3/19/93

3-19-93

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

RF

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: 93GA0006. Section 18 Exemption for Chlorothalonil on Collard, Mustard, and Turnip Greens. DRES Dietary Exposure Estimates.

FROM: Richard Griffin 3/19/93
Chemistry Branch I / Tolerance Support
Health Effects Division (H7509C)

THROUGH: Debra Edwards, Chief
Chemistry Branch I / Tolerance Support
Health Effects Division (H7509C)
Debra Edwards 3/19/93

TO: Susan Stanton, PM 41
Emergency Response and Minor Use Section
Registration Support Branch (H7505C)
Registration Division (H7505C)

Exposure/risk estimates are provided both for Chlorothalonil and the associated manufacturing impurity, hexachlorobenzene.

Toxicological endpoints for chronic risk assessment:

Chlorothalonil:

o RfD: The Agency approved reference dose for Chlorothalonil is 0.015 mg/kg body weight/day based on the NOEL (1.5 mg/kg/day) of a two-year dog study and an uncertainty factor of 100.

o Carcinogenicity: HED peer review has classified Chlorothalonil as a Group B2 (probable human carcinogen) with a Q_1^* of 1.1×10^{-2} $(mg/kg/day)^{-1}$.

Hexachlorobenzene:

o RfD: The Agency approved reference dose for HCB is 0.0008 mg/kg body weight/day based on the NOEL (0.08 mg/kg/day) of a 130 week rat study and an uncertainty factor of 100.

o Carcinogenicity: The Carcinogenicity Assessment Group (CAG) has classified HCB as a Group B2 carcinogen with a Q_1^* of 1.7 $(mg/kg/day)^{-1}$.

Residue:

Food uses/tolerances for Chlorthalonil are listed under 40 CFR 180.275 and summarized in Table 1. CBTS (M.I. Rodriquez and R. Lascola memo, 3/11/93) has recommended an enforcement level of 25 ppm for Chlorothalonil on collard, mustard, and turnip greens with an estimate of HCB at a level of 0.12 ppm (25 ppm x 0.5%).

Anticipated residues have been estimated for all Chlorthalonil registered commodities except a few minor crops (D. Edwards memos, 8/10/88 and 8/23/88).

Residues for HCB were estimated by multiplying Chlorthalonil anticipated residues by 0.5% (D. Edwards memo, 8/23/88).

Percent use estimates:

In 1988, BEAD provided percent crop treated estimates for Chlorothalonil which were used with FDA monitoring data to estimate averaged anticipated residues for Chlorothalonil and HCB.

Chronic exposure/risk estimates:

Chlorothalonil:

Published uses: tolerance x 100% crop treated (TMRC)

	mg/kg/day		carcinogenic risk
Overall U.S. population:	0.012611	(84% RfD)	1.4 E-4
Non nursing infants:	0.015674	(104% RfD)	
Children (1-6):	0.022415	(149% RfD)	

"Leafy greens": 25 ppm x 100% CT (TMRC)

Overall U.S. population:	0.001203	(8% RfD)	1.3 E-5
Non nursing infants:	0.000397	(3% RfD)	
Children (1-6):	0.001715	(11% RfD)	
High exposure estimates:			
U.S southern region:	0.002766	(18% RfD)	3.0 E-5
Non-hispanic blacks:	0.006753	(45% RfD)	7.4 E-5

Published uses: anticipated residues (ARC) (1988 memos)

Overall U.S. population:	0.000074	(< 1% RfD)	8.1 E-7
NN infants:	0.000048	(< 1% RfD)	
Children (1-6):	0.000100	(1% RfD)	

Hexachlorobenzene:

Published uses: Chlorothalonil AR's x 0.5%

	mg/kg/day		C Risk
Overall U.S. population:	< 0.000001	(< 1% RfD)	6.7 E-7
NN infants:	< 0.000001		
Children (1-6):	< 0.000001		

"Leafy greens" 25 ppm x 0.5%

Overall U.S. population:	0.000006	(1% RfD)	1.0 E-5
Non-nursing infants:	0.000002	(< 1% RfD)	
Children (1-6):	0.000008	(1% RfD)	
U.S southern region:	0.000013	(2% RfD)	2.2 E-5
Non-hispanic blacks:	0.000032	(4% RfD)	5.4 E-5

cc: R. Griffin
RF
18 File

TABLE 1.

CHEMICAL INFORMATION FOR CASWELL NUMBER 215B DATE: 03/17/93 PAGE: 1

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Chlorothalonil Caswell #215B CAS No. 1897-45-6 A.I. CODE: 081901 CFR No. 180.275	2yr feeding- dog NOEL= 1.5000 mg/kg 60.00 ppm LEL= 3.0000 mg/kg 120.00 ppm ONCO: B2 (HED WOTE)	Renal tubular vacuolization. Evidence of oncogenicity in rats and mice (kideny)	PADI UF -->100 OPP RfD= 0.015000 EPA RfD= 0.015000 Q*: 0.01100	No data gaps. Q* calculated.	HED complete 03/14/86. EPA verified 04/8/86. WHO last reviewed 1990. On IRIS.

FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM) NEW	PENDING	PUBLISHED
01010AA	CRANBERRIES	2E2939			5.000000
01010JA	CRANBERRIES-JUICE	2E2939			5.000000
05001AA	APRICOTS-FRESH	3F1382			0.500000
05001DA	APRICOTS-DRIED	3F1382			0.500000
05002AA	CHERRIES-FRESH	3F1382			0.500000
05002DA	CHERRIES-DRIED	3F1382			0.500000
05002JA	CHERRIES-JUICE	3F1382			0.500000
05003AA	NECTARINES	3F1382			0.500000
05004AA	PEACHES-FRESH	3F1382			0.500000
05004DA	PEACHES-DRIED	3F1382			0.500000
05005AA	PLUMS(DAMSONS)-FRESH	2F2602			0.200000
05005DA	PLUMS-PRUNES(DRIED)	2F2602			0.200000
05005JA	PLUMS,PRUNE-JUICE	2F2602			0.200000
06002AA	BANANAS-UNSPECIFIED	8F2067			0.050000
06002AB	BANANAS-FRESH	8F2067			0.050000
06002DA	BANANAS-DRIED	8F2067			0.050000
06010AA	PAPAYAS-UNSPECIFIED	6E1761			15.00000
06010AB	PAPAYAS-PULP	6E1761			15.00000
06010DA	PAPAYAS-DRIED	6E1761			15.00000
06010JA	PAPAYAS-JUICE	631761			15.00000
06014AA	PASSION FRUIT (GRANADILLA)	5E1569			3.000000
06016AA	PLANTAINS	8F2067			0.050000
07001FA	COCOA BUTTER	2E2744			0.050000
07001SA	CHOCOLATE	2E2744			0.050000
07002AA	COFFEE	2E2744			0.200000
10002AA	CANTALOUPES-UNSPECIFIED	1F1024			5.000000
10002AB	CANTALOUPES-PULP	1F1024			5.000000
10003AA	CASABAS	1F1024			5.000000
10004AA	CRENSHAWS	1F1024			5.000000
10005AA	HONEYDEW MELONS	1F1024			5.000000
10007AA	PERSION MELONS	1F1024			5.000000
10008AA	WATERMELON	1F1024			5.000000
10010AA	CUCUMBERS	1F1024			5.000000
10011AA	PUMPKIN	1F1024			5.000000
10013AA	SQUASH-SUMMER	1F1024			5.000000
10014AA	SQUASH-WINTER	1F1024			5.000000
10017AA	BITTER MELON	1F1024			5.000000
10020AA	TOWELGOURD	1F1024			5.000000
11005AA	TOMATOES-WHOLE	1F1024			5.000000
11005JA	TOMATOES-JUICE	1F1024			5.000000