

US EPA ARCHIVE DOCUMENT



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

MAR 25 1988

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Dietary Exposure Analysis of Iprodione on Potato, PP#6F3366

FROM: J. Robert Tomerlin, Ph.D. *JR Tomerlin 3/25/88*
Tolerance Assessment System Staff
HED/RCB (TS 769C)

TO: L. Rossi, PM 21
Registration Division (TS 769)

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

Action Requested

Provide a dietary exposure analysis for the proposed action to remove the food additive tolerance on potatoes (6H5496).

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 from a 1 year dog feeding study. This value has been approved by TOX branch (12/19/86) and ORD (7/15/87).
2. Food uses evaluated include published tolerances from CFR 180.399, the proposed action for potatoes (Cook to Rossi memo, 8/4/87), and food additive tolerances from CFR 193.253. A summary of the tolerance information used in the analysis is attached as Table 1.
3. The TAS routine analysis estimates the Theoretical Maximum Residue Contribution (TMRC) for the general U.S. population and 22 population sub-groups. The TMRC for the overall U.S. population is 0.041 mg/kg/day, which occupies 101.6 per cent of the ADI. The two most highly affected sub-groups are non-nursing infants less than 1 year old and children 1 to 6 years old. A summary of the effect of the current action on potatoes, PP#6F3366, is shown on page 2.

Iprodione Dietary Exposure Analysis, page 2

	<u>6F3366</u>	<u>CURRENT</u>	<u>TOTAL</u>
U.S. Population:			
mg/kg body weight/day	0.001	0.040	0.041
per cent of the ADI	1.4	100.2	101.6
Non Nursing Infants:			
mg/kg body weight/day	0.001	0.127	0.128
per cent of the ADI	1.7	317.8	319.5
Children, Aged 1 to 6:			
mg/kg body weight/day	0.001	0.100	0.101
per cent of the ADI	2.8	248.9	251.7

4. An examination of Figure 1 shows that the main contributors to the TMRC, particularly for the two juvenile sub-groups, are grapes, milk, and peaches. The effect of the new action for potatoes is insignificant. Since the last analysis, tolerances for beans have been published, and it has been decided to apply tolerances on grapes to wine. These two factors account for the difference in the 'current' TMRC figures between this analysis and the previous one (11/13/87).

cc: TAS Files
 Reading File
 circ.
 PMSD

TOX (Rathman)
 Iprodione SF
 PP#6F3366

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Iprodione (Glycophene)	1 yr feeding- dog	Increased number of RBC	ADI 100	Teratology- rat	TOX complete 12/19/86.
Caswell #470A	NOEL= 4.2000 mg/kg	Heinz bodies, decreased	OPP RfD= 0.040000	(under review).	ORD verified 7/15/87.
CAS No. 36734-19-7	NOEL= 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	ONCO: Negative- 2 species	No evidence of oncogeni-	WHO RfD 0.300000		
		city in rats or mice.	Type: ADI		

FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM)		
			NEW	PENDING	PUBLISHED
01003AA	BOYSENBERRIES	5F3214			15.0000
01006AA	RASPBERRIES	5F3214			15.0000
01009AA	BLUEBERRIES	5F3214			15.0000
01011AA	CURRANTS	5F3214			15.0000
01014AA	GRAPES-FRESH	3F2964			60.0000
01014DA	GRAPES-RAISINS	4H5415			300.0000 H
01014JA	GRAPES-JUICE	3F2964			60.0000
03001AA	ALMONDS	5F3241			0.3000
05001AA	APRICOTS-FRESH	3F2810			20.0000
05001DA	APRICOTS-DRIED	3F2810			20.0000
05002DA	CHERRIES-DRIED	2F2596			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
13005AA	BROCCOLI	6F3305			25.0000
13045AA	LETTUCE-HEAD VARIETIES	3F2840			15.0000
14003AA	CARROTS	7E3474			5.0000
14007AA	GARLIC	3F2841			0.1000
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			0.5000
15001AA	BEANS-DRY-GREAT NORTHERN			2.0000	
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	

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Iprodione (Glycophene) Caswell #470A CAS No. 36734-19-7 A.I. CODE: 109801 CFR No. 180.399	lyc feeding- dog NOEL= 4.2000 mg/kg 100.00 ppm LEL= 15.0000 mg/kg 600.00 ppm ONCO: Negative- 2 species	Increased number of RBC Heinz bodies, decreased prostate weights. NOEL based on calc. dose. No evidence of oncogeni- city in rats or mice.	ADI 100 OPP RED= 0.040000 EPA RED= 0.040000 WHO RED 0.300000 Type: ADI	Teratology- rat (under review).	TOX complete 12/19/86. ORD verified 7/15/87. WHO last reviewed 1977.

FOOD CODE	FOOD NAME	PETITION NUMBER	NEW	TOLERANCE (PPM)	PUBLISHED
15003AC	BEANS-SUCCULENTI-YELLOW, MAX	4F3150			2.0000
15006AA	PEANUTS-WHOLE	4F3129			0.5000
15013AA	MUNG BEANS (SPROUTS)				2.0000
15022AA	BEANS-DRY-BROADBEANS (MATURE SEED)	4F3150			2.0000
15022AB	BEANS-SUCCULENTI-BROADBEANS (IMMAT. SEED)	4F3150			2.0000
15023AA	BEANS-DRY-PIGEON BEANS				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-BLACKEY PEAS (COMPERS)				2.0000
15032AA	BEANS-DRY-GARBANZO (CHICK PEA)	4F3150			2.0000
270070A	PEANUTS-OIL	4F3129			0.5000
43058AA	WINE AND SHERRY				60.0000
50000DB	MILK-NON-FAT SOLIDS	4F3129			0.5000
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
53001LA	BEEF (ORGAN MEATS)-LIVER	3F2964			3.0000
53001WA	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
53002WA	GOAT (BONELESS)-LEAN (W/O REMOVEABLE FAT)	4F3129			0.5000
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
53005WA	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

4

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES		DATA GAPS/COMMENTS	STATUS
			ADI	100		
Iprodione (Glycophene)	1yr feeding- dog	Increased number of RBC	ADI	100	Teratology- rat	TOX complete 12/19/86.
Caswell #470A	NOEL= 4.2000 mg/kg	Heinz bodies, decreased	OPP RfD= 0.040000		(under review).	ORD 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-	WHO RfD 0.300000			
	ONCO: Negative- 2 species	city in rats or mice.	Type: ADI			

FOOD CODE	FOOD NAME	PETITION NUMBER	NEW	TOLERANCE (PPM)	
				PENDING	PUBLISHED
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

5

CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Iprodione (Glycophene) Caswell #470A CAS No. 36734-19-7 A.I. CODE: 109801 CFR No. 180.399	1yr feeding- dog NOEL= 4.2000 mg/kg 100.00 ppm LEL= 15.0000 mg/kg 600.00 ppm ONCO: Negative- 2 species	Increased number of RBC Heinz bodies, decreased prostate weights. NOEL based on calc. dose. No evidence of oncogeni- city in rats or mice.	ADI 100 OPP RfD= 0.040000 EPA RfD= 0.040000 WHO RfD 0.300000 Type: ADI	Teratology- rat (under review).	TOX complete 12/19/86. ORD verified 7/15/87. WHO last reviewed 1977.

EFFECT OF ANTICIPATED RESIDUES

POPULATION SUBGROUP	TOTAL TMRC (MG/KG BODY WEIGHT/DAY)	NEW TMRC AS PERCENT OF RFD	DIFFERENCE AS PERCENT OF RFD	ARC	SRFD
U.S. POPULATION - 48 STATES	0.040077	101.607690	1.416082		
U.S. POPULATION - SPRING SEASON	0.037071	94.047912	1.370520		
U.S. POPULATION - SUMMER SEASON	0.043855	110.992035	1.354495		
U.S. POPULATION - FALL SEASON	0.040143	101.828258	1.471722		
U.S. POPULATION - WINTER SEASON	0.039261	99.620155	1.467590		
NORTHEAST REGION	0.046072	116.512322	1.331385		
NORTH CENTRAL REGION	0.038821	98.628245	1.576563		
SOUTHERN REGION	0.029462	75.089015	1.434060		
WESTERN REGION	0.052260	131.913343	1.263895		
HISPANICS	0.039165	99.330580	1.417620		
NON-HISPANIC WHITES	0.042106	106.705377	1.439255		
NON-HISPANIC BLACKS	0.028217	71.861465	1.318270		
NON-HISPANICS OTHER	0.032871	83.130182	0.952050		
NURSING INFANTS (<1 YEAR OLD)	0.052917	132.714767	0.421880		
NON-NURSING INFANTS (<1 YEAR OLD)	0.127088	319.464703	1.743680		
FEMALES (13+ YEARS, PREGNANT)	0.031308	79.205490	0.935983		
FEMALES 13+ YEARS, NURSING	0.046935	118.363615	1.024880		
CHILDREN (1-6 YEARS OLD)	0.099557	251.706415	2.813543		
CHILDREN (7-12 YEARS OLD)	0.052796	134.095980	2.105585		
MALES (13-19 YEARS OLD)	0.026551	67.956765	1.578383		
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.026140	66.655863	1.306530		
MALES (20 YEARS AND OLDER)	0.028748	73.085780	1.214945		
FEMALES (20 YEARS AND OLDER)	0.031958	80.902987	1.008122		

*Current TMRC does not include new or pending tolerances.

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

Figure 1

Commodity Contribution of Selected RACs

To IPRADIONE ADI

