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

Smith

File petition

~~28 JUN 1982~~

MEMORANDUM

JUN 30 1982

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

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

THRU: Christine F. Chaisson, Ph.D. *C.F. Chaisson*
Toxicology Branch
Hazard Evaluation Division (TS-769)

SUBJECT: Bayleton on Pineapple (PP No. 2F2688, Caswell No. 862-AA).

Petitioner:

Mobay Chemical Corporation
Agricultural Chemicals Division
Kansas City, Missouri 64120

Action Requested:

Establishment of a tolerance of Bayleton on pineapple at the level of 3.0 ppm.

Conclusions and Recommendations:

1. Toxicology Branch can not recommend for the establishment of the requested tolerances at this time for the lack of information on workers exposure. Field re-entry is anticipated to be a major component of the risk assessment for this use, and the exposure estimates are crucial.
2. Based on dietary exposure, adequate margins of safety (MOS) exist for both maternal toxicity, embryonic and fetal development/teratology.
3. Toxicology Branch defers to the Environmental Fate Branch the question of worker exposure.

G. G. Holt

Detailed Considerations:

1. The ADI for bayleton has been established on the basis of a NOEL of 50 ppm generated from a two-year feeding study in rat with a safety factor of 100. The ADI is considered to be 0.025 mg/kg/day and the MPI is 1.5 mg/day (60 kg).

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The portion of the ADI utilized by tolerances that have been already approved by Tox. Branch is 6.19%. Granting the current tolerance would add 0.88% to the ADI.

2. Based on dietary exposure, adequate margins of safety exist for embryonic and fetal development/teratology and maternal toxicity. However, a the risk assessment can not be completed and final recommendations can not be made before the information on workers exposure become available.

Toxicology Profile:

Toxicology data are summarized in a memo by George Ghali, dated March 1982 to Henry Jacoby.

G. Ghali

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

dfn rsc/3d82

File last updated 6/9/82

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 |

Unpublished, Tox Approved 0G2300, 1G2432, 0E2393, 1E2459, 0F2349, 1F2474

| CROP | Tolerance | Food Factor | mg/day (1.5kg) |
|---------------------------|-----------|-------------|----------------|
| Apples(2) | 0.750 | 2.53 | 0.02846 |
| Pears(116) | 1.000 | 0.26 | 0.00383 |
| 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) | 0.100 | 2.00 | 0.00601 |
| <i>chick peas</i> (214) | 0.100 | 0.03 | 0.00005 |
| Meat, inc poultry(89) | 0.010 | 13.85 | 0.00208 |
| Grapes, not raisins(67) | 0.000 | 0.45 | 0.00000 |
| Apples(2) | 0.250 | 2.53 | 0.00949 |
| Wheat(170) | 0.100 | 10.36 | 0.01554 |
| Eggs(54) | 0.010 | 2.77 | 0.00042 |
| Milk&Dairy Products(93) | 0.010 | 28.82 | 0.00429 |

| MPI | TMRC | % ADI |
|----------------------|-----------------------|-------|
| 1.5000 mg/day (60kg) | 0.0928 mg/day (1.5kg) | 6.19 |

Current Action 2F2688

| CROP | Tolerance | Food Factor | mg/day (1.5kg) |
|-----------------|-----------|-------------|----------------|
| Pineapple (123) | 3.000 | 0.30 | 0.01334 |

| MPI | TMRC | % ADI |
|----------------------|-----------------------|-------|
| 1.5000 mg/day (60kg) | 0.1061 mg/day (1.5kg) | 7.07 |
