

US EPA ARCHIVE DOCUMENT



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

8-19-83
Smith
File petals

AUG 19 1983

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

TO: Henry Jacoby
Product Manager No. 21
Registration Division (TS-767)

THRU: Chad B. Sandusky, Acting Section Head
Toxicology Branch
Hazard Evaluation Division (TS-769C)

SUBJECT: RP#3F2887; Bayleton in/on Apricots, Peaches, Nectarines,
Plums, Cucurbits and Sugarbeets.

Caswell # 862 AA
Chad B Sandusky
8/15/83
H. Jacoby 8/19/83

Petitioner: Mobay Chemical Corporation, Kansas City, Missouri,
64120.

Action Requested:

1. Establishment of the following tolerances:

Apricots	4.0 ppm
Peaches	4.0 ppm
Nectarines	4.0 ppm
Plums (fresh prunes)	4.0 ppm
Cucurbits	0.3 ppm
Sugar beets	1.0 ppm
Sugar beet tops	3.0 ppm

2. Registration of an alternate formulation for Bayleton
50% WP with and without [redacted] water
soluble package.

INERT INGREDIENT INFORMATION IS NOT INCLUDED

Conclusions and Recommendations:

1. The proposed tolerances are toxicologically supported. Adequate margins of safety (over 1000) exist for maternal toxicity, and embryonic and fetal development for dietary exposure and worker exposure.
2. The ADI is considered to be 0.025 mg/kg/day based on a NOEL of 50 ppm generated from a 2-year rat feeding study. Published and tox approved tolerances in addition to the current tolerance utilized 33.55% of the ADI.

3. The inert ingredients in the alternate 50% WP formulation except [REDACTED] are cleared for food use. [REDACTED] are not identified (D. Ritter, 6/ /83, see attached printout).
4. Pursuant to C.F. Chaisson memo of January 14, 1983 addressed to H. Jacoby, protective clothing (including gloves) must be used by all workers during all agricultural practices.

Detailed Considerations:

1. Bayleton is teratogenic in rats (cleft palates) with NOEL's of 50 mg/kg/day and 10 mg/kg/day for maternal toxicity, and embryonic and fetal development respectively.
2. The risk assessment in such cases is considered to be of two components:

a) Risk associated with dietary exposure -

This type of risk is best expressed as the margin of safety "MOS" which is defined as the ratio between the NOEL in mg/kg and the exposure (dietary) in mg/kg. Assuming a reasonable worst case where a pregnant female consumes 200 g of a food commodity containing the highest proposed residue level of 4 ppm, the margins of safety were calculated to be 1000 and 5000 for maternal toxicity, and embryonic and fetal development respectively.

b) Risk associated with worker exposure -

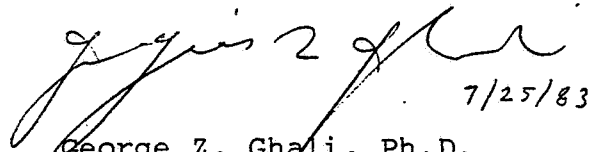
This is the risk arising from the exposure of farm workers during normal agricultural practices. This type of exposure can be significantly decreased to a reasonable safe level through the use of protective clothing. (see C.F. Chaisson memo of January 14, 1983 addressed to H. Jacoby). However crops like apricots, peaches, nectarine, plums and cucurbits are hand harvested. This may not constitute a problem in the case of cucurbits where gloves could be used but may constitute a problem in the case of stone fruits where wearing gloves is not practical for harvesting.

In a previous memo by G. Ghali dated December 7, 1982, Toxicology Branch considered an exposure of 0.5 mg/kg as the maximum allowable daily exposure to maintain a margin of safety of 1000 for female workers.

In a memo by J. Adams dated January 14, 1982, the EFB calculated the worker exposure level to be less than 0.187 mg/kg. This level of exposure is considered lower than the maximum allowable exposure and therefore adequate margins of safety are maintained for female workers under these conditions.

Toxicology Profile:

All relevant toxicology data are summarized in a memo by G. Ghali addressed to J. Jacoby on March 23, 1982 with respect to PP#s 1F2474 and 1H5292.



7/25/83

George Z. Ghali, Ph.D.
Toxicology Branch
Hazard Evaluation Division
(TS-769C)

File last updated 5/5/83

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

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
<i>Check...</i> (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(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)	0.3520 mg/day (1.5kg)	23.47

Unpublished, Tox Approved 2G2638, 0E2393, 0F2349, 3F2349

CROP	Tolerance	Food Factor	mg/day (1.5kg)
Almonds(1)	0.100	0.03	0.00005
Apricots(3)	0.000	0.11	0.00000
Nectarines(100)	0.000	0.03	0.00000
Peaches(114)	0.000	0.90	0.00000
Cucumbers, not pickl(47)	0.000	0.34	0.00000
Tomatoes(163)	0.200	2.87	0.00862
Melons(92)	0.000	2.00	0.00000
Almonds(1)	0.050	0.03	0.00002

MPI	TMRC	% ADI
1.5000 mg/day (60kg)	0.3607 mg/day (1.5kg)	24.05

Current Action 3F2887

CROP	Tolerance	Food Factor	mg/day (1.5kg)
Apricots(3)	4.000	0.11	0.00675
Pumpkin, inc squash(131)	0.300	0.11	0.00051
Watermelon(169)	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 pick- (47)	0.300	0.34	0.00152

MPI	TMRC	% ADI
1.5000 mg/day(60kg)	0.5033 mg/day(1.5kg)	33.55

DRAFT

TRIAMINOFON (BAYLETON)

Page 6 is not included in this copy.

Pages _____ through _____ are not included.

The material not included contains the following type of information:

- 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.
