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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

2-22-82 RCB
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MEMORANDUM

FEB 22 1982

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

DATE: February 9, 1982

SUBJECT: EPA Reg. #464-LLE; PP#2F2620, 2H5331; Chlorpyrifos in/on Apples
CASWELL #219AA Accession#070576

FROM: William Dykstra, Toxicologist
Toxicology Branch/HED (TS-769) WAD

LDC
2/9/82

TO: Jay Ellenberger (12)
Registration Division (TS-767) JEP
and
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

Recommendations:

- 1) The requested tolerances can be toxicologically supported.
- 2) A rat teratology study and a rat reproduction study are required to be submitted within a reasonable period of time.

Review:

1. Section F. PROPOSED TOLERANCES FOR THE PESTICIDE CHEMICAL.

A tolerance for combined residues of the insecticide chlorpyrifos [0,0-diethyl 0-(3,5,6-trichloro-2-pyridyl)phosphorothioate], and its metabolite 3,5,6-trichloro-2-pyridinol is proposed for addition to 40 CFR 180.342 as follows:

1 part per million in or on apples.

Under the provisions of Section 409 of the Federal Food, Drug, and Cosmetic Act a food additive tolerance for combined residues of the insecticide chlorpyrifos [0,0-diethyl 0-(3,5,6-trichloro-2-pyridyl)phosphorothioate] and its metabolite 3,5,6-trichloro-2-pyridinol is proposed for addition to 21 CFR 561.98 as follows:

8 parts per million in dried apples pomace intended for animal feed when present therein as a result of application of the insecticide to growing apples.

2. No new toxicity data were submitted with this petition.
3. The formulation proposed for use is Lorsban 50W (reviewed in memo of 8/30/79 from W. Dykstra to F. Sanders). Inerts are cleared under 180.1001.
4. Tolerances are established under 40 CFR 180.342.
5. Previously submitted toxicity data:
 - °Acute Rat Oral - LD₅₀ = 118-245 mg/kg
 - °Mouse Teratology: Negative at 25 mg/kg/day (highest dose)
 - °3-Generation Rat Reproduction Study: NOEL = 1.0 mg/kg/day (highest dose)
 - °Acute Delayed Neurotoxicity (hen): Negative at 100 mg/kg
 - °2-Year Mouse Oncogenicity Study: Negative at 15 ppm (highest dose)
 - °2-Year Rat Feeding Study: RBC ChE NOEL = 0.1 mg/kg/day
Systemic NOEL = 3.0 mg/kg/day (highest dose)
Oncogenic potential: Negative
 - °2-Year Dog Feeding Study: RBC ChE NOEL = 0.1 mg/kg/day
Systemic NOEL = 3.0 mg/kg/day (highest dose)
6. The ADI is based on the RBC ChE NOEL of 0.1 mg/kg/day in the 2-year rat feeding study. This is the most sensitive species for which chronic toxicity are available. A 10-fold safety factor was used to calculate the ADI.

$$ADI = NOEL \times \frac{1}{10}$$

$$ADI = 0.1 \text{ mg/kg/day} \times \frac{1}{10} = 0.01 \text{ mg/kg/day}$$

The MPI for a 60 kg person is 0.6 mg/day

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7. No RPAR criteria have been exceeded and no regulatory actions are pending against the pesticide.
8. Published tolerances utilize 59.16% of the ADI. Unpublished, Toxicology Branch tolerances utilize the ADI to 92.69%. The current action utilizes 6.01% of the ADI. All tolerances utilize 98.70% of the ADI.

Conclusions and Recommendations:

The requested tolerances can be toxicologically supported.

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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 (oil) (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
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
Broccoli (19)	2.000	0.10	0.00307
Cabbage, sauerkraut (22)	2.000	0.74	0.02207
Cauliflower (27)	2.000	0.07	0.00215
Rutabagas (139)	3.000	0.03	0.00135
Tomatoes (163)	0.500	2.87	0.02156
Radishes (133)	3.000	0.03	0.00135
Nectarines (100)	0.050	0.03	0.00002
Brussel Sprouts (20)	2.000	0.03	0.00090
Peanuts (115)	0.500	0.36	0.00268
Oranges (108)	2.500	2.17	0.08125
Lemons (82)	2.500	0.17	0.00652
Cucumbers, inc pickl (46)	0.100	0.73	0.00109
Pumpkin, inc squash (131)	0.100	0.11	0.00017
Seed&Pou Veg (143)	0.100	3.66	0.00549
Mint (193)	10.000	0.03	0.00450
Turnips (165)	3.000	0.05	0.00230
Turnip Greens (166)	1.000	0.03	0.00045
Chinese Cabbage (177)	2.000	0.03	0.00090
Peppers (120)	1.000	0.12	0.00184
Prunes (130)	0.050	0.04	0.00003
Apples (2)	0.050	2.53	0.00190

MPI	TMRC	% ADI
0.6000 mg/day (60kg)	0.3549 mg/day (1.5kg)	59.16

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