

US EPA ARCHIVE DOCUMENT



4-21-88

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

APR 21 1988

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Corrected Dietary Exposure Analysis for Iprodione on Potatoes (PP#6F3366)

FROM: J. Robert Tomerlin, Ph.D. *JRT*
Tolerance Assessment System Staff
HED/RCB (TS 769C)

THRU: Karl Arne, Ph.D. *KArne*
Branch Senior Scientist
HED/RCB (TS 769C)

TO: Lois Rossi, PM 21
Registration Division (TS 767)

Action Requested

Provide a corrected dietary exposure analysis for Iprodione on potatoes (6F3366) (Tomerlin to Rossi memoranda, 3/25/88 and 4/7/88) in accordance with a Federal Register Notice amendment in progress (Rossi to Arne memo, 4/19/88).

Discussion

1. A routine chronic TAS analysis was conducted with a reference dose (ADI) of 0.04 mg/kg/body weight/day, based upon a NOEL of 4.2 mg/kg body weight/day and a safety factor of 100 from a 1 year dog feeding study. This value was approved by TOX Branch (12/19/86) and verified by ORD (7/15/86).
2. Food uses evaluated include published tolerances from CFR 180.399, the proposed action for potatoes (Cook to Rossi memo, 8/4/87); food additive tolerances from CFR 193.253, and other pending tolerances. A summary of the tolerance information used in the analysis is attached as Table 1.
3. The TAS routine chronic analysis estimates the Theoretical Maximum Residue Contribution (TMRC) for the U.S. population and 22 population sub-groups. The TMRC for the U.S. population is 0.052 mg/kg body weight/day (130% of the ADI). A TMRC summary is attached as Table 2.
4. The total TMRC is the sum of the TMRC's for published and pending tolerances, and the new action. For the U.S. population, current published tolerances result in a TMRC of 0.043 mg/kg body

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weight/day (108% of the ADI); the action on potatoes adds an additional 0.0006 mg/kg body weight/day (1.4% of the ADI); and other pending tolerances add 0.008 mg/kg body weight/day (20.7% of the ADI), resulting in the total TMRC of 0.052 mg/kg body weight/day. Table 3 presents the 'partitioned' TMRC information for the U.S. population, infants, and children.

cc: TAS Files
Reading File
PMSD
PP#6F3366

TOX (Rathman)
circ.
Iprodione SF

Table 1

PAGE: 1

DATE: 04/19/88

CHEMICAL INFORMATION FOR CASWELL NUMBER 470A

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES		DATA GAPS/COMMENTS	STATUS
			ADI	SF -->		
Iprodione (Glycophene) Caswell #470A	1yr feeding- dog NOEL= 4.2000 mg/kg	Increased number of RBC Heinz bodies, decreased prostate weights. NOEL based on calc. dose.	100	Teratology- rat (under review).	TOX complete 12/19/86. EPA verified 7/15/87. WHO last reviewed 1977.	
CAS No. 36734-19-7	NOEL= 100.00 ppm		OPP RfD= 0.040000			
A.I. CODE: 109801	LEL= 15.0000 mg/kg		EPA RfD= 0.040000			
CFR No. 180.399	600.00 ppm	No evidence of oncogeni- city in rats or mice.				
	ONCO: Negative- 2 species					

FOOD CODE	FOOD NAME	PETITION NUMBER	NEW	TOLERANCE (PPM)	
				PENDING	PUBLISHED
01002AA	BLACKBERRIES	7F3542		25.0000	
01003AA	BOYSENBERRIES	5F3214			15.0000
01003AA	BOYSENBERRIES	7F3542		10.0000	
01004AA	DEWBERRIES	7F3542		25.0000	
01005AA	LOGANBERRIES	7F3542		25.0000	
01006AA	RASPBERRIES	5F3214			15.0000
01006AA	RASPBERRIES	7F3542		10.0000	
01007AA	YOUNGBERRIES	7F3542		25.0000	
01009AA	BLUEBERRIES	5F3214			15.0000
01011AA	CURRENTS	5F3214			15.0000
01014AA	GRAPES-FRESH	3F2964			60.0000
01014DA	GRAPES-RAISINS	4H5415			300.0000 H
01014JA	GRAPES-JUICE	3F2964			60.0000
01016AA	STRAWBERRIES	7F3510		15.0000	
03001AA	ALMONDS	5F3241			0.3000
05001AA	APRICOTS-FRESH	3F2810			20.0000
05001DA	APRICOTS-DRIED	3F2810			20.0000
05002AA	CHERRIES-FRESH				20.0000
05002DA	CHERRIES-DRIED				20.0000
05002JA	CHERRIES-JUICE	2F2596			20.0000
05003AA	NECTARINES	2F2596			20.0000
05004AA	PEACHES-FRESH	2F2596			20.0000
05004DA	PEACHES-DRIED	2F2596			20.0000
05005AA	PLUMS-(DAMSONS)-FRESH	3F2810			20.0000
05005DA	PLUMS-PRUNES (DRIED)	3F2810			20.0000
05005JA	PLUMS-PRUNE-JUICE	3F2810			20.0000
06018AA	KIWI	2F2596			10.0000
11005AA	TOMATOES-WHOLE	7F3545		3.0000	
11005JA	TOMATOES-JUICE	7F3545		3.0000	
11005RA	TOMATOES-PUREE	7F3545		3.0000	
11005TA	TOMATOES-PASTE	7F3545		3.0000	
11005UA	TOMATOES-CATSUP	7F3545		3.0000	
13002AA	CELERY	7F3554		25.0000	
13005AA	BROCCOLI	6F3305			25.0000
13013AA	LETTUCE-LEAFY VARIETIES	7F3481			25.0000
13016AA	FENNEL	7F3554		25.0000	
13020AA	LETTUCE-UNSPECIFIED				25.0000
13045AA	LETTUCE-HEAD VARIETIES				5.0000
14003AA	CARROTS				0.1000
14007AA	GARLIC				

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES		DATA GAPS/COMMENTS	STATUS
			ADI	SF -->		
Iprodione (Glycophene)	1 yr feeding- dog	Increased number of RBC	100	100	Teratology- rat	TOX complete 12/19/86.
Caswell #470A	4.2000 mg/kg	Heinz bodies, decreased	OPP RfD= 0.040000		(under review).	EPA verified 7/15/87.
CAS No. 36734-19-7	NOEL=	prostate weights. NOEL	EPA RfD= 0.040000			WHO last reviewed 1977.
A. I. CODE: 109801	100.00 ppm	based on calc. dose.				
CFR No. 180.399	LEL=	No evidence of oncogeni-				
	600.00 ppm	city in rats or mice.				
	ONCO: Negative- 2 species					

FOOD CODE	FOOD NAME	PETITION NUMBER	NEW	TOLERANCE (PPM)	
				PENDING	PUBLISHED
14011AA	ONIONS-DRY-BULB (CIPOLLINI)	4F3111			0.5000
14011DA	ONIONS-DEHYDRATED OR DRIED	4F3111			0.5000
14013AA	POTATOES(WHITE)-WHOLE	6F3366	0.5000		
14013AB	POTATOES(WHITE)-UNSPECIFIED	6F3366	0.5000		
14013AC	POTATOES(WHITE)-PEELED	6F3366	0.5000		
14013DA	POTATOES(WHITE)-DRY	6H5496	0.5000		
14013HA	POTATOES(WHITE)-PEEL ONLY	6F3366	0.5000		
14017AA	SHALLOTS	4F3111			
15001AA	BEANS-DRY-GREAT NORTHERN				0.5000
15001AB	BEANS-DRY-KIDNEY				2.0000
15001AC	BEANS-DRY-LIMA				2.0000
15001AD	BEANS-DRY-NAVY (PEA)				2.0000
15001AE	BEANS-DRY-OTHER				2.0000
15001AF	BEANS-DRY-PINTO				2.0000
15002AA	BEANS-SUCCULENT-LIMA				2.0000
15003AA	BEANS-SUCCULENT-GREEN	4F3150			2.0000
15003AB	BEANS-SUCCULENT-OTHER	4F3150			2.0000
15003AC	BEANS-SUCCULENT-YELLOW,WAX	4F3150			2.0000
15006AA	PEANUTS-WHOLE	4F3129			0.5000
15013AA	MUNG BEANS (SPROUTS)				2.0000
15022AA	BEANS-DRY-BROADBEANS(MATURE SEED)				2.0000
15022AB	BEANS-SUCCULENT-BROADBEANS(IMMAT. SEED)	4F3150			2.0000
15023AA	BEANS-DRY-PIGEON BEANS	4F3150			2.0000
15027AA	BEANS-UNSPECIFIED				2.0000
15030AA	BEANS-DRY-HYACINTH(MATURE SEEDS)	4F3150			2.0000
15030AB	BEANS-SUCCULENT-HYACINTH(YOUNG PODS)	4F3150			2.0000
15031AA	BEANS-DRY-BLACKEYE PEAS(COMPEAS)				2.0000
15032AA	BEANS-DRY-GARBANZO(CHICK PEA)				2.0000
24004AA	RICE-ROUGH	4F3150			
24004AB	RICE-MILLED	6F3443		10.0000	
27007AA	PEANUTS-OIL	6F3443		10.0000	
43058AA	WINE AND SHERRY	4F3129			0.5000
50000DB	MILK-NON-FAT SOLIDS	4F3129			60.0000
50000FA	MILK-FAT SOLIDS	4F3129			0.5000
50000SA	MILK SUGAR (LACTOSE)	4F3129			0.5000
53001BA	BEEF-MEAT BYPRODUCTS	4F3129			0.5000
53001BB	BEEF(ORGAN MEATS)-OTHER	4F3129			0.5000
53001DA	BEEF-DRIED	4F3129			0.5000
53001FA	BEEF(BONELESS)-FAT (BEEF TALLOW)	4F3129			0.5000
53001KA	BEEF(ORGAN MEATS)-KIDNEY	3F2964			3.0000

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CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES		DATA GAPS/COMMENTS	STATUS
			ADI	SF --> 100		
Iprodione (Glycophene)	lyr feeding- dog	Increased number of RBC				
Caswell #470A	4.2000 mg/kg	Heinz bodies, decreased	OPP RfD= 0.040000		Teratology- rat	TOX complete 12/19/86.
CAS No. 36734-19-7	100.00 ppm	prostate weights. NOEL	EPA RfD= 0.040000		(under review).	EPA verified 7/15/87.
A.I. CODE: 109801	LEL= 15.0000 mg/kg	based on calc. dose.				WHO last reviewed 1977.
CFR No. 180.399	600.00 ppm	No evidence of oncogeni-				
	ONCO: Negative- 2 species	city in rats or mice.				

FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM)	
			NEW	PUBLISHED
53001LA	BEEF (ORGAN MEATS)-LIVER	3F2964		3.0000
53001MA	BEEF (BONELESS)-LEAN (W/O REMOVEABLE FAT)	4F3129		0.5000
53002BA	GOAT-MEAT BYPRODUCTS	4F3129		0.5000
53002BB	GOAT (ORGAN MEATS)-OTHER	4F3129		0.5000
53002FA	GOAT (BONELESS)-FAT	4F3129		0.5000
53002KA	GOAT (ORGAN MEATS)-KIDNEY	3F2964		3.0000
53002LA	GOAT (ORGAN MEATS)-LIVER	3F2964		3.0000
53002MA	GOAT (BONELESS)-LEAN (W/O REMOVEABLE FAT)	4F3129		0.5000
53003AA	HORSE		3.0000	
53005BA	SHEEP-MEAT BYPRODUCTS	4F3129		0.5000
53005BB	SHEEP (ORGAN MEATS)-OTHER	4F3129		0.5000
53005FA	SHEEP (BONELESS)-FAT	4F3129		0.5000
53005KA	SHEEP (ORGAN MEATS)-KIDNEY	3F2964		3.0000
53005LA	SHEEP (ORGAN MEATS)-LIVER	3F2964		3.0000
53005MA	SHEEP (BONELESS)-LEAN (W/O REMOVEABLE FAT)	4F3129		0.5000
53006BA	PORK-MEAT BYPRODUCTS	4F3129		0.5000
53006BB	PORK (ORGAN MEATS)-OTHER	4F3129		0.5000
53006FA	PORK (BONELESS)-FAT (INCLUDING LARD)	4F3129		0.5000
53006KA	PORK (ORGAN MEATS)-KIDNEY	3F2964		3.0000
53006LA	PORK (ORGAN MEATS)-LIVER	3F2964		3.0000
53006MA	PORK (BONELESS)-LEAN (W/O REMOVEABLE FAT)	4F3129		0.5000
55008BA	TURKEY-BYPRODUCTS	3F2964		2.0000
55008LA	TURKEY-GIBLETS (LIVER)	3F2964		3.0000
55008MA	TURKEY-FLESH (W/O SKIN & W/O BONES)	4F3129		0.5000
55008MB	TURKEY-FLESH (+SKIN & W/O BONES)	3F2964		2.0000
55008MC	TURKEY-UNSPECIFIED	4F3129		0.5000
55013BA	POULTRY/OTHER-BYPRODUCTS	4F3129		0.5000
55013LA	POULTRY/OTHER-GIBLETS (LIVER)	3F2964		3.0000
55013MA	POULTRY/OTHER-FLESH (+SKIN & W/O BONES)	4F3129		0.5000
55014AA	EGGS-WHOLE	3F2964		0.8000
55014AB	EGGS-WHITE ONLY	3F2964		0.8000
55014AC	EGGS-YOLK ONLY	3F2964		0.8000
55015BA	CHICKEN-BYPRODUCTS	4F3129		0.5000
55015LA	CHICKEN-GIBLETS (LIVER)	3F2964		3.0000
55015MA	CHICKEN-FLESH (W/O SKIN & W/O BONES)	4F3129		0.5000
55015MB	CHICKEN-FLESH (+SKIN & W/O BONES)	3F2964		2.0000

Table 2

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

DATE: 04/19/88

PAGE: 1

CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES		DATA GAPS/COMMENTS	STATUS
			ADI	SF ^a →		
Iproclione (Glycophene)	lyr feeding- dog	Increased number of RBC		100	Teratology- rat	TOX complete 12/19/86.
Caswell #470A	NOEL= 4.2000 mg/kg	Heinz bodies, decreased	OPP RfD= 0.040000		(under review).	EPA verified 7/15/87.
CAS No. 36734-19-7	100.00 ppm	prostate weights. NOEL	EPA RfD= 0.040000			WHO last reviewed 1977.
A.I. CODE: 109801	LEL= 15.0000 mg/kg	based on calc. dose.				
CFR No. 180.399	600.00 ppm	No evidence of oncogeni-				
	ONCO: Negative- 2 species	city in rats or mice.				

POPULATION SUBGROUP	TOTAL TMRC (MG/KG BODY WEIGHT/DAY)		NEW TMRC AS PERCENT OF RFD	DIFFERENCE AS PERCENT OF RFD	EFFECT OF ANTICIPATED RESIDUES	
	CURRENT TMRC*	NEW TMRC**			ARC	%RFD
U.S. POPULATION - 48 STATES	0.043184	0.052017	130.042738	22.083250		
U.S. POPULATION - SPRING SEASON	0.040587	0.049730	124.324062	22.856833		
U.S. POPULATION - SUMMER SEASON	0.047210	0.056078	140.195647	22.169440		
U.S. POPULATION - FALL SEASON	0.042851	0.051324	128.309550	21.182453		
U.S. POPULATION - WINTER SEASON	0.042109	0.050645	126.612738	21.339775		
NORTHEAST REGION	0.049541	0.058960	147.399052	23.545482		
NORTH CENTRAL REGION	0.041858	0.050442	126.105815	21.460053		
SOUTHERN REGION	0.031710	0.039615	99.038522	19.763920		
WESTERN REGION	0.056473	0.066060	165.148910	23.966165		
HISPANICS	0.042411	0.053965	134.912198	28.883855		
NON-HISPANIC WHITES	0.045395	0.054076	135.188935	21.701900		
NON-HISPANIC BLACKS	0.030001	0.037202	93.004082	18.001018		
NON-HISPANIC OTHERS	0.036754	0.051814	129.533755	37.649613		
NURSING INFANTS (< 1 YEAR OLD)	0.053051	0.060325	150.812865	18.185635		
NON-NURSING INFANTS (< 1 YEAR OLD)	0.128562	0.146407	366.017493	44.612422		
FEMALES (13+ YEARS, PREGNANT)	0.034133	0.041099	102.747408	17.415390		
FEMALES 13+ YEARS, NURSING	0.050716	0.059010	147.525823	20.736618		
CHILDREN (1-6 YEARS OLD)	0.103271	0.119304	298.258897	40.082368		
CHILDREN (7-12 YEARS OLD)	0.056303	0.068770	171.924483	31.166520		
MALES (13-19 YEARS OLD)	0.029089	0.037843	94.606505	21.883690		
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.028817	0.036304	90.760865	18.718473		
MALES (20 YEARS AND OLDER)	0.031445	0.038805	97.013540	18.400315		
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)	0.035350	0.042196	105.490280	17.115005		

*Current TMRC does not include new or pending tolerances.

**New TMRC includes new, pending, and published tolerances.

Table 3

TOLERANCE ASSESSMENT SUMMARY FOR Iprodione (Glycophene)
CASWELL #470A

DATE: 04/19/88

ANALYSIS FOR POPULATION SUB-GROUP: U.S. POPULATION - 48 STATES

EXISTING TOLERANCES (PUBLISHED ONLY)		
RESULT IN A TMRC OF:	0.043184	MG/KG/DAY
THE EXISTING TMRC IS EQUIVALENT TO:	107.959488	% OF THE ADI.
PROPOSED NEW TOLERANCES (CURRENT PETITION ONLY)		
RESULT IN A TMRC OF:	0.000566	MG/KG/DAY
THESE NEW TOLERANCES WILL OCCUPY:	1.416082	% OF THE ADI.
IF THE NEW TOLERANCES (CURRENT PETITION ONLY)		
ARE APPROVED THE RESULTANT TMRC WILL BE:	0.043750	MG/KG/DAY
THE NEW TMRC WILL OCCUPY	109.375570	% OF THE ADI.
OTHER PENDING TOLERANCES EXCLUDING THE		
CURRENT NEW PETITION HAVE A TMRC OF:	0.008267	MG/KG/DAY
THIS TMRC WILL OCCUPY	20.667167	% OF THE ADI.
IF ALL PENDING TOLERANCES (INCLUDING THE		
CURRENT NEW PETITION) ARE GRANTED		
THE RESULTANT TMRC WILL BE:	0.052017	MG/KG/DAY
THE TOTAL TMRC WILL OCCUPY	130.042738	% OF THE ADI.

ANALYSIS FOR POPULATION SUB-GROUP: NON-NURSING INFANTS (< 1 YEAR OLD)

EXISTING TOLERANCES (PUBLISHED ONLY)		
RESULT IN A TMRC OF:	0.128562	MG/KG/DAY
THE EXISTING TMRC IS EQUIVALENT TO:	321.405070	% OF THE ADI.
PROPOSED NEW TOLERANCES (CURRENT PETITION ONLY)		
RESULT IN A TMRC OF:	0.000697	MG/KG/DAY
THESE NEW TOLERANCES WILL OCCUPY:	1.743680	% OF THE ADI.
IF THE NEW TOLERANCES (CURRENT PETITION ONLY)		
ARE APPROVED THE RESULTANT TMRC WILL BE:	0.129260	MG/KG/DAY
THE NEW TMRC WILL OCCUPY	323.148750	% OF THE ADI.
OTHER PENDING TOLERANCES EXCLUDING THE		
CURRENT NEW PETITION HAVE A TMRC OF:	0.017147	MG/KG/DAY
THIS TMRC WILL OCCUPY	42.868743	% OF THE ADI.
IF ALL PENDING TOLERANCES (INCLUDING THE		
CURRENT NEW PETITION) ARE GRANTED		
THE RESULTANT TMRC WILL BE:	0.146407	MG/KG/DAY
THE TOTAL TMRC WILL OCCUPY	366.017493	% OF THE ADI.

ANALYSIS FOR POPULATION SUB-GROUP: CHILDREN (1-6 YEARS OLD)

EXISTING TOLERANCES (PUBLISHED ONLY)		
RESULT IN A TMRC OF:	0.103271	MG/KG/DAY
THE EXISTING TMRC IS EQUIVALENT TO:	258.176530	% OF THE ADI.
PROPOSED NEW TOLERANCES (CURRENT PETITION ONLY)		
RESULT IN A TMRC OF:	0.001125	MG/KG/DAY
THESE NEW TOLERANCES WILL OCCUPY:	2.813543	% OF THE ADI.
IF THE NEW TOLERANCES (CURRENT PETITION ONLY)		
ARE APPROVED THE RESULTANT TMRC WILL BE:	0.104396	MG/KG/DAY
THE NEW TMRC WILL OCCUPY	260.990072	% OF THE ADI.
OTHER PENDING TOLERANCES EXCLUDING THE		
CURRENT NEW PETITION HAVE A TMRC OF:	0.014908	MG/KG/DAY
THIS TMRC WILL OCCUPY	37.268825	% OF THE ADI.
IF ALL PENDING TOLERANCES (INCLUDING THE		
CURRENT NEW PETITION) ARE GRANTED		
THE RESULTANT TMRC WILL BE:	0.119304	MG/KG/DAY
THE TOTAL TMRC WILL OCCUPY	298.258897	% OF THE ADI.

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