BB-3R
TXR-132-4

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DATE: APR 3 1980

001324

359C

SUBJECT: Section 18 Emergency Use of Pirimicarb on Alfalfa Hay and Seed to control Aphi in Nevada.

FROM: Robert B. Jaeger 3/27/80
Toxicology Branch, HED (TS-769)

TO: Don Stubbs
Emergency Response Section

THRU: M. Adrian Gross, Chief
Toxicology Branch, HED (TS-769) 4/1/80

The State of Nevada has requested an emergency exemption for the use of Pirimor 50W on alfalfa hay and seed for control of aphids.

The product involved is Pirimor 50W, EPA Reg. No. 10182-7, containing 2-(dimethylamino)-5,6-dimethyl-4-pyrimidinyl dimethylcarbamate, pirimicarb. The inert ingredients have been cleared under 40 CFR 180.1001.

Rate of Application: 2-6 ozs/acre (0.0625 to 0.1875 lb a.i./acre)

Duration of Application: April 1 to August 15

Frequency of Application: Repeat every 7 to 10 days

Method of Application: Mainly by air (some ground)

Residue Chemistry Branch has concluded previously (Section 24(c) for Alfalfa i Oregon, Idaho, Washington, Nevada and California, 7/24/79), that alfalfa grown for seed is a food use since treated seed may be directed to animal feed. On that basis, Residue Chemistry Branch recommended a tolerance be requested. Toxicology Branch does not considered such usage to contribute to the human dietary directly. It could contribute via residues in meat, fat, meat by-products of cattle, hogs, horses, sheep, poultry, eggs, and milk.

Residue Chemistry Branch has determined that such an emergency usage will not result in residues exceeding 0.05 ppm in any of these animal products. Toxicology Branch finds the toxicity data sufficient to support such a limited usage of pirimicarb.

ADI = 0.004 mg/kg/day (based on 2 year dog feeding study, NOEL 0.4 mg/kg)

MPI = 0.24 mg/day/60 kg		TMRC	% ADI
Meat (incl. poultry)	0.05 (13.85%)	= .0103875	4.32
Milk	0.05 (28.62%)	= .021465	8.94
Eggs	0.05 (2.77%)	= .0020775	0.86
			14.12
		(Published) potatoes	3.37
		Total =	17.49%

EPA Form 1320-6 (Rev. 3-76)

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Residue Chemistry Branch has raised the question of the significance of possib residue of nitrosamine from such a usage and has deferred to Toxicology Branch to address this issue. The following is determined (See Toxicology Branch review 2/22/80, PP#9F2235; Residue Chemistry Branch review 10/12/79, PP#7F1915 and 2/6/80 letter from Chief, Toxicology Branch to Director, Hazard Evaluation Division, Subject: Risk Analysis for Carcinogenicity of Nitroso Prowl.):

< 0.01 ppb DEN = 0.00001 mg/kg (cattle)

< 0.002 ppb DEN = 0.00002 mg/day (poultry)

cattle = 7.18% diet

poultry = 2.94% diet

Taking the worse case (cattle), we find:

1.5 kg X 0.0718 = .1077 kg

$$\frac{0.1077 \text{ kg} \times 0.00001 \text{ mg/kg}}{60 \text{ kg}} = \frac{.0000001077}{60}$$

or

0.000,000,017,9 mg/kg/day

Log-Probit Model

Upper Limit on Risk	Virtually Safe Level of DEN (mg/kg/day)
Less than 1/100,000,000	0.000,000,083

One-Hit Model

Upper Limit on Risk	Virtually Safe Level of DEN (mg/kg/day)
1/100,000,000	0,00,000,007,42
Between 5/100,000,000	0.000,000,037,1

Therefore, dependent upon the model selected, the worse case possible (as presented by Residue Chemistry Branch), cattle, the risk is either less than 1/100,000,000 (Log-Probit Model) or between 1/100,000,000 and 5/100,000,000 (One-Hit Model).

TOX/HED:th:Initial CFRICK:3-27-80

C. Trick
3/27/80

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Tox Chem No. 359

Study	Material	EPA Accession No.	Results	TOX Category	CORE Grade
Acute Oral - Rat	50% WP	097847	LD50 = 200 mg/kg (male) = 173 mg/kg (female)	II	Minimum
Acute Dermal - Rabbit	50% WP	097847	LD50 = 1000 mg/kg (highest level tested)	II	Minimum
Acute Dermal Irritation Rabbit	50% WP	097847	Slight to mild edema & erythema	IV	Minimum
Acute Eye Irritation - Rabbit	50% WP	097847	mild irritation	III	Minimum
Delayed Neurotoxicity - Hen		097847	negative at 25 mg/kg (highest level fed)		Supplementary
Teratology - Rabbit			negative at 25 mg/kg (highest level fed)		Minimum
3-Generation Reproduction - Rat			NEL = 750 ppm (reproduction effects) LEL = 250 ppm (systemic - growth depression in adult)		
Oncogenic - Mouse			negative at 1500 ppm (highest level fed)		Minimum
Dominant Lethal - Mouse			negative at 20 mg/kg/day (highest level fed)		
2-Year Feeding - Rat			NEL = 175 ppm LEL = 250 ppm (growth depression) NEL = 750 ppm (oncogenic - highest fed level)		
2-Year Feeding - Dog			NEL = ~~0.4~~ 1.8 mg/kg changed 6/30/89 RBJ LEL = ~~1.8~~ 4.0 mg/kg (hemolytic anemia and erythyropoiesis)		Minimum Minimum
90/180-Day Oral - Dog			NEL = ~~0.4~~ 1.8 mg/kg changed 6/30/89 RBJ LEL = ~~1.8~~ 4.0 mg/kg (hemolytic anemia and		Minimum

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