

CASWELL FILE

2930 7-10-98



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

DATE: 7/10/98

SUBJECT: Dietary Exposure Analysis for Sulfosate (Glyphosate-trimesium) in/on Pome Fruit, Wheat, Corn and Meat, Milk, Poultry, and Eggs. DP Barcode: D247231 Chem#:128501

FROM: William Cutchin, Chemist Registration Action Branch 2 Health Effects Division (7509C)

William D. Cutchin

THROUGH: Richard Loranger, Branch Senior Scientist Registration Action Branch 2 Health Effects Division (7509C)

R. Loranger

TO: Marion Copley Registration Action Branch 1 Health Effects Division (7509C)

Action Requested

Provide a Dietary Risk Evaluation System (DRES) analysis for sulfosate (glyphosate-trimesium) in/on pome fruit, wheat, corn and meat, milk, poultry, and eggs at the following proposed tolerance levels:

Pome Fruit	0.05 ppm	Liver	0.50 ppm
Wheat, grain	0.75 ppm	Meat**	0.40 ppm
Corn (field and pop)	0.20 ppm	Poultry Meat Byproducts*	0.10 ppm
Milk	0.50 ppm	Poultry Liver	0.05 ppm
Eggs	0.02 ppm	Poultry Meat	0.05 ppm
Meat Byproducts*	2.50 ppm	Poultry Fat	0.05 ppm

Fat**

0.10 ppm

*Except Liver

**of Cattle, Goats, Horses, Hogs, Sheep

Discussion

The proposed tolerances in/on pome fruit and wheat require the establishment of animal commodity tolerances (G. Kramer, November 28, 1995). However, with the exception of milk and meat/poultry byproducts, animal commodity tolerances currently exist at equal or higher levels than those proposed for this petition. Thus, the higher existing levels were used for the purposes of this analysis. Tolerances for milk and meat/poultry byproducts were raised accordingly.

Toxicological Endpoints

The chronic analysis for sulfosate used a reference dose (RfD) of 0.10 mg/kg/day based on a no observed effect level (NOEL) of 10 mg/kg/day and an uncertainty factor of 100. The NOEL is based on salivation and emesis at 50 mg/kg/day (LOEL) demonstrated in a one-year chronic dog study. The acute analysis for sulfosate used a reference dose (RfD) of 1.0 mg/kg/day based on a NOEL of 100 mg/kg/day and an uncertainty factor of 100. The NOEL is based on neurotoxicity at 300 mg/kg (LOEL) demonstrated in an acute rat neurotoxicity study. Sulfosate is classified as a Group E (not a carcinogen) chemical (*Memorandum: Sulfosate - Report of the Hazard Identification Assessment Review Committee, W. Dykstra to M. Morrow, April 23, 1998*). The FQPA Safety Factor Committee reduced the required 10x safety factor to 3x for all population subgroups (FQPA, 7/10/98).

Residue Information

Tolerances for Sulfosate (including Time Limited Tolerances) are published in 40 CFR §180.489. For this analysis, tolerance level residues and 100 percent crop treated (%CT) assumptions were made for the proposed commodities. Anticipated residue (AR) data and %CT information were not available.

Results

A summary of the residue information considered in this analysis is listed in Attachment 1.

Chronic Exposure Analysis

A Dietary Exposure Evaluation Model (DEEM) chronic exposure analysis was performed using tolerance level residues and the assumption of 100 percent crop treated to estimate the Theoretical Maximum Residue Concentration (TMRC) for the general population and 27 subgroups. Summaries of the TMRCs and their representations as percentages of RfD are included as Attachment 2. Using the FQPA 3x safety factor, the %RfD that would be above HED's level of concern would be 33.3%.

Total from new and published tolerances:

<u>Subgroup</u>	<u>TMRC (mg/kg/day)</u>	<u>%RfD</u>
U.S. Population	0.006873	6.9
Non-Nursing Infants (<1yr)	0.018680	18.7

Acute Exposure Analysis

A DEEM acute exposure analysis was performed using tolerance level residues and the assumption of 100 percent crop treated to estimate the TMRC for the general population and 13 subgroups. Summaries of the TMRCs and their representations as Margin of Exposure (MOE: NOEL/Exposure) at the 99.9th percentile are included as Attachment 3. Using the FQPA 3x safety factor any MOE below 300 would exceed HED's level of concern.

Total from new and published tolerances:

<u>Subgroup</u>	<u>TMRC (mg/kg/day)</u>	<u>MOE</u>
U.S. Population	0.055144	1813
Non-Nursing Infants (<1yr)	0.097174	1029

Conclusions

The chronic analysis for sulfosate is a worst case estimate of dietary exposure with all residues at tolerance level and 100 percent of the commodities assumed to be treated with sulfosate. Even without refinements, the risk from chronic dietary exposure to sulfosate, as represented by the %RfD, is not above HED's level of concern for any of the DRES subgroups.

The acute analysis for sulfosate is a worst case estimate of dietary exposure with all residues at tolerance level and 100 percent of the commodities assumed to be treated with sulfosate. Even without refinements, the risk from acute dietary exposure to sulfosate, as represented by the MOE, is not above HED's level of concern for any of the DRES subgroups.

Attachments: 1, 2, 3
cc: DRES, Caswell #893C

RDI:DRES SAC:7/1/98:BSS:7/10/98

Attachment 1

FILENAME: C:\Novigen\resdata\128501\128501.r91

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CHEMICAL NAME: Sulfosate

RfD(CHRONIC): .100000 mg/kg/DAY

NOEL(CHRONIC): .000000 mg/kg/day

RfD(ACUTE): .000000 mg/kg/DAY

NOEL(ACUTE): 100.000000 mg/kg/day

Q*=.0000 Date created/last modified: 06-24-1998/14:44:29/8 Program ver. 6.13

Comment: HIARC 4/23/98

Food Code	Crop Grp	Food Name	RESIDUE (ppm)	RDF #	Adj.Factors #1	Adj.Factors #2	Comment
040	R	ALMONDS	000.050000		01.000	01.000	4F4343
377	L	APPLES-JUICE-CONCENTRATE	000.050000		03.900	01.000	3F4258
053	L	APPLES-DRIED	000.050000		08.000	01.000	3F4258
054	L	APPLES-JUICE/CIDER	000.050000		01.000	01.000	3F4258
052	L	APPLES	000.050000		01.000	01.000	3F4258
410	M	APRICOT JUICE	000.050000		01.000	01.000	
060	M	APRICOTS-DRIED	000.050000		06.000	01.000	3F4238
059	M	APRICOTS	000.050000		01.000	01.000	3F4238
497	L	BALSAM PEAR	000.050000		01.000	01.000	3F4258
073	A	BANANAS-DRIED	000.050000		03.900	01.000	5E4479
378	A	BANANAS-JUICE	000.050000		01.000	01.000	5E4479
072	A	BANANAS	000.050000		01.000	01.000	5E4479
051	R	BEECHNUTS	000.050000		01.000	01.000	4F4343
324	U	BEEF-FAT W/O BONES	000.100000		01.000	01.000	3F4258
325	U	BEEF-KIDNEY	002.500000		01.000	01.000	3F4258
326	U	BEEF-LIVER	000.500000		01.000	01.000	3F4258
327	U	BEEF-LEAN(FAT/FREE)W/O BONES	000.400000		01.000	01.000	3F4258
322	U	BEEF-OTHER ORGAN MEATS	002.500000		01.000	01.000	3F4258
323	U	BEEF-DRIED	002.500000		01.920	01.000	3F4258
321	U	BEEF-MEAT BYPRODUCTS	002.500000		01.000	01.000	3F4258
041	R	BRAZIL NUTS	000.050000		01.000	01.000	4F4343
049	R	BUTTER NUTS	000.050000		01.000	01.000	4F4343
042	R	CASHEWS	000.050000		01.000	01.000	4F4343
062	M	CHERRIES-DRIED	000.050000		04.000	01.000	3F4238
063	M	CHERRIES-JUICE	000.050000		01.000	01.000	3F4238
061	M	CHERRIES	000.050000		01.000	01.000	3F4238
043	R	CHESTNUTS	000.050000		01.000	01.000	4F4343
368	V	CHICKEN-FAT W/O BONES	000.050000		01.000	01.000	3F4258
369	V	CHICKEN-LEAN/FATFREE W/O BONE	000.050000		01.000	01.000	3F4258
367	V	CHICKEN-GIBLETS(LIVER)	000.050000		01.000	01.000	3F4258
385	V	CHICKEN-GIBLETS (EXCL. LIVER)	000.100000		01.000	01.000	3F4258
366	V	CHICKEN-BYPRODUCTS	000.100000		01.000	01.000	3F4258
020	K	CITRUS CITRON	000.050000		01.000	01.000	0F3840
237	O	CORN/POP	000.200000		01.000	01.000	9F3796
267	O	CORN GRAIN-BRAN	000.200000		01.000	01.000	9F3796
268	O	CORN GRAIN/SUGAR/HFCS	000.200000		01.500	01.000	9F3796
266	O	CORN GRAIN-ENDOSPERM	000.200000		01.000	01.000	9F3796
388	O	CORN GRAIN/SUGAR-MOLASSES	000.200000		01.500	01.000	9F3796
289	O	CORN GRAIN-OIL	000.200000		01.000	01.000	9F3796
055	L	CRABAPPLES	000.050000		01.000	01.000	3F4258
365	X	EGGS-YOLK ONLY	000.020000		01.000	01.000	3F4258
363	X	EGGS-WHOLE	000.020000		01.000	01.000	3F4258
364	X	EGGS-WHITE ONLY	000.020000		01.000	01.000	3F4258
044	R	FILBERTS (HAZELNUTS)	000.050000		01.000	01.000	4F4343
332	U	GOAT-LIVER	000.500000		01.000	01.000	3F4258
329	U	GOAT-OTHER ORGAN MEATS	002.500000		01.000	01.000	3F4258
333	U	GOAT-LEAN (FAT/FREE) W/O BONE	000.400000		01.000	01.000	3F4258
331	U	GOAT-KIDNEY	002.500000		01.000	01.000	3F4258
328	U	GOAT-MEAT BYPRODUCTS	002.500000		01.000	01.000	3F4258
330	U	GOAT-FAT W/O BONE	000.100000		01.000	01.000	3F4258
023	K	GRAPEFRUIT-JUICE	000.050000		01.000	01.000	0F3840
448	K	GRAPEFRUIT PEEL	000.050000		01.000	01.000	0F3840
441	K	GRAPEFRUIT-JUICE-CONCENTRATE	000.050000		08.260	01.000	0F3840
022	K	GRAPEFRUIT-PEELED FRUIT	000.050000		01.000	01.000	0F3840
015	A	GRAPES-JUICE	000.100000		01.000	01.000	1f3950
014	A	GRAPES-RAISINS	000.200000		01.000	01.000	1f3950
013	A	GRAPES	000.100000		01.000	01.000	1f3950

A

Attachment 1

045	R	HICKORY NUTS	000.050000	01.000	01.000	4F4343
334	U	HORSEMEAT	002.500000	01.000	01.000	3F4258
024	K	KUMQUATS	000.050000	01.000	01.000	0F3840
442	K	LEMONS-JUICE-CONCENTRATE	000.050000	11.400	01.000	0F3840
026	K	LEMONS-PEELED FRUIT	000.050000	01.000	01.000	0F3840
027	K	LEMONS-PEEL	000.050000	01.000	01.000	0F3840
028	K	LEMONS-JUICE	000.050000	01.000	01.000	0F3840
032	K	LIMES-JUICE	000.050000	01.000	01.000	0F3840
030	K	LIMES-PEELED FRUIT	000.050000	01.000	01.000	0F3840
443	K	LIMES-JUICE-CONCENTRATE	000.050000	06.000	01.000	0F3840
031	K	LIMES-PEEL	000.050000	01.000	01.000	0F3840
081	L	LOQUATS	000.050000	01.000	01.000	
046	R	MACADAMIA NUTS (BUSH NUTS)	000.050000	01.000	01.000	4F4343
319	X	MILK-FAT SOLIDS	000.500000	01.000	01.000	3F4258
398	X	MILK-BASED WATER	000.500000	01.000	01.000	3F4258
320	X	MILK SUGAR (LACTOSE)	000.500000	01.000	01.000	3F4258
318	X	MILK-NONFAT SOLIDS	000.500000	01.000	01.000	3F4258
064	M	NECTARINES	000.050000	01.000	01.000	3F4238
033	K	ORANGES-JUICE-CONCENTRATE	000.050000	01.000	01.000	0F3840
035	K	ORANGES-PEEL	000.050000	01.000	01.000	0F3840
034	K	ORANGES-PEELED FRUIT	000.050000	01.000	01.000	0F3840
036	K	ORANGES-JUICE	000.050000	01.000	01.000	0F3840
066	M	PEACHES-DRIED	000.050000	07.000	01.000	3F4238
402	M	PEACHES-JUICE	000.050000	01.000	01.000	
065	M	PEACHES	000.050000	01.000	01.000	3F4238
404	L	PEARS-JUICE	000.050000	01.000	01.000	
057	L	PEARS-DRIED	000.050000	06.250	01.000	3F4258
056	L	PEARS	000.050000	01.000	01.000	3F4258
047	R	PECANS	000.050000	01.000	01.000	4F4343
094	A	PLANTAINS-RIPE	000.050000	01.000	01.000	5E4479
481	A	PLANTAINS-DRIED	000.050000	03.900	01.000	5E4479
480	A	PLANTAINS-GREEN	000.050000	01.000	01.000	5E4479
068	M	PLUMS-PRUNES(DRIED)	000.200000	01.000	01.000	3F4238
069	M	PLUMS/PRUNE ² JUICE	000.200000	01.000	01.000	3F4238
067	M	PLUMS(DAMSONS)	000.050000	01.000	01.000	3F4238
347	U	PORK-LEAN (FAT FREE) W/O BONE	000.400000	01.000	01.000	3F4258
346	U	PORK-LIVER	000.500000	01.000	01.000	3F4258
345	U	PORK-KIDNEY	002.500000	01.000	01.000	3F4258
344	U	PORK-FAT W/O BONE	000.100000	01.000	01.000	3F4258
343	U	PORK- OTHER ORGAN MEATS	002.500000	01.000	01.000	3F4258
342	U	PORK-MEAT BYPRODUCTS	002.500000	01.000	01.000	3F4258
362	V	POULTRY-OTHER-FAT W/O BONES	000.050000	01.000	01.000	3F4258
360	V	POULTRY-OTHER-LEAN (FAT FREE)	000.050000	01.000	01.000	3F4258
361	V	POULTRY-OTHER-GIBLETS(LIVER)	000.050000	01.000	01.000	3F4258
058	L	QUINCES	000.050000	01.000	01.000	3F4258
335	U	RABBIT	002.500000	01.000	01.000	3F4258
338	U	SHEEP-FAT W/O BONE	000.100000	01.000	01.000	3F4258
337	U	SHEEP-OTHER ORGAN MEATS	002.500000	01.000	01.000	3F4258
336	U	SHEEP-MEAT BYPRODUCTS	002.500000	01.000	01.000	3F4258
339	U	SHEEP-KIDNEY	002.500000	01.000	01.000	3F4258
340	U	SHEEP-LIVER	000.500000	01.000	01.000	3F4258
341	U	SHEEP-LEAN (FAT FREE)W/O BONE	000.400000	01.000	01.000	3F4258
303	G	SOYBEAN-OTHER	003.000000	01.000	01.000	0F3860
307	G	SOYBEANS-FLOUR (DEFATTED)	003.000000	01.000	01.000	0F3860
305	G	SOYBEANS-FLOUR (FULL FAT)	003.000000	01.000	01.000	0F3860
297	G	SOYBEANS-OIL	003.000000	01.000	01.000	0F3860
304	G	SOYBEANS-MATURE SEEDS DRY	003.000000	01.000	01.000	0F3860
306	G	SOYBEANS-FLOUR (LOW FAT)	003.000000	01.000	01.000	0F3860
255	G	SOYBEANS-SPROUTED SEEDS	003.000000	00.330	01.000	0F3860
482	A	SOYBEANS-PROTEIN ISOLATE	003.000000	01.000	01.000	0F3860
037	K	TANGELOS	000.050000	01.000	01.000	0F3840
420	K	TANGERINES-JUICE-CONCENTRATE	000.050000	07.350	01.000	0F3840
039	K	TANGERINES-JUICE	000.050000	01.000	01.000	0F3840
038	K	TANGERINES	000.050000	01.000	01.000	0F3840
357	V	TURKEY--FAT W/O BONES	000.050000	01.000	01.000	3F4258
356	V	TURKEY-GIBLETS (LIVER)	000.050000	01.000	01.000	3F4258
355	V	TURKEY-BYPRODUCTS	000.100000	01.000	01.000	3F4258

Attachment 1

449	V	TURKEY-OTHER ORGAN MEATS	000.100000	01.000	01.000	3F4258
358	V	TURKEY-LEAN/FAT FREE W/O BONE	000.050000	01.000	01.000	3F4258
424	U	VEAL-FAT W/O BONES	000.100000	01.000	01.000	3F4258
425	U	VEAL-LEAN (FATFREE) W/O BONES	000.400000	01.000	01.000	3F4258
430	U	VEAL-MEAT BYPRODUCTS	002.500000	01.000	01.000	3F4258
426	U	VEAL-KIDNEY	002.500000	01.000	01.000	3F4258
427	U	VEAL-LIVER	000.500000	01.000	01.000	3F4258
428	U	VEAL-OTHER ORGAN MEATS	002.500000	01.000	01.000	3F4258
429	U	VEAL-DRIED	002.500000	01.920	01.000	3F4258
431	R	WALNUT OIL	000.050000	01.000	01.000	4F4343
048	R	WALNUTS	000.050000	01.000	01.000	4F4343
277	O	WHEAT-GERM	000.750000	01.000	01.000	3F4258
278	O	WHEAT-BRAN	000.750000	01.000	01.000	3F4258
279	O	WHEAT-FLOUR	000.750000	01.000	01.000	3F4258
437	O	WHEAT-GERM OIL	000.750000	01.000	01.000	3F4258
276	O	WHEAT-ROUGH	000.750000	01.000	01.000	3F4258

Attachment 2

U.S. Environmental Protection Agency
 DEEM89N CHRONIC analysis for SULFOSATE
 Residue file name: 128501
 Analysis Date 07-01-1998
 Reference dose (Rfd, CHRONIC) = 0.100000 mg/kg body-wt/day
 COMMENT 1: HIARC 4/23/98
 COMMENT 2: 3F3796/Copley-RAB1/WDC

Ver. 6.11
 (1989-92 data)

Adjustment factor #2 NOT used.

Residue file dated: 07-01-1998/13:21:36/8

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Total exposure by population subgroup

Population Subgroup	Total Exposure	
	mg/kg body wt/day	Percent of Rfd
U.S. Pop - 48 states - all seasons	0.006873	6.9%
U.S. Population - spring season	0.006793	6.8%
U.S. Population - summer season	0.006773	6.8%
U.S. Population - autumn season	0.007183	7.2%
U.S. Population - winter season	0.006735	6.7%
Northeast region	0.006905	6.9%
Midwest region	0.007460	7.5%
Southern region	0.006449	6.4%
Western region	0.006854	6.9%
Pacific Region	0.006772	6.8%
Hispanics	0.007043	7.0%
Non-hispanic whites	0.006912	6.9%
Non-hispanic blacks	0.006447	6.4%
Non-hispanic other than black or white	0.007141	7.1%
All infants (<1 year)	0.014257	14.3%
Nursing infants (<1 year)	0.003749	3.7%
Non-nursing infants (<1 year)	0.018680	18.7%
Children (1-6 years)	0.020327	20.3%
Children (7-12 years)	0.011858	11.9%
Females (13-19 yrs/not preg. or nursing)	0.005915	5.9%
Females (20+ years/not preg. or nursing)	0.004105	4.1%
Females (13-50 years)	0.004511	4.5%
Females (13+/pregnant/not nursing)	0.005929	5.9%
Females (13+/nursing)	0.006031	6.0%
Males (13-19 years)	0.007485	7.5%
Males (20+ years)	0.004438	4.4%
Seniors (55+)	0.004012	4.0%

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Attachment 3

U.S. Environmental Protection Agency
 DEEM89N ACUTE89N analysis for SULFOSATE
 Residue file name: 128501.R91
 Analysis Date 07-01-1998
 NOEL (ACUTE89N) = 100.000000 mg/kg body-wt/day
 Bin intervals calibrated using computed means.
 COMMENT 1: HIARC 4/23/98
 COMMENT 2: 3F3796/Copley-RAB1/WDC

Ver. 6.12
 (1989-92 data)
 Adjustment factor #2 NOT used.
 Residue file dated: 07-01-1998/13:21:36/8

U.S. pop - all seasons -----	Daily Exposure Analysis 1/ (mg/kg body-weight/day)	
	per Capita	per User
Mean	0.006866	0.006883
Standard Deviation	0.006980	0.006980
Standard Error	0.000037	0.000037
Margin of Exposure 2/	14,564	14,528

Percent of Person-Days that are User-Days = 99.75%

Estimated percentile of user-days exceeding calculated exposure
 in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

Percentile	Exposure	MOE	Percentile	Exposure	MOE
90.00	0.001780	56,188	10.00	0.015108	6,619
80.00	0.002505	39,915	5.00	0.021076	4,745
70.00	0.003171	31,533	2.50	0.027147	3,684
60.00	0.003846	26,000	1.00	0.035328	2,831
50.00	0.004636	21,569	0.50	0.041788	2,393
40.00	0.005608	17,833	0.25	0.048830	2,048
30.00	0.007014	14,258	0.10	0.055154	1,813
20.00	0.009410	10,627			

Estimated percentile of per-capita days exceeding calculated exposure
 in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

Percentile	Exposure	MOE	Percentile	Exposure	MOE
90.00	0.001739	57,496	10.00	0.015093	6,625
80.00	0.002491	40,150	5.00	0.021061	4,748
70.00	0.003160	31,650	2.50	0.027132	3,686
60.00	0.003836	26,069	1.00	0.035315	2,832
50.00	0.004626	21,616	0.50	0.041771	2,394
40.00	0.005598	17,864	0.25	0.048812	2,049
30.00	0.007003	14,279	0.10	0.055144	1,813
20.00	0.009398	10,640			

1/ Analysis based on all three-day participant records in CSFII 1989-92 survey.
 2/ Margin of Exposure = NOEL/ Dietary Exposure.

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Attachment 3

U.S. Environmental Protection Agency Ver. 6.12
 DEEM89N ACUTE89N analysis for SULFOSATE (1989-92 data)
 Residue file name: 128501.R91 Adjustment factor #2 NOT used.
 Analysis Date 07-01-1998 Residue file dated: 07-01-1998/13:21:36/8
 NOEL (ACUTE89N) = 100.000000 mg/kg body-wt/day

Nursing infants (<1 year)	Daily Exposure Analysis (mg/kg body-weight/day)	
	per Capita	per User
Mean	0.003744	0.005578
Standard Deviation	0.005201	0.005483
Standard Error	0.000420	0.000595
Margin of Exposure	26,712	17,927

Percent of Person-Days that are User-Days = 67.11%

Estimated percentile of user-days exceeding calculated exposure
 in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

Percentile	Exposure	MOE	Percentile	Exposure	MOE
90.00	0.000843	118,684	10.00	0.014415	6,937
80.00	0.002129	46,972	5.00	0.017586	5,686
70.00	0.002664	37,532	2.50	0.019822	5,045
60.00	0.002832	35,307	1.00	0.023683	4,222
50.00	0.003010	33,228	0.50	0.024970	4,005
40.00	0.003469	28,830	0.25	0.026191	3,818
30.00	0.005603	17,848	0.10	0.029099	3,437
20.00	0.010562	9,468			

Estimated percentile of per-capita days exceeding calculated exposure
 in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

Percentile	Exposure	MOE	Percentile	Exposure	MOE
90.00	0.000000	>1,000,000	10.00	0.012527	7,983
80.00	0.000000	>1,000,000	5.00	0.016032	6,238
70.00	0.000000	>1,000,000	2.50	0.018726	5,340
60.00	0.000919	108,768	1.00	0.022422	4,460
50.00	0.002423	41,266	0.50	0.024339	4,109
40.00	0.002839	35,220	0.25	0.025593	3,907
30.00	0.003253	30,743	0.10	0.028149	3,553
20.00	0.005702	17,539			

Attachment 3

U.S. Environmental Protection Agency
 DEEM89N ACUTE89N analysis for SULFOSATE
 Residue file name: 128501.R91
 Analysis Date 07-01-1998
 NOEL (ACUTE89N) = 100.000000 mg/kg body-wt/day

Ver. 6.12
 (1989-92 data)
 Adjustment factor #2 NOT used.
 Residue file dated: 07-01-1998/13:21:36/8

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Non-nursing infants (<1 yr)	Daily Exposure Analysis (mg/kg body-weight/day)	
	per Capita	per User
Mean	0.018680	0.018680
Standard Deviation	0.013600	0.013600
Standard Error	0.000639	0.000639
Margin of Exposure	5,353	5,353

Percent of Person-Days that are User-Days =100.00%

Estimated percentile of user-days exceeding calculated exposure
 in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

Percentile	Exposure	MOE	Percentile	Exposure	MOE
90.00	0.008982	11,133	10.00	0.033028	3,028
80.00	0.011349	8,811	5.00	0.051830	1,929
70.00	0.012842	7,787	2.50	0.063413	1,577
60.00	0.013856	7,217	1.00	0.073670	1,357
50.00	0.014641	6,830	0.50	0.087608	1,141
40.00	0.015488	6,457	0.25	0.093587	1,069
30.00	0.017746	5,635	0.10	0.097174	1,029
20.00	0.020839	4,799			

Estimated percentile of per-capita days exceeding calculated exposure
 in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

Percentile	Exposure	MOE	Percentile	Exposure	MOE
90.00	0.008982	11,133	10.00	0.033028	3,028
80.00	0.011349	8,811	5.00	0.051830	1,929
70.00	0.012842	7,787	2.50	0.063413	1,577
60.00	0.013856	7,217	1.00	0.073670	1,357
50.00	0.014641	6,830	0.50	0.087608	1,141
40.00	0.015488	6,457	0.25	0.093587	1,069
30.00	0.017746	5,635	0.10	0.097174	1,029
20.00	0.020839	4,799			

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Attachment 3

U.S. Environmental Protection Agency
 DEEM89N ACUTE89N analysis for SULFOSATE
 Residue file name: 128501.R91
 Analysis Date 07-01-1998
 NOEL (ACUTE89N) = 100.000000 mg/kg body-wt/day

Ver. 6.12
 (1989-92 data)
 Adjustment factor #2 NOT used.
 Residue file dated: 07-01-1998/13:21:36/8

Females (13+/preg/not nsg)	Daily Exposure Analysis (mg/kg body-weight/day)	
	per Capita	per User
Mean	0.005929	0.005929
Standard Deviation	0.003366	0.003366
Standard Error	0.000170	0.000170
Margin of Exposure	16,867	16,867

Percent of Person-Days that are User-Days =100.00%

Estimated percentile of user-days exceeding calculated exposure in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

Percentile	Exposure	MOE	Percentile	Exposure	MOE
90.00	0.001977	50,588	10.00	0.010725	9,324
80.00	0.002832	35,314	5.00	0.012416	8,054
70.00	0.003623	27,601	2.50	0.013766	7,264
60.00	0.004503	22,208	1.00	0.015027	6,655
50.00	0.005536	18,065	0.50	0.016027	6,239
40.00	0.006324	15,813	0.25	0.017200	5,814
30.00	0.007506	13,322	0.10	0.018827	5,312
20.00	0.008699	11,495			

Estimated percentile of per-capita days exceeding calculated exposure in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

Percentile	Exposure	MOE	Percentile	Exposure	MOE
90.00	0.001977	50,588	10.00	0.010725	9,324
80.00	0.002832	35,314	5.00	0.012416	8,054
70.00	0.003623	27,601	2.50	0.013766	7,264
60.00	0.004503	22,208	1.00	0.015027	6,655
50.00	0.005536	18,065	0.50	0.016027	6,239
40.00	0.006324	15,813	0.25	0.017200	5,814
30.00	0.007506	13,322	0.10	0.018827	5,312
20.00	0.008699	11,495			

Attachment 3

U.S. Environmental Protection Agency
 DEEM89N ACUTE89N analysis for SULFOSATE
 Residue file name: 128501.R91
 Analysis Date 07-01-1998
 NOEL (ACUTE89N) = 100.000000 mg/kg body-wt/day

Ver. 6.12
 (1989-92 data)
 Adjustment factor #2 NOT used.
 Residue file dated: 07-01-1998/13:21:36/8

Females (13+/nursing)	Daily Exposure Analysis (mg/kg body-weight/day)	
	per Capita	per User
Mean	0.006032	0.006032
Standard Deviation	0.004159	0.004159
Standard Error	0.000287	0.000287
Margin of Exposure	16,579	16,579

Percent of Person-Days that are User-Days =100.00%

Estimated percentile of user-days exceeding calculated exposure in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

Percentile	Exposure	MOE	Percentile	Exposure	MOE
90.00	0.001420	70,438	10.00	0.011898	8,405
80.00	0.002571	38,895	5.00	0.013457	7,431
70.00	0.003338	29,958	2.50	0.017538	5,702
60.00	0.003959	25,258	1.00	0.019634	5,093
50.00	0.005143	19,443	0.50	0.020400	4,902
40.00	0.006674	14,983	0.25	0.020793	4,809
30.00	0.007625	13,114	0.10	0.021079	4,744
20.00	0.009093	10,997			

Estimated percentile of per-capita days exceeding calculated exposure in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

Percentile	Exposure	MOE	Percentile	Exposure	MOE
90.00	0.001420	70,438	10.00	0.011898	8,405
80.00	0.002571	38,895	5.00	0.013457	7,431
70.00	0.003338	29,958	2.50	0.017538	5,702
60.00	0.003959	25,258	1.00	0.019634	5,093
50.00	0.005143	19,443	0.50	0.020400	4,902
40.00	0.006674	14,983	0.25	0.020793	4,809
30.00	0.007625	13,114	0.10	0.021079	4,744
20.00	0.009093	10,997			

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Attachment 3

U.S. Environmental Protection Agency
 DEEM89N ACUTE89N analysis for SULFOSATE
 Residue file name: 128501.R91
 Analysis Date 07-01-1998
 NOEL (ACUTE89N) = 100.000000 mg/kg body-wt/day

Ver. 6.12
 (1989-92 data)
 Adjustment factor #2 NOT used.
 Residue file dated: 07-01-1998/13:21:36/8

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Children (1-6 years)	Daily Exposure Analysis (mg/kg body-weight/day)	
	per Capita	per User
Mean	0.020320	0.020327
Standard Deviation	0.010505	0.010501
Standard Error	0.000170	0.000170
Margin of Exposure	4,921	4,920

Percent of Person-Days that are User-Days = 99.97%

Estimated percentile of user-days exceeding calculated exposure
 in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

Percentile	Exposure	MOE	Percentile	Exposure	MOE
90.00	0.008688	11,510	10.00	0.033988	2,942
80.00	0.011436	8,745	5.00	0.040336	2,479
70.00	0.013872	7,209	2.50	0.046866	2,134
60.00	0.016250	6,154	1.00	0.051953	1,925
50.00	0.018666	5,357	0.50	0.057731	1,732
40.00	0.021216	4,713	0.25	0.064107	1,560
30.00	0.024196	4,133	0.10	0.072826	1,373
20.00	0.028185	3,548			

Estimated percentile of per-capita days exceeding calculated exposure
 in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

Percentile	Exposure	MOE	Percentile	Exposure	MOE
90.00	0.008665	11,541	10.00	0.033986	2,942
80.00	0.011429	8,750	5.00	0.040334	2,479
70.00	0.013867	7,211	2.50	0.046864	2,134
60.00	0.016246	6,155	1.00	0.051952	1,925
50.00	0.018662	5,358	0.50	0.057729	1,732
40.00	0.021213	4,714	0.25	0.064105	1,560
30.00	0.024193	4,133	0.10	0.072824	1,373
20.00	0.028182	3,548			

Attachment 3

U.S. Environmental Protection Agency
 DEEM89N ACUTE89N analysis for SULFOSATE
 Residue file name: 128501.R91
 Analysis Date 07-01-1998
 NOEL (ACUTE89N) = 100.000000 mg/kg body-wt/day

Ver. 6.12
 (1989-92 data)
 Adjustment factor #2 NOT used.

Residue file dated: 07-01-1998/13:21:36/8

Children (7-12 years)	Daily Exposure Analysis (mg/kg body-weight/day)	
	per Capita	per User
Mean	0.011855	0.011858
Standard Deviation	0.006124	0.006122
Standard Error	0.000104	0.000104
Margin of Exposure	8,435	8,433

Percent of Person-Days that are User-Days = 99.98%

Estimated percentile of user-days exceeding calculated exposure in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

Percentile	Exposure	MOE	Percentile	Exposure	MOE
90.00	0.005097	19,619	10.00	0.019795	5,052
80.00	0.006649	15,039	5.00	0.022902	4,366
70.00	0.008102	12,342	2.50	0.026280	3,805
60.00	0.009370	10,672	1.00	0.030147	3,317
50.00	0.010754	9,299	0.50	0.035107	2,848
40.00	0.012398	8,066	0.25	0.040422	2,474
30.00	0.014465	6,913	0.10	0.045059	2,219
20.00	0.016659	6,003			

Estimated percentile of per-capita days exceeding calculated exposure in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

Percentile	Exposure	MOE	Percentile	Exposure	MOE
90.00	0.005086	19,663	10.00	0.019794	5,052
80.00	0.006646	15,046	5.00	0.022901	4,367
70.00	0.008100	12,346	2.50	0.026279	3,805
60.00	0.009369	10,674	1.00	0.030146	3,317
50.00	0.010752	9,300	0.50	0.035106	2,849
40.00	0.012397	8,067	0.25	0.040420	2,474
30.00	0.014463	6,914	0.10	0.045059	2,219
20.00	0.016658	6,003			

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U.S. Environmental Protection Agency
 DEEM89N ACUTE89N analysis for SULFOSATE
 Residue file name: 128501.R91
 Analysis Date 07-01-1998
 NOEL (ACUTE89N) = 100.000000 mg/kg body-wt/day

Ver. 6.12
 (1989-92 data)
 Adjustment factor #2 NOT used.
 Residue file dated: 07-01-1998/13:21:36/8

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Males (13-19 years)	Daily Exposure Analysis (mg/kg body-weight/day)	
	per Capita	per User
Mean	0.007485	0.007485
Standard Deviation	0.004607	0.004607
Standard Error	0.000118	0.000118
Margin of Exposure	13,359	13,359

Percent of Person-Days that are User-Days =100.00%

Estimated percentile of user-days exceeding calculated exposure
 in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

Percentile	Exposure	MOE	Percentile	Exposure	MOE
90.00	0.002659	37,612	10.00	0.013174	7,591
80.00	0.003631	27,538	5.00	0.016536	6,047
70.00	0.004925	20,303	2.50	0.019144	5,224
60.00	0.005793	17,262	1.00	0.022117	4,521
50.00	0.006694	14,938	0.50	0.027456	3,642
40.00	0.007657	13,060	0.25	0.029079	3,439
30.00	0.008712	11,478	0.10	0.033266	3,006
20.00	0.010260	9,747			

Estimated percentile of per-capita days exceeding calculated exposure
 in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

Percentile	Exposure	MOE	Percentile	Exposure	MOE
90.00	0.002659	37,612	10.00	0.013174	7,591
80.00	0.003631	27,538	5.00	0.016536	6,047
70.00	0.004925	20,303	2.50	0.019144	5,224
60.00	0.005793	17,262	1.00	0.022117	4,521
50.00	0.006694	14,938	0.50	0.027456	3,642
40.00	0.007657	13,060	0.25	0.029079	3,439
30.00	0.008712	11,478	0.10	0.033266	3,006
20.00	0.010260	9,747			

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U.S. Environmental Protection Agency
 DEEM89N ACUTE89N analysis for SULFOSATE
 Residue file name: 128501.R91
 Analysis Date 07-01-1998
 NOEL (ACUTE89N) = 100.000000 mg/kg body-wt/day

Ver. 6.12
 (1989-92 data)
 Adjustment factor #2 NOT used.
 Residue file dated: 07-01-1998/13:21:36/8

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Females (13-19 yrs/np/nn) -----	Daily Exposure Analysis (mg/kg body-weight/day)	
	per Capita	per User
Mean	0.005907	0.005918
Standard Deviation	0.003689	0.003684
Standard Error	0.000089	0.000089
Margin of Exposure	16,929	16,897

Percent of Person-Days that are User-Days = 99.81%

Estimated percentile of user-days exceeding calculated exposure
 in mg/kg body-wt/day and corresponding Margin of Exposure (MOE):

Percentile	Exposure	MOE	Percentile	Exposure	MOE
90.00	0.002108	47,435	10.00	0.010563	9,467
80.00	0.002861	34,948	5.00	0.012661	7,898
70.00	0.003587	27,876	2.50	0.016135	6,198
60.00	0.004454	22,450	1.00	0.019328	5,174
50.00	0.005298	18,876	0.50	0.021409	4,671
40.00	0.006109	16,369	0.25	0.022685	4,408
30.00	0.007056	14,173	0.10	0.023451	4,264
20.00	0.008363	11,958			

Estimated percentile of per-capita days exceeding calculated exposure
 in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

Percentile	Exposure	MOE	Percentile	Exposure	MOE
90.00	0.002073	48,250	10.00	0.010559	9,470
80.00	0.002850	35,086	5.00	0.012657	7,901
70.00	0.003578	27,950	2.50	0.016128	6,200
60.00	0.004445	22,499	1.00	0.019324	5,175
50.00	0.005290	18,904	0.50	0.021405	4,672
40.00	0.006103	16,386	0.25	0.022683	4,409
30.00	0.007050	14,184	0.10	0.023450	4,264
20.00	0.008358	11,965			

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U.S. Environmental Protection Agency
 DEEM89N ACUTE89N analysis for SULFOSATE
 Residue file name: 128501.R91
 Analysis Date 07-01-1998
 NOEL (ACUTE89N) = 100.000000 mg/kg body-wt/day

Ver. 6.12
 (1989-92 data)
 Adjustment factor #2 NOT used.
 Residue file dated: 07-01-1998/13:21:36/8

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Males (20+ years)	Daily Exposure Analysis (mg/kg body-weight/day)	
	per Capita	per User
Mean	0.004435	0.004438
Standard Deviation	0.002762	0.002760
Standard Error	0.000027	0.000027
Margin of Exposure	22,549	22,532

Percent of Person-Days that are User-Days = 99.93%

Estimated percentile of user-days exceeding calculated exposure
 in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

Percentile	Exposure	MOE	Percentile	Exposure	MOE
90.00	0.001667	59,997	10.00	0.007905	12,649
80.00	0.002290	43,673	5.00	0.009584	10,434
70.00	0.002814	35,533	2.50	0.011500	8,696
60.00	0.003328	30,052	1.00	0.014411	6,939
50.00	0.003856	25,934	0.50	0.016565	6,037
40.00	0.004447	22,485	0.25	0.018727	5,340
30.00	0.005197	19,241	0.10	0.021197	4,718
20.00	0.006234	16,041			

Estimated percentile of per-capita days exceeding calculated exposure
 in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

Percentile	Exposure	MOE	Percentile	Exposure	MOE
90.00	0.001656	60,395	10.00	0.007904	12,651
80.00	0.002286	43,743	5.00	0.009583	10,436
70.00	0.002812	35,567	2.50	0.011498	8,697
60.00	0.003325	30,072	1.00	0.014409	6,940
50.00	0.003854	25,947	0.50	0.016564	6,037
40.00	0.004446	22,494	0.25	0.018725	5,340
30.00	0.005195	19,248	0.10	0.021195	4,718
20.00	0.006232	16,045			

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Attachment 3

U.S. Environmental Protection Agency Ver. 6.12
 DEEM89N ACUTE89N analysis for SULFOSATE (1989-92 data)
 Residue file name: 128501.R91 Adjustment factor #2 NOT used.
 Analysis Date 07-01-1998 Residue file dated: 07-01-1998/13:21:36/8
 NOEL (ACUTE89N) = 100.000000 mg/kg body-wt/day

Females (20+ years/np/nn)	Daily Exposure Analysis (mg/kg body-weight/day)	
	per Capita	per User
Mean	0.004029	0.004037
Standard Deviation	0.002464	0.002460
Standard Error	0.000021	0.000021
Margin of Exposure	24,819	24,770

Percent of Person-Days that are User-Days = 99.80%

Estimated percentile of user-days exceeding calculated exposure
 in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

Percentile	Exposure	MOE	Percentile	Exposure	MOE
90.00	0.001449	68,990	10.00	0.007127	14,031
80.00	0.002053	48,704	5.00	0.008658	11,550
70.00	0.002562	39,035	2.50	0.010194	9,810
60.00	0.003064	32,642	1.00	0.012066	8,288
50.00	0.003587	27,878	0.50	0.013701	7,299
40.00	0.004173	23,965	0.25	0.015746	6,351
30.00	0.004859	20,579	0.10	0.018781	5,325
20.00	0.005719	17,484			

Estimated percentile of per-capita days exceeding calculated exposure
 in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

Percentile	Exposure	MOE	Percentile	Exposure	MOE
90.00	0.001423	70,250	10.00	0.007124	14,036
80.00	0.002044	48,933	5.00	0.008655	11,554
70.00	0.002555	39,143	2.50	0.010191	9,813
60.00	0.003058	32,706	1.00	0.012063	8,290
50.00	0.003582	27,918	0.50	0.013698	7,301
40.00	0.004168	23,992	0.25	0.015742	6,352
30.00	0.004855	20,596	0.10	0.018777	5,326
20.00	0.005716	17,495			

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Attachment 3

U.S. Environmental Protection Agency Ver. 6.12
 DEEM89N ACUTE89N analysis for SULFOSATE (1989-92 data)
 Residue file name: 128501.R91 Adjustment factor #2 NOT used.
 Analysis Date 07-01-1998 Residue file dated: 07-01-1998/13:21:36/8
 NOEL (ACUTE89N) = 100.000000 mg/kg body-wt/day

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All infants (<1 year)	Daily Exposure Analysis (mg/kg body-weight/day)	
	per Capita	per User
Mean	0.014256	0.015794
Standard Deviation	0.013590	0.013429
Standard Error	0.000552	0.000579
Margin of Exposure	7,015	6,331

Percent of Person-Days that are User-Days = 90.26%

Estimated percentile of user-days exceeding calculated exposure in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

Percentile	Exposure	MOE	Percentile	Exposure	MOE
90.00	0.002638	37,901	10.00	0.026276	3,806
80.00	0.007374	13,561	5.00	0.047695	2,097
70.00	0.010522	9,504	2.50	0.059995	1,667
60.00	0.012660	7,899	1.00	0.070561	1,417
50.00	0.013743	7,276	0.50	0.083945	1,191
40.00	0.014629	6,836	0.25	0.090469	1,105
30.00	0.016534	6,048	0.10	0.094383	1,060
20.00	0.019270	5,189			

Estimated percentile of per-capita days exceeding calculated exposure in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

Percentile	Exposure	MOE	Percentile	Exposure	MOE
90.00	0.000075	>1,000,000	10.00	0.025520	3,919
80.00	0.003285	30,441	5.00	0.045383	2,203
70.00	0.008144	12,279	2.50	0.058667	1,705
60.00	0.011275	8,869	1.00	0.069801	1,433
50.00	0.013159	7,600	0.50	0.082500	1,212
40.00	0.014247	7,019	0.25	0.089765	1,114
30.00	0.015917	6,282	0.10	0.094102	1,063
20.00	0.018680	5,353			

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Attachment 3

U.S. Environmental Protection Agency Ver. 6.12
 DEEM89N ACUTE89N analysis for SULFOSATE (1989-92 data)
 Residue file name: 128501.R91 Adjustment factor #2 NOT used.
 Analysis Date 07-01-1998 Residue file dated: 07-01-1998/13:21:36/8
 NOEL (ACUTE89N) = 100.000000 mg/kg body-wt/day

Females (13-50 years)	Daily Exposure Analysis (mg/kg body-weight/day)	
	per Capita	per User
Mean	0.004503	0.004512
Standard Deviation	0.002946	0.002942
Standard Error	0.000029	0.000029
Margin of Exposure	22,207	22,166

Percent of Person-Days that are User-Days = 99.81%

Estimated percentile of user-days exceeding calculated exposure in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

Percentile	Exposure	MOE	Percentile	Exposure	MOE
90.00	0.001506	66,398	10.00	0.008283	12,074
80.00	0.002173	46,026	5.00	0.010044	9,957
70.00	0.002747	36,409	2.50	0.011642	8,589
60.00	0.003305	30,256	1.00	0.014446	6,922
50.00	0.003910	25,577	0.50	0.017064	5,860
40.00	0.004588	21,795	0.25	0.019881	5,030
30.00	0.005408	18,492	0.10	0.022694	4,406
20.00	0.006426	15,562			

Estimated percentile of per-capita days exceeding calculated exposure in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

Percentile	Exposure	MOE	Percentile	Exposure	MOE
90.00	0.001481	67,537	10.00	0.008279	12,079
80.00	0.002163	46,239	5.00	0.010040	9,960
70.00	0.002739	36,509	2.50	0.011639	8,592
60.00	0.003299	30,313	1.00	0.014443	6,924
50.00	0.003904	25,614	0.50	0.017059	5,862
40.00	0.004583	21,820	0.25	0.019876	5,031
30.00	0.005403	18,508	0.10	0.022691	4,407
20.00	0.006422	15,571			

Attachment 3

U.S. Environmental Protection Agency
 DEEM89N ACUTE89N analysis for SULFOSATE
 Residue file name: 128501.R91
 Analysis Date 07-01-1998
 NOEL (ACUTE89N) = 100.000000 mg/kg body-wt/day
 Bin intervals calibrated using computed means.
 COMMENT 1: HIARC 4/23/98
 COMMENT 2: 3F3796/Copley-RAB1/WDC

Ver. 6.12
 (1989-92 data)

Adjustment factor #2 NOT used.

Residue file dated: 07-01-1998/13:21:36/8

Summary calculations:

	95th Percentile		99th Percentile		99.9 Percentile	
	Exposure	MOE	Exposure	MOE	Exposure	MOE
U.S. pop - all seasons:	0.021061	4748	0.035315	2832	0.055144	1813
Nursing infants (<1 year):	0.016032	6238	0.022422	4460	0.028149	3553
Non-nursing infants (<1 yr):	0.051830	1929	0.073670	1357	0.097174	1029
Females (13+/preg/not nsg):	0.012416	8054	0.015027	6655	0.018827	5312
Females (13+/nursing):	0.013457	7431	0.019634	5093	0.021079	4744
Children (1-6 years):	0.040334	2479	0.051952	1925	0.072824	1373
Children (7-12 years):	0.022901	4367	0.030146	3317	0.045059	2219
Males (13-19 years):	0.016536	6047	0.022117	4521	0.033266	3006
Females (13-19 yrs/np/nn):	0.012657	7901	0.019324	5175	0.023450	4264
Males (20+ years):	0.009583	10436	0.014409	6940	0.021195	4718
Females (20+ years/np/nn):	0.008655	11554	0.012063	8290	0.018777	5326
All infants (<1 year):	0.045383	2203	0.069801	1433	0.094102	1063
Females (13-50 years):	0.010040	9960	0.014443	6924	0.022691	4407