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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

JUL 28 1986

MEMORANDUM

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

Caswell No. 862AA

FROM: George Z. Ghali, Ph.D.
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Toxicology Branch
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TO: Henry Jacoby, PM 21
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THUR: Reto Engler, Chief
Mission Support Staff
Toxicology Branch
Hazard Evaluation Division (TS-769C) 7/25/86

Registrant: Mobay Chemical Corporation
Kansas City, MO 64120

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

CROP	PROPOSED TOLERANCE (PPM)
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
Caswell #862AA
CFR No. 180.410
Status: TOX ADI complete 2/21/86. ORD verified 3/11/86.

2yr feeding- rat
NOEL = 2.5000 mg/kg
LEL = 25.0000 mg/kg

ADI = 0.025000 mg/kg/day
Safety Factor = 100

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RESIDUE CONTRIBUTION OF PUBLISHED TOLERANCES

	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		3.64	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)

% 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
