



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

1-3-90

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Reg. No./File Symbol 279-GNTR
Commandet 4 E Herbicide

FROM: William S. Woodrow WSW 12-19-89
Precautionary Review Section E 1/3/90
Registration Support Branch
Registration Division (H7505C)

TO: Robert Taylor (PM 257)
Fungicide-Herbicide Branch
Registration Division (H7505C)

APPLICANT: FMC Corporation
Agricultural Chemicals Group
Philadelphia, PA 19103

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
<u>clomezone: 2-(2-Chlorophenyl)methyl-4-</u>	<u>47.1</u>
<u>4-dimethyl-3-isoxazolidinone</u>	<u>52.9</u>
Inert Ingredient(s):	<u>52.9</u>
Total	100.0%

BACKGROUND:

An April 13, 1988 FMC Corp. letter to Robert Taylor questioned the EPA justification for requiring a DANGER signal word on the Commander 4 E Herbicide label, and the accompanying statement "Causes skin burns." Woodrow obtained the original study listed under Accession NO. 265608, FMC Lab. NO. A86-2153 and re-reviewed the study to double-check the EPA original decisions.

RECOMMENDATION:

- i) The primary dermal irritation study submitted by FMC to support Commander 4EC Herbicide registration is acceptable to RSB/PRS, and is hereby placed in Toxicity Category III. The Primary Irritation Index for this study was determined to be 1.5. At 72 hours post patch removal, the average irritation score was 1.6.
- 2) No additional acute toxicity studies are required for Commander 4 EC Herbicide;
Acute toxicity profile:

Commandet 4 EC Herbicide

	Toxicity Category
Acute oral	III
Acute dermal	III
Acute Inhalation	III
Primary eye irritation	III
" dermal "	III
Dermal sensitization	—
not a dermal sensitizer	

LABELLING:

- 1) Change the WARNING signal word to read "CAUTION".
- 2) The Precautionary Statements are appropriate
- 3) Under Statements of Practical Treatment, If on skin; add "Get medical attention".

DATA REVIEW DR SKIN IRRITATION TESTING (§81-5)

Product Manager: (25)

MRID No.: ALL # 265608

Testing Laboratory: EMC TOX. Lab., Princeton

Author(s): Christina Freeman

Species: Rabbit, N 2 white

Age: young adult

Sex: 3m & 3f

Weight: 2.4 - 2.72 Kg.

Dosage: 0.5 ml

Test Material: Commander 4 EC (Clonazepam A.I.), liquid

Quality Assurance (40 CFR §160.12): adequate

Reviewer: M. Waller

Report Date: 12-19-89

Report No.: AE6-2153

2-(2-Chlorophenyl) methyl-4,
4-dimethyl-3-isoxazolone

none
44.4%

Summary:

The Primary Irritation Index = 1.5

Toxicity Category: III

Classification: Guidelines

Procedure (~~Deviations From §81-5~~): 0.5ml undiluted test material introduced under 2" x 8 ply gauze pads on clipped backs of 3m & 3f rabbits; pads secured & taped. Entire trunk & semi-occlusive bandage, secured & taped. 4 hours contact - (wrappings removed, sites wiped & methanol & water - Body weights Day 0.

Results: Drainage system removed 30 minutes after unwrapping, scoring for erythema & edema against 24, 48, 72 hours, and daily until 14 days. Max score of 4 for erythema, and 4 for edema (total possible max. score of 8.0).

Irritation scores:		Day 4 - 2.9	Day 11 - 0.8
4.5 hrs - 0.3	" 5 - 3.2	" 12 - 0.6	
24.0 hrs - 1.4	" 6 - 2.3	" 13 - 0.3	
48.0 hrs - 1.5	" 7 - 1.8	" 14 - 0.0	
72.0 hrs - 1.6	" 8 - 1.4		
Special Comments:	" 9 - 0.3		
	" 10 - 0.8		

" Moderate irritation at 72 hours (moderate erythema)

Tox Cat. III

Tox Chem No. 4630 Command Current Date 12-19-89

File Last Updated _____

Study/Lab/Study #/Date	Material	EPA Accession No.	Results: LD50, LC50, PIS, NOEL, LEL	TOX. Cat.	CORE Grade/Doc. No.
Primary dermal irritation, Rabbit. FMC Tox. Lab. # A86-2153 10-16-86	Commander 4 EC	Acc. # 265608	P.I. Inducts 1.5 "Moderate irritation at 72 hours (moderate erythema)"	111	Guidelines