



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

SEP 1 1987

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

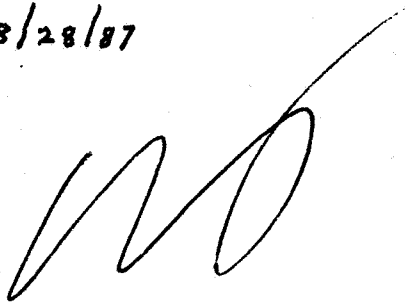
MEMORANDUM

Subject: Myclobutanil (Rally) Tolerance Assessment System Tolerance Assessment. ID Numbers, 7G3479 and 7H5523. Action Code 244 and 264.

To: Lois Rossi/Schnaubelt, PM# 21
Registration Division
and
Toxicology Branch

From: Charles Frick *e. Frick 8/28/87*
Tolerance Assessment Program
Residue Chemistry Branch, HED

Thru: Charles L. Trichilo, Ph.D.
Chief, Residue Chemistry Branch
Hazard Evaluation Division



Rohm and Haas Company has submitted petitions on the fungicide Myclobutanil (Rally), requesting temporary tolerances for processed commodities of apples and grapes, as well as for meat, milk, and eggs. These would allow removal of a fresh market restriction from the EUP labels and permit processing of damaged apples and grapes. RCB has concluded that previous data deficiencies have been resolved and toxicological considerations permitting, it can recommend for the establishment of the following temporary tolerances for residues of Myclobutanil and its metabolites containing both the chlorophenyl and triazole rings in/on the following: apple pomace 5 ppm, grape pomace 5 ppm, raisins 5 ppm, raisin waste 15 ppm, and meat, fat, and meat by-products (except liver) of cattle, goats, hogs, horses, and sheep at 0.2 ppm, also, milk 0.02 ppm, eggs, meat, fat, and meat by-products of poultry at 0.02 ppm. RCB has considered the established temporary tolerances of 0.5 ppm for the RACs apples and grapes, to be adequate (memo. R. Loranger, 8/13/87).

The Tolerances Assessment System (TAS) has been requested to perform a tolerance assessment on the theoretical dietary exposure of Rally that would result from the implementation of the requested temporary tolerances.

The TAS analysis estimates dietary exposure for the U.S. population average and for each of 22 subgroups. The TMRC for the U.S. population was calculated as 0.0009 mg/kg/day, which is equivalent to 294% of the PADI. The subgroups calculated to have the highest dietary exposure were non-nursing infants (0.0056 mg/kg/day, which is equivalent to 1873 % of the PADI) and nursing infants (0.0034 mg/kg/day, equivalent to 1120% of the PADI). For commodity contribution of selected RACs to the Myclobutanil ADI and TMRC, see tables 1 thru 3.

Discussion

The PADI used in this TAS analysis was 0.0003 mg/kg/day. This value was based on a NOEL of 0.3 mg/kg/day observed in a 90 day dog study with a safety factor of 1000. This value was approved by the Toxicology Branch Reference Dose Committee (4/10/87) because most of the critical toxicology studies for this chemical had not, at that point in time, been reviewed. When the scientific evaluations of these studies have been completed, a higher value for an ADI may be established thereby lowering the TAS calculated TMRC and percent ADI utilized. The review of these toxicology studies is now in progress (verbal communication, Pam Hurly, Tox. Branch 8/14/87). This TAS analysis has been conducted using the tolerance values as they would be published.

The Rohm and Haas Company has stated, "The actual residue contribution of Myclobutanil treated crops to the diet is very much lower than the theoretical maximum concentration, and, in fact, is negligible under the conditions of the EUP program" In defense of this statement the company offers the following "factors mitigating dietary exposure".

a. Only a very small fraction of the total apple crop is treated. In 1987, we treated 260 acres or 0.05% of total apple acreage. We treated 168 acres or 0.02% of the total grape acreage (730,000 acres est.).

b. A small fraction of the treated acreage will be processed. Based on the quantity of damaged, treated crop purchased in 1986, we estimate 10% of the crop will be processed in 1987.

c. Combining treated crop with untreated crop during processing will dilute residues to non-detectable levels.

A response to the above rational has been submitted by E. Neil Pelletier, Science Support Branch, Benefits and Use Division, 8/21/87, and reads as follows: "... Based on Dept of Commerce data presented in its Census of Agriculture, the production figures Rohn and Hass closely match those of the census and therefore the percentage crop treated figures are accurate.

In so far as the percentage of treated apples and grapes destined for processing, it is not possible to make a meaningful estimate based on national averages. Although about 45% of the U.S. apple crop is used for processing (the percentage for grapes is much higher), the percentage would vary with the crop variety, growing region, etc. Since these factors would enter into percentage of myclobutanil treated fruit entering into the process fruit market, it is not unreasonable to accept the Rohm Hass estimate that 10 percent of the crop might be fruit for processing".

This TAS analysis does not provide a realistic estimate of dietary risk because it is (1) based on a PADI that uses a 1000 fold safety factor, (2) is based on tolerance level residues in foods as consumed and (3) the percent of crop treated has not been taken into consideration. Any consideration of permanent tolerances on these crops, assuming the same PADI (or an ADI of similar magnitude) will need to be supported by data that will allow more precise estimates of dietary exposure (i.e. more extensive field trial data, cooking studies, processing studies, etc.). We note that processing studies have been submitted (see memo. of R. Loranger, 8/16/87, PP# 7G3479).

ATTACHMENT

cc. Rally S.F.
Reading File
TAS File
C. Frick (RCB)
Circ.
PMSD

TABLE 1

Commodity Contribution of Selected RACs to Myclobutanil ADI^c

<u>RAC</u>	<u>U.S. Average</u>	<u>Non-nursing Infants <1 yr</u>	<u>Children 1-6 yrs</u>
Apples	131.8% ^a (44.8%) ^b	1341.7% (71.6%)	453.6% (47.8%)
Grapes/Juice	25.3% (8.6%)	45.8% (2.4%)	97.0% (10.2%)
Raisins	28.3% (9.6%)	6.9% (0.4%)	120.2% (12.7%)
Red Meat	31.1% (10.6%)	31.1% (1.7%)	56.4% (5.9%)
Poultry	3.4% (1.1%)	7.0% (0.4%)	6.9% (0.7%)
Milk	70.5% (23.9%)	436.5% (23.3%)	207.0% (21.8%)
Eggs	3.8% (1.3%)	4.1% (0.2%)	8.6% (0.9%)

^aexpressed as percent of the ADI.

^bexpressed as percent of the total TMRC.

^canalysis based on a PADI of 0.0003 mg/kg/day.

Table 2

Commodity Contribution of Selected RACs

To Myclobutanil ADI

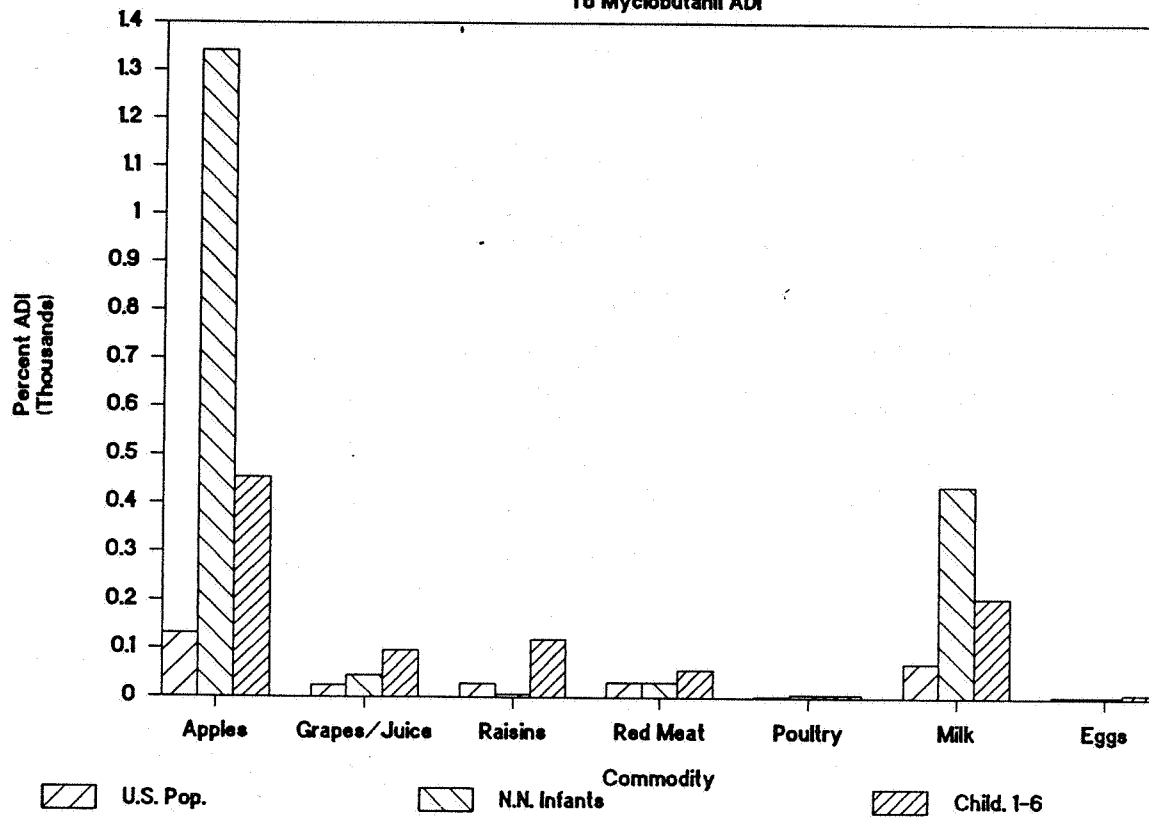
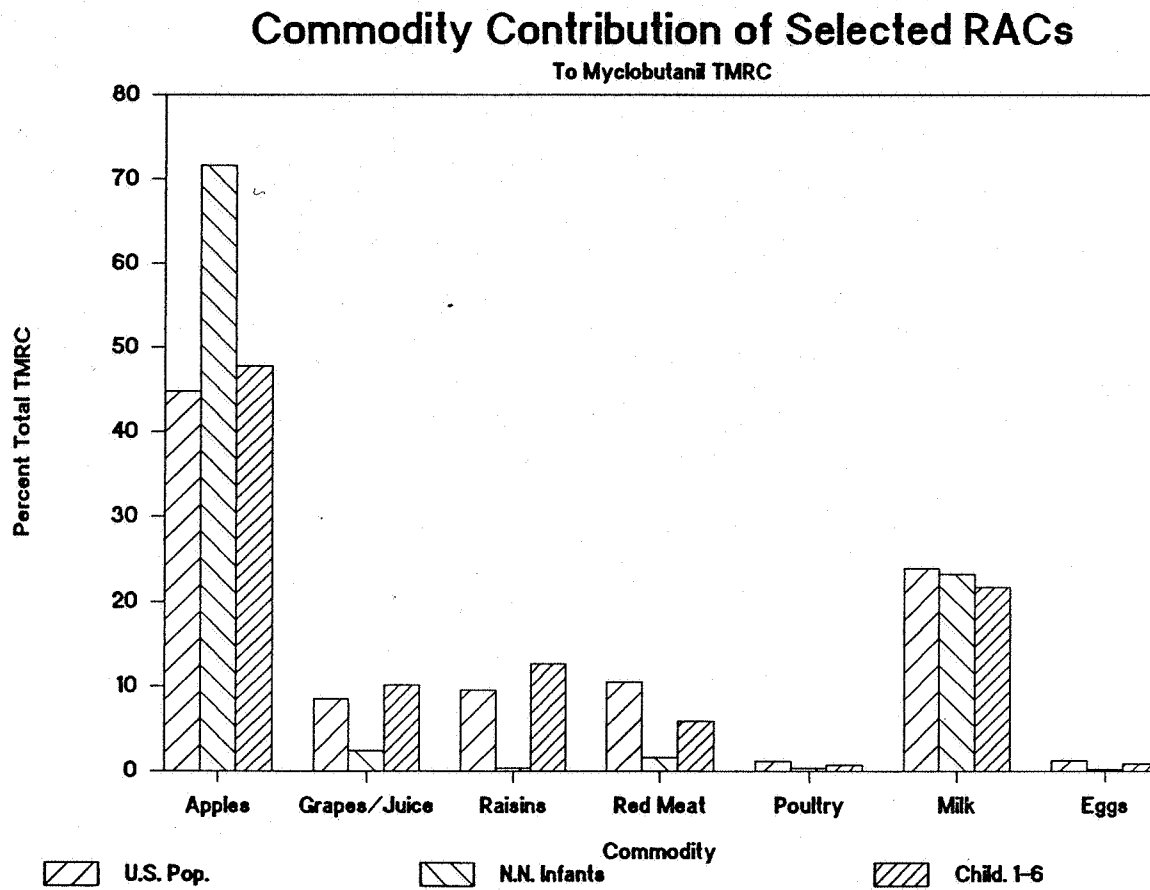


Table 3



CHEMICAL INFORMATION FOR CASWELL NUMBER 723K

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CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES		DATA GAPS/COMMENTS	STATUS
			PADI	1000		
Rally (Systhane) Caswell #723K CAS No. 88671-89-0 A.I. CODE: 128857 CFR No. 180.	90d feeding- dog MOEL= 0.3000 mg/kg LEL= 0.00 ppm 5.9000 mg/kg 0.00 ppm ONCO: Pending.	Hepatocellular hypertro- phy. Oncogenicity studies in rat and mouse under review.	OPP Rfd= 0.000300 EPA Rfd= 0.000000 WHO Rfd Type:	0.000300 0.000000 0.000000 0.500000	Chronic feeding- rat Teratology- rabbit Mouse oncogenicity. (studies under review)	TOX complete 4/10/87. ORD not scheduled.

FOOD CODE	FOOD NAME	PETITION NUMBER	NEW	TOLERANCE (PPM)	PUBLISHED
01014AA	GRAPES-FRESH	463149		0.500000	
01014DA	GRAPES-RAISINS	7H5523			
01014JA	GRAPES-JUICE	463149	5.000000		H
04001AA	APPLES-FRESH	463149		0.500000	
04001DA	APPLES-DRIED	463149		0.500000	
04001JA	APPLES-JUICE	463149		0.500000	
50000DB	MILK-NON-FAT SOLIDS	763479	0.020000		
50000FA	MILK-FAT SOLIDS	763479	0.020000		
50000SA	MILK SUGAR (LACTOSE)	763479	0.020000		
53001BA	BEEF-MEAT BYPRODUCTS	763479	0.040000		
53001BB	BEEF(ORGAN MEATS)-OTHER	763479	0.040000		
53001DA	BEEF-DRIED	763479	0.040000		
53001FA	BEEF(BONELESS)-FAT (BEEF TALLOW)	763479	0.040000		
53001KA	BEEF(ORGAN MEATS)-KIDNEY	763479	0.040000		
53001LA	BEEF(ORGAN MEATS)-LIVER	763479	0.200000		
53001MA	BEEF(BONELESS)-LEAN (W/O REMOVEABLE FAT)	763479	0.040000		
53002BA	GOAT-MEAT BYPRODUCTS	763479	0.040000		
53002BB	GOAT(ORGAN MEATS)-OTHER	763479	0.040000		
53002FA	GOAT(BONELESS)-FAT	763479	0.040000		
53002KA	GOAT(ORGAN MEATS)-KIDNEY	763479	0.040000		
53002LA	GOAT(ORGAN MEATS)-LIVER	763479	0.200000		
53002MA	GOAT(BONELESS)-LEAN (W/O REMOVEABLE FAT)	763479	0.040000		
53003AA	HORSE	763479	0.040000		
53005BA	SHEEP-MEAT BYPRODUCTS	763479	0.040000		
53005BB	SHEEP(ORGAN MEATS)-OTHER	763479	0.040000		
53005FA	SHEEP(BONELESS)-FAT	763479	0.040000		
53005KA	SHEEP(ORGAN MEATS)-KIDNEY	763479	0.040000		
53005LA	SHEEP(ORGAN MEATS)-LIVER	763479	0.200000		
53005MA	SHEEP(BONELESS)-LEAN (W/O REMOVEABLE FAT)	763479	0.040000		
53006BA	PORK-MEAT BYPRODUCTS	763479	0.040000		
53006BB	PORK(ORGAN MEATS)-OTHER	763479	0.040000		
53006FA	PORK(BONELESS)-FAT (INCLUDING LARD)	763479	0.040000		
53006KA	PORK(ORGAN MEATS)-KIDNEY	763479	0.040000		
53006LA	PORK(ORGAN MEATS)-LIVER	763479	0.200000		
53006MA	PORK(BONELESS)-LEAN (W/O REMOVEABLE FAT)	763479	0.040000		
55008BA	TURKEY-BYPRODUCTS	763479	0.020000		
55008LA	TURKEY-GIBLETS (LIVER)	763479	0.020000		
55008MA	TURKEY-FLESH(W/O SKIN, W/O BONES)	763479	0.020000		
55008MB	TURKEY-FLESH(+SKIN,W/O BONES)	763479	0.020000		
55008MC	TURKEY-UNSPECIFIED	763479	0.020000		

CHEMICAL INFORMATION FOR CASWELL NUMBER 723K

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CHEMICAL		STUDY TYPE		EFFECTS		REFERENCE DOSES		DATA GAPS/COMMENTS		STATUS	
Rally (Systhane) Caswell #723K CAS No. 88671-89-0 A.I. CODE: 128857 CFR No. 180.		90d feeding- dog NOEL= 0.3000 mg/kg 0.00 ppm LEL= 5.9000 mg/kg 0.00 ppm ONCO: Pending.		Hepatocellular hypertro- phy. Oncogenicity studies in rat and mouse under review.		PAD1 1000 OPP Rfd= 0.000300 EPA Rfd= 0.000000 WHO Rfd 0.000000 Type:		Chronic feeding- rat Teratology- rabbit Mouse oncogenicity (studies under review)		TOX complete 4/10/87. ORD not scheduled.	

FOOD CODE	FOOD NAME	PETITION NUMBER		TOLERANCE (PPM)	
		NEW	PENDING	PUBLISHED	
55013BA	POULTRY, OTHER-BYPRODUCTS	763479	0.020000		
55013LA	POULTRY, OTHER-GIBLETS(LIVER)	763479	0.020000		
55013MA	POULTRY, OTHER-FLESH (+SKIN, W/O BONES)	763479	0.020000		
55014AA	EGGS-WHOLE	763479	0.020000		
55014AB	EGGS-WHITE ONLY	763479	0.020000		
55014AC	EGGS-YOLK ONLY	763479	0.020000		
55015BA	CHICKEN-BYPRODUCTS	763479	0.020000		
55015LA	CHICKEN-GIBLETS(LIVER)	763479	0.020000		
55015MA	CHICKEN-FLESH(W/O SKIN, W/O BONES)	763479	0.020000		
55015MB	CHICKEN-FLESH(+SKIN, W/O BONES)	763479	0.020000		

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CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Rally (Systhane) Cassell #723K CAS No. 88671-89-0 A.I. CODE: 128857 CFR No. 180.	90d feeding- dog NOEL= 0.3000 mg/kg LEL= 0.00 ppm 5.9000 mg/kg 0.00 ppm ONCO: Pending.	Hepatocellular hypertrophy. Oncogenicity studies in rat and mouse under review.	PADI 1000 OPP RfD= 0.000300 EPA RfD= 0.000000 WHO RfD 0.000000 Type:	Chronic feeding- rat Teratology- rabbit Mouse oncogenicity (studies under review)	TOX complete 4/10/87. ORD not scheduled.

POPULATION SUBGROUP	TOTAL TMRC (MG/KG BODY WEIGHT/DAY)	NEW TMRC	AS PERCENT OF RFD	DIFFERENCE AS PERCENT OF RFD	EFFECT OF ANTICIPATED RESIDUES
U.S. POPULATION - 48 STATES	0.0005	0.0009	294.2373	137.1100	
U.S. POPULATION - SPRING SEASON	0.0004	0.0008	254.4397	126.6297	
U.S. POPULATION - SUMMER SEASON	0.0004	0.0008	269.4740	134.4067	
U.S. POPULATION - FALL SEASON	0.0006	0.0010	332.3213	146.5750	
U.S. POPULATION - WINTER SEASON	0.0005	0.0010	320.7927	140.8563	
NORTHEAST REGION	0.0006	0.0010	338.9937	143.7820	
NORTH CENTRAL REGION	0.0004	0.0009	285.9083	142.4037	
SOUTHERN REGION	0.0004	0.0007	237.5737	118.0150	
WESTERN REGION	0.0006	0.0010	344.4233	153.5087	
HISPANICS	0.0005	0.0010	324.4627	159.3427	
NON-HISPANIC WHITES	0.0005	0.0009	302.4920	138.7390	
NON-HISPANIC BLACKS	0.0003	0.0007	227.1493	115.9040	
NON-HISPANICS OTHER	0.0005	0.0009	290.0077	138.7680	
NURSING INFANTS (<1 YEAR OLD)	0.0030	0.0034	1120.5220	116.5963	
NON-NURSING INFANTS (<1 YEAR OLD)	0.0042	0.0056	1873.0460	485.5683	
FEMALES (13+ YEARS, PREGNANT)	0.0003	0.0006	194.3113	93.9887	
FEMALES 13+ YEARS, NURSING	0.0004	0.0008	250.6077	116.0190	
CHILDREN (1-6 YEARS OLD)	0.0017	0.0028	949.6427	399.0353	
CHILDREN (7-12 YEARS OLD)	0.0007	0.0013	438.9250	214.3150	
MALES (13-19 YEARS OLD)	0.0003	0.0007	236.2197	140.2390	
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.0003	0.0006	208.2453	107.6283	
MALES (20 YEARS AND OLDER)	0.0002	0.0005	157.3110	87.4427	
FEMALES (20 YEARS AND OLDER)	0.0002	0.0005	159.3457	79.6680	

*Current TMRC does not include new or pending tolerances.
**New TMRC includes new, pending, and published tolerances.

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LISTING OF EXPOSURE BY RAC FOR: U.S. POPULATION - 48 STATES

FOOD CODE	FOOD NAME	NEW TOLERANCE (PPM)	PENDING TOLERANCE (PPM)	PUBLISHED TOLERANCE (PPM)	EXISTING TOLERANCES (UG/KG/DAY)	NEW, PENDING & PUBLISHED TOLERANCES (UG/KG/DAY)	NEW %RFD	NEW %RFD
04001AA	APPLES-FRESH			0.5000	0.2284	76.1213	0.0007	0.2353
04001BA	APPLES-DRIED			0.5000	0.0008	0.2753	0.0002	0.0803
04001JA	APPLES-JUICE			0.5000	0.1662	55.4123	0.0001	0.0337
CROP GROUP TOTALS FOR POME FRUITS:								
01014AA	GRAPES-FRESH			0.5000	0.0219	7.2990	0.0149	4.9610
01014BA	GRAPES-RAISINS			0.5000	0.0541	18.0193	0.0000	0.0063
01014JA	GRAPES-JUICE			0.5000	0.0541	18.0193	0.0041	1.3800
CROP GROUP TOTALS FOR SMALL FRUITS AND BERRIES:								
53001BA	BEEF-MEAT BYPRODUCTS			0.0400	0.0760	25.3183	0.0000	0.0000
53001BB	BEEF(ORGAN MEATS)-OTHER			0.0400			0.0000	0.0000
53001DA	BEEF-DRIED			0.0400			0.0000	0.0000
53001FA	BEEF(BONELESS)-FAT (BEEF TALLOW)			0.0400			0.0000	0.0000
53001KA	BEEF(ORGAN MEATS)-KIDNEY			0.0400			0.0000	0.0000
53001LA	BEEF(ORGAN MEATS)-LIVER			0.0400			0.0000	0.0000
53001MA	BEEF(BONELESS)-LEAN (W/O REMOVABLE FAT)			0.0400			0.0000	0.0000
53002BA	GOAT-MEAT BYPRODUCTS			0.0400			0.0000	0.0000
53002BB	GOAT(ORGAN MEATS)-OTHER			0.0400			0.0000	0.0000
53002FA	GOAT(BONELESS)-FAT			0.0400			0.0000	0.0000
53002KA	GOAT(ORGAN MEATS)-KIDNEY			0.0400			0.0000	0.0000
53002LA	GOAT(ORGAN MEATS)-LIVER			0.0400			0.0000	0.0000
53002MA	GOAT(BONELESS)-LEAN (W/O REMOVABLE FAT)			0.0400			0.0000	0.0000
53003AA	HORSE			0.0400			0.0000	0.0000
53003BA	SHEEP-MEAT BYPRODUCTS			0.0400			0.0000	0.0000
53003BB	SHEEP(ORGAN MEATS)-OTHER			0.0400			0.0000	0.0000
53003FA	SHEEP(BONELESS)-FAT			0.0400			0.0000	0.0000
53003KA	SHEEP(ORGAN MEATS)-KIDNEY			0.0400			0.0000	0.0000
53003LA	SHEEP(ORGAN MEATS)-LIVER			0.0400			0.0000	0.0000
53003MA	SHEEP(BONELESS)-LEAN (W/O REMOVABLE FAT)			0.0400			0.0000	0.0000
53004AA	PORK-MEAT BYPRODUCTS			0.0400			0.0000	0.0000
53004BA	PORK(ORGAN MEATS)-OTHER			0.0400			0.0000	0.0000
53004FA	PORK(BONELESS)-FAT (INCLUDING LARD)			0.0400			0.0000	0.0000
53004KA	PORK(ORGAN MEATS)-KIDNEY			0.0400			0.0000	0.0000
53004LA	PORK(ORGAN MEATS)-LIVER			0.0400			0.0000	0.0000
53004MA	PORK(BONELESS)-LEAN (W/O REMOVABLE FAT)			0.0400			0.0000	0.0000
CROP GROUP TOTALS FOR RED MEAT:								
					0.0000	0.0000	0.0934	31.1177

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CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
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LISTING OF EXPOSURE BY RAC FOR: U.S. POPULATION - 48 STATES

FOOD CODE	FOOD NAME	NEW	TOLERANCE (PPM)	EXISTING TOLERANCES TMRC (UG/KG/DAY)	%RFD	NEW, PENDING & PUBLISHED TOLERANCES NEW TMRC (UG/KG/DAY)	NEW %RFD
55008BA	TURKEY-BYPRODUCTS		0.0200			0.0000	0.0017
55008LA	TURKEY-GIBLETS (LIVER)		0.0200			0.0000	0.0003
55008MA	TURKEY-FLESH(W/O SKIN, W/O BONES)		0.0200			0.0002	0.0530
55008MB	TURKEY-FLESH(+SKIN, W/O BONES)		0.0200			0.0010	0.3210
55008MC	TURKEY-UNSPECIFIED		0.0200			0.0000	0.0007
55013BA	POULTRY, OTHER-BYPRODUCTS		0.0200			0.0000	0.0000
55013LA	POULTRY, OTHER-GIBLETS(LIVER)		0.0200			0.0000	0.0017
55013MA	POULTRY, OTHER-FLESH (+SKIN, W/O BONES)		0.0200			0.0001	0.0360
55015BA	CHICKEN-BYPRODUCTS		0.0200			0.0000	0.0000
55015LA	CHICKEN-GIBLETS(LIVER)		0.0200			0.0001	0.0337
55015MA	CHICKEN-FLESH(W/O SKIN, W/O BONES)		0.0200			0.0012	0.4010
55015MB	CHICKEN-FLESH(+SKIN, W/O BONES)		0.0200			0.0076	2.5287
CROP GROUP TOTALS FOR POULTRY:			0.0000		0.0000	0.0101	3.3777
500000B	MILK-NON-FAT SOLIDS		0.0200			0.1427	47.5757
50000FA	MILK-FAT SOLIDS		0.0200			0.0679	22.6320
50000SA	MILK SUGAR (LACTOSE)		0.0200			0.0007	0.2497
55014AA	EGGS-WHOLE		0.0200			0.0113	3.7633
55014AB	EGGS-WHITE ONLY		0.0200			0.0002	0.0613
55014AC	EGGS-YOLK ONLY		0.0200			0.0001	0.0443
CROP GROUP TOTALS FOR DAIRY PRODUCTS:			0.0000		0.0000	0.2230	74.3263

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LISTING OF EXPOSURE BY RAC FOR: NON-NURSING INFANTS (<1 YEAR OLD)

FOOD CODE	FOOD NAME	NEW	TOLERANCE (PPM) PENDING PUBLISHED	EXISTING TOLERANCES TMRC (UG/KG/DAY) %RFD	NEW, PENDING & PUBLISHED TOLERANCES NEW TMRC (UG/KG/DAY) NEW %RFD
04001AA	APPLES-FRESH		0.5000	1.4270 475.6660	
04001DA	APPLES-DRIED		0.5000	0.0000 0.0000	
04001JA	APPLES-JUICE		0.5000	2.5982 866.0520	
CROP GROUP TOTALS FOR POME FRUITS:					
01014AA	GRAPES-FRESH		0.5000	4.0252 1341.7180	
01014DA	GRAPES-RAISINS		0.5000	0.0124 4.1227	
01014JA	GRAPES-JUICE		0.5000	0.1249 41.6370	
CROP GROUP TOTALS FOR SMALL FRUITS AND BERRIES:					
53001BA	BEEF-MEAT BYPRODUCTS		0.0400	0.1373 45.7597	0.1580 52.6663
53001BB	BEEF(ORGAN MEATS)-OTHER		0.0400		0.0004 0.1470
53001DA	BEEF-DRIED		0.0400		0.0001 0.0413
53001FA	BEEF(BONELESS)-FAT (BEEF TALLOW)		0.0400		0.0000 0.0000
53001KA	BEEF(ORGAN MEATS)-KIDNEY		0.0400		0.0077 2.5503
53001LA	BEEF(ORGAN MEATS)-LIVER		0.0400		0.0000 0.0000
53001MA	BEEF(BONELESS)-LEAN (W/O REMOVEABLE FAT)		0.0400		0.0062 2.0823
53002BA	GOAT-MEAT BYPRODUCTS		0.0400		0.0491 16.3713
53002BB	GOAT(ORGAN MEATS)-OTHER		0.0400		0.0000 0.0000
53002FA	GOAT(BONELESS)-FAT		0.0400		0.0000 0.0000
53002KA	GOAT(ORGAN MEATS)-KIDNEY		0.0400		0.0000 0.0000
53002LA	GOAT(ORGAN MEATS)-LIVER		0.0400		0.0000 0.0000
53002MA	GOAT(BONELESS)-LEAN (W/O REMOVEABLE FAT)		0.0400		0.0000 0.0000
53003AA	HORSE		0.0400		0.0000 0.0000
53003BA	SHEEP-MEAT BYPRODUCTS		0.0400		0.0000 0.0000
53003BB	SHEEP(ORGAN MEATS)-OTHER		0.0400		0.0000 0.0000
53003FA	SHEEP(BONELESS)-FAT		0.0400		0.0000 0.0000
53003KA	SHEEP(ORGAN MEATS)-KIDNEY		0.0400		0.0003 0.0967
53003LA	SHEEP(ORGAN MEATS)-LIVER		0.0400		0.0000 0.0000
53003MA	SHEEP(BONELESS)-LEAN (W/O REMOVEABLE FAT)		0.0400		0.0025 0.8407
53003BA	PORK-MEAT BYPRODUCTS		0.0400		0.0002 0.0767
53003BB	PORK(ORGAN MEATS)-OTHER		0.0400		0.0001 0.0203
53003FA	PORK(BONELESS)-FAT (INCLUDING LARD)		0.0400		0.0059 1.9537
53003KA	PORK(ORGAN MEATS)-KIDNEY		0.0400		0.0000 0.0000
53003LA	PORK(ORGAN MEATS)-LIVER		0.0400		0.0030 1.0047
53003MA	PORK(BONELESS)-LEAN (W/O REMOVEABLE FAT)		0.0400		0.0177 5.8900
CROP GROUP TOTALS FOR RED MEAT:			0.0000	0.0000	0.0932 31.0750

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

DATE: 08/20/87

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CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Rally (Systhane) Caswell #723K CAS No. 88671-89-0 A.I. CODE: 128857 CFR No. 180.	90d feeding - dog MOEL = 0.3000 mg/kg 0.00 ppm LEL = 5.9000 mg/kg 0.00 ppm ONCO: Pending.	Hepatocellular hypertrophy. Oncogenicity studies in rat and mouse under review.	PADI 1000 OPP RfD = 0.000300 EPA RfD = 0.000000 WHO RfD 0.000000 Type:	Chronic feeding - rat Teratology - rabbit Mouse oncogenicity (studies under review)	TOX complete 4/10/87. ORD not scheduled.

LISTING OF EXPOSURE BY RAC FOR: NON-NURSING INFANTS (<1 YEAR OLD)

FOOD CODE	FOOD NAME	NEW	TOLERANCE (PPM) PENDING PUBLISHED	EXISTING TOLERANCES TMRG (UG/KG/DAY) XRTD	NEW, PENDING & PUBLISHED TOLERANCES NEW, NEW TMRG (UG/KG/DAY) NEW XRTD
550088A	TURKEY-BYPRODUCTS	0.0200		0.0000	0.0000
550088A	TURKEY-GIBLETS (LIVER)	0.0200		0.0000	0.0000
550088A	TURKEY-FLESH(W/O SKIN, W/O BONES)	0.0200		0.0024	0.7993
550088B	TURKEY-FLESH(+SKIN, W/O BONES)	0.0200		0.0016	0.5423
550088C	TURKEY-UNSPECIFIED	0.0200		0.0000	0.0000
550138A	POULTRY, OTHER-BYPRODUCTS	0.0200		0.0000	0.0000
550138A	POULTRY, OTHER-GIBLETS(LIVER)	0.0200		0.0000	0.0000
550138A	POULTRY, OTHER-FLESH (+SKIN, W/O BONES)	0.0200		0.0000	0.0000
550158A	CHICKEN-BYPRODUCTS	0.0200		0.0000	0.0000
550158A	CHICKEN-GIBLETS(LIVER)	0.0200		0.0003	0.1067
550158A	CHICKEN-FLESH(W/O SKIN, W/O BONES)	0.0200		0.0066	2.1890
550158B	CHICKEN-FLESH(+SKIN, W/O BONES)	0.0200		0.0102	3.3897
CROP GROUP TOTALS FOR POULTRY:		0.0000	0.0000	0.0211	7.0270
500000B	MILK-NON-FAT SOLIDS	0.0200		1.0239	341.2900
500000A	MILK-FAT SOLIDS	0.0200		0.2251	75.0377
500000A	MILK SUGAR (LACTOSE)	0.0200		0.0606	20.2030
55014AA	EGGS-WHOLE	0.0200		0.0094	3.1423
55014AB	EGGS-WHITE ONLY	0.0200		0.0001	0.0273
55014AC	EGGS-YOLK ONLY	0.0200		0.0026	0.8593
CROP GROUP TOTALS FOR DAIRY PRODUCTS:		0.0000	0.0000	1.3217	440.5597