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ORIGINAL SUBMISSION

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July 17, 2002

nutrition&health

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.

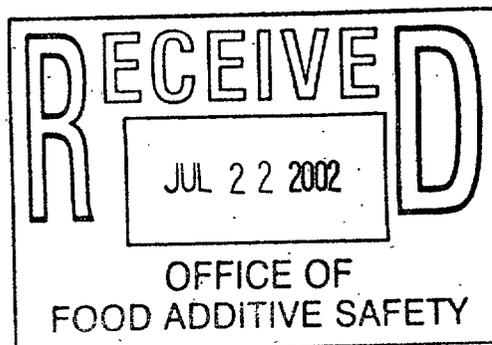
Detailed information about this GRAS notification is enclosed, including an address where FDA may review and copy additional data and information that are the basis for the GRAS determination.

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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**GRAS Notification
for
Xangold® lutein esters**

Submitted by:

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Contact:

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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 |

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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

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

^aLevels calculated using consumption values from CSFII 1994-1996, 1998 and lutein levels from USDA carotenoid database (Holden *et al.*, 1999 and USDA, 1998b).
^bAt 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.

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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:

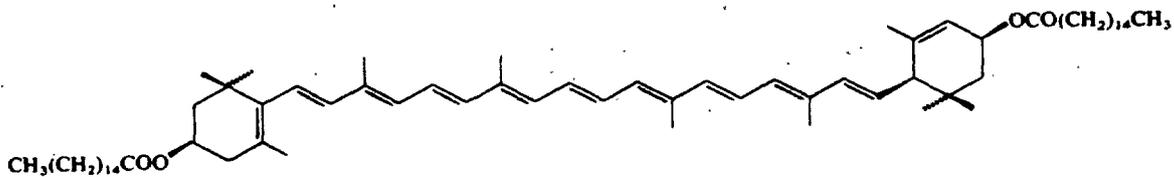
Xangold® lutein esters are comprised of a mixture of carotenoid xanthophyll esters (lutein esters and zeaxanthin esters) obtained from marigold flowers of the species *Tagetes erecta*. Lutein esters make up more than ninety three percent of the total carotenoid esters. Zeaxanthin esters also naturally 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: C₇₂H₁₁₆O₄ (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):

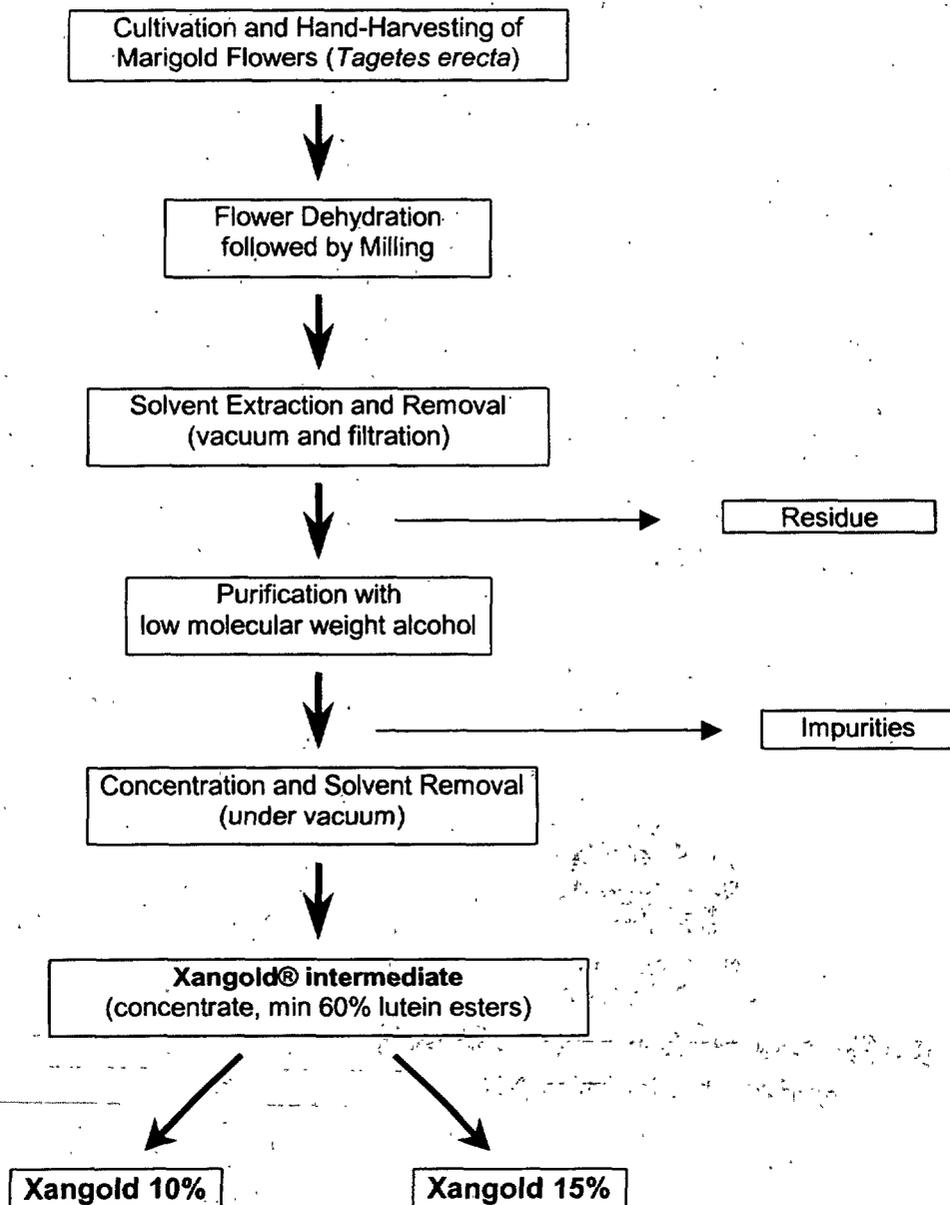
Xangold® concentrated natural lutein esters, a granular, dark orange-brown concentrate, is manufactured via a patented process (Levy 2001) using current Good Manufacturing Practice with all reagents used in

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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/cm³ |
| 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

(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 [¹³C]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 [¹³C]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 $\mu\text{mol/L}$. By comparison, studies on the serum distribution of carotenoids in humans consuming normal meals revealed an average background level of lutein plus zeaxanthin of $\sim 0.4 \mu\text{mol/L}$ (reviewed in Krinsky *et al.*, 1990). Data for all individuals surveyed from NHANES III revealed mean serum lutein plus zeaxanthin levels of 0.37 $\mu\text{mol/L}$ with maximum levels of 0.97 $\mu\text{mol/L}$ 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 carotenodermia 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).

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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 carotenoderma, 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.

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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

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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 MALT-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 STRAWBERRY-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, CALCIUM 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 DRESSING
 83103000 COLESLAW DRESSING
 83103500 FETA CHEESE SALAD DRESSING
 83104000 FRENCH DRESSING
 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 YOGANNNAISE)
 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

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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

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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 REPLACEMENT/SUPPLEMENT, 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 DROPS¹

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 RECONSTITUTED
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 JUICE
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 & VEGETABLE 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- <i>trans</i> 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- <i>trans</i> lutein | b) 20 mg | b) Single dose | b) 0.11 | b) 31 | b) No adverse events reported |
| Yao <i>et al.</i> , 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 <i>et al.</i> , 1995 | 4 x female 4 x male (24-38 yr) | All- <i>trans</i> lutein in oil purified by investigator from lutein-rich marigold extract (OroGlo; Kemin Industries, Des Moines, IA) | 0.5 μmol/kg body weight all- <i>trans</i> lutein | 20 mg | Single dose | 0.30 | 16 | No adverse events reported |
| Roodenburg <i>et al.</i> , 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% <i>trans</i> -lutein and 20% 13/15- <i>cis</i> -lutein) | ~30 mg/day | 15 mg/day | 7 days | ~0.58 ^d | nr | No adverse events reported |

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| 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 <i>et al.</i> , 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 <i>et al.</i> , 1999 | 21 x male (18-60 yr) | Capsules containing lutein ester rich marigold extract (Quest International Ltd., Cork Ireland) Each capsule contained 79% <i>trans</i> -lutein and 21% <i>cis</i> -lutein). | ~30 mg/day | 15 mg/day | 26 days | 1.40 | nr | No adverse events reported |
| van het Hof <i>et al.</i> , 1999 | 6 x female 4 x male (18-45 yr) | Salad dressing supplemented with FloraGlo lutein (all- <i>trans</i> 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 <i>et al.</i> , 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 <i>et al.</i> , 1998 | 10 female/male (25-45 yr) | Capsules containing lutein esters (Quest International Ltd., Cork Ireland). Each capsule contained 80% <i>trans</i> -lutein and 20% 13/15- <i>cis</i> -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 <i>et al.</i> , 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- <i>trans</i> -lutein, 3 mg 13/15- <i>cis</i> -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 carotenoderma by 4 months. |
| Olmedilla, <i>et al.</i> , 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 carotenoderma in 2 subjects with total carotenoids levels of 282 μg/dL |

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| 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) | |
| | | <i>trans</i> -lutein, 3 mg 13/15- <i>cis</i> -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 <i>et al.</i> , 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 <i>et al.</i> , 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 <i>et al.</i> , 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- <i>trans</i> -lutein, 3 mg 13/15- <i>cis</i> -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... |

^areported value, or when possible, estimated (~) by multiplying the reported free lutein equivalents value by a factor of 2

^breported value, or when possible, estimated (~) by dividing the reported lutein ester equivalents value by a factor of 2

^cnr, not reported

^destimated (~)

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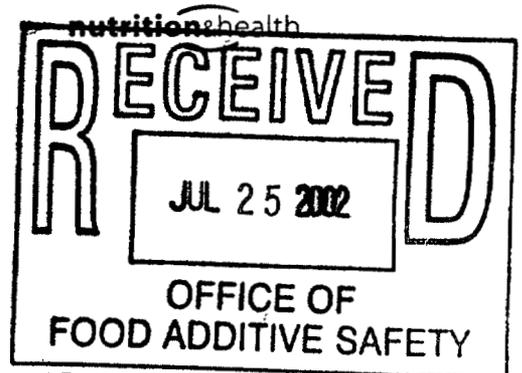


July 22, 2002

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Linda S. Kahl, Ph.D.
Division of Biotechnology and GRAS Notice Review
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: Notice of a GRAS Exemption Claim
For Xangold® Lutein Esters (submitted July 18, 2002)

Dear Dr. Kahl:

Pursuant to a telephone conversation between you and Daniel Dwyer, counsel for Cognis Corporation ("Cognis"), on July 22, 2002, this letter provides further information relating to the above-referenced GRAS notification dated July 17, 2002 and submitted to FDA on July 18, 2002. The following information is provided under proposed 21 CFR 170.36(c)(1) (62 Fed. Reg. 18938, 18961; April 17, 1997):

GRAS exemption claim: Cognis hereby claims that Xangold® Lutein Esters, for addition to specified foods (as described more fully in item (iii) below), is exempt from the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act because Cognis has determined that Xangold® Lutein Esters is generally recognized as safe (GRAS) for such use.

(i) **Name and address of notifier:** Cognis Corporation
5325 South Ninth Avenue
LaGrange, IL 60525

(ii) **Common or Usual Name of the Substance:** Lutein esters. (Lutein esters provide a source of lutein when ingested.)

(iii) **Applicable Conditions of Use:** Xangold® Lutein Esters is intended for use as an ingredient to provide consumers with a supplementary source of lutein in their diets in specified foods as summarized in the following table. Additional information on conditions of use is provided in the materials submitted to FDA on July 18, 2002.

| Food Group | mg lutein esters |
|--|------------------|
| Baked goods and baking mixes | 4.0 per serving |
| Soy milk | 3.0 per serving |
| Beverages and beverage powders | 4.0 per serving |
| Frozen dairy desserts and mixes | 2.0 per serving |
| Processed fruit and vegetable products | 4.0 per serving |
| Egg products and egg substitutes | 4.0 per serving |
| Breakfast cereals (ready-to-eat and hot) | 4.0 per serving |
| Fats and oils | 3.0 per serving |

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| | |
|---|-------------------------|
| Hard candy | 2.0 per serving |
| Fruit snacks | 2.0 per serving |
| Dairy products | 6.0 per serving |
| Medical foods intended as the sole item of the diet | Not to exceed 40 mg/day |

(iv) **Basis for the GRAS determination:** Scientific procedures.

(v) **Statement of Availability:** The data and information that are the basis for Cognis' GRAS determination are available for FDA review and copying at reasonable times at the offices of Kleinfeld, Kaplan and Becker, 1140 Nineteenth Street, N.W. Washington, D.C. 20036 (Daniel Dwyer, 202-223-5120), and such data and information will be sent to FDA upon request.

Additional required information, including a comprehensive summary of the data relied on to establish safety, is provided in the materials submitted to FDA on July 18, 2002.

Sincerely,

Cynthia M. Schweitzer, Ph.D.

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December 5, 2002



Dear Lisa,

Here is the additional information you requested.

1. The microencapsulation process includes mixing the intermediate concentrated Xangold product with ascorbyl palmitate, sugar, mixed tocopherols, corn oil and silicon dioxide to form an emulsion dispersed with porcine gelatin under high speeds. This paste is then atomized in a spray cooler at low temperatures to form the beadlets. The beadlets are then dried. No other reagents are used in this process.

The composition of a typical batch of Xangold(R) 10% is as follows (based on weight percent):

| | |
|-------------------------|----------------|
| Total carotenoid esters | minimum 10% |
| Lipids | 10-20% |
| Gelatin | 40-60% |
| Sucrose | 10-20% |
| Mixed tocopherols | 0-2% |
| Water | 0-7% |
| Ascorbyl palmitate | 2-6% |
| Silicon dioxide | 0 -0.5% |

These levels are not intended as a specification.

The production facility is a plant with ISO 9001 certification.

2. Xangold (R) 15% oil is suitable for products that have added fat during processing, such as baked goods, beverages, frozen dairy desserts, egg products, fats and oils and dairy products. Xangold 10% beadlets may be suitable for products such as baked goods and breakfast cereals. For both products, pilot testing with the manufacturer will be necessary to determine which product will work best. As you know, our GRAS notification is based on mg lutein esters per serving of food, so that either Xangold 10% or Xangold 15% could be used in a food within the stated lutein ester limits.

Please let me know if you need any further information.

Best regards,

Cindy Schweitzer, Ph.D.
 Senior Scientist

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January 8, 2003

**Via Hand Delivery
and Facsimile: (202) 418-3428**

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Re: GRAS Notification for Lutein Esters, GRN No. 110

Dear Ms. Lubin:

On behalf of Cognis Corporation, I am writing in reference to our telephone conversation of December 17, 2002, which also included Dr. Linda Kahl of your office, regarding the above-referenced GRAS notification. This notification covers lutein esters intended for use in certain specified foods to provide consumers with a supplementary source of lutein in their diets. During the call, FDA asked that Cognis provide additional information on the issue of whether this use of lutein esters (which are naturally reddish-brown) would be subject to regulation as a color additive.

In summary, under the Federal Food, Drug, and Cosmetic Act ("Act") and FDA regulations, the food use of an ingredient is not subject to regulation as a color additive when such use falls outside the definition of "color additive." All of Cognis' intended uses of lutein esters covered by the GRAS notification would fall outside of the definition of "color additive." Therefore, such uses would not cause lutein esters to be subject to regulation as a color additive.

These points are addressed in further detail in the paragraphs below.

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1. ***The food use of an ingredient is not subject to regulation as a color additive when such use falls outside the definition of "color additive."***

The Act defines a "color additive" as a material which, when added or applied to a food, "is capable ... of imparting color thereto; except that such term does not include any material which the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring." Act §201(t)(1).

FDA regulations implement this definition by providing that a food ingredient will not be regulated as a color additive if it is used solely as a food ingredient (for example, for its taste, aroma, or nutritive value), and is not deliberately used for purposes of coloring. Specifically, the regulations provide that a substance capable of imparting color is not a color additive if it meets one of the following three exemptions:

- a. **The "Non-apparent Color" Exemption:** "[S]ubstances ... which do not contribute any color apparent to the naked eye are not *color additives*." 21 CFR 70.3(f).
- b. **The "Unimportant Color" Exemption:** "For a material otherwise meeting the definition of *color additive* to be exempt ..., the material must be used in a way that any color imparted is clearly unimportant insofar as the appearance, value, marketability, or consumer acceptability is concerned. (It is not enough to warrant exemption if conditions are such that the primary purpose of the material is other than to impart color.)" 21 CFR 70.3(g).
- c. **The "Food Ingredient" Exemption:** "Food ingredients such as cherries, green or red peppers, chocolate, and orange juice which contribute their own natural color when mixed with other foods are not regarded as color additives; but where a food substance such as beet juice is deliberately used as a color, as in pink lemonade, it is a color additive." 21 CFR 70.3(f).

As discussed below, each of these exemptions applies to the uses of lutein esters covered by the GRAS notification.

2. ***All of Cognis' intended uses of lutein esters covered by the GRAS notification fall outside of the definition of "color additive."***

Cognis' GRAS notification for a lutein ester product refers to the use of the product as a supplemental source of lutein in certain specified foods. This is a *food* use, and does not relate to any use of the ingredient as a color additive. All of Cognis' intended uses of lutein esters covered by the GRAS notification are food uses, and are

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subject to the above-described exemptions from the color additive definition.
Specifically:

a. Lutein esters may be used consistently with the "Non-apparent Color" exemption.

Under many of the intended uses covered by the GRAS notification, lutein esters would not contribute any color apparent to the naked eye. Although lutein esters have a natural reddish-brown color, in many cases they may be added to foods at levels so low as not to affect the color of the food, or their color may be imperceptible in foods that already have a strongly characterizing color. For example, Cognis has prepared test formulations of lutein esters in a vanilla milkshake-type product and a brownie product, and has determined that the addition of lutein esters does not alter the color of these products in a manner apparent to the naked eye. Accordingly, for these types of uses, a lutein ester product would not be regulated as a "color additive."¹

b. Lutein esters may be used consistently with the "Unimportant Color" exemption.

For some of the intended uses covered by the GRAS notification, lutein esters, when added to food solely for purposes of providing nutritive value, would contribute a color in a manner that would conform to this exemption. For example, lutein esters may be added to a mango juice drink in a manner that would have the effect of causing a product that is already yellow to become a slightly different hue of yellow. In this case, the difference in color would have no important effect on the appearance, value, marketability, or consumer acceptability of the product. Accordingly, for these types of uses, a lutein ester product would not be regulated as a "color additive."

c. Lutein Esters may be Used Consistently with the "Food Ingredient" Exemption.

For some of the intended uses covered by the GRAS notification, lutein esters, when added to food solely for purposes of providing nutritive value, would also be an important characterizing ingredient in the food, similar to the chocolate in chocolate ice cream. For example, lutein esters might be added to a white grape juice-flavored beverage that is marketed under a name that refers to lutein esters. In this case, the beverage would be marketed based in part on the nutritive value of lutein esters (just as chocolate ice cream is marketed based in part on the taste of chocolate) and consumers

¹ In addition to the regulatory exemption, FDA has noted that the Color Additive Amendments of 1960, which enacted the current law, were intended to cover only substances whose coloring effect is "apparent to the naked eye." See e.g., 45 Fed. Reg. 77046 (Nov. 21, 1980).

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would expect the beverage to have a lutein-like appearance (just as they would expect chocolate ice cream to have a chocolate appearance). These circumstances would be consistent with the "food ingredient" exemption in that lutein esters would be used solely as a food, not deliberately as a coloring agent, but would contribute its own natural color when mixed with other foods. Accordingly, for these types of uses, a lutein ester product would not be regulated as a "color additive."²

3. *Conclusion*

At this time, Cognis anticipates that these exemptions from the color additive definition will cover all of its intended uses of lutein esters under the GRAS notification. Therefore, such uses would not cause lutein esters to be subject to regulation as a color additive. In this regard, a lutein ester product is similar to many other food ingredients that contain a pigment and that are used solely for food uses, not for coloring uses.³ If, in the future, Cognis decides to market lutein esters as a color additive, it will submit a color additive petition seeking approval for such use.⁴

During our telephone conversation, a question was raised as to whether FDA's response letter to Cognis' GRAS notification should include a reminder that any uses of lutein esters that fall within the "color additive" definition would need to be covered by a color additive regulation. We respectfully suggest that such a reminder is not necessary. A response to a GRAS notification, by its terms, addresses only that notification. It does not state or imply any conformance with (or exemption from) the legal requirements for any other uses to which the substance covered by the GRAS notification might be put. Therefore, it need not address uses (including color additive uses) that are separate from those covered by the GRAS notification. Further, as a practical matter, such a reminder is not necessary in this case because Cognis is well aware of the requirements applicable to the use of color additives in foods.

² FDA has noted that "[i]t ... is clear from the legislative history [of the Color Additive Amendments] that even substances that affect the color of food in readily apparent ways are not all considered 'color additives.'" 45 Fed. Reg. 77046. Further, FDA has always taken a practical approach to distinguishing color additives from other categories of substances added to food because, regardless of what regulatory category a substance is placed into (that is, whether it is a food additive, GRAS substance, or color additive), it will still be subject to acceptably rigorous regulatory standards. 45 Fed. Reg. 77045.

³ For example, many food ingredients have been affirmed as GRAS but are not the subject of color additive regulations for use in food, such as basil, cinnamon, marigolds, tea, calcium carbonate, and the like. See 21 CFR §§182.10, 182.20, 184.1191.

⁴ At this time, Cognis does not intend to market lutein esters as a color additive. Indeed, it is unlikely that customers would elect to use lutein esters as a color additive because lutein ester products are significantly more expensive than other sources of similar colors.

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Thank you for your kind consideration of this information. Please let me know if you have any further questions.

Sincerely,

Daniel R. Dwyer **U**

Counsel to Cognis Corporation

cc: Cindy Schweitzer, Ph.D.
Cognis Corporation

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