DATE: October 16, 1979
SUBJECT: EPA Reg. No. 464-236
Vikane Fumigant

FROM: Ray Jarmolt
Toxicology Branch/HEW (TS-769)

TO: William H. Miller, PM-16
Insecticide/Rxlenticide Branch, RD (TS-767)

Registrant: The Dow Chemical Company
Midland, Michigan 48640

Active Ingredient: Sulfuryl fluoride
Inert Ingredient: 1%

Action requested: To add the following to the label:

(1) Fumigation for control of cockroaches and carpet beetles

(2) Fumigation of dwellings (including mobil homes), buildings
construction materials, furnishing (household effects), vehicles
including automobiles, buses, surface ships, railcars, recreational
vehicles (but not including aircraft).

Conclusions: (1) The registrant should address the following questions
prior to acceptance of label changes.

a. What is the case history of adverse effects reported
from structural fumigation with Vikane?

b. Will mobil homes, surface ships, railcars and
recreational vehicles be fumigated during transport?

c. What value is the Vikane gas detector in monitoring
residue levels of sulfuryl fluoride in materials that
have an affinity for this fumigant?

(2) Add "Restricted Use Pesticide" to the top of the front
panel on the label.
Discussion: This fumigant is colorless, odorless gas that does not have adequate warning properties. A warning agent such as chloropicrin is recommended on the label for clearing a structure prior to treatment. The uses of chloropicrin are proposed for restricted use classification. (Federal Register Vol. 44, No. 149 Wednesday August 1, 1979). Sulfuryl fluoride is acknowledged to be highly toxic as demonstrated by the Category I labeling accepted in 1979 with the registration of this product. The label has been evaluated to assess the adequacy of the labeling to prevent unreasonable adverse effects to man.

1. The label directs the applicator to perform complex operations and procedures requiring specialized training and/or experience.

2. Failure to follow the use directions would result in reasonable adverse effects.

3. The directions for use recommends the use of specialized apparatus and protective equipment that would not be available to the general public.

Considering, the above criteria leads to the conclusion that a significant risk is associated with the use of sulfuryl fluoride and is therefore a candidate for restricted use classification.

Properties of Sulfuryl Fluoride

A colorless, odorless gas packaged as a compressed gas in 125 pound net weight cylinders. It has a high vapor pressure and a low heat of vaporization.

Molecular weight 102.07
Specific Gravity 1.342
Boiling point -55°C at 760 mm to (approximately -67°C)
Solubility: Practically insoluble in water
Slightly soluble in organic solvents
Miscible with methyl bromide.
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Stability: 1) Non-flammable under normal conditions in all atmospheric concentrations.

2) Relatively unreactive and non-corrosive

3) Reactive with strong bases

4) Affinity for proteinaceous and lipid materials.

Threshold Limit Values - 5 ppm for a 8-hour daily exposure for a 40-hour work week.

Label Limitations:

1 - Use only by Professional Fumigators

2 - Use does not include aircraft

3 - Do not ship or store with food, feed or drugs

4 - Remove from the structure to be fumigated all persons, domestic animals, pets - including fish and desirable growing plants.

5 - Remove mattresses and pillows completely enveloped in water proof covers or remove covers.

6 - Food, feed, drugs and medicinals (including those items in refrigerators and freezers) not in sealed glass, plastic, or metal containers must be either removed from the building, or sealed in polyethylene plastic bags of 4 mil or greater thickness.

7 - EXTINGUISH ALL FLAMES INCLUDING PILOT LIGHTS OF HOT WATER HEATERS, GAS REFRIGERATORS, OVENS, BROILERS, ETC. TURN OFF OR UNPLUG ALL ELECTRIC HEATING ELEMENTS SUCH AS TOWE IN HEATERS, RANGES, OVENs, ETC. SHUT OFF AUTOMATIC SWITCH CONTROLS FOR APPLIANCES AND LIGHTING SYSTEMS.

8 - The label recommends that fumigated structures should not be reoccupied until fumigation is complete as determined by a suitable fumigant monitoring instrument. The Dow Chemical Company brochure, available to applicators, recommends a Viloron gas detector. This detector measures color changes from combustion of the active ingredient.
Precautionary Labeling

DANGER
Hazardous Gas Under Pressure
Oderless - May be Fatal if Swallowed
Do Not Breathe Gas. Keep Cylinders Well Labeled
Keep Out of Reach of Children

Cylinder Handling and Storage Instructions: Store cylinders away from heat in a recessed well ventilated area away from dwellings and work areas. Do not contaminate or store near food, food, or drugs. When not in use, all full and partially used or empty cylinders must have the valve closed and the valve cover hood securely in place. Promptly return all empty cylinders to your VIKANE distributor. Do not transport any cylinders in closed vehicles where they occupy the same common airspace as personnel.

First Aid: Send for a doctor in case of overexposure. If a person should be overcome from breathing this gas, IMMEDIATELY place patient in fresh air, face down, with head slightly below level of lungs. Keep warm. If breathing stops, give artificial respiration.

Note to Physician: First symptoms expected are those of respiratory irritation and central nervous system depression; excitation may follow. Treat symptomatically. There is no known antidote.

Respiratory Protection: Do not breathe the gas vapors. May be fatal if inhaled. If it is necessary to enter a space under fumigation, a self-contained or full face gas mask with acid gas canister, approved by NIOSH of HSA, MUST be used.

Before using any make or brand of canister, consult the manufacturer to be certain the canister is effective against VIKANE fumigant. Do not use any canister longer than the manufacturer's suggested time even when used at lower concentrations or in fresh air. If a mask is used for a short period of time intermittently, record time used on the mask so an accurate record can be kept. Fresh canisters marketed under the following descriptions have been tested and found to provide effective protection under conditions described in the following table:
<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Size</th>
<th>Designation</th>
<th>1/4 lb./ 1000 cu ft.</th>
<th>1 lb./ 1000 cu ft.</th>
<th>2 lbs./ 1000 cu ft.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scott 1/</td>
<td>Large</td>
<td>064-ACK-L</td>
<td>2 Hours</td>
<td>15 Minutes</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Part No. 600 204-03</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MSA 2/</td>
<td>Indus-</td>
<td>GWV (Part No. 87081)</td>
<td>2 Hours</td>
<td>15 Minutes</td>
<td>No</td>
</tr>
<tr>
<td>MSA 2/</td>
<td>Large</td>
<td>GWV-SS (Part No. 87080)</td>
<td>2 Hours</td>
<td>2 Hours</td>
<td>15 Minutes</td>
</tr>
</tbody>
</table>

1/ Scott Aviation, Lancaster, NY 14086
Division of MSA, 225 Erie Street

2/ Mine Safety Appliance Company
400 Penn Center Boulevard
Pittsburgh, PA 15235

For higher concentrations of VIRANE fumigant or for longer periods of time, use air-supplied or self-contained breathing apparatus.

Do not use any canister longer than 2 hours even when used at lower concentrations or in fresh air.
Review of Acute Toxicity on VIKANE 99%
Dow Chemical October 22, 1959 Accession No. 238663

I. Acute Rat Oral Toxicity

A. Procedure: A 1% corn oil solution of sulfuryl fluoride was prepared by bubbling the gas through chilled oil. Three groups of four female rats per group were dosed orally at 40, 80, 160 mg/kg. Four groups of four male rats per group were dosed orally at 50, 100, 200 and 500 mg/kg. All surviving animal were observed for 14 days. Necropsy was conducted on each animal at the time of death.

Vehicle control: Two female rats were dosed orally with 40 ml of corn oil.

B. Results:

1. LD₅₀ approximately 100 mg/kg for both males and females. Vehicle control 0/2 mortality.

2. Pharmacotoxic signs - oily diarrhea with death reported within 2 hours.


C. Conclusion

1. Classification of data - core supplementary

   a. Deficiency: (1) Age and weight of animals not reported
      (2) Animal: not fasted
      (3) LD₅₀ or confidence interval was not calculated
      (4) Principal investigator not identified

   b. Comment: Sulfuryl Fluoride is packaged as a gas in 125 lb pressurized cylinders, it is only slightly soluble in liquids and therefore not likely to be inhaled.
2. Toxicity Category II

II. Acute Guinea Pig Oral Toxicity

A. Procedure: A 1% corn oil solution of sulfuryl fluoride was prepared by bubbling the gas through chilled oil. Four groups of four female guinea pigs per group were dosed orally at 50, 100, 200 and 400 mg/kg. All surviving animals were observed for 14 days. Necropsy was conducted on each animal at the time of death.

Vehicle controls: Four female guinea pigs were dosed with 40 ml of corn oil.

B. Results:

1. LD₅₀ approximate 100 mg/kg
   Vehicle controls 2/4 dead

2. Pharmacotoxic signs - none reported
   Oily diarrhea with death reported within 2-hours


C. Conclusion

1. Classification of data - core supplementary

   a. Deficiency (1) Age and weight of animals not reported
      (2) Animals not fasted
      (3) LD₅₀ or confidence interval was not calculated
      (4) Principal investigator not identified

   b. Comment: Sulfuryl fluoride is packaged as a gas in 125 lb pressurized cylinders, it is only slightly soluble in liquid and therefore not likely to be ingested.
2. Toxicity Category - Not applicable for regulator purposes.

III. Acute Rat Inhalation Toxicity

A. Procedure: Five levels with at least 18 male and 10 female rats per level were exposed to 15,000, 5000, 4000, 2000, and 1000 ppm of Vitame vapor for 0.1 to 6.0 hours. The airflow through the chamber was continuous and ranged from 4 to 19 liters per minute. Vapor concentrations were monitored by means of a Recording Infrared Spectrometer Analyzer and found to be within 10% of the calculated levels.

B. Results

1. LC$_{50}$ 17.5 mg/liter for one hour exposure

2. Pharmacotoxic signs: Tremors and repeated convulsions. The convulsions in rats were similar to those caused by strychnine and are characterized by opisthotonos and toppling over backwards. This was generally accompanied by excessive salivation, urination and bloody tears (choanalagryorrhea). Generally convulsions were followed by death within 2 to 5 hours. A few rats survived the convulsions and recovered.

3. Necropsy: None

C. Conclusions

1. Classification of Data - Core minimum data

   a. Deficiency (1) Animals not observed for 14-days
      (2) No necropy

2. Toxicity Category III