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

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

in petition

JL 28 86

MEMORANDUM

SUBJECT: Pesticide Petition No. 6F3419 - Bayleton in/on
Corn, Lettuce, Potatoes, Cottonseed, Peanuts

Caswell No. 862AA

FROM: George Z. Ghali, Ph.D.
Mission Support Staff
Toxicology Branch
Hazard Evaluation Division (TS-769C)

TO: Henry Jacoby, PM 21
Fungicide-Herbicide Branch
Registration Division (TS-767C)

THUR: Reto Engler, Chief
Mission Support Staff
Toxicology Branch
Hazard Evaluation Division (TS-769C)

Reto Engler
7/25/86

Registrant: Mobay Chemical Corporation
Kansas City, MO 64120

W.S.B.

Action Requested:

Establishment of tolerances for the residues of Bayleton 1-(4-chlorophenoxy)-3,3-dimethyl-1-(1H-1,2,4-triazole-1-yl)-2-butanone and its metabolites containing the chlorophenoxy and triazole moieties (expressed as the fungicide) in or on rotational crops planted 14 days after use on various crops based on the use pattern presented in "Section B" of this petition, at the levels indicated in the attached "Section F."

Conclusions

Toxicology Branch recommends for the establishment of the proposed tolerances for rotational crops.

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The proposed use and resulting residue level as indicated in "Section F" of this petition allow an adequate dietary margin of safety (over 1000) for maternal toxicity and fetal development.

Since worker exposure estimates are not available to us at this time, and pursuant to the C.F. Chaisson memorandum 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.

It should be emphasized also that "Baytan" a metabolite of "Bayleton," has been reported to be oncogenic in mice. A final determination of the weight-of-evidence and classification is pending. Once the report of the Peer Review Committee has been completed, a risk analysis may be performed to determine the magnitude of risk resulting from exposure to these two chemicals.

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 MOS is defined as the ratio of the "no observed effect level" of a given effect to exposure, and can be calculated as follows:

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

For example, the proposed tolerance for Bayleton residues on potatoes is 0.05 ppm. If we assume a reasonable worst-case where a pregnant female would consume about 200 gm of potatoes in a single serving, this would constitute about 10 ug (0.01 mg) of Bayleton/60 kg of body weight, or 0.00017 mg/kg of body weight. On this basis the MOS for dietary exposure can be calculated as follows:

$$\text{MOS terata (dietary)} = \frac{50 \text{ mg/kg}}{0.00017 \text{ mg/kg}} = > 1000$$

$$\text{MOS mat. tox (dietary)} = \frac{10 \text{ mg/kg}}{0.00017 \text{ mg/kg}} = > 1000$$

In the same manner, the MOS can be calculated for other crops. However, since the residue tolerance proposed on potatoes is the highest of all crops in the proposed use, therefore, the MOS for other crops should be higher than that calculated for potatoes.

Since no worker exposure estimates are available, the MOS for female workers based on worker exposure cannot be calculated, and the use of protective clothing by child-bearing-age female workers is again emphasized.

SECTION F

Tolerance Proposal

<u>CROP</u>	<u>PROPOSED TOLERANCE (PPM)</u>
Legume vegetables group seed, succulent ⁽¹⁾ and dry	0.05
Foliage of Legume vegetables group vines, green	1.0
hay	0.1
Corn forage, green	0.1
Corn kernel plus cob with husk removed	0.1
Corn fodder, dry	0.05
Corn kernel, dry	0.01
Cottonseed	0.02
Cotton forage	0.5
Lettuce	0.01
Peanuts (meats)	0.01
Peanut hulls	0.01
Peanut vines (dry)	0.01
Potatoes	0.05
Sorghum, grain	0.01
Sorghum, fodder and forage	0.1

(1) including pods

TOXICOLOGY BRANCH ADI PRINTOUT

Date: 07/21/86

Bayleton 2yr feeding- rat ADI = 0.025000 mg/kg/day
 Caswell #862AA NOEL = 2.5000 mg/kg Safety Factor = 100
 CFR No. 180.410 LEL = 25.0000 mg/kg
 Status: TOX ADI complete 2/21/86. ORD verified 3/11/86.

RESIDUE CONTRIBUTION OF PUBLISHED TOLERANCES

DRAFT

CROP	TOLERANCE (PPM)	PETITION NUMBER	FOOD FACTOR	MG/DAY
1 Almonds	0.050		0.03	0.000022500
2 Apples	1.000		2.53	0.037950000
3 Apricots	4.000		0.11	0.006600000
8 Barley	1.000		0.03	0.000450000
26 Cattle	1.000		7.18	0.107700000
49 Cucurbits	0.300		2.84	0.012780000
54 Eggs	0.040		2.77	0.001662000
62 Goats	1.000		0.03	0.000450000
67 Grapes, not including raisins	1.000		0.45	0.006750000
69 Hogs	0.040		3.43	0.002058000
93 Milk and dairy products	0.040		28.62	0.017172000
100 Nectarines	4.000		0.03	0.001800000
114 Peaches	4.000		0.90	0.054000000
116 Pears	1.000		0.26	0.003900000
123 Pineapple	3.000		0.30	0.013500000
125 Plums, including prunes	4.000		0.13	0.007800000
128 Poultry	0.040		2.94	0.001764000
145 Sheep	1.000		0.19	0.002850000
154 Sugar, cane and beet	0.500		3.54	0.027300000
170 Wheat	1.000		10.36	0.155400000
208 Horses	1.000		0.03	0.000450000
224 Chick peas	0.100		0.03	0.000045000

TMRC
 0.007707 mg/kg/day (60kg BW, 1.5kg diet)

$\frac{2}{3}$ ADI
 30.826900

RESIDUE CONTRIBUTION OF TOX-APPROVED TOLERANCES

CROP	TOLERANCE (PPM)	PETITION NUMBER	FOOD FACTOR	MG/DAY
15 Blackberries	1.000	4E3088	0.03	0.000450000
17 Boysenberries	1.000	4E3088	0.03	0.000450000
36 Coffee	0.050	3F2938	0.75	0.000562500
41 Cottonseed (oil)	0.200	3F2938	0.15	0.000450000
52 Dewberries	1.000	4E3088	0.03	0.000450000

RESIDUE CONTRIBUTION OF TOX-APPROVED TOLERANCES

CROP	TOLERANCE (PPM)	PETITION NUMBER	FOOD FACTOR	MG/DAY
86 Loganberries	1.000	4E3088	0.03	0.000450000
88 Mangoes	0.070	5E3168	0.03	0.000031500
135 Raspberries	1.000	4E3088	0.03	0.000450000
152 Strawberries	0.300	4F3124	0.18	0.000810000
163 Tomatoes	0.200	4F3148	2.87	0.008610000
172 Youngberries	1.000	4E3088	0.03	0.000450000

TMRC
0.007926 mg/kg/day (60kg BW, 1.5kg diet)

% ADI
31.704500

RESIDUE CONTRIBUTION OF NEW (PENDING) TOLERANCES

CROP	TOLERANCE (PPM)	PETITION NUMBER	FOOD FACTOR	MG/DAY
9 Beans	0.050	6F3419	2.04	0.001530000
38 Corn, all types	0.100	6F3419	2.51	0.003765000
41 Cottonseed (oil)	0.000	6F3419	0.15	0.000000000
83 Lentils	0.050	6F3419	0.04	0.000030000
84 Lettuce	0.010	6F3419	1.31	0.000196500
115 Peanuts	0.010	6F3419	0.36	0.000054000
117 Peas	0.050	6F3419	0.69	0.000517500
127 Potatoes	0.050	6F3419	5.43	0.004072500
148 Soybeans (oil)	0.050	6F3419	0.92	0.000690000
213 Pigeon beans	0.050	6F3419	0.03	0.000022500
224 Chick peas	0.000	6F3419	0.03	0.000000000

TMRC
0.008107 mg/kg/day (60kg BW, 1.5kg diet)

% ADI
32.429700