

11/3/86

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Shaughnessy No.: 109301

Date Out of EAB: _____

To: George Calocca
Product Manager #15
Registration Division (TS-767)

From: Michael P. Firestone, PhD, Acting Chief
~~Emil Regelman, Supervisory Chemist~~
~~Review Section #3 - Special Review Section~~
Exposure Assessment Branch
Hazard Evaluation Division (TS-769C)

Attached, please find the EAB review of...

Reg./File # : 20954-11

Chemical Name: Fenvaterate

Type Product : Termiticide

Product Name : ~~Gold Crest~~

Company Name : Velsicol Chemical Corporation

Purpose : Conditional Reg of Fenv. as a Termiticide

Action Code: 350

EAB #(s) : 70016

Date Received: _____

TAIS Code: _____

Date Completed: _____

Total Reviewing Time: _____

Monitoring study requested: _____

Monitoring study voluntarily: _____

Deferrals to: _____ Ecological Effects Branch

_____ Residue Chemistry Branch

☒ Toxicology Branch

1/4

MEMORANDUM

SUBJECT: Inhalation Exposure for Fenvalerate

THRU: David A. Jaquith, Acting Chief *Robert P. Firestone, Ph.D., Actg. Chief*
Special Review Section
Exposure Assessment Branch
Hazard Evaluation Division (TS-769C)

TO: George LaRocca, PM #15
Registration Division (TS-767C) *← Who's the PM for this?*
Same PM

In order to expedite the process of exposure assessment and perhaps eliminate the need for such a long and expensive study, EAB has calculated a theoretical maximum exposure ^{for members} based on the vapor pressure for fenvalerate found in the Farm Chemicals Handbook (1987). *EAB will retain the Velsicol proposal for future review pending Toxicology Branch's decisions on the ~~known~~ risks of such exposure.*

EAB has calculated a worst-case exposure scenario for fenvalerate via the inhalation route. This theoretical calculation is based on the following assumptions: 100% saturation of the fenvalerate in the air; a total of 15 hours spent in the home, 5 hours at light work and 10 hours at rest; and a 60 kg individual which accounts for the presence of women and children in the home. The respiratory rates used are those given in Subdivision U of the Pesticide Assessment Guidelines. The calculations are listed below.

<u>GIVEN:</u>	Vapor Pressure	1.1×10^{-8} mm Hg @ ⁵ 27°C
	Absolute Temperature	27°C + 273.15 = 298.15 K
	Universal Gas Constant	0.08206 L·atm/mol·K
	Formula Weight of Fenvalerate	419.9 g/mol

IDEAL GAS LAW: $pV = nRT$ where p = pressure
 V = volume
 n = number of moles
 R = universal gas constant
 T = absolute temperature

Velsicol Chemical Corporation has submitted a proposal for ^athe conditional registration of fenvalerate as a termiticide. Included in this proposal is a protocol for an exposure assessment study for inhabitants in treated homes and for applicators of fenvalerate. (2)

Assuming a volume of 1 L:

$$pV = nRT$$

$$n = \frac{pV}{RT}$$

$$n = \frac{[(1.1 \times 10^{-8} \text{ mm Hg}) \times (1 \text{ atm}/760 \text{ mm Hg})] \times (1 \text{ L})}{(0.08206 \text{ L} \cdot \text{atm}/\text{mol} \cdot \text{K}) \times (298.15 \text{ K})}$$

$$n = \frac{1.45 \times 10^{-11} \text{ atm} \cdot \text{L}}{24.7 \text{ L} \cdot \text{atm}/\text{mol}}$$

$$n = \frac{5.9}{6.0} \times 10^{-13} \text{ mol fenvalerate/L}$$

Assuming a 15 hr day, 5 hr at light work (29 L/min) and 10 hr at rest (7.4 L/min):

$$\begin{aligned} 29 \text{ L/min} \times 60 \text{ min/hr} \times 5 \text{ hr/day} &= 8700 \text{ L} \\ 7.4 \text{ L/min} \times 60 \text{ min/hr} \times 10 \text{ hr/day} &= 4440 \text{ L} \\ \hline &13140 \text{ L inhaled/day} \end{aligned}$$

moles inhaled/day:

$$\frac{5.9}{6.0} \times 10^{-13} \text{ mol/L} \times 13140 \text{ L/day} = \frac{7.8}{7.9} \times 10^{-9} \text{ mol/day}$$

ug/day:

$$\begin{aligned} (419.9 \text{ g/mol}) \times (1 \times 10^6 \text{ ug/g}) &= 4.199 \times 10^8 \text{ ug/mol} \\ (4.199 \times 10^8 \text{ ug/mol}) \times (\frac{7.8}{7.9} \times 10^{-9} \text{ mol/day}) &= 3.3 \text{ ug/day} \end{aligned}$$

ug/kg/day:

$$\frac{3.3 \text{ ug/day}}{60 \text{ kg individual}} = 5.5 \times 10^{-2} \text{ ug/kg/day or } 5.5 \times 10^{-5} \text{ mg/kg/day}$$

It should be noted that the utility of this theoretical approach will vary from compound to compound. The more toxic chemicals, such as organophosphates, will likely yield unacceptable risks when saturation of the indoor air is assumed.

The ADI for fenvalerate of $2.5 \times 10^{-2} \text{ mg/kg/day}$ is based on a 13-week rat study in which a NOEL of 2.5 mg/kg was determined.

The estimated exposure, based on ideal gas considerations, is only about 0.2% of the ADI ($\frac{5.5 \times 10^{-5} \text{ mg/kg/day}}{2.5 \times 10^{-2} \text{ mg/kg/day}} \times 100$). Thus, EAB questions the need for an ambient air monitoring study, and defers to TOX the actual need. (3)

It must be emphasized that this is a worst-possible-case scenario and that indoor air is not likely to approach saturation with the material. This theoretical exposure assessment should allow Toxicology Branch to estimate risks from this compound. If the risks are acceptable, EAB sees no reason to request an exposure monitoring study for fenvalerate.

Karen E. Warkentien
Special Review Section
Exposure Assessment Branch
Hazard Evaluation Division (TS-769C)

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Fenvalerate (Pydrin) Caswell #077A CAS No. 51630-58-1 A.I. CODE: 109301 CFR No. 180.379	13wk feeding- rat NOEL= 2,5000 mg/kg 50.00 ppm LEL= 7,5000 mg/kg 150.00 ppm ONCO: Negative- 2 species	Neurologic signs. No evidence of oncogeni- city in rats or mice.	PADI 100 OPP Rfd= 0.025000 EPA Rfd= 0.025000 WHO Rfd 0.020000 Type: ADI	Chronic feeding- dog MF of 10 not used because preliminary review indi- cates that NOEL will be higher in the dog than the rat.	TOX complete 8/15/86. ORD verified 9/16/86. WHO last reviewed 1986.
Ferbam Caswell #458 CAS No. 14484-64-1 A.I. CODE: 034R01 CFR No. 180.114	NOEL= 0.0000 mg/kg 0.00 ppm LEL= 0.0000 mg/kg 0.00 ppm ONCO:		OPP Rfd= 0.000000 EPA Rfd= 0.000000 WHO Rfd 0.020000 Type: ADI		WHO last reviewed 1983.
Fluchloralin Caswell #460B CAS No. 33245-39-5 A.I. CODE: 108701 CFR No. 180.363	NOEL= 0.0000 mg/kg 0.00 ppm LEL= 0.0000 mg/kg 0.00 ppm ONCO:		OPP Rfd= 0.000000 EPA Rfd= 0.000000 WHO Rfd 0.000000 Type:		
Flucythrinate Caswell #002AA CAS No. 70124-77-5 A.I. CODE: 118301 CFR No. 180.400	NOEL= 0.0000 mg/kg 0.00 ppm LEL= 0.0000 mg/kg 0.00 ppm ONCO:		OPP Rfd= 0.000000 EPA Rfd= 0.000000 WHO Rfd 0.020000 Type: ADI		WHO last reviewed 1985.
Fluometuron Caswell #460A CAS No. 2164-17-2 A.I. CODE: 035503 CFR No. 180.229	103wk feeding- rat NOEL= 12,5000 mg/kg 250.00 ppm LEL= 0.0000 mg/kg 0.00 ppm ONCO: Insufficient data.	No effects noted at the highest dose tested (NCI) study.	PLD 1000 OPP Rfd= 0.013000 EPA Rfd= 0.013000 WHO Rfd 0.000000 Type:	Chronic feeding- rat Chronic feeding- dog Reproduction Teratology- rat Extra UF of 10 used for data gaps.	TOX complete 5/8/86. ORD verified 7/8/86. TOX reassess 3/06/87. ORD confirmed 3/18/87.
Fluorodifen Caswell #462AA CAS No. 15457-05-3 A.I. CODE: 085001 CFR No. 180.290	NOEL= 0.0000 mg/kg 0.00 ppm LEL= 0.0000 mg/kg 0.00 ppm ONCO:		OPP Rfd= 0.000000 EPA Rfd= 0.000000 WHO Rfd 0.000000 Type:		TOX complete 3/31/86.

No data amps.