

US EPA ARCHIVE DOCUMENT



SR-EBDC

D-15557

2-3-94  
Ref  
#8

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**. Estimates Based on New Residue Studies.

FROM: Richard Griffin *Richard Griffin 2/3/94*  
Chemistry Branch I / Tolerance Support  
Health Effects Division (7509C)

THROUGH: Debra Edwards, Chief *Debra Edwards 2/3/94*  
Chemistry Branch I / Tolerance Support  
Health Effects Division (7509C)

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

The following exposure/risk estimates are based on the residue 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.
- Carcinogenicity: ETU is classified as a Group B2 carcinogen with an upper-bound potency factor (Q<sub>1</sub>\*) of 1.1 x 10<sup>-1</sup> (mg/kg/day)<sup>-1</sup>.

**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



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①

estimates for dietary exposure.

EBDC (maneb) and ETU residue estimates per DRES food-form for collards, mustard greens, and turnip tops are summarized in Table 1. EBDC/maneb 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.

**Percent crop treated:**

As in the PD 4, collards, mustard greens, and turnip tops are assessed with the BEAD estimate of 90% crop treated.

**Consumption database:**

1977-78 USDA Nationwide Individual Food Consumption Survey.

**ETU chronic exposure/percent RfD/carcinogenic risk estimates:**

Overall U.S. population:

Turnip tops.....	0.000002299	mg/kg/day	( 3% RfD)	(2.5E-7)
Collards.....	0.000003441		( 4% RfD)	(3.8E-7)
Mustard greens.....	0.000002639		( 3% RfD)	(2.9E-7)
Greens combined.....	0.000008380		(10% RfD)	(9.2E-7)

Non-nursing infants:

Turnip tops.....	<0.000000001	mg/kg/day	(<1% RfD)	
Collards.....	0.000002882		( 4% RfD)	
Mustard greens.....	<0.000000001		(<1% RfD)	

Children (1-6):

Turnip tops.....	0.000002840	mg/kg/day	( 4% RfD)	
Collards.....	0.000005661		( 7% RfD)	
Mustard greens.....	0.000003471		( 4% RfD)	

cc: R. Griffin files  
Dietary Exposure Section (SAB)  
Albin Kocialski (CCB)  
Chemistry Branch II  
RF

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES		DATA GAPS/COMMENTS	STATUS
			PADI	UF		
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 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).	0.11000	0.000080	Reproduction- rat Chronic feeding- dog UF 3000 for data gaps, lack of NOEL. q* calculated. EBDC plant metabolite.	EPA verified 12/09/86. HED reassess 10/30/87. EPA deferred 02/25/88. WHO last reviewed 1988. EPA verified 02/20/91. On IRIS.

FOOD CODE	FOOD	PET.#	TOLERANCE (ppm)	ANTICIPATED RESIDUE (ppm)	AR STATISTIC TYPE	% CROP TREATED	RES. VALUE USED IN TAS RUN (ppm)
13009AA	COLLARDS	51	0.000000	0.240000	FT	90.00	0.216000
13009AA	COLLARDS	63	0.000000	0.200000	FT	90.00	0.180000
13021AA	MUSTARD GREENS	21	0.000000	0.200000	FT	90.00	0.180000
13021AA	MUSTARD GREENS	63	0.000000	0.200000	FT	90.00	0.180000
13026AA	TURNIPS-TOPS	10	0.000000	0.050000	FT	90.00	0.045000
13026AA	TURNIPS-TOPS	21	0.000000	0.200000	FT	90.00	0.180000
13026AA	TURNIPS-TOPS	31	0.000000	0.200000	FT	90.00	0.180000

ANTICIPATED RESIDUE INFORMATION FOR CASHELL NUMBER 999ZZZ

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
EBDC'S COMBINED Cashell #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:		UF --->0 OPP Rfd= 1.000000 EPA Rfd= 1.000000		

FOOD CODE	FOOD	FOOD FORM	PET. #	TOLERANCE (ppm)	ANTICIPATED RESIDUE (ppm)	AR STATISTIC TYPE	% CROP TREATED	RES. VALUE USED IN TAS RUN (ppm)
13009AA	COLLARDS	51 COOKED-CANNED		P 0.000000	0.004000	FT	90.00	0.003600
13009AA	COLLARDS	63 COOKED-FRESH OR FROZEN-BOILED		P 0.000000	0.025000	FT	90.00	0.022500
13021AA	MUSTARD GREENS	21 COOKED-NFS		P 0.000000	0.025000	FT	90.00	0.022500
13021AA	MUSTARD GREENS	63 COOKED-FRESH OR FROZEN-BOILED		P 0.000000	0.025000	FT	90.00	0.022500
13026AA	TURNIPS-TOPS	10 RAW-FRESH OR NFS		P 0.000000	0.760000	FT	90.00	0.684000
13026AA	TURNIPS-TOPS	21 COOKED-NFS		P 0.000000	0.023000	FT	90.00	0.020700
13026AA	TURNIPS-TOPS	51 COOKED-FRESH OR CANNED		P 0.000000	0.023000	FT	90.00	0.020700

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Ethylene thiourea (ETU) Cashell #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. HED reassess 10/30/87. EPA deferred 02/25/88. WHO last reviewed 1988. EPA verified 02/20/91. On IRIS.

COMMODITY CONTRIBUTION BY RAC FOR: U.S. POPULATION - 48 STATES

FOOD CODE	FOODNAME/FOODFORM	TOLERANCE (PPH)	TYPE	TMRC (UG/KG/DAY)	%RFD	TMRC ONCO RISK	ANTICIPATED RESIDUE (PPM)	ARC (UG/KG/DAY)	%RFD	ARC ONCO RISK
13026AA	TURNIPS-TOPS 10 RAW-FRESH OR NFS 21 COOKED-NFS 31 COOKED-FRESH OR CANNED	0.000	P	0.000000	0.000	0.000000000000	0.04500 0.18000 0.18000	0.000196 0.000633 0.001231	0.245 0.791 1.539	0.00000002156 0.00000006963 0.00000013541
CROP GROUP TOTALS FOR LEAVES OF ROOT AND TUBER VEG.:										
		0.000	P	0.000000	0.000	0.000000000000	0.21600 0.18000	0.000049 0.003361	0.061 4.201	0.00000000539 0.00000036971
13021AA	MUSTARD GREENS 21 COOKED-NFS 63 COOKED-FRESH OR FROZEN-BOILED	0.000	P	0.000000	0.000	0.000000000000	0.18000 0.18000	0.000047 0.002568	0.059 3.210	0.00000000517 0.00000028248
CROP GROUP TOTALS FOR BRASSICA (COLE) LEAFY VEGETABLES:										
		0.000	P	0.000000	0.000	0.000000000000	0.006025	0.006025	7.531	0.000000066275

GRAND TOTALS FOR U.S. POPULATION - 48 STATES

		0.000000		0.000000	0.000	0.000000000000	0.008085	0.008085	10.106	0.00000088935
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TOLERANCE TYPE: N=NEW; A=PENDING; P=PUBLISHED  
 TMRC=THEORETICAL MAXIMUM RESIDUE CONTRIBUTION  
 ARC = ANTICIPATED RESIDUE CONTRIBUTION  
 RFD = REFERENCE DOSE

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TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

CHEMICAL INFORMATION		STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
EBDC'S COMBINED		NOEL= 0.0000 mg/kg		UF -->0		
Cashell #999ZZZ		0.00 ppm		OPP Rfd= 1.000000		
CAS No.		LEL= 0.0000 mg/kg		EPA Rfd= 1.000000		
A.I. CODE:		0.00 ppm				
CFR No. 180.		ONCO:				

COMMODITY CONTRIBUTION BY RAC FOR: U.S. POPULATION - 48 STATES

FOOD CODE	FOODNAME/FOODFORM	TOLERANCE (PPM)	TYPE	TMRC (UG/KG/DAY)	%RFD	TMRC ONCO RISK	ANTICIPATED RESIDUE (PPM)	ARC (UG/KG/DAY)	%RFD	ARC ONCO RISK
13026AA	TURNIPS-TOPS	0.000	P	0.000000	0.000	0.000000000000	0.68400	0.002980	0.000	0.00000002459
	10 RAW-FRESH OR NFS						0.02070	0.000073	0.000	0.00000000060
	21 COOKED-NFS						0.02070	0.000142	0.000	0.00000000117
	31 COOKED-FRESH OR CANNED									
CROP GROUP TOTALS FOR LEAVES OF ROOT AND TUBER VEG.:										
		0.000		0.000000	0.000	0.000000000000	0.003195	0.000000	0.000	0.00000002636
13009AA	COLLARDS	0.000	P	0.000000	0.000	0.000000000000	0.00360	0.000001	0.000	0.00000000001
	51 COOKED-CANNED						0.02250	0.000420	0.000	0.00000000347
	63 COOKED-FRESH OR FROZEN-BOILED									
13021AA	MUSTARD GREENS	0.000	P	0.000000	0.000	0.000000000000	0.02250	0.000006	0.000	0.00000000005
	21 COOKED-NFS						0.02250	0.000321	0.000	0.00000000265
	63 COOKED-FRESH OR FROZEN-BOILED									
CROP GROUP TOTALS FOR BRASSICA (COLE) LEAFY VEGETABLES:										
		0.000		0.000000	0.000	0.000000000000	0.000748	0.000000	0.000	0.00000000617

GRAND TOTALS FOR U.S. POPULATION - 48 STATES

0.000000	0.000	0.000000000000	0.003943	0.000	0.00000003253
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TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Ethylene thiourea (ETU) Cashell #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. HED reassess 10/30/87. EPA deferred 02/25/88. WHO last reviewed 1988. EPA verified 02/20/91. On IRIS.

COMMODITY CONTRIBUTION BY RAC FOR: NON-NURSING INFANTS (< 1 YEAR OLD)

FOOD CODE	FOODNAME/FOODFORM	TOLERANCE (PPH)	TYPE	TMRC (UG/KG/DAY)	%RFD	ANTICIPATED RESIDUE (PPM)	ARC (UG/KG/DAY)	%RFD
13026AA	TURNIPS-TOPS 10 RAW-FRESH OR NFS 21 COOKED-NFS 31 COOKED-FRESH OR CANNED	0.000	P	0.000000	0.000	0.04500 0.18000 0.18000	0.000000 0.000000 0.000000	0.000 0.000 0.000
CROP GROUP TOTALS FOR LEAVES OF ROOT AND TUBER VEG.:								
		0.000	P	0.000000	0.000	0.21600 0.18000	0.000000 0.002856	0.000 3.570
13009AA	COLLARDS 51 COOKED-CANNED 63 COOKED-FRESH OR FROZEN-BOILED	0.000	P	0.000000	0.000	0.18000 0.18000	0.000000 0.000000	0.000 0.000
13021AA	MUSTARD GREENS 21 COOKED-NFS 63 COOKED-FRESH OR FROZEN-BOILED	0.000	P	0.000000	0.000	0.18000 0.18000	0.000000 0.000000	0.000 0.000
CROP GROUP TOTALS FOR BRASSICA (COLE) LEAFY VEGETABLES:								
		0.000	P	0.000000	0.000	0.000000	0.000000	0.000

GRAND TOTALS FOR NON-NURSING INFANTS (< 1 YEAR OLD)

TOLERANCE TYPE: N=NEW; A=PENDING; P=PUBLISHED  
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 ARC = ANTICIPATED RESIDUE CONTRIBUTION  
 RFD = REFERENCE DOSE

0.002856

0.000000

0.000

3.570

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TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

CHEMICAL INFORMATION		STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
EBDC'S COMBINED						
Caswell #999ZZZ		NOEL= 0.0000 mg/kg		UF -->0		
CAS No.		0.00 ppm		OPP Rfd= 1.000000		
A.I. CODE:		LEL= 0.0000 mg/kg		EPA Rfd= 1.000000		
CFR No. 180.		ONCO:				

COMMODITY CONTRIBUTION BY RAC FOR: NON-NURSING INFANTS (< 1 YEAR OLD)

FOOD CODE	FOODNAME/FOODFORM	TOLERANCE (PPM)	TYPE	TMRC (UG/KG/DAY)	%RFD	ANTICIPATED RESIDUE (PPM)	ARC (UG/KG/DAY)	%RFD
13026AA	TURNIPS-TOPS	0.000	P	0.000000	0.000	0.68400	0.000000	0.000
	10 RAW-FRESH OR NFS					0.02070	0.000000	0.000
	21 COOKED-NFS					0.02070	0.000000	0.000
	31 COOKED-FRESH OR CANNED							
CROP GROUP TOTALS FOR LEAVES OF ROOT AND TUBER VEG.:								
		0.000		0.000000	0.000	0.000000	0.000000	0.000
13009AA	COLLARDS	0.000	P	0.000000	0.000	0.00360	0.000000	0.000
	51 COOKED-CANNED					0.02250	0.000357	0.000
	63 COOKED-FRESH OR FROZEN-BOILED							
13021AA	MUSTARD GREENS	0.000	P	0.000000	0.000	0.02250	0.000000	0.000
	21 COOKED-NFS					0.02250	0.000000	0.000
	63 COOKED-FRESH OR FROZEN-BOILED							
CROP GROUP TOTALS FOR BRASSICA (COLE) LEAFY VEGETABLES:								
		0.000		0.000000	0.000	0.000357	0.000357	0.000

GRAND TOTALS FOR NON-NURSING INFANTS (< 1 YEAR OLD)

TOLERANCE TYPE: N=NEW; A=PENDING; P=PUBLISHED  
 TMRC=THEORETICAL MAXIMUM RESIDUE CONTRIBUTION  
 ARC = ANTICIPATED RESIDUE CONTRIBUTION  
 RFD = REFERENCE DOSE

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TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

CHEMICAL INFORMATION	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. HED reassess 10/30/87. EPA deferred 02/25/88. WHO last reviewed 1988. EPA verified 02/20/91. On IRIS.

COMMODITY CONTRIBUTION BY RAC FOR: CHILDREN (1-6 YEARS OLD)

FOOD CODE	FOODNAME/FOODFORM	TOLERANCE (PPM)	TYPE	TMRC (UG/KG/DAY)	%RFD	ANTICIPATED RESIDUE (PPM)	ARC (UG/KG/DAY)	%RFD
13026AA	TURNIPS-TOPS 10 RAW-FRESH OR NFS 21 COOKED-NFS 31 COOKED-FRESH OR CANNED	0.000	P	0.000000	0.000	0.04500 0.18000 0.18000	0.000259 0.000632 0.001634	0.324 0.790 2.043
CROP GROUP TOTALS FOR LEAVES OF ROOT AND TUBER VEG.:								
		0.000	P	0.000000	0.000	0.21600 0.18000	0.000000 0.005609	0.000 7.011
13009AA	COLLARDS 51 COOKED-CANNED 63 COOKED-FRESH OR FROZEN-BOILED	0.000	P	0.000000	0.000	0.18000	0.000024 0.003415	0.030 4.269
13021AA	MUSTARD GREENS 21 COOKED-NFS 63 COOKED-FRESH OR FROZEN-BOILED	0.000	P	0.000000	0.000	0.18000	0.009048	11.310
CROP GROUP TOTALS FOR BRASSICA (COLE) LEAFY VEGETABLES:								
		0.000	P	0.000000	0.000	0.011573		14.466

GRAND TOTALS FOR CHILDREN (1-6 YEARS OLD)

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 ARC = ANTICIPATED RESIDUE CONTRIBUTION  
 RFD = REFERENCE DOSE

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

CHEMICAL INFORMATION		STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
EBDC'S COMBINED Caswell #999ZZZ		NOEL= 0.0000 mg/kg 0.00 ppm		UF -->0 OPP Rfd= 1.000000 EPA Rfd= 1.000000		
CAS No. A.I. CODE: CFR No. 180.		LEL= 0.0000 mg/kg 0.00 ppm				
		ONCO:				

COMMODITY CONTRIBUTION BY RAC FOR: CHILDREN (1-6 YEARS OLD)

FOOD CODE	FOODNAME/FOODFORM	TOLERANCE (PPM)	TYPE	TMRC (UG/KG/DAY)	%RFD	ANTICIPATED RESIDUE (PPM)	ARC (UG/KG/DAY)	%RFD
13026AA	TURNIPS-TOPS 10 RAW-FRESH OR NFS 21 COOKED-NFS 31 COOKED-FRESH OR CANNED	0.000	P	0.000000	0.000	0.68400 0.02070 0.02070	0.003940 0.000073 0.000188	0.000 0.000 0.000
CROP GROUP TOTALS FOR LEAVES OF ROOT AND TUBER VEG.:								
		0.000	P	0.000000	0.000	0.00360 0.02250	0.000000 0.000701	0.000 0.000
13009AA	COLLARDS 51 COOKED-CANNED 63 COOKED-FRESH OR FROZEN-BOILED	0.000	P	0.000000	0.000	0.02250 0.02250	0.000003 0.000427	0.000 0.000
13021AA	MUSTARD GREENS 21 COOKED-NFS 63 COOKED-FRESH OR FROZEN-BOILED	0.000	P	0.000000	0.000	0.001131		0.000
CROP GROUP TOTALS FOR BRASSICA (COLE) LEAFY VEGETABLES:								
		0.000	P	0.000000	0.000		0.005332	0.001

GRAND TOTALS FOR CHILDREN (1-6 YEARS OLD)

TOLERANCE TYPE: N=NEW; A=PENDING; P=PUBLISHED  
 TMRC=THEORETICAL MAXIMUM RESIDUE CONTRIBUTION  
 ARC = ANTICIPATED RESIDUE CONTRIBUTION  
 RFD = REFERENCE DOSE

DOCKET FILE ENTRY  
DOCUMENT COVER SHEET

CBI: \_\_\_\_\_ Appendix \_\_\_\_\_ In-Text \_\_\_\_\_ X No CBI

Docket No 30000 118 F Chemical EBDC

\_\_\_\_\_ Pre-SR \_\_\_\_\_ PD1 \_\_\_\_\_ PD2/3 \_\_\_\_\_ PD4 \_\_\_\_\_ Reg Std

Post  
SR

Document Title EBDC/ETU Special Review. DRES Dietary exposure and Risk Estimates for Use of Maneb on Collards, Mustard Greens, & Turnip Tops. Doc Date 2/3/94

Author/Affiliation Richard Griffin | MED/EPA

Submitter/Affiliation \_\_\_\_\_ | \_\_\_\_\_

\_\_\_\_\_ Doc Distributed in Meeting Meeting Date    /   /   

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