11-6-79

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DATE: November 5, 1979

SUBJECT: EPA Reg.#352-371; 352-372; "Free-Standing" Summary of PP#9F2238; petition proposing the establishment of a tolerance for residues of the insecticide oxamyl in or on peanuts at 0.2 ppm, peanut hulls at 0.2 ppm and peanut hay at 10.0 ppm. CASWELL#625A; Accession#098945

FROM: William Dykstra
Toxicology Branch (TS-769) 11/6/79 WSD WSD

TO: Frank Sanders
Product Manager#12 & Residue Chemistry Branch (TS-769)

THRU: Dr. Adrian Gross, Chief
Toxicology Branch (TS-769) William N. Butler for M Adrian Gross

Petitioner: E.I. Dupont De Nemours & Co.
Wilmington, Delaware 19898

Recommendations

1) The requested tolerance can be toxicologically supported. The data considered in setting the tolerance are summarized below:

Acute Oral LD50 in Rats = 37 mg/kg (26% formulation)

°Acute Delayed Neurotoxicity: negative at 40 mg/kg
°Rat Teratology: negative at 300 ppm
°3-Generation Rat Reproduction: NOEL = 50 ppm
°Ames Assay: negative
°Recessive Assay: negative
°Host-Mediated Assay: negative
°2-Year Rat Feeding Study: oncogenic potential: negative; NOEL = 50 ppm
°2-Year Dog Feeding Study: NOEL = 100 ppm

2) The following data are currently lacking and considered desirable:

(a) teratology - 2nd species
(b) oncogenicity - 2nd species

3) The petitioner will be informed of the data gap.

4 - 5. Tolerances have previously been established under 40 CFR 180.303. Published tolerances utilize 12.51% of the ADI. Unpublished, TOX approved tolerances utilize the ADI to 24.22%. The current action utilize 0.05% of the ADI. All tolerances on oxamyl utilize 24.29% of the ADI.

6) The ADI is based on the NOEL of 50 ppm (2.5 mg/kg/day) in a 2-year rat feeding study. A 100 fold safety factor was used to calculate the ADI.

$$\text{ADI} = 2.5 \text{ mg/kg/day} \quad X \quad \frac{1}{100} = 0.025 \text{ mg/kg/day}$$

The MPI for a 60 kg person is 1.5 mg/day

7) No RPAR criteria have been exceeded and no regulatory actions are pending against the pesticide.

8) No other relevant considerations were employed in setting the tolerance.

TOX/HED:th:RD Initial WWOODROW:11-2-79

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Seed&Pod Veg(143)	0.050	3.66	0.00274

MPI	TMRC	% ADI
0.6000 mg/day/60kg	0.3938 mg/day/1.5kg	65.63

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Current Action 9F2270

CROP	Tolerance	Food Factor	mg/day/1.5kg
Soybeans(148)	1.000	0.92	0.01377
Goats(62)	0.900	0.03	0.00041
Sheep(145)	0.900	0.19	0.00262

MPI	TMRC	% ADI
0.6000 mg/day/60kg	0.4105 mg/day/1.5kg	68.43

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CFR 180.342 Chlorpyrifos 11/9/79

File last updated 11/9/79

ACCEPTABLE DAILY INTAKE DATA

RAT,Older	NOEL	S.F.	ADI	MPI
mg/kg	ppm		mg/kg/day	mg/day/60kg
0.100	2.00	10	0.0100	0.6000

Published Tolerances

CROP	Tolerance	Food Factor	mg/day/1.5kg
Bananas(7)	0.050	1.42	0.00107
Beans,lima(11)	0.000	0.19	0.00000
Beans,snap(12)	0.000	0.98	0.00000
Cattle(26)	1.500	7.18	0.16165
Corn,all types(38)	0.100	2.51	0.00377
Cottonseed(41)	0.500	0.15	0.00112
Eggs(54)	0.010	2.77	0.00042
Goats(62)	0.100	0.03	0.00005
Hogs(69)	0.100	3.43	0.00515
Milk&Dairy Products(93)	0.010	28.62	0.00429
Peaches(114)	0.050	0.90	0.00067
Poultry,exc chic(129)	0.010	0.04	0.00001
Chicken(31)	0.010	2.58	0.00039
Sheep(145)	0.100	0.19	0.00029
Turkey(164)	0.200	0.33	0.00098
Almonds(1)	0.050	0.03	0.00002
Apples(2)	0.050	2.53	0.00190
Sugar,cane&beet(154)	0.200	3.64	0.01091
Pears(116)	0.050	0.26	0.00019
Plums,not prunes(124)	0.050	0.09	0.00007
Sweet Potatoes(157)	0.100	0.40	0.00060
Sorghum(147)	0.750	0.03	0.00034
Molasses(96)	3.000	0.03	0.00138

MPI	TMRC	% ADI
0.6000 mg/day/60kg	0.1953 mg/day/1.5kg	32.54

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Unpublished,Tox Approved 7E2010,8E2038,6F1786,9F2193,9E2215,9F2221,9H5227

CROP	Tolerance	Food Factor	mg/day/1.5kg
Broccoli(19)	0.500	0.10	0.00077
Cabbage,sauerkraut(22)	0.500	0.74	0.00552
Cauliflower(27)	0.500	0.07	0.00054
Rutabagas(139)	3.000	0.03	0.00135
Prunes(130)	0.050	0.04	0.00003
Tomatoes(163)	0.500	2.87	0.02156
All foods(197)	0.025	100.00	0.03750
Radishes(133)	3.000	0.03	0.00135
Oranges(108)	2.500	2.17	0.08125
Lemons(82)	2.500	0.17	0.00652
Peanuts(115)	0.500	0.36	0.00268
Nectarines(100)	0.050	0.03	0.00002
Apples(2)	0.950	2.53	0.03605
Cucumbers,inc pickl(46)	0.050	0.73	0.00054
Pumpkin,inc squash(131)	0.050	0.11	0.00008

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