

US EPA ARCHIVE DOCUMENT



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EBDC/ETU Special Review. DRES Dietary Exposure and Risk Estimates for Use of Maneb on Collards, Mustard Greens, and Turnip Tops.

FROM: Richard Griffin *Richard Griffin* 3/11/94
Chemistry Branch I / Tolerance Support
Health Effects Division (7509C)

THROUGH: Debra Edwards, Chief *Debra Edwards* 3/10/94
Chemistry Branch I / Tolerance Support
Health Effects Division (7509C)

TO: Amy Farrell
Special Review Branch
Special Review and Reregistration Division (7508W)

This memo provides possible EBDC (maneb) exposure and risk estimates with either a national registration or regional (Georgia, Tennessee) registration. Risk estimates are also provided for the population groups with a projected maximum consumption of leafy greens.

Exposure/risk estimates are based on the residue estimates and toxicology of the common EBDC metabolite/degradate, ETU.

Toxicological endpoints for ETU risk assessment:

- RfD: The Agency approved (2/20/91) Reference Dose for ETU is 0.00008 mg/kg body weight/day, based on the LEL (0.25 mg/kg body weight/day) of a 2-year rat study and an uncertainty factor of 3,000. The uncertainty factor of 3,000 accounts for inter/intra species extrapolation (x 100), the lack of a NOEL (x 10), and data gaps (x 3).
- Carcinogenicity: ETU is classified as a Group B2 carcinogen with an upper-bound potency factor (Q₁*) of 1.1 x 10⁻¹ (mg/kg/day)⁻¹.

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Residue chemistry:

In association with a request for a hearing on the cancellation of maneb use on leafy greens, growers have submitted field trial, residue decline, and residue reduction studies (2 studies, each with 3 parts) on collards, with an agreed translation to mustard greens and turnip tops. Based on new data, Chemistry Branch II (Susan Hummel memo, 1/25/94) has revised the EBDC and ETU residue estimates for dietary exposure.

EBDC (maneb) and ETU residue estimates per DRES food-form for collards, mustard greens, and turnip tops are attached.

EBDC (parent) exposure estimates are factored by a metabolic conversion rate of 7.5% to account for the in vivo metabolic conversion to ETU, then added to the ETU (direct) exposure estimates.

Consumption database:

1977-78 USDA Nationwide Individual Food Consumption Survey.

Percent crop treated:

PD/4 and subsequent EBDC/ETU risk assessments (R. Griffin memos, 10/11/91, 6/25/93, 2/3/94) have used a BEAD usage estimate of 90% each for collards, mustard greens, and turnips. The 90% estimate is based on national, historical use.

If the use of maneb on leafy greens is limited to the states of Georgia and Tennessee (a proposal), BEAD would estimate 23% crop treated for turnips, 26% for collards, and 13% for mustard greens.

Risk assessments, factored by the above percents crop treated, are provided below (and assume a national distribution of treated crops).

Exposure/risk estimates:

o 90% crop treated for collards, mustard greens, and turnips:

Overall U.S. population:

Turnip tops.....	0.000002299 mg/kg/day	2.5E-7	Carcinogenic risk
Collards.....	0.000003441	3.8E-7	
Mustard greens...	0.000002639	2.9E-7	
Greens combined..	0.000008380	9.2E-7	

Exposure/risk estimates cont.

○ Turnips/23% collards/26% mustard greens/13%

Overall U.S. population:

Turnip tops.....	0.000000587 mg/kg/day	6.5E-8	Carcinogenic risk
Collards.....	0.000000994	1.1E-7	
Mustard greens...	0.000000381	4.2E-8	
Greens combined..	0.000001962	2.2E-7	

The DRES consumption database shows two U.S. population groups with much higher than average (overall U.S.) consumption estimates for the "leafy greens". To demonstrate a possible maximum chronic exposure/risk due to maneb use on leafy greens, we have used the consumption estimates of these groups and have assumed a local consumption of treated greens (100% crop treated).

○ Maximum possible exposure: 100% crop treated

DRES population group "non-hispanic blacks"

Turnip tops.....	0.000011793 mg/kg/day	1.3E-6	Carcinogenic risk
Collards.....	0.000023816	2.6E-6	
Mustard greens...	0.000016645	1.8E-6	
Greens combined..	0.000052254	5.7E-6	

DRES population group "southern region"

Turnip tops.....	0.000006152 mg/kg/day	6.8E-7	Carcinogenic risk
Collards.....	0.000008673	9.5E-7	
Mustard greens...	0.000006614	7.3E-7	
Greens combined..	0.000021439	2.4E-6	

cc: R. Griffin files
RF
Albin Kocial
Chemistry Br
Dietary Expo

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Ethylene thiourea (ETU) Caswell #443AA CAS No. 96-45-7 A.I. CODE: 600016 CFR No. 180.	2yr feeding- rat NOEL= 0.0000 mg/kg 0.00 ppm LEL= 0.2500 mg/kg 5.00 ppm ONCO: B2 (CAG/HED)	Increased incidence of thyroid hyperplasia. Evidence of oncogenicity in rats (thyroid) and mice (liver).	PADI UF -->3000 OPP RfD= 0.000080 EPA RfD= 0.000080 q*: 0.11000	Reproduction- rat Chronic feeding- dog UF 3000 for data gaps, lack of NOEL. q* calculated. EBDC plant metabolite.	EPA verified 12/09/86. MED reassess 10/30/87. EPA deferred 02/25/88. WHO last reviewed 1988. EPA verified 02/20/91. On IRIS.

FOOD CODE	FOOD	FOOD FORM	ANTICIPATED RESIDUE (ppm)
13009AA	COLLARDS	51 COOKED-CANNED	0.240000 FT
13009AA	COLLARDS	63 COOKED-FRESH OR FROZEN-BOILED	0.200000 FT
13021AA	MUSTARD GREENS	21 COOKED-NFS	0.200000 FT
13021AA	MUSTARD GREENS	63 COOKED-FRESH OR FROZEN-BOILED	0.200000 FT
13026AA	TURNIPS-TOPS	10 RAW-FRESH OR NFS	0.050000 FT
13026AA	TURNIPS-TOPS	21 COOKED-NFS	0.200000 FT
13026AA	TURNIPS-TOPS	31 COOKED-FRESH OR CANNED	0.200000 FT

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CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
EBDC'S COMBINED Caswell #999ZZZ CAS No. A.I. CODE: CFR No. 180.	NOEL= 0.0000 mg/kg 0.00 ppm LEL= 0.0000 mg/kg 0.00 ppm ONCO:				

FOOD CODE	FOOD	FOOD FORM	ANTICIPATED RESIDUE (ppm)
13009AA	COLLARDS	51 COOKED-CANNED	0.004000 FT
13009AA	COLLARDS	63 COOKED-FRESH OR FROZEN-BOILED	0.025000 FT
13021AA	MUSTARD GREENS	21 COOKED-NFS	0.025000 FT
13021AA	MUSTARD GREENS	63 COOKED-FRESH OR FROZEN-BOILED	0.025000 FT
13026AA	TURNIPS-TOPS	10 RAW-FRESH OR NFS	0.760000 FT
13026AA	TURNIPS-TOPS	21 COOKED-NFS	0.023000 FT
13026AA	TURNIPS-TOPS	31 COOKED-FRESH OR CANNED	0.023000 FT

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DOCKET FILE ENTRY
DOCUMENT COVER SHEET

CBI: Appendix In-Text X No CBI

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Pre-SR PD1 PD2/3 PD4 Reg Std

Post SR

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