

US EPA ARCHIVE DOCUMENT

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:

0.5 part per million in or on sunflower seed hulls intended for animal feed when present therein as the result of application of the insecticide to growing sunflowers.

2. No new toxicity data were submitted.
3. The formulations proposed for use are Lorsban 15G (EPA Reg. #464-523) and Lorsban 4E (EPA Reg. #464-448). The inert ingredients 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 Oncogenicity 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)

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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.

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

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

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

7. Published tolerances utilize 56.36% of the ADI. TOX approved, unpublished tolerances utilize the ADI to 82.77%. The current action utilizes 0.02% of the ADI. All tolerances utilize 82.79% of the ADI (computer printout attached).

Conclusions and Recommendations:

The requested tolerances can be toxicologically supported.

Attachment

TS-769:th:TOX/HED:WDykstra:12-1-81:card 2

CFR 180.342

Chlorpyrifos

11/30/81

File last updated 11/30/81

ACCEPTABLE DAILY INTAKE DATA

RAT, Older mg/kg	NOEL ppm	S.F.	ADI mg/kg/day	MPI 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
Apples (2)	0.050	2.53	0.00190
Oranges (108)	2.500	2.17	0.08125
Lemons (82)	2.500	0.17	0.00652

MPI 0.6000 mg/day (60kg) TMRC 0.3382 mg/day (1.5kg) % ADI 56.36

Unpublished, Tox Approved 6F1786, 2191, 2221, 2270, 2575, 9H5227, 0E2283, 2387, 2411, 2412
 2E2587

CROP	Tolerance	Food Factor	mg/day (1.5kg)
Prunes (130)	0.050	0.04	0.00003
All foods (197)	0.025	100.00	0.03750
Cucumbers, inc pickl (46)	0.050	0.73	0.00054
Pumpkin, inc squash (131)	0.050	0.11	0.00008

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Seeds&Pod Veg(143)	0.050	3.66	0.00274
Goats(62)	0.900	0.03	0.00041
Sheep(145)	0.900	0.19	0.00262
Strawberries(152)	0.300	0.18	0.00083
Mint(193)	10.000	0.03	0.00450
Onion(dry bulb)(106)	0.500	0.72	0.00537
Turnips(165)	3.000	0.05	0.00230
Turnip Greens(166)	1.000	0.03	0.00045
Wheat(170)	0.150	10.36	0.02332
Chinese Cabbage(177)	0.500	0.03	0.00023
Peppers(120)	0.500	0.12	0.00092
Cherries(30)	1.500	0.10	0.00230
Soybeans (oil)(148)	1.000	0.92	0.01377
Citrus Fruits(33)	1.000	3.81	0.05718
Grapes, not raisins(67)	0.500	0.45	0.00337

-----MPI----- TMRC ----- % ADI
 0.6000 mg/day(60kg) 0.4966 mg/day(1.5kg) 82.77

Current Action PP# 2F2588

-----CROP----- Tolerance Food Factor mg/day(1.5kg)
 Sunflower(156) 0.200 0.03 0.00009

-----MPI----- TMRC ----- % ADI
 0.6000 mg/day(60kg) 0.4967 mg/day(1.5kg) 82.79
