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4

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY.

000721

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
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THRU: Dr. M. Adrian Gross, Chief William Sv. Estes for M. Adrian Gross
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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 benom yl 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 establishmer of tolerances for benomyl and metabolites in or on turnip green 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.

163

EPA FORM 1320-6 (REV. 3-76)

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)		>	4.01 mg cular a 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-Genereation Reproduction - Rat	Systemic NEL 10
Acute Oral - Rat (metabolite)	LD_{50} > 17 g/k
90-Day Feeding Study - Rat (metabolite)	Systemic NEL 250
3-Generation Reproduction - Rat (metabolite)	Systemic NEL 250

2

Conclusions

1) The requested tolerance of 5 ppm of Benomyl on Turni greens can not be toxicologically supported.

2) Benomyl is currently involved in RPAR proceedings. T basis of the rebuttable presumptions that have not b rebutted and which are relevant to the intended use o 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 approximatel 34% of the current ADI. Advanced information from a study now in progress suggests an adjustment of the AD based on teratogenic effects will soon be made. Resu of this study are preliminary at this point.

4) Using a food factor of .03% the recommended tolerance 5 ppm on turnip greens would result in a contribution of .00225% mg/day/1.5 kg. This is less than 1% of th ADI.

5) However, large quantities of this commodity are consu by a population subgroup based on both tradition and This subgroup may be expected to include young childr and pregnant women, both of whom are particularly sus to the effects of spindle inhibition on rapidly growi These effects would be expected to be seen as teratog embryotoxicity and developmental problems in young c

6) Due to the uncertainty of an ADI and the relatively h level of exposure of a population subgroup likely to from this action, it does not appear that this tolera be toxicologically supported.

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