



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Acute Exposure Analysis for Propargite (Omite) for Selected Food Commodities

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Action Requested

Provide an acute dietary exposure analysis, including Margins of Safety, for the currently established tolerances of propargite (Omite) on selected high exposure food commodities, as recommended in a previous TAS analysis (J. R. Tomerlin memorandum, 10/24/88).

Discussion

1. Toxicology Endpoint: The NOEL for developmental toxicity used in the analysis is 6 mg/kg body weight/day from a rat study (Quang Bui, memorandum, 11/13/88)
2. Residue Information: Food uses established by 40 CFR 180.259 and food additive uses in 40 CFR 185.5000 were evaluated. We assumed that residues were at tolerance levels and that 100 per cent of the crop was treated. Separate analyses were conducted for: cranberries, dry beans, grapefruit, grapes, hops, oranges, stone fruits, and succulent beans. A summary of the residue information used in the analyses is attached as Table 1.
3. Acute Exposure Analysis: The TAS acute exposure analysis estimates the distribution of single-day exposures for the overall U.S. population and certain population subgroups. The analysis evaluates individual food consumption, as reported by respondents in the 1977-78 USDA Food Consumption Survey, and accumulates exposure to propargite for each food consumed for which a tolerance has been established. Each analysis assumes

that propargite residues are present at tolerance levels in all foods consumed for which a tolerance is established.

The toxicologic endpoint pertains to developmental toxicity. The TAS subgroup of interest in this analysis is women aged 13 and above, which is the TAS subgroup most closely approximating women of child-bearing age. The MOS for the average consumer may be calculated according to the following relationship:

$$\text{Average MOS} = \text{NOEL} / \text{Exposure}$$

Such calculations may be made for each food commodity evaluated. The specific acute exposure analyses are summarized below.

Dry Beans: The acute exposure analysis (Table 2) shows that women are not expected to ingest more than 0.004 ug/kg/day of propargite in dry beans, representing an MOS of not less than 1500. This commodity group does not significantly contribute to the total estimated exposure reported previously (Tomerlin memorandum, 10/24/88).

Cranberries: Each day, 4.7 per cent of the adult female population are estimated to consume cranberries. Of these consumers, two per cent are expected to ingest enough propargite to have an MOS less than 100 (Table 2). Thus, each day, 0.1 per cent (2% x 4.7%) of the total adult female population is estimated to ingest enough propargite to have an MOS less than 100. The analysis predicts that each day, the average consumer of cranberries ingests 0.006764 mg/kg of propargite, yielding an average MOS of 887 (Table 2).

Stone Fruits: According to the TAS analysis, the average female consumer of stone fruits ingests 0.007216 mg/kg of propargite, representing an average MOS of 831 (Table 2). Each day, 23 per cent of the adult female population consume stone fruits, of which the entire supply is assumed to contain tolerance levels of propargite residues. The exposure distribution (Table 2) shows that none of the consumers have an MOS less than 100.

Grapes: The average consumer of grapes has an MOS of 655 from an estimated intake of 0.009162 mg/kg of propargite (Table 2). Each day, approximately 25 per cent of the adult female population are expected to consume grapes. Three per cent of these are estimated to have an MOS less than 100 (Table 2). None are expected to have an MOS less than 30.

Hops: Only three per cent of the adult female population are estimated to consume hops on any given day. The exposure distribution, based upon tolerance level propargite

residues (Table 2), shows that one per cent of the consumers are estimated to have an MOS less than 100. The average adult female consumer of hops, according to the TAS analysis, ingests 0.012241 mg/kg of propargite, for an average MOS of 490 (Table 2).

Grapefruit: The TAS analysis indicates that the average consumer of grapefruit ingests 0.015241 mg/kg of propargite, having an average MOS of 394 (Table 2). Only six per cent of the adult female population are estimated to consume grapefruit on any given day. One per cent of these consumers are estimated to have an MOS less than 100 (Table 2).

Oranges: Each day, approximately 29 per cent of the adult female population consume oranges. The average consumer is estimated to ingest 0.015547 mg/kg of propargite, having an average MOS of 386 (Table 2). Of these, one per cent are estimated to have an MOS of less than 100.

Succulent Beans: Approximately 15 per cent of the women consume succulent beans, all assumed to have 20 ppm propargite residues, on any given day. It is estimated that the average consumer ingests 0.028959 mg/kg of propargite, representing an average MOS of 207 (Table 2). Six per cent of these consumers are estimated to have an MOS less than 100 (Table 2). The distribution for succulent beans tapers gradually, so that one per cent of the consuming female population is estimated to have an MOS less than 60.

4. Comments: A previous analysis estimated acute exposure to propargite from all registered uses (Tomerlin memorandum, 10/24/88). In that analysis, as in the analyses presented here, tolerance levels of propargite were assumed to be present in all food commodities consumed. The previous analysis, however, used a NOEL of 2 mg/kg/day (J. Housenger memo, 10/13/88) as the toxicological endpoint instead of the 6 mg/kg/day, so the estimated Margins of Safety in the Tomerlin memorandum of 10/13/88 were not calculated with the same NOEL as the ones in this report. Dividing the revised NOEL of 6 mg/kg/day by the exposure levels estimated in the previous analysis yields an MOS for the average consumer of 283, not 94 as indicated previously. Of the adult women who consume any food potentially contaminated with propargite, eight, rather than 39, per cent are estimated to have an MOS less than 100.

The likelihood of the entire supply of any food commodity containing residues at tolerance levels is small. Even using this conservative assumption, the current analysis estimates the percentage of the consumers having Margins of Safety less than 100 ranged from 0 (stone fruit) to 6 per cent (succulent beans).

The NOEL to which acute exposure was compared changed from the previous analysis to this one. If review of additional data prompts further revisions of the NOEL, new TAS analyses are not necessarily required. Changes in the NOEL do not affect the exposure estimates. To estimate revised Margins of Safety, all that is required is to divide the revised NOEL by the exposure figures reported in this analysis or the previous one (Tomerlin memo, 10/24/88).

A final note of explanation is in order. The original analysis using all foods for which propargite is registered indicated that 8 per cent (using a NOEL of 6 mg/kg/day) of adult women had Margins of Safety less than 100 (Tomerlin memorandum, 10/24/88). In the analysis presented here, six per cent of the women consuming succulent beans have an MOS less than 100, making it appear that 75 per cent of the risk comes from consuming succulent beans. This is not the case. Each distribution in the current analysis, as well as the distribution reported in the previous analysis, applies only to consumers of the commodities. On any given day, 99.8 per cent of adult women are expected to consume at least one food potentially treated with propargite, whereas only 15 per cent of them are expected to consume succulent beans. Thus, approximately 8 per cent (8% x 99.8%) of all women are estimated to be at risk from all potential sources of propargite, but 1 per cent (6% x 15%) are estimated to be at risk from propargite residues in succulent beans.

Attachments

cc: Tomerlin (SACB), DEB, TAS File, Caswell File 130I

Table 1: Food Commodities Included in the
Propargite Acute Exposure Analysis

Commodity	Tolerance	"H" Means a Food Additive Tolerance
Analysis 1: Dry Beans, Including Guar and Mung Beans		
BEANS-DRY-BLACKEYE PEAS(COWPEAS)	0.200000	
BEANS-DRY-BROADBEANS(MATURE SEED)	0.200000	
BEANS-DRY-GARBANZO(CHICK PEA)	0.200000	
BEANS-DRY-GREAT NORTHERN	0.200000	
BEANS-DRY-HYACINTH(MATURE SEEDS)	0.200000	
BEANS-DRY-KIDNEY	0.200000	
BEANS-DRY-LIMA	0.200000	
BEANS-DRY-NAVY (PEA)	0.200000	
BEANS-DRY-OTHER	0.200000	
BEANS-DRY-PIGEON BEANS	0.200000	
BEANS-DRY-PINTO	0.200000	
GUAR BEANS	0.200000	
MUNG BEANS (SPROUTS)	0.200000	
Analysis 2: Cranberries		
CRANBERRIES	10.000000	
CRANBERRIES-JUICE	10.000000	
Analysis 3: Stone Fruits		
APRICOTS-DRIED	7.000000	
APRICOTS-FRESH	7.000000	
NECTARINES	4.000000	
PEACHES-DRIED	7.000000	
PEACHES-FRESH	7.000000	
PLUMS(DAMSONS)-FRESH	7.000000	
PLUMS,PRUNE-JUICE	7.000000	
PLUMS-PRUNES(DRIED)	7.000000	
Analysis 4: Grapes		
GRAPES-FRESH	10.000000	
GRAPES-JUICE	10.000000	
GRAPES-RAISINS	25.000000	H
WINE AND SHERRY	10.000000	

Table 1: Food Commodities Included in the
Propargite Acute Exposure Analysis

Commodity	Tolerance	"H" Means a Food Additive Tolerance
Analysis 5: Hops		
HOPS	30.000000	H
Analysis 6: Grapefruit		
GRAPEFRUIT-JUICE	5.000000	
GRAPEFRUIT-PULP	5.000000	
GRAPEFRUIT-UNSPECIFIED	5.000000	
Analysis 7: Oranges		
ORANGES-JUICE	5.000000	
ORANGES-PEEL	5.000000	
ORANGES-PULP	5.000000	
ORANGES-UNSPECIFIED	5.000000	
Analysis 8: Succulent Beans		
BEANS-SUCCULENT-BROADBEANS(IMMAT. SEED)	20.000000	
BEANS-SUCCULENT-GREEN	20.000000	
BEANS-SUCCULENT-HYACINTH(YOUNG PODS)	20.000000	
BEANS-SUCCULENT-LIMA	20.000000	
BEANS-SUCCULENT-OTHER	20.000000	
BEANS-SUCCULENT-YELLOW,WAX	20.000000	
BEANS-UNSPECIFIED	20.000000	

Table 2 Acute Exposure Summary for Propargite in Selected Food Commodities Consumed by Females

	<u>% User Days</u>	<u>MG/KG/DAY</u>	<u>Average MOS</u>
Dry Beans:	10.7	0.000178	33708
Cranberries:	4.7	0.006764	887
Stone Fruit:	23.0	0.007216	831
Grapes:	24.6	0.009162	655
Hops:	2.6	0.012241	490
Grapefruit:	6.4	0.015241	394
Oranges:	28.7	0.015547	386
Succulent Beans:	15.0	0.028959	207

Table 2b: Acute Exposure Distribution for Propargite in Selected Food Commodities Consumed by Females

	0	.004	.008	.012	.016	.02	.024	.028	.032	.036	.04	.06	.08	1	2	3	4
Dry Beans:	100	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Cranberries:	100	24	16	13	12	10	8	7	6	5	4	2	1	0	0	0	0
Stone Fruit:	100	40	32	23	17	11	7	5	4	3	2	0	0	0	0	0	0
Grapes:	100	29	23	21	18	16	13	11	9	8	7	3	1	1	0	0	0
Hops:	100	94	54	35	22	14	10	7	4	4	2	1	0	0	0	0	0
Grapefruit:	100	99	90	53	30	18	11	7	5	3	3	1	0	0	0	0	0
Oranges:	100	92	85	59	38	24	13	8	6	4	3	1	0	0	0	0	0
Succulent Beans:	100	98	92	83	75	65	50	39	32	28	22	6	3	1	0	0	0
MOS:	1500	750	500	375	300	250	214	188	167	150	100	75	60	30			

NOTE: The distributions shown above represent the exposure encountered by people who consume food containing residues at levels specified in the accompanying memorandum and tables.