed by sex, per. dose. Sites clipped and intact. 24 hour occluded exposure. 14 day observations. No signs of intoxication or dermal irritation. Necropsies unremarkable. Results:

Dose mg/kg	%Mortality	Male	Female
2000		0	0
LD50			
95% Confidence limits			

Core Minimum Data

#### TOXICITY CATEGORY III

3. Acute Inhalation Toxicity. HRC CHV 28/8640. 5 M and 5 F SD rats, group housed by sex. 4 hour group whole-body exposure. Particle sizes by multistage liquid impinger with acetone/methanol traps. Gravimetric concentrations by filter wts. and GLC. Signs include salivation and labored respiration. Necropsies unremarkable.

Conditions of exposure:						Percent Mortality:	
Nom. Conc	An. Conc	Grav. Conc.	mg/L	MMD	If RH	Male	Female
----	5.2	---		(2.0	68 --	00	00

Core Minimum Data

#### TOXICITY CATEGORY IV

2

4. Primary Eye Irritation. 851214d/chv 36/5E. 6 NZ rabbits, individually housed. Naked eye examination with penlight. Material administered at 0.1 ml per eye. None washed. Results:

Corneal Opacity- 0/6.  
Iritis- 0/6.  
Conjunctivae- 6/6. All clear d 7. Mean clear 2.9

Core Minimum Data

#### TOXICITY CATEGORY III

5. Primary Skin Irritation. 851221D/CHV 35/5E. 6 New Zealand White rabbits, individually housed. Sites clipped and intact. 0.5 ml. per site, 4 hour occluded exposure. Draize type scoring. PDIS= 1.1

Core Minimum Data

#### TOXICITY CATEGORY IV

6. Dermal Sensitization. 8666D/CHV 37/5S. 10 Hartley guinea pigs, housing not reported. Modified Buehler test. Sites clipped and intact. 0.5 ml per site. 6 hour exposure. 9 inductions 3X weekly of undiluted material. 14 day rest pre challenge. Challenge at 75% concentration. Vehicle control but no positive control Results:

	<u>Product</u>	<u>PDIS</u>
I-1	0.2	---
I-9	0.1	---
I-Mean	(.1	---
C-1	0.0	---
C-N	---	---

Core Minimum Data

Not a Sensitizer

#### SUMMARY OF THE SUBMITTED DATA

<u>Study</u>	<u>Class.</u>	<u>Results</u>	<u>Tox.Cat.</u>
Acute Oral Tox.	CMD	LD50 See study	III
A. Dermal Tox.	CMD	LD50 >2000 mg/kg	III
P. Dermal Irr.	CMD	PDIS=1.1	IV
P. Eye Irr.	CMD	6/6 clear 7 days	III
Inhalation Tox.	CMD	LC50 >5.2 mg/L	IV
D. Sensitization	CMD	Not a Sensitizer	

## CONCLUSIONS

1. The acute oral toxicity, acute dermal toxicity, eye irritation, dermal sensitization, acute inhalation and primary dermal irritation studies are acceptable.

## LABELING

1. The last submitted label in the jacket was accepted 9-15-67. The following revisions are necessary:

a. Put KEEP OUT OF REACH OF CHILDREN before CAUTION.

b. Change the precautionary labeling to:

Harmful if swallowed or absorbed through the skin. May cause eye irritation. Avoid contact with the eyes, skin or clothing. Wash with soap and water after handling.

c. Add the following statements of practical treatment:

IF SWALLOWED: Call a Physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching the back of the throat with finger. Do not induce vomiting or give anything by mouth to a unconscious person.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

IF IN EYES: Flush with plenty of water. Get medical attention if irritation persists.

Phil Hutton  
TSS/IRB