

MALATHION

DIETARY EXPOSURE ASSESSMENT

HEALTH ASSESSMENT SECTION

MEDICAL TOXICOLOGY BRANCH

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CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY

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EXECUTIVE SUMMARY

Introduction

Malathion is an organophosphate insecticide which is registered for agricultural uses and for landscape maintenance, vector control, and structural pest control (DPR, 1992). This assessment of potential dietary exposures addresses the residues that may occur as a result of agricultural uses of malathion. Organophosphate compounds inhibit the activity of cholinesterase which is an enzyme present in several body tissues and essential for the normal function of nerves. Exposure of test animals or humans to sufficient dosages of malathion and its primary active metabolite, malaoxon, may result in subsequent signs of toxicity, such as salivation and sweating.

Potential risks associated with acute and chronic dietary exposures to residues of malathion have been assessed under the provisions of Assembly Bill 2161, sometimes referred to as The Food Safety Act of 1989 (Bronzan and Jones), because of concerns raised as a result of use of malathion for control of Mediterranean fruit fly infestations in California.

Dietary Risk Assessment Process

The Department of Pesticide Regulation (DPR) uses the risk assessment process to evaluate potential adverse human health effects of dietary exposure to pesticide residues. The risk assessment process consists of four aspects: hazard identification, dose-response assessment, exposure evaluation, and risk characterization.

Hazard identification necessitates an evaluation of the toxicological properties of the pesticide. The dose-response assessment then considers the chemical's toxicological properties and estimates the amount which could potentially cause an effect. A basic supposition of toxicology is that at a high enough dosage, virtually all substances will result in some toxic manifestation. Although chemicals are often referred to as "dangerous" or "safe", as though these concepts were absolutes, in reality, these terms describe chemicals which require low or high dosages, respectively, to cause toxic effects. Toxicological activity is determined in a battery of experimental and epidemiological studies which define the types of toxic effects which can be caused. The study also determines the approximate lowest exposure levels (dosages) at which these effects might be seen. State and federal testing requirements, including California's Birth Defect Prevention Act of 1984 (SB950, Petris), mandate that substances be tested at dosages high enough to produce toxic effects, even if such testing involves dosages many times higher than those to which people might be exposed.

In addition to the intrinsic toxicological activity of the pesticide, other critical parameters used in the estimation of risk are evaluations of the route, level, frequency and duration of exposure. The purpose of the exposure evaluation is to determine the potential amount of pesticide likely to be delivered through a particular route on an acute or a chronic basis.

The risk characterization then relates toxic effects observed in the laboratory studies, conducted using high dosages, to potential human exposures to lower dosages. The likelihood of the occurrence of possible health effects in human populations is expressed as the margin of safety (MOS). The MOS is the ratio of the dosage which produced no effect in laboratory studies to the potential exposure dosage.

Toxicology

Based on currently available human data, it is the conclusion of DPR that dietary exposure to excessive dosages of malathion and malaoxon may result in cholinergic signs of toxicity. These signs are a result of inhibition of enzyme (cholinesterase) activity. The no-observable-effect-level (NOEL) in humans for cholinergic signs is 0.34 mg/kg. This dosage is the NOEL which will be used to evaluate both single (acute) and repeated exposures, since clinical signs were not observed at this dosage level following a single exposure on the first day of the study, after daily administrations for eight weeks, or during a subsequent three week recovery period.

Acute and Chronic Dietary Exposure Assessment

A margin of safety (MOS) is the ratio of the NOEL to the potential exposure dosage. Acute margins of safety (MOSs), based on the 95th percentile of single day consumer exposures, are at least 43, *i.e.*, the potential exposure is 43 times less than the NOEL for cholinergic signs from a human study. An MOS of at least ten is generally considered adequate for overt toxicological signs and symptoms when the MOS is based on a NOEL from an adequately conducted human study.

Margins of safety for repeated exposures for all population subgroups are greater than 340. Cholinergic signs were not observed in individuals who received daily dosages of 0.34 mg/kg for eight weeks. Signs were also not observed during a three week recovery period. An MOS of 100 or more is generally considered adequate when calculated from the results of a study of sub-chronic human exposures.

Tolerance Assessment

Margins of safety for acute exposures to theoretical residue levels equal to the tolerances, the highest legal residue levels, of malathion and malaoxon for consumption of several commodities have been calculated. The commodities analyzed were those which could potentially result in high consumer exposure based on consumption estimates, likelihood of consumption by children, or likelihood of application to commodities in California. Margins of safety for consumption of lettuce, celery, onions, lemons, peanuts, sugar beets, cottonseed products, strawberries, and sweet corn are adequate for all population subgroups. Theoretical MOSs for several other commodity/-population subgroup combinations are inadequate. In both cases, some of the population subgroups were not well represented in the consumption survey. However, an evaluation of specific consumption profiles for population subgroups indicates that the estimates of exposure to theoretical dietary residues equal to the tolerance are reasonable. The theoretical dietary assessment using residue values equal to the tolerance are likely to result in overestimation of actual dietary exposure, since residue monitoring data indicate that it is highly unlikely that a residue level will occur at the established tolerance.

Conclusions

The current potential acute and chronic dietary exposures to residues of malathion for the general U.S. population and all 22 consumer population subgroups result in MOSs which are considered adequately health protective. Theoretical acute MOSs based on consumption of commodities with residue levels equal to the United States Environmental Protection Agency (U.S. EPA) established tolerances are unacceptable for nearly all of the analyzed commodity/population subgroup combinations. However, current monitoring programs indicate that it is unlikely that consumers will be exposed to a commodity with a residue level which is equal to the tolerance.

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I. SUMMARY

Malathion is the active ingredient in pesticidal products registered for use in California with label-approved agricultural uses, landscape maintenance, vector control, and structural pest control. Agricultural uses accounted for approximately 25 percent of the malathion products sold in California (DPR, 1991a; DPR, 1991b). This dietary assessment addresses residues of malathion and its metabolite, malaaxon, which result from agricultural uses of malathion.

An assessment of risks which are associated with potential acute and chronic dietary exposures to primary and secondary malathion and malaaxon residues has been conducted because of concerns raised as a result of use of malathion for control of Mediterranean fruit fly infestations in California and as is mandated under the provisions of AB2161 - The Food Safety Act of 1989 (Bronzan and Jones). This legislation requires that a dietary risk assessment be conducted for all pesticides which may result in residues in food.

Oral (dietary) exposure to excessive dosages of malathion and malaaxon residues which may be present in label-approved commodities may result in cholinergic signs and symptoms of toxicity. These signs are a result of inhibition of enzyme (cholinesterase) activity. The no-observable-effect-level (NOEL) in humans for cholinergic signs was 0.34 mg/kg. This NOEL was used to evaluate both single (acute) and repeated exposures, since clinical signs were not observed at this dosage level following a single exposure on the first day of the study, after daily administrations for eight weeks, or during a subsequent three week recovery period.

The 95th percentiles of acute (single-day) consumer exposures for all population subgroups indicate that a margin of safety (MOS) of at least 43 exists between the NOEL which is based on absence of clinical signs and symptoms in humans and the potential acute dietary exposure dosages. Acute MOSs were based on the NOEL of 0.34 mg/kg. An MOS of at least ten is generally considered adequate for overt toxicological signs and symptoms when the MOS is based on a NOEL from an adequately conducted human study. An MOS of this magnitude accounts for variation in susceptibility between the study population and potential consumers.

Chronic MOSs were based on the human NOEL for clinical signs and symptoms established following the daily administration of malathion for eight-weeks. Chronic MOSs for all population subgroups examined were greater than 340. An MOS of 100 or more is generally considered adequate when calculated from the results of a study of subchronic human exposures. An MOS of 100 includes a safety factor of ten to protect the most susceptible consumer, who may be ten times as susceptible to chemical effects as the most susceptible person in the study population from which the NOEL was derived, and a safety factor of ten for extrapolation of the results of a subchronic study to a potentially chronic exposure scenario.

Margins of safety associated with consumption of certain commodities with theoretical residue levels equal to the United States Environmental Protection Agency (U.S. EPA) established tolerances were calculated. Residue levels for nine commodities with high consumption potential, e.g., lettuce, celery, sweet corn, onions, strawberries, lemons, cottonseed products, sugar beets, and peanuts, provided adequate MOSs for all population subgroups. All of the 17 remaining analyzed commodities with potential for high consumer exposure had inadequate MOSs for one or more population subgroups. In both circumstances, a low number of respondents in the survey results in uncertainty relative to the individual calculated MOSs in some population subgroups. However, an evaluation of specific consumption profiles for population subgroups indicates that estimates of exposure to theoretical dietary residues equal to the tolerance are reasonable. Based on current residue monitoring data, it is unlikely that consumers would be exposed to a commodity with a residue level equal to the tolerance.

II. INTRODUCTION

Malathion, an organophosphate insecticide, is the active ingredient in 94 different formulated products registered for use in California. Currently, there are 71 malathion formulations that have label-approved (registered) agricultural uses in California (DPR, 1992). Other major uses are for landscape maintenance, vector control, and structural pest control. Over 8,843,000 pounds of malathion were sold in California in 1990 (DPR, 1991a). Agricultural uses accounted for approximately 1,896,000 pounds (DPR, 1991b). This dietary assessment addresses agricultural uses of malathion.

An assessment of risks associated with potential acute and chronic dietary exposures to primary and secondary malathion and malaoxon residues has been conducted because of concerns raised as a result of use of malathion for control of Mediterranean fruit fly infestations in California and as is mandated under the provisions of AB2161 - The Food Safety Act of 1989 (Bronzan and Jones). This legislation directs that a dietary risk assessment be conducted for all pesticides which may result in residues in food. Additionally, margins of safety for theoretical acute exposures to residue levels equal to the tolerances established for malathion and malaoxon levels have been calculated for commodities with high potential consumption.

Tolerances (including four food additive tolerances) have been granted by the U.S. Environmental Protection Agency (U.S. EPA) for 148 commodities (PCNG, 1991). Federally approved application rates for agricultural uses range from 0.15 - 17.6 pounds/acre. The pre-harvest interval (PHI) ranges from 0 to 14 days depending on the commodity and application rate. The application rate for use in mosquito control is 0.12 pounds/acre (EPA, 1988). California-approved application rates are as low as 0.15 pounds per acre for grasshopper control, and a 21-day PHI for dates has been established (DPR, 1992).

III. TOXICOLOGICAL PROFILE

The toxicological profile of malathion has been extensively reviewed (DHS, 1991). Risks associated with occupational exposure to malathion have been previously characterized (CDFA, 1987). Toxic effects which have been identified as acute and chronic hazards, in laboratory animal studies (Appendix A. Toxicology Summary) or following oral human exposures, are identified and summarized in Section IV. Risk Assessment, A. Hazard Identification.

IV. RISK ASSESSMENT

A. Hazard Identification

1. Acute Toxicity

Acetylcholine is the chemical transmitter of nerve impulses in preganglionic neurons of the sympathetic and the parasympathetic nervous systems, postganglionic parasympathetic fibers to effector organs, postganglionic sympathetic fibers to sweat glands, motor nerves to skeletal muscles, and some nerve endings in the central nervous system (Murphy, 1986). Acute exposure to sufficient dosages of malathion may result in cholinergic signs and symptoms. Malaoxon, a biologically active oxidation product of malathion metabolism, binds to an enzyme, acetylcholinesterase (AChE) and inhibits the breakdown of acetylcholine at synaptic junctions (Murphy, 1986). Enzyme inhibition is due to binding at the active site of AChE, forming a phosphorylcholinesterase complex. The formation of this complex is initially reversible; however, it may become refractory. The presence of excess acetylcholine at effector sites is manifested by muscarinic, nicotinic, and central nervous system signs (Murphy, 1986).

The toxicological endpoints of primary concern in laboratory animals and in humans are clinical signs which result from inhibition of AChE activity. Inhibition of plasma cholinesterase (ChE) and/or AChE, in the absence of cholinergic signs, is generally considered a biological indication of exposure and systemic absorption rather than a toxicological endpoint (SAB, 1990).

A human oral exposure study was conducted in three phases utilizing experimental groups of five subjects (23 to 36 years of age), each of whom received daily doses of 8, 16, or 24 mg malathion for 32, 47, or 56 days, respectively (Moeller and Rider, 1962). Plasma ChE and red blood cell (AChE) activities were measured prior to administration, 24 hours after receiving the first dose, and twice weekly for the next 11 weeks. Inquiries and clinical observations were made daily throughout the study to identify possible toxic effects. The highest daily dosage (0.34 mg/kg - based on an average body weight of 70 kg) did not result in cholinergic signs or symptoms at any time during the study. Therefore, the NOEL for this study was considered to be 0.34 mg/kg-day. Inhibition of plasma ChE (25-30%) and red blood cell AChE (20-25%) activities did not result in clinical signs of toxicity under the conditions of this study. The NOEL of 0.34 mg/kg-day was used to calculate the MOSs for potential acute and repeated dietary exposures.

2. Chronic Toxicity

F344 rats were fed diets containing 0, 2000 or 4000 ppm technical grade (purity = 95%) malathion for a period of 103 weeks (Appendix A., Toxicology Summary; CDFA, 1987). Post-mortem examinations were performed on all animals which were sacrificed or found dead, and tissues were microscopically examined. Gastric inflammation and ulceration were histopathologically diagnosed at all levels and increased in a dose-related manner in male and female rats. Male rats were more susceptible to these effects. The lowest-observed-adverse-effect-level (LOAEL) for gastric inflammation and ulceration in this study was 2000 ppm (approximately 100 mg/kg-day) in male rats.

Male and female Osborne-Mendel rats, 50/sex/level, were fed diets containing technical-grade malathion (purity not indicated) for a period of 80 weeks (Appendix A., Toxicology Summary; CDFA, 1987). Time-weighted average concentrations were 0, 4700 and 8150 ppm. All animals found dead or moribund and those sacrificed at termination of the study were examined for macro- and microscopic lesions of the stomach, as well as of other major organs and tissues. Metastatic calcification was the only histopathologic change identified in the stomach of male rats; however the rate of occurrence was lower in both groups of treated rats than in the control group. Gastric erosion was diagnosed in one female rat at the lowest level (4700 ppm). The LOAEL for gastric lesions in this study was 4700 ppm (approximately 235 mg/kg-day) in rats of both sexes.

Malaoxon was fed to groups of F344 rats (50/sex/level) for a period of 103 weeks (Appendix A., Toxicology Summary; CDFA, 1987). Technical malaoxon (purity > 95%) was formulated in the diet at concentrations of 0, 500 or 1000 ppm. Post-mortem examinations (macro- and microscopic) were conducted on several organs and tissues from each animal. Gastric ulceration occurred at all concentrations in a positive, dose-related manner in rats of both sexes. The LOAEL in rats of both sexes for gastric ulceration due to dietary levels of malaoxon was 500 ppm (approximately 25 mg/kg-day).

Current data indicate that the subchronic (eight week) NOEL for cholinergic signs in humans is lower than the LOELs for gastric inflammation and ulceration in laboratory animals. Cholinergic signs were not observed in humans during the eight week dosing period or for three additional weeks after termination of dosing (Moeller and Rider, 1962). The chronic dietary assessment was based on this NOEL for cholinergic signs. The choice of this human NOEL avoids the uncertainty of interspecies extrapolation from an animal LOEL and the requirement for additional safety or uncertainty factors such as in a previous assessment of chronic occupational risk (CDFA, 1987). The DPR has identified a chronic NOEL of 0.34 mg/kg-day for cholinergic signs. Applying an uncertainty factor of 100 would lead to an exposure level of 0.003 mg/kg-day. The U.S. EPA reference dose (RfD) for chronic exposure is 0.02 mg/kg-day based on the NOEL (0.23 mg/kg-day) from this study for inhibition of AChE activity with an uncertainty factor of ten.

B. Dietary Exposure Assessment

I. Residue Data

Raw agricultural commodities (RACs) with established U.S. EPA tolerances and current California-registered direct food applications were included in these analyses. Residue data for each raw agricultural commodity (RAC) were obtained from DPR's pesticide residue monitoring programs (processing and priority pesticide programs) from 1986 through the first 6 months of 1990, the Food and Drug Administration (FDA) market surveillance and special programs (1988-1990), or the United States Department of Agriculture (USDA) survey results (1985-1989). All reported residue levels include malathion and malaoxon residues.

DPR samples RACs sold in California for several pesticide residues, including those of malathion. The minimum detection level (MDL) for malathion in these assays is 0.1 ppm. Residues of malathion in RACs, fruit juices, nuts, milk and eggs are monitored by FDA in the Domestic Market Surveillance Program and in other special programs. Residue levels for nuts and oils were based solely on FDA data. The MDL for assays in these programs is 0.05 ppm for milk and for eggs. The MDL for fruit juices under the FDA program is 0.01 ppm. The MDL for all other tested commodities is 0.01 ppm. FDA data utilized in these analyses were from samples collected within California. USDA Food Safety Inspection Service (FSIS) monitors beef, goat, horse, sheep, pork, turkey, chicken, and other poultry products through routine sampling performed by contract laboratories. The USDA laboratories' MDL for all organophosphates, including malathion, is 0.1 ppm. DPR data were utilized if positive results for a commodity occurred in more than one database; however, the lowest MDL was utilized if no residue levels above the MDL were detected in any survey.

If a processed food, *e.g.*, orange juice, had no detectable malathion residues, but the RAC from which it was derived had detectable residues, 50% of the MDL for the processed food was used as a hypothetical residue for that processed food. Potential acute and chronic exposures to residues in cherry, orange, grape, and grapefruit juices were evaluated in this manner. When an RAC had no detectable residues and data were not available on residue levels in processed foods, the foods derived from that RAC were assumed to have no residue. This assumption could underestimate exposure. The residue level in the processed food would exceed the MDL only if the concentration of the residue increased during processing.

a. Acute

The geometric mean of the positive residue samples was utilized in the acute dietary analyses if two or more samples of the commodity contained positive malathion residues. A positive sample is defined as a sample with a residue level above the MDL. Two or more positive samples was arbitrarily chosen as an adequate number, since only a small number of RACs had multiple residue values above the MDL. Only 20 RACs, out of 148 commodity/residue data sets conformed to the criterion of having two or more positive samples detected during the specified sampling periods. These RACs were: raspberries, grapes, strawberries, grapefruit, oranges, cherries, peaches, dates, cantaloupes, summer squash, sweet peppers, hot peppers, tomatoes, celery, head lettuce, mustard greens, onions, peas, okra, and green onions. The MDL was utilized as the default residue level when fewer than two positive residues were detected. The geometric mean of all positive samples is shown together with the sampling years (Table 1.). The residue file used for analysis of acute dietary exposure is included in Appendix B1.

b. Chronic

Many of the residue levels for RACs used in the chronic dietary exposure analysis were hypothetical, since many RACs had no actual residues detected in recent monitoring surveys (1986-1990). When no residues were detected, 50 % of the MDL was utilized as a default residue level for that sample. Commodities were given residue levels which corresponded to the mean of those samples which had residue levels above the MDL plus those samples which were assigned values of 50 % of the MDL. Since many of the samples had no detected residues, the potential Absorbed Daily Dosage (ADD) was greatly affected by these hypothetical residues below the MDL. The residue file used for analysis of chronic dietary exposure is included in Appendix B2.

2. Commodity Consumption

a. Acute

A distributional acute dietary exposure analysis was conducted using EXPOSURE-4™, (TAS, 1990). EXPOSURE-4™ contains food consumption data which are based on results of the latest U.S. Department of Agriculture Nationwide Survey of Individual Food Consumption. Current data are from the 1987-88 survey, a probability survey of over 10,000 individuals representing over 27,000 days of individual food consumption. It was conducted in all four seasons of the year and in all regions of the continental United States. The respondents provided details about their food consumption, including the quantity of each food consumed at each eating occasion. Each subject also provided demographic data including age, sex, ethnic/racial data, self-reported body weight and height.

EXPOSURE-4™ is designed to estimate the distribution of acute dietary dosages per "user-day". A "user-day" is defined as any day in which at least one food from the specific commodity list is reported to have been consumed. Potential "person-days" are the number of survey respondents multiplied by the number of days for which consumption was reported. The estimated percent of potential "person-days" that were "user-days" for all population subgroups was 100%.

In the absence of specific data, the following assumptions were made in estimating the acute dietary exposure: 1) 100% of the pesticide residue remains on the RAC or processed food, *i.e.*, residue degradation does not occur, 2) processing of RACs does not reduce pesticide residues, and 3) all label-approved commodities will contain the commodity-specific residue level. In general, these assumptions tend to overestimate the actual amount of residue consumed by an individual. Processing data were utilized in calculation of appropriate residue values for tomatoes (Elkins, 1989). The dietary exposure analyses account for potential concentration by increasing estimated exposures with adjustment factors to correct for changes in residue levels, *i.e.*, amount of water lost during processing. Analyses which were based on residue data identified in a food were conducted with the adjustment factor set to unity, while default adjustment factors were utilized when data for the RAC, alone, were available. A second adjustment factor was utilized, when data were available, to account for residue reduction during processing (Elkins, 1989).

Table 1. Geometric Means of Detected Malathion and Malaoxon Residue Levels in Raw Agricultural Commodities

Commodity ^a	Residue (ppm) ^b	Years ^c
Cantaloupes	0.205	1987,88,89
Celery	0.283	1987,89
Cherries	0.040	1988
Dates	0.418	1986,87,88,89
Grapefruit	0.301	1987,90
Grapes	1.350	1986,87,89
Green Onions	0.500	1986,87
Head Lettuce	0.696	1986,87,88,89,90
Hot Peppers	0.123	1989,90
Mustard Greens	0.303	1986,89
Okra	0.223	1987,90
Onions	0.780	1988,90
Oranges	0.163	1987,88,89,90
Peaches	0.236	1987,89
Peas	0.295	1987,88,89
Raspberries	0.446	1986,88,89
Strawberries	0.176	1987,88,89,90
Summer Squash	0.295	1986,88
Sweet Peppers	0.257	1986,88,89,90
Tomatoes	0.048	1989,90

^{a/} - RACs with two or more positive (above MDL) residue samples (1986-1990)

^{b/} - Geometric mean of positive samples

^{c/} - Years in which positive residues were detected

b. Chronic

The chronic dietary analysis software, EXPOSURE-1™ (TAS, 1985), is also based on the results of the 1987-1988 USDA survey. EXPOSURE-1™ calculates annual average daily dosage. The following assumptions have been made in choosing the appropriate residue value for each commodity: 1) 100% of the pesticide's residue remains on the RAC or processed food, *i.e.*, residue degradation does not occur, 2) processing of RAC into various forms does not reduce pesticide residues, and 3) all of the currently registered (label-approved) crops are treated with malathion. These assumptions generally tend to over-estimate chronic dietary exposure.

3. Dietary Exposure

a. Acute

The 95th percentiles of potential single-day exposure dosages are reported by population subgroup in Table 2. The residue file used in the acute dietary analyses includes all label-approved RACs and the residue value which was the geometric mean of the samples with levels above the MDL (Appendix B1.). The 95th percentile of potential single-day exposure represents 95 percent of the potential consumers, only 5 percent of the population who consume malathion-treated commodities have a higher predicted exposure. The population subgroup with the highest potential acute dietary exposure estimate was children, one to six years old. The 95th percentile of single-day exposure for this group was 0.008 mg/kg.

b. Chronic

Annual Average Daily Dosage (AADD) estimates for chronic dietary exposures are reported by population subgroup in Table 3. The residue file used for the chronic dietary analysis contains all commodities with label-approved direct food uses and the overall mean residue level of all samples (Appendix B2.). The population subgroup with the highest potential chronic dietary exposure was children one to six years of age. The estimated exposure dosage for this subgroup was approximately 0.001 mg/kg-day.

Table 2. Potential Acute Dietary Exposure to Residues of Malathion and Malaoxon

Population Subgroup	95 th Percentile of Exposure ^a (mg/kg)
US Pop. All Seasons	0.004
Western Region	0.005
Hispanics	0.004
Non-Hispanic Whites	0.004
Non-Hispanic Blacks	0.004
Non-Hispanic Other	0.005
Infants (nursing)	0.004
Infants (non-nursing)	0.007
Children (1-6 yrs.)	0.008
Children (7-12 yrs.)	0.005
Females (13-19 yrs.) (not pregnant, not nursing)	0.002
Females (13+ yrs.) (pregnant, not nursing)	0.003
Females (13+ yrs.) (nursing)	0.004
Females (20+ yrs.) (not pregnant, not nursing)	0.003
Males (13-19 yrs.)	0.003
Males (20+ yrs.)	0.003

^a/ - Absorbed Daily Dosage (ADD)
(from Appendix B1., rounded to 3 significant digits)

Table 3. Potential Chronic Dietary Exposures to Residues of Malathion and Malaoxon

Population Subgroup	Exposure ^a (mg/kg-day)
US Population - All Seasons	0.0003
Western Region	0.0003
Hispanics	0.0003
Non-Hispanic Whites	0.0003
Non-Hispanic Blacks	0.0003
Non-Hispanic Other	0.0004
Infants (nursing)	0.0001
Infants (non-nursing)	0.0007
Children (1-6 yrs.)	0.001
Children (7-12 yrs.)	0.0006
Females (13-19) (not pregnant, not nursing)	0.0003
Females (13+ yrs.) (pregnant, not nursing)	0.0003
Females (13+ yrs.) (nursing)	0.0003
Females (20+ yrs.) (not pregnant, not nursing)	0.0002
Males (13-19 yrs.)	0.0004
Males (20+ yrs.)	0.0002

^a/ - Annual Average Daily Dosage (AADD)
(from Appendix B2., rounded to 3 significant digits)

C. Risk Characterization

I. Acute Exposure

Margins of safety, based on the absence of cholinergic signs in humans after a single dose, were at least 43 for all population subgroups at the 95th percentile of the distribution of potential single-day exposures (Appendix B1.). Five population subgroups with the lowest MOSs are reported in Table 4. Other MOSs ranged from 81 to 138.

Table 4. Margins of Safety for Population Subgroups with the Highest Potential Acute Exposure to Residues of Malathion and Malaoxon

Population Subgroup	Exposure ^a (mg/kg)	MOS ^b
Children (1-6 yr.)	0.008	43
Non-Nursing Infants	0.007	49
Western Region	0.005	68
Non-Hispanic Other	0.005	68
Children (7-12 yr.)	0.005	68

^a/ - Absorbed Daily Dosage (ADD - Table 2)

^b/ - Margin of Safety

$$\text{MOS} = \text{NOEL (0.34 mg/kg-day)} / \text{ADD}$$

2. Chronic Exposure

The potential Annual Average Daily Dosages (AADDs) for all population subgroups resulted in MOSs of at least 340 based on the absence of cholinergic signs in humans after eight weeks of daily exposure to malathion (Table 5). The highest percent of U.S. EPA reference dose (%EPA RfD) was 4.8%. The lowest MOS was for children, one to six years of age.

Table 5. Margins of Safety and Percentage of U.S. EPA RfD for Population Subgroups with the Greatest Potential^a Chronic Dietary Exposure to Residues of Malathion and Malaoxon

Population Subgroup	Exposure ^b (mg/kg-day)	MOS ^c	Percentage U.S. EPA RfD
Children (1-6 yr.)	0.001	340	4.8
Non-Nursing Infants	0.0007	486	3.7
Children (7-12 yr.)	0.0006	567	2.9

^{a/} - Greater than 2% of U.S. EPA RfD

^{b/} - Annual Average Daily Dosage (AADD - Table 3.)

^{c/} - Margin of Safety

$$\text{MOS} = \text{NOEL (0.34 mg/kg-day)} / \text{AADD}$$

V. RISK APPRAISAL

A. Acute Dietary Risk

An MOS of ten for acute exposure is generally considered adequate when based upon a human NOEL. An MOS of ten accounts for consumers who might be more susceptible than the most sensitive person in the study from which the NOEL was derived. All MOSs for acute dietary exposure are considered adequate, since they are at least 43 for all population subgroups at the 95th percentile of single-day exposures. The MOSs may be higher, since cholinergic signs were not observed at the highest tested dosage. Additionally, the human study evaluated multiple, not single-day, exposures. A single-day exposure to an AChE inhibitor would be expected to result in a higher NOEL and, therefore, a larger MOS. These MOSs are based on the assumption that malathion residues do not decrease between sampling and consumption due to degradation, or cooking/processing factors. These activities may reduce residues substantially (Elkins, 1989).

B. Chronic Dietary Risk

MOSs for potential chronic dietary exposure of each population subgroup are considered adequate. An MOS of 100 or more is generally considered adequate when calculated from the results of a study of subchronic human exposures. An MOS of 100 includes a safety factor of ten to protect the most susceptible consumer, who may be ten times as susceptible to chemical effects as the most susceptible person in the study population from which the NOEL was derived, and a safety factor of ten for extrapolation of the results of a subchronic study to a chronic exposure scenario. In addition, chronic dietary malathion exposure is probably lower than the calculated exposure because the dietary assessment assumes that malathion is used on all crops which are label-approved. An average residue accurately reflects commodity mixing and is, therefore, an appropriate estimate of the chronic dietary exposure of a consumer. The MOSs are based on the assumption that malathion residues do not decrease between sampling and consumption due to degradation, washing, or cooking/processing factors. These activities may reduce residues substantially (Elkins, 1989).

Chronic exposure estimates are also considered adequate when compared to U.S. EPA's RfD. The estimated dosage for children, one to six years of age, of 0.001 mg/kg-day is 4.8% of the RfD (0.02 mg/kg-day). The highest potential AADD represents approximately 0.4 % of the human NOEL for subchronic inhibition of ChE activity.

VI. TOLERANCE ASSESSMENT

A. Background

The tolerance is the maximum, legal amount of a residue which is allowed on animal feed, on a raw or processed agricultural commodity, or in an animal tissue which is destined for human consumption. The U.S. EPA tolerance program was developed as an enforcement mechanism to identify illegal residue concentrations resulting from potential non-compliance with the product label requirements (*i.e.*, improper application rates or methods, inadequate pre-harvest intervals, or direct or indirect application to unapproved commodities). Tolerances are enforced by the Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and by some state regulatory agencies (*e.g.*, the Enforcement Branch of DPR).

Current pesticide tolerances (PCNG, 1991) are generally set at levels that are not expected to produce deleterious health effects in humans from chronic dietary exposure. The data requirements for establishing a commodity-specific tolerance include: 1) toxicology data for the parent compound, major metabolites, degradation products and impurities, 2) product chemistry, 3) analytical method(s) that are readily available, accurate and precise, 4) levels of residues in crops used for animal feeds, 5) levels of residues in animal tissues (*e.g.* meat, milk, eggs) from direct or indirect (animal feed) applications, and 6) RAC residue levels from field studies. The minimum requirements for a field study include: 1) an application rate at or above the highest recommended rate on the product label, 2) the greatest number of allowable applications, and 3) the shortest pre-harvest interval listed on the product label. Generally, the registrant of the pesticide requests a commodity-specific tolerance, which is equal to the highest measured residue, or some multiple of that value, from a field study conducted with the specific pesticide.

Assembly Bill 2161 (Bronzan and Jones, 1989) requires DPR to "conduct an assessment of dietary risks associated with the consumption of produce and processed food treated with pesticides". In a situation where "any pesticide use represents a dietary risk that is deleterious to the health of humans, the DPR shall prohibit or take action to modify that use or modify the tolerance ..." As part of the dietary risk assessment, a theoretical dietary exposure for each label-approved commodity as consumed by specific population subgroups can be calculated as the product of the tolerance and the estimated daily commodity consumption rate.

B. Acute Tolerance Assessment

Theoretical acute dietary exposure assessments using residue levels equal to the established tolerances were conducted for each of 21 highly consumed commodities (FDA, 1992). This reference lists 20 fruits and 20 vegetables which are the most highly consumed by members of the United States population. The most frequently consumed commodities from each list have been analyzed. Bananas were not included, since there is not an established tolerance for malathion on bananas. All of the highly-consumed commodities have an established tolerance of 8 ppm. No raw agricultural commodity has a tolerance above 8 ppm; therefore, other label-approved commodities are not expected to result in greater exposure than the fruits and vegetables included in this analysis (Table 6). Tolerances for other agricultural commodities (milk, soybean products, sugar beets, peanuts, and wheat - which are usually consumed as processed products) have also been evaluated due to anticipated consumption of these commodities by children. Cottonseed products were examined due to the large amount of aldicarb applied to cotton in California. Nectarines, plums, and sweet corn had inadequate numbers of survey respondents in all subgroups to establish valid theoretical exposure estimates. A low response rate in the survey may result in either over- or underestimation of consumption for some commodity/subgroup combinations. This results in more uncertainty relative to the individual calculated exposures. Most commodities had some population subgroups with low response rates. However, an evaluation of specific consumption profiles for population subgroups indicates that estimates of exposure to theoretical dietary residues equal to the tolerance are reasonable.

Margins of safety for theoretical exposures associated with acute consumption of commodities with potentially high consumption have been calculated. All MOSs are based on the acute human NOEL (0.34 mg/kg) for cholinergic signs in a human study. Ranges of MOSs for acute theoretical dietary exposures for commodity/population subgroup combinations with high exposure potential are summarized in Table 6., page 14.

An MOS, for acute exposures, of ten is generally considered adequate when it is based on an NOEL from a human study. Margins of safety for acute exposure to theoretical residues equal to the tolerance for malathion and malaoxon are not considered adequate for most analyzed commodities. Nineteen of twenty-seven commodities had at least one population subgroup with a theoretical MOS which was less than ten.

The acute tolerance assessment does not address the potential for consumption of multiple commodities. The probability of consuming multiple commodities, each with residues equal to the tolerance, decreases as the number of commodities included in the assessment increases. Dietary exposure resulting from consumption of commodities with residue levels equal to the tolerance is considered theoretical and unlikely, since less than one percent of the commodities sampled by DPR and FDA have residue levels which are above the legal tolerance (DPR, 1991b; FDA, 1991).

C. Chronic Tolerance Assessment

A theoretical chronic dietary exposure assessment using residue levels equal to the established tolerances for individual or combinations of commodities was not conducted because it is highly improbable that an individual would chronically consume single or multiple commodities, each with pesticide residues at the tolerance levels. Support for this conclusion comes from DPR and FDA pesticide monitoring programs which indicate that less than one percent of all sampled commodities have pesticide residue levels at or above the tolerance (CDEA, 1990; FDA, 1991).

Table 6. Range of Margins of Safety for Malathion Label-Approved Commodities with High Exposure Potential (Large Consumption Coefficients or with High Tolerances)

Commodity	U.S.EPA Tolerance (ppm)	MOS ^a (Range)
A. Fruits		
apple ^b	8	1 - 10
melon ^b	8	1 - 10
peach ^b	8	1 - 28
orange ^b	8	2 - 13
grapefruit ^b	8	3 - 11
pear ^b	8	3 - 15
grape ^b	8	4 - 16
plum/prunes ^b	8	4 - 9008 ^c
nectarine ^b	8	9 - 19
strawberry	8	15 - 337
lemon	8	26 - 2451 ^c
B. Vegetables		
carrot ^b	8	3 - 36
potato ^b	8	4 - 14
broccoli ^b	8	4 - 16
tomato ^b	8	5 - 17
cauliflower ^b	8	5 - 45
asparagus ^b	8	5 - 67
lettuce	8	14 - 19
sweet corn	8	19 - 76
onion	8	20 - 113
celery	8	43 - 101
C. Other Agricultural Commodities		
wheat ^b	8	6 - 19
soybean ^b	8	6 - 65
milk ^b	0.5	7 - 63
peanut	8	18 - 87
sugar beets	1	212 - 737
cottonseed	2	490 - 1358 ^c

^a/ - Margin of Safety

MOS = NOEL (0.34 mg/kg-day) / Theoretical ADD

^b/ - MOS less than 10 for at least two population subgroups

^c/ - Wide range due to disparate consumption estimates within one population subgroup (plum/prunes - pregnant females, 13+ years of age; cottonseed - non-pregnant females, 20+ years of age; lemon - nursing infants)

VII. CONCLUSIONS

A. Acute Exposure

The potential acute dietary exposure to primary and secondary malathion and malaoxon residues in foods, as consumed by members of specific population subgroups, has been assessed. Acute MOSs based on a NOEL for cholinergic signs in humans are greater than 43 and are considered adequate for the combination of all label-approved commodities.

B. Chronic Exposure

Margins of safety for chronic dietary exposure to residues of malathion and malaoxon are at least 340 based on a NOEL for cholinergic signs following repeated administration to humans. These MOSs are considered adequate.

C. Tolerance Assessment

Margins of safety for theoretical acute exposure to residues of malathion and malaoxon which are equal to the established tolerance are not considered adequate for most analyzed commodities. Nearly all of the examined commodities had at least one population subgroup with theoretical MOSs which were less than ten. However, monitoring programs indicate that less than one percent of all sampled commodities have pesticide residue levels at or above the tolerance (CDFA, 1990; FDA, 1991). Therefore, the consumption of commodities with residue levels of malathion and malaoxon which are equal to the tolerance is not considered a realistic representation of actual dietary exposure and does not represent a significant risk.

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IX. APPENDICES

Appendix A. Toxicology Summary

CALIFORNIA DEPARTMENT OF FOOD AND AGRICULTURE
SUMMARY OF TOXICOLOGICAL DATA

MEDICAL TOXICOLOGY BRANCH

SUMMARY OF TOXICOLOGY DATA

MALATHION

Chemical Code #: 000367; Tolerance #111
SB 950-343

July 30, 1986

Revised 2/23/87; 5/3/88; 10/2/89; 12/22/89; 4/5/90; 5/22/90; 9/5/90

I. DATA GAP STATUS

Combined (chronic + onco) rat: No data gap, no adverse effect
Chronic dog: No data gap, no adverse effect
Onco rat: No data gap, no adverse effect
Onco mouse: No data gap, no adverse effect
Repro rat: No data gap, no adverse effect
Terato rat: No data gap, no adverse effect
Terato rabbit: No data gap, no adverse effect
Gene mutation: No data gap, no adverse effect
Chromosome: No data gap, no adverse effect
DNA damage: No data gap, no adverse effect
Neurotox: No data gap, no adverse effect

ote, Toxicology one-liners are attached

** indicates acceptable study

Bold face indicates possible adverse effect

File name: T900905

Toxicology Summary by G. Chernoff, 9/5/90

Rectified through volume #: 126, record #: 091230

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II. TOXICOLOGY ONE-LINERS AND DISCUSSION

COMBINED (CHRONIC + ONCO) RAT

067 014771, "The Evaluation of the Chronic Toxicity Effects of Cythion Administered in the Diet to Sprague-Dawley Rats for 24 Consecutive Months", (Food and Drug Research Laboratories, Inc., Laboratory # 5436, 5/13/80), Malathion, 92.1%, Lot No. W70225-1; 50 Sprague-Dawley rats/sex/group were fed 0, 100, 1000 or 5000 ppm for 2 years; hematology at 12, 26, 53 and 104 weeks; sys NOEL = 100 ppm; chronic effects on liver and kidney by increased organ weight but this was not substantiated by microscopic findings; no oncogenic effect reported. **No adverse effect. Acceptable. These results differ from those of NCI below in which adverse effects on the GI tract were reported. Rereview finds that the initial review noting adverse effects in liver and kidney organ weight is not of biological significance in view of the pathology report in the supplemental submission, volumes 79-81. Document 111-097 contains a rebuttal dated 6/19/87. No change in status. (Gee, 8/5/85, 6/20/86 and 5/3/88)

EPA one-liner: Systemic NOEL = 100 ppm (decrease in body weight, decreased brain cholinesterase), systemic LEL = 1000 ppm, onco NOEL > 5000 ppm (HDT), guideline. In the February 1988, "Guidance for Reregistration....", EPA has reversed its decision and considers the study unacceptable upon reexamination due to deficiencies in data reporting, slide reading and intercurrent disease. A new study is being required in Fisher 344 rats.

079, 080, 081 037614, -15, -16 (Food and Drug Res. Lab., 1980). Addenda to 067 014771. Summary tables of organ weights, blood cholinesterase values, individual body weights and food consumption, histopathology report making reevaluation and upgrading of 014771 possible (Gee, 12/26/85).

088 051410 Addendum to 014771. Validation of analysis of fortified diets using 2 different detectors for GLC.

088 051411 Addendum to 014771. Analysis of diets by week plus stability data - upgrades Record # 014771 to acceptable.

CHRONIC RAT

022 024554 Summary only. Insufficient information to evaluate. Gee, 8/2/85.

007 024211 (Hazleton, 1952.) Summary only. Three formulations of malathion were given to 20 male rats/group at 500, 1000 or 5000 ppm. Survival data only over 109 weeks. **Unacceptable.** (Gee, 8/2/85)

EPA 1-liner: No CORE grade. Systemic NOEL = 1000 ppm (reduced food intake and weight gain), oncogenic NOEL > 5000 ppm (HDT), ChE NOEL = 100 ppm (LDT).

CHRONIC, DOG

098 058618, "One-Year Oral Toxicity Study in Purebred Beagle Dogs with AC 6,601." (Tegeris Laboratories, Inc., report # 85010, 2-10-87) AC 6,601, lot no. W40515-0011, 95.0%, was given to beagle dogs at 0, 62.5, 125 and 250 mg/kg/day by gelatin capsule, 7 days a week for 1 year, 6/sex/dose. No mortalities, no interim sacrifices. Systemic NOEL = 125 mg/kg/day, body weight depression, changes in hematological parameters and serum enzymes. ChE NOEL < 62.5 mg/kg/day. **No adverse effect. Acceptable. (Shimer, 2-23-88 and Gee 3/7/88)

EPA 1-liner: unacceptable because a NOEL was not established for increased liver and kidney weights, elevated platelet count, decreased creatinine, decreased BUN, inhibition of erythrocyte and plasma cholinesterases. A new study is required - see "Guidance for the Reregistration of Pesticide Products containing Malathion as an Active Ingredient", February, 1988.

Note: In a conversation with Dr. B. Dementi of EPA, CDFA was informed that EPA is no longer requiring a new study with non-rodents at this time. (Gee, 4/6/90)

ONCOGENICITY, RAT

068 014772, "Bioassay of Malathion for Possible Carcinogenicity", (NCI conducted at Gulf South Research Institute, report # (NIH) 78-824, December 1977), Malathion, >95% purity, lot SPS-10127; Osborne-Mendel rats; 10/sex in controls plus 40/sex pooled controls (from other studies conducted within the year at Gulf South Res. Inst.) and 50/sex/test group were fed 0, 4700 or 8150 ppm (TWA) for 80 weeks and observed for 33 -- initial doses were 8000 and 12000 which were decreased at week 14 for low dose group to 4000 ppm and at week 3 for the high dose group from 12000 to 8000 ppm for 77 weeks. **Unacceptable** (no hematology, inadequate number of controls and no historical control data, problems with dose selection and drastic changes in dose part way through study, missing data); not clear whether an oncogenic effect. A later volume, 111-086, contains a published article in Environmental Research 37: 154-173 (1985), record #041972, reviewing the pathological findings of this and 2 other NCI-sponsored onco studies. The authors conclude that malathion had no effect on survival of Osborne-Mendel rats. They also concluded that no evidence of carcinogenicity was found. The review by Remsen (Gee) indicated an oncogenic effect in the thyroid of male rats. The reexamination of the slides resulted in the finding of an additional adenoma in the pooled control and one in the low dose group so the incidence as reported in the cited publication in males is: follicular cell adenoma/carcinoma -- 1/14, 1/14 (control), 6/41, 2/41 (low dose) and 7/35, 2/35 (high dose); C-cell adenoma/carcinoma - 1/14, 0/14 (control), 3/41, 0/41 (low dose) and 1/35, 0/35 (high dose). By Fisher's exact test, the P value for the combined adenomas/carcinomas is 0.22 for high dose compared with control incidence. Therefore, the original finding of oncogenicity is no longer evaluated as significant in view of the added information. Due to lack of individual data in the NCI report, it is not possible to identify either when or in which rats the findings were made. Also, the numbers in the publication do not match those in the NCI report for thyroid findings even considering the added two adenomas. The numbers reported by NCI are:

Thyroid	Control	low dose	high dose
follicular-cell adenoma	1/5	1/41	1/47
follicular-cell carcinoma		2/41	6/47
C-cell adenoma		1/41	3/47

Report does not indicate any effect(s) on the stomach. NOEL cannot be determined accurately due to dosage changes but on the basis of body weight using the TWA, the NOEL would be 4700 ppm. **No adverse effect.** Document 111-097 contains a rebuttal dated 6/19/87. No change in status. (Gee, 8/9/85 and 5/3/88)

EPA one-liner: onco NOEL > 8150 ppm (HDT), minimum.

086 041972 (Publication in Environmental Res. 37: 154-173 (1985) by Huff, J. E. et al.). Paper addresses the pathology of three NCI/NTP onco studies in the 1970's with reevaluation of the slides. Using the data presented in this publication, the rereview of the studies has resulted in some changes in the findings originally stated by Remsen (Gee) in 014772, 014773 and 024193. (Gee, 6/19/86)

068 014773, "Bioassay of Malathion for Possible Carcinogenicity", (NCI, No. 192, Publication No. 79-1748, conducted at Gulf South Research Inst., 1979), Malathion, 95% purity, lot SPS-10127; 50 F344 rats/sex/group were fed 0, 2000 or 4000 ppm for 103 weeks; dose selection based on 13-week study from 0 - 16,000 ppm with 100% survival at 8000 ppm; decreased body weight in males only and decrease in survival at 4000<2000<control from toxicity. **Adverse effects:** Positive for chronic effects on gastrointestinal tract (forestomach: chronic inflammation, ulcers, others); the possible oncogenicity in the adrenals (pheochromocytoma) is not clear as the incidence is not dose dependent and occurred in males only at 2/49 (control), 11/49 (low dose) and 6/49 (high dose). A publication in Environmental Research 37: 154-173 (1985), 111-086, #041972, addressed the issue in a reexamination of the pathology slides and concluded that there was no oncogenicity effect but confirmed the chronic effect on the stomach. The number of animals, however, does not agree between the publication and the Report 192. The trend, however, is the same. In conclusion, the report shows a chronic effect with doubtful oncogenic effects. **Unacceptable** with missing individual data, doubtful high dose for females especially. Not upgradeable. NOEL < 2000 ppm. (Remsen, 8/9/85)
EPA one-liner: onco NOEL > 4000 ppm (HDT), Systemic NOEL < 2000 ppm, minimum.

058 034788, "Bioassay of Malaaxon for Possible Carcinogenicity", (NCI, No. 135, NIH publ. no. 79-1390, conducted at Gulf South Research Inst., 1979), Malaaxon analog of malathion, >95% purity; 50 F344 rats/sex/group were fed 0, 500 or 1000 ppm for 103 weeks; diet analyzed as within 2% of target ppm; dose selection based on subchronic study. Summary data only presented and no individual data, no third dose, no cholinesterase measurements, no hematology; equivocal evidence for oncogenicity in male and female F344 rats for C-cell adenoma/carcinomas in thyroid; positive for chronic toxicity to the gastrointestinal tract with dose-related increased incidence in ulcers of the forestomach with male rats being more sensitive than females. A publication (111-086, 041972) addresses these findings in a reexamination of the pathology slides from this and two other studies. The numbers in 041972 do not agree with those in this report although the trend is the same.

Thyroid		Control	low dose	high dose
C-cell adenoma/	M	2/49		4/49
carcinoma	F		1/49	5/47
Reexam	M	3/49	3/45	10/49*
	F	4/48	7/48	11/48*

The values from this report are not significant by Fisher exact in males but are in females. The reexam values are significant in both sexes. The publication does not discuss why the numbers are so different. In conclusion, malaaxon shows chronic toxicity and marginal oncogenicity as does malathion. NOEL < 500 ppm (body weight, behavior). **Unacceptable.** (Gee, 8/6/85)
EPA 1-liner: Minimum. Oncogenic NOEL > 1000 ppm (HDT). EPA is requiring a new study in the Fisher 344 rat with malaaxon to clarify the results in the above study - see February, 1988, "Guidance for the Reregistration...."

****SUMMARY:** From the above, it is concluded that malathion is not oncogenic at any of the doses tested in these studies nor is it unequivocally oncogenic in the mouse (see below). The major effect is a chronic one on the gastrointestinal tract at levels in the diet of 2000 ppm of malathion and of 500 ppm malaaxon, an analog of malathion. An assessment of the chronic effects should be made also considering the negative findings in 014771, listed above under COMBINED RAT, at diet levels up to 5000 ppm, much higher than that at which the NCI studies report seeing an effect. Considering all of the factors, collectively the multiple studies permit the decision that the rat oncogenicity data gap is filled in that chronic effects occur at levels in the diet which have not been demonstrated to be oncogenic in either of two species (rat and mouse). (Gee, 1986)

ONCOGENICITY, MOUSE

****068, 104 034789, 069632, "Bioassay of Malathion for Possible Carcinogenicity",** (NCI conducted at Gulf South Research Institute, report # (NIH) 78-824, December 1977), Malathion, \geq 95% purity, lot SPS-10127, identity of compound was verified by Gulf South Res. Inst., 10/sex for concurrent control and 50/sex/group for test were fed 0, 8000 or 16000 ppm for 80 weeks followed by 14 weeks observation; B6C3F1 mice. Oncogenic effect in liver of males at 16000 ppm. NOEL < 8000 ppm (body weight). Originally reviewed (Gee 8/9/85) unacceptable but possibly upgradeable with submission of missing data on histopathology, and as having a possible adverse effect (male liver oncogenic effect). Risk assessment by CDFA Medical Toxicology (T.R. Hathaway, 7/31/87) found the liver effect to not be of biological significance, hence, **no adverse effect** indicated. Subsequently reviewed (Gee 5/3/88) with no status change. Re-reviewed with submission of individual histopathology data (# 069632). **Status change to acceptable.** (Green and Silva, 8/28/89)

EPA one-liner: Onco NOEL > 16,000 ppm (HDT--questionable liver findings-not significant with Bonferroni criteria. However, related trench [sic] [p = 0.019] and increase of tumors at high dose [p = 0.031] - a level EPA normally considers significant), minimum.

Note: According to the 1988 reregistration standard, EPA has requested additional data addressing the equivocal effects seen in the mouse. In a conversation with Dr. Dementi, CDFA was informed that a new study with malathion in the mouse is being requested. (Gee, 4/1990)

058 034788, "Bioassay of Malaaxon for Possible Carcinogenicity", (NCI, No. 135, 1979, NIH publ. no. 79-1390, conducted at Gulf South Research Institute), Malaaxon analog of malathion, > 95% purity, 50 B6C3F1 mice/sex/group were fed 0, 500 or 1000 ppm for 103 weeks; dose selection based on a subchronic study - data not included; NO evidence of oncogenicity is reported. **Unacceptable** with no individual data, two doses only, no hematology, marginal chronic toxicity at high dose on body weight, etc., so questionable if adequate. The initial review indicated chronic toxicity was reported. Rereview of the study (Gee, 6/19/86) now indicates the findings of behavior modification and mortality are not of biological significance, the latter only indicating adequacy of dose level. NOEL: 500 ppm. **No adverse effect.** (Gee, 8/6/85 and 6/19/86)
EPA one-liner: onco NOEL > 1000 ppm (HDT), systemic NOEL < 500 ppm (decreased mean body weights in F), minimum. No additional data are required.

REPRODUCTION, RAT

083, 088 037620, 051409, "Report on Malathion: Successive Generation Studies with Rats, Final Report", (American Cyanamid Co., report # 68-64, 7/9/68), Malathion, 95% purity, SPS-6111; data on F2 breeding for F3 generations only - not on other generations; approximately 16 matings at each dose of 0, 100, 500 or 2500 ppm fed in the diet. Use of cedar shavings resulted in respiratory problems in F3b pups; reproduction, lactation, necropsy and histopath data for F3 pups; positive **adverse effect** identified for decrease in lactation index. Systemic NOEL = 500 ppm (decreased body weight), repro NOEL = 500 ppm (decreased lactation index). **Unacceptable** (no interim pup weights - days 1, 4, 7 or 14, no necropsy on adults, no analysis of diet, intercurrent disease, husbandry problem, single body weight for adults prior to mating only), not upgradeable. Document 111-097 contains a rebuttal dated 6/19/87. No change in status. (Gee, 12/26/85 and 5/3/88)
EPA is requiring a new reproduction study. The above study is considered unacceptable based on insufficient number of animals, lack of individual data and other deficiencies - see February, 1988, "Guidance for the Reregistration...."

****126 091230**, "A Two-Generation (Two Litters) Reproduction Study with AC 6,601 to Rats", (R.E. Schroeder, Bio/Dynamics Inc., Report 87-3243, June 28, 1990). Malathion, 94% purity, lot #AC6015-136, was administered in the diet to groups of 25 male and 25 female rats at dose levels of 0 (vehicle control), 550, 1700, 5000, or 7500 ppm for two generations, two litters per generation. At 7500 ppm, maternal gestational and lactation weights were consistently reduced in both litters of both generations, with statistical significance being obtained in the first pregnancy and both lactation periods of the P-1 generation. Pup weaning weights on day 21 post partum were consistently reduced at both 5000 and 7500 ppm, reaching statistical significance for all litters at 7500 ppm, and the first P-1 and second F-1 litters at 5000 ppm. At 7500 ppm, the postnatal growth retardation persisted through adulthood, with no indication of catch-up growth. Reproductive parameters were not adversely effected. Developmental NOEL = 1700 ppm; > 200 mg/kg/day (postnatal growth retardation); Parental NOEL = 5000 ppm; > 400 mg/kg/day (reduced body weight); Reproductive NOAEL = 7500 ppm (HDT); > 600 mg/kg/day. The study is **ACCEPTABLE**, and no adverse reproductive health effect is noted (G. Chernoff, 8/23/90).

SUMMARY: In the initial unacceptable rat reproduction study (record #'s 037620 and 051409), a decrease in the lactation index at 2500 ppm was identified as a possible adverse health effect, with a NOEL = 500 ppm. This outcome was not replicated in the acceptable two generation, two litters per generation repeat study (record # 091230). Given the superior quality of the repeat study, along with the failure to replicate the earlier reported adverse effect, the finding of the acceptable study, no potential adverse reproductive health effects, should be used for risk assessment purposes (G. Chernoff, 9/30/90).

TERATOLOGY, RAT

****111 074764**, "A Developmental Toxicity Study With AC 6,601 in Rats", (Argus Research Laboratories, Inc., Laboratory Project ID 101-005, 4/5/89). AC 6,601 (malathion), technical grade, purity 94.0%, was administered to groups of 25 Crl:CD (SD) BR female rats by gavage on days 6 through 15 of gestation at doses of 0 (corn oil vehicle control), 200, 400 or 800 mg/kg/day. The only significant finding in the dams was an increased incidence of urine stained abdominal fur at 800 mg/kg/day. Fetal parameters were unaffected by treatment and no adverse effect was noted. Maternal and Developmental NOEL = >800 mg/kg/day (the high dose tested). Originally reviewed as unacceptable (Kishiyama & Chernoff, 12/89), but with the submission of the dose justification

in CDFA Record No. 090478, the study is upgraded to **ACCEPTABLE** (G. Chernoff, 4/5/90).

111 074765, Supplement to 074764; dosing solution analyses. No Worksheet.

118 090478, Pilot study for dose justification in record no. 074764.

068 014778, "Teratogenicity Studies on Linuron, Malathion and Methoxychlor in Rats", (Bureau of Chemical Safety, Canada, 8/25/77, Publication in Toxicol. Appl. Pharmacol. 45: 435-444 (1978), accepted in 1977, Khera, K. S. et al.), Malathion technical, no purity stated; 20 Wistar rats/group were given 0, 50, 100, 200 or 300 mg/kg by oral gavage, days 6-15 of gestation. **No adverse effect** on reproduction or teratogenic effect is reported. Sacrificed on day 22 with 2/3 of fetuses for skeletal exam and 1/3 for visceral. One table only. **Unacceptable** (inadequate high dose) Sys NOEL > 300 mg/kg/day (HDT), Dev. toxicity NOEL \geq 300 mg/kg/day. (Gee, 8/9/85)

092 053281 Duplicate of publication, Record # 014778, plus copies of raw data for malathion. Includes mating identification, individual body weights and litter findings. Data from range-finding study to 600 mg/kg/day - 4 per group.

TERATOLOGY, RABBIT

089 051413, "A Teratology Study with AC 6,601 in Rabbits", (Food and Drug Research Laboratories, Inc., study # 8171, 2/28/85). Malathion, 92.4%, was administered by gavage to groups of 20 inseminated New Zealand rabbits at doses of 0, 25, 50 or 100 mg/kg/day on day 6-18 of gestation. Maternal weight gain during dosing was statistically reduced at 50 and 100 mg/kg/day. Mean numbers and percent fetal resorptions were also elevated at these two doses. The number of unexplained unscheduled deaths were elevated above historical control values in the low dose group, but did not achieve statistical significance. In addition, there was no evidence for a dose response effect. Maternal NOEL = 25 mg/kg/day (reduced weight gain during dosing); Developmental NOEL = 25 mg/kg/day (increase in resorptions). The study is **ACCEPTABLE, and no adverse developmental health effects are noted (Parker, 2/13/87; Chernoff, 9/3/90). EPA has accepted this study.

GENE MUTATION

068, 099 014776, 060150, "Microbiological Assays in: In vivo and in vitro Studies of Selected Pesticides to Evaluate their Potential as Chemical Mutagens", (SRI for EPA, project LSU-3493, February 1977), Malathion, technical grade, 92-97% purity, lot # 40216006.300; tested in Salmonella typhimurium strains TA1535, TA1537, TA1538 and TA100 (no TA98), single plate, several trials with and without activation at 0, 1, 5, 10, 50, 100, 500 or 1000 ug/plate. **No increase in reversion rate** is reported. 060150 contains individual plate counts. **Unacceptable** (lacks TA98, some positive controls). (Gee 8/9/85 and 3/3/88)

067 014770, "Mutagenicity Testing of Cythion Malathion in the Ames Bacterial Test", (American Cyanamid Co., 6/2/78), Malathion, 92.8% purity, Salmonella typhimurium strains TA 1535, TA1537, TA98 and TA100 with and without activation at 0, 10, 100 and 1000 ug/plate; also E. coli WP2. **Unacceptable** (too few plates, concentrations, inadequate controls). **No adverse effect** reported. Some suggestion of cytotoxicity at 1000 ug/plate. (Gee 8/2/85)

157-009 034551, "The Mutagenic Effect of Organophosphate Insecticides on Escherichia coli", (Tunstall Laboratory, 8/71), Malathion technical, 97.4% purity, tested at an unspecified amount with E. coli B/r WP2 strain for tryptophan reversion in triplicate; result reported as "-". **Unacceptable**, no data. (Gee 2/20/87)

122 086717, "Evaluation of CL 6,601 in the Bacterial/Microsome Mutagenicity Test", (Traul, K. A., American Cyanamid Company, Agricultural Research Division, Study No. 114, 3/9/87). Malathion (CL 6601, batch AC 4870-54B, 95.2% purity) was tested by the plate incorporation assay with Salmonella typhimurium strains TA1535, TA1537, TA1538, TA98 and TA100 as well as with Escherichia coli strain WP2 uvrA-. Concentrations tested were 0 (DMSO), 100, 500, 1000, 2500 or 5000 µg/plate with triplicate plates per concentration and two trials. Bacteria were plated with and without activation with S-9 prepared from livers of male Sprague-Dawley rats and purchased from Microbiological Associates. Positive controls with and without activation for each strain were effective. No increases in revertants with any strain were reported. **No adverse effect. Acceptable. (Gee, 5/18/90)

**SUMMARY: Although each study has deficiencies in design or reporting of data, when examined collectively the studies provide sufficient information to determine that malathion is not mutagenic in bacteria. The data gap is, therefore, filled for the gene mutation test type. (Gee, 1987) The most recent submission (Record 086717) is acceptable independent of the other studies and confirms the negative results. (Gee, 5/90)

CHROMOSOME EFFECTS

068, 099, 108 014774, 060282, 073931 "Dominant Lethal Test in the Mouse," (SRI for EPA, project LSU-3493, February, 1977). Malathion, technical grade, 92-97% pure was fed in the diet for 7 weeks to 20 ICR/SIM male mice/group at 0, 1250, 2500 or 5000 mg/kg, before the animals were mated 1:2 for one week over 8 intervals. **No evidence of a dominant lethal effect reported. Record 060282 contains the individual data and a statement addressing the purity of the technical malathion. Previously reviewed as unacceptable (Gee, 12/27/85 & 3/3/88), the study has been upgraded to **acceptable** with submission of the requested diet analysis. (M. Silva, 8/28/89.)

085 037622 Addendum with summary data by mating week for 014774.

068 014777, "Genetic and Cytogenetic Effects induced in the Mouse by an Organophosphorus Insecticide: Malathion", (Publication in Environmental Res. 34: 170-174 (1984) by Degraeve and Moutschen.), Malathion, > 99% purity, Q-strain male mice (number not stated) were given 0 or 300 mg/kg i.p. with 12, 24 or 36 hour recovery periods; 500 metaphases from bone marrow and varying number of spermatogonia were analyzed for aberrations. **No adverse effect** is reported in the publication. **Unacceptable** as is - need the full report. (Gee, 8/9/85)

** 122 086718 "Acute Test for Chemical Induction of Chromosome Aberration in Rat Bone Marrow Cells in vivo with AC 6,601." (Gudi, R., SITEK Research Laboratories, Rockville, MD, #0125-1531, 3/22/90) Malathion (AC 6,601, batch AC6015-136B, 94%) was given by oral gavage to Sprague-Dawley rats as a single dose. Based on a preliminary trial, doses selected were 0 (corn oil), 0.4, 0.8 and 1.6 ml/kg, equivalent to 0.5, 1.0 and 2.0 g/kg based on density of 1.25. There were 5/sex/group for the definitive assay with sacrifices at 12, 24 and 48 hours post-treatment. Mitotic indices as well as aberrations were scored.

Fifty cells per animal per sex per group were evaluated for aberrations excluding gaps. There was no effect on the incidence of aberrations and only a possible slight decrease in the MI at 24 and 48 hours in the high dose groups. **No adverse effect. Acceptable.** (Gee, 5/18/90)

DNA DAMAGE

068, 099 014775, 060284, "Mammalian in vitro Unscheduled DNA Synthesis Assays", (SRI for EPA, project no. LSU-3493, February 1977), Malathion, technical grade, 92%-97% purity, unscheduled DNA synthesis in human diploid fibroblasts WI-38, passage 28, tested with and without activation, cells were exposed for 3 hours in the presence of tritiated thymidine to 0, 10^{-7} , 10^{-6} , 10^{-5} , 10^{-4} , or 10^{-3} M, 6 flasks without activation and 3 with activation; No cytotoxicity reported except possibly at the highest concentration. **No evidence for unscheduled DNA synthesis is reported as increased DPM/ug DNA. Initially reviewed as unacceptable based on the lack of sufficient details in the protocol and information on the test material. Record # 060284 contains the detailed protocols including passage number of the WI-38. The study is upgraded to **acceptable** status with the supplementary information. (Gee, 8/9/85 and 3/3/88)

068 034790, "Microbiological Assays in: In vivo and in vitro Studies of Selected Pesticides to Evaluate their Potential as Chemical Mutagens", (SRI for EPA, project LSU-3493, February 1977), Escherichia coli. Malathion, no purity stated, 0 or 1 mg added to a disc on plates with E. coli W3110 or p3478 -- also with Bacillus subtilis strains H17 and m45. Zones of inhibition were measured. **No difference in growth between repair defective and repair effective strains. Unacceptable** (no justification for single concentration, single value only although report indicates three trials), because no cytotoxicity was demonstrated, the result is a "no test." (Gee, 8/9/85)

068 034791, "Microbiological Assays, in: In vivo and in vitro Studies of Selected Pesticides to Evaluate their Potential as Chemical Mutagens. (SRI for EPA, project LSU-3493, February 1977), Summary data only. Malathion, no purity stated; Saccharomyces cerevisiae strain D3 measured for mitotic crossing-over at 50 mg/ml (5%) with and without activation, 4 hour exposure. **No adverse effect** reported. **Unacceptable** due to missing information. (Gee, 8/9/85)

** 086716 "Test for Chemical Induction of Unscheduled DNA Synthesis in Rat Primary Hepatocyte Cultures by Autoradiography with AC 6,601." (Pant, K. J., SITEK Research Laboratories, Rockville, MD, 1/24/1990, Study No. 0125-5100) Malathion (technical, batch AC 6,601, 94%) was tested with primary hepatocytes from male Sprague-Dawley rats. After a preliminary range-finding assay, the concentrations used in the UDS assay were 0 (DMSO, untreated or ethanol), 0.02, 0.04, 0.08, 0.12 or 0.16 μ l/ml with an 18 hour incubation in the presence of 10 μ Ci/ml 3 H-thymidine. Incorporation of thymidine into nuclei was quantitated by autoradiography with 150 nuclei per concentration scored in morphologically normal cells in the 0.02 through 0.12 μ l/ml groups. The positive control was 2-AAF and that treatment gave the anticipated results with 100% of nuclei having \geq 5 net grains. Treatment with malathion did not induce an increase in unscheduled DNA synthesis. **No adverse effect** with hepatocytes. **Acceptable.** (Gee, 5/18/90)

NEUROTOXICITY

103 068075, "42-Day Neurotoxicity Study with AC 6,601 Technical in Mature White Leghorn Chickens", (Bio-Life Associates, Ltd., report # 87 DN 109, 4/1/88), AC 6,601 Technical (malathion), 93.6% purity, administered by gavage with protection (intramuscular injection of atropine sulfate at 10.0 mg/kg) at 1007.5 mg/kg to 60 hens. Survivors (21 hens) were redosed with protection at 852.5 mg/kg on day 21. Negative control (1.87 ml and 1.15 ml of tap water on day 1 and day 21 respectively) and positive control (TOTP at 500mg/kg) groups of 15 hens. 39 of the 60 hens dosed on day 1 at 1007.5 mg/kg died by day 15, the remaining 21 birds survived through day 21. 7 of the 21 birds re-dosed at 852.5 mg/kg on day 21 died by day 28. 14 survived through day 42. Reversible moderate/severe ataxia to paralysis of legs and wings and inability to stand reported in all malathion treated hens through day 4 and again, after redosing on day 21, through day 25. 10 hens/group for histopathology -unremarkable for malathion treated group. **No adverse effect. Acceptable. (Green and Silva 8/28/89)

SUPPLEMENTAL STUDIES

121 086381 "Disposition and Metabolism of ¹⁴C-Labeled Malathion in Rats (Preliminary and Definitive Study)." (Reddy, V., T. Freeman and M. Cannon, Midwest Research Laboratories, Project No. 9354-B, 12/20/89) Malathion (unlabeled at 94.6% and ¹⁴C-labeled at 98%) was given by oral gavage to 5/sex/group of Sprague-Dawley (Crl:CD BR) rats at single doses of 40 or 800 mg/kg or 15 doses of unlabeled malathion at 40 mg/kg followed by a 16th dose of radioactive malathion. Excretion was followed for 72 hours before sacrifice of the animals and measurement of tissue content. Most of the malathion was excreted in the first 12 hours predominantly in the urine of both males and females. Less than 1% was retained in the tissues with the level in the liver being the highest. Ten metabolites were identified by GC/MS of material eluted from HPLC. The major metabolites were the α and β isomers of the monocarboxylic acid derivative and the dicarboxylic acid derivative of malathion. The intravenous route was not used due to the insolubility of malathion in water or saline. Report is complete and acceptable. (Gee, 5/21/90)

Appendix B. Dietary Exposure Assessments

Appendix B1. Residue File and Acute Dietary Exposure Analysis

 ACUTE EXPOSURE (EX4) ANALYSIS FOR Malathion; Section 3 REGISTRATION
 RESIDUE FILE NAME: NEWMAL2A (NFCS87/88 DATA) ANALYSIS DATE: 02-04-1993
 DPR NOEL = 0.34 MG/KG BODY WT/DAY
 EPA REFERENCE DOSE (RfD) = 0.02 MG/KG BODY WT/DAY
 COMMENT 1: Geometric mean of Residue or MDL used (DPR, FDA Market S., USDA)
 COMMENT 2: All direct and indirect labeled food uses of malathion

RESIDUE FILE LISTING

TAS	CROP	RESIDUE	ADJ	FCTRS	SOURCE	
CODE	GRP	FOOD NAME	(PPM)	#1	#2	CODE ¹
1	N	BLACKBERRIES	0.010000	1.00	1.00	FDA
2	N	BOYSENBERRIES	0.010000	1.00	1.00	FDA
5	N	RASPBERRIES	0.446000	1.00	1.00	DPR
7	N	BLUEBERRIES	0.010000	1.00	1.00	FDA
8	N	CRANBERRIES	0.010000	1.00	1.00	FDA
9	N	CRANBERRIES-JUICE	0.010000	1.00	1.00	FDA
10	N	CURRANTS	0.010000	1.00	1.00	FDA
12	N	GOOSEBERRIES	0.010000	1.00	1.00	FDA
13	N	GRAPES	1.350000	1.00	1.00	DPR
14	N	GRAPES-RAISINS	1.350000	4.30	1.00	DPR
15	N	GRAPES-JUICE	0.010000	1.00	1.00	FDA
17	N	STRAWBERRIES	0.176000	1.00	1.00	DPR
22	K	GRAPEFRUIT-PEELED FRUIT	0.301000	1.00	1.00	DPR
23	K	GRAPEFRUIT-JUICE	0.010000	1.00	1.00	FDA
24	K	KUMQUATS	0.010000	1.00	1.00	FDA
26	K	LEMONS-PEELED FRUIT	0.010000	1.00	1.00	FDA
27	K	LEMONS-PEEL	0.010000	1.00	1.00	FDA
28	K	LEMONS-JUICE	0.010000	1.00	1.00	FDA
30	K	LIMES-PEELED FRUIT	0.010000	1.00	1.00	FDA
31	K	LIMES-PEEL	0.010000	1.00	1.00	FDA
32	K	LIMES-JUICE	0.010000	1.00	1.00	FDA
33	K	ORANGES-JUICE-CONCENTRATE	0.163000	1.00	1.00	DPR
34	K	ORANGES-PEELED FRUIT	0.163000	1.00	1.00	DPR
35	K	ORANGES-PEEL	0.163000	1.00	1.00	DPR
36	K	ORANGES-JUICE	0.010000	1.00	1.00	FDA
37	K	TANGELOS	0.010000	1.00	1.00	FDA
38	K	TANGERINES	0.010000	1.00	1.00	FDA
39	K	TANGERINES-JUICE	0.010000	1.00	1.00	FDA
40	R	ALMONDS	0.010000	1.00	1.00	FDA
43	R	CHESTNUTS	0.010000	1.00	1.00	FDA
44	R	FILBERTS (HAZELNUTS)	0.010000	1.00	1.00	FDA
46	R	MACADAMIA NUTS (BUSH NUTS)	0.010000	1.00	1.00	FDA
47	R	PECANS	0.010000	1.00	1.00	FDA
48	R	WALNUTS	0.010000	1.00	1.00	FDA

 ACUTE EXPOSURE (EX4) ANALYSIS FOR Malathion; Section 3 REGISTRATION
 RESIDUE FILE NAME: NEWMAL2A (NFCS87/88 DATA) ANALYSIS DATE: 02-04-1993
 DPR NOEL = 0.34 MG/KG BODY WT/DAY

TAS CODE	CROP GRP	FOOD NAME	RESIDUE (PPM)	ADJ #1	FCTRS #2	SOURCE CODE
52	L	APPLES	0.010000	1.00	1.00	FDA
53	L	APPLES-DRIED	0.010000	8.00	1.00	FDA
54	L	APPLES-JUICE/CIDER	0.010000	1.00	1.00	FDA
56	L	PEARS	0.010000	1.00	1.00	FDA
57	L	PEARS-DRIED	0.010000	6.25	1.00	FDA
59	M	APRICOTS	0.010000	1.00	1.00	FDA
60	M	APRICOTS-DRIED	0.010000	6.00	1.00	FDA
61	M	CHERRIES	0.040000	1.00	1.00	DPR
62	M	CHERRIES-DRIED	0.040000	4.00	1.00	DPR
63	M	CHERRIES-JUICE	0.010000	1.00	1.00	FDA
64	M	NECTARINES	0.010000	1.00	1.00	FDA
65	M	PEACHES	0.236000	1.00	1.00	DPR
66	M	PEACHES-DRIED	0.236000	7.00	1.00	DPR
67	M	PLUMS (DAMSONS)	0.010000	1.00	1.00	FDA
68	M	PLUMS-PRUNES (DRIED)	0.010000	5.00	1.00	FDA
69	M	PLUMS/PRUNE-JUICE	0.010000	1.00	1.00	FDA
77	A	DATES	0.418000	1.00	1.00	DPR
126	B	HORSERADISH	0.010000	1.00	1.00	FDA
141	J	CANTALOUPE-NECTAR	0.205000	1.00	1.00	DPR
142	J	CANTALOUPE-PULP (MUSKMELON)	0.205000	1.00	1.00	DPR
143	J	CASABAS	0.010000	1.00	1.00	FDA
144	J	CRENSHAW	0.010000	1.00	1.00	FDA
145	J	HONEYDEW MELONS	0.010000	1.00	1.00	FDA
146	J	PERSIAN MELONS	0.010000	1.00	1.00	FDA
147	J	WATERMELON	0.010000	1.00	1.00	FDA
148	J	CUCUMBERS	0.010000	1.00	1.00	FDA
149	J	PUMPKIN	0.010000	1.00	1.00	FDA
150	J	SQUASH-SUMMER	0.010000	1.00	1.00	FDA
151	J	SQUASH-WINTER	0.010000	1.00	1.00	FDA
154	I	EGGPLANT	0.010000	1.00	1.00	FDA
155	I	PEPPERS-SWEET (GARDEN)	0.257000	1.00	1.00	DPR
156	I	CHILI PEPPERS (JALAPENO)	0.010000	1.00	1.00	FDA
157	I	PEPPERS-OTHER	0.123000	1.00	1.00	DPR
159	I	TOMATOES-WHOLE	0.048000	1.00	1.00	DPR
160	I	TOMATOES-JUICE	0.048000	1.50	0.05	DPR
161	I	TOMATOES-PUREE	0.048000	3.30	0.05	DPR
162	I	TOMATOES-PASTE	0.048000	5.40	0.05	DPR
163	I	TOMATOES-CATSUP	0.048000	2.50	0.05	DPR
165	C	BEETS-TOPS (GREENS)	0.010000	1.00	1.00	FDA

 ACUTE EXPOSURE (EX4) ANALYSIS FOR Malathion; Section 3 REGISTRATION
 RESIDUE FILE NAME: NEWMAL2A (NFCS87/88 DATA) ANALYSIS DATE: 02-04-1993
 DPR NOEL = 0.34 MG/KG BODY WT/DAY

TAS CODE	CROP GRP	FOOD NAME	RESIDUE (PPM)	ADJ #1	FCTRS #2	SOURCE CODE
166	E	CELERY	0.283000	1.00	1.00	DPR
167	E	CHICORY (FRENCH/BELGIAN ENDIVE	0.010000	1.00	1.00	FDA
168	F	BROCCOLI	0.010000	1.00	1.00	FDA
169	F	BRUSSELS SPROUTS	0.010000	1.00	1.00	FDA
170	F	CABBAGE-GREEN AND RED	0.010000	1.00	1.00	FDA
171	F	CAULIFLOWER	0.010000	1.00	1.00	FDA
172	F	COLLARDS	0.010000	1.00	1.00	FDA
173	F	CABBAGE-CHINESE/CELERY/BOK CH	0.010000	1.00	1.00	FDA
174	F	KALE	0.010000	1.00	1.00	FDA
175	F	KOHLRABI	0.010000	1.00	1.00	FDA
176	E	LETTUCE-LEAFY VARIETIES	0.010000	1.00	1.00	FDA
177	E	DANDELION-GREENS	0.010000	1.00	1.00	FDA
178	E	ENDIVE-CURLY AND ESCAROLE	0.010000	1.00	1.00	FDA
182	E	LETTUCE-UNSPECIFIED	0.696000	1.00	1.00	DPR
183	F	MUSTARD GREENS	0.303000	1.00	1.00	DPR
184	E	PARSLEY	0.010000	1.00	1.00	FDA
185	E	RHUBARB	0.010000	1.00	1.00	FDA
186	E	SPINACH	0.010000	1.00	1.00	FDA
187	E	SWISS CHARD	0.010000	1.00	1.00	FDA
188	C	TURNIPS-TOPS	0.010000	1.00	1.00	FDA
192	E	LETTUCE-HEAD VARIETIES	0.010000	1.00	1.00	FDA
197	B	BEETS-ROOTS	0.010000	1.00	1.00	FDA
198	B	CARROTS	0.010000	1.00	1.00	FDA
202	D	GARLIC	0.010000	1.00	1.00	FDA
204	D	LEEKs	0.010000	1.00	1.00	FDA
205	D	ONIONS-DRY-BULB (CIPOLLINI)	0.780000	1.00	1.00	DPR
206	D	ONIONS-DEHYDRATED OR DRIED	0.780000	9.00	1.00	DPR
207	B	POTATOES (WHITE) -WHOLE	0.010000	1.00	1.00	FDA
208	B	POTATOES (WHITE) -UNSPECIFIED	0.010000	1.00	1.00	FDA
209	B	POTATOES (WHITE) -PEELED	0.010000	1.00	1.00	FDA
210	B	POTATOES (WHITE) -DRY	0.010000	6.50	1.00	FDA
211	B	POTATOES (WHITE) -PEEL ONLY	0.010000	1.00	1.00	FDA
212	B	RADISHES-ROOTS	0.010000	1.00	1.00	FDA
214	B	RUTABAGAS-ROOTS	0.010000	1.00	1.00	FDA
216	B	SALSIFY (OYSTER PLANT)	0.010000	1.00	1.00	FDA
218	B	SWEET POTATOES (INCLUDING YAM	0.010000	1.00	1.00	FDA
219	B	TURNIPS-ROOTS	0.010000	1.00	1.00	FDA
220	B	PARSNIPS	0.010000	1.00	1.00	FDA
227	G	BEANS-DRY-GREAT NORTHERN	0.010000	1.00	1.00	FDA
228	G	BEANS-DRY-KIDNEY	0.010000	1.00	1.00	FDA

 ACUTE EXPOSURE (EX4) ANALYSIS FOR Malathion; Section 3 REGISTRATION
 RESIDUE FILE NAME: NEWMAL2A (NFCS87/88 DATA) ANALYSIS DATE: 02-04-1993
 DPR NOEL = 0.34 MG/KG BODY WT/DAY

TAS CODE	CROP GRP	FOOD NAME	RESIDUE (PPM)	ADJ #1	FCTRS #2	SOURCE CODE
229	G	BEANS-DRY-LIMA	0.010000	1.00	1.00	FDA
230	G	BEANS-DRY-NAVY (PEA)	0.010000	1.00	1.00	FDA
231	G	BEANS-DRY-OTHER	0.010000	1.00	1.00	FDA
232	G	BEANS-DRY-PINTO	0.010000	1.00	1.00	FDA
233	G	BEANS-SUCCULENT-LIMA	0.010000	1.00	1.00	FDA
234	G	BEANS-SUCCULENT-GREEN	0.010000	1.00	1.00	FDA
235	G	BEANS-SUCCULENT-OTHER	0.010000	1.00	1.00	FDA
236	G	BEANS-SUCCULENT-YELLOW/WAX	0.010000	1.00	1.00	FDA
237	O	CORN/POP	0.010000	1.00	1.00	FDA
238	O	CORN/SWEET	0.010000	1.00	1.00	FDA
239	A	PEANUTS-WHOLE	0.010000	1.00	1.00	FDA
240	G	PEAS (GARDEN)-DRY	0.295000	1.00	1.00	DPR
241	G	PEAS (GARDEN)-GREEN	0.295000	1.00	1.00	DPR
242	G	LENTILS-WHOLE	0.010000	1.00	1.00	FDA
243	G	LENTILS-SPLIT	0.010000	1.00	1.00	FDA
245	A	OKRA	0.223000	1.00	1.00	DPR
246	A	SUNFLOWER-SEEDS-WITH HULLS	0.010000	1.00	1.00	FDA
249	G	BEANS-DRY-BROADBEANS	0.010000	1.00	1.00	FDA
250	G	BEANS-SUCCULENT-BROADBEANS	0.010000	1.00	1.00	FDA
251	G	BEANS-DRY-PIGEON BEANS	0.010000	1.00	1.00	FDA
253	G	BEANS-UNSPECIFIED	0.010000	1.00	1.00	FDA
256	G	BEANS-DRY-HYACINTH	0.010000	1.00	1.00	FDA
257	G	BEANS-SUCCULENT-HYACINTH	0.010000	1.00	1.00	FDA
258	G	BEANS-DRY-BLACK EYE PEAS/COWPE	0.010000	1.00	1.00	FDA
259	G	BEANS-DRY-GARBANZO/CHICK PEA	0.010000	1.00	1.00	FDA
260	A	ASPARAGUS	0.010000	1.00	1.00	FDA
261	A	MUSHROOMS	0.010000	1.00	1.00	FDA
262	D	ONIONS-GREEN	0.500000	1.00	1.00	DPR
265	O	BARLEY	0.010000	1.00	1.00	FDA
266	O	CORN/GRAIN-ENDOSPERM	0.010000	1.00	1.00	FDA
267	O	CORN/GRAIN-BRAN	0.010000	1.00	1.00	FDA
268	O	CORN SUGAR	0.010000	1.50	1.00	FDA
269	O	OATS	0.010000	1.00	1.00	FDA
270	O	RICE-ROUGH (BROWN)	0.010000	1.00	1.00	FDA
271	O	RICE-MILLED (WHITE)	0.010000	1.00	1.00	FDA
272	O	RYE-ROUGH	0.010000	1.00	1.00	FDA
273	O	RYE-GERM	0.010000	1.00	1.00	FDA
274	O	RYE-FLOUR	0.010000	1.00	1.00	FDA
276	O	WHEAT-ROUGH	0.010000	1.00	1.00	FDA

 ACUTE EXPOSURE (EX4) ANALYSIS FOR Malathion; Section 3 REGISTRATION
 RESIDUE FILE NAME: NEWMAL2A (NFCS87/88 DATA) ANALYSIS DATE: 02-04-1993
 DPR NOEL = 0.34 MG/KG BODY WT/DAY

TAS CODE	CROP GRP	FOOD NAME	RESIDUE (PPM)	ADJ #1	FCTRS #2	SOURCE CODE
277	O	WHEAT-GERM	0.010000	1.00	1.00	FDA
278	O	WHEAT-BRAN	0.010000	1.00	1.00	FDA
279	O	WHEAT-FLOUR	0.010000	1.00	1.00	FDA
282	B	BEEF SUGAR	0.010000	1.00	1.00	FDA
289	O	CORN GRAIN-OIL	0.010000	1.00	1.00	FDA
293	A	PEANUTS-OIL	0.010000	1.00	1.00	FDA
297	G	SOYBEANS-OIL	0.010000	1.00	1.00	FDA
298	A	SUNFLOWER-OIL	0.010000	1.00	1.00	FDA
303	G	SOYBEANS-UNSPECIFIED	0.010000	1.00	1.00	FDA
304	G	SOYBEANS-MATURE SEEDS DRY	0.010000	1.00	1.00	FDA
305	G	SOYBEANS-FLOUR (FULL FAT)	0.010000	1.00	1.00	FDA
306	G	SOYBEANS-FLOUR (LOW FAT)	0.010000	1.00	1.00	FDA
307	G	SOYBEANS-FLOUR (DEFATTED)	0.010000	1.00	1.00	FDA
315	A	GRAPES-WINE AND SHERRY	1.350000	1.00	1.00	DPR
318	X	MILK-NONFAT SOLIDS	0.050000	1.00	1.00	FDA
319	X	MILK-FAT SOLIDS	0.050000	1.00	1.00	FDA
320	X	MILK SUGAR (LACTOSE)	0.050000	1.00	1.00	FDA
321	U	BEEF-MEAT BYPRODUCTS	0.100000	1.00	1.00	USDA
322	U	BEEF(ORGAN MEATS)-OTHER	0.100000	1.00	1.00	USDA
323	U	BEEF-DRIED	0.100000	1.92	1.00	USDA
324	U	BEEF(BONELESS)-FAT	0.100000	1.00	1.00	USDA
325	U	BEEF(ORGAN MEATS)-KIDNEY	0.100000	1.00	1.00	USDA
326	U	BEEF(ORGAN MEATS)-LIVER	0.100000	1.00	1.00	USDA
327	U	BEEF(BONELESS)-LEAN (FAT/FREE	0.100000	1.00	1.00	USDA
328	U	GOAT-MEAT BYPRODUCTS	0.100000	1.00	1.00	USDA
329	U	GOAT(ORGAN MEATS)-OTHER	0.100000	1.00	1.00	USDA
330	U	GOAT(BONELESS)-FAT	0.100000	1.00	1.00	USDA
331	U	GOAT(ORGAN MEATS)-KIDNEY	0.100000	1.00	1.00	USDA
332	U	GOAT(ORGAN MEATS)-LIVER	0.100000	1.00	1.00	USDA
333	U	GOAT(BONELESS)-LEAN (FAT/FREE	0.100000	1.00	1.00	USDA
336	U	SHEEP-MEAT BYPRODUCTS	0.100000	1.00	1.00	USDA
337	U	SHEEP(ORGAN MEATS)-OTHER	0.100000	1.00	1.00	USDA
338	U	SHEEP(BONELESS)-FAT	0.100000	1.00	1.00	USDA
339	U	SHEEP(ORGAN MEATS)-KIDNEY	0.100000	1.00	1.00	USDA
340	U	SHEEP(ORGAN MEATS)-LIVER	0.100000	1.00	1.00	USDA
341	U	SHEEP(BONELESS)-LEAN (FAT FRE	0.100000	1.00	1.00	USDA
342	U	PORK-MEAT BYPRODUCTS	0.100000	1.00	1.00	USDA
343	U	PORK(ORGAN MEATS)-OTHER	0.100000	1.00	1.00	USDA
344	U	PORK(BONELESS)-FAT	0.100000	1.00	1.00	USDA

ACUTE EXPOSURE (EX4) ANALYSIS FOR Malathion;
 RESIDUE FILE NAME: NEWMAL2A (NFCS87/88 DATA)
 DPR NOEL = 0.34 MG/KG BODY WT/DAY

Section 3 REGISTRATION
 ANALYSIS DATE: 02-04-1993

TAS CODE	CROP GRP	FOOD NAME	RESIDUE (PPM)	ADJ #1	FCTRS #2	SOURCE CODE
345	U	PORK(ORGAN MEATS)-KIDNEY	0.100000	1.00	1.00	USDA
346	U	PORK(ORGAN MEATS)-LIVER	0.100000	1.00	1.00	USDA
347	U	PORK(BONELESS)-LEAN (FAT FREE	0.100000	1.00	1.00	USDA
355	V	TURKEY-BYPRODUCTS	0.100000	1.00	1.00	USDA
356	V	TURKEY-GIBLETS (LIVER)	0.100000	1.00	1.00	USDA
357	V	TURKEY-(BONELESS)-FAT	0.100000	1.00	1.00	USDA
358	V	TURKEY-(BONELESS)LEAN/FAT FRE	0.100000	1.00	1.00	USDA
359	V	TURKEY-UNSPECIFIED	0.100000	1.00	1.00	USDA
360	V	POULTRY-OTHER-LEAN (FAT FREE)	0.100000	1.00	1.00	USDA
361	V	POULTRY-OTHER-GIBLETS (LIVER)	0.100000	1.00	1.00	USDA
362	V	POULTRY-OTHER-FAT	0.100000	1.00	1.00	USDA
363	X	EGGS-WHOLE	0.050000	1.00	1.00	FDA
364	X	EGGS-WHITE ONLY	0.050000	1.00	1.00	FDA
365	X	EGGS-YOLK ONLY	0.050000	1.00	1.00	FDA
366	V	CHICKEN-BYPRODUCTS	0.100000	1.00	1.00	USDA
367	V	CHICKEN-GIBLETS (LIVER)	0.100000	1.00	1.00	USDA
368	V	CHICKEN (BONELESS)-FAT	0.100000	1.00	1.00	USDA
369	V	CHICKEN (BONELESS)LEAN/FAT FRE	0.100000	1.00	1.00	USDA
377	L	APPLES-JUICE-CONCENTRATE	0.010000	3.90	1.00	FDA
379	B	BEEET SUGAR-MOLASSES	0.010000	1.00	1.00	FDA
383	F	CABBAGE-SAVOY	0.010000	1.00	1.00	FDA
385	V	CHICKEN-GIBLETS (EXCL. LIVER)	0.100000	1.00	1.00	USDA
388	O	CORN SUGAR-MOLASSES	0.010000	1.50	1.00	FDA
389	N	CRANBERRIES-JUICE-CONCENTRATE	0.010000	1.00	1.00	FDA
392	N	GRAPES-JUICE-CONCENTRATE	0.010000	1.00	1.00	FDA
398	X	MILK-BASED WATER	0.050000	1.00	1.00	FDA
399	O	OATS-BRAN	0.010000	1.00	1.00	FDA
403	A	PEANUT-BUTTER	0.010000	1.89	1.00	FDA
405	G	PEAS-SUCCULENT/BLACKEYE/COWPE	0.010000	1.00	1.00	FDA
408	O	RICE-BRAN	0.010000	1.00	1.00	FDA
413	G	SNOWPEAS	0.010000	1.00	1.00	FDA
417	A	SUNFLOWER-SEEDS-HULLED	0.010000	1.00	1.00	FDA
420	K	TANGERINES-JUICE-CONCENTRATE	0.010000	1.00	1.00	FDA
424	U	VEAL-(BONELESS)-FAT	0.100000	1.00	1.00	USDA
425	U	VEAL-(BONELESS)-LEAN (FAT FRE	0.100000	1.00	1.00	USDA
426	U	VEAL-(ORGAN MEATS)-KIDNEY	0.100000	1.00	1.00	USDA
427	U	VEAL-(ORGAN MEATS)-LIVER	0.100000	1.00	1.00	USDA
428	U	VEAL-(ORGAN MEATS)-OTHER	0.100000	1.00	1.00	USDA
429	U	VEAL-DRIED	0.100000	1.92	1.00	USDA

 ACUTE EXPOSURE (EX4) ANALYSIS FOR Malathion; Section 3 REGISTRATION
 RESIDUE FILE NAME: NEWMAL2A (NFCS87/88 DATA) ANALYSIS DATE: 02-04-1993
 DPR NOEL = 0.34 MG/KG BODY WT/DAY

TAS CODE	CROP GRP	FOOD NAME	RESIDUE (PPM)	ADJ #1	FCTRS #2	SOURCE CODE
430	U	VEAL-MEAT BYPRODUCTS	0.100000	1.00	1.00	USDA
441	K	GRAPEFRUIT-JUICE-CONCENTRATE	0.010000	1.00	1.00	FDA
442	K	LEMONS-JUICE-CONCENTRATE	0.010000	1.00	1.00	FDA
443	K	LIMES-JUICE-CONCENTRATE	0.010000	1.00	1.00	FDA
448	K	GRAPEFRUIT PEEL	0.301000	1.00	1.00	DPR
449	V	TURKEY-(ORGAN MEATS)-OTHER	0.100000	1.00	1.00	USDA
940	A	PEANUTS HULLED	0.010000	1.00	1.00	FDA

- 1/ DPR = Department of Pesticide Regulation Monitoring Programs
 EPA = U.S. EPA Tolerance
 FDA = Food and Drug Administration Monitoring Programs
 USDA= United States Department of Agriculture FSIS Program

 ACUTE EXPOSURE (EX4) ANALYSIS FOR Malathion; Section 3 REGISTRATION
 RESIDUE FILE NAME: NEWMAL2A (NFCS87/88 DATA) ANALYSIS DATE 02-04-1993
 DPR NOEL = 0.34 MG/KG BODY WT/DAY
 EPA REFERENCE DOSE = 0.02 MG/KG BODY WT/DAY
 COMMENT 1: Geometric mean of residue or MDL used (DPR, FDA Market S., USDA)
 COMMENT 2: All direct and indirect labeled food uses of malathion
 Initial estimate of user-days as % of person-days in survey = 100.00%

U.S. POP - ALL SEASONS

ESTIMATED PERCENT OF PERSON-DAYS THAT ARE USER-DAYS	MEAN DAILY EXPOSURE PER USER-DAY (MG/KG BODY WT/DAY)			
	MEAN	STANDARD DEVATION	STANDARD ERROR	MARGIN OF SAFETY
100.0%	0.001324	0.001962	0.000012	257

ESTIMATED PERCENTILE OF POPULATION USER-DAYS EXCEEDING CALCULATED EXPOSURE
 IN MG/KG BODY WT/DAY AND CORRESPONDING MARGIN OF SAFETY (MOS)

PERCENTILE	EXPOSURE	MOS	PERCENTILE	EXPOSURE	MOS
90.0	0.000273	1246	20.0	0.001816	187
80.0	0.000399	852	10.0	0.002910	117
70.0	0.000526	646	5.0	0.004103	83
60.0	0.000666	511	2.5	0.005539	61
50.0	0.000820	414	1.0	0.008146	42
40.0	0.001022	333	0.5	0.010275	33
30.0	0.001307	260	0.0	0.102255	3

 ACUTE EXPOSURE (EX4) ANALYSIS FOR Malathion;
 RESIDUE FILE NAME: NEWMAL2A (NFCS87/88 DATA)
 DPR NOEL = 0.34 MG/KG BODY WT/DAY

Section 3 REGISTRATION
 ANALYSIS DATE 02-04-1993

 WESTERN REGION

ESTIMATED PERCENT OF PERSON-DAYS THAT ARE USER-DAYS	MEAN DAILY EXPOSURE/USER-DAY (MG/KG BD WT/DAY)			
	MEAN	STANDARD DEVATION	STANDARD ERROR	MARGIN OF SAFTEY
100.0%	0.001510	0.001908	0.000026	225

ESTIMATED PERCENTILE OF POPULATION USER-DAYS EXCEEDING CALCULATED EXPOSURE
 IN MG/KG BODY WT/DAY AND CORRESPONDING MARGIN OF SAFETY (MOS)

PERCENTILE	EXPOSURE	MOS	PERCENTILE	EXPOSURE	MOS
90.0	0.000273	1245	20.0	0.002143	159
80.0	0.000421	808	10.0	0.003474	98
70.0	0.000564	603	5.0	0.005040	67
60.0	0.000728	467	2.5	0.006938	49
50.0	0.000909	374	1.0	0.009593	35
40.0	0.001178	289	0.5	0.012162	28
30.0	0.001523	223	0.0	0.037180	9

HISPANICS

ESTIMATED PERCENT OF PERSON-DAYS THAT ARE USER-DAYS	MEAN DAILY EXPOSURE/USER-DAY (MG/KG BD WT/DAY)			
	MEAN	STANDARD DEVATION	STANDARD ERROR	MARGIN OF SAFTEY
100.0%	0.001320	0.001423	0.000042	258

ESTIMATED PERCENTILE OF POPULATION USER-DAYS EXCEEDING CALCULATED EXPOSURE
 IN MG/KG BODY WT/DAY AND CORRESPONDING MARGIN OF SAFETY (MOS)

PERCENTILE	EXPOSURE	MOS	PERCENTILE	EXPOSURE	MOS
90.0	0.000263	1291	20.0	0.001952	174
80.0	0.000396	859	10.0	0.003257	104
70.0	0.000531	641	5.0	0.004183	81
60.0	0.000668	509	2.5	0.004844	70
50.0	0.000833	408	1.0	0.006996	49
40.0	0.001050	324	0.5	0.008800	39
30.0	0.001409	241	0.0	0.014471	23

 ACUTE EXPOSURE (EX4) ANALYSIS FOR Malathion;
 RESIDUE FILE NAME: NEWMAL2A (NFCS87/88 DATA)
 DPR NOEL = 0.34 MG/KG BODY WT/DAY

Section 3 REGISTRATION
 ANALYSIS DATE 02-04-1993

 NON-HISPANIC WHITES

ESTIMATED PERCENT OF PERSON-DAYS THAT ARE USER-DAYS	MEAN DAILY EXPOSURE/USER-DAY (MG/KG BD WT/DAY)			
	MEAN	STANDARD DEVATION	STANDARD ERROR	MARGIN OF SAFTEY
100.0%	0.001353	0.002071	0.000014	251

ESTIMATED PERCENTILE OF POPULATION USER-DAYS EXCEEDING CALCULATED EXPOSURE
 IN MG/KG BODY WT/DAY AND CORRESPONDING MARGIN OF SAFETY (MOS)

PERCENTILE	EXPOSURE	MOS	PERCENTILE	EXPOSURE	MOS
90.0	0.000287	1186	20.0	0.001824	186
80.0	0.000415	820	10.0	0.002923	116
70.0	0.000544	625	5.0	0.004145	82
60.0	0.000684	497	2.5	0.005718	59
50.0	0.000840	405	1.0	0.008433	40
40.0	0.001044	326	0.5	0.010939	31
30.0	0.001311	259	0.0	0.102255	3

 NON-HISPANIC BLACKS

ESTIMATED PERCENT OF PERSON-DAYS THAT ARE USER-DAYS	MEAN DAILY EXPOSURE/USER-DAY (MG/KG BD WT/DAY)			
	MEAN	STANDARD DEVATION	STANDARD ERROR	MARGIN OF SAFTEY
100.0%	0.001086	0.001261	0.000023	313

ESTIMATED PERCENTILE OF POPULATION USER-DAYS EXCEEDING CALCULATED EXPOSURE
 IN MG/KG BODY WT/DAY AND CORRESPONDING MARGIN OF SAFETY (MOS)

PERCENTILE	EXPOSURE	MOS	PERCENTILE	EXPOSURE	MOS
90.0	0.000207	1645	20.0	0.001589	214
80.0	0.000314	1084	10.0	0.002562	133
70.0	0.000418	813	5.0	0.003652	93
60.0	0.000537	633	2.5	0.004697	72
50.0	0.000666	510	1.0	0.006644	51
40.0	0.000841	404	0.5	0.008616	39
30.0	0.001094	311	0.0	0.014830	23

 ACUTE EXPOSURE (EX4) ANALYSIS FOR Malathion;
 RESIDUE FILE NAME: NEWMAL2A (NFCS87/88 DATA)
 DPR NOEL = 0.34 MG/KG BODY WT/DAY

Section 3 REGISTRATION
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 NON-HISPANIC OTHER

ESTIMATED PERCENT OF PERSON-DAYS THAT ARE USER-DAYS	MEAN DAILY EXPOSURE/USER-DAY (MG/KG BD WT/DAY)			
	MEAN	STANDARD DEVATION	STANDARD ERROR	MARGIN OF SAFTEY
100.0%	0.001523	0.001801	0.000066	223

ESTIMATED PERCENTILE OF POPULATION USER-DAYS EXCEEDING CALCULATED EXPOSURE
 IN MG/KG BODY WT/DAY AND CORRESPONDING MARGIN OF SAFETY (MOS)

PERCENTILE	EXPOSURE	MOS	PERCENTILE	EXPOSURE	MOS
90.0	0.000291	1169	20.0	0.002286	149
80.0	0.000425	799	10.0	0.003415	100
70.0	0.000558	609	5.0	0.004913	69
60.0	0.000736	462	2.5	0.005913	57
50.0	0.000945	360	1.0	0.009012	38
40.0	0.001204	282	0.5	0.012060	28
30.0	0.001583	215	0.0	0.023497	14

 NURSING INFANTS (<1 YEAR)

ESTIMATED PERCENT OF PERSON-DAYS THAT ARE USER-DAYS	MEAN DAILY EXPOSURE/USER-DAY (MG/KG BD WT/DAY)			
	MEAN	STANDARD DEVATION	STANDARD ERROR	MARGIN OF SAFTEY
100.0%	0.000980	0.001754	0.000203	347

ESTIMATED PERCENTILE OF POPULATION USER-DAYS EXCEEDING CALCULATED EXPOSURE
 IN MG/KG BODY WT/DAY AND CORRESPONDING MARGIN OF SAFETY (MOS)

PERCENTILE	EXPOSURE	MOS	PERCENTILE	EXPOSURE	MOS
90.0	0.000109	3107	20.0	0.001238	275
80.0	0.000177	1919	10.0	0.003056	111
70.0	0.000229	1482	5.0	0.004099	83
60.0	0.000266	1277	2.5	0.004980	68
50.0	0.000303	1122	1.0	0.007379	46
40.0	0.000469	724	0.5	0.010615	32
30.0	0.000689	493	0.0	0.014692	23

 ACUTE EXPOSURE (EX4) ANALYSIS FOR Malathion;
 RESIDUE FILE NAME: NEWMAL2A (NFCS87/88 DATA)
 DPR NOEL = 0.34 MG/KG BODY WT/DAY

Section 3 REGISTRATION
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 NON-NURSING INFANTS (<1)

ESTIMATED PERCENT OF PERSON-DAYS THAT ARE USER-DAYS	MEAN DAILY EXPOSURE/USER-DAY (MG/KG BD WT/DAY)			
	MEAN	STANDARD DEVATION	STANDARD ERROR	MARGIN OF SAFTEY
100.0%	0.002167	0.002365	0.000130	157

ESTIMATED PERCENTILE OF POPULATION USER-DAYS EXCEEDING CALCULATED EXPOSURE
 IN MG/KG BODY WT/DAY AND CORRESPONDING MARGIN OF SAFETY (MOS)

PERCENTILE	EXPOSURE	MOS	PERCENTILE	EXPOSURE	MOS
90.0	0.000334	1019	20.0	0.003638	93
80.0	0.000548	621	10.0	0.005198	65
70.0	0.000722	471	5.0	0.007482	45
60.0	0.000924	368	2.5	0.009713	35
50.0	0.001199	284	1.0	0.011230	30
40.0	0.001678	203	0.5	0.012020	28
30.0	0.002629	129	0.0	0.012810	27

 FEMALES (13+/PREG/NOT NSG)

ESTIMATED PERCENT OF PERSON-DAYS THAT ARE USER-DAYS	MEAN DAILY EXPOSURE/USER-DAY (MG/KG BD WT/DAY)			
	MEAN	STANDARD DEVATION	STANDARD ERROR	MARGIN OF SAFTEY
100.0%	0.001089	0.001391	0.000087	312

ESTIMATED PERCENTILE OF POPULATION USER-DAYS EXCEEDING CALCULATED EXPOSURE
 IN MG/KG BODY WT/DAY AND CORRESPONDING MARGIN OF SAFETY (MOS)

PERCENTILE	EXPOSURE	MOS	PERCENTILE	EXPOSURE	MOS
90.0	0.000349	973	20.0	0.001520	224
80.0	0.000465	731	10.0	0.002012	169
70.0	0.000536	634	5.0	0.002710	125
60.0	0.000607	560	2.5	0.003651	93
50.0	0.000708	480	1.0	0.006031	56
40.0	0.000819	415	0.5	0.008928	38
30.0	0.001018	334	0.0	0.011826	29

ACUTE EXPOSURE (EX4) ANALYSIS FOR Malathion;
 RESIDUE FILE NAME: NEWMAL2A (NFCS87/88 DATA)
 DPR NOEL = 0.34 MG/KG BODY WT/DAY

Section 3 REGISTRATION
 ANALYSIS DATE 02-04-1993

FEMALES (13+/NURSING)

MEAN DAILY EXPOSURE/USER-DAY (MG/KG BD WT/DAY)

ESTIMATED PERCENT OF PERSON-DAYS THAT ARE USER-DAYS	MEAN DAILY EXPOSURE/USER-DAY (MG/KG BD WT/DAY)			
	MEAN	STANDARD DEVATION	STANDARD ERROR	MARGIN OF SAFTEY
100.0%	0.001288	0.001186	0.000095	264

ESTIMATED PERCENTILE OF POPULATION USER-DAYS EXCEEDING CALCULATED EXPOSURE
 IN MG/KG BODY WT/DAY AND CORRESPONDING MARGIN OF SAFETY (MOS)

PERCENTILE	EXPOSURE	MOS	PERCENTILE	EXPOSURE	MOS
90.0	0.000370	919	20.0	0.001795	189
80.0	0.000504	674	10.0	0.003298	103
70.0	0.000596	571	5.0	0.004214	81
60.0	0.000687	495	2.5	0.004620	74
50.0	0.000823	413	1.0	0.004864	70
40.0	0.001023	332	0.5	0.005237	65
30.0	0.001385	245	0.0	0.005680	60

CHILDREN (1-6 YEARS)

MEAN DAILY EXPOSURE/USER-DAY (MG/KG BD WT/DAY)

ESTIMATED PERCENT OF PERSON-DAYS THAT ARE USER-DAYS	MEAN DAILY EXPOSURE/USER-DAY (MG/KG BD WT/DAY)			
	MEAN	STANDARD DEVATION	STANDARD ERROR	MARGIN OF SAFTEY
100.0%	0.003388	0.004477	0.000085	100

ESTIMATED PERCENTILE OF POPULATION USER-DAYS EXCEEDING CALCULATED EXPOSURE
 IN MG/KG BODY WT/DAY AND CORRESPONDING MARGIN OF SAFETY (MOS)

PERCENTILE	EXPOSURE	MOS	PERCENTILE	EXPOSURE	MOS
90.0	0.001013	336	20.0	0.004373	78
80.0	0.001438	236	10.0	0.006044	56
70.0	0.001765	193	5.0	0.008451	40
60.0	0.002112	161	2.5	0.011091	31
50.0	0.002488	137	1.0	0.022425	15
40.0	0.002900	117	0.5	0.038486	9
30.0	0.003414	100	0.0	0.102255	3

 ACUTE EXPOSURE (EX4) ANALYSIS FOR Malathion;
 RESIDUE FILE NAME: NEWMAL2A (NFCS87/88 DATA)
 DPR NOEL = 0.34 MG/KG BODY WT/DAY

Section 3 REGISTRATION
 ANALYSIS DATE 02-04-1993

 CHILDREN (7-12 YEARS)

ESTIMATED PERCENT OF PERSON-DAYS THAT ARE USER-DAYS	MEAN DAILY EXPOSURE/USER-DAY (MG/KG BD WT/DAY)			
	MEAN	STANDARD DEVATION	STANDARD ERROR	MARGIN OF SAFTEY
100.0%	0.001921	0.001661	0.000033	177

ESTIMATED PERCENTILE OF POPULATION USER-DAYS EXCEEDING CALCULATED EXPOSURE
 IN MG/KG BODY WT/DAY AND CORRESPONDING MARGIN OF SAFETY (MOS)

PERCENTILE	EXPOSURE	MOS	PERCENTILE	EXPOSURE	MOS
90.0	0.000620	548	20.0	0.002722	125
80.0	0.000874	389	10.0	0.003504	97
70.0	0.001078	315	5.0	0.004601	74
60.0	0.001310	260	2.5	0.005496	62
50.0	0.001562	218	1.0	0.007454	46
40.0	0.001854	183	0.5	0.008882	38
30.0	0.002287	149	0.0	0.039076	9

 MALES (13-19 YEARS)

ESTIMATED PERCENT OF PERSON-DAYS THAT ARE USER-DAYS	MEAN DAILY EXPOSURE/USER-DAY (MG/KG BD WT/DAY)			
	MEAN	STANDARD DEVATION	STANDARD ERROR	MARGIN OF SAFTEY
100.0%	0.001131	0.000979	0.000028	301

ESTIMATED PERCENTILE OF POPULATION USER-DAYS EXCEEDING CALCULATED EXPOSURE
 IN MG/KG BODY WT/DAY AND CORRESPONDING MARGIN OF SAFETY (MOS)

PERCENTILE	EXPOSURE	MOS	PERCENTILE	EXPOSURE	MOS
90.0	0.000344	988	20.0	0.001605	212
80.0	0.000493	690	10.0	0.002044	166
70.0	0.000616	552	5.0	0.002547	134
60.0	0.000755	450	2.5	0.003403	100
50.0	0.000914	372	1.0	0.004981	68
40.0	0.001093	311	0.5	0.006408	53
30.0	0.001339	254	0.0	0.014830	23

ACUTE EXPOSURE (EX4) ANALYSIS FOR Malathion;
 RESIDUE FILE NAME: NEWMAL2A (NFCS87/88 DATA)
 DPR NOEL = 0.34 MG/KG BODY WT/DAY

Section 3 REGISTRATION
 ANALYSIS DATE 02-04-1993

FEMALES (13-19 YRS/NP/NN)

ESTIMATED PERCENT OF PERSON-DAYS THAT ARE USER-DAYS	MEAN DAILY EXPOSURE/USER-DAY (MG/KG BD WT/DAY)			
	MEAN	STANDARD DEVATION	STANDARD ERROR	MARGIN OF SAFTEY
100.0%	0.000938	0.000826	0.000023	363

ESTIMATED PERCENTILE OF POPULATION USER-DAYS EXCEEDING CALCULATED EXPOSURE
 IN MG/KG BODY WT/DAY AND CORRESPONDING MARGIN OF SAFETY (MOS)

PERCENTILE	EXPOSURE	MOS	PERCENTILE	EXPOSURE	MOS
90.0	0.000271	1256	20.0	0.001305	261
80.0	0.000397	855	10.0	0.001823	186
70.0	0.000509	667	5.0	0.002468	138
60.0	0.000629	540	2.5	0.002978	114
50.0	0.000757	449	1.0	0.003484	98
40.0	0.000897	379	0.5	0.004419	77
30.0	0.001101	309	0.0	0.014596	23

MALES (20+ YEARS)

ESTIMATED PERCENT OF PERSON-DAYS THAT ARE USER-DAYS	MEAN DAILY EXPOSURE/USER-DAY (MG/KG BD WT/DAY)			
	MEAN	STANDARD DEVATION	STANDARD ERROR	MARGIN OF SAFTEY
100.0%	0.000991	0.001093	0.000012	343

ESTIMATED PERCENTILE OF POPULATION USER-DAYS EXCEEDING CALCULATED EXPOSURE
 IN MG/KG BODY WT/DAY AND CORRESPONDING MARGIN OF SAFETY (MOS)

PERCENTILE	EXPOSURE	MOS	PERCENTILE	EXPOSURE	MOS
90.0	0.000251	1354	20.0	0.001329	256
80.0	0.000369	922	10.0	0.001902	179
70.0	0.000471	721	5.0	0.002885	118
60.0	0.000571	595	2.5	0.004195	81
50.0	0.000686	495	1.0	0.006210	55
40.0	0.000820	415	0.5	0.007828	43
30.0	0.001028	331	0.0	0.019613	17

ACUTE EXPOSURE (EX4) ANALYSIS FOR Malathion;
 RESIDUE FILE NAME: NEWMAL2A (NFCS87/88 DATA)
 DPR NOEL = 0.34 MG/KG BODY WT/DAY

Section 3 REGISTRATION
 ANALYSIS DATE 02-04-1993

FEMALES (20+ YEARS/NP/NN)

ESTIMATED PERCENT OF PERSON-DAYS THAT ARE USER-DAYS	MEAN DAILY EXPOSURE/USER-DAY (MG/KG BD WT/DAY)			
	MEAN	STANDARD DEVATION	STANDARD ERROR	MARGIN OF SAFTEY
99.9%	0.001022	0.001386	0.000014	333

ESTIMATED PERCENTILE OF POPULATION USER-DAYS EXCEEDING CALCULATED EXPOSURE
 IN MG/KG BODY WT/DAY AND CORRESPONDING MARGIN OF SAFETY (MOS)

PERCENTILE	EXPOSURE	MOS	PERCENTILE	EXPOSURE	MOS
90.0	0.000218	1560	20.0	0.001329	256
80.0	0.000323	1052	10.0	0.001943	175
70.0	0.000429	793	5.0	0.003290	103
60.0	0.000535	636	2.5	0.004912	69
50.0	0.000653	521	1.0	0.007573	45
40.0	0.000795	428	0.5	0.009504	36
30.0	0.000989	344	0.0	0.043109	8

CUSTOM DEMOGRAPHICS 1: Seniors 55+ Years

ESTIMATED PERCENT OF PERSON-DAYS THAT ARE USER-DAYS	MEAN DAILY EXPOSURE/USER-DAY (MG/KG BD WT/DAY)			
	MEAN	STANDARD DEVATION	STANDARD ERROR	MARGIN OF SAFTEY
100.0%	0.001151	0.001343	0.000017	295

ESTIMATED PERCENTILE OF POPULATION USER-DAYS EXCEEDING CALCULATED EXPOSURE
 IN MG/KG BODY WT/DAY AND CORRESPONDING MARGIN OF SAFETY (MOS)

PERCENTILE	EXPOSURE	MOS	PERCENTILE	EXPOSURE	MOS
90.0	0.000279	1217	20.0	0.001581	215
80.0	0.000399	851	10.0	0.002391	142
70.0	0.000519	655	5.0	0.003724	91
60.0	0.000637	534	2.5	0.004999	68
50.0	0.000755	450	1.0	0.007378	46
40.0	0.000924	368	0.5	0.008361	41
30.0	0.001149	296	0.0	0.043109	8

Appendix B2. Residue File and Chronic Dietary Exposure Analysis

 CHRONIC EXPOSURE (EX1) ANALYSIS FOR Malathion; Section 3 REGISTRATION
 RESIDUE FILE NAME: NEWMAL2C (NFCS87/88 DATA) ANALYSIS DATE: 02-04-1993
 DPR NOEL = 0.34 MG/KG BODY WT/DAY
 EPA REFERENCE DOSE (RfD) = 0.02 MG/KG BODY WT/DAY
 COMMENT 1: AVG of Residue or 1/2 MDL used (DPR & FDA Market Surveys, USDA)
 COMMENT 2: All direct and indirect labeled food uses of malathion

RESIDUE FILE LISTING

TAS	CROP	RESIDUE	ADJ	FCTRS	SOURCE	
CODE	GRP	FOOD NAME	(PPM)	#1	#2	CODE ¹
1	N	BLACKBERRIES	0.005000	1.00	1.00	FDA
2	N	BOYSENBERRIES	0.005000	1.00	1.00	FDA
5	N	RASPBERRIES	0.030000	1.00	1.00	DPR
7	N	BLUEBERRIES	0.005000	1.00	1.00	FDA
8	N	CRANBERRIES	0.005000	1.00	1.00	FDA
9	N	CRANBERRIES-JUICE	0.005000	1.00	1.00	FDA
10	N	CURRANTS	0.005000	1.00	1.00	FDA
12	N	GOOSEBERRIES	0.005000	1.00	1.00	FDA
13	N	GRAPES	0.008000	1.00	1.00	DPR
14	N	GRAPES-RAISINS	0.008000	4.30	1.00	DPR
15	N	GRAPES-JUICE	0.005000	1.00	1.00	FDA
17	N	STRAWBERRIES	0.020000	1.00	1.00	DPR
22	K	GRAPEFRUIT-PEELED FRUIT	0.001000	1.00	1.00	DPR
23	K	GRAPEFRUIT-JUICE	0.005000	1.00	1.00	FDA
24	K	KUMQUATS	0.005000	1.00	1.00	FDA
26	K	LEMONS-PEELED FRUIT	0.005000	1.00	1.00	FDA
27	K	LEMONS-PEEL	0.005000	1.00	1.00	FDA
28	K	LEMONS-JUICE	0.005000	1.00	1.00	FDA
30	K	LIMES-PEELED FRUIT	0.005000	1.00	1.00	FDA
31	K	LIMES-PEEL	0.005000	1.00	1.00	FDA
32	K	LIMES-JUICE	0.005000	1.00	1.00	FDA
33	K	ORANGES-JUICE-CONCENTRATE	0.005000	1.00	1.00	FDA
34	K	ORANGES-PEELED FRUIT	0.002000	1.00	1.00	DPR
35	K	ORANGES-PEEL	0.002000	1.00	1.00	DPR
36	K	ORANGES-JUICE	0.005000	1.00	1.00	FDA
37	K	TANGELOS	0.005000	1.00	1.00	FDA
38	K	TANGERINES	0.005000	1.00	1.00	FDA
39	K	TANGERINES-JUICE	0.005000	1.00	1.00	FDA
40	R	ALMONDS	0.005000	1.00	1.00	FDA
43	R	CHESTNUTS	0.005000	1.00	1.00	FDA
44	R	FILBERTS (HAZELNUTS)	0.005000	1.00	1.00	FDA
46	R	MACADAMIA NUTS (BUSH NUTS)	0.005000	1.00	1.00	FDA
47	R	PECANS	0.005000	1.00	1.00	FDA
48	R	WALNUTS	0.005000	1.00	1.00	FDA

CHRONIC EXPOSURE (EX1) ANALYSIS FOR Malathion; Section 3 REGISTRATION
 RESIDUE FILE NAME: NEWMAL2C (NFCS87/88 DATA) ANALYSIS DATE: 02-04-1993
 DPR NOEL = 0.34 MG/KG BODY WT/DAY

TAS CODE	CROP GRP	FOOD NAME	RESIDUE (PPM)	ADJ #1	FCTRS #2	SOURCE CODE
52	L	APPLES	0.005000	1.00	1.00	FDA
53	L	APPLES-DRIED	0.005000	8.00	1.00	FDA
54	L	APPLES-JUICE/CIDER	0.005000	1.00	1.00	FDA
56	L	PEARS	0.005000	1.00	1.00	FDA
57	L	PEARS-DRIED	0.005000	6.25	1.00	FDA
59	M	APRICOTS	0.005000	1.00	1.00	FDA
60	M	APRICOTS-DRIED	0.005000	6.00	1.00	FDA
61	M	CHERRIES	0.003000	1.00	1.00	DPR
62	M	CHERRIES-DRIED	0.003000	4.00	1.00	DPR
63	M	CHERRIES-JUICE	0.005000	1.00	1.00	FDA
64	M	NECTARINES	0.005000	1.00	1.00	FDA
65	M	PEACHES	0.001000	1.00	1.00	DPR
66	M	PEACHES-DRIED	0.001000	7.00	1.00	DPR
67	M	PLUMS (DAMSONS)	0.005000	1.00	1.00	FDA
68	M	PLUMS-PRUNES (DRIED)	0.005000	5.00	1.00	FDA
69	M	PLUMS/PRUNE-JUICE	0.005000	1.00	1.00	FDA
77	A	DATES	0.300000	1.00	1.00	DPR
126	B	HORSERADISH	0.005000	1.00	1.00	FDA
141	J	CANTALOUPE-NECTAR	0.001000	1.00	1.00	DPR
142	J	CANTALOUPE-PULP (MUSKMELON)	0.001000	1.00	1.00	DPR
143	J	CASABAS	0.005000	1.00	1.00	FDA
144	J	CRENSHAW	0.005000	1.00	1.00	FDA
145	J	HONEYDEW MELONS	0.005000	1.00	1.00	FDA
146	J	PERSIAN MELONS	0.005000	1.00	1.00	FDA
147	J	WATERMELON	0.005000	1.00	1.00	FDA
148	J	CUCUMBERS	0.005000	1.00	1.00	FDA
149	J	PUMPKIN	0.005000	1.00	1.00	FDA
150	J	SQUASH-SUMMER	0.005000	1.00	1.00	FDA
151	J	SQUASH-WINTER	0.005000	1.00	1.00	FDA
154	I	EGGPLANT	0.005000	1.00	1.00	FDA
155	I	PEPPERS-SWEET (GARDEN)	0.003000	1.00	1.00	DPR
156	I	CHILI PEPPERS (JALAPENO)	0.005000	1.00	1.00	FDA
157	I	PEPPERS-OTHER	0.003000	1.00	1.00	DPR
159	I	TOMATOES-WHOLE	0.000500	1.00	1.00	DPR
160	I	TOMATOES-JUICE	0.000500	1.50	0.05	DPR
161	I	TOMATOES-PUREE	0.000500	3.30	0.05	DPR
162	I	TOMATOES-PASTE	0.000500	5.40	0.05	DPR
163	I	TOMATOES-CATSUP	0.000500	2.50	0.05	DPR
165	C	BEETS-TOPS (GREENS)	0.005000	1.00	1.00	FDA
166	E	CELERY	0.001000	1.00	1.00	DPR

CHRONIC EXPOSURE (EX1) ANALYSIS FOR Malathion;
 RESIDUE FILE NAME: NEWMAL2C (NFCS87/88 DATA)
 DPR NOEL = 0.34 MG/KG BODY WT/DAY

Section 3 REGISTRATION
 ANALYSIS DATE: 02-04-1993

TAS CODE	CROP GRP	FOOD NAME	RESIDUE (PPM)	ADJ #1	FCTRS #2	SOURCE CODE
167	E	CHICORY (FRENCH/BELGIAN ENDIVE	0.005000	1.00	1.00	FDA
168	F	BROCCOLI	0.005000	1.00	1.00	FDA
169	F	BRUSSELS SPROUTS	0.005000	1.00	1.00	FDA
170	F	CABBAGE-GREEN AND RED	0.005000	1.00	1.00	FDA
171	F	CAULIFLOWER	0.005000	1.00	1.00	FDA
172	F	COLLARDS	0.005000	1.00	1.00	FDA
173	F	CABBAGE-CHINESE/CELERY/BOK CH	0.005000	1.00	1.00	FDA
174	F	KALE	0.005000	1.00	1.00	FDA
175	F	KOHLRABI	0.005000	1.00	1.00	FDA
176	E	LETTUCE-LEAFY VARIETIES	0.005000	1.00	1.00	FDA
177	E	DANDELION-GREENS	0.005000	1.00	1.00	FDA
178	E	ENDIVE-CURLEY AND ESCAROLE	0.005000	1.00	1.00	FDA
182	E	LETTUCE-UNSPECIFIED	0.020000	1.00	1.00	DPR
183	F	MUSTARD GREENS	0.001000	1.00	1.00	DPR
184	E	PARSLEY	0.005000	1.00	1.00	FDA
185	E	RHUBARB	0.005000	1.00	1.00	FDA
186	E	SPINACH	0.005000	1.00	1.00	FDA
187	E	SWISS CHARD	0.005000	1.00	1.00	FDA
188	C	TURNIPS-TOPS	0.005000	1.00	1.00	FDA
192	E	LETTUCE-HEAD VARIETIES	0.005000	1.00	1.00	FDA
197	B	BEETS-ROOTS	0.005000	1.00	1.00	FDA
198	B	CARROTS	0.005000	1.00	1.00	FDA
202	D	GARLIC	0.005000	1.00	1.00	FDA
204	D	LEEKS	0.005000	1.00	1.00	FDA
205	D	ONIONS-DRY-BULB (CIPOLLINI)	0.002000	1.00	1.00	DPR
206	D	ONIONS-DEHYDRATED OR DRIED	0.002000	9.00	1.00	DPR
207	B	POTATOES (WHITE) -WHOLE	0.005000	1.00	1.00	FDA
208	B	POTATOES (WHITE) -UNSPECIFIED	0.005000	1.00	1.00	FDA
209	B	POTATOES (WHITE) -PEELED	0.005000	1.00	1.00	FDA
210	B	POTATOES (WHITE) -DRY	0.005000	6.50	1.00	FDA
211	B	POTATOES (WHITE) -PEEL ONLY	0.005000	1.00	1.00	FDA
212	B	RADISHES-ROOTS	0.005000	1.00	1.00	FDA
214	B	RUTABAGAS-ROOTS	0.005000	1.00	1.00	FDA
216	B	SALSIFY (OYSTER PLANT)	0.005000	1.00	1.00	FDA
218	B	SWEET POTATOES (INCLUDING YAM	0.005000	1.00	1.00	FDA
219	B	TURNIPS-ROOTS	0.005000	1.00	1.00	FDA
220	B	PARSNIPS	0.005000	1.00	1.00	FDA
227	G	BEANS-DRY-GREAT NORTHERN	0.005000	1.00	1.00	FDA
228	G	BEANS-DRY-KIDNEY	0.005000	1.00	1.00	FDA

 CHRONIC EXPOSURE (EX1) ANALYSIS FOR Malathion; Section 3 REGISTRATION
 RESIDUE FILE NAME: NEWMAL2C (NFCS87/88 DATA) ANALYSIS DATE: 02-04-1993
 DPR NOEL = 0.34 MG/KG BODY WT/DAY

TAS CODE	CROP GRP	FOOD NAME	RESIDUE (PPM)	ADJ #1	FCTRS #2	SOURCE CODE
229	G	BEANS-DRY-LIMA	0.005000	1.00	1.00	FDA
230	G	BEANS-DRY-NAVY (PEA)	0.005000	1.00	1.00	FDA
231	G	BEANS-DRY-OTHER	0.005000	1.00	1.00	FDA
232	G	BEANS-DRY-PINTO	0.005000	1.00	1.00	FDA
233	G	BEANS-SUCCULENT-LIMA	0.005000	1.00	1.00	FDA
234	G	BEANS-SUCCULENT-GREEN	0.005000	1.00	1.00	FDA
235	G	BEANS-SUCCULENT-OTHER	0.005000	1.00	1.00	FDA
236	G	BEANS-SUCCULENT-YELLOW/WAX	0.005000	1.00	1.00	FDA
237	O	CORN/POP	0.005000	1.00	1.00	FDA
238	O	CORN/SWEET	0.005000	1.00	1.00	FDA
239	A	PEANUTS-WHOLE	0.005000	1.00	1.00	FDA
240	G	PEAS (GARDEN)-DRY	0.016000	1.00	1.00	DPR
241	G	PEAS (GARDEN)-GREEN	0.016000	1.00	1.00	DPR
242	G	LENTILS-WHOLE	0.005000	1.00	1.00	FDA
243	G	LENTILS-SPLIT	0.005000	1.00	1.00	FDA
245	A	OKRA	0.004000	1.00	1.00	DPR
246	A	SUNFLOWER-SEEDS-WITH HULLS	0.005000	1.00	1.00	FDA
249	G	BEANS-DRY-BROADBEANS	0.005000	1.00	1.00	FDA
250	G	BEANS-SUCCULENT-BROADBEANS	0.005000	1.00	1.00	FDA
251	G	BEANS-DRY-PIGEON BEANS	0.005000	1.00	1.00	FDA
253	G	BEANS-UNSPECIFIED	0.005000	1.00	1.00	FDA
256	G	BEANS-DRY-HYACINTH	0.005000	1.00	1.00	FDA
257	G	BEANS-SUCCULENT-HYACINTH	0.005000	1.00	1.00	FDA
258	G	BEANS-DRY-BLACKEYE PEAS/COWPE	0.005000	1.00	1.00	FDA
259	G	BEANS-DRY-GARBANZO/CHICK PEA	0.005000	1.00	1.00	FDA
260	A	ASPARAGUS	0.005000	1.00	1.00	FDA
261	A	MUSHROOMS	0.005000	1.00	1.00	FDA
262	D	ONIONS-GREEN	0.004000	1.00	1.00	DPR
265	O	BARLEY	0.005000	1.00	1.00	FDA
266	O	CORN/GRAIN-ENDOSPERM	0.005000	1.00	1.00	FDA
267	O	CORN/GRAIN-BRAN	0.005000	1.00	1.00	FDA
268	O	CORN SUGAR	0.005000	1.50	1.00	FDA
269	O	OATS	0.005000	1.00	1.00	FDA
270	O	RICE-ROUGH (BROWN)	0.005000	1.00	1.00	FDA
271	O	RICE-MILLED (WHITE)	0.005000	1.00	1.00	FDA
272	O	RYE-ROUGH	0.005000	1.00	1.00	FDA
273	O	RYE-GERM	0.005000	1.00	1.00	FDA
274	O	RYE-FLOUR	0.005000	1.00	1.00	FDA
276	O	WHEAT-ROUGH	0.005000	1.00	1.00	FDA

CHRONIC EXPOSURE (EX1) ANALYSIS FOR Malathion;
 RESIDUE FILE NAME: NEWMAL2C (NFCS87/88 DATA)
 DPR NOEL = 0.34 MG/KG BODY WT/DAY

Section 3 REGISTRATION
 ANALYSIS DATE: 02-04-1993

TAS CODE	CROP GRP	FOOD NAME	RESIDUE (PPM)	ADJ #1	FCTRS #2	SOURCE CODE
277	O	WHEAT-GERM	0.005000	1.00	1.00	FDA
278	O	WHEAT-BRAN	0.005000	1.00	1.00	FDA
279	O	WHEAT-FLOUR	0.005000	1.00	1.00	FDA
282	B	BEEF SUGAR	0.005000	1.00	1.00	FDA
289	O	CORN GRAIN-OIL	0.005000	1.00	1.00	FDA
293	A	PEANUTS-OIL	0.005000	1.00	1.00	FDA
297	G	SOYBEANS-OIL	0.005000	1.00	1.00	FDA
298	A	SUNFLOWER-OIL	0.005000	1.00	1.00	FDA
303	G	SOYBEANS-UNSPECIFIED	0.005000	1.00	1.00	FDA
304	G	SOYBEANS-MATURE SEEDS DRY	0.005000	1.00	1.00	FDA
305	G	SOYBEANS-FLOUR (FULL FAT)	0.005000	1.00	1.00	FDA
306	G	SOYBEANS-FLOUR (LOW FAT)	0.005000	1.00	1.00	FDA
307	G	SOYBEANS-FLOUR (DEFATTED)	0.005000	1.00	1.00	FDA
315	A	GRAPES-WINE AND SHERRY	0.008000	1.00	1.00	DPR
318	X	MILK-NONFAT SOLIDS	0.025000	1.00	1.00	FDA
319	X	MILK-FAT SOLIDS	0.025000	1.00	1.00	FDA
320	X	MILK SUGAR (LACTOSE)	0.025000	1.00	1.00	FDA
321	U	BEEF-MEAT BYPRODUCTS	0.050000	1.00	1.00	USDA
322	U	BEEF(ORGAN MEATS)-OTHER	0.050000	1.00	1.00	USDA
323	U	BEEF-DRIED	0.050000	1.92	1.00	USDA
324	U	BEEF(BONELESS)-FAT	0.050000	1.00	1.00	USDA
325	U	BEEF(ORGAN MEATS)-KIDNEY	0.050000	1.00	1.00	USDA
326	U	BEEF(ORGAN MEATS)-LIVER	0.050000	1.00	1.00	USDA
327	U	BEEF(BONELESS)-LEAN (FAT/FREE	0.050000	1.00	1.00	USDA
328	U	GOAT-MEAT BYPRODUCTS	0.050000	1.00	1.00	USDA
329	U	GOAT(ORGAN MEATS)-OTHER	0.050000	1.00	1.00	USDA
330	U	GOAT(BONELESS)-FAT	0.050000	1.00	1.00	USDA
331	U	GOAT(ORGAN MEATS)-KIDNEY	0.050000	1.00	1.00	USDA
332	U	GOAT(ORGAN MEATS)-LIVER	0.050000	1.00	1.00	USDA
333	U	GOAT(BONELESS)-LEAN (FAT/FREE	0.050000	1.00	1.00	USDA
336	U	SHEEP-MEAT BYPRODUCTS	0.050000	1.00	1.00	USDA
337	U	SHEEP(ORGAN MEATS)-OTHER	0.050000	1.00	1.00	USDA
338	U	SHEEP(BONELESS)-FAT	0.050000	1.00	1.00	USDA
339	U	SHEEP(ORGAN MEATS)-KIDNEY	0.050000	1.00	1.00	USDA
340	U	SHEEP(ORGAN MEATS)-LIVER	0.050000	1.00	1.00	USDA
341	U	SHEEP(BONELESS)-LEAN (FAT FRE	0.050000	1.00	1.00	USDA
342	U	PORK-MEAT BYPRODUCTS	0.050000	1.00	1.00	USDA
343	U	PORK(ORGAN MEATS)-OTHER	0.050000	1.00	1.00	USDA
344	U	PORK(BONELESS)-FAT	0.050000	1.00	1.00	USDA

CHRONIC EXPOSURE (EX1) ANALYSIS FOR Malathion;
 RESIDUE FILE NAME: NEWMAL2C (NFCS87/88 DATA)
 DPR NOEL = 0.34 MG/KG BODY WT/DAY

Section 3 REGISTRATION
 ANALYSIS DATE: 02-04-1993

TAS CODE	CROP GRP	FOOD NAME	RESIDUE (PPM)	ADJ #1	FCTRS #2	SOURCE CODE
345	U	PORK(ORGAN MEATS)-KIDNEY	0.050000	1.00	1.00	USDA
346	U	PORK(ORGAN MEATS)-LIVER	0.050000	1.00	1.00	USDA
347	U	PORK(BONELESS)-LEAN (FAT FREE	0.050000	1.00	1.00	USDA
355	V	TURKEY-BYPRODUCTS	0.050000	1.00	1.00	USDA
356	V	TURKEY-GIBLETS (LIVER)	0.050000	1.00	1.00	USDA
357	V	TURKEY-(BONELESS)-FAT	0.050000	1.00	1.00	USDA
358	V	TURKEY-(BONELESS)LEAN/FAT FRE	0.050000	1.00	1.00	USDA
359	V	TURKEY-UNSPECIFIED	0.050000	1.00	1.00	USDA
360	V	POULTRY-OTHER-LEAN (FAT FREE)	0.050000	1.00	1.00	USDA
361	V	POULTRY-OTHER-GIBLETS(LIVER)	0.050000	1.00	1.00	USDA
362	V	POULTRY-OTHER-FAT	0.050000	1.00	1.00	USDA
363	X	EGGS-WHOLE	0.025000	1.00	1.00	FDA
364	X	EGGS-WHITE ONLY	0.025000	1.00	1.00	FDA
365	X	EGGS-YOLK ONLY	0.025000	1.00	1.00	FDA
366	V	CHICKEN-BYPRODUCTS	0.050000	1.00	1.00	USDA
367	V	CHICKEN-GIBLETS(LIVER)	0.050000	1.00	1.00	USDA
368	V	CHICKEN (BONELESS)-FAT	0.050000	1.00	1.00	USDA
369	V	CHICKEN(BONELESS)LEAN/FAT FRE	0.050000	1.00	1.00	USDA
377	L	APPLES-JUICE-CONCENTRATE	0.005000	3.90	1.00	FDA
379	B	BEET SUGAR-MOLASSES	0.005000	1.00	1.00	FDA
383	F	CABBAGE-SAVOY	0.005000	1.00	1.00	FDA
385	V	CHICKEN-GIBLETS (EXCL. LIVER)	0.050000	1.00	1.00	USDA
388	O	CORN SUGAR-MOLASSES	0.005000	1.50	1.00	FDA
389	N	CRANBERRIES-JUICE-CONCENTRATE	0.005000	1.00	1.00	FDA
392	N	GRAPES-JUICE-CONCENTRATE	0.005000	1.00	1.00	FDA
398	X	MILK-BASED WATER	0.025000	1.00	1.00	FDA
399	O	OATS-BRAN	0.005000	1.00	1.00	FDA
403	A	PEANUT-BUTTER	0.005000	1.89	1.00	FDA
405	G	PEAS-SUCCULENT/BLACKEYE/COWPE	0.005000	1.00	1.00	FDA
408	O	RICE-BRAN	0.005000	1.00	1.00	FDA
413	G	SNOWPEAS	0.005000	1.00	1.00	FDA
417	A	SUNFLOWER-SEEDS-HULLED	0.005000	1.00	1.00	FDA
420	K	TANGERINES-JUICE-CONCENTRATE	0.005000	1.00	1.00	FDA
424	U	VEAL-(BONELESS)-FAT	0.050000	1.00	1.00	USDA
425	U	VEAL-(BONELESS)-LEAN (FAT FRE	0.050000	1.00	1.00	USDA
426	U	VEAL-(ORGAN MEATS)-KIDNEY	0.050000	1.00	1.00	USDA
427	U	VEAL-(ORGAN MEATS)-LIVER	0.050000	1.00	1.00	USDA
428	U	VEAL-(ORGAN MEATS)-OTHER	0.050000	1.00	1.00	USDA
429	U	VEAL-DRIED	0.050000	1.92	1.00	USDA

CHRONIC EXPOSURE (EX1) ANALYSIS FOR Malathion;
RESIDUE FILE NAME: NEWMAL2C (NFCS87/88 DATA)
DPR NOEL = 0.34 MG/KG BODY WT/DAY

Section 3 REGISTRATION
ANALYSIS DATE: 02-04-1993

TAS CROP RESIDUE ADJ FCTRS SOURCE
CODE GRP FOOD NAME (PPM) #1 #2 CODE

430 U VEAL-MEAT BYPRODUCTS 0.050000 1.00 1.00 USDA
441 K GRAPEFRUIT-JUICE-CONCENTRATE 0.005000 1.00 1.00 FDA
442 K LEMONS-JUICE-CONCENTRATE 0.005000 1.00 1.00 FDA
443 K LIMES-JUICE-CONCENTRATE 0.005000 1.00 1.00 FDA
448 K GRAPEFRUIT PEEL 0.001000 1.00 1.00 DPR
449 V TURKEY-(ORGAN MEATS)-OTHER 0.050000 1.00 1.00 USDA
940 A PEANUTS HULLED 0.005000 1.00 1.00 FDA

- 1/ DPR = Department of Pesticide Regulation Monitoring Programs
EPA = U.S. EPA Tolerance
FDA = Food and Drug Administration Monitoring Programs
USDA= United States Department of Agriculture FSIS Program

 CHRONIC EXPOSURE (EX1) ANALYSIS FOR Malathion; Section 3 REGISTRATION
 RESIDUE FILE NAME: NEWMAL2C (NFCS87/88 DATA) ANALYSIS DATE: 02-04-1993
 DPR NOEL = 0.34 MG/KG BODY WT/DAY
 EPA REFERENCE DOSE (RfD) = 0.02 MG/KG BODY WT/DAY
 COMMENT 1: AVG of Residue or 1/2 MDL used (DPR & FDA Market Surveys, USDA)
 COMMENT 2: All direct and indirect labeled food uses of malathion

TOTAL EXPOSURE BY POPULATION SUBGROUP

POPULATION SUBGROUP	TOTAL EXPOSURE		
	MG/KG BODY WT/DAY	MARGIN OF SAFETY ¹	PERCENT OF RfD
U.S. POP - 48 STATES - ALL SEASONS	0.000330	1,030	1.65%
U.S. POPULATION - SPRING SEASON	0.000318	1,069	1.59%
U.S. POPULATION - SUMMER SEASON	0.000334	1,018	1.67%
U.S. POPULATION - AUTUMN SEASON	0.000328	1,037	1.64%
U.S. POPULATION - WINTER SEASON	0.000342	994	1.71%
NORTHEAST REGION	0.000314	1,083	1.57%
NORTH CENTRAL REGION	0.000335	1,015	1.68%
SOUTHERN REGION	0.000330	1,030	1.65%
WESTERN REGION	0.000340	1,000	1.70%
HISPANICS	0.000312	1,090	1.56%
NON-HISPANIC WHITES	0.000326	1,043	1.63%
NON-HISPANIC BLACKS	0.000344	988	1.72%
NON-HISPANIC OTHER THAN BLACK OR WHITE	0.000391	870	1.96%
NURSING INFANTS (<1 YEAR OLD)	0.000132	2,576	0.66%
NON-NURSING INFANTS (<1 YEAR OLD)	0.000733	464	3.67%
FEMALES (13+/PREGNANT/NOT NURSING)	0.000252	1,349	1.26%
FEMALES (13+/NURSING)	0.000269	1,264	1.35%
CHILDREN (1-6 YEARS)	0.000957	355	4.79%
CHILDREN (7-12 YEARS)	0.000578	588	2.89%
MALES (13-19 YEARS)	0.000360	944	1.80%
FEMALES (13-19 YRS/NOT PREG. OR NURSING)	0.000278	1,223	1.39%
MALES (20+ YEARS)	0.000226	1,504	1.13%
FEMALES (20+ YEARS/NOT PREG. OR NURSING)	0.000203	1,675	1.01%

¹/ Margin of Safety = DPR NOEL/Dietary Exposure Dosage