



## **Estimated Daily Intake of L-Carnitine from Proposed and Permitted Food Uses of L-Carnitine or L-Carnitine L-Tartrate by the U.S. Population**

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## Estimated Daily Intake of L-Carnitine from Proposed and Permitted Food Uses of L-Carnitine or L-Carnitine L-Tartrate by the U.S. Population

### 1.0 INTRODUCTION

L-Carnitine from L-carnitine or L-carnitine L-tartrate is currently permitted for use in herbal teas, carbonated soft drinks, imitation and soy milks, health and breakfast bars, meal replacement bars, fruit juices, fruit-flavored drinks and ades, nectars, and energy and sports drinks, at levels ranging from 50 to 250 mg per serving. Cantox Health Sciences International has completed an additional assessment of the consumption of L-carnitine or L-carnitine L-tartrate in all permitted food categories using more recent food consumption data. In addition, it is proposed that the food uses of L-carnitine and L-carnitine L-tartrate be expanded to include instant coffee, milk and non milk-based meal replacement beverages, flavored milks and milk-based drinks, yogurt, yogurt drinks, and soft candy, chocolate, and hard candy. It also is proposed that higher use levels be permitted for the current food use of L-carnitine and L-carnitine L-tartrate in fruit-flavored drinks, energy and sports drinks, health and breakfast bars, meal replacement bars, and fruit juices.

L-carnitine is a purified, crystallized powder, whereas L-carnitine L-tartrate is the crystallized stable salt produced from the combination of Lonza's L-carnitine free base and food-grade equivalent L-tartaric acid, in a molar ratio of 2:1 (*i.e.*, approximately 68% L-carnitine and 32% L-tartaric acid). Estimates for the intake of L-carnitine were based on the permitted and proposed food uses of L-carnitine or L-carnitine L-tartrate and corresponding proposed use levels for L-carnitine in conjunction with food consumption data included in the National Center for Health Statistics' (NCHS) 2003-2004, 2005-2006 National Health and Nutrition Examination Surveys (NHANES) (CDC, 2006, 2009; USDA, 2009). Calculations for the mean and 90<sup>th</sup> percentile all-person and all-user intakes, and percent consuming were performed for each of the individual proposed and permitted food uses of L-carnitine or L-carnitine L-tartrate. Similar calculations were used to determine the estimated total intake of L-carnitine resulting from all proposed and permitted food uses of L-carnitine or L-carnitine L-tartrate combined. In both cases, the per person and per kilogram body weight intakes were reported for the following population groups:

- infants, ages 0 to 2;
- children, ages 3 to 11;
- female teenagers, ages 12 to 19;
- male teenagers, ages 12 to 19;

female adults, ages 20 and up;  
male adults, ages 20 and up; and  
total population (all age and gender groups combined).

## **2.0 FOOD AND DIETARY SUPPLEMENT CONSUMPTION SURVEY DATA**

### **2.1 Survey Description**

NHANES for the years 2003-2004 and 2005-2006 are available for public use. NHANES are conducted as a continuous, annual survey, and are released in 2-year cycles. Each year about 7,000 people from 15 different locations across the U.S. are interviewed, and approximately 5,000 complete the health examination component of the survey. Any combination of consecutive years of data collection is a nationally representative sample of the U.S. population. It is well established that the length of a dietary survey affects the estimated consumption of individual users and that short-term surveys, such as the typical 1-day dietary survey, overestimate consumption over longer time periods (Anderson, 1988). Because two 24-hour dietary recalls administered on 2 non-consecutive days (Day 1 and Day 2) are available from the NHANES 2003-2004, 2005-2006 survey, these data were used to generate estimates for the current intake analysis.

NHANES 2003-2004, 2005-2006 survey data were collected from individuals and households *via* 24-hour dietary recalls administered on 2 non-consecutive days (Day 1 and Day 2) throughout all 4 seasons of the year. Day 1 data were collected in-person, and Day 2 data were collected by telephone in the following 3 to 10 days, on different days of the week, to achieve the desired degree of statistical independence. The data were collected by first selecting Primary Sampling Units (PSUs), which were counties throughout the U.S., of which 15 PSUs are visited per year. Small counties were combined to attain a minimum population size. These PSUs were segmented and households were chosen within each segment. One or more participants within a household were interviewed. For NHANES 2003-2004 12,761 individuals were selected for the sample, 10,122 were interviewed (79.3%), and 9,643 were sampled (75.6%). For NHANES 2005-2006 12,862 individuals were selected for the sample, 10,348 were interviewed (80.4%), and 9,950 were sampled (77.4%).

In addition to collecting information on the types and quantities of foods being consumed, NHANES 2003-2004 and 2005-2006 collected socioeconomic, physiological and demographic information from individual participants in the survey, such as sex, age, height and weight, and other variables useful in characterizing consumption. The inclusion of this information allows for further assessment of food intake based on consumption by specific population groups of interest within the total population. Sample weights were incorporated with NHANES 2003-

2004 and 2005-2006 data to compensate for the potential under-representation of intakes from specific population groups as a result of sample variability due to survey design, differential non-response rates, or other factors, such as deficiencies in the sampling frame (CDC, 2006, 2009; USDA, 2009).

## **2.2 Statistical Methods**

Consumption data from individual dietary records, detailing food items ingested by each survey participant, were collated by computer and used to generate estimates for the intake of L-carnitine by the U.S. population. Estimates for the daily intake of L-carnitine from the consumption of L-carnitine or L-carnitine L-tartrate represent projected 2-day averages for each individual from Day 1 and Day 2 of NHANES 2003-2004 and 2005-2006 data; these average amounts comprised the distribution from which mean and percentile intake estimates were produced. Mean and percentile estimates were generated incorporating survey weights in order to provide representative intakes for the entire U.S. population. All-person intake refers to the estimated intake of L-carnitine averaged over all individuals surveyed, regardless of whether they potentially consumed food products containing L-carnitine or L-carnitine L-tartrate, and therefore includes “zero” consumers (those who reported no intake of food products containing L-carnitine during the 2 survey days). All-user intake refers to the estimated intake of L-carnitine by those individuals potentially consuming food products containing L-carnitine or L-carnitine L-tartrate, hence the “all-user” designation. Individuals were considered users if they consumed 1 or more food products containing L-carnitine or L-carnitine L-tartrate on either Day 1 or Day 2 of the survey.

## **2.3 Statistical Reliability**

Mean or percentile intake estimates based on small sample sizes or with high variability relative to the mean [assessed using the coefficient of variation (CV)] may be less statistically reliable than estimates based on adequate sample sizes or low variability relative to the mean (LSRO, 1995). Data presented herein for the estimated daily intake of L-carnitine from the consumption of L-carnitine or L-carnitine L-tartrate follow the guidelines proposed by the Human Nutrition Information Service/National Center for Health Statistics Analytic Working Group for evaluating the reliability of statistical estimates adopted in the “Third Report on Nutrition Monitoring in the United States”, whereby an estimated mean may be unreliable if the CV is equal to or greater than 30% (LSRO, 1995). The CV is the ratio of the estimated standard error of the mean to the estimated mean, expressed as a percentage (LSRO, 1995). Therefore, for the estimated intakes of L-carnitine from the consumption of L-carnitine or L-carnitine L-tartrate presented herein, values were considered statistically unreliable if the CV was equal to or greater than 30% or the sample size is less than 30 respondents. These values were not considered when

assessing the relative contribution of specific food uses to total L-carnitine consumption from L-carnitine or L-carnitine L-tartrate and are marked with an asterisk.

### 3.0 FOOD USAGE DATA

The individual proposed and permitted food uses for L-carnitine from L-carnitine or L-carnitine L-tartrate and proposed use levels employed in the current intake analysis are summarized in Table 3-1. Food codes representative of each proposed and permitted food use were chosen from the NHANES 2003-2006 (CDC, 2006, 2009; USDA, 2009). Food codes were grouped in food use categories according to Title 21, Section §170.3 of the Code of Federal Regulations (CFR, 2010a). Product-specific adjustment factors were developed based on data provided in the standard recipe file for the Continuing Survey of Food Intake by Individuals (CSFII) 1994-1996, 1998 survey (USDA, 2000). All food codes included in the current intake assessment are listed in Appendix C. The use levels presented in Table 3-1 represent the amount of L-carnitine expected to be present in the final food resulting from the addition of the L-carnitine or L-carnitine L-tartrate.

<b>Table 3-1 Summary of the Individual Permitted and Proposed Food Uses for L-Carnitine from L-Carnitine or L-Carnitine L-Tartrate in the U.S.</b>					
<b>Food Category</b>	<b>Food Use</b>	<b>Current GRAS Use Levels</b>		<b>New Proposed Use Levels</b>	
		<b>(mg/RACC)<sup>a</sup></b>	<b>(%)</b>	<b>(mg/RACC)<sup>a</sup></b>	<b>(%)</b>
Beverages and Beverage Bases	Carbonated Soft Drinks	250	0.10	500	0.21
	Energy and Sports Drinks	250	0.10	100	0.04
	Fruit-Flavored Drinks (RTD and Powdered)	50	0.02	250	0.10
	Non Milk-Based Meal Replacement Beverages	N/A	N/A	No Change	No Change
Coffee and Teas	Herbal Teas	250	0.10	No Change	No Change
	Instant Coffee	New	New	250	0.10
Dairy Product Analogs	Imitation and Soy Milks	250	0.10	No Change	No Change
Grain Products and Pastas	Health and Breakfast Bars	250	0.625	No Change	No Change
	Meal Replacement Bars	250	0.625	50	0.33
Hard Candy	Hard Candy	New	New	250	0.10
Milk Products	Flavored Milks and Milk-Based Drinks	New	New	250	0.10
	Milk-Based Meal Replacement Beverages	New	New	250	0.11
	Yogurt	New	New	250	0.10
	Yogurt Drinks	New	New	100	0.04



<b>Table 3-1 Summary of the Individual Permitted and Proposed Food Uses for L-Carnitine from L-Carnitine or L-Carnitine L-Tartrate in the U.S.</b>					
<b>Food Category</b>	<b>Food Use</b>	<b>Current GRAS Use Levels</b>		<b>New Proposed Use Levels</b>	
		<b>(mg/RACC)<sup>a</sup></b>	<b>(%)</b>	<b>(mg/RACC)<sup>a</sup></b>	<b>(%)</b>
Processed Fruits and Fruit Juices	Fruit Juice (RTD and Frozen Concentrates)	50	0.02	No Change	No Change
	Nectars	50	0.02	50	0.125
Soft Candy	Chocolate	New	New	50	0.125
	Soft Candy	New	New	50	0.125

GRAS = Generally Recognized as Safe; N/A = not applicable; NC = no change (*i.e.*, no change to permitted use levels for L-carnitine from L-carnitine or L-carnitine L-tartrate); RTD = ready-to-drink

<sup>a</sup> RACC – Reference amounts customarily consumed per eating occasion (21 CFR §101.12) (CFR, 2010b).

## 4.0 FOOD SURVEY RESULTS

Estimates for the total daily intakes of L-carnitine from all proposed and permitted food uses of L-carnitine or L-carnitine L-tartrate are provided in Tables 4.1-1 and 4.1-2. Estimates for the daily intake of L-carnitine from individual proposed and permitted food uses in the U.S. are summarized in Tables A-1 to A-7 and B-1 to B-7 of Appendices A and B, respectively. Tables A-1 to A-7 provide estimates for the daily intake of L-carnitine per person (mg/person/day), whereas Tables B-1 to B-7 provide estimates for the daily intake of L-carnitine on a per kilogram body weight basis (mg/kg body weight/day).

### 4.1 Estimated Daily Intake of L-Carnitine from All Proposed and Permitted Food Uses of L-Carnitine or L-Carnitine L-Tartrate

The estimated total intake of L-carnitine from all proposed and permitted food uses of L-carnitine or L-carnitine L-tartrate in the U.S. by population group is summarized in Table 4.1-1. Table 4.1-2 presents these data on a per kilogram body weight basis. Approximately 92.5% of the total U.S. population was identified as potential consumers of L-carnitine from the permitted and proposed food uses of L-carnitine or L-carnitine L-tartrate (15,435 actual users identified). Consumption of these types of foods by the total U.S. population resulted in estimated mean all-person and all-user intakes of L-carnitine of 598 mg/person/day (9.6 mg/kg body weight/day) and 636 mg/person/day (10.2 mg/kg body weight/day), respectively. The 90<sup>th</sup> percentile all-person and all-user intakes of L-carnitine from all proposed and permitted food-uses of L-carnitine or L-carnitine L-tartrate by the total population were 1,323 mg/person/day (21.6 mg/kg body weight/day) and 1,357 mg/person/day (22.2 mg/kg body weight/day), respectively.

On an individual population basis, the greatest mean all-person and all-user intakes of L-carnitine on an absolute basis were determined to occur in male teenagers at 939 and 958 mg/person/day, respectively. Infants displayed the lowest mean all-person and all-user L-carnitine intake estimates with values of 173 and 234 mg/person/day, respectively. On a body weight basis, the highest estimates for the mean all-person intakes were observed to occur in children at 16.1 mg/kg body weight/day, while the highest estimated all-user intakes were observed to occur in infants at 18.9 mg/kg body weight/day.

**Table 4.1-1 Summary of the Estimated Daily Intake of L-Carnitine from All Permitted and Proposed Food Uses of L-Carnitine or L-Carnitine L-Tartrate in the U.S. by Population Group (NHANES 2003-2004, 2005-2006)**

Population Group	Age Group (Years)	% Users	Actual # of Total Users	All-Person Consumption		All-User Consumption	
				Mean (mg)	90 <sup>th</sup> Percentile (mg)	Mean (mg)	90 <sup>th</sup> Percentile (mg)
Infants	0 to 2	67	1,284	173	434	234	493
Children	3 to 11	99	2,701	444	890	453	900
Female Teenagers	12 to 19	98	1,951	576	1,145	587	1,150
Male Teenagers	12 to 19	99	1,910	939	1,854	958	1,854
Female Adults	20 and up	94	4,018	510	1,174	544	1,213
Male Adults	20 and up	93	3,571	748	1,690	798	1,732
Total Population	All ages	93	15,435	598	1,323	636	1,357

When heavy consumers (90<sup>th</sup> percentile) were assessed, all-person and all-user intakes of L-carnitine from all proposed and permitted food-uses of L-carnitine or L-carnitine L-tartrate were again determined to be greatest in male teenagers at 1,854 mg/person/day, respectively. The lowest 90<sup>th</sup> percentile all-person and all-user intakes occurred in infants at 434 and 493 mg/person/day, respectively, on an absolute basis. On a body weight basis, infants were determined to have the greatest all-person and all-user 90<sup>th</sup> percentile intakes of L-carnitine at 33.4 and 38.3 mg/kg body weight/day, respectively. Female adults were identified as having the lowest mean and 90<sup>th</sup> percentile all-user intakes of L-carnitine at 7.5 and 16.9 mg/kg body weight/day, respectively.

**Table 4.1-2 Summary of the Estimated Daily Per Kilogram Body Weight Intake of L-Carnitine from All Permitted and Proposed Food Uses of L-Carnitine or L-Carnitine L-Tartrate in the U.S. by Population Group (NHANES 2003-2004, 2005-2006)**

Population Group	Age Group (Years)	% Users	Actual # of Total Users	All-Person Consumption		All-User Consumption	
				Mean (mg/kg bw)	90 <sup>th</sup> Percentile (mg/kg bw)	Mean (mg/kg bw)	90 <sup>th</sup> Percentile (mg/kg bw)
Infants	0 to 2	67	1,284	14.0	33.4	18.9	38.3
Children	3 to 11	99	2,701	16.1	31.0	16.4	31.1
Female Teenagers	12 to 19	98	1,951	9.7	20.3	9.9	20.6
Male Teenagers	12 to 19	99	1,910	14.1	27.6	14.4	27.7
Female Adults	20 and up	94	4,018	7.0	16.5	7.5	16.9
Male Adults	20 and up	93	3,571	8.7	19.0	9.3	19.6
Total Population	All ages	93	15,435	9.6	21.6	10.2	22.2

## 4.2 Estimated Daily Intake of L-Carnitine from All Individual Proposed and Permitted Food Uses of L-Carnitine or L-Carnitine L-Tartrate

### 4.2.1 All-Person Intakes

Estimates for the mean and 90<sup>th</sup> percentile daily intakes of L-carnitine from each individual proposed and permitted food use of L-carnitine or L-carnitine L-tartrate are summarized in Tables A-1 to A-7 and B-1 to B-7 on a mg/person/day and mg/kg body weight/day basis, respectively. Tables A-7 and B-7 summarize the estimates for the mean all-person intakes of L-carnitine by the total population (all ages) from each of the individual proposed and permitted food uses of L-carnitine or L-carnitine L-tartrate on a mg/person/day and mg/kg body weight/day basis, respectively. The total U.S. population was identified as being significant consumers of carbonated soft drinks (62.9% users), fruit juices (44.1% users), and fruit-flavored drinks (37.7% users).

Consumption of carbonated soft drinks and energy and sports drinks provided the largest mean all-person intakes of L-carnitine at 387 (5.5 mg/kg body weight/day) and 54 mg/person/day (0.9mg/kg body weight/day), respectively. The highest 90<sup>th</sup> percentile all-person intakes were determined to occur from the consumption of carbonated soft drinks and fruit-flavored drinks at 1,016 (14 mg/kg body weight/day) and 129 (2.5 mg/kg body weight/day) mg/person/day, respectively.

Of the individual population groups, the consumption of carbonated soft drinks by children, male and female teenagers, and male and female adults, and the consumption of fruit juices by

infants resulted in the highest mean all-person intakes of L-carnitine (Tables A-1 to A-6 and Tables B-1 to B-6). The consumption of fruit juices by infants, flavored milks in children, energy and sport drinks in male teenagers, and carbonated soft drinks by female teenagers and male and female adults resulted in the highest 90<sup>th</sup> percentile all-person intakes of L-carnitine.

The highest mean and 90<sup>th</sup> percentile all-person intakes of L-carnitine were reported in male teenagers consuming carbonated soft drinks and energy and sport drinks, respectively, at 555 mg/person/day (8.2 mg/kg body weight/day) and 1,174 mg/person/day (17.1 mg/kg body weight/day), respectively. On a body weight basis, consumption of fruit juices by infants led to the highest mean and 90<sup>th</sup> percentile all-person intakes of L-carnitine (4.5 and 13.2 mg/kg body weight/day, respectively).

#### 4.2.2 All-User Intakes

Tables A-7 and B-7 also summarize the estimates for the mean all-user intakes of L-carnitine by the total population (all ages) from each individual food use on a mg/person/day and mg/kg body weight/day basis, respectively. For all-user intakes, the contribution of each food use to the overall intake is a function of both the estimated intake of L-carnitine resulting from the consumption of the food, as well as the percentage of users identified as consumers of the food. For example, for the total population, the consumption of milk-based meal replacement beverages resulted in an estimated mean all-user L-carnitine intake of 319 mg/person/day; however, only 202 users (1.2% of the total population) of milk-based meal replacement beverages were identified. As a result, the contribution of this food use to the mean all-user intake of L-carnitine was not as important as the contribution of carbonated soft drinks with a mean all-user intake estimate of 579 mg/person/day in 10,498 users (62.9% of the total population).

Consumption of carbonated soft drinks provided the largest mean and 90<sup>th</sup> percentile all-user intake of L-carnitine at 579 mg/person/day (8.2 mg/kg body weight/day) and 1,242 mg/person/day (17.2 mg/kg body weight/day), respectively. In addition, high mean and 90<sup>th</sup> percentile all-user intakes of L-carnitine resulted from the consumption of fruit-flavored drinks (131 and 282 mg/person/day, respectively), energy and sport drinks (803 and 1,557 mg/person/day, respectively), and fruit juices (99 and 188 mg/person/day, respectively). On a body weight basis, mean and 90<sup>th</sup> percentile all-user intakes for fruit-flavored drinks were 2.6 and 5.4 mg/kg body weight/day, for energy and sport drinks were 13.6 and 27.4 mg/kg body weight/day, and for fruit juices were 2.3 and 4.9 mg/kg body weight/day, respectively.

On an individual population group basis, the most significant contribution to the mean and 90<sup>th</sup> percentile all-user intakes of L-carnitine were determined in children, male and female teenagers, and male and female adults consuming carbonated soft drinks (Tables A-1 to A-6

and Tables B-1 to B-6). Male teenagers consuming carbonated soft drinks made the largest contribution to the mean all-user intakes of L-carnitine at 670 mg/person/day (9.9 mg/kg body weight/day), while male adults consuming carbonated soft drinks made the largest contribution to the 90<sup>th</sup> percentile all-user intakes of L-carnitine at 1,530 mg/person/day (16.9 mg/kg body weight/day), respectively. On a per kilogram body weight basis, infants consuming energy and sport drinks were determined to have the highest mean and 90<sup>th</sup> percentile all-user intakes of L-carnitine at 40.5 and 106.8 mg/kg body weight/day, respectively.

The estimated intakes of L-carnitine were considered statistically unreliable if the CV was equal to or greater than 30% or the sample size was less than 30 individuals. Assessing the CV for all-user intake estimates found the intake for yogurt drinks to be statistically unreliable in all population groups (as zero users were identified in the children, and male and female teenager populations groups, and a low number of users were identified in the infant, and male and female adult population groups). Imitation and soy milks, and meal replacement beverages (both milk- and non milk-based) also had a low number of identified users in the infant, children, and male and female teenager population groups. Meal replacement bars were statistically unreliable in the infant, children, and male teenager population groups due to the low number of potential users identified. In addition, herbal teas and nectars had a low number of identified users in the infant, children, and male teenager population groups, and in the male and female teenager population groups, respectively. Hard candy also was statistically unreliable in the female teenager population group.

#### **4.3 Estimated Daily Intake of Tartaric Acid from All Proposed and Permitted Food Uses of L-Carnitine L-Tartrate**

L-Carnitine L-tartrate is composed of 68% L-carnitine and 32% L-tartaric acid. Estimated L-carnitine intake values summarized in Table 4.1-1 above were used to calculate the exposure to L-tartaric acid from the proposed and permitted food uses of L-carnitine L-tartrate on a body weight basis. The estimated intake of L-tartaric acid on a per person and a body weight basis is summarized in Tables 4.3-1 and 4.3-2, respectively.

On an all-absolute basis, the mean intake and 90<sup>th</sup> percentile all-user intakes of L-tartaric acid by the total population from all proposed and permitted food uses were estimated to be 309 and 658 mg/person/day. On an individual population basis, male teenagers were determined to have the highest mean and 90<sup>th</sup> percentile all-user intakes of L-tartaric acid at 453 and 874 mg/person/day, respectively.

**Table 4.3-1 Summary of the Estimated Daily Intake of L-Tartaric Acid from All Proposed and Permitted Food Uses of L-Carnitine L-Tartrate in the U.S. by Population Group (NHANES 2003-2004, 2005-2006)**

Population Group	Age Group (Years)	% Users	Actual # of Total Users	All-Person Consumption		All-Users Consumption	
				Mean (mg)	90 <sup>th</sup> Percentile (mg)	Mean (mg)	90 <sup>th</sup> Percentile (mg)
Infants	0-2	67	1,284	82	204	110	233
Children	3-11	99	2,701	209	419	213	424
Female Teenagers	12-19	98	1,951	274	548	278	551
Male Teenagers	12-19	99	1,910	444	873	453	874
Female Adults	20 and Up	94	4,018	256	581	269	586
Male Adults	20 and Up	93	3,571	368	814	389	834
Total Population	All Ages	93	15,435	293	640	309	658

**Table 4.3-2 Summary of the Estimated Daily Per Kilogram Body Weight Intake of L-Tartaric Acid from All Proposed and Permitted Food Uses of L-Carnitine L-Tartrate in the U.S. by Population Group (NHANES 2003-2004, 2005-2006)**

Population Group	Age Group (Years)	% Users	Actual # of Total Users	All-Person Consumption		All-Users Consumption	
				Mean (mg/kg)	90 <sup>th</sup> Percentile (mg/kg)	Mean (mg/kg)	90 <sup>th</sup> Percentile (mg/kg)
Infants	0-2	67	1,284	6.6	15.7	8.9	18.0
Children	3-11	99	2,701	7.6	14.6	7.7	14.6
Female Teenagers	12-19	98	1,951	4.6	9.6	4.7	9.7
Male Teenagers	12-19	99	1,910	6.7	13.0	6.8	13.1
Female Adults	20 and Up	94	4,018	3.5	8.0	3.7	8.2
Male Adults	20 and Up	93	3,571	4.3	9.2	4.6	9.4
Total Population	All Ages	93	15,435	4.7	10.3	4.9	10.6

On an all-user basis, the mean intake of L-tartaric acid by the total population from all proposed and permitted food uses was estimated to be 4.9 mg/kg body weight/day. The heavy consumer (90<sup>th</sup> percentile) all-user intake of L-tartaric acid by the total population from all proposed and permitted food uses was determined to be 10.6 mg/kg body weight/day. Infants were determined to have the greatest mean and 90<sup>th</sup> percentile all-user intakes of L-tartaric acid at 8.9 and 18.0 mg/kg body weight/day, respectively.

## 5.0 CONCLUSIONS

Consumption data and information pertaining to the individual proposed and permitted food uses of L-carnitine and L-carnitine L-tartrate were used to estimate the all-person and all-user intakes of L-carnitine for specific demographic groups and for the total U.S. population. This type of intake methodology is generally considered to be 'worst case' as a result of several conservative assumptions made in the consumption estimates. For example, it is often assumed that all food products within a food category contain the ingredient at the maximum specified level of use. In addition, it is well established that the length of a dietary survey affects the estimated consumption of individual users. Short-term surveys, such as the typical 2- or 3-day dietary surveys, overestimate the consumption of food products that are consumed relatively infrequently.

In summary, on an all-user basis, the mean all-user intakes of L-carnitine by the total U.S. population from all proposed and permitted food uses of L-carnitine or L-carnitine L-tartrate was estimated to be 598 mg/person/day or 9.6 mg/kg body weight/day. The heavy consumer (90<sup>th</sup> percentile) all-user intakes of L-carnitine by the total U.S. population from all proposed and permitted food uses of L-carnitine or L-carnitine L-tartrate was estimated to be 1,357 mg/person/day or 22.2 mg/kg body weight/day. Given that L-carnitine L-tartrate is composed of 68% L-carnitine and 32% L-tartaric acid, the corresponding mean and 90<sup>th</sup> percentile all-user intakes of L-tartaric acid from the consumption of all proposed and permitted food uses of L-carnitine L-tartrate, on a body weight basis, was estimated to be 4.9 and 10.6 mg/kg body weight/day, respectively.

## 6.0 REFERENCES

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## **APPENDIX A**

**Estimated Daily Intake of L-Carnitine from Individual Proposed Food Uses of L-Carnitine  
or L-Carnitine L-Tartrate by Different Population Groups Within the United States**

**Table A-1 Estimated Daily Intake of L-Carnitine from Individual Proposed and Permitted Food Uses of L-Carnitine or L-Carnitine L-Tartrate by Infants (Aged 0 to 2 Years) Within the United States (2003-2004, 2005-2006 NHANES Data)**

Food Use Category	% Users	Actual # of Total Users	All-Person Consumption		All-User Consumption	
			Mean (mg)	90 <sup>th</sup> Percentile (mg)	Mean (mg)	90 <sup>th</sup> Percentile (mg)
<u>Beverages and Beverage Bases</u>						
Carbonated Soft Drinks	20.2	388	21	62	114	261
Energy and Sports Drinks	3.5	66	22	na	502	1,250
Fruit-Flavored Drinks (RTD and Powdered)	27.9	533	27	87	93	182
Non Milk-Based Meal Replacement Beverages	0.2	4	<1*	na*	147*	180*
<u>Coffee and Teas</u>						
Herbal Teas	1.0	20	<1*	na	50*	89*
<u>Dairy Product Analogs</u>						
Imitation and Soy Milks	1.0	20	5*	na	342*	780*
<u>Grain Products and Pastas</u>						
Health and Breakfast Bars	2.6	50	5	na	129	231
Meal Replacement Bars	0.1	1	<1*	na	27*	27*
<u>Hard Candy</u>						
Hard Candy	9.2	176	2	na	25	70
<u>Milk Products</u>						
Flavored Milks and Milk-Based Drinks	8.1	156	13	na	140	471
Milk-Based Meal Replacement Beverages	0.2	3	<1*	na	57*	129*
Yogurt	14.7	281	17	67	84	152
Yogurt Drinks	0.1	1	<1*	na	314*	314*
<u>Processed Fruits and Fruit Juices</u>						
Fruit Juices (RTD and Frozen Concentrates)	48.8	935	55	155	102	207
Nectars	1.6	31	<1	na	25	61
<u>Soft Candy</u>						
Chocolate	8.3	159	1	<1	12	26
Soft Candy	11.9	228	3	8	18	38

na = not applicable; RTD = ready to drink

\*Indicates an intake estimate that may not be statistically reliable, as the CV of the mean is equal to or greater than 30% or fewer than 30 users were identified (see Section 2.3).

**Table A-2 Estimated Daily Intake of L-Carnitine from Individual Proposed and Permitted Food Uses of L-Carnitine or L-Carnitine L-Tartrate by Children (Aged 3 to 11 Years) Within the United States (2003-2004, 2005-2006 NHANES Data)**

Food Use Category	% Users	Actual # of Total Users	All-Person Consumption		All-User Consumption	
			Mean (mg)	90 <sup>th</sup> Percentile (mg)	Mean (mg)	90 <sup>th</sup> Percentile (mg)
<u>Beverages and Beverage Bases</u>						
Carbonated Soft Drinks	60.8	1,664	174	453	287	601
Energy and Sports Drinks	8.1	222	57	94	557	1,047
Fruit-Flavored Drinks (RTD and Powdered)	60.1	1,642	56	155	107	211
Non Milk-Based Meal Replacement Beverages	0.3	7	<1*	na	126*	164*
<u>Coffee and Teas</u>						
Herbal Teas	0.8	22	1*	na	146*	311*
<u>Dairy Product Analogs</u>						
Imitation and Soy Milks	1.0	26	3*	na	217*	490*
<u>Grain Products and Pastas</u>						
Health and Breakfast Bars	4.9	135	10	na	130	226
Meal Replacement Bars	0.3	8	1*	na	188*	266*
<u>Hard Candy</u>						
Hard Candy	17.6	480	7	23	36	77
<u>Milk Products</u>						
Flavored Milks and Milk-Based Drinks	31.6	864	57	227	177	325
Milk-Based Meal Replacement Beverages	0.4	10	1*	na	206*	434*
Yogurt	13.5	368	15	64	99	187
Yogurt Drinks	0	0	na	na	na	na
<u>Processed Fruits and Fruit Juices</u>						
Fruit Juices (RTD and Frozen Concentrates)	62.7	1,713	51	137	87	171
Nectars	1.6	45	<1	na	27	45
<u>Soft Candy</u>						
Chocolate	19.8	542	5	22	24	51
Soft Candy	26.9	735	6	17	20	44

na = not applicable; RTD = ready-to-drink

\*Indicates an intake estimate that may not be statistically reliable, as the CV of the mean is equal to or greater than 30% or fewer than 30 users were identified (see Section 2.3).

**Table A-3 Estimated Daily Intake of L-Carnitine from Individual Proposed and Permitted Food Uses of L-Carnitine or L-Carnitine L-Tartrate by Female Teenagers (Aged 12 to 19 Years) Within the United States (2003-2004, 2005-2006 NHANES Data)**

Food Use Category	% Users	Actual # of Total Users	All-Person Consumption		All-User Consumption	
			Mean (mg)	90 <sup>th</sup> Percentile (mg)	Mean (mg)	90 <sup>th</sup> Percentile (mg)
<u>Beverages and Beverage Bases</u>						
Carbonated Soft Drinks	74.3	1,477	376	893	494	990
Energy and Sports Drinks	7.4	148	44	na	568	1,017
Fruit-Flavored Drinks (RTD and Powdered)	47.9	950	50	159	129	276
Non Milk-Based Meal Replacement Beverages	0.3	5	<1*	na	241*	679*
<u>Coffee and Teas</u>						
Herbal Teas	1.7	33	3	na	157	311
<u>Dairy Product Analogs</u>						
Imitation and Soy Milks	0.8	15	3*	na	320*	605*
<u>Grain Products and Pastas</u>						
Health and Breakfast Bars	12.4	247	12	na	130	231
Meal Replacement Bars	6.3	125	2	na	192	213
<u>Hard Candy</u>						
Hard Candy	0.7	13	3*	5*	28*	69*
<u>Milk Products</u>						
Flavored Milks and Milk-Based Drinks	15.7	313	21	65	165	319
Milk-Based Meal Replacement Beverages	0.7	13	3*	na	256*	290*
Yogurt	6.6	131	9	na	125	218
Yogurt Drinks	0	0	na	na	na	na
<u>Processed Fruits and Fruit Juices</u>						
Fruit Juices (RTD and Frozen Concentrates)	44.2	877	39	129	98	188
Nectars	1.2	24	<1*	na	38*	61*
<u>Soft Candy</u>						
Chocolate	22.7	453	8	31	32	65
Soft Candy	20.8	416	5	16	24	53

na = not applicable; RTD = ready-to-drink

\*Indicates an intake estimate that may not be statistically reliable, as the CV of the mean is equal to or greater than 30% or fewer than 30 users were identified (see Section 2.3).

**Table A-4 Estimated Daily Intake of L-Carnitine from Individual Proposed and Permitted Food Uses of L-Carnitine or L-Carnitine L-Tartrate by Male Teenagers (Aged 12 to 19 Years) Within the United States (2003-2004, 2005-2006 NHANES Data)**

Food Use Category	% Users	Actual # of Total Users	All-Person Consumption		All-User Consumption	
			Mean (mg)	90 <sup>th</sup> Percentile (mg)	Mean (mg)	90 <sup>th</sup> Percentile (mg)
<u>Beverages and Beverage Bases</u>						
Carbonated Soft Drinks	80.1	1,555	555	1,174	671	1,256
Energy and Sports Drinks	14.6	282	62	213	162	334
Fruit-Flavored Drinks (RTD and Powdered)	46.2	898	193	656	1,014	2,000
Non Milk-Based Meal Replacement Beverages	0.6	12	3*	na	412*	582*
<u>Coffee and Teas</u>						
Herbal Teas	1.2	23	3*	na	190*	296*
<u>Dairy Product Analogs</u>						
Imitation and Soy Milks	0.5	9	1*	na	206*	315*
<u>Grain Products and Pastas</u>						
Health and Breakfast Bars	4.2	82	9	na	166	269
Meal Replacement Bars	0.8	15	1*	na	183*	203*
<u>Hard Candy</u>						
Hard Candy	9.4	182	3	na	32	70
<u>Milk Products</u>						
Flavored Milks and Milk-Based Drinks	17.8	345	39	130	229	456
Milk-Based Meal Replacement Beverages	0.6	11	1*	na	254*	532*
Yogurt	3.7	72	8	na	149	278
Yogurt Drinks	0	0	na	na	na	na
<u>Processed Fruits and Fruit Juices</u>						
Fruit Juices (RTD and Frozen Concentrates)	44.6	865	47	155	124	255
Nectars	1.2	24	<1*	na	37*	62*
<u>Soft Candy</u>						
Chocolate	18.7	362	7	28	34	65
Soft Candy	18.8	364	6	16	32	59

na = not applicable; RTD = ready-to-drink

\*Indicates an intake estimate that may not be statistically reliable, as the CV of the mean is equal to or greater than 30% or fewer than 30 users were identified (see Section 2.3).

**Table A-5 Estimated Daily Intake of L-Carnitine from Individual Proposed and Permitted Food Uses of L-Carnitine or L-Carnitine L-Tartrate by Female Adults (Aged 20 Years and Over) Within the United States (2003-2004, 2005-2006 NHANES Data)**

Food Use Category	% Users	Actual # of Total Users	All-Person Consumption		All-User Consumption	
			Mean (mg)	90 <sup>th</sup> Percentile (mg)	Mean (mg)	90 <sup>th</sup> Percentile (mg)
<u>Beverages and Beverage Bases</u>						
Carbonated Soft Drinks	63.7	2,729	352	950	537	1,177
Energy and Sports Drinks	2.4	103	15	na	683	1,875
Fruit-Flavored Drinks (RTD and Powdered)	28.7	1,228	31	113	121	250
Non Milk-Based Meal Replacement Beverages	1.2	54	4	na	282	485
<u>Coffee and Teas</u>						
Herbal Teas	5.4	228	13	na	274	500
<u>Dairy Product Analogs</u>						
Imitation and Soy Milks	2.7	115	6	na	188	440
<u>Grain Products and Pastas</u>						
Health and Breakfast Bars	7.5	318	9	na	152	265
Meal Replacement Bars	4.9	210	5	na	227	469
<u>Hard Candy</u>						
Hard Candy	1.7	73	2	na	33	70
<u>Milk Products</u>						
Flavored Milks and Milk-Based Drinks	6.3	270	13	na	197	367
Milk-Based Meal Replacement Beverages	2.3	99	8	na	292	532
Yogurt	10.9	469	13	62	115	194
Yogurt Drinks	<0.1	1	<1*	na	181*	181*
<u>Processed Fruits and Fruit Juices</u>						
Fruit Juices (RTD and Frozen Concentrates)	38.2	1,637	29	103	89	165
Nectars	1.5	62	<1	na	29	75
<u>Soft Candy</u>						
Chocolate	23.9	1,023	7	27	26	54
Soft Candy	10.5	447	2	1	19	49

na = not applicable; RTD = ready-to-drink

\*Indicates an intake estimate that may not be statistically reliable, as the CV of the mean is equal to or greater than 30% or fewer than 30 users were identified (see Section 2.3).

**Table A-6 Estimated Daily Intake of L-Carnitine from Individual Proposed and Permitted Food Uses of L-Carnitine or L-Carnitine L-Tartrate by Male Adults (Aged 20 Years and Over) Within the United States (2003-2004, 2005-2006 NHANES Data)**

Food Use Category	% Users	Actual # of Total Users	All-Person Consumption		All-User Consumption	
			Mean (mg)	90 <sup>th</sup> Percentile (mg)	Mean (mg)	90 <sup>th</sup> Percentile (mg)
<u>Beverages and Beverage Bases</u>						
Carbonated Soft Drinks	70.1	2,685	522	1294	720	1,530
Energy and Sports Drinks	7.9	302	78	na	917	1875
Fruit-Flavored Drinks (RTD and Powdered)	27.1	1,038	38	122	160	334
Non Milk-Based Meal Replacement Beverages	1.8	67	7	na	388	861
<u>Coffee and Teas</u>						
Herbal Teas	2.8	106	9	na	370	607
<u>Dairy Product Analogs</u>						
Imitation and Soy Milks	1.6	62	4	na	205	452
<u>Grain Products and Pastas</u>						
Health and Breakfast Bars	5.8	221	10	na	159	269
Meal Replacement Bars	4.0	154	4	na	241	406
<u>Hard Candy</u>						
Hard Candy	1.2	46	2	na	34	80
<u>Milk Products</u>						
Flavored Milks and Milk-Based Drinks	5.8	222	13	na	216	471
Milk-Based Meal Replacement Beverages	1.7	66	7	na	379	907
Yogurt	5.4	205	8	na	121	219
Yogurt Drinks	0.1	2	<1*	na	294*	510*
<u>Processed Fruits and Fruit Juices</u>						
Fruit Juices (RTD and Frozen Concentrates)	34.5	1,328	36	120	113	207
Nectars	1.2	45	<1	na	36	66
<u>Soft Candy</u>						
Chocolate	19.8	754	7	28	35	71
Soft Candy	8.0	306	3	na	33	77

na = not applicable; RTD = ready-to-drink

\*Indicates an intake estimate that may not be statistically reliable, as the CV of the mean is equal to or greater than 30% or fewer than 30 users were identified (see Section 2.3).

**Table A-7 Estimated Daily Intake of L-Carnitine from Individual Proposed and Permitted Food Uses of L-Carnitine or L-Carnitine L-Tartrate by the Total Population (All Ages) Within the United States (2003-2004, 2005-2006 NHANES Data)**

Food Use Category	% Users	Actual # of Total Users	All-Person Consumption		All-User Consumption	
			Mean (mg)	90 <sup>th</sup> Percentile (mg)	Mean (mg)	90 <sup>th</sup> Percentile (mg)
<u>Beverages and Beverage Bases</u>						
Carbonated Soft Drinks	62.9	10,498	387	1,016	579	1,242
Energy and Sports Drinks	6.7	1,123	54	na	803	1557
Fruit-Flavored Drinks (RTD and Powdered)	37.7	6,289	39	129	131	282
Non Milk-Based Meal Replacement Beverages	0.9	149	4	na	335	590
<u>Coffee and Teas</u>						
Herbal Teas	2.6	432	8	na	288	500
<u>Dairy Product Analogs</u>						
Imitation and Soy Milks	1.5	247	4	na	203	482
<u>Grain Products and Pastas</u>						
Health and Breakfast Bars	4.5	756	9	na	149	269
Meal Replacement Bars	0.9	156	4	na	228	417
<u>Hard Candy</u>						
Hard Candy	9.7	1624	3	na	33	70
<u>Milk Products</u>						
Flavored Milks and Milk-Based Drinks	13.0	2,170	21	11	192	365
Milk-Based Meal Replacement Beverages	1.2	202	6	na	319	626
Yogurt	9.1	1,526	11	na	112	202
Yogurt Drinks	<0.1	4	<1*	na	280*	510*
<u>Processed Fruits and Fruit Juices</u>						
Fruit Juices (RTD and Frozen Concentrates)	44.1	7,355	37	119	99	188
Nectars	1.4	231	<1	na	32	62
<u>Soft Candy</u>						
Chocolate	19.8	3,293	7	27	29	63
Soft Candy	15.0	2,496	3	6	24	53

na = not applicable; RTD = ready-to-drink

\*Indicates an intake estimate that may not be statistically reliable, as the CV of the mean is equal to or greater than 30% or fewer than 30 users were identified (see Section 2.3).



## **APPENDIX B**

**Estimated Daily per Kilogram Body Weight Intake of L-Carnitine from Individual  
Proposed and Permitted Food Uses of L-Carnitine or L-Carnitine L-Tartrate by Different  
Population Groups Within the United States**

**Table B-1 Estimated Daily per Kilogram Body Weight Intake of L-Carnitine from Individual Proposed and Permitted Food Uses of L-Carnitine or L-Carnitine L-Tartrate by Infants (Aged 0 to 2 Years) Within the United States (2003-2004, 2005-2006 NHANES Data)**

Food Use Category	% Users	Actual # of Total Users	All-Person Consumption (mg/kg)		All-User Consumption (mg/kg)	
			Mean	90 <sup>th</sup> Percentile	Mean	90 <sup>th</sup> Percentile
<u>Beverages and Beverage Bases</u>						
Carbonated Soft Drinks	20.2	388	1.6	4.5	8.7	19.3
Energy and Sports Drinks	3.5	66	1.8	na	40.5	106.8
Fruit-Flavored Drinks (RTD and Powdered)	27.9	533	2.1	6.7	7.2	15.3
Non Milk-Based Meal Replacement Beverages	0.2	4	<0.1*	na	10.8*	15.1*
<u>Coffee and Teas</u>						
Herbal Teas	1.0	20	<0.1*	na	5.0*	9.1*
<u>Dairy Product Analogs</u>						
Imitation and Soy Milks	1.0	20	0.4*	na	29.1*	72.4*
<u>Grain Products and Pastas</u>						
Health and Breakfast Bars	2.6	50	0.4	na	10.7	21.0
Meal Replacement Bars	0.1	1	<0.1*	na	2.3*	2.3*
<u>Hard Candy</u>						
Hard Candy	9.2	176	0.2	na	1.9	5.3
<u>Milk Products</u>						
Flavored Milks and Milk-Based Drinks	8.1	156	1.1	na	11.2	41.3
Milk-Based Meal Replacement Beverages	0.2	3	<0.1*	na	4.6*	10.7*
Yogurt	14.7	281	1.5	5.9	7.2	12.6
Yogurt Drinks	0.1	1	<0.1*	na	27.3*	27.3*
<u>Processed Fruits and Fruit Juices</u>						
Fruit Juices (RTD and Frozen Concentrates)	48.8	935	4.5	13.2	8.4	17.8
Nectars	1.6	31	<0.1	na	1.9	3.3
<u>Soft Candy</u>						
Chocolate	8.3	159	0.1	0.0	0.9	1.9
Soft Candy	11.9	228	0.2	0.7	1.4	3.1

na = not applicable; RTD = ready-to-drink

\*Indicates an intake estimate that may not be statistically reliable, as the CV of the mean is equal to or greater than 30% or fewer than 30 users were identified (see Section 2.3).

**Table B-2 Estimated Daily per Kilogram Body Weight Intake of L-Carnitine from Individual Proposed and Permitted Food Uses of L-Carnitine or L-Carnitine L-Tartrate by Children (Aged 3 to 11 Years) Within the United States (2003-2004, 2005-2006 NHANES Data)**

Food Use Category	% Users	Actual # of Total Users	All-Person Consumption (mg/kg)		All-User Consumption (mg/kg)	
			Mean	90 <sup>th</sup> Percentile	Mean	90 <sup>th</sup> Percentile
<u>Beverages and Beverage Bases</u>						
Carbonated Soft Drinks	60.8	1,664	5.8	15.5	9.6	19.0
Energy and Sports Drinks	8.1	222	1.8	3.3	17.8	32.9
Fruit-Flavored Drinks (RTD and Powdered)	60.1	1,642	2.2	6.1	4.1	8.0
Non Milk-Based Meal Replacement Beverages	0.3	7	<0.1*	na	8.6*	13.7*
<u>Coffee and Teas</u>						
Herbal Teas	0.8	22	<0.1*	na	5.4*	11.5*
<u>Dairy Product Analogs</u>						
Imitation and Soy Milks	1.0	26	0.1*	na	9.4*	19.8*
<u>Grain Products and Pastas</u>						
Health and Breakfast Bars	4.9	135	0.4	na	5.3	9.6
Meal Replacement Bars	0.3	8	<0.1*	na	6.1*	8.1*
<u>Hard Candy</u>						
Hard Candy	17.6	480	0.3	0.9	1.4	3.1
<u>Milk Products</u>						
Flavored Milks and Milk-Based Drinks	31.6	864	2.1	7.5	6.5	13.5
Milk-Based Meal Replacement Beverages	0.4	10	<0.1*	na	7.7*	20.6*
Yogurt	13.5	368	0.6	2.4	4.3	7.8
Yogurt Drinks	0	0	na	na	na	na
<u>Processed Fruits and Fruit Juices</u>						
Fruit Juices (RTD and Frozen Concentrates)	62.7	1,713	2.2	6.2	3.8	8.1
Nectars	1.6	45	<0.1	na	1.3	2.6
<u>Soft Candy</u>						
Chocolate	19.8	542	0.2	0.7	0.9	1.8
Soft Candy	26.9	735	0.2	0.8	0.8	2.0

na = not applicable

\*Indicates an intake estimate that may not be statistically reliable, as the CV of the mean is equal to or greater than 30% or fewer than 30 users were identified (see Section 2.3).

**Table B-3 Estimated Daily per Kilogram Body Weight Intake of L-Carnitine from Individual Proposed and Permitted Food Uses of L-Carnitine or L-Carnitine L-Tartrate by Female Teenagers (Aged 12 to 19 Years) Within the United States (2003-2004, 2005-2006 NHANES Data)**

Food Use Category	% Users	Actual # of Total Users	All-Person Consumption (mg/kg)		All-User Consumption (mg/kg)	
			Mean	90 <sup>th</sup> Percentile	Mean	90 <sup>th</sup> Percentile
<u>Beverages and Beverage Bases</u>						
Carbonated Soft Drinks	74.3	1,477	6.2	14.9	8.2	16.7
Energy and Sports Drinks	7.4	148	0.8	na	10.1	18.8
Fruit-Flavored Drinks (RTD and Powdered)	47.9	950	0.8	2.6	2.2	4.3
Non Milk-Based Meal Replacement Beverages	0.3	5	<0.1*	na	4.5*	12.9*
<u>Coffee and Teas</u>						
Herbal Teas	1.7	33	<0.1	na	2.5	5.1
<u>Dairy Product Analogs</u>						
Imitation and Soy Milks	0.8	15	<0.1*	na	5.6*	9.6*
<u>Grain Products and Pastas</u>						
Health and Breakfast Bars	12.4	247	0.2	na	2.3	4.7
Meal Replacement Bars	6.3	125	<0.1	na	2.6	3.2
<u>Hard Candy</u>						
Hard Candy	0.7	13	0.1*	0.1*	0.5*	1.2*
<u>Milk Products</u>						
Flavored Milks and Milk-Based Drinks	15.7	313	0.4	1.3	2.9	5.2
Milk-Based Meal Replacement Beverages	0.7	13	<0.1*	na	4.2*	5.9*
Yogurt	6.6	131	0.1	na	2.1	4.0
Yogurt Drinks	0	0	na	na	na	na
<u>Processed Fruits and Fruit Juices</u>						
Fruit Juices (RTD and Frozen Concentrates)	44.2	877	0.7	2.3	1.7	3.2
Nectars	1.2	24	<0.1*	na	0.7*	1.2*
<u>Soft Candy</u>						
Chocolate	22.7	453	0.1	0.5	0.6	1.2
Soft Candy	20.8	416	0.1	0.3	0.4	1.1

na = not applicable; RTD = ready-to-drink

\*Indicates an intake estimate that may not be statistically reliable, as the CV of the mean is equal to or greater than 30% or fewer than 30 users were identified (see Section 2.3)

**Table B-4 Estimated Daily per Kilogram Body Weight Intake of L-Carnitine from Individual Proposed and Permitted Food Uses of L-Carnitine or L-Carnitine L-Tartrate by Male Teenagers (Aged 12 to 19 Years) Within the United States (2003-2004, 2005-2006 NHANES Data)**

Food Use Category	% Users	Actual # of Total Users	All-Person Consumption (mg/kg)		All-User Consumption (mg/kg)	
			Mean	90 <sup>th</sup> Percentile	Mean	90 <sup>th</sup> Percentile
<u>Beverages and Beverage Bases</u>						
Carbonated Soft Drinks	80.1	1,555	8.2	17.1	9.9	19.0
Energy and Sports Drinks	14.6	282	0.9	3.3	2.5	4.9
Fruit-Flavored Drinks (RTD and Powdered)	46.2	898	2.9	10.4	15.1	31.6
Non Milk-Based Meal Replacement Beverages	0.6	12	0.1*	na	6.2*	8.8*
<u>Coffee and Teas</u>						
Herbal Teas	1.2	23	0.1*	na	3.4*	6.0*
<u>Dairy Product Analogs</u>						
Imitation and Soy Milks	0.5	9	<0.1*	na	3.4*	5.2*
<u>Grain Products and Pastas</u>						
Health and Breakfast Bars	4.2	82	0.2	na	3.0	6.0
Meal Replacement Bars	0.8	15	<0.1*	na	2.8*	3.8*
<u>Hard Candy</u>						
Hard Candy	9.4	182	0.1	na	0.6	1.1
<u>Milk Products</u>						
Flavored Milks and Milk-Based Drinks	17.8	345	0.6	2.6	3.8	7.0
Milk-Based Meal Replacement Beverages	0.6	11	<0.1*	na	4.3*	5.1*
Yogurt	3.7	72	0.1	na	2.7	4.7
Yogurt Drinks	0	0	na	na	na	na
<u>Processed Fruits and Fruit Juices</u>						
Fruit Juices (RTD and Frozen Concentrates)	44.6	865	0.7	2.4	1.9	3.7
Nectars	1.2	24	<0.1*	na	0.7*	1.4*
<u>Soft Candy</u>						
Chocolate	18.7	362	0.1	0.4	0.5	1.2
Soft Candy	18.8	364	0.1	0.3	0.5	1.1

na = not applicable; RTD = ready-to-drink

\*Indicates an intake estimate that may not be statistically reliable, as the CV of the mean is equal to or greater than 30% or fewer than 30 users were identified (see Section 2.3).

**Table B-5 Estimated Daily per Kilogram Body Weight Intake of L-Carnitine from Individual Proposed and Permitted Food Uses of L-Carnitine or L-Carnitine L-Tartrate by Female Adults (Aged 20 Years and Over) Within the United States (2003-2004, 2005-2006 NHANES Data)**

Food Use Category	% Users	Actual # of Total Users	All-Person Consumption (mg/kg)		All-User Consumption (mg/kg)	
			Mean	90 <sup>th</sup> Percentile	Mean	90 <sup>th</sup> Percentile
<u>Beverages and Beverage Bases</u>						
Carbonated Soft Drinks	63.7	2,729	4.8	13.0	7.3	16.1
Energy and Sports Drinks	2.4	103	0.2	na	10.2	22.8
Fruit-Flavored Drinks (RTD and Powdered)	28.7	1,228	0.4	1.5	1.7	3.3
Non Milk-Based Meal Replacement Beverages	1.2	54	0.1	na	4.3	9.6
<u>Coffee and Teas</u>						
Herbal Teas	5.4	228	0.2	na	4.0	7.0
<u>Dairy Product Analogs</u>						
Imitation and Soy Milks	2.7	115	0.1	na	2.9	6.3
<u>Grain Products and Pastas</u>						
Health and Breakfast Bars	7.5	318	0.1	na	2.1	3.5
Meal Replacement Bars	4.9	210	0.1	na	3.5	7.2
<u>Hard Candy</u>						
Hard Candy	1.7	73	<0.1	na	0.5	1.0
<u>Milk Products</u>						
Flavored Milks and Milk-Based Drinks	6.3	270	0.2	na	2.8	4.5
Milk-Based Meal Replacement Beverages	2.3	99	0.1	na	4.1	7.8
Yogurt	10.9	469	0.2	0.7	1.6	3.0
Yogurt Drinks	<0.1	1	<0.1*	na	2.0*	2.0*
<u>Processed Fruits and Fruit Juices</u>						
Fruit Juices (RTD and Frozen Concentrates)	38.2	1,637	0.4	1.4	1.2	2.5
Nectars	1.5	62	<0.1	na	0.4	1.2
<u>Soft Candy</u>						
Chocolate	23.9	1,023	0.1	0.4	0.4	0.8
Soft Candy	10.5	447	<0.1	<0.1	0.3	0.6

na = not applicable; RTD = ready-to-drink

\*Indicates an intake estimate that may not be statistically reliable, as the CV of the mean is equal to or greater than 30% or fewer than 30 users were identified (see Section 2.3).

**Table B-6 Estimated Daily per Kilogram Body Weight Intake of L-Carnitine from Individual Proposed and Permitted Food Uses of L-Carnitine or L-Carnitine L-Tartrate by Male Adults (Aged 20 Years and Over) Within the United States (2003-2004, 2005-2006 NHANES Data)**

Food Use Category	% Users	Actual # of Total Users	All-Person Consumption (mg/kg)		All-User Consumption (mg/kg)	
			Mean	90 <sup>th</sup> Percentile	Mean	90 <sup>th</sup> Percentile
<u>Beverages and Beverage Bases</u>						
Carbonated Soft Drinks	70.1	2,685	6.0	14.6	8.3	16.9
Energy and Sports Drinks	7.9	302	0.9	na	10.9	21.3
Fruit-Flavored Drinks (RTD and Powdered)	27.1	1,038	0.4	1.5	1.9	4.1
Non Milk-Based Meal Replacement Beverages	1.8	67	0.1	na	4.7	9.8
<u>Coffee and Teas</u>						
Herbal Teas	2.8	106	0.1	na	4.6	8.5
<u>Dairy Product Analogs</u>						
Imitation and Soy Milks	1.6	62	0.1	na	2.6	5.2
<u>Grain Products and Pastas</u>						
Health and Breakfast Bars	5.8	221	0.1	na	1.8	3.5
Meal Replacement Bars	4.0	154	0.1	na	3.0	6.0
<u>Hard Candy</u>						
Hard Candy	1.2	46	<0.1	na	0.4	0.9
<u>Milk Products</u>						
Flavored Milks and Milk-Based Drinks	5.8	222	0.2	na	2.5	5.1
Milk-Based Meal Replacement Beverages	1.7	66	0.1	na	4.7	15.0
Yogurt	5.4	205	0.1	na	1.4	2.7
Yogurt Drinks	0.1	2	<0.1*	na	4.1*	6.8*
<u>Processed Fruits and Fruit Juices</u>						
Fruit Juices (RTD and Frozen Concentrates)	34.5	1,328	0.4	1.5	1.4	2.6
Nectars	1.2	45	<0.1	na	0.4	0.8
<u>Soft Candy</u>						
Chocolate	19.8	754	0.1	0.3	0.4	0.9
Soft Candy	8.0	306	<0.1	na	0.4	0.8

na = not applicable; RTD = ready-to-drink

\*Indicates an intake estimate that may not be statistically reliable, as the CV of the mean is equal to or greater than 30% or fewer than 30 users were identified (see Section 2.3).

**Table B-7 Estimated Daily per Kilogram Body Weight Intake of L-Carnitine from Individual Proposed and Permitted Food Uses of L-Carnitine or L-Carnitine L-Tartrate by the Total Population (All Ages) Within the United States (2003-2004, 2005-2006 NHANES Data)**

Food Use Category	% Users	Actual # of Total Users	All-Person Consumption (mg/kg)		All-User Consumption (mg/kg)	
			Mean	90 <sup>th</sup> Percentile	Mean	90 <sup>th</sup> Percentile
<u>Beverages and Beverage Bases</u>						
Carbonated Soft Drinks	62.9	10,498	5.5	14.2	8.2	17.2
Energy and Sports Drinks	6.7	1,123	0.9	na	13.6	27.4
Fruit-Flavored Drinks (RTD and Powdered)	37.7	6,289	0.8	2.5	2.6	5.4
Non Milk-Based Meal Replacement Beverages	0.9	149	0.1	na	4.7	9.8
<u>Coffee and Teas</u>						
Herbal Teas	2.6	432	0.1	na	4.1	8.1
<u>Dairy Product Analogs</u>						
Imitation and Soy Milks	1.5	247	0.1	na	4.3	7.9
<u>Grain Products and Pastas</u>						
Health and Breakfast Bars	4.5	756	0.2	na	2.8	5.3
Meal Replacement Bars	0.9	156	0.1	na	3.3	7.2
<u>Hard Candy</u>						
Hard Candy	9.7	1,624	0.1	na	0.8	1.9
<u>Milk Products</u>						
Flavored Milks and Milk-Based Drinks	13.0	2,170	0.5	0.3	4.6	9.8
Milk-Based Meal Replacement Beverages	1.2	202	0.1	na	4.4	8.1
Yogurt	9.1	1,526	0.3	na	2.7	5.3
Yogurt Drinks	<0.1	4	<0.1*	na	5.0*	6.8*
<u>Processed Fruits and Fruit Juices</u>						
Fruit Juices (RTD and Frozen Concentrates)	44.1	7,355	0.9	2.3	2.3	4.9
Nectars	1.4	231	<0.1	na	0.6	1.5
<u>Soft Candy</u>						
Chocolate	19.8	3,293	0.1	0.4	0.5	1.0
Soft Candy	15.0	2,496	0.1	0.1	0.5	1.3

na = not applicable

\*Indicates an intake estimate that may not be statistically reliable, as the CV of the mean is equal to or greater than 30% or fewer than 30 users were identified (see Section 2.3).



## **APPENDIX C**

### **Representative NHANES 2003-2006 Food Codes for All Proposed and Permitted Food Uses of L-Carnitine or L-Carnitine L-Tartrate in the United States**

**Representative 2003-2006 NHANES Food Codes for All Proposed and Permitted Food Uses L-Carnitine or L-Carnitine L-Tartrate in the United States**

**Beverages and Beverage Bases**

**Carbonated Soft Drinks**

[L-Carnitine] = 0.10%

92400000	Soft drink, NFS
92400100	Soft drink, NFS, sugar-free
92410110	Carbonated water, sweetened
92410210	Carbonated water, unsweetened
92410250	Carbonated water, sugar-free
92410310	Soft drink, cola-type
92410315	Soft drink, cola type, reduced sugar
92410320	Soft drink, cola-type, sugar-free
92410330	Soft drink, cola-type, with higher caffeine
92410340	Soft drink, cola-type, decaffeinated
92410350	Soft drink, cola-type, decaffeinated, sugar-free
92410360	Soft drink, pepper-type
92410370	Soft drink, pepper-type, sugar-free
92410390	Soft drink, pepper-type, decaffeinated
92410400	Soft drink, pepper-type, decaffeinated, sugar-free
92410410	Cream soda
92410420	Cream soda, sugar-free
92410510	Soft drink, fruit-flavored, caffeine free
92410520	Soft drink, fruit-flavored, sugar free, caffeine free
92410550	Soft drink, fruit flavored, caffeine containing
92410560	Soft drink, fruit flavored, caffeine containing, sugar-free
92410610	Ginger ale
92410620	Ginger ale, sugar-free
92410710	Root beer
92410720	Root beer, sugar-free
92410810	Chocolate-flavored soda
92410820	Chocolate-flavored soda, sugar-free
92411510	Cola with fruit or vanilla flavor
92411520	Cola with chocolate flavor
92411610	Cola with fruit or vanilla flavor, sugar-free
92411620	Cola with chocolate flavor, sugar-free
92416010	Mavi drink
92417010	Soft drink, ale type
92431000	Carbonated juice drink, NS as to type of juice
92432000	Carbonated citrus juice drink
92433000	Carbonated noncitrus juice drink

**Mixed Foods Containing Carbonated Soft Drinks**

[Adjusted for carbonated soft drink content of ~18.1 to 74.5%]

[L-Carnitine] = ~0.02 to 0.074%

13120800	Ice cream soda, flavors other than chocolate
13120810	Ice cream soda, chocolate

92510720	Fruit punch, made with fruit juice and soda
92510730	Fruit punch, made with soda, fruit juice, and sherbet or ice cream
92804000	Shirley Temple
93301031	Canadian Club and soda
93301060	Gin and Tonic
93301080	High ball
93301142	Seven and Seven
93301150	Tom Collins
93301170	Bourbon and soda
93301190	Rum and cola
93301230	Sloe gin fizz
93301270	Fruit punch, alcoholic
93301280	Singapore Sling
93301330	Gin Rickey
93301360	Long Island iced tea
93301600	Gin fizz
93404000	Wine cooler
93404500	Sangria
93404600	Sangria, Puerto Rican style
93405000	Wine spritzer

#### **Fruit-Flavored Drinks and Ades (Ready-to-Drink)**

[L-Carnitine] = 0.04%

92510120	Apple-cherry drink
92510150	Apple juice drink
92510170	Apple-cranberry-grape juice drink
92510200	Apple-orange-pineapple juice drink
92510220	Apricot-pineapple juice drink
92510310	Banana-orange drink
92510410	Black cherry drink
92510610	Fruit drink
92510630	Fruit juice drink, NFS
92510650	Tamarind drink, Puerto Rican (Refresco de tamarindo)
92510810	Grapeade and grape drink
92510820	Grape juice drink
92510910	Grapefruit juice drink
92510950	Guava juice drink
92511010	Lemonade
92511020	Lemon-limeade
92511110	Limeade
92511200	Orange-mango juice drink
92511220	Orange drink
92511230	Orange-apricot juice drink
92511240	Orange-lemon drink
92511250	Citrus fruit juice drink
92511260	Orange-cranberry juice drink
92511270	Orange-peach juice drink
92511280	Orange-grape-banana juice drink
92511290	Papaya juice drink
92511310	Pineapple-grapefruit juice drink
92511340	Pineapple-orange juice drink
92511350	Orange-raspberry juice drink

92511400	Raspberry-flavored drink
92511510	Strawberry-flavored drink
92512050	Frozen daiquiri mix, from frozen concentrate, reconstituted
92512110	Whiskey sour, nonalcoholic
92520410	Fruit drink, low calorie
92520810	Grape drink, low calorie
92520910	Lemonade, low calorie
92530210	Black cherry drink with vitamin C added
92530310	Cherry drink with vitamin C added
92530410	Citrus drink with vitamin C added
92530510	Cranberry juice drink with vitamin C added
92530520	Cranberry-apple juice drink with vitamin C added
92530610	Fruit punch, fruit drink, or fruitade, with vitamin C added
92530710	Grape drink with vitamin C added
92530810	Grapefruit juice drink with vitamin C added
92530840	Guava juice drink with vitamin C added
92530910	Lemonade with vitamin C added
92530950	Vegetable and fruit juice drink, with vitamin C added
92531010	Orange drink and orangeade with vitamin C added
92531020	Orange breakfast drink, made from frozen concentrate
92531030	Orange breakfast drink
92531110	Pineapple-grapefruit juice drink with vitamin C added
92531120	Pineapple-orange juice drink with vitamin C added
92531150	Pineapple-orange-grapefruit juice drink with vitamin C added
92531210	Strawberry-flavored drink with vitamin C added
92541010	Fruit-flavored drink, made from sweetened powdered mix (fortified with vitamin C)
92541020	Lemonade-flavored drink, made from powdered mix, with sugar and vitamin C added
92541040	Lemonade-flavored drink, made from powdered mix, low calorie, with vitamin C added
92541100	Apple cider-flavored drink, made from powdered mix, with sugar and vitamin C added
92541120	Apple cider-flavored drink, made from powdered mix, low calorie, with vitamin C added
92542000	Fruit-flavored drink, made from powdered mix, mainly sugar, with high vitamin C added
92544000	Fruit-flavored drink, made from unsweetened powdered mix (fortified with vitamin C), with sugar added
92550030	Fruit juice drink, low calorie
92550050	Apple-white grape juice drink, low calorie, with vitamin C added
92550110	Cranberry juice drink, low calorie, with vitamin C added
92550210	Cranberry-apple juice drink, low calorie, with vitamin C added
92550300	Grapefruit juice drink, low calorie, with vitamin C added
92550350	Light orange juice beverage, 40-50% juice, lower sugar and calories, with artificial sweetener
92550610	Fruit-flavored drinks, punches, ades, low calorie, with vitamin C added
92550620	Fruit flavored drink, low calorie
92551700	Juice drink, low calorie
92552000	Fruit-flavored drink, made from powdered mix with high vitamin C added, low calorie
92552010	Fruit flavored drink, made from powdered mix, low calorie
92552020	Fruit juice drink, reduced sugar, with thiamin (vitamin B1) and vitamin C
92552100	Orange-cranberry juice drink, low calorie, with vitamin C added
92582000	Fruit-flavored drink, low calorie, calcium fortified
92582100	Citrus juice drink, calcium fortified
92582110	Orange breakfast drink, calcium fortified
92731000	Fruit-flavored drink, non-carbonated, made from powdered mix, with sugar
92741000	Fruit-flavored drink, non-carbonated, made from low calorie powdered mix

### **Fruit-Flavored Drinks and Ades (Powdered)**

(Adjusted for not being reconstituted, 16 g of powder to 240 mL of water)

[L-Carnitine] = 0.64%

92900100	Tang, dry concentrate
92900110	Fruit-flavored concentrate, dry powder, with sugar and vitamin C added
92900200	Fruit-flavored beverage, dry concentrate, low calorie, not reconstituted

### **Fruit-Flavored Drinks and Ades (Frozen Concentrate)**

(Adjusted for not being reconstituted, 1 cup of concentrate mixed with 3 cups of water)

[L-Carnitine] = 0.16%

92511000	Lemonade, frozen concentrate, not reconstituted
92512040	Frozen daiquiri mix, frozen concentrate, not reconstituted

### **Energy and Sport Drinks**

[L-Carnitine] = 0.21%

92553000	Fruit-flavored thirst quencher beverage, low calorie
92560000	Fruit-flavored thirst quencher beverage
92560100	Gatorade Thirst Quencher sports drink
92560200	Powerade sports drink
92650000	Red Bull Energy Drink
92651000	Energy drink

### **Non-Reconstituted Energy and Sport Drinks**

(Adjusted for not being reconstituted, 16 g of powder to 240 mL)

[L-Carnitine] = 3.2%

92900300	Fruit-flavored thirst quencher beverage, dry concentrate, not reconstituted
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### **Non Milk-Based Meal Replacements**

[L-Carnitine]= 0.10%

41430200	Meal replacement or supplement, soy- and milk-base, powder, reconstituted with water
41430310	Protein diet powder with soy and casein
41440010	Meal replacement or supplement, liquid, soy-base, high protein
41440020	Ensure with fiber, liquid
41440050	Ensure Plus liquid nutrition
41440100	Meal replacement or supplement, liquid, soy-based

### **Non-Reconstituted Non Milk-Based Meal Replacements**

(Adjusted for not being reconstituted, 16 g of powder to 240 mL)

[L-Carnitine] = 1.56%

11832000	Meal replacement, protein type, milk- and soy-based, powdered, not reconstituted
41430000	Protein powder, NFS
41430010	Protein supplement, powdered

## **Coffee and Tea**

### **Herbal Teas**

[L-Carnitine] = 0.10%

92306000	Tea, herbal
92306020	Tea, herbal, presweetened with sugar
92306030	Tea, herbal, presweetened with low calorie sweetener
92306040	Tea, herbal, presweetened, NS as to sweetener
92306700	Tea, chamomile
92306050	Tea, made from caraway seeds

### **Instant Coffee**

[L-Carnitine] = 0.10%

92100000	Coffee, NS as to type
92103000	Coffee, made from powdered instant, regular
92104000	Coffee, made from powdered instant, 50% less caffeine
92106000	Coffee, acid neutralized, from powdered instant
92111000	Coffee, decaffeinated, NS as to ground or instant
92114000	Coffee, decaffeinated, made from powdered instant
92121000	Coffee, made from powdered instant mix, with whitener and sugar, instant
92121010	Coffee, made from powdered instant mix, presweetened, no whitener
92121020	Coffee and cocoa (mocha), made from powdered instant mix, with whitener, presweetened
92130000	Coffee, presweetened with sugar, pre-lightened
92130010	Coffee, pre-lightened, no sugar
92130020	Coffee, presweetened with sugar
92151000	Coffee and chicory, made from powdered instant
92151100	Coffee, decaffeinated, and chicory, made from powdered instant
92153000	Coffee, regular, with cereal
92153100	Coffee, decaffeinated, with cereal

### **Non-Reconstituted Instant Coffee**

(Adjusted for not being reconstituted, 15 g of concentrate to 340 mL of water)

[L-Carnitine] = 2.27%

92105000	Coffee, liquid concentrate
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(Adjusted for not being reconstituted, 5 g of powder to 175 mL of water)

[L-Carnitine] = 3.5%

92191000	Coffee, dry instant powder, NS as to regular or decaffeinated
92191100	Coffee, dry instant powder, regular
92191200	Coffee, dry instant powder, decaffeinated
92191250	Coffee, dry, acid neutralized
92191500	Coffee and chicory, dry instant powder
92191520	Coffee, decaffeinated, and chicory, dry instant powder
92192000	Coffee and cocoa (mocha) mix, dry instant powder with whitener, presweetened
92193000	Coffee, dry instant powder, with whitener and sugar

## **Dairy Product Analogs**

### **Imitation and Soy Milks**

[L-Carnitine] = 0.10%

11320000	Milk, soy, ready-to-drink, not baby's
11321000	Milk, soy, ready-to-drink, not baby's, chocolate
11340000	Milk, imitation, fluid, non-soy, sweetened, flavors other than chocolate

## **Grain Products and Pastas**

### **Health and Breakfast Bars**

[L-Carnitine] = 0.625%

53540600	Milk 'n Cereal bar
53540700	Kellogg's Special K bar
53542100	Granola bar, oats, sugar, raisins, coconut
53542200	Granola bar, oats, fruit and nuts, lowfat
53542210	Granola bar, nonfat
53543100	Granola bar, peanuts, oats, sugar, wheat germ
53540000	Breakfast bar, NFS
53540200	Breakfast bar, cereal crust with fruit filling, lowfat
53540250	Breakfast bar, cereal crust with fruit filling, fat free
53540500	Breakfast bar, date, with yogurt coating
53544200	Granola bar, chocolate-coated
53544210	Granola bar, with coconut, chocolate-coated
53544220	Granola bar with nuts, chocolate-coated
53544250	Granola bar, coated with non-chocolate coating
53544300	Granola bar, high fiber, coated with non-chocolate yogurt coating
53544400	Granola bar, with rice cereal

### **Meal Replacement Bars**

[L-Carnitine] = 0.625%

41435110	High protein bar, candy-like, soy and milk base
53541200	Meal replacement bar
53544450	PowerBar (fortified high energy bar)
91780010	Snickers Marathon Energy bar
91781010	Snickers Marathon Protein bar

## **Hard Candy**

### **Hard Candy**

[L-Carnitine] = 0.33%

91718000	Honey-combed hard candy with peanut butter
91733000	Peanut brittle
91742010	Sesame Crunch (Sahadi)
91745020	Hard candy
91745040	Butterscotch hard candy
91770000	Dietetic or low calorie candy, NFS
91770020	Dietetic or low calorie hard candy
91770050	Dietetic or low calorie mints

## **Milk Products**

### **Flavored Milk and Milk Drinks**

[L-Carnitine] = 0.10%

11511000	Milk, chocolate, NFS
11511100	Milk, chocolate, whole milk-based
11511200	Milk, chocolate, reduced fat milk-based (formerly "lowfat")
11511300	Milk, chocolate, skim milk-based
11511400	Milk, chocolate, lowfat milk-based
11512510	Hot chocolate, Puerto Rican style, made with low fat milk
11518000	Milk beverage with nonfat dry milk and low calorie sweetener, water ad
11518050	Milk beverage with nonfat dry milk and low calorie sweetener, water ad
11518100	Milk beverage with nonfat dry milk and low calorie sweetener, high cal
11519000	Milk beverage, made with whole milk, flavors other than chocolate
11519050	Milk, flavors other than chocolate, whole milk-based
11520000	Milk, malted, unfortified, NS as to flavor, made with milk
11521000	Milk, malted, unfortified, chocolate, made with milk
11521010	Milk, malted, unfortified, chocolate, made with skim milk
11522000	Milk, malted, unfortified, natural flavor, made with milk
11525000	Milk, malted, fortified, natural flavor, made with milk
11526000	Milk, malted, fortified, chocolate, made with milk
11527000	Milk, malted, fortified, NS as to flavor, made with milk
11531000	Eggnog, made with whole milk
11531500	Eggnog, made with 2% reduced fat milk (formerly eggnog, made with "2% lowfat" milk)
11541000	Milk shake, NS as to flavor or type
11541100	Milk shake, homemade or fountain-type, NS as to flavor
11541110	Milk shake, homemade or fountain-type, chocolate
11541120	Milk shake, homemade or fountain-type, flavors other than chocolate
11541400	Milk shake with malt
11541500	Milk shake, made with skim milk, chocolate
11541510	Milk shake, made with skim milk, flavors other than chocolate
11542000	Carry-out milk shake, NS as to flavor
11542100	Carry-out milk shake, chocolate
11542200	Carry-out milk shake, flavors other than chocolate
11551050	Milk fruit drink
11552200	Milk-based fruit drink
11553100	Fruit smoothie drink, NFS
11560000	Chocolate-flavored drink, whey- and milk-based
11560020	Flavored milk drink, whey- and milk-based, flavors other than chocolate

### **Mixed Foods Containing Flavored Milks and Milk Drinks**

(Adjusted for a flavored milk and milk drink content of 50%)

[L-Carnitine] = 0.05%

11553000	Fruit smoothie drink, made with fruit or fruit juice and dairy product
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### **Powdered Flavored Milks and Milk Drinks**

(Adjusted for not being reconstituted, 16 g of powder to 240 mL of water)

[L-Carnitine] = 1.56%

11830100	Cocoa (or chocolate) with dry milk and sugar, dry mix, not reconstituted
11830110	Cocoa powder with nonfat dry milk and low calorie sweetener, dry mix,
11830120	Cocoa, whey, and low calorie sweetener, fortified, dry mix, not recons



11830140	Chocolate, instant, dry mix, fortified with vitamins and minerals, not
11830160	Cocoa (or chocolate) flavored beverage powder with sugar, dry mix, not
11830170	Cocoa, whey, and low-calorie sweetener mixture, not reconstituted
11830200	Milk, malted, dry mix, unfortified, not reconstituted, flavors other than chocolate
11830210	Milk, malted, dry mix, fortified, not reconstituted, flavors other than
11830250	Milk, malted, dry mix, unfortified, not reconstituted, chocolate
11830260	Milk, malted, dry mix, fortified, not reconstituted, chocolate
11830400	Milk beverage, powder, dry mix, not reconstituted, flavors other than
11830450	Milk beverage with sugar, dry milk, and egg white powder, dry mix, not
11830500	Milk beverage, powder, with nonfat dry milk and low calorie sweetener,
11830550	Milk beverage, powder, with nonfat dry milk and low calorie sweetener,

**Milk-Based Meal Replacements**

[L-Carnitine] = 0.10%

11611000	Instant breakfast, fluid, canned
11612000	Instant breakfast, powder, milk added
11613000	Instant breakfast, powder, sweetened with low calorie sweetener, milk
11622010	Diet beverage, powder, reconstituted with skim milk
11641000	Meal supplement or replacement, milk-based, high protein, liquid
11641020	Meal replacement or supplement, milk based, ready-to-drink
11830940	Meal replacement, high protein, milk based, fruit juice mixable formula
41430200	Meal replacement or supplement, soy- and milk-base, powder, reconstitu
41440020	Ensure with fiber, liquid
41440050	Ensure Plus liquid nutrition

**Powdered Milk-Based Meal Replacements**

(Adjusted for not being reconstituted, 16 g of powder to 240 mL of water)

[L-Carnitine] = 1.56%

11830900	Protein supplement, milk-based, powdered, not reconstituted
11830970	Meal replacement, protein type, milk-based, powdered, not reconstitute
11830990	Nutrient supplement, milk-based, powdered, not reconstituted
11831500	Nutrient supplement, milk-based, high protein, powdered, not reconstit
11832000	Meal replacement, protein type, milk- and soy-based, powdered, not rec

**Yogurt**

[L-Carnitine] = 0.11%

11410000	Yogurt, NS as to type of milk or flavor
11411010	Yogurt, plain, NS as to type of milk
11411100	Yogurt, plain, whole milk
11411200	Yogurt, plain, lowfat milk
11411300	Yogurt, plain, nonfat milk
11420000	Yogurt, vanilla, lemon, or coffee flavor, NS as to type of milk
11421000	Yogurt, vanilla, lemon, or coffee flavor, whole milk
11422000	Yogurt, vanilla, lemon, maple, or coffee flavor, lowfat milk
11423000	Yogurt, vanilla, lemon, maple, or coffee flavor, nonfat milk
11424000	Yogurt, vanilla, lemon, maple, or coffee flavor, nonfat milk, sweetened with low calorie sweetener
11425000	Yogurt, chocolate, NS as to type of milk
11426000	Yogurt, chocolate, whole milk
11427000	Yogurt, chocolate, nonfat milk
11430000	Yogurt, fruit variety, NS as to type of milk

11431000	Yogurt, fruit variety, whole milk
11432000	Yogurt, fruit variety, lowfat milk
11432500	Yogurt, fruit variety, lowfat milk, sweetened with low-calorie sweetener
11433000	Yogurt, fruit variety, nonfat milk
11433500	Yogurt, fruit variety, nonfat milk, sweetened with low-calorie sweetener
11444000	Yogurt, fruit and nuts, NS as to type of milk
11445000	Yogurt, fruit and nuts, lowfat milk

Mixed Foods Containing Yogurt  
 (Adjusted for yogurt content of ~5.1 to 80%)  
 [L-Carnitine] = ~0.006 to 0.018%

27516010	Gyro sandwich (pita bread, beef, lamb, onion, condiments), with tomato and spread
53104580	Cheesecake -type dessert, made with yogurt, with fruit
53441210	Basbousa (semolina dessert dish)
83115000	Yogurt dressing

### **Yogurt Drinks**

[L-Carnitine] = 0.10%

11112120	Milk, cow's, fluid, acidophilus, 1% fat
11112130	Milk, cow's, fluid, acidophilus, 2% fat

### **Processed Fruit and Fruit Juices**

#### **Fruit Juices (Ready-to Drink)**

[L-Carnitine] = 0.04%

61200500	Acerola juice
61101200	Grapefruit, canned or frozen, NS as to sweetened or unsweetened; sweetened, NS as to type of sweeten
61201020	Grapefruit juice, unsweetened, NS as to form
61201220	Grapefruit juice, canned, bottled or in a carton, unsweetened
61201620	Grapefruit juice, frozen, unsweetened (reconstituted with water)
61210000	Orange juice, NFS
61210220	Orange juice, canned, bottled or in a carton, unsweetened
61210250	Orange juice, with calcium added, canned, bottled or in a carton, unsweetened
61210620	Orange juice, frozen, unsweetened (reconstituted with water)
61210820	Orange juice, frozen, with calcium added (reconstituted with water)
61213000	Tangerine juice, NFS
61213220	Tangerine juice, canned, unsweetened
61213230	Tangerine juice, canned, with sugar
61213620	Tangerine juice, frozen, unsweetened (reconstituted with water)
61213800	Fruit juice blend, including citrus, 100% juice
61213900	Fruit juice blend, including citrus, 100% juice, with calcium added
61214000	Grape-tangerine-lemon juice
61216000	Grapefruit and orange juice, NFS
61216220	Grapefruit and orange juice, canned, unsweetened
61216230	Grapefruit and orange juice, canned, with sugar
61216620	Grapefruit and orange juice, frozen (reconstituted with water)
61219000	Orange and banana juice
61219100	Pineapple-orange-banana juice
61219150	Orange-white grape-peach juice
61219650	Apricot-orange juice

61222000	Pineapple-grapefruit juice, NFS
61222200	Pineapple-grapefruit juice, canned, bottled or in a carton, NS as to sweetened or unsweetened
61222220	Pineapple-grapefruit juice, canned, bottled or in a carton, unsweetened
61222230	Pineapple-grapefruit juice, canned, bottled or in a carton, with sugar
61222600	Pineapple-grapefruit juice, frozen (reconstituted with water)
61225000	Pineapple-orange juice, NFS
61225200	Pineapple-orange juice, canned, NS as to sweetened or unsweetened; sweetened, NS as to type of sweetener
61225220	Pineapple-orange juice, canned, unsweetened
61225230	Pineapple-orange juice, canned, with sugar
61225600	Pineapple-orange juice, frozen (reconstituted with water)
61226000	Strawberry-banana-orange juice
64100100	Fruit juice, NFS
64100110	Fruit juice blend, 100% juice, with added Vitamin C
64100120	Ambrosia juice
64100200	Fruit juice blend, with cranberry, 100% juice
64101010	Apple cider
64104010	Apple juice
64104150	Apple-cherry juice
64104200	Apple-pear juice
64104450	Apple-raspberry juice
64104500	Apple-grape juice
64104550	Apple-grape-raspberry juice
64104600	Blackberry juice
64105400	Cranberry juice, unsweetened
64105500	Cranberry-white grape juice mixture, unsweetened
64116020	Grape juice, unsweetened
64120010	Papaya juice
64121000	Passion fruit juice
64122030	Peach juice, with sugar
64124020	Pineapple juice, unsweetened
64124200	Pineapple-apple-guava juice, with added vitamin C
64125000	Pineapple juice-non-citrus juice blend, unsweetened, with added vitamin C
64126000	Pomegranate juice
64132010	Prune juice, NS as to added sweetener
64132020	Prune juice, unsweetened
64132030	Prune juice, with sugar
64132500	Strawberry juice
64133100	Watermelon juice
64134000	Fruit smoothie drink, made with fruit or fruit juice only (no dairy products)
92512090	Pina Colada, nonalcoholic

Mixed Foods Containing Fruit Juices  
 (Adjusted for a fruit juice content of ~50%)  
 [L-Carnitine] = ~0.02%

92510720	Fruit punch, made with fruit juice and soda
92510730	Fruit punch, made with soda, fruit juice, and sherbet or ice cream

### **Fruit Juices (Frozen Concentrate)**

(Adjusted for not being reconstituted, 1 cup of juice mixed with 3 cups of water)  
[L-Carnitine] = 0.16%

61210720 Orange juice, frozen, unsweetened, not reconstituted

### **Nectars**

[L-Carnitine] = 0.02%

64200100	Fruit nectar, NFS
64201010	Apricot nectar
64201500	Banana nectar
64202010	Cantaloupe nectar
64203020	Guava nectar
64204010	Mango nectar
64205010	Peach nectar
64210010	Papaya nectar
64213010	Passion fruit nectar
64215010	Pear nectar
64221010	Soursop (Guanabana) nectar

### **Mixed Foods Containing Nectars**

(Adjusted for nectar content of ~15%)  
[L-Carnitine] = ~0.003%

91361020 Fruit sauce

### **Soft Candy**

#### **Chocolate**

[L-Carnitine] = 0.125%

91700500	M & M's Almond Chocolate Candies
91701010	Almonds, chocolate covered
91703040	Caramel, chocolate covered
91703050	Caramel with nuts and cereal, chocolate covered
91703060	Caramel with nuts, chocolate covered
91703070	Rolo
91703150	Toblerone, milk chocolate with honey and almond nougat
91703200	TWIX Cookie Bars
91703250	TWIX Chocolate Fudge Cookie Bars
91703300	TWIX Peanut Butter Cookie Bars
91703400	Whatchamacallit
91703600	Espresso coffee beans, chocolate-covered
91705010	Chocolate, milk, plain
91705020	Chocolate, milk, with cereal
91705030	Kit Kat
91705040	Chocolate, milk, with nuts, not almond or peanuts
91705050	Chocolate, milk, with fruit and nuts
91705060	Chocolate, milk, with almonds
91705070	Chocolate, milk, with peanuts
91705090	Chocolate with fondant and caramel
91705200	Chocolate, semi-sweet morsel
91705300	Chocolate, sweet or dark
91705400	Chocolate, white

91705410	Chocolate, white, with almonds
91705500	Mexican chocolate (tablet)
91706000	Coconut candy, chocolate covered
91707010	Fondant, chocolate covered
91709000	Gumdrops, chocolate covered
91713010	Fudge, chocolate, chocolate-coated
91713020	Fudge, chocolate, chocolate-coated, with nuts
91713030	Fudge, chocolate
91713040	Fudge, chocolate, with nuts
91715000	Fudge, caramel and nut, chocolate-coated
91715100	SNICKERS Bar
91715200	Baby Ruth
91715300	100 GRAND Bar
91716110	Halvah, chocolate covered
91718050	Honey-combed hard candy with peanut butter, chocolate covered
91718100	Butterfinger
91723010	Marshmallow, chocolate covered
91726110	Nougat, with caramel, chocolate covered
91726130	MILKY WAY Bar
91726140	MILKY WAY DARK Bar
91726150	MARS Bar
91726410	Nougat, chocolate covered
91726420	3 MUSKETEER Bar
91727010	Nuts, chocolate covered, not almonds or peanuts
91731000	Peanuts, chocolate covered
91731010	M & M's Peanut Chocolate Candies
91731060	M & M's Peanut Butter Chocolate Candies
91733200	Peanut Bar, chocolate covered
91734000	Peanut butter, chocolate covered
91734100	Reese's Peanut Butter Cup
91734200	Reese's Pieces
91734300	Reese Sticks
91734400	Reese's Fast Break
91739010	Raisins, chocolate covered
91746010	Sugar-coated chocolate discs
91746100	M & M's Plain Chocolate Candies
91746120	Sixlets
91746150	Easter egg, candy coated chocolate
91760100	Toffee, chocolate covered
91760200	Toffee, chocolate-coated, with nuts
91760500	Truffles
91770030	Dietetic or low calorie candy, chocolate covered

### **Soft Candy**

[L-Carnitine] = 0.125%

91700010	Candy, NFS
91702010	Butterscotch morsels
91703010	Caramel, chocolate-flavored roll
91703020	Caramel, flavor other than chocolate
91703030	Caramel, with nuts
91703080	Caramel, all flavors, sugar free
91706100	Coconut candy, no chocolate covering
91706400	Coconut candy, Puerto Rican style

91707000	Fondant
91708000	Fruit peel, candied
91708010	Date candy
91708020	Soft fruit confections
91708030	Fruit leather
91708040	Fun Fruits Creme Supremes
91708070	Tamarind candy
91708100	Fruit snack candy, with added vitamin C
91716010	Halvah, plain
91718200	Chocolate-flavored sprinkles
91721000	Licorice
91723000	Marshmallow
91723020	Marshmallow, candy-coated
91723050	Marshmallow, coconut-coated
91726000	Nougat, plain
91728000	Nut roll, fudge or nougat, caramel and nuts
91734500	Peanut butter morsels
91735000	Pralines
91736000	Pineapple candy, Puerto Rican style
91745010	Gumdrops
91745100	Skittles
91750000	Taffy
91760000	Toffee, plain
91760700	Wax candy, liquid filled
91770010	Dietetic or low calorie gumdrops