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ORIGINAL SUBMISSION

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nutrition&health

July 17, 2002

Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
Food And Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

Re: GRAS Notification For Xangold® Lutein Esters

To Whom It May Concern:

Pursuant to proposed 21 CFR 170.36, 62 Fed. Reg. 18960 (April 17, 1997), Cognis Corporation hereby provides notice of a claim that the food ingredient Xangold® Lutein Esters is exempt from the premarket approval requirement of the Federal Food, Drug, and Cosmetic Act because it has been determined to be Generally Recognized As Safe (GRAS), based on scientific procedures, for addition to food as an ingredient to provide consumers with a supplementary source of lutein in their diets.

Detailed information about this GRAS notification is enclosed, including an address where FDA may review and copy additional data and information that are the basis for the GRAS determination.

If you have any questions about this notification, please contact the undersigned at 708-579-6159 or Cindy.Schweitzer@Cognis-US.com.

Sincerely,

Cynthia M. Schweitzer, Ph.D.

enclosure

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JUL 22 2002
OFFICE OF
FOOD ADDITIVE SAFETY

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nutrition&health

GRAS Notification
for
Xangold® lutein esters

Submitted by:
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Washington, D.C. 20036
202-223-5120

July 17, 2002

Introduction
Pursuant to proposed 21 CFR 170.36, 62 Fed. Reg. 18960 (April 17, 1997), Cognis Corporation hereby provides notice of a claim that the food ingredient Xangold® Lutein Esters is exempt from the premarket approval requirement of the Federal Food, Drug, and Cosmetic Act because it has been determined to be Generally Recognized As Safe (GRAS), based on scientific procedures, for addition to food as an ingredient to provide consumers with a supplementary source of lutein in their diets. The following provides the detailed information required by proposed 21 CFR 170.36(c).

Summary
An independent panel of recognized experts (hereinafter referred to as the Expert Panel), qualified by their scientific training and experience to evaluate the safety of food ingredients, was requested by Cognis Corporation's Nutrition & Health group to determine the safety of Xangold® lutein esters used as a food ingredient to provide consumers with a supplementary source of lutein in their diets. The Expert Panel concluded that a total daily consumption of 40 mg per day of lutein esters (or lutein esters equivalents) from all sources is safe. The Expert Panel evaluated the proposed use of Xangold® lutein esters at specified levels in the following foods: baked goods and baking mixes, soy milk, beverages and beverage powders, frozen dairy desserts and mixes, processed fruit and vegetable products, egg products and egg substitutes, breakfast cereals (ready-to-eat and hot), fats and oils, hard candy, fruit snacks and dairy products, and concluded that these proposed uses would result in total daily consumption well below 40 mg/day. The Expert Panel also concluded that Xangold® lutein esters as an ingredient in medical foods intended as the sole item of the diet is safe at levels not to exceed a total of 40 mg/day. A comprehensive search of the literature for safety and toxicity information on lutein esters and related compounds was conducted by Burdock Group in September 2001 and was summarized in a report to the Expert Panel. The Expert Panel also independently evaluated materials submitted by Cognis Nutrition & Health and other materials deemed appropriate and necessary. Following an independent, critical evaluation, the Expert Panel conferred and unanimously agreed to the decision described herein.

Sec. 170.36
(c) (1) (ii) Common or usual name of the substance that is the subject of the GRAS exemption claim:
The common or usual name of the substance that is the subject of this GRAS notification is lutein esters. Lutein esters provide a source of lutein when ingested. Lutein esters are the principal component of Xangold® natural lutein esters products of Cognis Corporation, including Xangold® Concentrate (HC or LEC), an intermediate product, and Xangold® 15% and Xangold® 10%, end products that are intended for use as ingredients in the specific food described below.

(c) (1) (iii) Applicable conditions of use: foods in which to be used, purpose of use, population to consume the substance:
Selected foods within the following food categories have been identified for use of Xangold® lutein esters as an ingredient to provide consumers of all ages with a supplementary source of lutein in their diets. Appendix 1 contains a detailed list of the individual foods within these categories.

Table 1

Food group	mg lutein ester/serving
Baked goods and baking mixes	4.0
Soy milk	3.0
Beverages and beverage powders	4.0
Frozen dairy desserts and mixes	2.0
Processed fruit and vegetable products	4.0
Egg products and egg substitutes	4.0
Breakfast cereals (ready-to-eat and hot)	4.0
Fats and oils	3.0
Hard candy	2.0
Fruit snacks	2.0
Dairy products	6.0

Determination of lutein esters intake levels from diet and selected supplemented foods:
The estimations of current intake of lutein esters from the diet, and the proposed intake of lutein esters from the foods selected for lutein ester supplementation in Table 1 (based on the number of servings consumed per day) were calculated (Rachman, 2002) from USDA's Continuing Survey of Food Intakes by Individuals 1994-96 (CSFII; USDA, 1998a) and the USDA carotenoid database (Holden *et al.*, 1999 and USDA, 1998b).

The USDA carotenoid database reports the combined lutein and zeaxanthin content for each food. Data are not available on lutein levels alone. Relatively low levels of zeaxanthin usually accompany lutein in foods, and therefore the use of these values as a proxy for lutein levels overestimates lutein consumption. The lutein intakes reported in this database were converted to equivalent values of lutein esters on a molecular basis. A factor of 1.8, which represents the ratio of the molecular weight of lutein dipalmitate to lutein, was used in calculations to convert between lutein and lutein ester equivalents.

Using this conservative approach, the current mean and 90th percentile lutein ester consumption levels are estimated to be 2.0 mg/day and 4.4 mg/day, respectively (Table 2). If the selected foods are supplemented with the level of Xangold® lutein esters specified in Table 1, the mean and 90th percentile lutein ester consumption levels from these sources will be an estimated 9.7 mg/day and 19 mg/day, respectively. Combining the current dietary intake and the proposed intake from the foods in Table 1 results in a total estimated mean lutein ester consumption of 11.7 mg/day. The total consumption at the 90th percentile is estimated to be 22.3 mg/day. (Note: at the 90th percentile the total is non-additive; DiNovi and Kuznesof, 1995).

Table 2. Estimated current lutein ester intake, predicted lutein ester intake following supplementation of selected foods at the indicated levels (Table 1) and total lutein ester intake (predicted + current) for individuals consuming selected supplemented foods (Rachman, 2002)[a]

	Per User (mg/day)	
Lutein ester intake from:	Mean	90th Percentile
Diet	2.0	4.4
Supplemented foods (Table 6)	9.7	19.0
Total	11.7	22.3[b]

[a]Levels calculated using consumption values from CSFII 1994-1996, 1998 and lutein levels from USDA carotenoid database (Holden et al., 1999 and USDA, 1998b).
[b]At the 90th percentile the total is non-additive (DiNovi and Kuznesof, 1995).

The contribution of lutein esters from tagetes oil to the total daily lutein esters consumption is estimated to be negligible (< 30 µg/day). (Tagetes oil containing high levels of lutein ester is approved as a food additive (21CFR § 172.510) by the FDA for use as a direct food flavoring agent. Tagetes meal and extract are approved as color additives for use in animal feed (21CFR § 73.295). The Flavor and Extract Manufacturers Association has listed tagetes oil (FEMA No. 3040) as GRAS for human consumption as a food flavoring ingredient (Hall and Oser, 1965).)

The contribution of dietary supplements to consumption of lutein esters (and lutein ester equivalents) was also considered. The 1987 National Health Interview Survey identified that 51.1% of the adults aged 19-99 years in the US consumed a vitamin/mineral supplement in the past year, but that only 23.1% did so daily (Subar and Block, 1990). Multivitamins were the most commonly consumed supplement at that time. Commercially available multivitamins such as Centrum® (American Home Products, Madison, NJ) contain a recommended daily dose of 250 µg unesterified lutein (~500 µg lutein ester equivalents). A national dietary supplement retailer, General Nutrition Centers, Inc. (GNC), offers a lutein ester supplement, Natural Brand™ Eyegold™, with a recommended daily dose of 12 mg lutein ester. Since there are no available statistical data on consumption of dietary supplements that are a source of lutein, we have used the levels recommended in labeling as a basis for estimating consumption ranges. Thus, the potential theoretical lutein ester consumption from dietary supplements may range from 500 µg to 12 mg per day, with the median probably closer to 500 µg.

The addition of Xangold® lutein esters to medical foods (21 CFR §101.9(j)(8)) intended as the sole item of the diet was separately evaluated. Consumption of lutein esters from medical foods used as the sole item of the diet would replace, not be additive to, lutein ester consumption from conventional foods. Therefore, medical foods could be supplemented with lutein esters at levels not to exceed the acceptable daily intake.

(c) (1) (iv) Basis for GRAS determination:
The basis for this GRAS determination is scientific procedures.

(c) (1) (v) The data and information that are the basis for the GRAS determination:
The data and information that are the basis for Cognis' determination that Xangold® lutein esters are Generally Recognized As Safe (GRAS) are available for FDA's review and copying upon request at the offices of Kleinfeld, Kaplan and Becker, 1140 Nineteenth Street, N.W. Washington, D.C. 20036 (contact Daniel Dwyer, 202-223-5120).

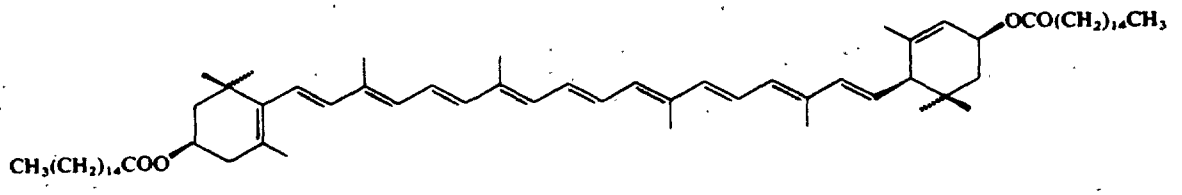
(c) (2) Detailed information about the identity of the substance:
Xangold® lutein esters are comprised of a mixture of carotenoid xanthophyll esters (lutein esters and zeaxanthin esters) obtained from marigold flowers of the species *Tagetes erecta.* Lutein esters make up more than ninety three percent of the total carotenoid esters. Zeaxanthin esters also naturally present comprise less than seven percent of the total carotenoid esters. The information provided below is for the major lutein ester component which is lutein dipalmitate.

Chemical name: (3R,3'S,6'R)-β,ε-Carotene-3,3'-diol dipalmitate (lutein dipalmitate)

Chemical Abstracts Service (CAS) Registry Number: 547-17-1(lutein dipalmitate)

Empirical Formula: $C_{72}H_{116}O_4$ (lutein dipalmitate)
Molecular wt: 1045.71 g/mol

Structural Formula: Lutein dipalmitate



Quantitative Composition: Analysis by an independent laboratory provided the following composition of Xangold® HC.

Table 3

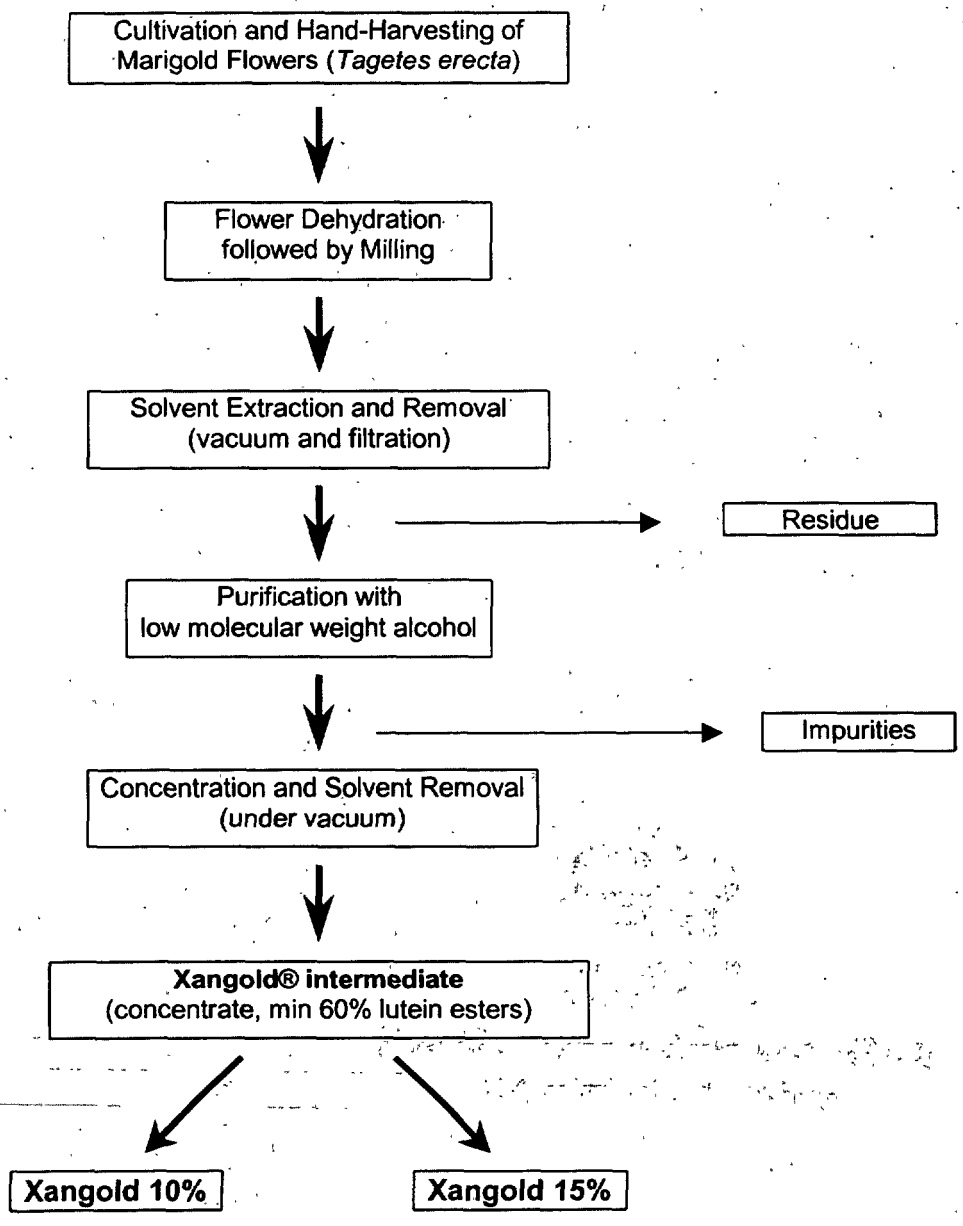
Constituent	Amount (%)
Lutein and zeaxanthin esters	>60
C21-C31 Alkanes	25
Free fatty acids	11
Terpenoids	<4
Di- and triglycerides	<0.1
Total	100

Method of Manufacture (Figure 1):
Xangold® concentrated natural lutein esters, a granular, dark orange-brown concentrate, is manufactured via a patented process (Levy 2001) using current Good Manufacturing Practice with all reagents used in

the process conforming to Food Chemical Codex specifications. Key elements of the manufacturing process are shown in the diagram below. The intermediate product, Xangold® concentrate (HC or LEC), is further processed into the two existing commercial products, Xangold® 15% and Xangold® 10% using Good Manufacturing Practices and food grade reagents.

Xangold®10% is a tablet-grade powder microencapsulated with preservative-free ingredients and contains at least 10% total carotenoid esters, mainly lutein esters, which equate to a minimum of 5% (50,000 mcg/gram) unesterified lutein after saponification. Xangold®15% is made by diluting Xangold® concentrate into vegetable oil to a final concentration of at least 15% total carotenoid esters, mainly lutein esters, which equate to a minimum of 7.5% (75,000 mcg/gram) unesterified lutein after saponification. This GRAS determination includes all three of the Xangold® natural lutein esters products (Xangold® concentrate, Xangold® 15% and Xangold® 10%).

Figure 1. Xangold® Manufacturing Process



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Characteristic Properties:

Physical Form	Xangold® intermediate:	solid, granules
	Xangold® 15%:	oil suspension
	Xangold® 10%:	microencapsulated beadlets, powder

Melting point 53.5-55.0° C (*tagetes erecta* extract)

Solubility Insoluble in water, soluble in benzene and chloroform, slightly soluble in hexane and ethanol.

Specifications for food grade material:
The following specifications are based on the Xangold® lutein esters intermediate concentrate, the parent product for Xangold® 15% and Xangold® 10%.

Appearance	**Dark orange-brown granules**
Odor	None
Bulk density	Approximately 0.40 g/cm^3
Stability	Stable for at least 12 months when stored in an unopened container between 55° and 77° Fahrenheit
Chromatographic (HPLC)	Matches unesterified lutein and zeaxanthin standards
Spectral	Typical visible spectrum of marigold extract in hexane
Total carotenoid esters as lutein esters	60% minimum
Total carotenoid esters as lutein equivalent	32% minimum of which 80% is all trans-lutein equivalent
Total lutein esters (as a % of the total carotenoid esters)	93% minimum
Total zeaxanthin esters (as a % of the total carotenoid esters)	7% maximum
Ash	<2%
Heavy metals[a]	<10 ppm
Lead[a]	<10 ppm
Arsenic[a]	<3 ppm
Pesticides	Below reporting limit, method SW 846-8080A[b]
Organic solvents	<50 ppm USP[c] OVI[d] method IV
Natural and mixed tocopherols	1.5% to 2.0% AOCS[e] method Ce 3-74
Ascorbyl palmitate	1.0% to 1.5% USP 23 NF[f] 18
Total aerobic microbial count	< or = 1,000 per gram
Yeasts and molds	< or = 300 per gram
Salmonella	Negative per 25 grams
E. coli	Negative per 25 grams
Staphylococcus	Negative per 25 grams
Total coliforms	<10 per gram

[a]Determined by colorimetric assay
[b]Severn Trent Laboratories, Colchester, VT
[c]United States Pharmacopoeia
[d]Organic Volatile Impurities
[e]American Oil Chemists' Society
[f]National Formulary

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(c) (4) Detailed summary of the basis for the determination that Xangold® Lutein Esters is GRAS by scientific procedures:

A comprehensive literature search for safety and toxicity information on lutein esters and related compounds was conducted by the Burdock Group in September 2001, summarized and provided to the Expert Panel. Additional supportive information from Cognis Corporation was also provided for the Panel's review. Upon critical evaluation of all of the information, the Expert Panel conferred and agreed to the decision described herein.

Appendix 2 contains a summary Table of published human clinical studies orally administering esterified or unesterified lutein. Appendix 3 provides the Reference List of published studies used in the safety evaluation of lutein esters.

Absorption, Distribution, Metabolism and Excretion

Lutein esters are a form of lutein (*n*, LATIN luteum = egg yolk, from luteus = yellow), a yellow pigment in the chemical family of fat soluble carotenoids, which includes more than 600 naturally-occurring members (Moeller *et al.*, 2000 and Rice-Evans *et al.*, 1997). In nature, lutein and lutein esters are found mainly in green leafy vegetables, yellow-orange vegetables, yellow-orange fruits and egg yolks. Humans do not synthesize lutein and depend entirely on dietary sources of lutein and lutein esters such as vegetables, eggs or supplements. Human clinical and animal studies indicate that administration of both lutein esters and unesterified lutein result in lutein being bioavailable. Lutein esters are hydrolyzed in the gut to unesterified lutein and it is the unesterified lutein that is absorbed and enters circulation. Thus, the results from studies that used lutein esters or unesterified lutein are equally valid for purposes of assessing the safety of lutein esters. Lutein is increasingly the subject of intense study because of its potential ability to help maintain the healthy structure or function of the body.

Data from NHANES III (CDC, 1998) showed that Americans consume approximately 1.35-1.97 mg/day lutein+zeaxanthin (median intake) from dietary sources, mainly fruits and vegetables. This consumption results in serum lutein concentrations of approximately 0.4 µmol/L. Lutein appears to be absorbed intact with intestinal hydrolysis of lutein esters to lutein prior to absorption. At least six lutein metabolites have been identified in serum. Four of the metabolites resulted from oxidation and two from non-enzymatic dehydration (Khachik et al, 1995). Several human clinical studies using unesterified lutein or lutein esters to assess bioavailability were identified. These studies revealed that steady-state serum lutein levels of 0.26-1.76 µmol/L were achieved in humans consuming supplements containing 16-62 mg/day lutein esters equivalents (8-31.2 mg/day unesterified lutein). Single dose studies measured maximum serum lutein levels between 2 and 33 hours after lutein consumption with the peak serum concentration most likely reached by ~15 hours and a serum half-life between 33 and 76 days. Limited information about the kinetics of lutein depletion exists. Based on other carotenoid studies, lutein is likely to be mainly excreted through the bile into feces (Leo et al, 1995), with some excretion by sebaceous glands and sweat but not urine (Bendich, 1988).

Overview of Human Studies

The results from several human clinical studies measuring serum lutein levels following consumption of lutein supplements (acute and chronic) are discussed below and are summarized in Appendix 3.

Five single dose studies (O'Neill and Thurnham, 1998; van den Berg and van Vliet, 1998; Herbst et al, 1997; Yao, et al 2000; Kostic et al, 1995) provide information about the bioavailability of lutein from lutein esters or unesterified lutein. In general, there is a wide variation in the reported maximum serum peak concentration times (t_{max}) and the area under the concentration vs. time curve (AUC) from a single unesterified lutein or lutein esters supplement dose. In spite of this, one study in particular that used a [^{13}C]lutein tracer to measure the plasma clearance of lutein in women (Yao *et al.*, 2000), might be considered indicative of lutein bioavailability, given that bioavailability is proportional to the AUC (Rowland and Tozer, 1995). These investigators measured a serum lutein t_{max} of 14.8 hours and a mean AUC of 0.93 µmol · h/L from a single oral dose of 3 mg [^{13}C]lutein. The slow elimination kinetics of lutein are

consistent with the known slow turnover rates of lipoproteins such as LDL and HDL that transport carotenoids (Swanson *et al.*, 1996).

Twelve studies of chronic supplementation (7 days to 3 years) with lutein esters or unesterified lutein were also evaluated. These studies, at levels ranging from 8-30 mg unesterified lutein equivalents/day, resulted in serum lutein steady-state levels that ranged between 0.26-1.76 µmol/L. By comparison, studies on the serum distribution of carotenoids in humans consuming normal meals revealed an average background level of lutein plus zeaxanthin of ~0.4 µmol/L (reviewed in Krinsky *et al.*, 1990). Data for all individuals surveyed from NHANES III revealed mean serum lutein plus zeaxanthin levels of 0.37 µmol/L with maximum levels of 0.97 µmol/L reported in the 99th percentile (CDC, 1998). The results from these studies indicate that both lutein esters and unesterified lutein are sources of bioavailable lutein. Lutein esters are hydrolyzed in the gut to unesterified lutein, which is absorbed and enters circulation. Unless otherwise stated, these studies were restricted to measuring endpoints associated with bioavailability and did not report the effects of lutein consumption on other parameters such as blood and urine chemistries.

No toxicity from lutein ester supplement consumption has been reported and human clinical studies indicate that long term consumption of lutein esters is well tolerated. Seven clinical studies ranging from 84 days to 3 years reported that consumption of between 18 and 60 mg/day lutein ester equivalents is safe. The only adverse effect that has been reported in humans is carotenodermia, a yellowing of the skin, especially the palms of the hands and soles of feet, which is not considered a health hazard and is reversible. This effect has been reported in only one arm of one study among 7 of 17 subjects consuming 30 mg/day lutein esters for 112 days. There were no reports of carotenodermia developing in subjects from the other arms of this study nor was carotenodermia reported in other clinical studies of lutein including an ongoing study in which subjects consumed up to 40 mg/day Xangold® lutein esters supplements for >90 days. Therefore, it appears that carotenodemia may be associated with factors other than Xangold® lutein esters supplementation.

Animal Studies

Acute and chronic supplementation studies in a number of animal species provides corroborative evidence of bioavailability and safety. A single dose of lutein in oil given to preruminant calves resulted in peak serum lutein levels at 12 hours (Bierer et al, 1995). Chronic supplementation of esterified and unesterified lutein fed to rodents (mice and rats), dogs, cats and non-human primates significantly increased plasma lutein levels without any effects on body weights or organ weights (Park et al, 1998; Jenkins et al, 2000; Kim et al, 2000a; Kim et al, 2000b; Snodderly et al, 1990). In dogs and to a lesser extent in cats, lutein supplementation resulted in enhanced cell-mediated immunity and humoral response (Kim et al, 2000a; Kim et al, 2000b). Two rat studies in which esterified lutein was fed in amounts up to 750 mg per day for two weeks showed no effect on Phase I or Phase II enzymes in livers, lungs or kidneys, except for reduced lung benzyloxyresorufin-O-dealkylase activity, a non-specific indicator of P450 activities (Jewell and O'Brien, 1999; Gradelet et al, 1996). In mice fed 67 mg/kg/day dietary unesterified lutein for seven weeks there were no effects on body weights and kidney or liver histopathology (Kim et al, 1998). Several reports indicated that lutein was anti-mutagenic, anti-genotoxic and anti-carcinogenic (Nishino et al, 2000, Garcia-Gasca et al, 1998; Rauscher et al, 1998; Gonzalez de Mejia et al, 1997a,b; Okai et al, 1996 and Yoshikawa et al, 1996). No long-term lutein supplement studies were identified that measured carcinogenicity from esterified or unesterified lutein.

Proprietary unpublished studies showed that a single administration of 3.75 g/kg lutein esters oleoresin to rats resulted in no lethality or toxicity within two weeks and was non-irritating to the eyes or skin of rabbits (Hoyer 1998a,b,c).

Lutein and zeaxanthin were found to have negligible vitamin A activity in hypersensitive animal models consistent with other reports that these carotenoids are not provitamin A compounds (Weiser and Kormann, 1993).

Beta-carotene
The Expert Panel considered whether reported results of β-carotene studies have any relevance to the safety of lutein esters. Some studies have raised a question as to whether pharmacologic doses of beta-carotene are related to an increased risk of lung cancer, whereas other studies have not reported this association. At this time the data are inconclusive and the risk, if any, from β-carotene consumption will require further study. In any event, it does not appear that these beta-carotene studies are relevant to lutein esters. The specific molecular and cellular mechanism(s) underlying the reported effects of β-carotene in these studies has not been identified, but the most credible hypothesis relates to β-carotene's pro-vitamin A activity and altered retinoid signaling. Whereas β-carotene alters retinoid signaling, this activity has not been reported for lutein, a non-provitamin A carotenoid. Therefore, it is the Expert Panel's view that the data described above with respect to β-carotene are not relevant to a safety assessment of lutein esters.

Summary
Based on the extensive generally available data establishing that lutein esters are safe at levels of consumption up to at least 60 mg/day, and taking into consideration that Xangold® lutein esters have been administered at 40 mg/day without evidence of carotenodermia, the Panel has established a conservative acceptable daily intake of Xangold® lutein esters (or lutein ester equivalents) of 40 mg/day.

The estimated 90th percentile intake of lutein esters (or equivalents) from diet and selected foods supplemented with Xangold® lutein esters (from Table 2) is 22.3 mg/day. The potential lutein ester consumption from dietary supplements may increase intake by an additional maximum of 12 mg/day (based on current labeled recommendations for use rather than on a statistical analysis of consumption because consumption data are unavailable). Thus, the potential theoretical maximum lutein ester consumption at the 90th percentile may reach 34.3 mg/day. This theoretical intake level represents a conservative estimate since it is unlikely that an individual would consume lutein from both conventional foods and dietary supplements at the 90th percentile level. Even this conservative estimate, however, is well within the ADI of 40 mg/day and is therefore safe.

Conclusion
Cognis convened a panel of independent experts qualified by scientific training and experience to evaluate the safety of substances added to food. This panel consisted of the following individuals: Joseph F. Borzelleca, Ph.D., Professor Emeritus, Department of Pharmacology and Toxicology, Medical College of Virginia, Walter H. Glinsmann, M.D. Adjunct Professor, Center for Food and Nutrition Policy, Georgetown University and Norman I. Krinsky, Ph.D., Professor, Department of Biochemistry, Tufts University.

The Expert Panel considered all of the available data and information on Xangold® lutein esters, including data and information on the chemistry, composition and manufacturing process, and including a critical evaluation of the human and animal studies. The Expert Panel concluded that, based on common knowledge throughout the scientific community knowledgeable about the safety of substances added to food, there is reasonable certainty that Xangold® lutein esters, produced in accordance with current Good Manufacturing Practice (cGMP), will not be harmful under the intended conditions of use as an ingredient to provide a supplementary source of lutein in the diet..

The estimated safe total daily consumption is 40 mg per day of lutein esters (or lutein ester equivalents) from all sources. In particular, the Expert Panel evaluated the proposed use of Xangold® lutein esters at specified levels in the following foods: baked goods and baking mixes, soy milk, beverages and beverage powders, frozen dairy desserts and mixes, processed fruit and vegetable products, egg products and egg substitutes, breakfast cereals (ready-to-eat and hot), fats and oils, hard candy, fruit snacks and dairy products; and concluded that such use would result in an estimated daily intake that is below 40 mg/day lutein esters. The Expert Panel also concluded that Xangold® lutein esters are reasonably expected to be safe when used as an ingredient in medical foods (21 CFR §101.9(j)(8)) intended as the sole item of the diet, not to exceed 40 mg per day. Based on all of the above information, Xangold® lutein esters are therefore generally recognized as safe (GRAS) for their intended use in food.

Appendix 1: All foods included in the consumption analysis

BREAKFAST CEREALS (READY TO EAT AND HOT)

56200300 CEREAL, COOKED, NFS
56200350 CEREAL, COOKED, INSTANT, NS AS TO GRAIN
56202500 MUESLI, PREPARED, INSTANT (INCLUDE MICRO MUESLI)
56202960 OATMEAL,COOKED,NS AS TO REG,QUICK/INST,NS TO FAT
56202970 OATMEAL, COOKED, QUICK, NS TO FAT ADDED
56202980 OATMEAL, COOKED, REG, NS TO FAT ADDED
56203000 OATMEAL, COOKED, NFS, NO FAT ADDED
56203010 OATMEAL, COOKED, REGULAR, NO FAT ADDED
56203020 OATMEAL, COOKED, QUICK, NO FAT ADDED
56203030 OATMEAL, COOKED, INSTANT, NO FAT ADDED IN COOKING
56203040 OATMEAL, FAT ADDED IN COOKING, NFS
56203050 OATMEAL, REGULAR, FAT ADDED IN COOKING
56203060 OATMEAL, QUICK, FAT ADDED IN COOKING
56203070 OATMEAL, INSTANT, FAT ADDED
56203080 OATMEAL, INSTANT, NS AS TO ADDED FAT
56203090 OATMEAL, FORTIFIED, INSTANT, NO FAT ADDED
56203100 OATMEAL, FORTIFIED, INSTANT, FAT ADDED
56203110 OATMEAL, MAPLE FLAVOR, COOKED (INCL MAYPO)
56203120 OATMEAL W/ OAT BRAN, FORTIFIED, CKD, INSTANT, NO FAT
56203140 TOTAL OATMEAL, CKD, QUICK, NO FAT
56203200 OATMEAL, W/ FRUIT, COOKED
56203210 OATMEAL, NS TYPE, MADE W/ MILK, NO FAT ADDED
56203220 OATMEAL, NS TYPE, MADE W/ MILK, FAT ADDED
56203230 OATMEAL, NS TYPE, MADE W/ MILK, NS AS TO ADDED FAT
56203540 OATMEAL, W/ EVAPORATED MILK & SUGAR, P.R. STYLE
56203600 OATMEAL, MULTIGRAIN, COOKED, NS FAT ADDED
56203610 OATMEAL, MULTIGRAIN, COOKED, FAT NOT ADDED
56203620 OATMEAL, MULTIGRAIN, COOKED, FAT ADDED
56206970 WHEAT, CREAM OF,COOKED,QUICK,NS AS TO ADDED FAT
56206980 WHEAT, CREAM OF,COOKED,REG,NS AS TO ADDED FAT
56206990 WHEAT, CREAM OF,COOKED,NS AS REG,QUICK,/INST
56207000 WHEAT, CREAM OF, COOKED, NFS, NO FAT ADDED
56207010 WHEAT, CREAM OF, COOKED, REGULAR, NO FAT ADDED
56207020 WHEAT, CREAM OF, COOKED, QUICK, NO FAT ADDED
56207030 WHEAT, CREAM OF, COOKED, INSTANT, NO FAT ADDED
56207040 WHEAT, CREAM OF, MADE W/ MILK
56207050 WHEAT, CREAM OF, MADE W/ MILK & SUGAR, P.R. STYLE
56207060 WHEAT, CREAM OF, INSTANT, COOKED, FAT ADDED
56207070 WHEAT, CREAM OF, INSTANT,COOKED, NS AS TO ADDED FAT
56207080 WHEAT, CREAM OF,COOKED,NS AS TO REG,QUICK, OR INST
56207100 WHEAT, ROLLED, COOKED, NO FAT ADDED
56207140 WHEAT ROLLED,COOKED,NS AS TO ADDED FAT
56207190 WHOLE WHEAT CEREAL, COOKED, NS AS TO ADDED FAT
56207200 WHOLE WHEAT CEREAL, COOKED, NO FAT ADDED
56207210 WHOLE WHEAT CEREAL, COOKED, FAT ADDED
56207220 WHEAT, CREAM OF, COOKED, REGULAR, FAT ADDED
56207230 WHEAT, CREAM OF, COOKED,QUICK,FAT ADDED IN COOKING
56207290 WHEAT HEARTS, COOKED, NS AS TO ADDED FAT
56207300 WHOLE WHEAT CEREAL, W/ BARLEY, COOKED, NO FAT ADDED
56207310 WHEAT HEARTS, COOKED, NO FAT ADDED
56207330 WHOLE WHEAT CEREAL, WHEAT & BARLEY, FAT ADDED
56207340 WHOLE WHEAT CEREAL, WHEAT & BARLEY, ADDED FAT NS
56207350 WHEAT CEREAL, CHOC FLAVORED, COOKED W/ MILK
56207360 WHEAT CEREAL, CHOC FLAVORED, COOKED, NO FAT ADDED
56207370 WHEAT CEREAL, CHOC FLAV,COOKED,NS AS TO ADDED FAT

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56208000 MULTIGRAIN CEREAL, COOKED
56208010 MULTIGRAIN CEREAL, FAT ADDED
56208020 MULTIGRAIN CEREAL, NS AS TO ADDED FAT
56208500 OAT BRAN CEREAL, COOKED, NO FAT ADDED
56208510 OAT BRAN CEREAL, COOKED, FAT ADDED
56208520 OAT BRAN CEREAL, COOKED, NS AS TO ADDED FAT
56208530 OAT BRAN CEREAL, MADE W/ MILK, NO FAT ADDED
56208540 OAT BRAN CEREAL, MADE W/ MILK, FAT ADDED
56208550 OAT BRAN CEREAL, MADE W/ MILK, NS AS TO ADDED FAT
57000000 CEREAL, NFS
57000050 KASHI CEREAL, NS AS TO READY-TO-EAT OR COOKED
57000100 OAT CEREAL, NFS
57100100 CEREAL, READY-TO-EAT, NFS
57101000 ALL-BRAN CEREAL
57101020 ALL BRAN CEREAL W/ EXTRA FIBER
57101500 ALMOND DELIGHT CEREAL
57102000 ALPEN CEREAL
57103000 ALPHA-BITS CEREAL
57103020 ALPHA-BITS W/ MARSHMALLOWS CEREAL
57103050 AMARANTH FLAKES CEREAL
57103100 APPLE CINNAMON CHEERIOS
57103400 APPLE CINNAMON OH'S CEREAL
57103450 APPLE CINNAMON RICE KRISPIES CEREAL
57103500 APPLE CINNAMON SQUARES MINI-WHEATS CEREAL, KELLOGG'S
57104000 APPLE JACKS CEREAL
57105000 APPLE RAISIN CRISP CEREAL
57106050 BANANA NUT CRUNCH CEREAL (POST)
57106100 BASIC 4 (RTE CEREAL)
57106250 BERRY BERRY KIX
57106530 BLUEBERRY MORNING, POST
57107000 BOOBERRY CEREAL
57109000 BODY BUDDIES CEREAL, NATURAL FRUIT FLAVOR
57110000 ALL-BRAN BRAN BUDS CEREAL, KELLOGG'S (FORMERLY BRAN BUDS)
57111000 BRAN CHEX CEREAL
57112000 BRANOLA CEREAL
57117000 CAP'N CRUNCH CEREAL
57117500 CAP'N CRUNCH'S CHRISTMAS CRUNCH CEREAL
57119000 CAP'N CRUNCH'S CRUNCH BERRIES CEREAL
57119500 CAP'N CRUNCH'S DEEP SEA CRUNCH CEREAL
57120000 CAP'N CRUNCH'S PEANUT BUTTER CRUNCH CEREAL
57123000 CHEERIOS
57124000 CHEX CEREAL, NFS
57124200 CHOCOLATE FLAVORED FROSTED PUFFED CORN CEREAL
57124500 CINNAMON GRAHAMS CEREAL, GENERALMILLS
57125000 CINNAMON TOAST CRUNCH CEREAL
57125900 HONEY NUT CLUSTERS CEREAL
57126000 COCOA KRISPIES CEREAL
57126500 COCOA BLASTS CEREAL, QUAKER
57127000 COCOA PEBBLES CEREAL
57128000 COCOA PUFFS CEREAL
57128880 COMMON SENSE OAT BRAN CEREAL, PLAIN
57128900 COMMON SENSE OAT BRAN CEREAL, W/ RAISINS
57130000 COOKIE-CRISP CEREAL (INCLUDE ALL FLAVORS)
57131000 CRUNCHY CORN BRAN CEREAL, QUAKER
57132000 CORN CHEX CEREAL
57134000 CORN FLAKES, NFS (INCLUDE STORE BRANDS)
57134090 CORN FLAKES, LOW SODIUM
57135000 CORN FLAKES, KELLOGG
57137000 CORN PUFFS CEREAL

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57138000 TOTAL CORN FLAKES
57139000 COUNT CHOCULA CEREAL
57143000 CRACKLIN' OAT BRAN CEREAL
57144000 CRISP CRUNCH CEREAL
57148000 CRISPIX CEREAL
57148500 CRISPY BROWN RICE CEREAL
57151000 CRISPY RICE CEREAL
57152000 CRISPY WHEATS'N RAISINS CEREAL
57205250 DOUBLE CHEX CEREAL
57205260 DOUBLE DIP CRUNCH, KELLOGG'S
57206000 FAMILIA CEREAL
57206700 FIBER ONE CEREAL
57206800 FIBER 7 FLAKES CEREAL, HEALTH VALLEY
57207000 BRAN FLAKES CEREAL, NFS (FORMERLY 40% BRAN FLAKES, NFS)
57208000 COMPLETE WHEAT BRAN FLAKES, KELLOGG'S (FORM.40% BRAN FLAKES)
57209000 NATURAL BRAN FLAKES CEREAL, POST
57210100 40+ BRAN FLAKES CEREAL
57211000 FRANKENBERRY CEREAL
57212100 FRENCH TOAST CRUNCH CEREAL, GENERAL MILLS
57213000 FROOT LOOPS CEREAL
57213800 FROSTED BRAN,KELLOGG'S
57213850 FROSTED CHEERIOS CEREAL
57214000 FROSTED MINI-WHEATS CEREAL (INCL ALL FLAVORS)
57214100 FROSTED WHEAT BITES
57215000 FROSTY O'S CEREAL
57216000 FROSTED RICE CEREAL, NFS
57217000 FROSTED RICE KRINKLES CEREAL
57218000 FROSTED RICE KRISPIES CEREAL
57219000 FRUIT & FIBRE CEREAL, NFS
57220000 FRUIT & FIBRE CEREAL, W/ APPLES & CINNAMON
57221000 FRUIT & FIBRE CEREAL, W/ DATES, RAISINS, & WALNUTS
57221600 FRUIT&FIBRE CEREAL W/PEACH,RAISIN,ALMOND&OAT CLUST
57221700 FRUIT RINGS, NFS (INCLUDE STORE BRANDS)
57221800 FRUIT WHIRLS CEREAL
57222500 FRUIT WHEATS CEREAL
57223000 FRUITY PEBBLES CEREAL
57223200 FRUITY YUMMY MUMMY CEREAL
57224000 GOLDEN GRAHAMS CEREAL
57225000 GOLDEN HARVEST PROTEINOLA CEREAL
57227000 GRANOLA, NFS
57229000 GRANOLA, LOWFAT, KELLOGG'S
57229500 GRANOLA W/ RAISINS, LOWFAT, KELLOGG'S
57230000 GRAPE-NUTS CEREAL
57231000 GRAPE-NUT FLAKES
57231200 GREAT GRAINS, RAISIN, DATE, & PECAN,WHOLE GRAIN CEREAL, POST
57231250 GREAT GRAINS DOUBLE PECAN WHOLE GRAIN CEREAL, POST
57232100 HEALTHY CHOICE ALMOND CRUNCH CEREAL W/ RAISINS
57232110 HEALTHY CHOICE MULTI-GRAIN SQUARES, KELLOGG'S
57232120 HEALTHY CHOICE MULTI-GRAIN FLAKES CEREAL, KELLOGG'S
57233000 HEARTLAND NATURAL CEREAL, PLAIN
57234000 HEARTLAND NATURAL CEREAL, W/ RAISINS
57235000 HEARTLAND NATURAL CEREAL, W/ COCONUT
57235650 HIDDEN TREASURES, GENERAL MILLS
57237000 HONEY BRAN CEREAL
57237100 HONEY BUNCHES OF OATS CEREAL
57237300 HONEY BUNCHES OF OATS W/ ALMONDS, POST
57238000 HONEYCOMB CEREAL, PLAIN
57239000 HONEYCOMB CEREAL, STRAWBERRY
57239100 HONEY CRUNCH CORN FLAKES CEREAL, KELLOGG'S

57240000 HONEY GRAHAM CHEX CEREAL
57240100 HONEY NUT CHEX CEREAL
57241000 HONEY NUT CHEERIOS
57241200 HONEY NUT SHREDDED WHEAT CEREAL, POST
57243000 HONEY SMACKS CEREAL
57243870 JENNY O'S
57244000 JUST RIGHT CEREAL
57245000 JUST RIGHT FRUIT & NUT CEREAL (W/ RAISINS, DATES, NUTS)
57301100 KABOOM CEREAL
57301500 KASHI, PUFFED
57302100 KING VITAMAN CEREAL
57303100 KIX CEREAL
57304100 LIFE CEREAL (PLAIN & CINNAMON)
57305100 LUCKY CHARMS CEREAL
57305150 FROSTED OAT CEREAL W/ MARSHMALLOWS
57305170 MALT-O-MEAL COCO-ROOS CEREAL
57305180 MALT-O-MEAL CORN BURSTS CEREAL
57305200 MALT-O-MEAL CRISPY RICE CEREAL
57305500 MALT-O-MEAL HONEY & NUT TOASTY O'S CEREAL
57305600 MALT-O-MEAL MARSHMALLOW MATEYS CEREAL
57306100 MALT-O-MEAL PUFFED RICE CEREAL
57306120 MALTO-O-MEAL PUFFED WHEAT CEREAL
57306500 MALT-O-MEAL GOLDEN PUFFS CEREAL (FORMERLY SUGAR PUFFS)
57306700 MALT-O-MEAL TOASTED OAT CEREAL
57306800 MALT-O-MEAL TOOTIE FRUITIES (RTE CEREAL)
57307100 FRUITY MARSHMALLOW KRISPIES CEREAL
57307150 MARSHMALLOW SAFARI CEREAL, QUAKER
57307500 MILLET, PUFFED (CEREAL)
57307550 MINI BUNS CEREAL (CINNAMON)
57308150 MUESLIX CEREAL, NFS
57308160 MUESLI W/ RAISINS, WALNUTS, AND CRANBERRIES
57308170 MUESLI W/ RAISINS, PEACHES & PECANS
57308180 MUESLIX CRISPY BLEND
57308190 MUESLI WITH RAISINS, DATES, AND ALMONDS
57308200 MUESLIX GOLDEN CRUNCH CEREAL
57308210 MUESLI, W/ APPLES & ALMONDS, RALSTON PURINA
57308220 STRAWBERRY MUESLI W/ PECANS & RAISINS, RALSTON
57308300 MULTI BRAN CHEX
57308400 MULTI GRAIN CHEERIOS
57308410 MULTI-GRAIN CHEERIOS PLUS CEREAL
57308900 NATURAL MUESLI, JENNY'S CUISINE
57309100 NATURE VALLEY GRANOLA, W/ FRUIT & NUTS
57310000 NATURE VALLEY GRANOLA, W/ CINNAMON & RAISINS
57311000 NATURE VALLEY GRANOLA, TOASTED OAT MIXTURE
57311700 NU SYSTEM CUISINE TOASTED GRAIN CIRCLES CEREAL
57311800 NUT AND HONEY CRUNCH FLAKED CEREAL
57312100 NUTRI-GRAIN BISCUITS, SHREDDED WHEAT CEREAL
57315000 NUTRI-GRAIN GOLDEN WHEAT CEREAL (FORMERLY NUTRI-GRAIN WHEAT)
57316100 NUTRI-GRAIN ALMOND RAISIN CEREAL
57316200 NUTTY NUGGETS (RALSTON)
57316300 OAT BRAN FLAKES, HEALTH VALLEY
57316400 OATMEAL CRISP (RTE CEREAL)
57316410 APPLE CINNAMON OATMEAL CRISP CEREAL (OATMEAL CRISP W/ APPLES
57316450 OATMEAL CRISP W/ ALMONDS CEREAL
57316500 OATMEAL RAISIN CRISP CEREAL
57316700 OH'S, CRUNCHY NUT CEREAL
57316710 OH'S, HONEY GRAHAM CEREAL
57316750 OH'S, FRUITANGY CEREAL
57317000 OAT FLAKES, FORTIFIED

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57317200 OAT FLAKES CEREAL, POST
57318000 100% BRAN CEREAL
57319000 100% NATURAL CEREAL, PLAIN, QUAKER
57319500 SUN COUNTRY 100% NATURAL GRANOLA, WITH ALMONDS
57320500 100 % NATURAL CEREAL, W/ OATS,HONEY & RAISINS,QUAKER
57321000 100% NATURAL CEREAL, W/ RAISINS & DATES, QUAKER
57321500 100% NATURAL WHOLEGRAIN CEREAL W/ RAISINS, LOWFAT, QUAKER
57322500 OREO O'S CEREAL, POST
57323000 SWEET CRUNCH CEREAL, QUAKER (FORMERLY POPEYE)
57323050 SWEET PUFFS CEREAL, QUAKER
57323200 POP TARTS CRUNCH CEREAL
57325000 PRODUCT 19 CEREAL
57327450 QUAKER OAT BRAN CEREAL
57327500 QUAKER OATMEAL SQUARES CEREAL (FORMERLY QUAKER OAT SQUARES)
57328000 QUISP CEREAL
57329000 RAISIN BRAN CEREAL, NFS
57330000 RAISIN BRAN CEREAL, KELLOGG
57330500 RAISIN BRAN CEREAL, NUTRI/SYSTEM
57331000 RAISIN BRAN CEREAL, POST
57332000 RAISIN BRAN CEREAL, RALSTON PURINA
57332050 RAISIN BRAN, TOTAL
57332100 RAISIN NUT BRAN CEREAL
57332300 SUPER RAISIN BRAN, NEW MORNING
57333000 RAISIN GRAPE-NUTS CEREAL
57334000 RAISIN LIFE CEREAL
57335500 RAISIN SQUARES MINI-WHEATS CEREAL (FORMERLY RAISIN SQUARES)
57335530 RAZZLE DAZZLE RICE KRISPIES CEREAL
57335550 REESE'S PEANUT BUTTER PUFFS CEREAL
57336000 RICE CHEX CEREAL
57337000 RICE FLAKES, NFS
57339000 RICE KRISPIES CEREAL
57339500 RICE KRISPIES TREATS CEREAL (KELLOGG'S)
57340000 PUFFED RICE CEREAL
57340200 RIPPLE CRISP GOLDEN CORN
57340210 RIPPLE CRISP HONEY BRAN CEREAL, GENERAL MILLS
57341000 SHREDDED WHEAT 'N BRAN CEREAL
57342500 S'MORES CRUNCH CEREAL
57344000 SPECIAL K CEREAL
57344050 SPIDER-MAN CEREAL, RALSTON
57344100 SPRINKLE SPRANGLE CEREAL
57346200 SUN CRUNCHERS CEREAL, GENERAL MILLS
57346500 TOASTED OATMEAL, HONEY NUT (QUAKER)
57347000 CORN POPS CEREAL
57347500 STRAWBERRY SQUARES MINI-WHEATS CEREAL(STRAWBERRY SQUARES)
57348000 FROSTED CORN FLAKES, NFS
57349000 FROSTED FLAKES, KELLOGG
57349010 COCOA FROSTED FLAKES CEREAL, KELLOGG'S
57350000 FROSTED FLAKES, RALSTON PURINA
57352000 SUGAR-SPARKLED FLAKES
57353000 SUGAR-SPARKLED RICE KRINKLES CEREAL
57354000 SUN FLAKES CEREAL
57355000 GOLDEN CRISP CEREAL
57401100 TOASTED OAT CEREAL
57402000 TEAM CEREAL
57402600 TEMPTATIONS CEREAL, FRENCH VANILLA ALMOND, KELLOGG'S
57402610 TEMPTATIONS CEREAL, HONEY ROASTED PECAN, KELLOGG'S
57403100 TOASTIES, POST
57404100 MALT-O-MEAL TOASTY O'S CEREAL
57406100 TOTAL CEREAL

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57406200 TRIPLES (RTE CEREAL)
57407100 TRIX CEREAL
57408100 UNCLE SAM'S HI FIBER CEREAL
57409100 WAFFLE CRISP CEREAL, POST
57410000 WEETABIX WHOLE WHEAT CEREAL
57411000 WHEAT CHEX CEREAL
57412000 WHEAT GERM CEREAL, PLAIN
57413000 WHEAT GERM CEREAL, W/ SUGAR & HONEY
57416000 PUFFED WHEAT CEREAL, PLAIN
57416010 WHEAT, PUFFED, PRESWEETENED W/ SUGAR
57417000 SHREDDED WHEAT, 100%
57417500 SHREDDED WHEAT WITH OAT BRAN (RTE CEREAL)
57418000 WHEATIES CEREAL
57418200 WHEATIES CEREAL, HONEY FROSTED (FORMERLY WHEATIES HONEY GOLD
57601100 WHEAT BRAN, UNPROCESSED
57602100 OATS, RAW
57602500 OAT BRAN, UNCOOKED
57603100 RICE POLISHINGS
57603200 RICE BRAN CEREAL, UNCOOKED
57604100. WHOLE WHEAT, CRACKED
57801000 BARLEY CEREAL, BABY, DRY, INSTANT
57801200 CORN CEREAL, BABY, DRY, INSTANT
57802000 HIGH PROTEIN CEREAL, BABY, DRY, INSTANT
57803000 MIXED CEREAL, BABY, DRY, INSTANT
57804000 OATMEAL CEREAL, BABY, DRY, INSTANT
57805000 RICE CEREAL, BABY, DRY, INSTANT
57805080 RICE CEREAL W/ APPLES, BABY, DRY, INSTANT
57805100 RICE CEREAL W/ BANANAS, BABY, DRY, INSTANT
57805200 RICE CEREAL W/ MANGO, BABY, DRY, INSTANT
57805500 BROWN RICE CEREAL, BABY FOOD, DRY, INSTANT
57806000 MIXED CEREAL W/ BANANAS, BABY, DRY, INSTANT
57806100 OATMEAL CEREAL W/ BANANAS, BABY, DRY, INSTANT
57806200 OATMEAL W/ FRUIT, BABY, DRY, INSTANT, TODDLER
57807010 WHOLE WHEAT CEREAL W/ APPLES, BABY, DRY, INSTANT
57820000 CEREAL, BABY, JARRED, NFS
57820100 RICE CEREAL, BABY FOOD, JARRED, NFS
57822000 MIXED CEREAL W/ APPLESAUCE & BANANAS, BABY, JARRED
57823000 OATMEAL W/ APPLESAUCE & BANANAS, BABY, JARRED
57824000 RICE CEREAL, W/ APPLESAUCE & BANANAS, BABY, JARRED
57824500 RICE CEREAL W/ MIXED FRUIT, BABY, JARRED
57830100 GERBER GRADUATES FINGER SNACKS CEREAL,BABY FOOD

BEVERAGES AND BEVERAGE POWDERS

11340000 MILK,IMITATION,FLUID,NONSOY,SWEETENED,NOT CHOCOLATE
11340100 MILK,IMITATION,FLUID,NON-SOY,SWEETENED,CHOCOLATE
11612000 INSTANT BREAKFAST, POWDER, MILK ADDED
11613000 INSTANT BFAST,PWDR,SWT W/ LO CAL SWT, MILK ADDED
11830120 COCOA W/ WHEY, LO CAL SWEETENER, FORTIFIED, DRY MIX
11830140 CHOCOLATE, INST, DRY MIX, FORTIFD, NOT RECONST,P.R.
11830160 COCOA-FLAVORED BEVERAGE POWDER W/ SUGAR, DRY MIX
11830170 COCOA, WHEY, LO CAL SWEETNER MIX, NOT RECONST
11830180 COCOA-FLAV BEV MIX, LOW CALORIE, DRY, NOT RECONST
11830800 INSTANT BREAKFAST POWDER, NOT RECONSTITUTED
11830810 INSTANT BFAST,PWDR,SWT W/ LO CAL SWT,NOT RECONSTUT
11830850 HIGH CALORIE MILK BEVERAGE, POWDER, NOT RECONST
11835000 MEAL REPLACEMENT, CAMBRIDGE, POWDER, NOT RECONST
11835100 MEAL REPLACEMENT, POSITRIM DRINK MIX, DRY POWDER

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11835150 DYNATRIM, MEAL REPLACEMENT, POWDER
11835200 LOSE-IT (NANCI), MEAL REPLACEMENT, POWDER
11940100 NUTRAMIGEN, DRY, NOT RECONSTITUTED
28401000 MEAL REPLACEMENT, GELATIN BASE, POWDER, NOT RECONST
28401010 MEAL REPLACEMENT, GELATIN BASE, POWDER, RECONST
28401200 GELATIN DRINK, FLAVORED, W/ LOW CALORIE SWEETENER
41430000 PROTEIN POWDER, NFS
41430010 PROTEIN SUPPLEMENT, POWDERED
41430100 FORMULATED DIET MEAL, POWDER, SOY PROTEIN ISOLATE
41430200 MEAL REPLACE / SUPP, SOY-MILK-BASE,POWD,WATER ADDED
41430310 PROTEIN DIET POWDER W/ SOY & CASEIN
92510110 APPLE DRINK
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 (INCLUDE FRUIT PUNCH & FRUIT ADE)
92510630 FRUIT JUICE DRINK, NFS
92510650 TAMARIND DRINK, P.R. (REFRESCO DE TAMARINDO)
92510720 FRUIT PUNCH, MADE W/ FRUIT JUICE & SODA
92510730 FRUIT PUNCH, MADE W/ SODA, FRUIT JUICE & SHERBET
92510810 GRAPEADE & GRAPE DRINK
92510820 GRAPE JUICE DRINK
92510910 GRAPEFRUIT JUICE DRINK
92510950 GUAVA JUICE DRINK
92511000 LEMONADE, FROZEN CONCENTRATE, NOT RECONSTITUTED
92511010 LEMONADE
92511020 LEMON-LIMEADE
92511110 LIMEADE
92511190 ORANGE JUICE DRINK
92511200 ORANGE-MANGO JUICE DRINK
92511220 ORANGE DRINK (INCLUDE ORANGE ADE, YABA DABA DEW)
92511230 ORANGE-APRICOT JUICE DRINK
92511240 ORANGE-LEMON DRINK
92511250 CITRUS FRUIT JUICE DRINK (INCL 5-ALIVE)
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
92520410 FRUIT DRINK, LOW CALORIE
92520810 GRAPE DRINK, LOW CALORIE
92520910 LEMONADE, LOW CALORIE
92530110 APPLE DRINK W/ VITAMIN C ADDED
92530210 BLACK CHERRY DRINK W/ VITAMIN C ADDED
92530310 CHERRY DRINK W/ VITAMIN C ADDED
92530410 CITRUS DRINK W/ VITAMIN C ADDED
92530510 CRANBERRY JUICE DRINK W/VIT C ADDED(INCL COCKTAIL)
92530520 CRANBERRY-APPLE JUICE DRINK W/ VITAMIN C ADDED
92530610 FRUIT PUNCH/DRINK/ADE W/ VIT C ADDED (INCL HI-C)
92530710 GRAPE DRINK W/ VITAMIN C ADDED
92530810 GRAPEFRUIT JUICE DRINK W/ VITAMIN C ADDED

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92530840 GUAVA JUICE DRINK W/ VIT C ADDED
92530910 LEMONADE W/ VITAMIN C ADDED
92530950 VEGETABLE & FRUIT JUICE DRINK, W/ VIT C
92531010 ORANGE DRINK & ORANGEADE W/ VITAMIN C ADDED
92531020 ORANGE BREAKFAST DRINK, FROM FROZEN CONCENTRATE
92531030 ORANGE BREAKFAST DRINK
92531110 PINEAPPLE-GRAPEFRUIT JUICE DRINK W/ VIT C ADDED
92531120 PINEAPPLE-ORANGE JUICE DRINK W/ VITAMIN C ADDED
92531150 PINEAPPLE-ORANGE-GRAPEFRUIT JUICE DRINK W/VITAMIN C
92531210 SRAWBERRY-FLAVORED DRINK W/ VITAMIN C ADDED
92541010 FRUIT-FLAVORED DRINK, FROM SWEETENED PWDR,FORTIFIED W/ VIT C
92541020 LEMONADE-FLAV DRINK, FROM POWDER, W/ SUGAR & VIT C
92541040 LEMONADE-FLAV DRINK, FROM POWDER, LO CAL, W/ VIT C
92541100 APPLE CIDER DRINK, FROM MIX, SUGAR & VIT C ADDED
92541120 APPLE CIDER DRINK, FROM MIX, LOW CAL, VIT C ADDED
92542000 FRUIT-FLAVORED DRINK, FROM POWDER, W/HI VIT C(TANG)
92544000 FRUIT-FLAVOR DRINK, FROM UNSWEET PWDR,W/ VIT C,W/ SUGAR
92550050 APPLE-WHITE GRAPE JUICE DRINK,LOW CAL,W/VIT C ADDED
92550110 CRANBERRY JUICE COCKTAIL, LO CAL, W/ VIT C ADDED
92550210 CRANBERRY-APPLE JUICE DRINK, LO CAL, VIT C ADDED
92550300 GRAPEFRUIT JUICE DRINK,LOW CALORIE,W/ VITAMIN C
92550610 FRUIT-FLAVORED DRINK, LOW CAL, W/ VITAMIN C ADDED
92551600 CITRUS JUICE DRINK, LOW CALORIE
92551700 JUICE DRINK, LOW CALORIE
92552000 FRUIT-FLAV DRINK, FROM MIX, HI VIT C ADDED, LOW CAL
92552050 ORANGE BREAKFAST DRINK, LOW CALORIE
92552100 ORANGE-CRANBERRY JUICE DRINK,LOW CAL,W/ VIT C ADDED
92553000 FRUIT-FLAVORED THIRST QUENCHER BEVERAGE, LOW CAL
92560000 FRUIT-FLAVORED THIRST QUENCHER BEVERAGE
92570100 FLUID REPLACEMNT,ELECTROLYTE SOLUTN(INCL PEDIALYTE)
92570500 FLUID REPLACEMENT, 5% GLUCOSE IN WATER
92582000 FRUIT-FLAVORED DRINK, LOW CALORIE, CALCIUM-FORTIFD
92582050 FRUIT-FLAVORED DRINK, VITAMIN & MINERAL FORTIFIED
92582100 CITRUS JUICE DRINK, CALCUIM FORTIFIED
92582110 ORANGE BREAKFAST DRINK, CALCIUM FORTIFIED
92731000 FRUIT-FLAVORED DRINK,NON-CARB,FROM POWDER, W/ SUGAR
92741000 FRUIT-FLAVORED DRINK, NON-CARB, FROM LO CAL POWDER
92751000 ROOT BEER, NONCARBONATED, MADE FROM MIX, W/ SUGAR
92900100 TANG, DRY CONCENTRATE
92900110 FRUIT-FLAVORED CONCENTRATE, DRY, W/ SUGAR & VIT C
92900200 FRUIT-FLAV BEV, DRY CONC,LO CAL(INCL CRYSTAL LIGHT)
92900300 FRUIT-FLAV THIRST QUENCH BEV, DRY CONC (GATORADE)

FATS AND OILS

81103080 MARGARINE-LIKE SPREAD, TUB, SALTED
81103090 MARGARINE-LIKE SPREAD, LIQUID, SALTED
81103100 MARGARINE-LIKE SPREAD, STICK, UNSALTED
81103120 MARGARINE-LIKE SPREAD, TUB, UNSALTED
81103130 MARGARINE-LIKE SPREAD, WHIPPED, TUB, SALTED
81103140 MARGARINE-LIKE SPREAD, TUB, SWEETENED
81104010 MARGARINE-LIKE SPREAD, RED CAL, 40% FAT, TUB, SALTED
81104011 MARGARINE-LIKE SPREAD,RED CAL,40% FAT,MADE W/ YOGURT,TUB
81104020 MARGARINE-LIKE SPREAD, RED CAL, 40% FAT, STICK, SALTED
81104050 MARGARINE-LIKE SPREAD, RED CAL, 20% FAT, TUB, SALTED
81104070 MARGARINE-LIKE SPREAD, RED CAL, 20% FAT, TUB, UNSALTED
81104100 MARGARINE-LIKE SPREAD, FAT-FREE, TUB, SALTED
81104110 MARGARINE-LIKE SPREAD, FAT FREE, LIQUID, SALTED

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81104500 VEGETABLE OIL-BUTTER SPREAD, STICK, SALTED
81104510 VEGETABLE OIL-BUTTER SPREAD, TUB, SALTED
81104550 VEGETABLE OIL-BUTTER SPREAD, RED CAL, STICK, SALTED
81104560 VEGETABLE OIL-BUTTER SPREAD, RED CAL, TUB, SALTED
83100100 SALAD DRESSING, NFS
83101000 BLUE OR ROQUEFORT CHEESE DRESSING
83101500 BACON DRESSING (HOT)
83101600 BACON & TOMATO DRESSING
83102000 CAESAR DRESSSING
83103000 COLESLAW DRESSSING
83103500 FETA CHEESE SALAD DRESSING
83104000 FRENCH DRESSSING
83105000 FRUIT DRESSING W/ FRUIT JUICE & CREAM
83105100 FRUIT DRESSING, MADE W/ HONEY, OIL, WATER
83105500 HONEY MUSTARD DRESSING
83106000 ITALIAN DRESSING, W/ VINEGAR & OIL
83107000 MAYONNAISE, REGULAR
83107100 MAYONNAISE, MADE W/ YOGURT (INCLUDE YOGANNAISE)
83107200 MAYONNAISE, MADE W/ TOFU
83108000 MAYONNAISE, IMITATION
83108100 MAYONNAISE, IMITATION, NO CHOLESTEROL
83109000 RUSSIAN DRESSING
83110000 MAYONNAISE-TYPE SALAD DRESSING
83110010 MAYONNAISE-TYPE SALAD DRESSING, CHOLESTEROL-FREE
83111000 BOILED, COOKED-TYPE DRESSING
83112000 GREEN GODDESS DRESSING
83112500 CREAMY DRESSING, W/SOUR CREAM/BUTTERMILK & OIL
83112600 CREAM CHEESE DRESSING
83112950 POPPY SEED DRESSING
83112960 PEPPERCORN DRESSING
83112980 CELERY SEED DRESSING
83112990 SESAME DRESSING
83113000 SWEET & SOUR DRESSING
83114000 THOUSAND ISLAND DRESSING
83115000 YOGURT DRESSING
83200100 SALAD DRESSING, LOW CALORIE, NFS
83200500 BACON & TOMATO DRESSING, LOW CALORIE
83201000 BLUE OR ROQUEFORT CHEESE DRESSING, LOW CALORIE
83201050 BLUE OR ROQUEFORT CHEESE DRESSING, REDUCED CALORIE
83201200 BLUE/ROQUEFORT CHEESE DRESSING,RED CAL,NO FAT/CHOL
83201400 COLESLAW DRESSING, REDUCED CALORIE
83202000 FRENCH DRESSING, LOW CALORIE
83202010 FRENCH DRESSING, REDUCED CALORIE,FAT-FREE,CHOL-FREE
83202020 FRENCH DRESSING, REDUCED CALORIE
83203000 CAESAR DRESSING, LOW CALORIE
83203250 MAYONNAISE-TYPE SALAD DRESSING, FAT-FREE
83204000 MAYONNAISE, LOW CALORIE OR DIET
83204010 MAYONNAISE, LOW CALORIE OR DIET, LOW SODIUM
83204020 MAYONNAISE, REDUCED-CALORIE/DIET, CHOLESTEROL-FREE
83204050 MAYONNAISE-TYPE SALAD DRESSING, LOW CALORIE
83204060 MAYONNAISE-TYPE SALAD DRESSING,DIET,NO CHOLESTEROL
83205000 ITALIAN DRESSING, LOW CALORIE
83205450 ITALIAN DRESSING, REDUCED CALORIE
83205500 ITALIAN DRESSING, REDUCED CALORIE, FAT-FREE
83206000 RUSSIAN DRESSING, LOW CALORIE
83207000 THOUSAND ISLAND DRESSING, LOW CALORIE
83207100 THOUSAND ISLAND DRSG,REDUCED CAL,FAT-FREE,CHOL-FREE
83210000 CREAMY DRESSING W/ BUTTERMILK, NS LOW/REDUCED CAL
83210050 CRMY DRSG W/ SOUR CRM &/ BUTTERMILK & OIL, LOW CAL

83210100 CRMY DRSG W/ SOUR CRM &/ BUTTERMILK & OIL, RED CAL
83210200 CRMY DRSG W/SOUR CRM&/BTTRMILK,RED CAL,NOFAT/CHOL
83210250 CRMY DRSG W/SOUR CRM&/BUTTRMILK&OIL,RED CAL,NOCHOC
83220000 SALAD DRESSING, LOW CALORIE, OIL-FREE

BAKED GOODS AND BAKING MIXES

41435010 HIGH PROTEIN BAR, SOY BASE
41435110 HIGH PROTEIN BAR, CANDY-LIKE, SOY & MILK BASE
41435200 HIGH PROTEIN BAR, COOKIE TYPE,SOY & MILK BASE
41460010 HI-PROTEIN WAFERS
53540000 BREAKFAST BAR, NFS
53540100 BREAKFAST BAR, CAKE-LIKE
53540200 BREAKFAST BAR, CEREAL CRUST W/ FRUIT FILLING, LOWFAT
53540250 BREAKFAST BAR, CEREAL CRUST W/ FRUIT FILLING, FAT FREE
53540500 BREAKFAST BAR, DATE, W/ YOGURT COATING
53541100 BREAKFAST BAR, DIET MEAL TYPE
53541200 MEAL REPLACEMENT BAR (INCL SLIM FAST BAR)
53542100 GRANOLA BAR W/ OATS, SUGAR, RAISINS, COCONUT
53542200 GRANOLA BAR, OATS, FRUIT, NUTS, LOWFAT
53542210 GRANOLA BAR, NONFAT
53543100 GRANOLA BAR W/ PEANUTS, OATS, SUGAR, WHEAT GERM
53544100 GRANOLA BAR, W/ NOUGAT
53544200 GRANOLA BAR, CHOCOLATE-COATED
53544210 GRANOLA BAR, W/ COCONUT, CHOCOLATE-COATED
53544220 GRANOLA BAR W/ NUTS, CHOCOLATE-COATED
53544250 GRANOLA BAR, COATED W/ NONCHOCOLATE COATING
53544300 GRANOLA BAR, HIGH FIBER, YOGURT COATING, NOT CHOC
53544400 GRANOLA BARS, W/ RICE CEREAL
53544450 POWERBAR (FORTIFIED HIGH ENERGY BAR)
54202010 CRACKERS, SALTINE, LOW SODIUM
54202050 CRACKERS, SALTINE, FAT FREE, LOW SODIUM
54203010 CRACKERS, TOAST THINS (RYE/WHEAT/WHITE), LOW SODIUM
54204010 CRACKER, 100% WHOLE WHEAT,LO SODIUM
54205010 CRACKER, SNACK, LOW SODIUM
54205030 CRACKER, CHEESE, LOW SODIUM
54205100 CRACKER, SNACK, LOWFAT, LOW SODIUM
54207010 CRISPBREAD, WHEAT, LOW SODIUM
54210010 CRACKER, MULTIGRAIN, SALT-FREE
54222000 CRISPBREAD, RYE, LOW SODIUM
54301000 CRACKER, SNACK
54301100 CRACKER, SNACK, REDUCED FAT
54301200 CRACKER, SNACK, FAT FREE
54304000 CRACKERS, CHEESE
54304100 CRACKER, CHEESE, REDUCED FAT
54304500 CRACKER, HIGH FIBER, NO ADDED FAT
54305000 CRISPBREAD, WHEAT, NO ADDED FAT
54305500 CRISPBREAD,WHEAT / RYE, EXTRA CRISPY
54309000 CRACKERS, OAT BRAN (INCLUDE NABISCO OAT THINS)
54322000 CRISPBREAD, RYE, NO ADDED FAT
54325000 CRACKERS, SALTINES
54325050 CRACKERS, SALTINE, WHOLE WHEAT
54328200 CRACKER,SANDWICH-TYPE, CHEESE-FILLED
54334000 CRACKERS, TOAST THINS
54336000 CRACKER, WATER BISCUIT
54337000 CRACKER, 100% WHOLE WHEAT
54337050 CRACKER, 100% WHOLE WHEAT, REDUCED FAT
54337100 CRACKER,WHOLE WHEAT & BRAN (INCL WH & BRAN TRISCUIT

54338000 CRACKERS, WHEAT
54338100 CRACKERS, WHEAT, REDUCED FAT

EGG PRODUCTS AND EGG SUBSTITUTES

33000100 EGG SUBSTITUTE, NS AS TO POWDERED, FROZEN OR LIQUID
33102010 SCRAMBLED EGGS, FROM POWDERED MIXTURE
33201010 SCRAMBLED EGGS, FROM CHOLESTEROL-FREE FROZEN MIX
33201110 SCRAMBLED EGG, CHOLESTEROL-FREE, W/ CHEESE
33201500 SCRAMBLED EGG,CHOL-FREE FROZ MIXTURE,W/VEGETABLES
33202010 SCRAMBLED EGGS, FROM FROZEN MIXTURE
33301010 SCRAMBLED EGGS, FROM PACKAGED LIQUID MIXTURE

DAIRY PRODUCTS

11410000 YOGURT, NS AS TO TYPE OF MILK/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, COFFEE, NS AS TO MILK TYPE
11421000 YOGURT, VANILLA, LEMON, COFFEE, WHOLE MILK
11422000 YOGURT, VANILLA, LEMON, COFFEE, LOWFAT MILK
11423000 YOGURT, VANILLA, LEMON, COFFEE, NONFAT MILK
11424000 YOGURT, VANILLA, LEMON, COFFEE, NONFAT MILK, LOW CAL SWEET
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 MILK TYPE
11431000 YOGURT, FRUIT VARIETY, WHOLE MILK
11432000 YOGURT, FRUIT VARIETY, LOWFAT MILK
11433000 YOGURT, FRUIT VARIETY, NONFAT MILK
11433500 YOGURT, FRUITED, NONFAT MILK, LOW CAL SWEETENER
11444000 YOGURT, FRUIT & NUTS, NS AS TO TYPE OF MILK
11445000 YOGURT, FRUIT & NUTS, LOWFAT MILK
11525000 MILK,MALTED,FORTIFIED,NATURAL FLAVOR (INCL OVALTINE
11526000 MILK, MALTED, FORTIFIED, CHOCOLATE (INCL OVALTINE)
11527000 MILK, MALTED, FORTIFIED, (INCL OVALTINE)
11552200 MILK-BASED FRUIT DRINK (INCL ORANGE JULIUS)
11553000 FRUIT SMOOTHIE DRINK, W/ FRUIT AND DAIRY PRODUCTS
11553100 FRUIT SMOOTHIE DRINK, NFS
11560020 MILK DRINK, WHEY&MILK-BASE, NOT CHOC (INCL YOO-HOO)
11560100 FLAV MILK DRINK,SKIM MILK&CREAM-BASED,NOT CHOC
11611000 INSTANT BREAKFAST, FLUID, CANNED
11621000 DIET BEVERAGE, LIQUID, CANNED
11622000 DIET BEVERAGE POWDER, MILK ADDED
11622010 DIET BEVERAGE,PWDR,RECONST W/SKIM (INCL CARNATION)
11623000 MEAL SUPPLEMENT / REPLACEMENT,PREPARED,RTD
11631000 HIGH CALORIE BEV, CANNED OR POWDERED, RECONSTITUTED
11641000 MEAL REPLACEMENT, MILK BASED, HIGH PROTEIN, LIQUID
11651010 MEAL REPLACEMENT, CAMBRIDGE, RECONST, ALL FLAVORS
11810000 MILK, DRY, NOT RECONSTITUTED, NS AS TO FAT
11811000 MILK, DRY, WHOLE, NOT RECONSTITUTED
11812000 MILK, DRY, LOWFAT, NOT RECONSTITUTED
11813000 MILK, DRY, NONFAT, NOT RECONSTITUTED
11830400 MILK BEV POWDER, DRY, NOT RECONST, NOT CHOC
11830450 MILK BEV MIX, W/ SUGAR,EGG WHITE, NOT RECONSTITUTED
11830500 MILK BEV POWDER W/ NFD MILK, LOW CAL, DRY, CHOC

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11830550 MILK BEV POWDER W/ NFD MILK, LOW CAL, DRY, NOT CHOC
11830900 PROTEIN SUPPLEMENT, MILK BASED, DRY POWDER
11830940 MEAL REPLACEMENT,PROTEIN,MILK BASED,FRUIT JUICE MIX
11830950 NUTRIENT SUPP,MILK-BASED,POWDERED,NOT RECONSTITUTED
11830960 PROTEIN SUPP, MILK BASE, SODIUM CONTROLLED, POWDER
11830970 MEAL REPLACEMENT, PROTEIN TYPE, MILK-BASE, POWDER
11830980 PROTEIN SUPP, MILK-BASE, POWDER (INCL SUSTACAL)
11830990 NUTRIENT SUPP, MILK-BASE, POWDER (INCL SUSTAGEN)
11831500 NUTRIENT SUPPLEMENT,MILK-BASE,HIGH PROT,NOT RECONST
11832000 MEAL REPLACEMENT,MILK-&SOY-BASE,POWDER,NOT RECONST
11832500 MEAL REPLACEMENT,PROTEIN TYPE,MILK-BASE,W/SUGAR&ART
41440010 MEAL REPLACEMENT/SUPPLEMENT, LIQUID, HI PROTEIN
41440020 ENSURE W/ FIBER, LIQUID
41440050 ENSURE PLUS LIQUID NUTRITION
41450010 MEAL REPLACEMT/SUPPLEMT, LIQUID, PREDIGEST PROTEIN

FROZEN DAIRY DESSERTS AND MIXES

11459990 YOGURT, FROZEN, NS AS TO FLAVOR, NS TO TYPE OF MILK
11460000 YOGURT, FROZEN, NOT CHOCOLATE, TYPE OF MILK NS
11460100 YOGURT, FROZEN, CHOCOLATE, TYPE OF MILK NS
11460150 YOGURT, FROZEN, NS AS TO FLAVOR, LOWFAT MILK
11460160 YOGURT, FROZEN, CHOCOLATE, LOWFAT MILK
11460170 YOGURT, FROZEN, NOT CHOCOLATE, LOWFAT MILK
11460190 YOGURT, FROZEN, NS AS TO FLAVOR, NONFAT MILK
11460200 YOGURT, FROZEN, CHOCOLATE, NONFAT MILK
11460250 YOGURT,FROZEN,NOT CHOCOLATE,W/ SORBET/SORBET-COATED
11460300 YOGURT, FROZEN, NOT CHOCOLATE, NONFAT MILK
11460400 YOGURT,FRZ,CHOCOLATE,NONFAT MILK,W/ LOW-CAL SWEET
11460410 YOGURT,FRZ,NOT CHOC,NONFAT MILK,W/ LOW-CAL SWEET
11460420 YOGURT, FROZEN, NS AS TO FLAVOR, WHOLE MILK
11460430 YOGURT, FROZEN, CHOCOLATE, WHOLE MILK
11460440 YOGURT, FROZEN, NOT CHOCOLATE, WHOLE MILK
11461000 YOGURT, FROZEN, CHOCOLATE-COATED
11461100 YOGURT, FROZEN, CAROB-COATED
11461200 YOGURT, FROZEN, SANDWICH
11461250 YOGURT, FROZEN, CONE, CHOCOLATE
11461260 YOGURT, FROZEN, CONE, NOT CHOCOLATE
11461270 YOGURT, FROZEN, CONE, NOT CHOCOLATE, LOWFAT MILK
11461280 YOGURT, FROZ, CONE, CHOCOLATE, LOWFAT MILK

FRUIT SNACKS

91708030 FRUIT LEATHER (INCLUDE FRUIT ROLL-UP)
91708040 FUN FRUITS CREME SUPREMES CANDY
91708100 FRUIT SNACK CANDY, W/ VIT C

HARD CANDY AND COUGH DROPS[1]

91700010 CANDY, NFS
91745020 HARD CANDY
91745040 BUTTERSCOTCH HARD CANDY
91770020 DIETETIC OR LOW CALORIE HARD CANDY

[1] Cough Drops are often considered medication, therefore are not included in the CSFII

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SOY MILK

11310000 MILK, IMITATION, FLUID, SOY BASED
11320000 MILK, SOY, READY-TO-DRINK, NOT BABY.
11330000 MILK, SOY, DRY, RECONSTITUTED, NOT BABY
41440100 MEAL REPLACEMENT,LIQUID,SOY-BASE (ISOCAL, OSMOLITE)

PROCESSED FRUIT AND VEGETABLE PRODUCTS

61210000 ORANGE JUICE, NFS
61210010 ORANGE JUICE, FRESHLY SQUEEZED
61210220 ORANGE JUICE, CANNED/BOTTLED/CARTON, UNSWEETENED
61210230 ORANGE JUICE, CANNED/BOTTLED/CARTON, W/ SUGAR
61210250 ORANGE JUICE, W/ CALCIUM, CAN/BOTTLE/CARTON, UNSWEETENED
61210620 ORANGE JUICE, FROZEN, UNSWEETENED, RECONST W/ WATER
61210630 ORANGE JUICE, FROZEN, W/ SUGAR, RECONST W/ WATER
61210720 ORANGE JUICE, FROZEN, UNSWEETENED, NOT RECONSTITUTD
61210730 ORANGE JUICE, FROZEN, W/ SUGAR, NOT RECONSTITUTED
61210820 ORANGE JUICE,FROZ, W/,CALCIUM ADDED,RECON W/WATER
61213000 TANGERINE JUICE, NFS
61213220 TANGERINE JUICE, CANNED, UNSWEETENED
61213230 TANGERINE JUICE, CANNED, W/ SUGAR
61213620 TANGERINE JUICE, FROZEN, UNSWEET, RECONST W/ WATER
61214000 GRAPE-TANGERINE-LEMON JUICE
61216000 GRAPEFRUIT & ORANGE JUICE, NFS
61216010 GRAPEFRUIT & ORANGE JUICE, FRESH
61216220 GRAPEFRUIT & ORANGE JUICE, CANNED, UNSWEETENED
61216230 GRAPEFRUIT & ORANGE JUICE, CANNED, W/ SUGAR
61216620 GRAPEFRUIT & ORANGE JUICE, FROZEN, (RECONSTITUTED)
61219000 ORANGE & BANANA JUICE
61219100 PINEAPPLE-ORANGE-BANANA JUIICE
61219150 ORANGE-WHITE GRAPE-PEACH JUICE
61219650 APRICOT-ORANGE JUICE
61222000 PINEAPPLE-GRAPEFRUIT JUICE, NFS
61222200 PINEAPPLE-GRAPEFRUIT JUICE, CANNED, NS SWEETENED
61222220 PINEAPPLE-GRAPEFRUIT JUICE, CANNED, UNSWEETENED
61222230 PINEAPPLE-GRAPEFRUIT JUICE, CANNED, W/ SUGAR
61222600 PINEAPPLE-GRAPEFRUIT JUICE, FROZEN, RECONST W/WATER
61225000 PINEAPPLE-ORANGE JUICE, NFS
61225200 PINEAPPLE-ORANGE JUICE, CANNED, NS AS TO SWEETENER
61225220 PINEAPPLE-ORANGE JUICE, CANNED, UNSWEETENED
61225230 PINEAPPLE-ORANGE JUICE, CANNED, W/ SUGAR
61225600 PINEAPPLE-ORANGE JUICE, FROZEN, RECONST W/ WATER
61226000 STRAWBERRY-BANANA-ORANGE JUICE
63420100 FRUIT JUICE BAR, FROZEN, ORANGE FLAVOR
63420110 FRUIT JUICE BAR, FROZEN, FLAVOR OTHER THAN ORANGE
63420200 FRUIT JUICE BAR, FROZ, LOW CAL SWEETNER, NOT ORANGE
63430100 SORBET, FRUIT, NONCITRUS FLAVOR
63430110 SORBET, FRUIT, CITRUS FLAVOR
63430500 FRUIT JUICE BAR W/ CREAM, FROZEN
64100100 FRUIT JUICE, NFS (INCLUDE MIXED FRUIT JUICES)
64100110 FRUIT JUICE BLEND, 100% JUICE, W/ VITAMIN C
64100120 AMBROSIA JUICE (INCL KNUDSEN'S)
64101010 APPLE CIDER (INCLUDE CIDER, NFS)
64104010 APPLE JUICE
64104050 APPLE JUICE, W/ ADDED VITAMIN C

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64104090	APPLE JUICE WITH ADDED VITAMIN C AND CALCIUM
64104150	APPLE-CHERRY JUICE
64104200	APPLE-PEAR JUICE
64104450	APPLE-RASPBERRY JUICE
64104500	APPLE-GRAPE JUICE
64104550	APPLE-GRAPE-RASPBERRY JUICE
64104600	BLACKBERRY JUICE (INCL BOYSENBERRY JUICE)
64105400	CRANBERRY JUICE, UNSWEETENED
64105500	CRANBERRY-WHITE GRAPE JUICE MIXTURE, UNSWEETENED
64116010	GRAPE JUICE, NS AS TO ADDED SWEETENER
64116020	GRAPE JUICE, UNSWEETENED
64116030	GRAPE JUICE, W/ SUGAR
64116040	GRAPE JUICE, LOW CALORIE SWEETENER
64116050	GRAPE JUICE, NS AS TO SWEETENED, W/ ADDED VITAMIN C
64116100	GRAPE JUICE, UNSWEETENED, W/ ADDED VITAMIN C
64116150	GRAPE JUICE, W/ SUGAR, W/ ADDED VITAMIN C
64120010	PAPAYA JUICE
64121000	PASSION FRUIT JUICE
64122030	PEACH JUICE, W/ SUGAR
64123000	PEAR-WHITE-GRAPE-PASSION FRUIT JUICE,W/ADDED VIT C
64124010	PINEAPPLE JUICE, NS AS TO SWEETENED
64124020	PINEAPPLE JUICE, UNSWEETENED
64124030	PINEAPPLE JUICE, W/ SUGAR
64124060	PINEAPPLE JUICE, UNSWEETENED, W/ VIT C
64124200	PINEAPPLE-APPLE-GUAVA JUICE, W/ ADDED VITAMIN C
64125000	PINEAPPLE JUICE-NON-CITRUS JUICE BLEND, UNSWEETENED
64132010	PRUNE JUICE, NS AS TO ADDED SWEETENER
64132020	PRUNE JUICE, UNSWEETENED
64132030	PRUNE JUICE, W/ SUGAR
64132500	STRAWBERRY JUICE
64133100	WATERMELON JUICE
64134000	FRUIT SMOOTHIE DRINK, W/ FRUIT ONLY
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
73105010	CARROT JUICE
74301100	TOMATO JUICE
74301150	TOMATO JUICE, LOW SODIUM
74302000	TOMATO JUICE COCKTAIL
74303000	TOMATO & VEGETABLE JUICE, MOSTLY TOMATO (INCL V-8)
74303100	TOMATO & VEGETAGLE JUICE, MOSTLY TOMATO, LOW SODIUM
74304000	TOMATO JUICE W/ CLAM OR BEEF JUICE
75132000	MIXED VEGETABLE JUICE (OTHER THAN TOMATO)
75132100	CELERY JUICE
92530950	VEGETABLE & FRUIT JUICE DRINK, W/ VIT C

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Appendix 2: Summary of results from human clinical studies on the oral administration of purified unesterified lutein or lutein esters

Study/Reference	Study Group	Test Substance	Dose (equivalent dose)		Duration	Serum lutein		Comments
			Lutein esters[a]	(Unesterified Lutein)[b]		C_{max} (µmol/L)	t_{max} (h)	
O'Neill and Thurnham, 1998	3 x female 3 x male (20-25 yr)	Capsules containing mixed lutein esters from marigold extract (Quest International Ltd., Cork Ireland) Each capsule contained 7.8 mg lutein	~62.4 mg	31.2 mg	Single dose	nr[c]	2	No adverse events reported
van den Berg and van Vliet, 1998	12 x male (22-29 yr)	Lutein rich marigold extract (Quest International Ltd., Cork Ireland).	~30 mg	15 mg	Single dose	0.016	6	No adverse events reported
Herbst, 1999	8 x female 10 x male (21-35 yr)	a) Lutein diester ((Cognis Corp. (formerly Henkel Corp.) La Grange, IL))	a) 0.5 or 0.65 µmol/kg body weight all-*trans* lutein	a) 20 mg	a) Single dose	a) 0.20	a) 33	a) No adverse events reported
		b) Unesterified Lutein (FloraGLO™,Kemin Industries, Des Moines, IA)	b) 0.5 or 0.65 µmol/kg body weight all-*trans* lutein	b) 20 mg	b) Single dose	b) 0.11	b) 31	b) No adverse events reported
Yao *et al.*, 2000	4 x female (25-38 yr)	[^{13}C]lutein (investigator prepared and purified)	3 mg	3 mg	Single dose	0.007	14.8	No adverse events reported
Kostic *et al.*, 1995	4 x female 4 x male (24-38 yr)	All-*trans* lutein in oil purified by investigator from lutein-rich marigold extract (OroGlo; Kemin Industries, Des Moines, IA)	0.5 µmol/kg body weight all-*trans* lutein	20 mg	Single dose	0.30	16	No adverse events reported
Roodenburg *et al.*, 2000	9 x female 6 x male (18-70 yr)	Lutein diesters-enriched spread (3.2% suspension in oil; Vegex Lutein OS30; Quest International Ltd., Cork Ireland	~16 mg/day	8 mg/day	7 days	0.365	nr	No adverse events reported. Two women (study group not identified)withdrawn from the study. One due to a cholesterol level above acceptable study threshold, the other due to non-study related illness.
Torbergsen and Collins, 2000	3 x female 5 x male (24-34 yr)	Capsules containing lutein esters (Quest International Ltd., Cork Ireland). Each capsule contained 80% *trans*-lutein and 20% 13/15-*cis*-lutein)	~30 mg/day	15 mg/day	7 days	~0.58[d]	nr	No adverse events reported

Study/Reference	Study Group	Test Substance	Dose (equivalent dose)		Duration	Serum lutein		Comments
			Lutein esters[a]	(Unesterified Lutein)[b]		C_{max} (µmol/L)	t_{max} (h)	
Khachik *et al.*, 1995	3 x male (42-59 yr)	Lutein diesters-enriched olive oil solution. Investigator purified lutein diesters from marigolds	~20 mg/day	10 mg/day	18 days	1.40	~7 days	No adverse events reported. Serum levels never reached a plateau.
Wright *et al.*, 1999	21 x male (18-60 yr)	Capsules containing lutein ester rich marigold extract (Quest International Ltd., Cork Ireland) Each capsule contained 79% *trans*-lutein and 21% *cis*-lutein).	~30 mg/day	15 mg/day	26 days	1.40	nr	No adverse events reported
van het Hof *et al.*, 1999	6 x female 4 x male (18-45 yr)	Salad dressing supplemented with FloraGlo lutein (all-*trans* lutein; Kemin Foods LC, DesMoines, IA)	9 mg/day x 6 days/week	9 mg/day x 6 days/week	28 days	0.64	nr	No adverse events reported
Bausch-Goldbohm and Klöpping-Ketelaars, 1998; Berendschot *et al.*, 2000	8 x male (18-50 yr)	Lutein diester capsules (Henkel KgaA, Düsseldorf, Germany).	18mg/day	10 mg/day	84 days	0.90	nr	One subject reported headaches, 2-3 times/day lasting for 4 weeks
Collins *et al.*, 1998	10 female/male (25-45 yr)	Capsules containing lutein esters (Quest International Ltd., Cork Ireland). Each capsule contained 80% *trans*-lutein and 20% 13/15-*cis*-lutein)	~30 mg/day	15 mg/day	84 days	~1.71[d]	nr	No adverse events reported
Bone, 2001	>50 male and female	Xangold® lutein esters capsules (total carotenoid esters, >93% as lutein esters)	40 mg/day	20 mg/day	>90 days	~1.3	nr	No adverse events reported
Granado *et al.*, 1998	9 x female 8 x male (25-45 yr)	Capsules containing mixed lutein esters from marigold extract (Quest International Ltd., Cork Ireland) Each capsule contained 12 mg all-*trans*-lutein, 3 mg 13/15-*cis*-lutein, 3.3 mg α-tocopherol	~30 mg/day	15 mg/day	112 days	1.42	nr	One male subject dropped out of the study but the reason was not reported. 7/17 subjects developed carotenodermia by 4 months.
Olmedilla, *et al.*, 1997	8 x male (25-45 yr)	Capsules containing mixed lutein esters from marigold extract (Quest International Ltd., Cork Ireland) Each capsule contained 12 mg all-	~30 mg/day	15 mg/day	112 days	~1.35	nr	Slight carotenodermia in 2 subjects with total carotenoids levels of 282 µg/dL

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Study/Reference	Study Group	Test Substance	Dose (equivalent dose) Lutein esters[a]	(Unesterified Lutein)[b]	Duration	Serum lutein C_{max} (µmol/L)	t_{max} (h)	Comments
		trans-lutein, 3 mg 13/15-*cis*-lutein, 3.3 mg α-tocopherol						(lutein=99 µg/dL; 1.74 µmol/L) and 337 µg/dL (lutein=151 µg/dL; 2.65 µmol/L)
Landrum *et al.*, 1997	2 x male (42 & 51 yr)	Lutein esters rich oleoresin from Aztec marigolds (source not stated)	~60 mg/day	30 mg/day	140 days	~1.76	nr	No adverse events reported
Aleman *et al.*, 2001	12 x female 11 x male (12-59 yr)	Capsules containing mixed lutein esters from marigold extract (Twin Laboratories, Inc., Ronkonkoma, NY)	20 mg/day	~10 mg/day	180 days	0.26	nr	No adverse events reported
Olmedilla *et al.*, 2001	a) 5 x female (55-73 yr)	Capsules containing mixed lutein esters from marigold extract (Quest International Ltd., Cork Ireland) Each capsule contained 12 mg all-*trans*-lutein, 3 mg 13/15-*cis*-lutein, 3.3 mg α-tocopherol	a) ~30 mg/day x 3 day/week (~12.8 mg/day)	a) 15 mg/day x 3 day/week (~6.4 mg/day)	a) 24 months	a) ~0.62	a) nr	a) No adverse events reported
	b) 2 x female 3 x male (69-75 yr)		b) ~30 mg/day x 3 day/week (~12.8 mg/day)	b) 15 mg/day x 3 day/week (~6.4 mg/day)	b) 12 months	b) ~0.60	b) nr	b) No adverse events reported One subject dropped out for unstated reasons.

[a]reported value, or when possible, estimated (~) by multiplying the reported free lutein equivalents value by a factor of 2
[b]reported value, or when possible, estimated (~) by dividing the reported lutein ester equivalents value by a factor of 2
[c]nr, not reported
[d]estimated (~)

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Appendix 3. References

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