MEMORANDUM

DATE:

December 16, 1986

SUBJECT:

EPA REG NO. 4787-7, CHEMATHOATE TECHNICAL

FROM:

Donna Williams

IRB/TSS

TO:

William Miller

Product Manager-16

Registrant: A/S Cheminova

PO BOX 9

DK-7620 Lemvig Denmark

Active Ingredient:

Dimethoate 96 % Inert Ingredients: 4 %

BACKGROUND INFORMATION:

Registrant submits acute toxicity studies for review. Registered product is for formulating use only.

- 1. Registrant needs to inform contract lab, that for every study submitted and conducted after 1974 a Good Laboratory Practice Statement must accompany each study (see CFR 40 Part 160 Subpart A). Also please inform registrant that a study can be consider unacceptable without said statement irrespective of the study content.
- 2. Submitted studies are acceptable and based on their acute toxicities the product was assinged the following categories.

•	Study Class.	Tox Cat	EPA Acc #
Acute Oral LD50	Core Min.	II	265675
Acute Dermal LD50	Core Min.	III	265675
Dermal Irritation	Core Min.	IV	265675
Eye Irritation	Core Min.	III	265675

3. Note to PM: review of jacket indicates that the current label was accepted July 25, 1985. Precautionary wording needs to be modified, the use of an "blunt object" to induce vomiting should be deleted.

STUDY REVIEW:

DOSE

All studies were conducted on CHEMATHOATE, by Huntingdon Research Centre LTD, Cambridgeshire, England.

1. ACUTE ORAL LD50 Study no. HRC-851338D/CHV 33/AC, initated 10/17/85.

Groups of 5M & 5F SD rats received a single oral gavage dose of test material dissolved in corn oil. Animals were observed 14 days post-treatment.

Toxic Signs: Piloerection, hunched posture, abnormal gait, lethargy and reduced body weight.

Necropsies: Unremakable.

D001	0		
(MG/KG)	Males	<u>Females</u>	
250	0	0	
320	0	0	
400	100	60	\$ - *
500	100	80	
640	100	100	
LD ₅₀	358 mg/	/kg 414 mg/kg	
95% C.L	. (311-4]	(363-463)	
Combine	d 387 mg/	/kg (348-423)95	& C.L.
Study Cla	ssification	on: Core Minimu	m
Toxicity	Catego		

% MORTALITY

2. Acute Dermal LD₅₀ (LIMIT TEST) Study no. HRC-851333D/CHV 34/AC, initiated 10/23/85.

5M & 5F SD rats received a single 24-hr occluded dermal exposure to 2.0 g/kg of test material (83.3% w/v paste in distilled water) applied to shaven intact skin. Animals were observed for 14 days post-treatment.

Toxic Signs: Hunched posture.

Necropsies: Unremarkable.

Acute Dermal LD50 >2.0 g/kg 0% Mortality

Study Classification: Core Minimum

Toxicity Category: III

 Primary Dermal Irritation Study no. HRC-851223D/CHV 35/SE, initiated 10/08/85.

6 NZ White rabbits received a single 4-hr occluded dermal exposure to 0.5mls of test material moistened with water and applied to shaven intact skin. Animals were observed 4 days post-treatment.

Toxic Signs: Very slight erythema and edema was exhibited 30 minutes post-treatment in (3/6) clearing by day 2.

PDIS-0.0

Study Classification: Core Minimum

Toxicity Category: IV

4. Primary Eye Irritiation Study no. HRC-851218D/CHV 36/SE, initiated 10/14/85.

6 NZ White rabbits received a single ocular application of test material instilled into one eye. Treated eyes were not rinsed and were examined and scored for 7 days post-instillation.

Toxic Signs:

IRRITATION:	1-HR	24-HRS	72-HRS	DAY-7
CORNEAL OP.	-	$\overline{(4/6)}$	(4/6)	clear
IRISTIS	-	(2/6)	(1/6)	clear
CONJUNCTIVAE	(6/6)	(6/6)	(4/6)	clear

Study Classification: Core Minimum

Toxicity Category: III

ACCSN: 265675 A MRID: 00164219 ACCSN: 265675 B MRID: 00164220 ACCSN: 265675 C MRID: 00164221 ACCSN: 265675 D MRID: 00164222

* Year CST also asong up review

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