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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

JUN 25 1981

MEMORANDUM

DATE:

SUBJECT: Bayleton 25% W.P.; Tolerance of 0.1 ppm on Chick Peas. (Acc. # 099850-51, Caswell 862 AA, Petition # 1E2459).

FROM: George Z. Ghali, Ph.D.
Toxicology Branch, HED (TS-769)

TO: Henry Jacoby (PM. 21)
Registration Division (TS-767)

Registrant:

Mobay Chemical Corporation
St. Louis, Missouri

Action Requested:

Establishment of a tolerance of 0.1 ppm of Bayleton residues on chick peas.

Conclusion and Recommendations:

Toxicology Branch recommends for the establishment of the proposed tolerance.

Background Information:

Existing Toleramces:

There are no existing tolerances for this pesticide. However, temporary tolerances were established as follows:

Apples, fresh	0.75 ppm
Pears, fresh	0.75 ppm
Grapes	1.00 ppm
Wheat	0.10 ppm
Barley	0.10 ppm

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Toxicology Data:

(memo by John Doherty, 2/15/78)

A. Bayleton 25% W.P.

Acute oral LD_{50}, rat, 2,828 mg/kg (male), 3,668 mg/kg (female)

Acute dermal LD_{50}, rabbit, > 5,000 mg/kg

Acute inhalation LC_{50}, rat > 20 mg/l

Primary eye irritation; reversible corneal opacity.

Primary skin irriation: not irritating.

B. Bayleton, technical:

(memo by J. Doherty 1/9/80, A. Arce 1/24/80)

1. Acute Studies:

Acute oral, rats 568 mg/kg (male), 363 mg/kg (female).

Acute I.P. rats, LD_{50} 293 and 321 mg/kg for females and males respectively.

Acute dermal, rats LD_{50} > 1000 mg/kg.

Acute inhalation; mice, rabbits, hamsters and rats. LC_{50} > 174 mg/m^3.

Primary skin irritation: rabbits negative.

Skin ittitation: rabbits negative.

Skin irritation; human. not irritant.

Eye irritation; invalid study, dose eas not reported.

2. Mutagenicity:

Dominant lethal test, negative for mutagenicity.

Micronucleos test, negative for mutagenicity.

Ames test, negative at doses from 5 to 1000 ug/ml.

3. Subchronic toxicity:

Twelve-week feeding, rats. NOEL > 2000 ppm.

Thirteen-week feeding, dogs NOEL > 2400 ppm.

4. Subacute toxicity:

Thirty-day oral administration, rats, NOEL 3mg/kg (m), 10 mg/kg (f).

Four-hours inhalation, rats, LC_{50} > 453 mg/m^3.

Six-hours inhalation, rats 15 exposure, NOEL 78.7 mg/m^3.

Cumulative subacute dermal application for four weeks, rabbits, NOEL 250 mg/kg.

5. Embryotoxicity and Teratology:

In an oral administration study in rats, occasionally cleft palates were seen in the groups treated with 75 mg/kg/day and above. These equaled only 4 of the 211 of one experiment and 3 of 183 in another experiment. However, this deformity is seldom seen in this strain. A no-effect level for embryonic and fetal development/teratology was at least 50 mg/kg/day (J. Doherty, 1978).

In a later memo by Roger Gardner dated 4/16/81 it was concluded that the cleft palates observed in this study may not be attributable to Bayleton treatment. However, the memo also indicated that the raw data and background on the historical terata incidence in this strain of rats are needed to further evaluate the significance of this effect.

From the information available until now, the compound is questionably positive with a clear-cut no-effect level for teratogenic effect of 50 mg/kg/day.

Inhalation administration, rats, negative for terata and embryotoxicity of a dose level of 113.6 mg/m^3.

Oral administration, rabbits, negative up to and including 50 mg/kg (highest dose tested).

6. Chronic Toxicity:

(memo by George Z. Ghali, 3/81)

Two-year feeding (oncogenicity) in rats; not onocgenic, NOEL 50 ppm.

Two-year feeding study in dogs, not oncogenic, NOEL 100 ppm.

Multigeneration reproduction study, rats NOEL 50 ppm.

Toxicology Data Gap:

An adequate metabolism study in an appropriate animal species.

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ACCEPTABLE DAILY INTAKE DATA

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

Unpublished, Tox Approved PP# 0G2300,1G2432

CROP	Tolerance	Food Factor	mg/day(1.5kg)
Apples(2)	0.750	2.53	0.02846
Pears(116)	1.000	0.26	0.00383
Barley(8)	0.100	0.03	0.00005
Wheat(170)	0.100	10.36	0.01554

MPI	TMRC	% ADI
1.5000 mg/day(60kg)	0.0479 mg/day(1.5kg)	3.19

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Current Action PP# 0E2393,1E2459,0F2349

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
Grapes, not raisins(67)	2.000	0.45	0.01349
Melons(92)	0.200	2.00	0.00601
Chick Peas (214)	0.100	0.03	0.00005

MPI	TMRC	% ADI
1.5000 mg/day(60kg)	0.0766 mg/day(1.5kg)	5.10

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Proposed, [illegible]

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