4-6-83 RCB

5114

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

MEMORANDUM APR 6 1983

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

TO: Henry Jacoby, Product Manager #21
Registration Division (TS-767)

THRU: Christine F. Chaisson, Section Head C.F. Chaisson 3/18/83
Section IV, Toxicology Branch
Hazard Evaluation Division (TS-769)

SUBJECT: Bayleton on Almonds; PP 2F2837.

TOX Chem No. 862AA

Action Requested:

Establishment of tolerances for the combined residues of Bayleton and its metabolite B-(4-chloro-phenoxy)-α-(1,1-dimethyl-ethyl)-1H-1,2,4-triazol-1-ethanol in/on almond meats and hulls at 0.05 and 0.10 ppm, respectively.

Conclusions and Recommendations:

1. Toxicology Branch recommends for the establishment of the proposed tolerance on almond meats. We defer to the Residue Chemistry Branch the question of whether the currently established tolerances for eggs, milk, meat and meat by-products are adequately covered under the proposed residue tolerance for hulls.

2. Adequate margins of safety exist for embryonic/fetal development and maternal toxicity.

3. The inerts of the alternate 50% WP formulation are all cleared for food use except for [redacted], since it is not identified (see attached computer printout for inert clearance).

Detailed Considerations: INERT INGREDIENT INFORMATION IS NOT INCLUDED

1. The ADI for Bayleton is considered to be 0.025 mg/kg/day based on a NOEL of 2.5 mg/kg in a long-term feeding study in the rat, using a 100 fold safety factor.

2. Published and TOX approved tolerances utilize 25.48% of the ADI. This represents 0.3821 mg/day (1.5 kg diet). Establishment of the proposed tolerance on almond meat will not practically increase the utilized portion of the ADI and will only increase the TMRC with about 0.0001 mg/day.

3. Bayleton is known to be teratogenic in rats with NOEL's of 10 and 50 mg/kg for maternal toxicity and teratogenicity, respectively. The margins of safety for dietary exposure were calculated for both of these effects and found to be 12,500 and 62,500 for maternal toxicity and teratogenicity, respectively.

Toxicology Profile:

All relevant toxicology data are summarized in a memo addressed to H. Jacoby on 7/16/82.

George Z. Ghali, Ph.D. G. Ghali 3/11/8
Section IV, Toxicology Branch
Hazard Evaluation Division (TS-769)
for WLB 4/5/83

Attachment

OPP:HED:TOX:G.GHALI:sb 3/10/83 X77395 Rm 820 #m25

TRIADIMEFON

Page 3 is not included in this copy.

Pages _____ through _____ are not included.

The material not included contains the following type of information:

X Identity of product inert ingredients.

____ Identity of product impurities.

____ Description of the product manufacturing process.

____ Description of quality control procedures.

____ Identity of the source of product ingredients.

____ Sales or other commercial/financial information.

____ A draft product label.

____ The product confidential statement of formula.

____ Information about a pending registration action.

____ FIFRA registration data.

____ The document is a duplicate of page(s) _____.

____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

File last updated 3/8/83

ACCEPTABLE DAILY INTAKE DATA

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

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
Chick peas (214)	0.100	0.03	0.00005
Eggs(54)	0.400	2.77	0.01662
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(208)	1.000	0.03	0.00045
Milk&Dairy Products(93)	0.040	28.62	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
Wheat(170)	1.000	10.36	0.15544

MPI	TMRC	% ADI
1.5000 mg/day(60kg)	0.3670 mg/day(1.5kg)	24.47

****

Unpublished,Tox Approved 0E2393,0F2349

CROP	Tolerance	Food Factor	mg/day(1.5kg)
Cucumbers,not pickl(47)	0.100	0.34	0.00051
Tomatoes(163)	0.200	2.87	0.00862
Melons(92)	0.200	2.00	0.00601

MPI	TMRC	% ADI
1.5000 mg/day(60kg)	0.3821 mg/day(1.5kg)	25.48

****

Current Action 3F2837

CROP	Tolerance	Food Factor	mg/day(1.5kg)
Almonds(1)	0.050	0.03	0.00002

MPI	TMRC	% ADI
1.5000 mg/day(60kg)	0.3822 mg/day(1.5kg)	25.48

****