

US EPA ARCHIVE DOCUMENT



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

12-10-85
RCB

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Krat...
File...*

DEC 10 1985

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM:

SUBJECT: Pesticide Petition No. 4E 3088; Bayleton (Triadimefon)[®]
on Raspberries
Caswell No. 862AA

TO: Hoyt Jamerson
Product Manager (43)
Registration Division (TS-767)

THRU: Robert P. Zendzian, Ph.D. *12/9/85*
Section Head, Review Section IV
Toxicology Branch
Hazard Evaluation Division (TS-769)

FROM: George Z. Ghali, Ph.D. *G. Ghali*
Toxicology Branch *12/10/85*
Hazard Evaluation Division (TS-769) *12/10/85*

Petitioner: IR-4 Project
Agricultural Experimental Station
Rutgers University
New Brunswick, NJ 08903

Action Requested:

Establishment of a tolerance for the combined residues of the fungicide Bayleton and its metabolites containing chlorophenoxy and triazole moities in or on the raw agricultural commodity raspberries at 2.0 ppm.

Conclusions and Recommendations:

Toxicology Branch recommends for the establishment of the proposed tolerance of 2.0 ppm for the residues of Bayleton and its metabolites containing chlorophenoxy and triazole moities on raspberries.

The proposed use and the resulting residue level of 2.0 ppm allow adequate dietary margin of safety (over 1000) for maternal toxicity and teratogenic effects.

Since worker exposure estimates are not available to us at this time, and pursuant to C.F. Chaisson memo of January 14, 1983 to H. Jacoby, protective clothing must be used by all child bearing age-female workers throughout the application and all other farming processes.

Risk Assessment:

Bayleton is teratogenic in animals (cleft palates in rats) with NOEL's of 50 mg/kg/day for embryonic/fetal development, and 10 mg/kg/day for maternal toxicity. This fact implies that any current or future regulatory decision should be based on a complete exposure profile. This includes; exposure due to dietary ingestion (dietary exposure) as well as other types of exposures associated with the use of this pesticide (worker exposure). The risk can be best expressed in this case by the margin of safety (MOS). The margin of safety is defined as the ratio of the "no observed effect level" of a given effect to exposure, and can be calculated as follows:

$$\text{MOS} = \frac{\text{NOEL (mg/kg)}}{\text{Exposure (mg/kg)}}$$

The proposed tolerance of Bayleton residues on raspberries is 2.0 ppm. If we assume a reasonable worst case where a pregnant woman may consume about 100 gm of caneberrries in a single serving. This constitute 200 ug (0.2mg) of bayleton/60 kg person or 0.0032 mg/kg. On this basis the margin of safety for dietary exposure can be calculated as follows:

$$\text{MOS terata (dietary)} = \frac{50 \text{ mg/kg}}{0.0032 \text{ mg/kg}} = 15151$$

$$\text{MOS mat. tox (dietary)} = \frac{10 \text{ mg/kg}}{0.0032 \text{ mg/kg}} = 3030$$

Since no worker exposure estimats are available, the margin of safety for female workers can not be calculated, and the use of protective clothing by child bearing age-female workers is again emphasized.

File last updated 4/1/85

ACCEPTABLE DAILY INTAKE DATA

RAT, Older	NOEL	S.F.	ADI	MPI
mg/kg	ppm		mg/kg/day	mg/day (60kg)
2.500	50.00	100	0.0250	1.5000

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Published Tolerances

CROP	Tolerance	Food Factor	mg/day (1.5kg)
Apples(2)	1.000	2.53	0.03795
Barley(8)	1.000	0.03	0.00045
<u>chick peas</u> (214)	0.100	0.03	0.00005
Eggs(54)	0.040	2.77	0.00166
Cattle(26)	1.000	7.18	0.10777
Grapes, not raisins(67)	1.000	0.45	0.00675
Goats(62)	1.000	0.03	0.00045
Hogs(69)	0.040	3.43	0.00206
Horses(203)	1.000	0.03	0.00045
Milk&Dairy Products(93)	0.040	23.62	0.01717
Pears(116)	1.000	0.26	0.00383
Pineapple(123)	3.000	0.30	0.01334
Poultry(128)	0.040	2.94	0.00177
Sheep(145)	1.000	0.19	0.00291
Meat(170)	1.000	10.36	0.15544
Almonds(1)	0.050	0.03	0.00002

MPI	MTRC	% ADI
1.5000 mg/day (60kg)	0.3521 mg/day (1.5kg)	23.47

Unpublished, Fox Approved 0E2393, 0F2349, 3F2387, 3F2938, 4E3088, 4F3124, 5E3168

CROP	Tolerance	Food Factor	mg/day (1.5kg)
Cucumbers, not pickl(47)	0.000	0.34	0.00000
Tomatoes(163)	0.200	2.67	0.00862
Melons(92)	0.000	2.00	0.00000
Apricots(3)	4.000	0.11	0.00675
Pumpkin, inc squash(131)	0.300	0.11	0.00051
Watermelon(153)	0.300	1.43	0.00644
Nectarines(100)	4.000	0.03	0.00180
Peaches(114)	4.000	0.90	0.05396
Plums, inc prunes(125)	4.000	0.13	0.00797
Sugar, cane&beet(154)	1.000	3.64	0.05457
Melons(92)	0.300	2.00	0.00901
Cucumbers, not pickl(47)	0.300	0.34	0.00152
Coffee(36)	0.050	0.75	0.00056
Cottonseed (oil)(41)	0.200	0.15	0.00045
Sugar, cane&beet(154)	0.000	3.64	0.00000
Strawberries(152)	0.300	0.13	0.00083
Blackberries(15)	1.000	0.03	0.00045
Boysenberries(17)	1.000	0.03	0.00045
Dewberries(52)	1.000	0.03	0.00045
Loganberries(86)	1.000	0.03	0.00045
Raspberries(135)	1.000	0.03	0.00045
Youngberries(172)	1.000	0.03	0.00045

Tomatoes(163)	0.200	2.87	0.00862
Mangoes(38)	0.070	0.03	0.0003

MPI	TMRC	% ADI
1.5000 mg/day(60kg)	0.5164 mg/day(1.5kg)	34.43

Current Action 4E3088 [Revised Sec F]

CROP	Tolerance	Food Factor	mg/day(1.5kg)
Raspberries(135)	1.000	0.03	0.00045

MPI	TMRC	% ADI
1.5000 mg/day(60kg)	0.5169 mg/day(1.5kg)	34.46
