



## FLORAGLO<sup>®</sup> LUTEIN: SEE THE DIFFERENCE

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### KEY CONCLUSIONS

- *FloraGLO<sup>®</sup> Lutein is a brand of purified lutein produced according to a proprietary manufacturing process, naturally contains zeaxanthin, does not contain lutein esters, zeaxanthin esters or synthetic carotenoids.*
- *FloraGLO Lutein is trusted: it is the most clinically researched lutein brand and is the lutein ingredient used in the AREDS2 Study. FloraGLO Lutein is the lutein ingredient used by the leading ocular supplement brands worldwide.*
- *FloraGLO Lutein provides efficient formulations, confirmed stability and shelf life, a critical factor to quality.*
- *FloraGLO Lutein is proven: it is absorbed by the body and has been shown to improve eye and skin health.*
- *The FloraGLO Lutein branding program offers customers Marketing, Regulatory and Technical support that extends around the globe.*

### INTRODUCTION

There is a growing body of evidence that lutein, a non-pro-vitamin A carotenoid pigment naturally found in plants, plays an important role in human health.

The rationale for the protective role of lutein in the body stems from the ability of this carotenoid to: 1) filter harmful short-wavelengths of visible light (i.e. blue light), 2) function as antioxidant and 3) stabilize membrane integrity. These biological functions allow lutein to reduce the number of free radicals generated in the body directly by filtering blue light filter, or indirectly by working as an antioxidant.

Lutein can exist in nature in its true “free” form (“lutein” or “free lutein”) or bound to fatty acids (lutein esters). Lutein is not synthesized by the body and thus must be ingested as part of the diet in order for it to be utilized. Dark green leafy vegetables like spinach and kale are the richest sources of lutein, and its isomer zeaxanthin, but other foods such as corn or eggs also provide these carotenoids. It is estimated that 93% of total daily intake of lutein and zeaxanthin is present as free forms while only about 7% is present in the esterified form [1]. The unesterified form of lutein and zeaxanthin is the only form directly absorbed by the human body and found in the human serum [2]. Lutein and zeaxanthin are deposited in almost all the structures of the eye and are selectively concentrated in the *macula lutea*, the region of the retina responsible for central vision. The skin is the second largest repository of lutein in the body [3-5].

Due to its specific deposition in the eye and skin and its reported protective role, lutein is believed to play an important role in reducing light-induced oxidative damage in the eye and skin, the only two organs directly exposed to light.

The daily lutein and zeaxanthin intake in the industrialized world is quite low, averaging between 1-2.5 mg/day in the USA [6] and between 0.45-4 mg/day in EU [7-9]. Although there is no recommended daily intake for lutein and zeaxanthin, many intervention trials support the intake of at least 10 mg lutein for increasing plasma concentration, macular pigment accumulation, improvements in visual function and protection of the skin from environmental hazards [10-15].

FloraGLO<sup>®</sup> Lutein is a branded lutein ingredient manufactured by Kemin Foods L.C. It naturally contains both lutein and zeaxanthin and is intended for inclusion in food supplements or as a food ingredient for use in foods and beverages to increase the dietary intake of total lutein and zeaxanthin.

In 2008, Kemin and DSM joined forces working under an exclusive strategic alliance. Kemin supplies FloraGLO Lutein exclusively through DSM, which globally commercializes FloraGLO Lutein products through distributors and directly to

customers. Under this collaboration, customers and consumers benefit from the combination of DSM's strengths: global reach, unique formulation technology and broad product portfolio, and Kemin's strengths: lutein expertise, intellectual property, technical know-how and market development experience.

## **YOUR SOURCE FOR PEACE OF MIND**

FloraGLO Lutein is more than just the original source of purified lutein commercialized worldwide. It is your source for peace of mind:

- Proprietary Manufacturing process<sup>1</sup> and uncompromised quality guarantee:
  - FloraGLO Lutein is a brand of purified lutein that naturally contains zeaxanthin, does not contain esterified lutein or zeaxanthin or synthetic carotenoids.
  - The petals of the flowers of *Tagetes erecta* (marigold) are the starting material of the quality controlled Food Grade Marigold Oleoresin used to manufacture FloraGLO Crystalline Lutein under Kemin's proprietary, manufacturing process.
  - FloraGLO Lutein provides assurances of supply chain management including traceability down to the seeds and fields used to grow the marigold flowers. Good Agricultural Practices (GAP) are used by to grow and harvest the flowers. The use of pesticides, antioxidants and solvents is tightly controlled to ensure that the marigold oleoresin is consistently a quality food grade material.
  - FloraGLO Crystalline Lutein is of U.S. origin and manufactured in compliance with US FDA's current Food Good Manufacturing Practices (CGMPs). At the end of 2009 Kemin received a certification of compliance from NSF® to its NSF/ANSI Standard 173, Section 8, which is based upon the U.S. Food and Drug Administration (FDA) Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements, 21 C.F.R. Part 1108111.
  - FloraGLO Lutein has been the subject of quality review by the United States Pharmacopoeia (USP).
- Customer Focus and Efficient Formulation:
  - FloraGLO Lutein is available in different product forms and concentrations making it suitable for inclusion in many different types of functional foods and food supplement formulations. Similar flexibility can be found in delivery forms for topical applications.
  - The excellent flowability and uniform particle size of the dry forms make formulation convenient. FloraGLO Lutein dry product forms utilize DSM's Actilease® technology to offer superior stability, greater nutrient absorption or bioavailability, and very low extrusion losses. The end result is a premium FloraGLO product form that provides cost savings for the customer and enables them to cost-effectively produce quality nutritional products.
  - FloraGLO Lutein has a confirmed stability and shelf life, a critical factor to quality. Stability analyses, performed in both the ingredient and the finished products, ensure that our customers' finished products meet their label claim throughout shelf life.
- Confirmed safety and World Friendly™ regulatory status provide customers the ability to quickly enter key global markets:
  - FloraGLO Lutein has been the subject of safety reviews by the Food and Drug Administration (FDA) in its Generally Recognized as Safe (GRAS) process and the globally recognized World Health Organization Joint Food Expert Committee on Food Additives (JECFA). JECFA, after reviewing the FloraGLO Lutein specifications, determined an acceptable daily intake (ADI) level for lutein of 2 mg/day per kg of body weight. The European

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<sup>1</sup> FloraGLO Lutein's innovative purification process is patent protected in the European Union, Canada, Mexico, Japan and other countries worldwide.

Food Safety Authority (EFSA) Panel taking a more conservative approach determined an ADI for lutein of 1mg/day per Kg of body weight[16]. These ADIs do not apply to other lutein products not in compliance with the specifications set by JECFA.

- The French Agency for Food Safety (AFSSA) in conjunction with the General Directorate for Competitive Policy, Consumer Affairs, and Fraud Control (DGCCRF) has also reviewed the specifications and safety of FloraGLO Lutein and approved it as food supplement active ingredient.
  - FloraGLO Lutein is an ingredient for use in dietary supplements in the US and for conventional foods. Its GRAS status allows manufacturers to add FloraGLO Lutein to a variety of conventional food and beverages at specified inclusion levels in the US market. Additionally, Kemin received a letter of Non-Objection from the FDA to the use of FloraGLO Lutein 20% Safflower Oil as an ingredient in term infant formula at a maximum level of 250 µg/l.
  - FloraGLO Lutein can be used as nutritional ingredient in food supplements and conventional foods in the European Union and is not considered a novel food. Food supplement with daily dosages up to 20 mg FloraGLO Lutein per day can be found in the EU market.
  - FloraGLO Lutein is suitable for use in many other countries worldwide (e.g. Canada, Brazil, Japan, China, Taiwan, Korea, Australia) where it can be used in conventional foods and/or food supplements.
- Worldwide Marketing, Regulatory and Technical Support:
    - The FloraGLO Lutein branding program offers customers support that extends around the globe. This partnerships includes:
      - Customers formulation assistance, validated analytical methods, customer laboratory support;
      - Scientific training of sales force, regulatory affairs and quality support;
      - Participation as speakers in trade, scientific and medical conferences and meetings;
      - Support of advertising campaigns, joint development of literature and promotional materials;
      - The sharing of information about health professionals' and consumers' product requirements and preferences that is obtained through surveys commissioned by Kemin and conducted by specialized well-known market research specialized companies.

## **TRUSTED AND PROVEN**

Researchers choose FloraGLO Lutein. In fact, FloraGLO Lutein is the most clinically researched lutein ingredient brand <sup>2</sup>. A comprehensive review of the scientific literature reporting the research on human health in which an exogenous source of lutein was used as the test product, FloraGLO Lutein was chosen more often than any other commercially available brand of lutein or lutein esters, and more often than any synthetic source of lutein or any one food source. FloraGLO Lutein was the lutein ingredient used in the AREDS2 study.

- FloraGLO Lutein is proven to be absorbed by the body:
  - FloraGLO Lutein is a purified form of free lutein, chemically identical to the lutein found in abundance in the diet.
  - A pharmacokinetic study conducted in healthy volunteers has clearly demonstrated that lutein from FloraGLO Lutein is absorbed unmodified by the body and circulates in bloodstream [17].
  - Several intervention trials have confirmed that FloraGLO Lutein supplementation significantly increases serum levels of lutein and zeaxanthin vs placebo in young and old subjects [18-21]. Additionally FloraGLO Lutein

<sup>2</sup> Kemin Foods L.C. Internal Memorandum based on Pubmed search.

absorption is not impaired in the elderly [22].

- FloraGLO Lutein has been shown to help improve eye health:
  - Intervention studies confirm that the supplementation with 10 mg FloraGLO Lutein or more results in significant and sustained increased macular pigment optical density (MPOD) in both subjects with ocular diseases and healthy subjects [10, 23, 24].
  - The daily administration of 10-15 mg of FloraGLO Lutein over a 6 to 12 month period improved visual and macular function in patients suffering from AMD [10-12, 24, 25].
  - FloraGLO Lutein was the source of lutein chosen by the investigators of the AREDS2 study, sponsored by the National Eye Institute of the National Institutes of Health in USA., The AREDS2 study supports the daily supplementation with 10 mg FloraGLO lutein and 2 mg zeaxanthin in reducing the progression to advanced AMD by 10%[26, 27].
  - FloraGLO Lutein was additionally used in a recent research showing that the daily administration of 10 mg lutein or more, alone or in combination with 2 mg zeaxanthin, improves contrast acuity and reduces glare disability and photostress recovery time in healthy young adults[14, 28].
  - FloraGLO Lutein is the lutein ingredient used in the leading ocular supplement brands worldwide.
- FloraGLO Lutein has been shown to help improve skin health:
  - The administration of FloraGLO Lutein together with other carotenoids and antioxidants has been shown to be effective against free radical-induced damage in human skin, including that associated with UV light, and resulted in direct improvements in skin density, hydration and elasticity [29].
  - FloraGLO Lutein administered orally (10 mg lutein/day), topically (50 ppm twice daily) or in combination as the only treatment for skin health, significantly improved five important parameters of skin health (skin hydration, skin elasticity, skin lipids, skin lipid peroxidation, and skin photoprotective activity) in comparison to placebo ingested and/or topically applied [15].

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