

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY.

000721

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DATE: October 31, 1979

SUBJECT: PP#9E2259; Request for the establishment of a tolerance for benomyl at 5 ppm on turnip greens. CASWELL #75A, Acc. #098945

FROM: Gary J. Burin *GJB WSW*
Toxicology Branch (TS-769)

TO: Clint Fletcher
ERS, RD, (TS-767)

THRU: Dr. M. Adrian Gross, Chief *William S. Burin for M. Adrian Gross*
Toxicology Branch (TS-769)

Petitioner: IR-4
G.M. Markle, Assistant Coordinator
Rutgers University
The State of University of New Jersey
New Brunswick, New Jersey 08903

Recommendations

The requested tolerance of 5 ppm of benomyl on turnip greens can not be toxicologically supported; due to the relatively high level of exposure of a population subgroup likely to result from this action and the uncertainty of an ADI (See rationale under Conclusions). Potential toxicological effects cited in current Benomyl RPAR proceedings include spindle inhibition, mutagenic effects, teratogenic effects in rats and mice, and reduction of spermatogenic activity in dogs and rats.

Tolerance Requested

The petitioner, IR-4 Asst. Coordinator, G.M. Markle, on behalf of the IR-4 Technical Committee and the Agricultural Experiment Stations of Georgia and North Carolina requests the establishment of tolerances for benomyl and metabolites in or on turnip greens at 5 ppm.

Review

- 1) Tolerances have been established under 40 CFR 180.294 for benomyl.
- 2) No new toxicity data was submitted by the petitioner.
- 3) Related Petitions: 0F0906, 0F1000, 1F1010, 1F1033, 1F1045, 1F1145, 2F1291, 2F1192, 2F1212, 2F1218, 0G0936, 1G1038, 2G1197, 4E1479, 6F1810.

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4) Relevant toxicity data (From memo of Sept. 26, 1979, A

Brief Summary of Selected Toxicity Data

Acute Oral LD ₅₀ - Rat (50% WP)	LD ₅₀	>	10,000
Acute Oral LD ₅₀ - Rat (Tech)	LD ₅₀	>	10,000
Acute Oral	LD ₅₀	>	9,590
Acute Oral - Rabbit (50% WP)	LD ₅₀	>	3,400
Acute Dermal - Rabbit (50% WP)	LD ₅₀	>	10,000
Acute Inhalation - Rat (50% WP)	LC ₅₀	>	2.0 mg/
Acute Inhalation - Rat	LC ₅₀	>	1.37 mg
Acute Inhalation - Rat (50% AI)	50	>	4.01 mg
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			noted a
			level t
			(0.27,
			and 4.0

Primary Skin Irritation - Guinea Pig (50% WP) mild irritat

Sensitization - Guinea Pig (50% WP) mild sensitization not

Eye Irritation - Rabbit (53%) Mild Irritation - not an eye
as per FHS.

14-Day Intubation - Rat (Unformulated) - NEL 200 mg/kg/day

21-Day Inhalation - Rat (53.5% in sugar) - NEL > 0.2 mg/L

90-Day Feeding Study - Rat Systemic NEL 50

90-Day Feeding Study - Dog Systemic NEL 50

2-Year Feeding Study - Rat Systemic NEL 25

2-Year Feeding Study - Dog Systemic NEL 50

3-Generation Reproduction - Rat Systemic NEL 10

Acute Oral - Rat (metabolite) LD₅₀ > 17 g/k

90-Day Feeding Study - Rat (metabolite) Systemic NEL 250

3-Generation Reproduction - Rat
(metabolite) Systemic NEL 250

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Conclusions

- 1) The requested tolerance of 5 ppm of Benomyl on Turnip greens can not be toxicologically supported.
- 2) Benomyl is currently involved in RPAR proceedings. The basis of the rebuttable presumptions that have not been rebutted and which are relevant to the intended use of turnip greens are; mutagenic effects due to spindle inhibition, teratogenic effects in rats and mice and reduction of spermatogenic activity in dogs and rats (See Benomyl Position Document 2/3).
- 3) Published and pending tolerances utilize approximately 34% of the current ADI. Advanced information from a study now in progress suggests an adjustment of the ADI based on teratogenic effects will soon be made. Results of this study are preliminary at this point.
- 4) Using a food factor of .03% the recommended tolerance of 5 ppm on turnip greens would result in a contribution of .00225% mg/day/1.5 kg. This is less than 1% of the ADI.
- 5) However, large quantities of this commodity are consumed by a population subgroup based on both tradition and health. This subgroup may be expected to include young children and pregnant women, both of whom are particularly susceptible to the effects of spindle inhibition on rapidly growing cells. These effects would be expected to be seen as teratogenic, embryotoxicity and developmental problems in young children.
- 6) Due to the uncertainty of an ADI and the relatively high level of exposure of a population subgroup likely to result from this action, it does not appear that this tolerance can be toxicologically supported.

TOX/HED:th:RD Initial WWOODROW:10-23-79

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