Toxicology Branch/HED Review

JUN 18 19

6/18/84 RCB

To: Jay Ellenberger

Registration No(s).: 464-

Pesticide Petition No(s).: 4F3008 / 1H5295

Caswell No(s).: 219AA

Chemical(s).: Chlorpyrifos

RAC(s) - tolerance(s): Tomatoes, ~~1.5~~ 1.5 ppm total, 1.0 ppm chlorpyrifos per se, also establish related milk & meat tolerances (see attached Section F

Inert(s) cleared 180.1001: YES

% of ADI occupied: Existing: 350.83 Resulting 409.10

Attached (?): ADI printout: (YES)/NO; TOX "one-liner": YES/(NO); DER: YES/NO

Existing regulatory actions against registration: None

RPAR status: None

New Data: See Registration Standard

Data considered in setting the ADI: Human Study with NOEL of 0.03 mg/kg/day for plasma ChE and clinical effects.

Data gaps: Chronic dog, chronic rat, mutagenicity, metabolism and mouse oncogenicity (see Registration Standard).

Recommendation: Toxicology Branch cannot recommend favorably for this action due to the major data gaps (see above) and large % of ADI currently utilized. Incremental risk is also large (16% increase in the TMRC).

Comments:

Reviewer: Gary J. Burin Gary J. Burin Date: 6/15/84

Section Head: Laurence D. Chitlik LDC 6/18/84

JUN 18 1984

December 15, 1983

SECTION F. PROPOSED TOLERANCES FOR THE PESTICIDE CHEMICAL

Tolerances 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 are proposed as revisions to 40 CFR 180.342 as follows:

1.5 parts per million (of which no more than 1 ppm is chlorpyrifos) in or on tomatoes;

2.5 parts per million (of which no more than 2.0 ppm is chlorpyrifos) in or on cattle, meat, fat and meat byproducts;

2.0 parts per million (of which no more than 1.0 ppm is chlorpyrifos) in or on goats, meat, fat and meat byproducts;

0.5 part per million (of which no more than 0.3 ppm is chlorpyrifos) in or on hogs, meat, fat and meat byproducts;

1.5 parts per million (of which no more than 0.8 ppm is chlorpyrifos) in or on horses, meat, fat and meat byproducts;

2.0 parts per million (of which no more than 1.0 ppm is chlorpyrifos) in or on sheep, meat, fat and meat byproducts;

0.5 part per million (of which no more than 0.25 ppm is chlorpyrifos) in or on milk, fat; and

0.03 part per million (of which no more than 0.02 ppm is chlorpyrifos) in or on milk, whole.

Under the provisions of Section 409 of the Federal Food, Drug, and Cosmetic Act a feed 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 as a revision to 21 CFR 561.98 as follows:

100 parts per million (of which no more than 65 ppm is chlorpyrifos) in or on tomato pomace intended for animal feed, resulting from application of the insecticide to the growing crop tomatoes.

File last updated 6/14/84

ACCEPTABLE DAILY INTAKE DATA

Human mg/kg	NOEL ppm	S.F.	ADI mg/kg/day	HPI mg/day(60kg)
0.030	1.20	10	0.0030	0.1800

Published Tolerances

CROP	Tolerance	Food Factor	mg/day(1.5kg)
Bananas(7)	0.050	1.42	0.00107
Corn,all types(38)	0.100	2.51	0.00377
Cottonseed (oil)(41)	0.500	0.15	0.00112
Eggs(54)	0.100	2.77	0.00416
Hogs(69)	0.500	3.43	0.02575
Milk&Dairy Products(93)	0.020	28.62	0.00858
Peaches(114)	0.050	0.90	0.00067
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
Sorgnum(147)	0.750	0.03	0.00034
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(106)	0.050	0.03	0.00002
Brussel Sprouts(20)	2.000	0.03	0.00090
Peanuts(115)	0.500	0.36	0.00268
Cucumbers,inc pickl(46)	0.200	0.73	0.00109
Pumpkin,inc squash(131)	0.100	0.11	0.00017
Seed&Pod Veg(143)	0.100	3.66	0.00549
Mint(193)	1.000	0.03	0.00045
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
Goats(62)	1.000	0.03	0.00045
Sheep(145)	1.000	0.19	0.00291
Poultry(128)	0.500	2.94	0.02207
Horses(208)	1.000	0.03	0.00045
Strawberries(152)	0.500	0.18	0.00138
Soybeans (oil)(148)	0.500	0.92	0.00689
Cattle(26)	2.000	7.18	0.21553
Onion(dry bulb)(106)	0.500	0.72	0.00537
Sunflower(156)	0.250	0.03	0.00011
Citrus Fruits(33)	1.000	3.81	0.05715
Grapes, not raisins(67)	0.500	0.45	0.00337
Cherries(30)	2.000	0.10	0.00307
Figs(57)	0.100	0.03	0.00005
Cranberries(44)	1.000	0.03	0.00045
Apples(2)	1.500	2.53	0.05693
Sugar,cane&beet(154)	1.000	3.64	0.05457
Molasses(96)	15.000	0.03	0.00690

Almonds(1)	0.200	0.03	0.00009
Walnuts(167)	0.200	0.03	0.00009
Asparagus(5)	5.000	0.14	0.01073
Kiwi Fruit(204)	2.000	0.03	0.00090

MPI	TMRC	% ADI
0.1800 mg/day(60kg)	0.5637 mg/day(1.5kg)	313.15

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Unpublished,Tox Approved 1G2438,3E2819,3E2886

CROP	Tolerance	Food Factor	mg/day(1.5kg)
All Foods(197)	0.025	100.00	0.03750
Wheat(170)	0.150	10.36	0.02332
Collards(37)	2.000	0.08	0.00245
Kale(75)	2.000	0.03	0.00090
Kohlrabi(76)	2.000	0.03	0.00090
Mustard Greens(99)	2.000	0.06	0.00184
Rest of Brassica group(214)	2.000	0.03	0.00090
Mushrooms(97)	0.050	0.03	0.00002

MPI	TMRC	% ADI
0.1800 mg/day(60kg)	0.6315 mg/day(1.5kg)	350.83

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Current Action 4/3008

CROP	Tolerance	Food Factor	mg/day(1.5kg)
Tomatoes(163)	1.000	2.87	0.04312
Cattle(26)	0.500	7.18	0.05388
Goats(62)	1.000	0.03	0.00045
Horses(208)	0.500	0.03	0.00023
Sheep(145)	1.000	0.19	0.00291
Milk&Dairy Products(93)	0.010	28.62	0.00429

MPI	TMRC	% ADI
0.1800 mg/day(60kg)	0.7364 mg/day(1.5kg)	409.10

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