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KEMIN TECHNICAL LITERATURE

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Updated GRAS Status for FloraGLO® Lutein Expanded for New Food-Uses and Increased Inclusion Levels

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KEY CONCLUSIONS

- *FloraGLO Crystalline Lutein may now be added to soy milk products at a higher inclusion levels of between 6 and 10 milligrams of lutein per RACC.*
- *FloraGLO Crystalline Lutein may also be added to a variety of items such as baked goods and baking mixes (cookies); beverages and beverage bases (powdered tea); gelatins, puddings and fillings (gelatin and pudding); and nuts and nut products (trail mix), cereal; granola; energy and nutrition bars; ready-to-drink tea; soy milks; frozen yogurt; energy/sports/isotonic drinks; fruit-flavored drinks; fruit juice; nectars and vegetable juice; and both ready-to-serve and condensed canned soups.*

Kemin Health, L.C. is pleased to announce that the Generally Recognized as Safe (GRAS) status for FloraGLO® Crystalline Lutein has recently been updated to include a new use-level of 6-10 mg lutein per serving or RACC (reference amounts customarily consumed per eating occasion) for soy milk. This new GRAS level of FloraGLO Lutein when used in soy milk products is a significant increase over the previous GRAS inclusion level of 2 mg per RACC. FloraGLO Lutein, which contains both lutein and zeaxanthin, is intended for direct addition to foods and beverages in order to increase the dietary intake of total lutein and zeaxanthin which ranges from 1.71 (mean) to 3.01 (90th percentile) mg/person/day in the U.S. diet.[1] The self-affirmed GRAS inclusion levels for FloraGLO Lutein currently range from 0.3 to 10.0 mg of lutein per serving or RACC in various food categories, with the new GRAS level for FloraGLO Lutein in soy milk products now being at the higher end of this range.

The newest GRAS intended use levels for soy milk appear in the attached summary table that details all of the GRAS food applications for FloraGLO Lutein.

FLORAGLO LUTEIN GRAS HISTORY

Kemin successfully expanded the GRAS food applications of FloraGLO Lutein, as well as increased the GRAS levels of FloraGLO Lutein in some existing food categories through a self-affirmation process in 2008. Expanded food uses included baked goods and baking mixes (cookies); beverages and beverage bases (powdered tea); gelatins, puddings, and fillings (gelatin and pudding); and nuts and nut products (trail mix). In addition, Kemin proposed that higher use levels of FloraGLO Lutein be permitted for the food uses of baked goods and baking mixes (cereal, granola, energy, and nutrition bars); beverages and beverage bases (carbonated beverages and ready-to-drink tea); dairy product analogs (soy milks); frozen dairy desserts and mixes (frozen yogurt); processed fruits and fruit juices (energy, sports, and isotonic drinks, fruit-flavored drinks, fruit juice, nectars, and vegetable juice); and soups and soup mixes (canned soups; both ready-to-serve and condensed).

The dossier was submitted to an Expert Panel of qualified scientists to review the safety of FloraGLO Crystalline Lutein in the new categories and at the newly proposed levels. The

[1] IOM. 2001. Vitamin A. In: IOM. Dietary Reference Intakes: For Vitamin A, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, Manganese, Molybdenum, Nickel, Silicon, Vanadiam, and Zinc (Prepub Ed.). National Academy of Sciences, Panel on Micronutrients, Food and Nutrition Board, Institute of Medicine (IOM). National Academy Press (NAP); Washington, DC, pp. 82-161 & 602-603.

Panel critically examined a package of publicly available scientific information, data compiled from the literature and other published sources, as well as information provided by Kemin. The latter includes method of manufacture, product specifications, analytical data, intended use levels in specified food products, consumption estimates for all intended uses, data on the safety of lutein and zeaxanthin, and safety studies conducted with FloraGLO Crystalline Lutein. Following a critical evaluation of the above information, the Expert Panel concluded that expanded use of FloraGLO Crystalline Lutein in the new food applications and at higher levels, meeting appropriate food grade specifications and manufactured in compliance with current Good Manufacturing Practices (cGMP), is GRAS based on scientific procedures. These GRAS uses and limits have been incorporated into the attached table.

Kemin's FloraGLO Lutein has also previously been the subject of two GRAS notifications to the U.S. Food and Drug Administration (FDA) which issued letters of no objection in 2003 and 2007. Prior to these notifications, at the request of Kemin, an expert panel of independent scientists, qualified by relevant experience, as well as scientific training to evaluate the safety of food ingredients, was convened to evaluate the safety of FloraGLO Lutein and to determine its status for use in foods. This first self-determination regarding the safety of FloraGLO Lutein by food safety experts was completed in May 2001. Subsequently, a June 2003 evaluation by additional experts further expanded the intended food uses and inclusion levels. These self-determinations formed the bases for Kemin's 2003 GRAS Notification to the FDA.

In 2007, Kemin assembled an additional dossier regarding the safety of Kemin's FloraGLO® Lutein 20% Liquid in Safflower Oil for use in infant formula. This dossier was submitted to an Expert Panel, which included experts from the 2003 Expert Panel, familiar with the safety of FloraGLO Crystalline Lutein, and experts from the field of infant health and nutrition. A GRAS Notification was submitted to the FDA and Kemin received a subsequent letter of no objection. This GRAS status permits Kemin's FloraGLO Lutein 20% Liquid in Safflower Oil to be used in term infant formula up to 250 μg lutein/L.

CONCLUSIONS

These latest GRAS self-affirmations come at a key time when conventional food companies are becoming increasingly interested in adding beneficial nutrients with strong clinical support, such as FloraGLO Lutein, to food products to supplement the lower levels reported from dietary exposure. Companies wishing to market FloraGLO Lutein in food applications are able to include FloraGLO Lutein in a broader variety of foods and most recently in the case of soy milk, at higher levels, to deliver its important health benefits to consumers.

The GRAS status of FloraGLO Crystalline Lutein and FloraGLO Lutein 20% Liquid in Safflower Oil is specific to purified lutein made by Kemin according to Kemin's stringent quality specifications. FloraGLO Lutein is covered by patents in the U.S. and throughout the world.[2] Under FDA requirements, in the absence of an approved food additive regulation or other lawful basis, a particular manufacturer's lutein must have GRAS status to be added to conventional foods and beverages intended for the U.S. market.

[2] U.S. Patents US RE40,912 E; US RE40,931 E; US RE40,938 E; Canadian Patent 2,239,971; Japanese Patents 2,790,212 and 190,686; European Union Patents 0672655 and 0904258; Australian Patent 700,719; German Patent 69516031T2; New Zealand Patent 319,825; Mexican Patent 205122; and Israeli Patent 124987.

Summary of GRAS Food Categories, Food Uses, Examples, and Use Levels for FloraGLO Crystalline Lutein

Food Category	Broad Food-Use	Form	Additional Food Examples	Use-Levels for Lutein (mg/RACC[1])
Baked Goods and Baking Mixes	Cereal, Granola, Energy, and Nutrition Bars		High protein bar, breakfast bar, granola bar, power bar	10.0
	Cookies			6.0
	Crackers and Crispbreads		Snack crackers, filled snack crackers	2.0
Beverages and Beverage Bases	Bottled Water		Flavored or unflavored water	0.5
	Carbonated Beverages		Water, soft drinks-clear, cola, and pepper-type, ginger ale, root beer, citrus juice, drink mixtures-tonics, Collins, coolers, fizzes, spritzers	2.0
	Energy, Sport or Isotonic Drinks	Liquid or powder	Thirst quenchers, fluid replacements, electrolyte solutions	3.0 (RTD), 5.0 (Powdered)
	Non-Milk-Based Meal Replacements	Liquid or powder	Instant breakfast, soy-based, high protein, high calorie, low calorie, gelatins	2.0
	Ready-to-Drink and Nonreconstituted Tea Drinks	Liquid or powder		3.0 (RTD), 5.0 (Powdered)
Breakfast Cereals	Instant and Regular Hot Cereals			2.0
	Ready-to-Eat Cereals			2.0
Chewing Gum	Chewing Gum			1.0
Dairy Product Analogs	Imitation Milks	Liquid or powder		2.0
	Soy Milks			6.0-10.0
Egg Products	Liquid, Frozen, or Dried Egg Substitutes	Liquid or powder	Scrambled eggs from liquid or powder mixes	2.0
Fats and Oils	Margarine-like Spreads		Vegetable oil spreads	1.5
	Salad Dressings		Oil & vinegar type, creamy, tartar sauce, dips, mayo-type dressings, salads with mayo or mayo-type dressing- tuna, chicken, potato	1.5
	Mayonnaise			1.5
Frozen Dairy Desserts and Mixes	Frozen Yogurt		Frozen yogurt novelties and desserts containing frozen yogurt	2.0
Gelatins, Puddings, and Fillings	Gelatin			6.0
	Pudding			6.0
Gravies and Sauces	Tomato-Based Sauces		Pasta sauce, chili sauce, catsup, taco sauce, salsa, sauces for stews, casseroles, frozen foods with sauces and gravies	0.3
Hard Candy	Hard Candy			1.0
Milk Products	Dry Milk			3.0
	Fermented Milk Beverages		Buttermilk	0.6
	Flavored Milk and Milk Drinks	Liquid or powder	Smoothies, cocoa or chocolate mix, malted milk, fruit smoothie, chocolate-flavored milk drink	3.0
	Milk-Based Meal Replacements	Liquid or powder	Supplements, instant breakfast	3.0
	Yogurt		Yogurt	3.0
Nuts and Nut Products	Trail Mix			10.0
Processed Fruits and Fruit Juices	Energy, Sport, or Isotonic Drinks	Liquid or powder	Thirst quenchers, fluid replacements, electrolyte solutions	3.0 (RTD), 5.0 (Powdered)
Processed Fruits and Fruit Juices	Fruit-Flavored Drinks	Liquid or powder	Lemonade, punch	3.0 (RTD), 5.0 (Powdered)
	Fruit Juice	Liquid or powder		3.0
	Nectars	Liquid or powder		3.0
Processed Vegetable and Vegetable Juices	Vegetable Juice	Liquid or powder	Vegetable drinks	3.0
Soft Candy	Chewy and Nougat Candy		Taffy, marshmallows, caramel, licorice, chocolate-covered raisins, gum drops	1.0
	Fruit Snacks			1.0
Soups and Soup Mixes	Canned Soups	Liquid or powder	Frozen meals containing soup, dry soup mixes	1.5
Infant and Toddler Foods	Junior, Strained, and Toddler Type Baby Foods (not infant formula)	Liquid or solid	Fruits, fruit juices, meats, vegetables, soups, desserts, yogurts, cereals, pastas, sauces, cookies, toast, pretzels, crackers, egg yolk	1.0
Medical Foods	Intended as Sole Item in Diet	Liquid or powder		20 mg/day

[1]RACC – Reference amounts customarily consumed per eating occasion (21 CFR §101.12).