

3-16-82 RCB (Pet
her)

To: Hoyt Jamison (43)
RD, TS-767
RCB, TS-769

Toxicology Branch/HED Review

Arne
File petition

Registration No(s): _____

Pesticide Petition No(s): 1E2529

Caswell No(s): 219AA

Chemical(s): Chlorpyrifos

RAC(s) - tolerance(s): 2.0 ppm in/on cherries

Inert(s) cleared 180.1001: YES

Existing % of ADI occupied: 99.41%

Resulting % of ADI occupied: 99.54%

Resulting % increase in TMRC: .00077 mg/day; 0.12%

ADI printout attached: ☒ YES ☐ NO

Existing regulatory actions against registration: NONE

RPAR status: NONE

TOX "one-liner" attached: ☒ YES ☐ NO

Data considered in setting the tolerance: Federal Register Notice attached. - 1/15/82 data

Data gaps: rat teratology and rat reproduction

Recommendation: The requested tolerance can be toxicologically supported.

Comments: _____

Reviewer: William Dykstra WYD

Date: March 16, 1982

Section Head: Laurence D. Chitlik LDC

MAR 23 1982



RCB has not received petition
as of 7/1/81. Requested copy from RD (Critchlow) on 7/1/81
RCB
R44

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

DATE: June 23, 1981

SUBJECT: PP#1E2529; Chlorpyrifos in/on Cherries at 1.5 ppm
CASWELL#219AA Accession#070135

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

WAD for LDC
6/23/81

TO: Pat Critchlow (43)
Registration Division (TS-769)
and
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

11/1/81 WLB

Recommendations:

1. The requested tolerance can be toxicologically supported.

Review:

- A. Proposed Tolerance for the Pesticide Chemical Chlorpyrifos in or on Cherries.

The petitioner, IR-4 National Director, Dr. R.H. Kupelian, on behalf of the IR-4 Technical Committee and the Agricultural Experiment Stations of Michigan and Ohio, requests the establishment of a tolerance for combined residues of the pesticide chlorpyrifos (0,0-diethyl-0-(3,5,6-trichloro-2-pyridyl)phosphorothioate and its metabolite 3,5,6-trichloro-2-pyridinol in or on the raw agricultural commodity cherries at 1.5 ppm.

- B. 1) No new toxicity data were submitted with this petition.
- 2) The formulation proposed for use is Lorsban 4E (EPA Reg.#464-448). The inert ingredients are cleared under 180.1001.
- 3) Tolerances are established under 40 CFR 180.342.
- 4) Previously Submitted Toxicity Data

°Acute Rat Oral LD₅₀ = 118-245 mg/kg

°180-Day Rat Feeding Study: RBCChE NOEL = 0.15 mg/kg/day
Systemic NOEL = 0.75 mg/kg/day
(highest dose)

°90-Day Dog Feeding Study: RBCChE NOEL = 0.03 mg/kg/day
Systemic NOEL = 20 ppm

°Mouse Teratology: Negative at 25 mg/kg/day (highest dose)

°3-Generation Rat Reproduction Study: NOEL = 1.0 mg/kg
(highest dose)

°2-Year Rat Feeding Study: RBCChE NOEL = 0.1 mg/kg/day
Systemic NOEL = 3.0 mg/kg/day
(highest dose)

Oncogenic potential: negative

°2-Year Dog Feeding Study: RBCChE NOEL = 0.1 mg/kg/day
Systemic NOEL = 3.0 mg/kg/day
(highest dose)

- 5) The ADI is based on the RBCChE 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

- 6) Published tolerance utilize 41.29% of the ADI. Unpublished Toxicology Branch approved tolerances utilize the ADI to 78.31%. The current action utilizes 0.38% of the ADI. All tolerances utilize 78.69% of the ADI (computer printout attached).

Conclusion and Recommendations:

The requested tolerance can be toxicology supported.

File last updated 6/23/81

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
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

MPI 0.6000 mg/day (60kg) TMRC 0.2477 mg/day (1.5kg) % ADI 41.29

Unpublished, Tox Approved 6F1786, 9F2191, 2221, 2270, 9H5227, 0E2283, 2387, 2411, 241
1G2438, 1E2523

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
Oranges (108)	2.500	2.17	0.08125
Lemons (82)	2.500	0.17	0.00652
Peanuts (115)	0.500	0.36	0.00268
Apples (2)	0.950	2.53	0.03605

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Pumpkin, i	squash(131)	0.050	0.11	0.00008
Seed&Pod	Veg(143)	0.050	3.66	0.00274
Soybeans	(148)	1.000	0.92	0.01377
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

MPI	TMRC	% ADI
0.6000 mg/day(60kg)	0.4698 mg/day(1.5kg)	78.31

Current Action PP# 1E2529

CROP	Tolerance	Food Factor	mg/day(1.5kg)
Cherries(30)	1.500	0.10	0.00230

MPI	TMRC	% ADI
0.6000 mg/day(60kg)	0.4721 mg/day(1.5kg)	78.69
