MEMORANDUM

SUBJECT: EPA Reg. No./File Symbol 279-GNTR

Commander 4 E Herbicide

FROM: William S. Woodrow 12-19-89
Precautionary Review Section
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):

Clomazone: 2-(2-Chlorophenyl)methyl-4-
4-dimethyl-3-1H-pyrazolidinone

8 by wt.

47.1

Inert Ingredient(s): . . . . . . . . . . . .

52.9

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:

1) The primary dermal irritation study submitted by FMC to support Commander 4 EC 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:
Commander 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

LABLING:

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."


Product Manager: (25)  
MRID No.: 265-607  
Testing Laboratory: EMC TOX Lab., Princeton  
Author(s): Christine Freeman  
Species: Rabbit, N 2 white  
Age: Young adult  
Sex:  
Weight: 2.4-7.22 kg  
Dosage: 0.5 mL  
Test Material: Commander  
Quality Assurance (40 CFR §160.12): Adequate  

Summary:

The Primary Irritation Index = 1.5  
Toxicity Category: III  
Classification: Guidelines  

Procedure (Departures from §161-5): 0.5 mL undiluted test material introduced under 2.5 g polygaze pads on clipped backs of 31-34 rabbits; pads secured w/ tape. Entire procedure - excluding cleansing/disinfecting soln. - repeated 4 times contact - 1 week apart. - Bodgeweights day 0  

Results:

Drain system recharging 30 minutes after removing, assessed for skin reaction again at 24, 48, 72 hours, and daily until 14 days. Most scored 4 for erythema, and 4 for edema (total possible max. score of 8.0).  

Irritation scores:

<table>
<thead>
<tr>
<th>Day</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>2.9</td>
</tr>
<tr>
<td>4.5 hrs</td>
<td>0.3</td>
</tr>
<tr>
<td>6</td>
<td>2.3</td>
</tr>
<tr>
<td>12</td>
<td>0.6</td>
</tr>
<tr>
<td>24</td>
<td>1.4</td>
</tr>
<tr>
<td>24.5 hrs</td>
<td>0.3</td>
</tr>
<tr>
<td>48</td>
<td>1.5</td>
</tr>
<tr>
<td>72</td>
<td>1.6</td>
</tr>
<tr>
<td>Special Comments:</td>
<td></td>
</tr>
</tbody>
</table>

Special Comments:

"Moderate irritation at 72 hours (moderate erythema)"

For Cat. III
<table>
<thead>
<tr>
<th>Study/Lab/Study ID/Date</th>
<th>Material</th>
<th>EPA Accession No.</th>
<th>Results:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary dermal irritation, Rabbit, FMC Tox. Lab. # A86-2153 10-16-86</td>
<td>Commander 4 EC</td>
<td>Acc. # 265-60T</td>
<td>P.I. 4A(5) 1.5 &quot;Moderate irritation at 72 hours (moderate erythema)&quot;</td>
</tr>
</tbody>
</table>

Guidelines