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ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20560

003807

Date: September 4, 1973  
Reply to  
Attn of:

Subject: Human Safety Review

To: Mr. Lee TerBush, Acting Chief  
Coordination Branch  
Registration Division

File Symbol: 352-EXP-X Temporary Permit

Dupont de Nemours  
Wilmington, Del.

Registrant proposes this new chemical, Ammonium ethyl carbamoyl phosphonate (Kernite<sup>(tm)</sup>) for use in non-crop brush control situations. No food tolerances appear to be involved.

Toxicity data are submitted for the formulation\*:

| Species    | Route                           | LD50         | Toxic Signs                                                 |
|------------|---------------------------------|--------------|-------------------------------------------------------------|
| Rot        | Acute Oral                      | 24,400 mg/kg | Respiratory distress; diarrhea & weight loss                |
| Guinea Pig | Acute Oral                      | 7380 mg/kg   | Tremors, Pallor, convulsions                                |
| Rabbit     | Dermal Irritation (single dose) | >1685 mg/kg  | none observed systemically; transient, mild skin irritation |

\* Composition: Active ingredient .....43%

Direct ingredient information is not included

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| <u>Species</u> | <u>Route</u>                    | <u>LD<sub>50</sub></u>                                                                                                                                           | <u>Toxic Signs</u>         |
|----------------|---------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|
| Rat            | Acute Inhalation                | Male >56.6 mg/L air<br>Female >42.0 mg/L air                                                                                                                     | none of significance<br>CG |
| Rat            | 10 dose subacute oral           | 2200 mg/kg/day for ten doses failed to elicit toxic signs                                                                                                        |                            |
| Guinea Pig     | Skin irritation & sensitization | neither an irritant nor a sensitizer at up to 50% on intact and abraded skin                                                                                     |                            |
| Rabbit         | 10 day skin exposure            | 0, 50% and 100% dilutions applied to occluded dorsal skin failed to induce signs of toxicity or alterations in blood ChE activity, hematology or histopathology. |                            |

Comments

Krenite appears to be singularly non-toxic in animals.

Our only concern is that no acute ChE inhibition studies were done in order to more clearly define the potential hazard to users. Nevertheless, we find that the label signal word and precautionary statement is adequate for the temporary permit.

A ninety day rat feeding study is included; apparently registrant contemplates crop use at some future date, we therefore defer evaluation of this study until such time as residue tolerances are sought.

*David L. Ritter* 7/5/73  
David L. Ritter, Pharmacologist  
Toxicology Branch  
Registration Division

cc: DR, FEB, HEB, IRB, McCritchlow, GWhitmore, Division Reading File,  
Branch Reading File

DLRitter/km 09-05-73

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352-EXP-846 Krenette

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| ROUTING AND TRANSMITTAL SLIP                               |          | ACTION           |  |
|------------------------------------------------------------|----------|------------------|--|
| 1 TO (Name, office symbol or location)<br><br>David Ritter | INITIALS | CIRCULAR         |  |
|                                                            | DATE     | COORDINATION     |  |
| 2                                                          | INITIALS | FILE             |  |
|                                                            | DATE     | INFORMATION      |  |
| 3                                                          | INITIALS | NOTE AND RETURN  |  |
|                                                            | DATE     | PER CONVERSATION |  |
| 4                                                          | INITIALS | SEE ME           |  |
|                                                            | DATE     | SIGNATURE        |  |

**REMARKS**

Please review and return to PCO room 211.

I believe that you reviewed this permit on 9/5/73. They have now asked for a change in the permit. The change consist of an aerial application use. Does this change anything from the Toxicology view point?

The new label attached, is identical to the original except for the addition of the aerial application use.

Don: no need to change anything - all Toxicity is in and material is OK for aerial application. Label Safety statements are adequate. Don't

Do NOT use this form as a RECORD of approvals, concurrences, 2/12/74  
disapprovals, clearances, and similar actions.

|                                                                    |                 |
|--------------------------------------------------------------------|-----------------|
| FROM (Name, office symbol or location)<br><br>Ronald Stubble # 211 | DATE<br>2/13/74 |
|                                                                    | PHONE<br>62601  |

OPTIONAL FORM 41  
AUGUST 1967  
GSA FPMR (41CFR) 100-11.208

GPO : 1972 O - 479-797

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