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PETITION FOR THE ADDITION OF LUTEIN (USP) TO THE NATIONAL LIST UNDER 7 CFR § 205.606

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Submitted to:

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1. INTRODUCTION

Kemin Foods, L.C., d/b/a Kemin Health ("Kemin"), respectfully submits this Petition to the National Organic Standards Board ("NOSB"), seeking the placement of an appropriately food-grade version of lutein, purified from marigold, with a suitable status for use in infant formula, on the National List of Allowed and Prohibited Substances ("National List") under 7 C.F.R. § 205.606, "Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as 'organic'". Based on the practice of allowing additional descriptive information to appear with substances appearing on the National List, and in order to avoid confusion related to another Listed substance,[1] Kemin requests that the proposed listing wording include a compendial reference to the U.S. Pharmacopeia ("USP") to generally identify lutein that is food grade. Specifically, Kemin requests that lutein be listed as **"Lutein - derived from marigold (*Tagetes erecta*), and meeting the "Lutein" monograph established by the U.S. Pharmacopeia ("USP")."**[2] referred to within this Petition as "Lutein (USP)".[3]

Lutein (USP) is derived from food grade marigolds, which are harvested and dried. This plant-based material is then minimally processed in a similar manner to other ingredients recommended by the NOSB for listing under 7 CFR § 205.606, including non-amidated low-methoxy pectin (produced by de-esterification using an acid, alkali, or enzyme in the presence of an alcohol), and lecithin-

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[1] Notably, under 7 C.F.R. § 205.606, 42 of the 46 Listed substances contain supplemental information aside from the substance name. In 28 cases, this additional information is in the form of a Chemical Abstract Services or "CAS" number and in the remaining cases the text varies, but in all cases the additional information provides clarification or qualification related to the listed substances. It therefore appears that Listings with supplemental qualifying information, CAS number or otherwise, are acceptable. In the case of lutein, a listing of "Lutein" without qualification could be interpreted to include lutein esters, which are not chemically identical to the non-esterified lutein found in dietary foods such as spinach and kale, and also does not have a suitable status for addition to infant formula. Additionally, the CAS # 127-40-2 that would be used to denote lutein is already used to in conjunction with another Listed substance, "pumpkin color extract" [7 C.F.R. § 205.606(d)(14)]. CAS #127-40-2 is the CAS number for "xanthophylls", which is not a single substance but a subclass of carotenoids which consist of oxygenated carotenes, such as lutein [IUPAC. Compendium of Chemical Terminology, 2nd ed. (the "Gold Book")]. Currently, there is no discrete CAS number for lutein. In terms of the National List, listing lutein coupled with CAS #127-40-2 would not generally describe lutein, and moreover it would likely cause confusion based on the existing use of the CAS number for "pumpkin color extract". The proposed listing wording, including the USP reference, most accurately describes the non-esterified dietary form of lutein that is food grade, and may be added to both foods/beverages and infant formula.

[2] A monograph for lutein is contained in the "Dietary Supplement" section of the USP compendia, pages 1188-1189. Lutein meeting the USP monograph may only be obtained from Tagetes erecta, must be saponified, and may contain not less than 74% lutein, and not more than 8.5% zeaxanthin. Additionally, the chromatically detected peak area of lutein may not be less than 85% and the zeaxanthin peak may not be more than 9% of the total peak area detected. Kemin's FloraGLO Crystalline Lutein fully complies with the USP monograph. (United States Pharmacopeia and the National Formulary [USP 34 - NF 29]). (USP Monograph for Lutein, Appendix A)

[3] Kemin manufactures a product that is compliant with the USP monograph for lutein, known as FloraGLO® Crystalline Lutein that is GRAS (Generally Recognized as Safe) for use in specific foods and beverages, and also for use in infant formula. As support for the listing request above, this Petition presents specific and detailed information for Kemin's Lutein (USP), FloraGLO Crystalline Lutein. Importantly, references to "Lutein (USP)" within this Petition include Kemin's form of Lutein (USP), FloraGLO Crystalline Lutein.

unbleached (which employs hexane). Food grade marigold oleoresin is Kemin's starting material for production of its Lutein (USP) product. While the material is not organic, because of its specifications **[ ]**, the marigold oleoresin is of high quality with a low impurity profile. **CBI Deleted**

Lutein (USP) contains at minimum 74% non-esterified, "free" form of the dietary substance, lutein. The free-form is the same form found in commonly consumed foods, such as spinach and kale, and is also the form found in human breast milk. Importantly, lutein is a beneficial nutrient that is not produced by the body and must be obtained from the diet.

The free form of lutein comprises the macular pigment (Bone *et al.,* 1985), and is found in the lens (Yeum *et al.,* 1999; Yeum *et al.,* 1995), in both cases acting to filter out damaging blue light (Landrum and Bone, 2001). It is well recognized for its reported benefits for eye health and function, and for its protective role as an antioxidant. Lutein is also present in serum, the skin, brain and a number of other organ systems of the body. Conventional foods are being increasingly fortified with lutein as the scientific literature reports its new benefits for eye health and function, skin health, and cognition (Section 9.2.4.2.2). The scientific literature reports that 6 – 10 mg of lutein should be consumed daily to achieve its nutritional benefits. However, traditional consumption of lutein (and zeaxanthin) from dietary sources in the U.S. population (as surveyed) is an estimated 1.71 (mean) and 3.01 (90th percentile) mg/person/day (IOM, 2001). Based on this typical intake, and the resulting gap where less than one-third of the amount of lutein necessary for health benefits comes from traditional dietary sources, lutein-fortified foods are important sources of this key nutrient.

With respect to infants and young children, the presence of lutein in newborn eyes can reduce the oxidative and blue-light damage that can occur (Granot and Kohen, 2004; Hardy *et al.,* 2000; Dillon *et al.,* 2000; Hammond, 2007) (Section 9.2.4.2.1). While the free-form of lutein does appear in human breast milk, study results discussed more fully in Section 9.2.4.2.1 suggest that the lutein levels in breast milk of women consuming a traditional Western diet are lower than those measured in countries where more leafy green vegetables appear to be consumed (Canfield *et al.*, 2003). Further, it's estimated that only half of U.S. infants are exclusively breast fed at birth according to the American Academy of Pediatrics; accordingly, many formula-fed infants may not be provided with a number of the nutrients found in breast milk (Pediatrics, 2005). Under the conditions of intended use for infant formula, the targeted lutein levels will be 25 µg/L for infant formulas (not to exceed 250 µg/L in the finished formula), which is an amount consistent with the reported range of mean lutein concentrations of 15-44 µg/L in breast milk, and also with the overall mean of 25 ± 19 µg/L (Canfield *et al.,* 2003). Additionally, nursing mothers may benefit from the availability of lutein-fortified organically labeled foods in order to increase their overall consumption of lutein.

The safety of Lutein (USP) is well-documented. Kemin's Lutein (USP) ingredient has been the subject of a number of GRAS reviews, including two GRAS notifications to FDA, both resulting in letters of non-objection from the Agency (one for a list of conventional foods [June 2004 FDA Letter of Non-Objection, Appendix A] and one for inclusion of FloraGLO Crystalline Lutein as FloraGLO Lutein

20% Liquid in Safflower Oil in infant formula [October 2007 FDA Letter of Non-Objection, Appendix A]). Importantly, the GRAS reviews and subsequent letter of non-objection cited here pertain only to FloraGLO® Crystalline Lutein, Kemin's Lutein (USP) and not to other Lutein (USP) products; however, other Lutein (USP) suppliers may choose to assemble their own information to obtain GRAS status for similar or additional uses in conventional foods. A detailed account of the GRAS applications and use levels is provided in Section 3.1 and further details of FloraGLO Crystalline Lutein's GRAS status are discussed in Section 7.1. Additionally, the Joint WHO/FAO Expert Committee on Food Additives ("JECFA"), which is specifically charged with reviewing the toxicity of food additives, has determined that lutein meeting FloraGLO Crystalline Lutein's specifications, has an Acceptable Daily Intake ("ADI") of 2 mg/kg/bw. Moreover, as discussed in Sections 7.4 and 10.1, the safety of both lutein and Kemin's Lutein (USP) (FloraGLO Crystalline Lutein) has been reviewed by other authoritative governmental bodies in regions such as the European Union, Canada, Brazil and Korea, as well as by other scientific bodies such as the European Food Safety Authority ("EFSA"), and has been determined to be safe for its intended uses.

Kemin submits that the information contained herein related to its Lutein (USP) product, and Lutein (USP) generally, supports that this material, when mixed with organic delivery ingredients, is eligible for addition to the National List, and further that its inclusion is consistent with the National Organic Program objectives of selective listing of substances that may be used in organic handling. This listing will allow Lutein (USP) to be available to purchasers of organic infant formula and other organically labeled food which can serve as mechanisms to provide this important nutrient, consistent with the organic philosophy, to mother and baby.

ITEM A

1. CATEGORY

Kemin respectfully submits this petition requesting the inclusion of Lutein (USP), as **"Lutein--derived from marigold (*Tagetes erecta*), and meeting the "Lutein" monograph established by the U.S. Pharmacopeia ("USP")"** (when mixed with organic delivery ingredients including organic corn or safflower oil, and organic sugar and starch)[4] as a listed substance pursuant to 7 CFR § 205.606, on the National List of Allowed and Prohibited Substances in the category of "Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as 'organic'". This Petition is submitted pursuant to The Organic Foods Production Act of 1990 ("OFPA")[5], and the National Organic Program ("NOP") regulations codified at 7 CFR § 205.

2. CATEGORY JUSTIFICATION

Lutein (USP) is an agricultural product, obtained from an agricultural source of nonorganically produced marigold *(Tagetes erecta)* flower petals, containing a purified form of the marigold-derived substance lutein, in a form recognizable as obtained from marigold. Accordingly, Lutein (USP) is eligible for listing under 7 CFR § 205.606.[6] As discussed more fully in Section 5 using Kemin's process for its Lutein (USP) (FloraGLO Crystalline Lutein) as an example, Lutein (USP) is not derived from a synthetic source, nor are any processing steps employed that would render the material synthetic.

In further support of listing Lutein (USP) under 7 CFR § 205.606, Kemin compares substances currently listed or recommended to be listed under the same category with similar processing principles: the pectins, which includes both high- and low- methoxyl pectins ("HMP and LMP") [7], and lecithin-unbleached.

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[4] Two product forms, manufactured by DSM Nutritional Products, LLC ("DSM"), also use a small amount of DL-alpha-tocopherol (vitamin E) which is listed under 21 CFR § 104.20.

[5] 7 U.S.C § § 6501-6522, P.L. 101-624, Title XXI.

[6] Per 7 CFR § 205.2, an agricultural commodity or product that is further processed and marketed in the US for human consumption would be considered an "agricultural product." Alternatively, non-agricultural substances under the same regulations are defined as 1) products not from agriculture, or 2) substances which are obtained from an agricultural product, but are not recognizable as the agricultural source in the finished form of the processed product, with the examples given as gums, pectin, and citric acid.

[7] Both low- and high- methoxyl pectins are alternatively referred to as low- and high- "methoxy" in documents reviewed by the NOSB, and posted on the NOP site. Kemin understands in terms of NOSB/NOP documents that "methoxyl" and "methoxy" are interchangeable and to refer to the same substances.

Agricultural Product Classification

The manufacture of Kemin's Lutein (USP) uses a patented, purified extract from an agricultural product, marigold flower (*Tagetes erecta*). The characteristic color-component of marigolds is a class of compounds called xanthophylls, which include lutein and zeaxanthin, and marigolds are purposely used since they offer an abundant source of these pigments. Through Kemin's process (described in detail in Section 5), the xanthophylls contained in the marigold petals are extracted and processed into a marigold oleoresin, which is then further processed into Lutein (USP). At no point in production is there a processing step whereby Lutein (USP) would be considered synthetic. Upon finishing, the Lutein (USP) retains the orange-red pigment characteristic to the source marigolds, and is also composed majorly of the marigold-derived xanthophylls lutein and zeaxanthin which are the most abundant pigment components found in the marigold flower. In fact, the characteristic marigold color ("orange-red") and xanthophyll content are indicators of material quality for Kemin's Lutein (USP) and are checked by Kemin's Quality department as a requirement of material release. Moreover, labeling of certain foods (dietary supplements) containing Lutein (USP) must indicate not only lutein as an ingredient, but must also list both the source plant and plant part parenthetically, e.g. lutein (*Tagetes erecta*) (flowers) under applicable food labeling regulations.[8] While Lutein (USP) is significantly purified so as not to contain marigold petals or petal-parts, it nonetheless does retain the original pigment from marigolds, and food product labeling clearly indicates Lutein (USP) products are derived from marigold flowers.

In a directly analogous case, pectin is also a component of various agricultural products, and is sourced commercially from fruits such as apples and oranges (Technical Evaluation Supplemental Report, Non Amidated Low Methoxyl Pectin, 2010). Commercial processing of pectin is mainly from apple pomace and orange peel (Technical Evaluation Report, Non Amidated Low Methoxyl Pectin, 2009) and this material undergoes a multi-step process first to become HMP, and then HMP is further processed to become LMP. Both forms of pectin occur as a dry product that is cited in NOSB documents as "…a white, yellowish, light grayish or light brownish power [*sic*]" (Technical Evaluation Report, Non Amidated Low Methoxyl Pectin, 2009).

HMP is currently listed under 7 § CFR 205.606, and there has been a recent recommendation to modify this HMP listing to include both HMP and LMP (LMP is currently listed as a synthetic substance) under the heading "Pectin (non-amidated forms only)". In their present forms of a light colored powder, HMP and LMP appear to be sufficiently unaltered from their agricultural source to qualify for listing as an agricultural product under 7 CFR § 205.606.

Both the pectins and Lutein (USP) are derived from agricultural products and both occur in finished form as a dry powder. Lutein (USP) can clearly be recognized as a product of marigold

[8] 21 C.F.R. §101.36.

based on its retention of the specific marigold pigments and labeling requirements; therefore, Lutein (USP) should be considered similarly eligible for listing under 7 CFR § 205.606.

Non-Synthetic

Solvent Use

In the production of a Lutein (USP), the marigold petals are extracted with hexane to obtain xanthophylls in the form of a marigold oleoresin. The solvent is then removed and analytical results demonstrate that residual hexane in Kemin's finished Lutein (USP) product is **[ ]** A product already listed under 7 CFR § 205.606, "Lecithin-unbleached", also uses hexane in its production.

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Soybeans are generally known as the best source of naturally occurring lecithin, and all documentation regarding lecithin posted online by the NOP indicates that soy is the reviewed source for the lecithin listings on the National List.[11] Soy lecithin is obtained from soybean oil that is extracted using hexane, with subsequent separation of the lecithin fraction by centrifugation for potential further refining. Importantly, when soy is the source of lecithin, hexane is likely used to obtain the starting soybean oil regardless of the further refining of the lecithin by bleaching or de-oiling. The NOSB, after reviewing a petition requesting the removal of bleached lecithin from the National List, recommended its removal based on the availability of organic lecithin and not based

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[10] According to the NOSB Recommendation for Classification of Materials of November 5, 2009, extraction using a synthetic solvent would not render a substance synthetic, unless the synthetic solvent chemically altered the substance or the synthetic material remained in the resulting product at significant levels. Additionally, in the NOSBs subsequent draft guidance document, (National Organic Standards Board – Joint Materials and Handling Committee Classification of Materials – DRAFT Guidance document March 1, 2010) also made a similar statement (page 6) and further, noted that;

"…if a synthetic chemical used in the process is not removed from the final material, then the material is classified as synthetic…"

A reasonable interpretation of the above statement, consistent with the current listing of an ingredient that uses a solvent in its production, is that if a synthetic chemical is used, AND removed from the material, the subject material would NOT be classified as synthetic. "Removed" is not defined; however, a possible definition may be that non-detection at a reasonable detection limit by a scientifically valid method would demonstrate appropriate removal of a compound. This is the case with Kemin's FloraGLO Crystalline Lutein material.

[11] National Organic Program Petitioned Substances Database. http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateJ&page=NOPPetitionedSubstancesDatabase.

on use of hexane.[12] Within the same recommendation, the NOSB also recommended to list "lecithin-de-oiled" under 7 CFR § 205.606. In November, 2010, a notice of a proposed rulemaking appeared in the Federal Register to remove "Lecithin-bleached" from the National List, and consistent with the NOSB recommendation, the removal was based on availability of organic lecithin and not the use of hexane. The proposed rule also did not propose to delist "Lecithin-unbleached", listed in 7 CFR § 205.606, but rather it stated that "This proposed action would not prohibit nonorganic forms of bleached, de-oiled lecithin…"[13] The recommendation by the NOSB, as well as the text published in the proposed rule related to "Lecithin-de-oiled" indicates that use of hexane during processing, subject to its removal from the finished product, does not preclude a substance from being listed under 7 CFR § 205.606.

De-Esterification

The main raw material used to produce a Lutein (USP), marigold oleoresin, undergoes de-esterification, **[**

] to produce a material comprised primarily of a purified "free" or non-esterified form of lutein. Again, using the example of the pectin group, the defining difference between HMP and LMP is the degree of methyl-esterification, with HMP >50% esterified and LMP being <50% esterified. Discussed fully in Section 5.3.1, LMP is produced directly from the de-esterification of HMP. As mentioned in the previous section, there has been a recent NOSB recommendation to group HMP and LMP into one listing for "Pectin (non-amidated forms only)" under 7 CFR § 205.606. Specifically, the NOSB recommendation states:

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> "Both high and low methoxy pectin result from the same origin and process which is an extraction and hence non-synthetic. The amidation process creates a synthetic. The placement of pectin on 205.606 is consistent with OFPA and the NOP."[14]

Based on the available evidence provided to the NOSB in the Technical Evaluation Report demonstrating LMP is a de-esterified form of HMP, the NOSB recommendation did not cite the de-esterification as rendering LMP synthetic, rather only amidated-LMP was identified as synthetic. In similar fashion to non-amidated LMP, marigold oleoresin undergoes only a simple

[12] NOSB Recommendation May, 20069. *Petition for Lecithin, bleached for removal from the National List _§ 205.605b*. http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5079953&acct=nosb.

[13] Federal Register: November 8, 2010 (Volume 75, Number 215).

[14] Formal Recommendation by the National Organic Standards Board (NOSB) to the National Organic Program (NOP). Response to Pectin Petition. October 28, 2010.

de-esterification with minimal further processing to obtain Lutein (USP) and likewise would be as eligible for listing under the same regulation.

Conclusion

Based on the above, Lutein (USP) meets the definition of an "agricultural product" established by the NOP regulations because its obtained from an agricultural source, is identifiable as derived from its botanical source and the processing and materials used in the production of the product do not render the material to be synthetic. Further, Lutein (USP) and its manufacturing process, in principle, are similar to some materials already listed or recommended to be listed 7 CFR § 205.606, namely high- and low- methoxyl pectins (HMP and LMP), and unbleached lecithin. Consequently, Kemin submits that Lutein (USP) is eligible for listing under 7 CFR § 205.606, and is eligible for use in organic handling when mixed with organic delivery ingredients.

ITEM B

1. COMMON NAME OF THE SUBSTANCE

1.1. Common Name or Usual Name

Lutein (USP)

1.2. Trade Names

FloraGLO® Crystalline Lutein

1.3. Commercial Grades of Lutein (USP) Products[15]

FloraGLO® Lutein 5% Liquid in Corn Oil
FloraGLO® Lutein 20% Liquid in Corn Oil
FloraGLO® Lutein 20% Liquid in Safflower Oil
FloraGLO® Lutein 5% VG Granules
FloraGLO® Lutein 10% VG TabGrade™
FloraGLO® Lutein 20% FS
FloraGLO® Lutein 20% SAF

[15] All commercial FloraGLO Crystalline Lutein-containing products are manufactured by Kemin, or Kemin's sole licensee and distributor, DSM Nutritional Products, LLC ("DSM").

2. MANUFACTURER INFORMATION

Name of the Manufacturer

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3. CURRENT AND INTENDED USES OF LUTEIN (USP)

3.1. Intended Use of Lutein (USP)

The overall intended use of Lutein (USP) (in one of the afore-mentioned product forms) is as a dietary substance for use to supplement the diet by increasing the total dietary intake of the beneficial nutrient, lutein.

More specifically related to this petition, Kemin desires to obtain a clearance for use of Lutein (USP) in organically labeled foods and infant formula, with usage to be consistent with FloraGLO Crystalline Lutein's, and FloraGLO Lutein 20% Liquid in Safflower Oil's and Lutein 20% SAF's, existing GRAS status for certain food applications (October 2007 FDA Letter of Non-Objection, May 12, 2011 Assessment of the Equivalence of FloraGLO Lutein 20% Safflower Oil Manufactured by DSM and Kemin for Use in Infant Formula, both Appendix A). The conditions of FloraGLO Crystalline Lutein's inclusion in organically labeled products are detailed in Sections 3.1.1 and 3.1.2.

3.1.1. Current and Intended Use of Lutein (USP) in Organically Labeled Infant Formula

FloraGLO Lutein 20% Liquid in Safflower Oil and FloraGLO Lutein 20% SAF, both suspensions of Kemin's Lutein (USP), and organic safflower oil, are intended for use as a source of "free" lutein for addition to organically labeled infant formulas in the U.S. Under the conditions of intended use, the targeted lutein levels will be 25 µg/L for infant formulas, which is an amount consistent with reported mean lutein concentrations in breast milk of women ranging from 15-44 µg/L and an overall mean of 25 ± 19 µg/L (Canfield *et al.,* 2003), not to exceed 250 µg/L. This GRAS condition of use would also apply to organically labeled infant formula.

Based on the maximum GRAS inclusion level, FloraGLO Lutein 20% Liquid in Safflower Oil and FloraGLO Lutein 20% SAF would comprise approximately 0.00017% of a finished infant formula by weight and FloraGLO Crystalline Lutein would be present at no more than 0.000034% by

weight.[16] At this maximum allowed inclusion level, Lutein (USP) accordingly does not comprise more than 5% of any finished infant formula product by weight, making it suitable for use in infant formula labeled either as “organic” or "made with organic (specified ingredients or food group(s))".[17]

3.1.2. Current and Intended Use of Lutein (USP) in Organically Labeled Foods

Provided in Table 3.1.2.a is a list of categories of foods and beverages, with inclusion level ranges related to specific food uses of Kemin’s form of Lutein (USP) that may currently be added via its GRAS status.[18] Importantly, the GRAS status afforded Kemin’s Lutein (USP) product does not apply to all Lutein (USP) products; however, other suppliers of Lutein (USP) may assemble the necessary information to affirm GRAS status for these food applications as well as other food applications.

Table 3.1.2.a Summary of Individual Current GRAS Food-Uses for FloraGLO® Crystalline Lutein and Corresponding Use-Levels

Food Category	GRAS Food-Use	GRAS Use-Levels for Lutein (mg/RACC)
Baked Goods and Baking Mixes	Cereal, Granola, Energy, and Nutrition Bars	10.0
	Cookies	6.0
	Crackers and Crisp breads	2.0
Beverages and Beverage Bases	Bottled Water	0.5
	Carbonated Beverages	2.0
	Meal Replacements	2.0
	Tea	3.0 (RTD) 5.0 (Powdered)
Breakfast Cereals	Instant and Regular Hot Cereals	2.0

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[17] 7 CFR § 205.301.

[18] Organically labeled food may not contain FloraGLO Crystalline Lutein above these GRAS limits. Based on the GRAS levels and the low inclusion levels of FloraGLO Crystalline Lutein relative to the typical composition and weight of the reference amount customarily consumed of the GRAS Food-Uses, the amount of FloraGLO Crystalline Lutein in these foods should fall substantially below the 5% by weight limit established by 7 CFR §205.301.

Table 3.1.2.a Summary of Individual Current GRAS Food-Uses for FloraGLO® Crystalline Lutein and Corresponding Use-Levels

Food Category	GRAS Food-Use	GRAS Use-Levels for Lutein (mg/RACC)
	Ready-to-Eat Cereals	2.0
Chewing Gum	Chewing Gum	1.0
Dairy Product Analogs	Imitation Milks	2.0
	Soy Milks	6.0-10.0
Egg Products	Liquid, Frozen, or Dried Egg Substitutes	2.0
Fats and Oils	Margarine-like Spreads	1.5
	Salad Dressings	1.5
Frozen Dairy Desserts and Mixes	Frozen Yogurt	2.0
Gelatins, Puddings, and Fillings	Gelatin	6.0
	Pudding	6.0
Gravies and Sauces	Tomato-Based Sauces	0.3
Hard Candy	Hard Candy	1.0
Infant and Toddler Foods	Junior, Strained, and Toddler Type Baby Foods	1.0
Milk Products	Dry Milk	3.0
	Fermented Milk Beverages	0.6
	Flavored Milk and Milk Drinks	3.0
	Milk-Based Meal Replacements	3.0
	Yogurt	3.0
Nuts and Nut Products	Trail Mix	10.0
Processed Fruits and Fruit Juices	Energy, Sport, and Isotonic Drinks	3.0 (RTD) 5.0 (Powdered)
	Fruit-Flavored Drinks	3.0 (RTD) 5.0 (Powdered)
	Fruit Juice	3.0
	Nectars	3.0
	Vegetable Juice	3.0
Soft Candy	Chewy and Nougat Candy	1.0
	Fruit Snacks	1.0
Soups and Soup Mixes	Canned Soups	1.5

4. HANDLING ACTIVITIES FOR WHICH LUTEIN (USP) WILL BE USED AND ITS MODE OF ACTION

4.1. Handling Activities

4.1.1. General Food and Supplement Use if Lutein (USP) is Listed Under 7 C.F.R. § 205.606

Lutein (USP) would be mixed with organic ingredients to produce Lutein (USP) finished products, which are the dry and liquid product forms appropriate for addition to organically labeled products. Organic delivery ingredients would include safflower or corn oil for Kemin's liquid products, or sugar and tapioca starch for its dry product forms. In the liquid product forms listed in this petition produced by Kemin's sole licensee and distributor, DSM, would also use organic corn and safflower oil. Additionally, DSM adds minimal amounts of DL-alpha-tocopherol (vitamin E) to its liquid formulations.[19]

Optimal use of the Lutein (USP) product forms in supplements, foods, and beverages is highly dependent on the finished product matrix and manufacturing process. Each finished food or supplement product manufacturer desiring the inclusion of lutein from a Lutein (USP) product must evaluate which commercial product is most suitable for its product matrix and how to optimally use the product within its process.

As stated previously, Lutein (USP) is intended for use as a GRAS ingredient in the afore-listed foods and beverages. Its potential use in products falling within the GRAS food applications and labeled as "organic" is subject further to the product composition requirements established by 7 CFR § 205.301.

4.1.2. For Use in Infant Formula: FloraGLO Lutein 20% Liquid in Safflower Oil; FloraGLO Lutein 20% SAF

Two lutein products, both containing Kemin's Lutein (USP), are currently allowed for use in infant formula; FloraGLO Lutein 20% Liquid in Safflower Oil and FloraGLO Lutein 20% SAF. When used as an ingredient in infant formula, FloraGLO Lutein 20% Liquid in Safflower Oil and FloraGLO Lutein 20% SAF are suspended in the oil macronutrient sources. Optimal use is highly dependent on the finished product matrix and manufacturing process.

[19] Vitamin E is a listed nutrient under 21 CFR §104.20.

Based on the inclusion limit established by these products' GRAS status, inclusion of up to 250 µg/L of lutein from FloraGLO Crystalline Lutein comprises significantly less than 5% of a finished infant formula by weight, and therefore does not negatively impact any organic labeling statement.

5. SOURCE OF LUTEIN (USP) AND DESCRIPTION OF ITS MANUFACTURE: KEMIN'S PROCESS

As discussed in the Introduction, the USP monograph (Appendix A) requires lutein material to be obtained from a natural source, *Tagetes erecta*, undergo saponification, and meet specific requirements for high purities of beneficial marigold-derived xanthophylls, and low residuals of other compounds. Kemin's FloraGLO Crystalline, meets all of the USP requirements regarding source material, manufacturing principles, and finished product specifications, and is therefore considered a Lutein (USP). Accordingly, information contained in Section 5 includes details related to Kemin's process for its Lutein (USP) in support of the Petition information requirements.

5.1. Source of Lutein (USP)

5.1.1. Marigold Oleoresin

The starting material for the production of Lutein (USP) is a food grade marigold oleoresin[20] which is extracted from dried petals of non-organically grown marigold flowers [*Tagetes erecta,* Compositae (Asteraceae)] with food grade hexane. **[** **CBI Deleted**

] The marigold oleoresin obtained from this extraction contains the pigments from the marigold flowers in their original forms, which include esterified lutein and zeaxanthin, and other lipid soluble pigments and waxes. The xanthophyll component of the marigold oleoresin is what subsequently yields the lutein contained in Lutein (USP)

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commercial ingredients, and offers the nutritional benefits that are well documented in the scientific literature to be associated with lutein.

Upon receipt of marigold oleoresin, Kemin tests each lot of material against its internal specifications to assure that the material has the requisite quality and purity, and meets all of Kemin's established requirements including for those for levels of residual hexane, before being approved for use in Lutein (USP) processing. Importantly, hexane used in the production of marigold oleoresin is used in accordance with Current Good Manufacturing Practice ("CGMP") principles and therefore used only in the amount necessary and significant measures are taken to remove it to the extent possible. The processing of marigold oleoresin into Kemin's Lutein (USP) results in hexane being **[ ]** verified by product testing on multiple lots. As discussed in Section A.2, the use and removal of hexane would be similar in principle to hexane use in the extraction of soybean oil in the production of soy lecithin, which already appears on the National List under 7 CFR § 205.606.

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This residual level of hexane is then further reduced by production of subsequent Lutein (USP) commercial product forms, and reduced again by inclusion of commercial Lutein (USP) product forms in other finished products. **[**

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] The hexane contribution from Kemin's Lutein (USP) to other GRAS foods and beverages would be similarly low.

5.1.2. Other Raw Materials

Other ingredients used in the production of Lutein (USP) include **[**

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Different, readily-available organic ingredients can be used in the manufacture of the Lutein (USP) commercial grade products intended for use in organically labelled foods. Currently, these include organic safflower oil, corn oil, tapioca starch, sugar, and in the case of DSM's products, DL-alpha-tocopherol (Vitamin E) which is a listed nutrient under 21 CFR § 104.20.

5.2. Manufacturing Process

Kemin manufactures its Lutein (USP) product in accordance with 21 CFR § 110 and § 111 of the CGMPs of the U.S. FDA (21 CFR § 110 "Current Good Manufacturing Practice in Manufacturing, Packaging or Holding Human Food" and 21 CFR § 111, "Current Good Manufacturing Practice in Manufacturing, Packaging, Labelling or Holding Operations for Dietary Supplements") and uses a patented technology in a 3-step process that does not include chemical synthesis, but rather extracts the lutein from the agricultural source material. **[**

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] In order to produce Lutein (USP) meeting the GRAS specifications reviewed by FDA and the USP monograph, this patented process using the identified materials is the only process that may be used. The process is described hereafter and shown in Figure 5.2.a.

Kemin's manufacturing facilities and processes used to manufacture Lutein (USP) products have been reviewed and certified as compliant with NSF International, Inc.'s ("NSF's") Dietary Supplement Good Manufacturing Practices which are based on 21 CFR § 111 regulations. Kemin's partner, DSM, manufactures Lutein (USP) products based on 21 CFR § 110 or the equivalent food good manufacturing practices requirements applicable to European food facilities.

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[25] FDA defines processing aids as "Substances that are added to a food for their technical or functional effect in the processing but are present in the finished food at insignificant levels and do not have any technical or functional effect in that food." 21 CFR §100.101(a)(3)(ii)(c).

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5.3. Manufacturing Discussion

5.3.1. Kemin's Process Principles

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The defining difference between HMP and LMP is the degree of methyl-esterification, with HMP >50% esterified and LMP being <50% esterified. HMP is initially produced by extracting various types of plant material with acidified water. Production of LMP, as described in the Technical Report, is a de-esterification of HMP. LMP can be produced by reacting HMP with one of four substances (an acid, alkali, enzymes, or ammonia) in the presence of an alcohol to de-esterify HMP. Typically, LMP is produced from HMP reacted with an acid and alcohol, but when LMP is

manufactured with ammonia, in addition to a de-esterification, an amidation reaction occurs. (Technical Evaluation Report, Non Amidated Low Methoxyl Pectin, 2009).

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5.3.2. Process Controls

Kemin has established a Hazard Analysis and Critical Control Points plan for the processing of Lutein (USP). Additionally, Kemin has voluntarily established procedures within this process which are compliant with the more stringent dietary supplement CGMPs, 21 CFR § 111. As part of this system, Kemin has established comprehensive specifications for all raw materials used in Lutein (USP) processing. Also established are master manufacturing records and batch record procedures for each Lutein (USP), and Lutein (USP) products. Kemin's Quality Unity performs extensive testing to ensure that both the raw materials used and finished products meet the established specifications for identity, strength, quality, purity and composition. The Quality Unit also performs verification of in-process production information, and reconciles all production records upon completion of each batch of Lutein (USP) product. CGMP audits are conducted monthly by a Food Safety Team assembled of both Quality and Operations personnel, and identified deficiencies are handled through Kemin's Corrective/Preventive Action program, with appropriate follow up.

5.3.3. Process Patents

Kemin's Lutein (USP) process and compositional profile described above have been patented by Kemin under U.S. Patents US RE40,912 E, RE40,931 E, RE40,938 E, 5,648,564, and 6,663,900.[27] In order for Kemin to produce Lutein (USP) within the scope of the claims of the listed patents and meeting the specifications in the GRAS documentation and the USP monograph for lutein, this patented process using the identified materials is the only process that may be used.

[27] Also protected under Canadian Patent 2,239,971, Japanese Patents 2,790,212 and 3,190,686, European Patent Conventions 0672655 and 0904258, Australian Patent 700,719, Austria Patents 215059 and E191475, Belgium Patents 0904258 and 0672655, Denmark Patent 0672655, France Patents 0904258 and 0672655, Germany Patents 69516031T2 and 69620258, Ireland Patents 0904258 and 0672655, Israeli Patent 124987, Italy Patent 0672655, Korea Patent 214430, Netherlands Patent 0672655, New Zealand Patent 319,825, Mexico Patent 205122, Portugal Patent 0672655, Spain Patent 2147261, Sweden Patent 95300273, Switzerland Patents 0904258 and 0672655, and United Kingdom Patents 0904258 and 0672655.

6. SUMMARY OF PREVIOUS REVIEWS OF LUTEIN (USP) BY STATE OR PRIVATE CERTIFICATION PROGRAMS OR OTHER ORGANIZATIONS

6.1. Kosher

Both Kemin's and DSM's Lutein (USP) products are certified Kosher by the Union of Orthodox Jewish Congregation of America ("OU") (certificates in Appendix B).

6.2. Halal

Kemin's Lutein (USP) products are certified Halal by the Islamic Food and Nutrition Council of America ("IFANCA"). Currently, all Lutein (USP) product forms manufactured by DSM referenced in Section 1.3 of this petition are Halal certified (certificates are in Appendix B).

6.3. Good Manufacturing Practices ("GMP")

Kemin's manufacturing facilities and processes used to manufacture Lutein (USP) related products have been reviewed and certified as compliant with NSF International, Inc.'s ("NSF's") Dietary Supplement Good Manufacturing Practices (based on 21 CFR § 111) (Certificate in Appendix B). Kemin's commercial partner, DSM, manufactures Lutein (USP) products based on current CGMPs for food, 21 CFR § 110, equivalent food good manufacturing regulations applicable to its European manufacturing facilities, as well as an overarching quality system certification (ISO 9001:2008).

7. INFORMATION REGARDING EPA, FDA, AND STATE REGULATORY REGISTRATION OF LUTEIN (USP)

7.1. United States Food and Drug Administration ("FDA")

The GRAS status of Kemin's Lutein (USP) was initially reviewed by FDA in 2004, upon which Kemin received a letter of non-objection from the Agency (June 2004 FDA Letter of Non-Objection, Appendix A). **[**

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FloraGLO Lutein 20% Liquid in Safflower Oil has been GRAS for use as a food ingredient in infant formulas in the U.S. since 2007 (October 2007 FDA Letter of Non-Objection, Appendix A). This GRAS determination was recently amended to include DSM's FloraGLO Lutein 20% SAF (May 12, 2011 Assessment of the Equivalence of FloraGLO Lutein 20% Safflower Oil Manufactured by DSM and Kemin for Use in Infant Formula, Appendix A). The total lutein content from either source of GRAS safflower oil lutein ingredient in finished infant formula product may not exceed 250 µg lutein/L, which is equivalent to 37.2 µg/100 kcal.

7.2. State of Iowa

Kemin's facilities are registered Food Processing Plants with the state of Iowa and are subject to annual audits by the Iowa Department of Inspections and Appeals. Kemin Health's most recent certificate is attached in Appendix B.

7.3. Environmental Protection Agency ("EPA")

Kemin's facilities are regulated by the Environmental Protection Agency and are in compliance with relevant EPA regulations.

7.4. International Reviews

7.4.1. Canada

Xanthophylls, including lutein, are permitted for use as coloring agents in food in Canada according the Food and Drug Regulations ("FDR"), Part B, Division 16, and are considered to have a history of safe use for that intended purpose. Health Canada also approved six lutein-enriched novel food products recently. These lutein-enriched products include two juice applications (A. Lassonde and Rubicon Food Products, Ltd.) and four lutein-enriched egg products (Burnbrae Farms, Ltd., L.H. Gray and Son Limited, and Maple Leaf Foods Agresearch, SHUR-GAIN).

With respect to Lutein (USP), A. Lassonde, Inc. (a Canadian company) submitted a Novel Food notification to Health Canada in 2006, for a juice product containing Lutein (USP), in the form of Kemin's FloraGLO Lutein 5% Liquid in Corn Oil. Health Canada subsequently determined that Lutein (USP) was safe for addition to juice at 2 mg per serving (250 mL).

In addition, various product forms of Lutein (USP) are the subject of Ingredient Master Files submitted to the Natural Health Products Directorate of Health Canada and are widely used in Natural Health Products in Canada.

7.4.2. European Union

Lutein has a long history of safe use in Europe as well as in many other countries around the world. Lutein currently has a "green" (permissible to use) status as a non-novel food on the European Commission's Novel Food catalogue. Lutein is also authorized as a "FS" ingredient for use in food supplements according to the Novel Food catalogue. Lutein (USP) has been widely used in a variety of food and food supplements as a nutrient at dosage up to 20 mg per day since the 1990s.

Additionally, lutein from *Tagetes erecta* has been used as a permitted food color in European countries since the 1970s and is included in the EU Directive on colors for use in foodstuffs (E161b – Directive EC/1994/36).

7.4.3. Japan

In Japan, lutein is classified as marigold colorant that is regulated as a food additive in accordance with Japan Food Sanitation Law.[28] Lutein (USP) products are widely available in Japan and are permitted for use in foodstuffs and supplements.

7.4.4. China

In China, lutein extracted from marigolds was approved as a food and nutritional additive in April 2007 in accordance with the Food Hygiene Law of the People's Republic of China and Hygiene Administration of Food Additives.[29] Accordingly, lutein can be used as a colorant in specified foods including baked foods, drinks (excluding prepackaged drinking water), frozen foods, and jellies and jams; and as a nutrition fortifier in infant formula, formula for follow-up and young children, and formula for preschoolers.

Importantly, the approval of lutein as a nutrition fortifier in infant formula was based on the data previously submitted to the Ministry of Health ("MOH") for Kemin's Lutein (USP), and the specification for lutein appearing in the approval Annex was set based on information submitted for Kemin's product. There are currently a variety of food products containing Lutein (USP) on the Chinese market following the approval.

[28]Substances that were already marketed or used on the date of the amendment of the Food Sanitation Law and appear in the List of Existing Food Additives.

[29] http://www.moh.gov.cn/newshtml/18668.htm

7.4.5. Brazil

Agência Nacional de Vigilância Sanitária ("National Health Surveillance Agency" or "ANVISA"), Brazil's health and food safety agency, has evaluated lutein as a raw material intended for the food, cosmetic, and drug industry. Identity and quality standards for lutein have been reviewed by ANVISA, and with respect to its food characteristics and oral use, lutein has been accepted as a food with functional properties.[30] Currently, Lutein (USP) products intended as a raw material for the Brazilian food industry do not need to be individually registered with ANVISA. ANVISA has also granted lutein an approved allegation (claim) as follows:

"'LUTEIN. Allegation: "Lutein has an antioxidant action, which protects cells against free radicals. Its consumption shall be associated to a balanced diet and healthy life habits.'

Remarks: The quantity of lutein contained in the daily portion of the product ready for consumption shall be stated in the label, next to the allegation."[31]

8. CHEMICAL ABSTRACT SERVICE ("CAS") NUMBER AND LABELS

8.1. Chemical Names and CAS Numbers

The chemical name and CAS number for lutein are listed in Table 8.1.a.[32]

Table 8.1.a Chemical Names and CAS Numbers

Ingredient	Chemical Names	CAS Number
Lutein	xanthophyll; β,ε-carotene-3,3'-diol; vegetable lutein; vegetable luteol; Bo-Xan; all-*trans*-(+)-xanthophyll; all-trans-lutein	127-40-2

[30] Silva de Moraes Advogados Associados Law Firm, *Legal Opinion Lutein*.

[31] ***(ANVISA, National Agency of Sanitary Supervision. VII – List of Approved Allegations.*** (In: http://www.anvisa.gov.br/alimentos/comissoes/tecno_lista_alega.htm Access on March 13, 2007).

[32] As mentioned in the Introduction, the CAS number above is for xanthophylls, which includes lutein. The CAS number for xanthophylls is currently being used to describe "pumpkin color extract" on the National List. Accordingly, Kemin requests that this number not be used to also describe "lutein"; rather, Kemin requests the USP designation be used, which identifies the material as non-esterified lutein, and also specifies that it is obtained from a natural source, marigold flowers.

8.2. Product Labels

Sample labels for all of Kemin's Lutein (USP) products are included in Appendix C. Also contained in Appendix C, are labels for products that contain Kemin's Lutein (USP).

The product labels included for supplements and infant formula cite Kemin's Lutein (USP) as "lutein" on their labels, with the supplement further identifying the source of "lutein" as FloraGLO® Lutein. Regarding the conventional beverage label, Lutein (USP) is indicated as "marigold flower extract (source of lutein and zeaxanthin)". The subject material of this Petition has been identified as Lutein (USP), however the desired listing wording proposed by Kemin is for "**Lutein - derived from marigold (*Tagetes erecta*), and meeting the "Lutein" monograph established by the U.S. Pharmacopeia ("USP").**" Such a listing would ensure the Listed material would be "Lutein", but also "Lutein" meeting specific composition and quality criteria, suitable for use in supplements, foods, and infant formula. This additional criteria, which may not be obvious based on reconciling a "Lutein" listed in a product's ingredient list, is verifiable by organic formulators and certifiers through a review of lutein product specifications.

9. LUTEIN (USP) PHYSICAL PROPERTIES AND CHEMICAL MODE OF ACTION

9.1. Chemical and Physical Properties

9.1.1. Lutein Background

Lutein is a carotenoid naturally found in many fruits and vegetables. While lutein is found in high concentrations in the macula of the eye, lutein must be consumed from the diet. Humans cannot synthesize lutein, and, unlike beta-carotene, humans also cannot convert lutein into vitamin A. Accordingly, lutein cannot be considered to have any vitamin A activity. Lutein, together with zeaxanthin, is found in high concentrations in dark green leafy vegetables (Holden *et al.,* 1999) such as raw kale and spinach, in broccoli and brussel sprout and in egg yolks. Lutein is naturally present in different forms as all-trans lutein, cis-lutein, epoxi-lutein and lutein linked to proteins. Lutein, as found in fruits and vegetables, has been traditionally consumed as part of a natural diet. Additionally, purified lutein in the form of Lutein (USP) is chemically identical to its form found in the natural diet, has been consumed in several countries as an ingredient in dietary and food supplements, and in natural health products in Canada, as well as being present as a constituent of many conventional foods in countries such as the U.S., Europe, China and Japan (see Section 7.4).

Lutein is an oxycarotenoid, or xanthophyll, containing 2 cyclic end groups (one β- and one ε-ionone ring) and the basic C_{40} isoprenoid structure common to all carotenoids (see Figure

9.1.1.a). Lutein occurs together with zeaxanthin, an oxycarotenoid that is isomeric with lutein, containing 2 β-ionone rings rather than one β- and one ε-ionone ring (see Figure 9.1.1.b). In principle, each of the polyene chain double bonds present in lutein and zeaxanthin could exist in a *cis* or *trans* conformation, giving rise to a large number of possible mono-*cis* and poly-*cis* isomers; however, in practice, the vast majority of carotenoids are in the all-*trans* configurations (Rice-Evans *et al.*, 1997; IOM, 2000), as depicted in Figures 9.1.1.a and 9.1.1.b. Small amounts of *cis* isomers of lutein and zeaxanthin, accompanied by their respective all-*trans* configurations, have been isolated and purified from extracts of marigold flowers, fresh raw kale, corn meal, spinach, and human plasma (Krinsky *et al.*, 1990; Khachik *et al.*, 1999).

Figure 9.1.1.a Structural Formula of Lutein

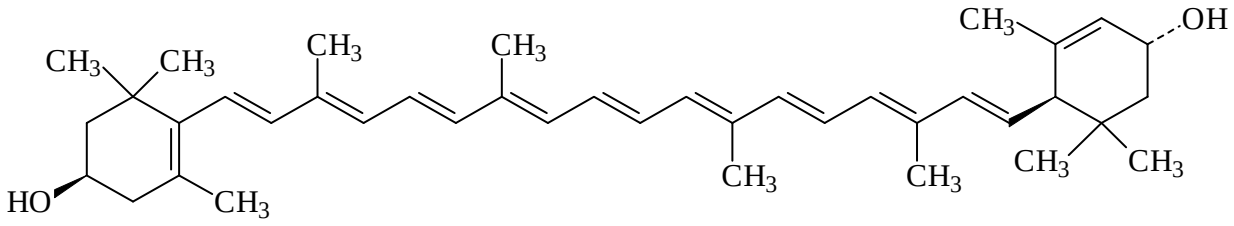
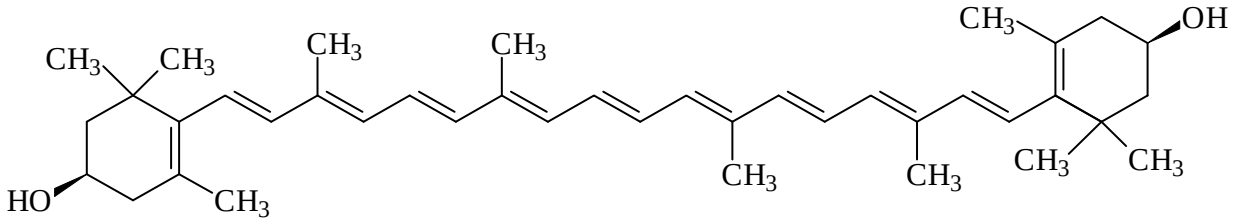


Figure 9.1.1.b Structural Formula of Zeaxanthin



9.1.2. Chemical and Physical Characteristics

The chemical and physical characteristics of lutein and zeaxanthin are outlined in Tables 9.1.2.a and 9.1.2.b, respectively.

Table 9.1.2.a Chemical and Physical Characteristics of Lutein	
Property/Parameter	**Value**
CAS Registry No.	127-40-2
Empirical formula	$C_{40}H_{56}O_2$
Molecular weight	568.88
Physical state	Crystalline

Table 9.1.2.a Chemical and Physical Characteristics of Lutein	
Property/Parameter	**Value**
Melting point	177-178ºC
Density	0.35-0.40 g/mL
Solubility in water	Insoluble
Solubility in ethanol	Soluble
Solubility in ethyl ether	Soluble
Solubility in benzene	Soluble
Solubility in petroleum ether	Soluble
Solubility in diethyl ether	Soluble
Solubility in tetrahydrofuran	Very Soluble
Solubility in methylene chloride	Very Soluble
Solubility in ethyl acetate	Soluble
Solubility hexane	Partially soluble
Solubility in acetonitrile	Partially soluble
Solubility in acetone	Soluble
Data provided in this table is from Kemin Foods, 2002.	

Table 9.1.2.b Chemical and Physical Characteristics of Zeaxanthin	
Property/Parameter	**Value**
CAS Registry No.	144-68-3
Empirical formula	$C_{40}H_{56}O_2$
Molecular weight	568.88
Physical state	Crystalline
Melting point	207-215.5°C
Solubility in water	Insoluble
Solubility in ethanol	Partially Soluble
Solubility in ethyl ether	Soluble
Solubility in benzene	Soluble
Solubility in chloroform	Soluble
Solubility in petroleum ether	Insoluble (hot)
Solubility in tetrahydrofuran	Very soluble
Solubility in diethyl ether	Partially soluble
Solubility in hexane	Partially soluble

Table 9.1.2.b Chemical and Physical Characteristics of Zeaxanthin	
Property/Parameter	**Value**
Solubility in acetonitrile	Partially soluble
Solubility in acetone	Soluble
Solubility in ethyl acetate	Soluble
Solubility in methanol	Partially soluble
Data provided in this table is from Kemin Foods, 2002.	

9.2. Additional Items

9.2.1. Chemical Interactions With Other Substances, Especially Substances Used in Organic Production

Lutein (USP), outside of its scientifically supported beneficial function in the human body, is a relatively inert substance not currently known to chemically react with other substances, including those used in organic production.

9.2.2. Toxicity and Environmental Persistence

Lutein (USP) is not intended for release into the environment. However, it is a plant-derived substance and biodegradable; upon exposure to light, heat, and oxygen, it would not persist in the environment. There are no known environmental risks or toxicity associated with the use or disposal of Lutein (USP).

As discussed more fully at Section 10.1.2, toxicological information regarding lutein has been evaluated by the Joint WHO/FAO Expert Committee on Food Additives ("JECFA"). JECFA reviewed various types of toxicity data, and the Committee specifically determined that there was no need for a study of carcinogenicity, taking into consideration data showing that lutein was not genotoxic, had no structural alert, did not exhibit tumor-promoting activity, and is a natural component of the human body.

For further environmental information related to Lutein (USP), please see Kemin's Material Safety Data Sheet ("MSDS") contained in Appendix D.

9.2.3. Environmental Impacts From Its Use or Manufacture

9.2.3.1. Marigold Oleoresin Production

The botanical source of Kemin's Lutein (USP) is food grade marigold flowers, from sustainable plant stock, **[**

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] During cultivation of marigolds intended for production of food grade marigold oleoresin, [

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9.2.3.2. Lutein (USP) Production

Presented in Section 5.2 is information related to the manner in which Kemin manufactures Lutein (USP). Kemin does not use volatile organic solvents during processing; therefore there are no issues with human handling, air handling, solvent disposal or solvent recapture. [

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] Energy consumption from processing is maintained as low as necessary and closely monitored to minimize both cost and environmental impact. There are no other process steps that would significantly impact the environment.

9.2.4. Effects on Human Health; and Effects on Soil Organisms, Crops, or Livestock

9.2.4.1. Soil Organisms, Crops, or Livestock

Lutein (USP) is not intended for use with soil organisms, crops or livestock.

9.2.4.2. A Summary of Beneficial Effects of Lutein (USP) on Human Health

9.2.4.2.1. Infant Formula

Lutein is a component of human breast milk, with free lutein considered the predominant form. Human milk contains at least 300 defined nutrients (Jensen, 1995), including more than 30 carotenoids, counting geometrical isomers and metabolites (Khachik *et al.,* 1997). Lycopene, lutein, zeaxanthin, and beta-carotene are among the predominant carotenoids in both serum and human milk (Giuliano *et al.,* 1994; Khachik *et al.,* 1997).

Several studies report lutein's presence in infant eyes[33] as early as 17-22 weeks gestation (Bone *et al.,* 1988; Handelman *et al.,* 1988). The newborn eye, being a vulnerable organ, is likely protected by lutein from oxidative damage and oxidative stress (Perrone *et al.,* 2010), as well as damaging blue light (Granot and Kohen, 2004; Hardy *et al.,* 2000 Dillon *et al.,* 2004; Hammond, 2007). Because only half of U.S. infants are exclusively breast fed, infants not receiving breast milk may not be provided a number of nutrients found in breast milk (Pediatrics, 2005), including lutein.

The lutein form contained in infant formulas supplemented specifically with FloraGLO Crystalline Lutein (in the forms of FloraGLO Lutein 20% Liquid in Safflower Oil and FloraGLO Lutein 20% SAF), is the same free- or non-esterified form of lutein found in human breast milk. For infants not exclusively breast fed, lutein supplemented infant formula offers an additional source of this important nutrient and its benefits.

9.2.4.2.1.1. Lutein is a Component of Human Milk

Free, non-esterified lutein is generally considered to be the predominant form of lutein in human milk. Most studies of human milk carotenoids have included a saponification of the milk, saponification being a hydrolysis of ester bonds by a base. Saponification also converts lutein esters to free lutein; therefore, traditional assays of carotenoids in human milk would not detect lutein esters as such, even if present. There is evidence however, that the predominant form of lutein in human milk is free lutein. Schweigert *et al.* (2000) extracted free lutein from human milk and obtained a higher estimate of total lutein, as well as a higher recovery of spiked lutein, than that obtained by methods that include saponification. Schweigert *et al.* (2000) extracted lipids into hexane and then back-extracted polar xanthophylls into ethanol/water. Substantially more lutein was present in the back-extracted polar xanthophylls fraction (i.e., without saponification) than in the saponified fraction. The small amount of all-trans lutein that was extracted after saponification

[33] Donor eyes.

of the aqueous fraction could represent either free lutein that was not quantitatively extracted prior to saponification, or lutein esters initially in milk. Schweigert *et al.* (2000) interpreted the result to be free lutein that was incompletely partitioned into the original hexane extract. Regardless, the quantitatively dominant form of lutein in human milk was free lutein, as the amount of lutein measured without saponification was a high percentage of total lutein measured and recovery of lutein was greater than 90%. The amount of lutein in the initial aqueous phase, even if corrected for lower recovery following the saponification step, was small.

Information specific to infant intakes of lutein/zeaxanthin from human milk is not found in the published literature, though the presence of these carotenoids in human colostrum, transitional, and mature human milk has been documented by several investigators. Canfield *et al.* (2003) measured carotenoid concentrations in human milk samples from healthy, lactating mothers of healthy full-term infants. Human milk samples were collected from 465 women 18 to 40 years of age from nine countries, including Australia, Canada, Chile, China, Japan, Mexico, the Philippines, the United Kingdom, and the United States. The study participants breast fed infants at least five times per day, and reported consuming at least 3 servings of fruits and vegetables (combined) per day. All milk samples were collected between 1 and 12 months postpartum, and therefore represent mature human milk. The overall mean concentration of lutein/zeaxanthin across all study sites was 25 ± 19 µg/L range of lutein/zeaxanthin, and the range of the individual site means was from 15 to 44 µg/L, with the highest mean concentrations in milk samples collected from women in China and Japan (44 and 43 µg/L, respectively). These women were presumably consuming traditional Asian diets rich in leafy greens. The lowest mean lutein/zeaxanthin concentrations were found in milk samples from women in Australia, Canada, the United Kingdom, and the United States; the range of mean lutein/zeaxanthin concentrations in milk from women in these countries, who are likely consuming more traditional Western diets, was 15 to 17 µg /L, or approximately one-third of the levels identified in samples from the Chinese and Japanese women.

The mechanisms underlying the apparent wide variation in milk composition that exists among and between women are not yet fully understood (Picciano, 2001); however, just as dietary intake of carotenoid-rich foods is associated with increased serum carotenoid concentrations (Al-Delaimy *et al.,* 2005; Campbell *et al.,* 1994), dietary intake of carotenoids appears to have an impact on milk carotenoid levels. As shown in other studies, consumption of carotenoid-rich vegetables or supplements by lactating women increased milk levels of these nutrients (Allen *et al.,* 2002; Canfield *et al.,* 1997).

9.2.4.2.1.2. Lutein From Lutein-Supplemented Infant Formula is Bioavailable

Infant formulas for term infants in the United States may contain up to 250 µg lutein /L (October 2007 FDA Letter of Non-Objection, Appendix A). However, typical maximum exposures to term

infants from consumption of U.S. formulas that are fortified with lutein are only 30% of that amount, or approximately 15 mcg/kg bw/day. These estimates are based on the formula intakes reported for healthy term infants 14 to 35 days of age in a clinical study (adapted from Mackey *et al.,* 2008). In that study, twenty-two (22) infants consumed the control formula, 27 infants consumed the low carotenoid (32 mcg lutein (FloraGLO®)/L) formula, 23 infants consumed the high carotenoid (52 mcg lutein (FloraGLO)/L) formula, and 27 infants were fed human milk. Plasma concentrations of lutein were correlated with intake (r=0.473, p=0.0002).

Among the formula-fed infants, baseline plasma concentrations of lutein were not different, though plasma concentrations of the carotenoids in the low and high carotenoid formula groups were significantly lower than concentrations in the human milk group. After 8 weeks of feeding, plasma lutein concentrations in infants fed the high carotenoid formula were significantly higher than levels in infants fed the low carotenoid formula or the control formula. The high-carotenoid formula resulted in plasma levels in the range of infants fed human milk, and comparable to the levels in human-milk fed infants as reported by other investigators (Bettler *et al.,* 2009).

In another dose-response study in term infants, infants were randomized to consume formula containing 20 (control formula), 45, 120 or 225 mcg lutein/L, and a group of 14 infants were exclusively breast fed (Bettler *et al.,* 2009). At the end of the 12 week feeding study, serum lutein concentrations increased in a dose-dependent manner in the formula groups; the serum lutein concentrations in infants consuming 45, 120 or 225 mcg lutein/L were 3.59, 10.75, and 19.21 mcg/dL, respectively (geometric means). While the increase in serum lutein concentration from human milk lutein was found to be approximately 4 times higher than the increase from infant formula lutein, the results indicate that consumption of lutein-fortified infant formula also increase serum lutein levels in infants.

A prospective, randomized, double-blind, multicenter, clinical trial fed formulas (SSC and NeoSure) with added lutein (FloraGLO® Lutein, Kemin Health, LC) to preterm infants (born less than 37 weeks gestation) (Rubin *et al.*, 2011). The mean concentration of lutein in the in-hospital preterm infant formulas was 211 µg/L, and the mean concentration in the post-discharge preterm formula was 68.7 µg/L. The population in this study was a representative sample of infants who are fed preterm infant formulas in the U.S. Formula intake was monitored daily during the in-hospital phase, and at 40, 44, and 50 weeks post-menstrual age (“PMA”) during the post-discharge phase (based on 3-day infant dietary intake diaries).

In the evaluable group (*i.e*., the subpopulation of infants who consumed exclusively or nearly exclusively the assigned study formula), plasma lutein concentrations were higher in the carotenoid formula group compared to the control group ($p<0.01$). Similarly, at hospital discharge and at 40 and 50 weeks PMA, plasma concentrations of lutein were higher in infants fed the carotenoid formula as compared to infants fed the control formula. Mean plasma concentrations of lutein in infants consuming the carotenoid formulas at 50 weeks were in the range of carotenoid

concentrations in a reference group of term infants 10 to 13 weeks of age in the U.S. who had been fed human milk (Mackey *et al*., 2008).

The bioavailability of carotenoids naturally occurring in human milk is unknown. While the bioavailability of carotenoids from infant formula appears to be lower than from human milk, the results of these studies demonstrate that the carotenoids added to infant formula are absorbed and appear in the plasma of infants. Lutein fortification of infant formula, therefore, provides a bioavailable source of lutein when mother's milk is not available.

9.2.4.2.1.3. Lutein Benefits for Infants

As stated in Section 9.2.4.2.1, lutein and zeaxanthin are present in human eyes[34] as early as 17-22 weeks gestation (Bone *et al.,* 1988; Handelman *et al.,* 1988). The presence of lutein likely protects the vulnerable newborn eye from severe oxidative damage occurring during childhood, as well as higher levels of oxidative stress in the retina during this time, which have been linked to clinical disorders and disease states (Granot and Kohen. 2004; Hardy *et al.,* 2000). Additionally, because the infant lens is more transparent than that of an adult, the infant retina may be more susceptible to damaging blue light (Dillon *et al.,* 2004; Hammond, 2007). Thus, the very young could likely benefit from the blue light filtering and antioxidant properties of lutein.

Perrone *et al.* examined the effects of lutein on oxidative stress in infants in a study published in 2010 (Perrone *et al.,* 2010). This randomized, double-blind comparative study was conducted in 20 healthy term infants who received either a liquid supplement containing FloraGLO Lutein (0.28 mg) or a control supplement at 12 and 36 hrs after birth. Blood was drawn immediately after birth and at 48 hrs after birth and analyzed for biological antioxidant potential ("BAP") and total hydroperoxides ("TH"). There was no difference in BAP and TH between the two groups at birth. TH significantly increased from birth to 48 hrs in the infants fed control formula ($p = 0.023$) while no increase was observed in the group fed lutein-containing formula. BAP significantly increased in the lutein group from birth to 48 hrs ($p = 0.028$) with no corresponding increase in the infants fed control formula. These results indicate that lutein-containing formula can reduce oxidative stress and protect against oxidation in newborn infants. The authors also noted that no adverse events were observed during the study.

9.2.4.2.1.4. Lutein (USP) - The Same Lutein Form Found in Human Milk

In the preparation of Lutein (USP) a saponification step is utilized that liberates free lutein from lutein esters, forming the same lutein molecule predominating in human breast milk (Schweigert

[34] These studies used human donor eyes.

et al., 2000). Scientific evidence supports that lutein, including Kemin's Lutein (USP), provided in an infant formula matrix, is bioavailable to infants both term and preterm (Mackey *et al.,* 2008; Bettler *et al.,* 2009; Rubin *et al.,* 2011). Moreover, infants exposed to Lutein (USP) through supplementation exhibited beneficial effects in terms of oxidative stress (Perrone *et al.,* 2010) and may also be provided lutein's established benefits related to eye health.

FloraGLO Lutein 20% Liquid in Safflower Oil and FloraGLO Lutein 20% SAF, both suspensions of Kemin's Lutein (USP) and safflower oil and GRAS for use in infant formula, provide a source of non-esterified lutein (the same form found in mother's milk) that can be successfully incorporated into infant formula formulations. Lutein (USP) in a formula matrix is a bioavailable source of lutein for infants, and can serve to offer formula-fed infants the benefits of lutein consumption when breast milk is not available.

9.2.4.2.2. Food and Dietary/Food Supplements

The role of lutein as a beneficial ingredient for inclusion in foods and dietary/food supplements is thus of increasing importance because of its protective role in eye and skin health. Lutein is the major xanthophyll found in human serum (Yeum *et al.,* 1995) and is concentrated in ocular tissues such as the lens and the macula lutea (Yeum *et al.,* 1995; Landrum and Bone, 2001). Just like other carotenoids, lutein is not synthesized by humans and is only obtained from dietary sources.

Lutein is highly concentrated in the central part of the retina called the macula where it works as an antioxidant and as a blue light filter. Lutein's reported antioxidant activity is highly reinforced by the presence in the retina of lutein metabolites coming from lutein oxidation (Bernstein et al., 2001). Findings from a growing collection of placebo-controlled intervention trials indicate that ingestion of lutein containing foods or supplements results in increased macular pigment optical density ("MPOD") (Shao and Hathcock, 2006) and may help to improve visual function in patients suffering from Age-Related Macular Degeneration ("AMD") and other ocular diseases (Richer, 1999; Dagnelie *et al.,* 2000; Falsini *et al.,* 2003; Olmedilla, *et al.,* 2003; Richer *et al.,* 2004, Stringham and Hammond, 2008). The explanation for these findings is both physiological and metabolic, in that lutein and zeaxanthin are the only carotenoids present in the retina and lens, where they act as a filter of blue light and as antioxidants. Lutein is currently a test article in a large, multi-center trial sponsored by the National Institutes of Health National Eye Center, Age-Related Eye Disease Study ("AREDS2") that will evaluate the effects of 10 mg of lutein supplementation, daily on patients with AMD.

Published relevant human clinical trials (double-blind, randomised, controlled trials and non-randomised, uncontrolled or open-label clinical trials) involved lutein doses from 2.4 to 40 mg/day (Dagnelie *et al.,* 2000; Hughes *et al.,* 2000; Roodenburg *et al,.* 2000; Aleman *et al,.* 2001; Hininger *et al.,* 2001; Olmedilla *et al.,* 2002; Richer *et al.,* 2004; Thürmann *et al.,* 2005; Bahrami, *et al.,* 2006; Shao and Hathcock, 2006; Zhao, 2006). All the results are consistent with respect to

safety, showing no observed or reported adverse effects (Berendschot *et al.,* 2000; Duncan *et al.,* 2002; Bone *et al.,* 2003; Cardinault *et al.,* 2003; Koh *et al.,* 2004). The most recent published scientific literature reports that free lutein, taken at 10 mg daily in combination with 2 mg zeaxanthin, is found in the serum and macula, and can significantly improve visual performance parameters related to veiling glare and photostress recovery in healthy individuals (Stringham and Hammond, 2008). Veiling glare and photostress recovery are associated with night time driving; accordingly improvements in these parameters may translate to improved night driving performance.

As with the eyes, lutein has been detected in the skin and is believed to play a similar beneficial role providing antioxidant protection and acting as a filter of high-energy blue light. Published human clinical trials and other data support that lutein, when ingested alone or with other antioxidants, can positively impact skin health by reducing reactive oxygen species and lipid peroxidation, while increasing skin lipid content and hydration (Palombo *et al.,* 2007). These data support that lutein's antioxidant properties evidenced in the eye, can be extended to provide the same protective effects against light-induced damage in the skin. Lutein is also believed to play a positive role in age-related cognitive decline (Johnson *et al.,* 2008).

Lutein's beneficial effects have been recognized by the French health authorities in its issuance of claims that may be made on products containing lutein.

The Agence française de sécurité sanitaire des aliments ("AFFSA") in France determined that two claims regarding lutein (below) were scientifically supported (AFSSA Statement, Appendix A):

- "Lutein helps protect the retina and lens from oxidation."
- "Lutein is one (of the) constituent(s) of the retina and the lens."

10. INFORMATION PERTAINING TO THE SAFETY OF LUTEIN (USP) AS A FOOD INGREDIENT

10.1. Authoritative Safety Reviews of Lutein (USP)

10.1.1. Generally Recognized as Safe ("GRAS")

The safety of Kemin's Lutein (USP) and hence Kemin's Lutein (USP) products, including FloraGLO Lutein 20% Liquid in Safflower Oil and FloraGLO Lutein 20% SAF, has been established in toxicological studies in rats, mice, monkeys and dogs, mutagenicity studies conducted with *Salmonella typhimurium*, and is further supported by intervention studies conducted with healthy subjects designed to measure metabolic endpoints. The safety of Lutein

(USP) is also corroborated by additional animal and human studies conducted with other sources of lutein, lutein-rich foods and lutein supplements. Measurements of safety-related endpoints have indicated that oral exposure up to 30 mg lutein per day is not associated with any adverse health effects in healthy human subjects and oral exposure to FloraGLO Lutein 20% Liquid in Safflower Oil at a dose level of 200 µg lutein/L in infant formula, resulting in a mean intake ranging from 193 to 247 µg lutein/day, for a period of 16 weeks did not result in any adverse health effects in healthy term infants.

In addition, the safety of lutein and zeaxanthin is well established in the literature based on the historical consumption of fruits and vegetables where these carotenoids predominate (*e.g.*, green leafy vegetables, such as spinach and kale), and the safety of lutein and zeaxanthin for use in infant formulas is demonstrated through their presence in human breast milk. Exposure to lutein from human breast milk varies widely based on the stage of lactation, geographical location, and individual diets, and has been demonstrated to range from 3 to 232 µg/L in individual mothers from around the world. Mean concentrations at individual sites ranged from 15 µg/L in Australia, Canada, the UK, and the U.S. to 43-44 µg/L in China and Japan. The average lutein and zeaxanthin concentration across all of the sites investigated was 25 ± 19 µg/L (Canfield *et al.*, 2003).

In June, 2004, the United States Food and Drug Administration (“FDA”) issued a letter of no objection to an expert panel’s finding that Kemin’s form of Lutein (USP) is Generally Recognized as Safe for a variety of food applications, ranging from 0.3 mg to 3 mg per serving, and for medical foods at 10 mg per day (June 2004 FDA Letter of Non-Objection, Appendix A).

In October, 2007, the FDA issued a letter of no objection to an expert panel’s finding that suspended Lutein (USP) in the form of FloraGLO Crystalline Lutein may be used as an ingredient in term infant formula at a maximum level of 250 µg/L is GRAS (October 2007 FDA Letter of Non-Objection, Appendix A). Within the letter, FDA defined the term "suspended lutein" to denote the mixture of the carotenoids lutein and zeaxanthin (free lutein) that are suspended in safflower oil. FloraGLO Lutein 20% SAF, manufactured by DSM, also contains Lutein (USP) suspended lutein in safflower oil, and therefore is also covered under this FDA clearance.

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10.1.2. Joint WHO/FAO Expert Committee on Food Additives ("JECFA") Review 2006

The Joint FAO/WHO Expert Committee on Food Additives ("JECFA"), which reviews the toxicity of food additives, completed a safety evaluation of lutein and zeaxanthin from *Tagetes erecta* and assigned a group acceptable daily intake ("ADI") of 0 to 2 mg lutein and zeaxanthin/kg body weight (JECFA, 2006). The JECFA evaluation included consideration of information on the toxicity, identity and purity of Kemin's Lutein (USP). This comprehensive assessment included reviews of acute toxicity in rats, short-term toxicity in mice, rats and monkeys and long-term studies of toxicity, carcinogenicity and genotoxicity. Additionally, JECFA reviewed reproductive toxicity, inclusive of developmental toxicity data. Special studies evaluating cardiovascular effects and immune response in mice, cats and dogs, and ocular toxicity and dermal and ocular irritation were considered. Observations in humans were also part of the JECFA evaluation, with the recognition that although studies designed to investigate the pharmacokinetics of lutein did not necessarily include safety end-points, they also did not report any adverse effects of lutein/zeaxanthin, including at "high concentrations."

In its evaluation, JECFA noted that in several studies of toxicity, including developmental toxicity, no adverse effects were documented in animals including monkeys or in humans. The Committee specifically determined that there was no need for a study of carcinogenicity, taking into account data showing that lutein was not genotoxic, had no structural alert, did not exhibit tumor-promoting activity, and is a natural component of the human body.

Upon reviewing the body of scientific evidence, JECFA determined that "the available comparative toxicokinetic data for humans and rats indicated that the studies of toxicity in rats could be used to derive an ADI" (JECFA, 2006). The ADI, 2 mg/kg/bw, was established based on a NOEL of 200 mg lutein/kg body weight/day (the highest dose tested) reported in a 90-day rat study (Pfannkuch *et al.* 2000a,b), to which a safety factor of 100 was applied. This safety factor was considered appropriate given the lack of adverse effects reported at much higher doses than 200 mg/kg body weight [up to 1,000 mg/kg body weight/day in a study of developmental toxicity (Edwards *et al.*, 2002)]. As determined by JECFA, the ADI is a group ADI for lutein and zeaxanthin and is applicable to children who are older than 12 weeks, and only for lutein (and zeaxanthin) meeting the specifications established by JECFA.

10.1.3. European Food Safety Authority ("EFSA") Reviews of Lutein for Use in Foods for Particular Nutritional Uses

10.1.3.1. Foods for Special Medical Purpose

The AFC (Food Additives, Flavorings, and Processing Aids) Scientific Panel from the European Food Safety Authority ("EFSA") was asked to evaluate lutein extracted from *Tagetes erecta* (marigold flowers) and from some species of edible plants for use in the manufacture of foods for

particular nutritional uses ("FPNUs") (EFSA Scientific Opinion, 2006). In 2006, the Panel concluded that the use of lutein, obtained as an extract from *Tagetes erecta* and from the natural strains of edible fruits and plants, grass, Lucerne (alfalfa), in foods for special medical purposes ("FSMPs"), is not of safety concern under the proposed use levels which are in the range of the regular dietary intake of lutein, provided that it is in compliance with the existing EU specifications of lutein as a food additive. The petitioner's proposed uses of lutein in FSMPs were at levels that would give rise to daily intakes within the range of a regular dietary intake of 0.5 mg to 2 mg lutein per day (EFSA Scientific Opinion, 2006).

10.1.3.2. Infant Formula

In 2008, EFSA's Panel on Dietetic Products, Nutrition and Allergies ("NDA") was requested to evaluate the safety, bioavailability and suitability of lutein for the particular nutritional use by infants and young children. The panel evaluated a "purified lutein" obtained by saponification from an oleoresin extracted with hexane from dried marigold flower (*Tagetes erecta*) petals, specifically, the commercial ingredient as "FloraGLO Lutein 20% liquid in safflower oil" made of "purified lutein" suspended in edible triglyceride oil and containing at least 20% lutein and 0.8% zeaxanthin by weight. The Panel evaluated the scientific data and concluded that lutein from FloraGLO is bio-available in infant formula, and there are no concerns about the safety of lutein in infant formula at the levels achieved through the natural content of ingredients nor at the level of use (concentration of added lutein 250 µg/L) proposed by the applicant for infant formulae with a low natural lutein content (about 20 µg/L or lower) (EFSA Scientific Opinion, 2008).

10.1.4. Detailed Review of the Safety of Lutein (USP)

A more detailed discussion of the safety of Kemin's Lutein (USP) is contained in Appendix E.

10.1.5. Material Safety Data Sheet ("MSDS")

MSDSs are included for Kemin's Lutein (USP) products in Appendix D.

10.1.6. National Institute of Environmental Health Studies Substance Report

No National Institute of Environmental Health Studies substance report for lutein, Lutein (USP) or FloraGLO Crystalline Lutein was identified.

11. COMPREHENSIVE RESEARCH REVIEWS AND RESEARCH BIBLIOGRAPHIES FOR LUTEIN (USP)

11.1. Research Bibliography

A comprehensive literature search was conducted September 23rd, 2009, via PubMed[35] (http://www.ncbi.nlm.nih.gov/pubmed/) using simply "lutein" as a keyword. This initial search resulted in the finding of 2831 items. Subsequent updated searches have increased this number to 3051. Additionally, on a weekly basis, literature reviews are conducted by Kemin via PubMed and Scopus, using the keywords "Carotenoids", "Lutein", and "Zeaxanthin". From these reviews, articles regarding lutein's role in the body have been compiled in a bibliography contained in Appendix F.

11.2. Why Should the Substance Be Permitted in the Handling of an Organic Product?

Unavailability of Organic Alternatives

Kemin has reviewed the marketplace and is unaware of any commercially available certified organic lutein products from any source. The resources reviewed included information from official organic regulatory programs including USDA's National Organic Program, Canadian Organic Products Regulations, the European Commission Organic Farming legislation, the Japanese Agricultural Organic Standard, as well as organic certifying bodies such as BIOHellas, and BIOSUISSE. A review was also conducted of recognized marketing reports and compilations for the nutritional industry including Frost & Sullivan, Euromonitor, Natural Products Insider, and NutraIngredients. Additionally, general searches were conducted using recognized search engines such as Google.[36] Several lutein products marketed from Chinese based companies were found to use the term "organic" on their websites; however, none listed a certifying body establishing that the term "organic" was validly supported.

While no organically certified lutein products are available, one may consider supplementing foods with an organic form of lutein by using a certified organic lutein-containing vegetable itself, such as spinach. Importantly, spinach represents one of the most highly concentrated sources of lutein in the normal diet with a lutein + zeaxanthin content of 3.7 mg/30 g raw spinach (USDA,

[35] PubMed is a search engine for accessing the MEDLINE database of international citations and abstracts of research on the life sciences and biomedical subjects. It is maintained by the United States National Library of Medicine at the National Institutes of Health and is thought to be the most comprehensive and objective resource for searches of this kind.

[36] These search activities were conducted by Kemin Industries, Inc.'s Global Business Intelligence Unit at the direction of Kemin Health, May, 2011.

2010); however, raw spinach, dehydrated spinach, or spinach puree are not practical sources with which to supplement specific types or serving sizes of processed foods.

Provided below in Table 11.2.a is the list of the food categories and specific foods to which Kemin's Lutein (USP) may be added based on the GRAS status of these particular food applications, with the GRAS lutein levels being based on the Reference Amounts Customarily Consumed ("RACCs"). GRAS status is specific to a manufacturer and its manufacturing processes; other suppliers of Lutein (USP) may already have or can assemble the data to affirm GRAS status for these food applications as well as other food applications. Included is a comparison of the amount of Lutein (USP) versus the amounts of both raw/pureed spinach and dehydrated spinach powder necessary to reach the GRAS levels per RACC. The amounts of spinach, spinach puree, or dehydrated spinach powder required to achieve the GRAS levels established for Lutein (USP) are between 600-6000 times higher, and inclusion of any of these spinach products to most of these foods (or other foods for which Lutein (USP) may ultimately be determined to be GRAS) would likely increase the fiber content, impart appearance/color, flavor, and possibly mouth-feel issues, and importantly may also change the organoleptic properties or even affect or change the identity of some foods.

Table 11.2.a Comparison of Lutein Amounts Required to Reach GRAS Levels from Lutein (USP) (FloraGLO® Crystalline Lutein) Versus Raw and Pureed Spinach, and Dehydrated Spinach Powder

Food Category	GRAS Food-Use	GRAS Use-Levels for Lutein (mg/RACC)	Amount of Lutein (USP) required to obtain GRAS usage level for lutein per RACC in mg (assuming 74% lutein content)[1]	Amount of raw or pureed spinach required to obtain GRAS usage level for lutein per RACC in mg (assuming 0.012% lutein content)[2]	Amount of dehydrated spinach powder required to obtain GRAS usage level for lutein per RACC in mg (assuming 0.12% lutein content)[3]
Baked Goods and Baking Mixes	Cereal, Granola, Energy, and Nutrition Bars	10.0	13.5	83,333	8,333
	Cookies	6.0	8.1	50,000	5,000
	Crackers and Crisp breads	2.0	2.7	16,666	1,666

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Beverages and Beverage Bases	Bottled Water	0.5	0.68	4,166	416
	Carbonated Beverages	2.0	2.7	16,666	1,666
	Meal Replacements	2.0	2.7	16,666	1,666
	Tea	3.0 (RTD) 5.0 (Powdered)	4.1 6.8	25,000 41,666	2,500 4,166
Breakfast Cereals	Instant and Regular Hot Cereals	2.0	2.7	16,666	1,666
	Ready-to-Eat Cereals	2.0	2.7	16,666	1,666
Chewing Gum	Chewing Gum	1.0	1.4	8,333	833
Dairy Product Analogs	Imitation Milks	2.0	2.7	16,666	1,666
	Soy Milks	6.0-10.0	8.1-13.5	50,000-83,333	5000-8333
Egg Products	Liquid, Frozen, or Dried Egg Substitutes	2.0	2.7	16,666	1,666

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Fats and Oils	Margarine-like Spreads	1.5	2.0	12,500	1,250
	Salad Dressings	1.5	2.0	12,500	1,250
Frozen Dairy Desserts and Mixes	Frozen Yogurt	2.0	2.7	16,666	1,666
Gelatins, Puddings, and Fillings	Gelatin	6.0	8.1	50,000	5,000
	Pudding	6.0	8.1	50,000	5,000
Gravies and Sauces	Tomato-Based Sauces	0.3	0.4	2,500	250
Hard Candy	Hard Candy	1.0	1.4	8,333	833
Infant and Toddler Foods	Junior, Strained, and Toddler Type Baby Foods	1.0	1.4	8,333	833

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Milk Products	Dry Milk	3.0	4.1	25,000	2,500
	Fermented Milk Beverages	0.6	0.8	5,000	500
	Flavored Milk and Milk Drinks	3.0	4.1	25,000	2,500
	Milk-Based Meal Replacements	3.0	4.1	25,000	2,500
	Yogurt	3.0	4.1	25,000	2,5000
Nuts and Nut Products	Trail Mix	10.0	13.5	83,333	8,333
Processed Fruits and Fruit Juices	Energy, Sport, and Isotonic Drinks	3.0 (RTD) 5.0 (Powdered)	4.1 6.8	25,000 41,666	2,500 4,166

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	Fruit-Flavored Drinks	3.0 (RTD) 5.0 (Powdered)	4.1 6.8	25,000 41,666	2,500 4,166
	Fruit Juice	3.0	4.1	25,000	2,500
	Nectars	3.0	4.1	25,000	2,500
	Vegetable Juice	3.0	4.1	25,000	2,500
Soft Candy	Chewy and Nougat Candy	1.0	1.4	8,333	833
	Fruit Snacks	1.0	1.4	8,333	833
Soups and Soup Mixes	Canned Soups	1.5	2.1	12,500	1,250

[1]Lutein (USP) contains at minimum 74% lutein. Using the first GRAS category as an example calculation, 74 mg lutein/100mg Lutein (USP) = 10 mg lutein/X, with X equaling 13.5 mg of Lutein (USP).

[2]Example calculation for first GRAS category: 3.7 mg lutein/30 g spinach =0.012mg lutein/100 mg spinach. 0.012mg lutein/100mg spinach = 10 mg lutein/X mg spinach. X calculates to 83,333 mg, or 83.3 g of spinach.

[3] An example calculation for first GRAS category. Based on 90% water content, 3.7 mg lutein/30 g spinach becomes 3.7 mg lutein/3 g dry spinach, or 0.12mg lutein/100 mg dry spinach. 0.12mg lutein/100mg dry spinach = 10 mg lutein/X mg dry spinach. X calculates to 8,333 mg, or 8.3 g of dry spinach.

Depending on the baseline lutein content of specific foods and serving sizes, attempts to supplement specific foods with even fractional amounts of lutein using raw spinach, without changing significant characteristics of the food, are not feasible. For example, in order for raw spinach to provide 6 mg of lutein to a 30 g cookie, 50 g of spinach must be added. 50 g is more than the RACC established for a cookie.[37] Additionally, raw spinach cannot be added to some specific types of foods, namely beverages, without resulting in obvious visual changes that may be undesirable.

Because spinach is composed of approximately 90% water (Davis *et al., 2004*), a spinach product that may more readily be considered for addition to various foods to increase the lutein content would be a dehydrated spinach powder. Based on the lutein + zeaxanthin amount estimated by USDA (3.7 mg/30 g), a fully dehydrated spinach powder could contain 0.12% of lutein + zeaxanthin by weight. Using another example product to which Lutein may be added, powdered tea, (Table 11.2.a) lutein supplementation of up to 5 mg with Lutein (USP) per RACC (240 mL) is acceptable, requiring 6.8 mg to of Lutein (USP) to reach this level. Alternatively, approximately 4.2 g of dry spinach powder would be required. The amount of dried spinach powder necessary is 600 times higher than the amount of Lutein (USP) required. Moreover, in the case of both liquid and powdered tea, only about 2 g of tea leaves are used in a typical 240 mL serving of initial tea brew. The 4.2 g of dry spinach powder in a tea powder would comprise more of the tea product than the tea components themselves.

Benefits for Organic Consumers

The marigold-derived lutein contained in Lutein (USP) is the same lutein form contained naturally in other agricultural products consumed as part of the human diet and is also the same form

[37] Based on this calculation, a question may arise on the suitability of simply consuming spinach by itself to obtain more lutein. As mentioned in the Introduction, the scientific evidence supports that the benefits of lutein are realized upon consumption of between 6-10mg of lutein on a daily basis. Using the U.S. Third National Health and Nutrition Examination Survey, 1988-1994 (NHANES III), the Institute of Medicine (IOM) used an expanded carotenoid database for foods reported in NHANES III, to estimate the usual consumption of lutein and zeaxanthin by the total U.S. population greater than 2 months of age (29,015 individuals). IOM calculated the mean level of lutein most Americans are obtaining from their diet is 1.71 mg (IOM, 2001). Alternatively, Kruger *et al*. (2002) estimated the intake of lutein and zeaxanthin using the dietary records for only those respondents to NHANES III who met their recommended daily intake of vegetables, as described in the Dietary Guidelines for Americans, and the carotenoid database employed by the IOM. The mean total lutein and zeaxanthin intakes for these individuals (5,708 participants, approximately 25% of the total surveyed sample) were 3.83 mg/person/day, respectively. Therefore, estimated intakes of lutein and zeaxanthin based on recommended levels of vegetable consumption appear to be greater than twice the estimated actual intakes for the total U.S. population (Kruger *et al*., 2002). Anecdotally, individuals identifying themselves as organic consumers may fall within the category of responders in NHANES III who are consuming the recommended daily amounts of fruits and vegetables, however even these individuals are unlikely to reach the recommended 6-10 mg of lutein from diet alone.

contained in human breast milk. It is also the form of lutein reported to be ultimately absorbed by the body, when consumed in the esterified form. [38]

It is estimated that only half of U.S. infants are exclusively breast fed at birth according to the American Academy of Pediatrics; accordingly, many formula-fed infants may not be ingesting a number of nutrients found in breast milk (Pediatrics, 2005). Because the chemical form of lutein in Lutein (USP) is the same as in human breast milk, FloraGLO Lutein 20% Liquid in Safflower Oil and FloraGLO Lutein 20% SAF [both containing Kemin's Lutein (USP)] provide the optimal source of lutein for use in infant formulas. Parents who select infant formula should have the option to provide their infants with nutritionally complete formulas that include as many of the same nutrients as are contained in human milk.

The role of lutein as a beneficial ingredient for inclusion in foods and dietary/food supplements is also of increasing importance because of its protective role in eye and skin health (Section 9.2.4.2.2). The scientific literature reports that the benefits of lutein for eye health, which include its activity as an antioxidant and blue light filter, its role in glare recovery and visual performance, as well as lutein's skin health benefits are realized with regular, daily intake of sufficient levels (reported as between 6-10 mg) of this nutrient that exceed typical dietary exposure levels. Current estimates are that less than one-third of the amount of lutein necessary for health benefits, or approximately 1.71 mg (mean), comes from traditional dietary sources (IOM, 2001). Accordingly, lutein intake from Lutein (USP) fortified dietary/food supplements and foods and beverages can help provide the specific eye, skin, antioxidant and other protective benefits demonstrated by scientific evidence.

Overall, the inclusion of Lutein (USP) to the National List will allow for the fortification of organic foods and infant formula with a safe, beneficial ingredient that is becoming increasingly recognized for its healthful benefits (Section 9.2.4.2.1 and 9.2.4.2.2), and thereby allow organic consumers the opportunity to enjoy the benefits of lutein without deviating wholly from organic products.

[38] Lutein esters ingested from foods or supplements requires the conversion to free, unesterified lutein in order to be absorbed. This conversion is likely mediated by pancreatic enzymes such as cholesterol esterase (Breithaup *et al.,* 2002).

12. PETITION JUSTIFICATION STATEMENT

12.1. Justification for Lutein Supplementation of Organically Labeled Products with Lutein (USP)

12.1.1. Provide Comparative Description on Why the Non-Organic Form of the Substance is Necessary for Use in Organic Handling

As stated in Section 11.2, Kemin has reviewed the marketplace and is unaware of any commercially available certified organic lutein products from any source.

Marigold flowers contain lutein in the form of lutein esters. Marigolds themselves cannot be saponified to efficiently produce large amounts of a significantly pure non-esterified lutein that can be considered a Lutein (USP). Marigolds must undergo further processing with other ingredients to produce marigold oleoresin, a product which can then be saponified to produce lutein material that meets the purity requirements for Lutein (USP). Even if organically certified marigolds were used as the starting material for marigold oleoresin, if the other ingredients used in marigold oleoresin manufacture are not certified organic or appropriately Listed, the product could not be certified organic and could not offer this organic status to a Lutein (USP) product. **[**

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Also, as discussed in Section 12.1.2, while lutein can be produced from other sources which could potentially be organic, these sources present significant commercial impracticability and quality issues.

12.1.2. Current and Historical Industry Information/Research/Evidence That Explains Why the Substance Cannot Be Obtained Organically

12.1.2.1. Appropriate Form

Lutein (USP), in its overall finished form, is unique for its high purity (74%) of the same lutein molecule consumed as part of the human diet, and low impurity content. Marigolds, while a preferred agricultural source because of the general abundance of the lutein pigment in the flower, are not the only source of non-esterified lutein. Free lutein can be obtained from

[39] Brackets indicate Confidential Business Information ("CBI").

extraction of table foods such as spinach, and also from green algae. However, issues with the types of materials and processing steps needed to extract the free lutein, as well as the low yield of free lutein from these sources, preclude them from being practical. These issues are detailed in the following subsections.

12.1.2.2. Appropriate Quality

As discussed more fully in the next section, extraction of free lutein from other certified organic foods such as spinach requires more processing and solvents than extraction from marigolds, and would likely yield a product with less free lutein than Lutein (USP). Lutein from spinach would therefore be more likely to be a more impure final product. Lutein may also be obtained from microalgae, but again, the free lutein purity is low as compared to Lutein (USP). While these lower purities may or may not translate into less safe products, in terms of commercial perception of quality, a lower purity non-esterified lutein is less desirable because of the potential for the presence of unknown and/or undesirable impurities that would necessarily accompany the lutein component of the ingredient.

12.1.2.3. Appropriate Quantity to Fulfill an Essential Function in a System of Organic Handling

While it may be considered that, due to a relatively high level of non-esterified lutein contained in some dietary foods such as spinach (which may be certified organic), extraction of “free” lutein from such a source would be feasible. Kemin has previously investigated this option and there are several reasons why this is not the case. Spinach and other table foods as raw materials are much more expensive than marigolds. Also, the dietary or free lutein contained in spinach is significantly bound in the plant material and is present with various other carotenoids from which it must be separated. In order to adequately isolate lutein from spinach, simple extraction is insufficient. Spinach must be dehydrated, the spinach plant cell matrix disrupted, and generally a solvent separation of the chlorophyll containing fraction is necessary prior to another solvent separation step to isolate lutein from other contained carotenoids such as beta-carotene. Moreover, the lutein content in one cup of spinach (30 g) is estimated, combined with zeaxanthin to be approximately 3.7 mg (USDA, 2010). A theoretical extraction ratio of spinach (assuming all lutein + zeaxanthin [L + Z] could be obtained) would be 123 mg (L + Z)/kg spinach. **[** **CBI Deleted** **]** Comparatively, marigold flowers provide high lutein yields, are not subject to interferences from chlorophyll, and also do not contain significant levels of other carotenoids.

Also, the use of additional or increased amounts of solvents in spinach extraction may have a potential negative impact on both the product and the environment. Assuming a high water

content in spinach nearing 90% (Davis *et al.,* 2004), it is likely that significant measures to remove the excess moisture would also be necessary. **[**

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] Additionally, there is increased potential for impurities, and the use of additional solvents required to isolate lutein from these types of green vegetables is likely to result in a greater environmental impact. Taken together, these issues establish obtaining lutein from spinach, or another similar type food, as less desirable than obtaining lutein from marigolds.

Lutein is also known to be present in green algae; however Kemin has not identified any algal-derived products currently marketed as "lutein". Kemin is unaware of any algal-processes that could produce a lutein product containing the same level of non-esterified lutein as contained in Lutein (USP), and experts have stated that microbial sources cannot compete with marigold flower as a source of lutein (Dufosse, 2009), supporting Kemin's findings. Currently, in terms of marketed algal-derived carotenoids, the most notable is beta-carotene, with a product called Betatene® being the most prominently known. Betatene is a mixed carotenoid product obtained from the microalgae, *Dunaliella salinas*. Betatene contains lutein, zeaxanthin, and cryptoxanthin, but its major carotenoid constituent is beta-carotene. Lutein, in a 30% Betatene product, only comprises 1500 ppm, or 0.15% of the Betatene composition. [41] Lutein (USP) contains, at minimum, 74% lutein, with commercial forms of Lutein (USP) products offering between 5-20% lutein. When compared to Lutein (USP) products, Betatene could not be considered to provide a significant source of purified lutein, supporting that algal sources do not offer a viable source for this material.

12.1.3. Describe Industry Information on Substance Non-availability of Organic Sources, Including But Not Limited to, the Following Guidance Regarding Commercial Availability Evaluation Criteria

12.1.3.1. Regions of Production, Including Factors Such as Climate and Number of Regions

Kemin manufactures its Lutein (USP) in the United States. Lutein products are manufactured in several countries worldwide. Climate and climate changes do not generally affect actual lutein

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[40] Kemin internal memo, March, 2011 (Appendix G).

[41] Cognis Corporation. "Natural Carotenoids. The Color of Health." *http://www.cognis.com/NR/rdonlyres/CBA4E8A2-D3F3-4E60-A254-10FB3CCF8298/0/Betatene_Brochure.pdf*. Brochure. Last accessed June 10, 2011.

processing. Rather, climate affects the raw marigold crop for lutein products derived from that source.

The majority of commercially available lutein is obtained from marigolds and 75% of marigolds intended for production into marigold oleoresin, both food and feed grade, are grown in China. The remaining growing regions for this type of marigold are India, Thailand, and a few South American countries.

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12.1.3.2. Number of Suppliers and Amount Produced

In addition to Kemin (in partnership with DSM), there are approximately 10 other lutein suppliers.

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12.1.3.3. Current and Historical Supplies Related to Weather Events Such as Hurricanes, Floods, and Droughts That May Temporarily Halt Production or Destroy Crops or Supplies

Adverse or erratic weather patterns do affect marigold crops intended for marigold oleoresin production. Recently in China, there have been reports of erratic frost and rain conditions adversely affecting marigold crops and causing a shortage of marigold flowers for use in the production of feed grade marigold oleoresin. As China is the largest growing region of marigolds for use in this feed grade product, this does affect the global supply of feed grade marigold oleoresin. Because other producers may use feed grade oleoresin as their starting material for food grade lutein, this does affect the global supply of lutein for human use.

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12.1.3.4. Trade Related Issues Such as Evidence of Hoarding, War, Trade Barriers, or Civil Unrest That May Temporarily Restrict Supplies

Traditionally, these have not been concerns with lutein, marigold oleoresin, or marigolds.

12.1.3.5. Other Issues Which May Present a Challenge to a Consistent Supply

As stated, Kemin is unaware of any other issues which may cause challenges or interruptions to supply.

13. COMMERCIAL CONFIDENTIAL INFORMATION STATEMENT

Kemin has marked specific information within the petition as Confidential Business Information (CBI) as specified in the Federal Register Notice[43] which provides guidance on the procedures for submitting National List petitions. Kemin respectfully requests this CBI be redacted from the published version of this petition. Desired redactions related to confidential business information appear in the following sections; Introduction, Section 5.1.1, Section 7.1, Section 9.2.3.1, Section 10.1.1, Section 12.1.1, Section 12.1.3.1, Section 12.1.3.2, Section 12.1.3.3, and two documents contained in Appendix A (Assessment of the Equivalence of FloraGLO® Lutein 20% Safflower Oil Manufactured by DSM and Kemin for Use in Infant Formula and 2008 Expert Opinion on FloraGLO® Crystalline Lutein Self-Affirmed GRAS Dossier) and two finished product labels for infant formula and a food/beverage product containing lutein contained in Appendix C. The two finished product labels are considered commercial information which should not be disclosed for competitive reasons. By virtue of Kemin including these labels in the Petition and having knowledge that the lutein contained in the product meets the conditions specified in the Petition, the customer relationship of the manufacturer(s) of these finished products to Kemin or its sole licensee and distributor would be disclosed. As such customer information is of commercial value, these finished product labels are considered CBI. Confidential analytical information appears in Section A.2 and 5.1.1 marked for redaction. Detailed manufacturing information noted for redaction appears in Section 5.1.2, Section 5.2, Sections 5.2.1-5.2.6, Section 5.3.1, Section 9.2, Section 9.2.3.2, Section 12.1.2.3, as Figure 5.2.a, and in Appendix. G. Confidential formulation information appears in Section 3.1.2. Kemin is also submitting a redacted version of this Petition.

[43] National Organic Program—Submission of Petitions of Substances for Inclusion on or Removal From the National List of Substances Allowed and Prohibited in Organic Production and Handling. Notice on Guidelines on Procedures for Submitting National List Petitions. 72 Fed. Reg. 2167-2170 (January 18, 2007).

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PETITIONER SIGNATURES

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Appendix A

Regulatory Clearances

1. USP Monograph for Lutein
2. June 2004 FDA Letter of Non-Objection
3. October 2007 FDA Letter of Non-Objection
4. Assessment of the Equivalence of FloraGLO® Lutein 20% Safflower Oil Manufactured by DSM and Kemin for Use in Infant Formula (**CBI deleted**)
5. 2008 Expert Opinion on FloraGLO® Crystalline Lutein Self-Affirmed GRAS Dossier (**CBI deleted**)
6. AFSSA Statement
7. Lutein from Tagetes erecta L. In: Chemical and Technical Assessment (CTA): Sixty-third Meeting of the Joint FAO/WHO Expert Committee on Food Additives, 2006.

ADDITIONAL REQUIREMENTS
- **PACKAGING AND STORAGE:** Preserve in well-closed containers.
- **USP REFERENCE STANDARDS** ⟨**11**⟩
  USP Alpha Lipoic Acid RS

Alpha Lipoic Acid Tablets

DEFINITION
Alpha Lipoic Acid Tablets contain NLT 90.0% and NMT 115.0% of the labeled amount of $C_8H_{14}O_2S_2$.

IDENTIFICATION
- The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the test for *Content of Alpha Lipoic Acid*.

STRENGTH
- **CONTENT OF ALPHA LIPOIC ACID**
  Mobile phase: 0.025 M phosphoric acid and acetonitrile (62:38)
  Standard solution: 0.05 mg/mL of USP Alpha Lipoic Acid RS in acetonitrile and water (1:1)
  Sample solution: Transfer the equivalent of 100 mg of alpha lipoic acid from NLT 20 finely powdered Tablets to a suitable container. Add 70 mL of a mixture of acetonitrile and water (1:1), and shake for 45 min by mechanical means. Transfer to a 100-mL volumetric flask, dilute with the mixture of acetonitrile and water (1:1) to volume, and filter a portion of this preparation, discarding the first 5 mL of the filtrate. Transfer 5.0 mL of the remaining filtrate to a 100-mL volumetric flask, and dilute with acetonitrile and water (1:1) to volume.
  Chromatographic system
  (See *Chromatography* ⟨621⟩, *System Suitability*.)
  Mode: LC
  Detector: UV 220 nm
  Column: 3.9-mm × 30-cm; packing L1
  Flow rate: 1.5 mL/min
  Injection size: 20 µL
  System suitability
  Sample: *Standard solution*
  Suitability requirements
  Column efficiency: NLT 1300 theoretical plates
  Tailing factor: NMT 1.2 for alpha lipoic acid
  Relative standard deviation: NMT 1.0%
  Analysis
  Samples: *Standard solution* and *Sample solution*
  Calculate the percentage of the labeled amount of alpha lipoic acid ($C_8H_{14}O_2S_2$) in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

  r_U = peak response from the *Sample solution*
  r_S = peak response from the *Standard solution*
  C_S = concentration of USP Alpha Lipoic Acid RS in the *Standard solution* (mg/mL)
  C_U = nominal concentration of alpha lipoic acid in the *Sample solution* (mg/mL)
  Acceptance criteria: 90.0%–115.0%

PERFORMANCE TESTS

Change to read:

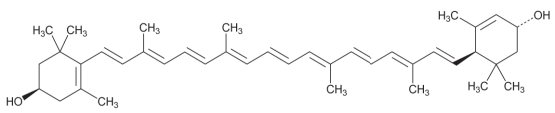
- **DISINTEGRATION AND DISSOLUTION OF DIETARY SUPPLEMENTS** ⟨**2040**⟩**:** ▲Meet the requirements for *Dissolution*▲*USP34*
  Medium: Water; 900 mL
  Apparatus 2: 75 rpm
  Time: 60 min
  Standard stock solution: 1 mg/mL of USP Alpha Lipoic Acid RS in a mixture of acetonitrile and water (1:1)
  Standard solution: 0.02 mg/mL from the *Standard stock solution* in water
  Sample solution: Withdraw a portion of the solution under test, and filter, discarding the first portion of the filtrate. Transfer an aliquot to a volumetric flask, and dilute with water to volume to obtain a solution having an expected concentration of 0.02 mg/mL of alpha lipoic acid.
  Mobile phase and **Chromatographic system:** Proceed as directed in the test for *Content of Alpha Lipoic Acid*.
  Injection size: 50 µL
  Analysis
  Samples: *Standard solution* and *Sample solution*
  Calculate the percentage of alpha lipoic acid ($C_8H_{14}O_2S_2$) dissolved:

$$\text{Result} = (r_U/r_S) \times (V \times C \times D/L) \times 100$$

  r_U = peak area from the *Sample solution*
  r_S = peak area from the *Standard solution*
  V = volume of dissolution *Medium*, 900 mL
  C = concentration of USP Alpha Lipoic Acid RS in the *Standard solution* (mg/mL)
  D = dilution factor of the sample
  L = label claim of alpha lipoic acid (mg/Tablet)
  Tolerances: NLT 70% of the labeled amount of alpha lipoic acid ($C_8H_{14}O_2S_2$) is dissolved.
- **WEIGHT VARIATION OF DIETARY SUPPLEMENTS** ⟨**2091**⟩**:** Meet the requirements

ADDITIONAL REQUIREMENTS
- **PACKAGING AND STORAGE:** Preserve in well-closed containers.
- **LABELING:** Tablets that are coated are so labeled.
- **USP REFERENCE STANDARDS** ⟨**11**⟩
  USP Alpha Lipoic Acid RS

Lutein



$C_{40}H_{56}O_2$ 568.87
β-ε-carotene-3,3′-diol (3*R*, 3′*R*, 6′*R*) [*127-40-2*].

» Lutein is the purified fraction obtained from saponification of the oleoresin of *Tagetes erecta* L. It contains not less than 80.0 percent of total carotenoids calculated as lutein ($C_{40}H_{56}O_2$). It contains not less than 74.0 percent of lutein and not more than 8.5 percent of zeaxanthin, both calculated as ($C_{40}H_{56}O_2$) on the anhydrous basis.

Packaging and storage—Preserve in tightly sealed, light- and oxygen-resistant containers. Store in a cool place.

USP Reference standards ⟨11⟩**—**
USP Lutein RS

Identification—

A: *Ultraviolet Absorption* ⟨197U⟩—

Spectral range: 300 to 700 nm.

Solution—Prepare as directed for the *Test solution* in the test for *Content of total carotenoids.*

Ratio: A_{446} / A_{474}, between 1.09 and 1.14.

B: The retention time for the major peak in the chromatogram of the *Test solution* corresponds to that in the chromatogram of the *Standard solution,* as obtained in the test for *Content of lutein.*

Water, *Method I* ⟨921⟩**:** not more than 1.0%.

Residue on ignition ⟨281⟩: not more than 2.0%.

Lead ⟨251⟩: not more than 1 µg per g.

Heavy metals, *Method II* ⟨231⟩: not more than 5 µg per g.

Zeaxanthin and other related compounds—[NOTE—Use low-actinic glassware.]

Solvent, Mobile phase, Standard solution, Test solution, and *Chromatographic system*—Proceed as directed under *Content of lutein*.

Procedure—Inject a volume (about 10 µL) of the *Test solution* into the chromatograph, record the chromatogram, and measure the peak responses. The peak area of zeaxanthin is not more than 9.0% of the total detected area of peaks in the chromatogram of the *Test solution*. Calculate the percentage of zeaxanthin in the portion of Lutein taken by the formula:

$$T(r_i / r_s)$$

in which T is the content, in percentage, of total carotenoids as determined in the test for *Content of total carotenoids;* r_i is the individual peak response of zeaxanthin; and r_s is the sum of the responses of all the peaks: not more than 8.5% of zeaxanthin is found. Calculate the percentage of other related compounds in the portion of Lutein taken by the formula:

$$100(r_i / r_s)$$

in which r_i is the individual peak response of any other peak in the chromatogram (excluding zeaxanthin and lutein); and r_s is the sum of the responses of all the peaks: not more than 1.0% of any other single related compound is found.

Content of lutein—

Solvent: a mixture of hexanes, acetone, toluene, and dehydrated alcohol (10 : 7 : 7 : 6).

Mobile phase—Prepare a filtered and degassed mixture of hexane and ethyl acetate (75 : 25). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Standard solution—Dissolve a suitable quantity of USP Lutein RS in *Mobile phase* to obtain a solution containing about 150 µg per mL.

Test solution—Transfer about 1 mL of *Test stock solution* from the test for *Content of total carotenoids*, and evaporate under a stream of nitrogen to dryness. Add 1 mL of *Mobile phase,* and sonicate to dissolve.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 446-nm detector and a 4.6-mm × 25-cm column that contains 5-µm packing L3. The flow rate is about 1.5 mL per minute. Chromatograph the *Standard solution,* and record the peak responses as directed for *Procedure:* the relative retention times are about 1.05 for zeaxanthin and 1.0 for lutein; the resolution, *R,* between lutein and zeaxanthin is not less than 1.0; the tailing factor is not more than 2; and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Inject a volume (about 10 µL) of the *Test solution* into the chromatograph, record the chromatogram, and measure the peak area responses. The peak area of lutein is not less than 85.0% of the total detected area of peaks in the chromatogram. Calculate the percentage of Lutein taken by the formula:

$$T(r_i / r_s)$$

in which T is the content, in percentage, of total carotenoids as determined in the test for *Content of total carotenoids;* r_i is the individual peak response of lutein in the *Test solution;* and r_s is the sum of the responses of all the peaks: not less than 74.0% of lutein is found.

Content of total carotenoids—[NOTE—Use low-actinic glassware.]

Solvent: a mixture of hexanes, acetone, toluene, and dehydrated alcohol (10 : 7 : 7 : 6).

Test stock solution—Transfer about 30 mg of Lutein to a 100-mL volumetric flask, and dissolve in and dilute with *Solvent* to volume.

Test solution—Quantitatively dilute the *Test stock solution* (1 in 100) with dehydrated alcohol to obtain a solution having a final concentration of about 3.0 µg per mL.

Procedure—Determine the absorbance of the *Test solution* at the wavelength of maximum absorbance at about 446 nm, with a suitable spectrophotometer, using dehydrated alcohol as a blank. Calculate the percentage of total carotenoids as lutein ($C_{40}H_{56}O_2$) by the formula:

$$10{,}000A / 2550W$$

in which A is the absorbance of the *Test solution; W* is the weight, in g, of Lutein taken to prepare the *Test stock solution;* and 2550 is the absorptivity of the lutein in alcohol.

Lutein Preparation

DEFINITION

Lutein Preparation is a combination of Lutein with one or more inert substances. It may be in a solid or a liquid form. It contains NLT 95.0% and NMT 130.0% of the labeled amount of lutein, calculated as $C_{40}H_{56}O_2$ on the anhydrous basis. It contains NLT 85.0% of lutein and NMT 9.0% of zeaxanthin of the total carotenoid content.

IDENTIFICATION

- **A. Ultraviolet Absorption** ⟨197U⟩
  Analytical wavelength: 300–700 nm
  Sample solution: Prepare as directed for the *Sample solution* in the test for *Content of Total Carotenoids*.
  Ratio: A_{446}/A_{474}, 1.09–1.14
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the test for *Content of Lutein*.

COMPOSITION

- **Content of Total Carotenoids**
  Diluent: Hexanes, acetone, toluene, and dehydrated alcohol (10:7:7:6)
  Sample stock solution A (for solid lutein preparations labeled as containing gelatin)**:** Transfer an amount of Preparation, equivalent to 3.5 mg of lutein, to a 50-mL centrifuge tube. Add 15 mL of warm water, 60 units of bacterial alkaline protease preparation, and 1 mg of bromelain. Cap and sonicate for 20 min with occasional swirling. Cool to room temperature, and add 20.0 mL of methylene chloride. Shake for 1 min, and centrifuge for 5 min at 2000 rpm. Remove the upper aqueous phase, and add 2–3 g of anhydrous sodium sulfate to the remaining red layer.
  Sample stock solution B (for other solid lutein preparations)**:** Transfer an amount of Preparation, equivalent to 1.5 mg of lutein, to a 50-mL centrifuge tube. Add 15 mL of warm water, cap, and sonicate for 30 min with occasional swirling. Cool to room temperature, and add 30.0 mL of ethyl acetate and 2–3 g of sodium chloride. Shake for 1 min, and centrifuge for 5 min at 2000 rpm. Use the upper orange-red layer.
  Sample stock solution C (for liquid lutein suspensions in oil)**:** Transfer a weighed amount of Preparation equivalent to 20 mg of lutein to a 100-mL volumetric flask, and dilute with *Diluent* to volume. Add a magnetic bar, and stir for 30 min.
  Sample solution: Transfer 1.0 mL of *Sample stock solution A*, or 1.0 mL of *Sample stock solution B*, or 1.0 mL of *Sample stock solution C* into a 100-mL volumetric flask, and dilute with dehydrated alcohol to volume.
  Spectrometric conditions
  (See *Spectrophotometry and Light-Scattering* ⟨851⟩.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

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JUN 14 2004

Re: GRAS Notice No. GRN 000140

Dear Dr. DeFreitas:

The Food and Drug Administration (FDA) is responding to the notice, dated November 14, 2003, that you submitted in accordance with the agency's proposed regulation, proposed 21 CFR 170.36 (62 FR 18938; April 17, 1997; Substances Generally Recognized as Safe (GRAS); the GRAS proposal). FDA received the notice on November 18, 2003, filed it on November 21, 2003, and designated it as GRAS Notice No. GRN 000140.

The subject of the notice is a mixture of the carotenoids lutein and zeaxanthin referred to by Kemin Foods, L.C. (Kemin) as "crystalline lutein." The notice informs FDA of the view of Kemin that crystalline lutein is GRAS, through scientific procedures, for use as an ingredient in baked goods and baking mixes, beverages and beverage bases, breakfast cereals, chewing gum, dairy product analogs, egg products, fats and oils, frozen dairy desserts and mixes, gravies and sauces, hard candy, infant and toddler foods (other than infant formula), milk products, processed fruits and fruit juices, soft candy, soups and soup mixes, and in medical foods intended as the sole item of the diet. The levels of crystalline lutein in the above listed food items range from 0.3 to 3.0 milligrams (mg) per eating occasion (Table 1).

Table 1
Food categories and use levels for crystalline lutein

Food Category	Proposed food use	Use level (mg crystalline lutein per RACC*)
Baked goods and baking mixes	Cereal and energy bars Crackers and crisp bread	2.0 2.0
Beverages and beverage bases	Bottled water Carbonated beverages Meal replacements Tea, ready-to-drink	0.5 2.0 2.0 0.6

Food Category	Proposed food use	Use level (mg crystalline lutein per RACC*)
Breakfast cereals	Instant & regular hot cereal Ready-to-eat-cereal	2.0 2.0
Chewing gum	Chewing gum	1.0
Dairy product analogs	Imitation milks Soy milks	2.0 1.5
Egg products	Liquid, frozen, dried egg substitutes	2.0
Fats and oils	Margarine-like spreads Salad dressings	1.5 1.5
Frozen dairy desserts and mixes	Frozen yogurt	1.0
Gravies and sauces	Tomato-based sauces	0.3
Hard candy	Hard candy	1.0
Infant** and toddler foods	Junior, strained, and toddler type baby foods	1.0
Soft candy	Chewy and nougat candy Fruit snacks	1.0 1.0
Soups and soup mixes	Canned soups	0.6
Milk products	Dry milk Fermented milk beverages Flavored milk & milk drinks Milk-based meal replacement Yogurt	3.0 0.6 3.0 3.0 3.0
Processed fruit and fruit juices	Energy, sport and isotonic drink Fruit-flavored drinks Fruit juice Nectars Vegetable juice	2.0 2.0 2.0 2.0 2.0
Medical foods	Medical foods	≤20 mg/day

* RACC is defined as "reference amounts customarily consumed per eating occasion" (21 CFR 101.12).
** Kemin states the infant food category does not include infant formula.

For clarity, in the remainder of this letter FDA uses the term "crystalline lutein" to denote the mixture of the carotenoids lutein and zeaxanthin that is the subject of the notice and the term "lutein" to denote the principal component of this mixture.

Our use of "crystalline lutein" in this letter should not be considered an endorsement or recommendation of that term as an appropriate common or usual name for the purpose of declaring the substance in the ingredient statement of foods that contain that ingredient. 21 CFR 101.4 states that all ingredients must be declared by their common or usual name. In addition, 21 CFR 102.5 outlines general principles to use when establishing common or usual names for nonstandardized foods. Issues associated with labeling and the appropriate common or usual name of a food are the responsibility of the Office of Nutritional Products, Labeling, and Dietary Supplements.

As part of its notice, Kemin includes the report of a panel of individuals (Kemin's GRAS panel) who evaluated the data and information that are the basis for Kemin's GRAS determination. Kemin considers the members of its GRAS panel to be qualified by scientific training and experience to evaluate the safety of substances added to food. Kemin's GRAS panel evaluated estimates of dietary exposure, method of manufacture, product specifications, and published studies on crystalline lutein and related compounds. Based on this review, Kemin's GRAS panel concluded that crystalline lutein that meets appropriate food grade specifications and is manufactured in compliance with current good manufacturing practices is GRAS under the conditions of its intended use.

Kemin describes the method of manufacture for crystalline lutein. The process begins with marigold oleoresin, which is derived from the hexane extraction of dried marigold flower petals (*Tagetes erecta*). The oleoresin is extracted with a basic solution, organic solvent, and water yielding a crystalline product containing lutein and zeaxanthin. This product is then diluted with water, centrifuged, washed, and dried to form the final product, crystalline lutein. Kemin notes that crystalline lutein is packaged under nitrogen.

Kemin provides product specifications for crystalline lutein. These specifications include limits on lead, arsenic, pesticides, organic solvents, yeasts and molds, and microbiological contaminants. Kemin also provides specifications on the total carotenoids in crystalline lutein and the percentages of lutein and zeaxanthin. Kemin reports that crystalline lutein contains approximately 76 percent lutein by weight and approximately 7 percent zeaxanthin by weight (for a total of approximately 83 percent total carotenoids by weight).

Using its proposed use levels and data from the United States Department of Agriculture 1994-1996 Continuing Survey of Food Intakes by Individuals and 1998 Supplemental Children's Survey, Kemin estimates that the intake of crystalline lutein would be approximately 10 milligrams per person per day (mg/person/day) at the mean and approximately 18 mg/person/day at the 90th percentile. Based on the carotenoid composition of crystalline lutein, Kemin also estimates that the intake of lutein and zeaxanthin would be approximately 7mg/person/day (lutein) and 0.7 mg/person/day (zeaxanthin) at the mean and approximately 13 mg/person/day (lutein) and 1.2 mg/person/day (zeaxanthin) at the 90th percentile, respectively. Kemin notes that the average dietary intake of lutein and zeaxanthin from plant sources ranges from 2 to 4 mg/person/day. However, Kemin notes that there are no consumption data from which to reliably estimate the intake of lutein and zeaxanthin from dietary supplements.

Kemin discusses published studies conducted in humans and various animal species regarding the absorption, distribution, metabolism, excretion, bioavailability, toxicity and mutagenicity of crystalline lutein and its primary components, lutein and zeaxanthin. Kemin concludes that results of these studies show no toxic or adverse effects (including ocular damage) from the consumption of crystalline lutein or lutein and zeaxanthin from other sources. Kemin notes that carotenodermia[1] was reported in a study in which healthy subjects consumed 15 mg/person/day of lutein (from mixed ester forms extracted from marigold) for 4 months. Kemin notes, however, that carotenodermia is considered a harmless and reversible biological effect of high carotenoid intake, and that no signs of its occurrence have been reported in other populations (e.g., patients with cataracts or patients with age-related macular degeneration) following exposure 3 times per week for 13 months of approximately 25 mg/person/day of lutein.

Use of crystalline lutein in medical foods

In its notice, Kemin informs FDA that one intended use of crystalline lutein is in medical foods intended as the sole item of the diet. Section 5(b)(3) of the Orphan Drug Act defines a medical food as a food that is formulated to be consumed or administered enterally under the supervision of a physician and that is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. Section 403 (q) of the Federal Food, Drug, and Cosmetic Act (FFDCA) lays out the statutory framework for nutrition labeling of food products. Section 403(r) of the FFDCA lays out the statutory framework for health claims and nutrient content claims. Under section 403(q)(5)(A)(iv) of the FFDCA and FDA's implementing regulations in 21 CFR 101.9(j)(8), the requirements for nutrition labeling do not apply to medical foods as defined in section 5(b) of the Orphan Drug Act. Under section 403 (r)(5)(A) and FDA's implementing regulations in 21 CFR 101.13(q)(4) and 21CFR 101.14(f)(2), the requirements for nutrient content claims and health claims do not apply to medical foods as defined in section 5(b) of the Orphan Drug Act. For your information, FDA's response to Kemin's notice that crystalline lutein is GRAS for use in medical foods intended as the sole item of the diet does not address the question of whether any particular food product that contains crystalline lutein as an ingredient would be a medical food within the meaning of section 503(b) of the Orphan Drug Act and, thus would be exempt from requirements for nutrition labeling, nutrient content claims, and health claims.

Potential requirement for a color additive petition

FDA notes that Kemin's crystalline lutein product has the potential to impart color in food products that contain it. As such, the use of crystalline lutein in food products may constitute the use of a color additive under section 201(t)(1) of the Federal Food, Drug and Cosmetic Act (FFDCA) and FDA's implementing regulations in 21 CFR Part 70. Under section 201(t)(1) and 21 CFR 70.3(f), the term color additive means a material that is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived from a vegetable, animal, mineral, or other source, and that is capable (alone or through reaction with another substance) of imparting color when added or applied to a food; except that

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[1]A reversible condition described as a yellowing of the skin, especially the palms of the hands and the soles of the feet

such term does not include any material which the Secretary[2] by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring. Under 21 CFR 70.3(g), a material that otherwise meets the definition of color additive can be exempt from that definition on the basis that it is used or intended to be used solely for a purpose or purposes other than coloring, as long as the material is used in a way that any color imparted is clearly unimportant insofar as the appearance, value, marketability, or consumer acceptability is concerned. Given the construct of section 201(t)(1) of the FFDCA and 21 CFR 70.3(f) and (g), the use of a substance that is capable of imparting color may constitute use as a color additive in addition to use as a food additive or GRAS substance. For example, beta-carotene is both approved for use as a color additive (21 CFR 73.95) and affirmed as GRAS for use as a nutrient supplement (21 CFR 184.1245); in some food products, beta-carotene is used for both purposes. Importantly, if the use of crystalline lutein constitutes use as a color additive within the meaning of section 201(t)(1) of the FFDCA and FDA's implementing regulations in 21 CFR 70.3(f) and(g), section 721(a) of the FFDCA requires premarket review and approval of that use by FDA. Under section 402(c) of the FFDCA, a food product that contains an unapproved color additive would be deemed adulterated[3].

In a telephone conference on April 21, 2004, between representatives of FDA and Kemin, FDA requested that Kemin present its view on whether any of the intended uses of crystalline lutein would be exempt from the definition of color additive. In an amendment dated April 27, 2004, Kemin presented its reasons for concluding that all of the intended uses of crystalline lutein would be exempt from the definition of color additive under section 201(t) of the FFDCA and FDA's implementing regulations in 21 CFR 70.3(f) and (g). Importantly, FDA's response to GRN 000140 does not include any comment by FDA about Kemin's view on this issue. If, after receipt of this letter, Kemin has any specific questions about this issue, we recommend that Kemin contact the Division of Petition Review (HFS-265), Office of Food Additive Safety, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740. You can reach this division by telephone at (202) 418-3217.

Standards of identity

In the notice, Kemin states its intention to use crystalline lutein in several food categories, including foods for which standards of identity exist, located in Title 21 of the Code of Federal Regulations. We note that an ingredient that is lawfully added to food products may be used in a standardized food only if permitted by the applicable standard of identity. If you have any questions about the use of crystalline lutein in standardized foods that would be marketed in the

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[2]The Secretary of the Department of Health and Human Services (DHHS). The Secretary of DHHS has delegated the authority for this provision of the FFDCA to FDA.

[3]We note that section 721(b)(4) of the FFDCA provides that color additive shall be deemed to be safe and suitable for the purpose of listing under section 721(b) of the FFDCA while there is in effect a published findings of the Secretary declaring that the substance is exempt from the definition of "food additive" because of its being generally recognized by qualified expert as safe for its intended use as provided in section 201(s) of the FFDCA. Importantly, FDA's response to GRN 000140 does not constitute a "finding of the Secretary " within the meaning of section 721(b)(4) of the FFDCA.

United States, you should contact the staff in the Office of Nutritional Products, Labeling and Dietary Supplements, Division of Standards and Labeling Regulations (HFS-820), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740. You can reach this division by telephone at (301) 436-2371.

Conclusions

Based on the information provided by Kemin, as well as other information available to FDA, the agency has no questions at this time regarding Kemin's conclusions that crystalline lutein is GRAS under the intended conditions of use. The agency has not, however, made its own determination regarding the GRAS status of the subject use of crystalline lutein. As always, it is the continuing responsibility of Kemin to ensure that food ingredients it markets are safe, and are otherwise in compliance with all applicable legal and regulatory requirements. In particular, we note that any use of crystalline lutein that constitutes as a color additive requires premarket review and approval by FDA.

In accordance with proposed 21 CFR 170.36(f), a copy of the text of this letter, as well as a copy of the information in your notice that conforms to the information in proposed 21 CFR 170.36 (c)(1), is available for public review and copying on the homepage of the Office of Food Additive Safety (on the Internet at http://www.cfsan.fda.gov/~lrd/foodadd.html).

Sincerely,

George H. Pauli, Ph.D.
Acting Director
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition

CFSAN/Office of Food Additive Safety
October 23, 2007

Agency Response Letter
GRAS Notice No. GRN 000221

Debbie Trinker
Vice President, Regulatory Affairs
Kemin Health, L.C.
600 E. Court Avenue, Suite A
Des Moines, IA 50309-2021

Re: GRAS Notice No. GRN 000221

Dear Ms. Trinker:

The Food and Drug Administration (FDA) is responding to the notice, dated April 4, 2007, that you submitted in accordance with the agency's proposed regulation, proposed 21 CFR 170.36 (62 FR 18938; April 17, 1997; Substances Generally Recognized as Safe (GRAS); the GRAS proposal). FDA received the notice on April 9, 2007, filed it on April 11, 2007, and designated it as GRAS Notice No. GRN 000221.

The subject of the notice is suspended lutein. The notice informs FDA of the view of Kemin Health L.C. (Kemin) that suspended lutein is GRAS, through scientific procedures, for use as an ingredient in term infant formula at a maximum level of 250 micrograms per liter (µg/l). In this letter the term "suspended lutein" denotes the mixture of the carotenoids lutein and zeaxanthin (crystalline lutein) that are suspended in safflower oil.

21 CFR 101.4 states that all ingredients must be declared by their common or usual name. In addition, 21 CFR 102.5 outlines general principals to use when establishing common or usual names for nonstandarized foods. Our use of "suspended lutein" in this letter should not be considered an endorsement or recommendation of that term as an appropriate common or usual name for the purpose of declaring the substance in the ingredient statement of foods that contain

that ingredient. Issues associated with labeling and the appropriate common or usual name of a food are the responsibility of the Office of Nutritional Products, Labeling, and Dietary Supplements in the Center for Food Safety and Applied Nutrition.

As part of GRN 000221, Kemin includes the report of a panel of individuals (Kemin's GRAS panel) who evaluated the data and information that are the basis for Kemin's GRAS determination. Kemin considers the members of its GRAS panel to be qualified by scientific training and experience to evaluate the safety of substances added to food. Kemin's GRAS panel evaluated estimates of dietary exposure, method of production, and product specifications as well as published and unpublished studies. Based on this review, Kemin's GRAS panel concluded that suspended lutein that meets appropriate food grade specifications and is manufactured in accordance with current good manufacturing practices is GRAS under the conditions of its intended use.

Crystalline lutein was the subject of GRN 000140 and is incorporated by reference into GRN 000221. The notified substance in GRN 000221 is a safflower oil suspension of crystalline lutein. GRN 000140 includes the identity and composition of, as well as, the method of manufacture of crystalline lutein. GRN 000221 discusses the identity, composition, and method of manufacture of suspended lutein. Kemin reports that the main components of suspended lutein are at least 21 percent lutein by weight and at least 0.8 per cent zeaxanthin by weight and provides specifications for this ingredient.

In GRN 000221, Kemin describes the use of suspended lutein in term infant formula at levels not to exceed 250 μg/l, which Kemin notes is equivalent to 37 micrograms per 100 kilocalories. Kemin estimates the mean and 90th percentile intake of dietary carotenoids for children from 2 through 6 months to be 200 and 820 micrograms per day (μg/d) respectively, and for children between 7 months to 11 months of age to be 460 and 1,100 μg/d, respectively. For the use in term infant formula, as described in GRN 000221, Kemin estimates a daily intake of 195 μg/d of suspended lutein.

GRN 000221 discusses published and unpublished studies in GRN 000140, as well as several published animal studies that became available after the agency review of GRN 000140, and two unpublished growth studies conducted in healthy term infants. Kemin concludes that the growth studies provide corroborative evidence for the safety of suspended lutein.

In GRN 000221, Kemin describes the crystalline lutein that it uses to prepare its

suspended lutein. As such, the use of suspended lutein in food products may constitute the use of a color additive under section 201(t)(1) of the Federal Food, Drug and Cosmetic Act (FFDCA) and FDA's implementing regulations in 21 CFR Part 70. During the review of GRN 000221, FDA requested that Kemin present its view on whether the intended use of suspended lutein would be exempt from the definition of color additive. In an amendment to GRN 000221, dated September 4, 2007, Kemin presented its reasons for concluding that the intended use of suspended lutein would be exempt from the definition of color additive under section 201(t) of the FFDCA and FDA's implementing regulations in 21 CFR 70.3 (f) and (g). Importantly, if the use of suspended lutein constitutes use as a color additive within the meaning of section 201(t)(1) of the FFDCA and FDA's implementing regulations in 21 CFR 70.3(f) and (g), section 721(a) of the FFDCA requires premarket review and approval of that use by FDA.

Under section 412 of the FFDCA, a manufacturer of a new infant formula must make a submission to FDA, providing required assurances about the formula, at least 90 days before the formula is marketed. Kemin should be aware that FDA's response to Kemin's GRAS notice does not alleviate the responsibility of any infant formula manufacturer who intends to market an infant formula that contains suspended lutein to make the submission required by section 412.

Based on the information provided by Kemin, as well as other information available to FDA, the agency has no questions at this time regarding Kemin's conclusion that suspended lutein is GRAS under the intended conditions of use. The agency has not, however, made its own determination regarding the GRAS status of the subject use of suspended lutein. As always, it is the continuing responsibility of Kemin to ensure that food ingredients that the firm markets are safe, and are otherwise in compliance with all applicable legal and regulatory requirements.

In accordance with proposed 21 CFR 170.36(f), a copy of the text of this letter responding to GRN 000221, as well as a copy of the information in this notice that conforms to the information in the proposed GRAS exemption claim (proposed 21 CFR 170.36(c)(1)), is available for public review and copying on the homepage of the Office of Food Additive Safety (on the Internet at http://www.cfsan.fda.gov/~lrd/foodadd.html).

Sincerely,

Laura M. Tarantino, Ph.D.
Director

Office of Food Additive Safety
Center for Food Safety and Applied Nutrition

Food Ingredients and Packaging | Summary of all GRAS Notices

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FDA Home Page | Search FDA Site | FDA A-Z Index | Contact FDA

FDA/Center for Food Safety & Applied Nutrition
Hypertext updated by jmf/emw December 18, 2007

SAISINE Nº2003-SA-0205

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R E P U B L I Q U E F R A N Ç A I S E

Maisons-Alfort, January 23 2004

Statement

From the AFSSA (Agence française de sécurité sanitaire des aliments) related to the evaluation of the scientiphic justifications of the following claims: « Lutein helps protect the retina and lens from the oxidation » « Lutein strengthens the retina and lens protection from oxidation » « Lutein is one of the major constituents of the retina and the lens » «Lutein , constituent of the retina and the lens, helps protect the retina and the lens from oxidation » concerning food supplements containing free lutein

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Following a mail received on June 20, 2003, the French food safety agency (AFSSA) has been requested on June 17, 2003 by the Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes (DGCCRF) to evaluate the scientiphic justification of the following claims :
« Lutein helps protect the retina and lens from oxidation »
« Lutein reinforces the retina and lens protection from oxidation »
« Lutein is one of the major constituents of the retina and the lens »
«Lutein, constituent of the retina and the lens, helps protect the retina and the lens from oxidation »
concerning food supplements containing free lutein.

In its statement of December 19, 2002, the AFSSA had considered that the two following claims: « contributes to eye health" and « contributes to good ocular functioning" were not scientiphically supported by the petitioner. This statement was justified by an insufficient level of proof supporting the proposed claims as well as by the absence of any interventional study demonstrating the effects of the product consumption at the proposed dose, for the aimed population.
Based on the same technical dossier, the petitioner submits four new claims.

After consultation of the expert committee specialized in human nutrition on November 20, 2003, the AFSSA made the following statement:

Considering that lutein is a pigment belonging to the carotenoid's family, found in the retina, that it is highly concentrated in the central part of the retina called *macula* where it works as a blue light filter and probably as an antioxidant, that this hypothesis is highly reinforced by the presence into the retina of lutein metabolites coming from lutein oxidation, that, moreover, these pigments are not synthesized by the human body, that it has been shown that their dietary intake is indispensable for macular pigment constitution,
Considering that the lens is a transparent membrane located in the front part of the eye; that the lens' structure is mainly proteinic, that the cataract is a disease linked to clouding of the lens; that

this clouding results from oxidative modifications of lens structure proteins, that the main antioxidants found in the lens are: ascorbate, glutathion, tocophérols and caroténoïds; that among these last category, we can find essentially lutein and zéaxanthin; that these substances act by lysis of the denature proteins, responsible for the lens transparency diminution.

Considering the scientiphic arguments in favor of the lutein antioxidant role in the retina and the lens, that, furthermore a study has shown the existence of an inversed relation between the macular pigment density and the lens density, the claim « lutein helps protect the retina and the lens from the oxidation" is scientiphically justified.

Considering that the petitioner is demanding the following claim: "lutein strengthens the protection of the retina and the lens from the oxidation", that a so called reinforcement implies the demonstration that lutein consumption leads to the protection mechanism fortification or the reparation of the retina and lens in front of the damages due to the oxidative stress, that the study AREDS (Age Related Disease Study) showed that a supplementation in antioxidant micronutrients (vitamin C and E, β carotene and zinc) at supra-nutritional doses permitted a 25% reduction of the AMD (Age Related Macular Disease) incidence in people with a particular form of AMD with macular drusens.
Considering that results on lens density or cataract formation from studies performed with various antioxidants do not allow the confirmation of these hypothesis, that these studies conclusions mentioned in particular that "specific responsible nutrients (of the cataract action) are not determined today and the non evaluated different ways of life between those that have been taken vitamin supplements and those that have not, could give the explanation for the results (of the study) (1) and that the inverse relation between the lens and the macular pigment optical densities suggests that lutein and zeaxanthin could delay the lens aging (2), that, thus, peer-reviewed articles presented by the petitioner did not scientiphically establish the effects of lutein supplementation on the protection of lens and retina from the oxidation, at the proposed dose, for the adult target population (excluding pregnant and breast-feeding women)

Considering that in the claims: "Lutein is one of the major constituents of the retina and lens" and "lutein, major constituent of the retina and lens, contribute to protect the retina and the lens from oxidation", the word "major" can at the same time imply a quantitative superiority and the very important (even the most important") role of the lutein in the retina and the lens, that lutein's concentrations in the lens are quite low in front of those of the proteins constituting 98% of the dry mass of the lens, that, moreover, the possible superiority of the lutein antioxidant capacity compared to others substances such as ascorbate, vitamin E has not been demonstrated, consequently, the use of the word: "major" into these two claims is excessive, thus the word "major" should be delete and the claims reformulated on the following way: "lutein is one (of the) constituent(s) of the retina and the lens".

The AFSSA considers that:

- Claims:
  « Lutein strengthens the retina and lens protection from oxidation »
  « Lutein is one of the major constituents of the retina and the lens »
  « Lutein, major constituent of the retina and the lens, helps protect the retina and the lens from the oxidation »

are not scientiphically established.

- Claims:
  « Lutein helps protect the retina and lens from oxidation »
  «Lutein is one (of the) constituent(s) of the retina and the lens»

are justified

Martin Hirsch

[1] Mares-Perlman JA *et al*. Vitamin supplement use and incident cataracts in a population-based study. *Arch* Ophthalmol 2000 118 :1556-63

2 Berendschot TT *et al.* Lens aging in relation to nutritional determinants and possible risk factors for age-related cataract. *Arch Ophthalmol* 2002 ; 120 : 1732-7

Lutein from *Tagetes erecta*

Chemical and Technical Assessment (CTA)
First draft prepared by Richard Cantrill

1 Summary

Lutein from *Tagetes erecta* L. is a purified extract obtained from marigold oleoresin, which is extracted from the petals of marigold flowers with organic solvents. The final product, after saponification, contains, as a major component, lutein and a smaller proportion of zeaxanthin. Lutein (3R,3'R,6'R-βε-carotene-3,3'-diol) is a member of a group of pigments known as xanthophylls and has no provitamin A activity.

Lutein from *Tagetes erecta* L. has not previously been evaluated by JECFA although xanthophylls, of which lutein is a member, were considered at the 31st JECFA (1987). Commercial xanthophyll preparations (Tagetes extract) were again considered at the 55th JECFA and tentative specifications were published in FNP 52 Add 8 (2000) and were superseded by specifications published in FNP 52 Add 9 (2001) following the 57th JECFA (2001).

It is used as a food colouring agent and nutrient supplement (food additive) in a wide range of baked goods and baking mixes, beverages and beverage bases, breakfast cereals, chewing gum, dairy product analogs, egg products, fats and oils, frozen dairy desserts and mixes, gravies and sauces, soft and hard candy, infant and toddler foods, milk products, processed fruits and fruit juices, soups and soup mixes in levels ranging from 2 to 330 mg/kg.

Specifications for lutein were prepared at the 63rd JECFA and published in FNP 52 Add 12 (2004).

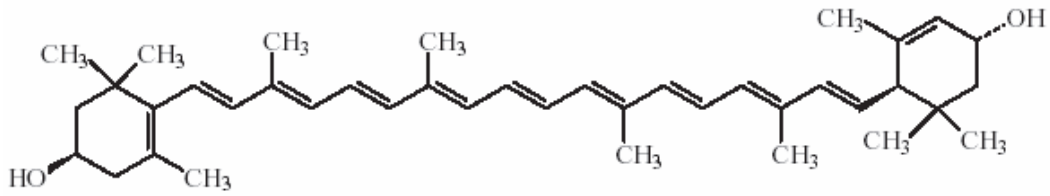
2 Description

2.1 Chemistry and nature of the product

Lutein is an oxycarotenoid, or xanthophyll, (synonyms: vegetable lutein; vegetable luteol; Bo-Xan; all-*trans*-lutein; 4',5'-didehydro-5',6'-dihydro-beta,beta-carotene-3,3'-diol) containing 2 cyclic end groups (one beta - and one alpha -ionone ring) and the basic C40 isoprenoid structure common to all carotenoids (see Figure 1). Although the polyene chain double bonds present in lutein could exist in a *cis* or *trans* conformation, giving rise to a large number of possible mono-*cis* and poly-*cis* isomers, the vast majority of carotenoids are in the all-*trans* configurations (Rice-Evans *et al.*, 1997; IOM, 2000), as depicted in Figure 1. Lutein has been assigned Chemical Abstract Service (CAS) number 127-40-2 with a chemical formula of $C_{40}H_{56}0_2$ and a molecular weight of 568.88.

Extracts of marigold flowers, fresh raw kale, corn meal, spinach, and human plasma also contain small amounts of *cis* isomers of lutein (Krinsky *et al.*, 1990; Khachik *et al.*, 1999). Lutein is commonly isolated from marigold oleoresin together with zeaxanthin.

Figure 1. Structural formula of lutein



3 Manufacturing

3.1 Manufacturing Principle

Lutein from *Tagetes erecta* L. is produced from marigold oleoresin. The marigold oleoresin is extracted from dried marigold flower petals (*Tagetes erecta* L) with hexane and contains lutein, lutein esters, other carotenoids and waxes. Purified lutein is obtained from the oleoresin by saponification and crystallisation. Other raw materials used in the manufacturing process are potassium hydroxide, methanol or propylene glycol.

3.2 Detailed Description

The Committee received details of two separate manufacturing processes. The differences in the processes are in the method of saponification and crystallization. Both approaches have been incorporated into the CTA.

The preparation of the marigold oleoresin from marigold flowers relies on the extraction of xanthophylls from the natural source material with hexane and does not include chemical synthesis. Lutein is prepared from the oleoresin by saponification and crystallization. Under saponification conditions, fatty acids and waxes are removed from lutein esters and zeaxanthin esters. This process employs mixing and heating and the reactions use potassium hydroxide, methanol or propylene glycol and water. During these processes crystals of lutein are formed. The reaction mixture from the crystallization step is then diluted with water and the resulting crystals are dried by the removal of the residual water.

4 Chemical Characterization

4.1 Composition of lutein

Lutein prepared in this manner contains more than 80% total carotenoids of which lutein is present at 70 – 78 %. Zeaxanthin (2 – 9%) and other carotenoids are also present. Waxes (14%) and fatty acids (1%), present in the unprocessed oleoresin, make up the balance of the material.

4.2 Physico-chemical properties

Lutein is a free-flowing orange-red powder. It is insoluble in water but it is soluble in hexane.

4.3 Possible Impurities (including degradation products)

Based on the information received, hexane and propylene glycol and methanol may be present at low levels following the oleoresin preparation and subsequent saponification step.

4.4 Analytical Methods

The analytical methods employed are found in FNP 5, the standards of other respected organizations, journal references and were developed in-house.

4.5 Rationale for Proposed Specifications

The specifications are based on the manufacturing process and raw materials to define the composition of the crystalline material. Furthermore, the specifications have been produced to differentiate this material from the specification for *Tagetes* extract (FNP 52 Add 9 (2001). These specifications include some of the parameters of lutein tested and identified above. The purity assay is designed to identify the levels of lutein and total carotenoids within the final product. Batches containing less than 70.0% lutein would not meet specifications. Furthermore, the extraction solvents hexane, methanol and propylene glycol are included in the specifications to ensure residual levels of these are kept to a minimum. Ash, moisture and waxes are included since they form the major non-carotenoid portion of the final crystalline lutein product. Lead is included in the specification for safety purposes, since high levels of the metal could have toxicity

implications. In addition, analytical data from several different manufacturing lots of lutein indicate that the methods of production give rise to a consistent product. The data supplied also support the proposed specifications, and suggest that the finished product produced by the manufacturing processes described is well within the product specifications.

5 Functional Use

5.1 Technological Function

Lutein is intended for use as a colouring agent and a nutrient supplement.

5.2 Food Categories and Use Levels

Lutein is used as a colouring agent in foods such as baked goods and baking mixes, beverages and beverage bases, breakfast cereals, chewing gum, dairy product analogs, egg products, fats and oils, frozen dairy desserts and mixes, gravies and sauces, hard candy, infant and toddler foods (other than infant formula), milk products, processed fruits and fruit juices, soft candy, and soups and soup mixes. The intended food uses and use levels (2.0 –330 mg/kg) are presented in Appendix 1.

6 Reactions and Fate in Foods

Stability testing performed on the lutein products in commerce indicated that they are stable at room temperature for a period of 12 months. Stability testing also was performed on lutein in various food products, including pasta sauce, cereal bars and baked, ready-to-eat cereal, which showed that they are stable at room temperature for a period of 12 months. Lutein is not anticipated to react with other components of the food matrix or with environmental constituents.

7 References

FAO (1991) Guide to Specifications. Food and Agriculture Organization of the United Nations (FAO); Rome. FAO Food and Nutrition Paper, No. 5, Rev. 2.

IOM (2000) β-carotene and other carotenoids. In: IOM. Dietary Reference Intakes for Vitamin C, Vitamin E, Selenium, and Carotenoids. Panel on Dietary Antioxidants and Related Compounds, Subcommittees on Upper Reference Levels of Nutrients and Interpretation and Uses of DRIs, Standing Committee on the Scientific Evaluation of Dietary Reference Intakes, Food and Nutrition Board, Institute of Medicine (IOM). National Academy Press (NAP); Washington, DC, pp. 325-382.

Khachik, F.; Steck, A.; Pfander, H. (1999) Isolation and structural elucidation of (13Z,13'Z,3R,3'R,6'R)-lutein from Marigold flowers, kale, and human plasma. J Agric Food Chem 47:455-481.

Krinsky, N.I.; Russett, M.D.; Handelman, G.J.; Snodderly, D.M. (1990) Structural and geometrical isomers of carotenoids in human plasma. J Nutr 120:1654-1662.

Rice-Evans, C.A.; Sampson, J.; Bramley, P.M.; Holloway, D.E. (1997) Why do we expect carotenoids to be anioxidants *in vivo*? Free Rad Res 26:381-398.

Appendix 1.

Intended Food-Uses and Use-Levels for Lutein

Food Category	GSFA Food Categorization and Food-Use[1]	Use-Levels for Lutein mg/kg[2]
Baked Goods and Baking Mixes	15.1 Cereal and Energy Bars	50
	07.1.2 Crackers and Crispbreads	67
Beverages and Beverage Bases	14.1.1.1 Bottled Water	2.1
	14.1.4.1 Carbonated Beverages	8.3
	13.4 Meal Replacements	8.3
	14.1.5 Tea, Ready-to-Drink	2.6
Breakfast Cereals	06.5 Instant and Regular Hot Cereals	8.3
	06.3 Ready-to-Eat Cereals	36 - 130
Chewing Gum	05.3 Chewing Gum	330
Dairy Product Analogs	01.3.3 Imitation Milks	8.3
	01.5.2 Soy Milks	6.3
Egg Products	10.2 Liquid, Frozen, or Dried Egg Substitutes	40
Fats and Oils	02.2.1.2 Margarine-like Spreads	100
	12.6.1 Salad Dressings	50 – 100
Frozen Dairy Desserts and Mixes	01.7 Frozen Yogurt	8.3
Gravies and Sauces	12.6.2 Tomato-Based Sauces	2.6
Hard Candy	05.2 Hard Candy	67
Infant and Toddler Foods*	13.2 Junior, Strained, and Toddler Type Baby Foods	5.9 - 140
Milk Products	01.5 Dry Milk	13
	01.2.1 Fermented Milk Beverages	2.6
	01.1.2 Flavoured Milk and Milk Drinks	13
	13.4 Milk-Based Meal Replacements	13
	01.7 Yogurt	13
Processed Fruits and Fruit Juices	14.1.4 Energy, Sport, and Isotonic Drinks	8.3
	14.1.4.2 Fruit-Flavoured Drinks	8.3
	14.1.2.1 Fruit Juice	8.3
	14.1.3 Nectars	8.3
	14.1.2.2 Vegetable Juice	8.3
Soft Candy	05.2 Chewy and Nougat Candy	25

	05.2 Fruit Snacks	25
Soups and Soup Mixes	12.5.1 Canned Soups	2.6

[1] Food categorization system for the General Standard for Food Additives

[2] When a range of use-levels (mg/kg) is reported for a proposed food-use, particular foods within that food-use may differ with respect to their serving size.

*Does not include infant formula.

Appendix B

Certificates

1. Kosher Certificate - Kemin
2. Halal Certificate – Kemin
3. Kosher Certificate – DSM
4. Halal Certificate – DSM
5. NSF GMP Certificate - Maury Site
6. NSF GMP Certificate - E. 17 St. Site
7. State of Iowa Processing Plant License - Maury Site
8. State of Iowa Processing Plant License - E. 17 St. Site
9. DSM’s ISO 9001:2008 Certificate

בס״ד

Orthodox Union
Letter of Certification

Union of Orthodox Jewish Congregations of America
איחוד קהילות האורתודוקסים באמריקה

August 10, 2011

This is to certify that the following product(s) prepared by

Kemin Health L.C., 600 E. Court Avenue SUITE A, Des Moines, IA 50309

at the following facilitie(s) are under the supervision of the Kashruth Division of the Orthodox Union and are kosher as indicated below.

Kemin Health L.C. #1, Des Moines, IA
Kemin Health L.C. #2, Des Moines, IA

Product Name	UKD-ID	Status	Certification Requirements
Brand: AssuriTEA (TM)			
• AssuriTEA Green	OUV3-D88C349	Pareve	Ⓤ Symbol required.
• Wellbeing	OUV3-4C9FBEB	Pareve	Ⓤ Symbol required.
Brand: Cr-Pro (TM)			
• 4% Chromium Propionate	OUV3-AA86E7F	Pareve	Ⓤ Symbol required.
Brand: Kemin			
• Flora GLO Crystalline Lutein	OUV3-7324232	Pareve	Ⓤ Symbol required.
• Flora GLO Lutein 5% VG Granules	OUV3-B23EFCA	Pareve	Ⓤ Symbol required.
• FloraGLO Lutein 10% VG TabGrade	OUV3-8116F94	Pareve	Ⓤ Symbol required.
• FloraGlo Lutein 20% Liquid in Corn Oil	OUV3-D449FC8	Pareve	Ⓤ Symbol required.
• FloraGlo Lutein 20% Liquid in Safflower Oil	OUV3-D98AE0C	Pareve	Ⓤ Symbol required.

Placing the OU logo on products not listed above constitutes an unauthorized use of the OU symbol, which is a federally registered trademark.

Menachem Genack

This certification is valid through 08/31/2012

Rabbi Menachem Genack, *Rabbinic Administrator, CEO*

Eleven Broadway - New York, NY 10004 - (212) 613-8382 - Fax: (212) 613-0654 - Email: KosherLetter@ou.org - www.oukosher.org

בס״ד

Orthodox Union
Letter of Certification

Union of Orthodox Jewish Congregations of America
איחוד קהילות האורתודוקסים באמריקה

August 10, 2011

Kemin Health L.C. (continued)

This is to certify that the following product(s) prepared by this company at the facilitie(s) listed above are under the supervision of the Kashruth Division of the Orthodox Union and are kosher as indicated below.

Product Name	UKD-ID	Status	Certification Requirements
Brand: Kemin (continued)			
• FloraGlo Lutein 5% Liquid in Corn Oil	OUV3-BF17244	Pareve	Ⓤ Symbol required.
• Lutein Dry Cake Base	OUV3-0A85F0D	Pareve	Ⓤ Symbol required.
• Lutein Wet Cake	OUV3-D6473AB	Pareve	Ⓤ Symbol required.
Brand: Slendesta			
• Slendesta (R) Potato Extract 10% Powder	OUV3-C59FC2F	Pareve	Ⓤ Symbol required.
• Slendesta (R) Potato Extract 5% Powder	OUV3-3C2EF28	Pareve	Ⓤ Symbol required.
• Slendesta (R) SG Potato Extract 5% Powder	OUV3-66C1417	Pareve	Ⓤ Symbol required.
• Slendesta (R) WD Potato Extract 5% Powder	OUV3-B06850C	Pareve	Ⓤ Symbol required.
• Slendesta Clear Potato Extract 5% Powder	OUV3-FBCF176	Pareve	Ⓤ Symbol required.
Brand: Welcose(TM)			
• Welcose(TM) Glucose Support Formula	OUV3-FCFC13D	Pareve	Ⓤ Symbol required.

Placing the OU logo on products not listed above constitutes an unauthorized use of the OU symbol, which is a federally registered trademark.

Menachem Genack

Rabbi Menachem Genack, *Rabbinic Administrator, CEO*

This certification is valid through 08/31/2012

Eleven Broadway - New York, NY 10004 - (212) 613-8382 - Fax: (212) 613-0654 - Email: KosherLetter@ou.org - www.oukosher.org

THE ISLAMIC FOOD AND NUTRITION COUNCIL OF AMERICA
المجلس الأسلامي الأمريكي للغذاء و التغذية

IFANCA HALAL PRODUCT CERTIFICATE

Certificate No.: **KEM. M. 110016. US**

July 5, 2011

KEMIN HEALTH L.C.
600 E. Court Avenue Suite A
Des Moines, Iowa 50309 USA

To Whom It May Concern:

This is to certify that **KEMIN HEALTH L.C., Des Moines, Iowa,** produces **Halal** products under the supervision of the Islamic Food and Nutrition Council of America (IFANCA), at the following location(s):

- KH Maury Facility, Des Moines, IA 50301-0070 USA
- KH E. 17th Facility, Des Moines, IA 50316 USA

The following products are **Halal**, when bearing the **Crescent M Halal** logo:

- **AssuriTEA™ Green**
- **AssuriTEA™ Wellbeing**
- **CR Pro™ 4% Chromium Propionate (Cr-Pro)**
- **Lutein Wet Cake Base**
- **Lutein Dry Cake Base**
- **FloraGLO® Crystalline Lutein**
- **FloraGLO® Lutein 20% Liquid in Safflower Oil**
- **FloraGLO® Lutein 20% Liquid in Corn Oil**
- **FloraGLO® Lutein 5% Liquid in Corn Oil**
- **FloraGLO® Lutein 5% VG Granules**
- **FloraGLO® Lutein 10% VG TabGrade**
- **Slendesta® Potato Extract 5% Powder**
- **Slendesta® SG Potato Extract 5% Powder**
- **Slendesta® WD Potato Extract 5% Powder**
- **Slendesta® Potato Extract 10% Powder**
- **Slendesta® Clear Potato Extract 5% Powder**
- **Welcose™ Glucose Support Formula**

This certificate is valid until **April 30, 2012**, and subject to renewal at that time.

Muhammad Munir Chaudry, Ph.D.
Halal Administrator

THE ISLAMIC FOOD AND NUTRITION COUNCIL OF AMERICA INCORPORATED ILLINOIS 1982

בס״ד

Orthodox Union
Letter of Certification

Union of Orthodox Jewish Congregations of America
איחוד קהילות האורתודוקסים באמריקה

March 01, 2011

This is to certify that the following product(s) prepared by

DSM Nutritional Products, & Its Affiliates (3341), 260 Macks Island Drive, Belvidere, NJ 07823-1113

are under the supervision of the Kashruth Division of the Orthodox Union and are kosher as indicated below.

Product Name	UKD-ID	Status	Certification Requirements
Brand: DSM Nutritional Products			
• 04-08050 Ascorbic Acid	OUV3-3A9EE35	Pareve	Ⓤ Symbol required.
• 04-08107 Ascorbic Acid Ultra Fine Powder	OUV3-50CB6BE	Pareve	Ⓤ Symbol required.
• 04-08174 Sodium Ascorbate (Crystalline)	OUV3-2B93522	Pareve	Ⓤ Symbol required.
• 04-10136 Vitamin B12 0.1% Type SD	OUV3-132CDC3	Pareve	Ⓤ Symbol required.
• 04-10276 dl-a-Tocopherol (Vitamin E)	OUW3-98EC3B4	Pareve	Ⓤ Symbol required. Certified for Passover and year-round use.
• 04-11604 Pyridoxine Hydrochloride	OUV3-A600C30	Pareve	Ⓤ Symbol required.
• 04-12678 Calcium D-Pantothenate	OUV3-F4CE786	Pareve	Ⓤ Symbol required.
• 04-13038 Thiamine Hydrochloride	OUW3-222B0D5	Pareve	Ⓤ Symbol required. Certified for Passover and year-round use.
• 04-13852 D-Panthenol	OUV3-BDC2A0D	Pareve	Ⓤ Symbol required.
• 04-16118 D-Panthenol 75 L	OUV3-1D87984	Pareve	Ⓤ Symbol required.
• 04-17203 Aldehyde C-14	OUV3-91695F5	Pareve	Ⓤ Symbol required.

Placing the OU logo on products not listed above constitutes an unauthorized use of the OU symbol, which is a federally registered trademark.

Menachem Genack

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Rabbi Menachem Genack, *Rabbinic Administrator, CEO*

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March 01, 2011

DSM Nutritional Products, & Its Affiliates (3341) (continued)

This is to certify that the following product(s) prepared by this company are under the supervision of the Kashruth Division of the Orthodox Union and are kosher as indicated below.

Product Name	UKD-ID	Status	Certification Requirements
Brand: DSM Nutritional Products (continued)			
• 04-17459 D-Biotin	OUV3-28ABF2C	Pareve	Ⓤ Symbol required.
• 04-17823 Folic Acid	OUV3-A8C5CB7	Pareve	Ⓤ Symbol required.
• 04-18129 Dry Vitamin D3 Type 100 CWS/A	OUV3-40C08B2	Pareve	Ⓤ Symbol required.
• 04-18579 Vitamin A Palmitate 1.7 MIU/g (Tocopherol)	OUW3-566CC58	Pareve	Ⓤ Symbol required. Certified for Passover and year-round use.
• 04-18595 Ascorbyl Palmitate	OUV3-4C7E993	Pareve	Ⓤ Symbol required.
• 04-18846 Vitamin A Acetate 1.5 MIU/g	OUV3-4793950	Pareve	Ⓤ Symbol required.
• 04-18943 Thiamine Mononitrate	OUW3-933957A	Pareve	Ⓤ Symbol required. Certified for Passover and year-round use.
• 04-19125 Vitamin D3 Cryst.	OUW3-44EB158	Pareve	Ⓤ Symbol required. Certified for Passover and year-round use.
• 04-19133 Vitamin D3 1.0 MIU/g	OUV3-E9E8D57	Pareve	Ⓤ Symbol required.

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DSM Nutritional Products, & Its Affiliates (3341) (continued)

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Product Name	UKD-ID	Status	Certification Requirements
Brand: DSM Nutritional Products (continued)			
• 04-19435 ROPUFA® '25' N-6 Oil	OUV2-11E1E9F	Pareve	Symbol not required. Letter Required
• 04-19443 Calcium Ascorbate	OUV3-9C18D85	Pareve	Ⓤ Symbol required.
• 04-20085 dl-a-Tocopheryl Acetate	OUW3-018F822	Pareve	Ⓤ Symbol required. Certified for Passover and year-round use.
• 04-20085 dl-a-Tocopheryl Acetate	OUW4-54AD4CD	Pareve	Certified when bulk shipped in OU approved carriers. Certified for Passover and year-round use.
• 04-20603 Vitamin A Palmitate 1.0 MIU/g (BHA/BHT)	OUV3-A7A617D	Pareve	Ⓤ Symbol required.
• 04-21049 Ronotec 201	OUV3-452F851	Pareve	Ⓤ Symbol required.
• 04-21413 Riboflavin 5'-Phosphate Sodium	OUV3-249AF9B	Pareve	Ⓤ Symbol required.
• 04-21871 Dry Vitamin A Palmitate 250 CWS/F	OUV3-8C4EF3B	Pareve	Ⓤ Symbol required.
• 04-22460 Ascorbic Acid Fine Powder	OUV3-15E0CE0	Pareve	Ⓤ Symbol required.

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DSM Nutritional Products, & Its Affiliates (3341) (continued)

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Product Name	UKD-ID	Status	Certification Requirements
Brand: DSM Nutritional Products (continued)			
• 04-24005 Vitamin A Palmitate 1.7 m.I.U./g	OUW3-0EA6B2A	Pareve	Ⓤ Symbol required. Certified for Passover and year-round use.
• 04-24013 Vitamin A Palmitate 1.7 MIU/g (BHA/BHT)	OUW3-2B89506	Pareve	Ⓤ Symbol required. Certified for Passover and year-round use.
• 04-25117 Coated Ascorbic Acid, Type EC	OUV3-1E5A51F	Pareve	Ⓤ Symbol required.
• 04-25621 Tocopherol-Acetate Techn. Offen	OUV3-4EB0857	Pareve	Ⓤ Symbol required.
• 04-27233 Beta Carotene 30% FS	OUV3-0D09334	Pareve	Ⓤ Symbol required.
• 04-29090 Vitamin B12 0.1% WS Offen	OUV3-712C353	Pareve	Ⓤ Symbol required.
• 04-29139 Vit B12 1% Trituration With Mannitol	OUV3-8B81868	Pareve	Ⓤ Symbol required.
• 04-29155 Vitamin B12 Crystalline	OUV3-0C7DB3E	Pareve	Ⓤ Symbol required.
• 04-29449 ROCOAT® Niacinamide 33 1/3%	OUV3-8C07716	Pareve	Ⓤ Symbol required.
• 04-29457 ROCOAT® Pyridoxine 33 1/3%	OUV3-3AB1D95	Pareve	Ⓤ Symbol required.
• 04-29465 ROCOAT® Riboflavin 33 1/3%	OUV3-CDC2503	Pareve	Ⓤ Symbol required.

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DSM Nutritional Products, & Its Affiliates (3341) (continued)

This is to certify that the following product(s) prepared by this company are under the supervision of the Kashruth Division of the Orthodox Union and are kosher as indicated below.

Product Name	UKD-ID	Status	Certification Requirements
Brand: DSM Nutritional Products (continued)			
• 04-29473 ROCOAT® Thiamine Mononitrate 33 1/3%	OUV3-707ECB7	Pareve	Ⓤ Symbol required.
• 04-29716 Dry Vitamin A Acetate, Type 250 CWS/A	OUV3-0677D91	Pareve	Ⓤ Symbol required.
• 04-31400 Vitamin A Palmitate 1.0 MIU/g (Tocopherol)	OUV3-01B1BB1	Pareve	Ⓤ Symbol required.
• 04-32210 Ascorbic Acid Coated Type SC	OUV3-33239CB	Pareve	Ⓤ Symbol required.
• 04-34523 B-Carotene 1% CWS	OUV3-C665557	Pareve	Ⓤ Symbol required.
• 04-34825 Beta Carotene 10% CWS	OUV3-A5ABC7B	Pareve	Ⓤ Symbol required.
• 04-34833 B-Carotene 10% B	OUV3-5712285	Pareve	Ⓤ Symbol required.
• 04-34922 Vitamin K1 5% SD	OUV3-C1CCF64	Pareve	Ⓤ Symbol required.
• 04-35015 Vitamin K1 Phytonadione	OUV3-FF2203A	Pareve	Ⓤ Symbol required.
• 04-37239 Dry Vit E 50% Type CWS/F	OUV3-C262686	Pareve	Ⓤ Symbol required.
• 04-40809 Ascorbic Acid Coated Type FC	OUV3-ED37983	Pareve	Ⓤ Symbol required.
• 04-42321 Ascorbic Acid 95% Granulation	OUV3-765382E	Pareve	Ⓤ Symbol required.
• 04-42534 Ronoxan A	OUV3-FCFC9C9	Pareve	Ⓤ Symbol required.

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DSM Nutritional Products, & Its Affiliates (3341) (continued)

This is to certify that the following product(s) prepared by this company are under the supervision of the Kashruth Division of the Orthodox Union and are kosher as indicated below.

Product Name	UKD-ID	Status	Certification Requirements
Brand: DSM Nutritional Products (continued)			
• 04-42623 Vitamin A Palmitate 1.0 MIU/g and Vitamin D3 100'000 IU/g (Tocopherol)	OUV3-A311440	Pareve	Ⓤ Symbol required.
• 04-43174 Ascorbic Acid 90%	OUD3-4807BA9	Dairy	Ⓤ-D Symbol required.
• 04-65046 Dry Vitamin D3 TYPE 100-SD	OUD3-DA9516F	Dairy	Ⓤ-D Symbol required.
• 04-66042 B-Carotene 22% HSS	OUV3-A6AB02B	Pareve	Ⓤ Symbol required.
• 04-66921 Niacinamide Free Flowing	OUV3-7B3898B	Pareve	Ⓤ Symbol required.
• 04-67650 Vit B12 1% SD	OUV3-0669C77	Pareve	Ⓤ Symbol required.
• 04-67707 Romax (Niacinamide Ascorbate)	OUV3-F7E82DC	Pareve	Ⓤ Symbol required.
• 04-68363 Folic Acid 10% Trituration	OUV3-2B17A66	Pareve	Ⓤ Symbol required.
• 04-70295 Riboflavin TG	OUV3-FF37E59	Pareve	Ⓤ Symbol required.
• 04-70309 Ascorbic Acid	OUV3-F569D94	Pareve	Ⓤ Symbol required.
• 04-70406 Riboflavin Universal	OUV3-94BA9C0	Pareve	Ⓤ Symbol required.
• 04-80487 Beta Carotene USP	OUV3-3C6695D	Pareve	Ⓤ Symbol required.
• 04-80541 Carotenal Solution #73	OUV3-589DE95	Pareve	Ⓤ Symbol required.

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DSM Nutritional Products, & Its Affiliates (3341) (continued)

This is to certify that the following product(s) prepared by this company are under the supervision of the Kashruth Division of the Orthodox Union and are kosher as indicated below.

Product Name	UKD-ID	Status	Certification Requirements
Brand: DSM Nutritional Products (continued)			
• 04-80703 Bitrit-1	OUV3-40C0C02	Pareve	Ⓤ Symbol required.
• 04-80932 Apocarotenal 20% S	OUV3-5DEC130	Pareve	Ⓤ Symbol required.
• 04-81041 redivivo (Lycopene) 10% WS	OUV3-2E2E45F	Pareve	Ⓤ Symbol required.
• 04-82277 Carotenal Solution #2	OUV3-34A7220	Pareve	Ⓤ Symbol required.
• 04-82285 B-Carotene 7% CWS	OUV3-B8904B4	Pareve	Ⓤ Symbol required.
• 04-83125 Vitamin B12 0.1% WS N	OUV3-6732C76	Pareve	Ⓤ Symbol required.
• 04-83567 Vitamin E 75% HP	OUV3-C10554A	Pareve	Ⓤ Symbol required.
• 04-86221 Liquid Vitamin D3 (in corn oil)	OUV3-EF62225	Pareve	Ⓤ Symbol required.
• 04-86574 d-a-Tocopheryl Acetate	OUV3-2764684	Pareve	Ⓤ Symbol required.
• 04-86582 Mixed Tocopherols	OUV3-867E971	Pareve	Ⓤ Symbol required.
• 04-86884 Dry Vitamin E Acetate 950 NS	OUV3-4844B62	Pareve	Ⓤ Symbol required.
• 0486922911 Blend 638922501 Global Code	OUV3-310B4DB	Pareve	Ⓤ Symbol required.
• 04-87147 Niacinamide Fine Granular	OUV3-770FC64	Pareve	Ⓤ Symbol required.

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DSM Nutritional Products, & Its Affiliates (3341) (continued)

This is to certify that the following product(s) prepared by this company are under the supervision of the Kashruth Division of the Orthodox Union and are kosher as indicated below.

Product Name	UKD-ID	Status	Certification Requirements
Brand: DSM Nutritional Products (continued)			
• 04-87236 Niacin	OUV3-4693A1F	Pareve	Ⓤ Symbol required.
• 04-87244 Niacin Fine Granular	OUV3-5681CF9	Pareve	Ⓤ Symbol required.
• 04-87325 Folic Acid 10% Trit	OUV3-D36072E	Pareve	Ⓤ Symbol required.
• 04-87848 Niacinamide	OUV3-CF96B22	Pareve	Ⓤ Symbol required.
• 04-88917 Ascorbic Acid	OUV3-1E549AE	Pareve	Ⓤ Symbol required.
• 04-89999 Beta Carotene 10% CWS/S	OUV3-C632871	Pareve	Ⓤ Symbol required.
• 50-00149 Dry Mixed Tocopherols 30%	OUV3-4F92D1B	Pareve	Ⓤ Symbol required.
• 50-00203 redivivo (lycopene) 10% FS	OUV3-0A1760E	Pareve	Ⓤ Symbol required.
• 50-00238 Beta-Carotene 30% FS/SF	OUV3-2B9729A	Pareve	Ⓤ Symbol required.
• 50-00343 Lutein 5% CWS	OUV3-8F592FD	Pareve	Ⓤ Symbol required.
• 50-00718 Dry Vitamin A Palmitate 250 S/N	OUV3-92D4921	Pareve	Ⓤ Symbol required.
• 50-00742 Lutein 20% FS	OUV3-E6D6490	Pareve	Ⓤ Symbol required.
• 50-01129 Dry Vitamin E 50% CWS/S	OUV3-52991C5	Pareve	Ⓤ Symbol required.

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DSM Nutritional Products, & Its Affiliates (3341) (continued)

This is to certify that the following product(s) prepared by this company are under the supervision of the Kashruth Division of the Orthodox Union and are kosher as indicated below.

Product Name	UKD-ID	Status	Certification Requirements
Brand: DSM Nutritional Products (continued)			
• 50-01285 Dry Vitamin E 15% CC	OUV3-1FF9FA1	Pareve	Ⓤ Symbol required.
• 50-01420 Sodium Ascorbate 99% TG	OUV3-CC5FC43	Pareve	Ⓤ Symbol required.
• 50-02001 OPTISHARP (Zeaxanthin) 20% FS	OUV3-18A4969	Pareve	Ⓤ Symbol required.
• 50-02141 Niacinamide Free Flowing	OUV3-ECB8BBF	Pareve	Ⓤ Symbol required.
• 50-02427 Beta Carotene 10% EM Yellow	OUV3-EF0C1AB	Pareve	Ⓤ Symbol required.
• 50-02850 TEAVIGO	OUV3-C32B9E9	Pareve	Ⓤ Symbol required.
• 50-02869 TEAVIGO TG	OUV2-0C6C980	Pareve	Symbol not required. Letter Required
• 50-02893 Mixed Tocopherols 95%	OUV3-F1BE443	Pareve	Ⓤ Symbol required.
• 50-03024 Beta Carotene 10% EM Red	OUV3-CCB98E4	Pareve	Ⓤ Symbol required.
• 50-03520 Dry Vitamin A Acetate 325 CWS/S	OUV3-E7DA99B	Pareve	Ⓤ Symbol required.
• 50-03563 OPTISHARP (Zeaxanthin) 5% CWS/S-TG	OUV3-591B700	Pareve	Ⓤ Symbol required.
• 50-03636 B-Carotene 3% CWS/M	OUV3-95BE2F8	Pareve	Ⓤ Symbol required.

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DSM Nutritional Products, & Its Affiliates (3341) (continued)

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Product Name	UKD-ID	Status	Certification Requirements
Brand: DSM Nutritional Products (continued)			
• 50-03652 Dry Vitamin D3 100 CWS/AM	OUV3-F3357D5	Pareve	Ⓤ Symbol required.
• 50-03741 B-Carotene 1% CWS/M	OUV3-7B7A2AB	Pareve	Ⓤ Symbol required.
• 50-03768 Sodium Ascorbate Technical Grade	OUV3-9D0CDF2	Pareve	Ⓤ Symbol required.
• 50-03792 redivivo (lycopene) 10% CWS/S-TG	OUV3-F20501F	Pareve	Ⓤ Symbol required.
• 50-03814 Vitamin A Palmitate 250 S/N-B	OUV3-12E33A0	Pareve	Ⓤ Symbol required.
• 50-04004 Betatab 20% S	OUV3-531241D	Pareve	Ⓤ Symbol required.
• 50-04144 Dry dl-a-Tocopherol 30%	OUV3-73B07EF	Pareve	Ⓤ Symbol required.
• 50-04160 ALL-Q (Coenzyme Q10) 10% CWS/S	OUV3-A753523	Pareve	Ⓤ Symbol required.
• 50-04357 Folic Acid Food Grade	OUV3-2A41779	Pareve	Ⓤ Symbol required.
• 50-04675 CaroCare Nat. B-Carotene 30% S	OUV3-FE7870F	Pareve	Ⓤ Symbol required.
• 50-04683 CaroCare Natural Beta Carotene Crystalline	OUV3-BED9A89	Pareve	Ⓤ Symbol required.
• 50-05043 Dry Vitamin D3 100 SD/S	OUV3-AC9B19B	Pareve	Ⓤ Symbol required.
• 50-05213 Lutein 5% CWS/S-TG	OUV3-AF174AD	Pareve	Ⓤ Symbol required.

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Orthodox Union
Letter of Certification

Union of Orthodox Jewish Congregations of America
איחוד קהילות האורתודוקסים באמריקה

March 01, 2011

DSM Nutritional Products, & Its Affiliates (3341) (continued)

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Product Name	UKD-ID	Status	Certification Requirements
Brand: DSM Nutritional Products (continued)			
• 50-05221 B-Carotene 10% CWS Star	OUV3-BA45554	Pareve	Ⓤ Symbol required.
• 50-05256 Canthaxanthin 10% CWS/S	OUV3-1FF5E9E	Pareve	Ⓤ Symbol required.
• 50-06066 Niacinamide PC	OUV3-5E33175	Pareve	Ⓤ Symbol required.
• 50-06201 Sodium Ascorbate 250	OUV3-5F4C1F7	Pareve	Ⓤ Symbol required.
• 50-06244 Bitrit 1 - Type A	OUV3-2F09489	Pareve	Ⓤ Symbol required.
• 50-06317 Apocarotenal 1% CWS/M	OUV3-F1F1BC3	Pareve	Ⓤ Symbol required.
• 50-06376 Ascorbic Acid 97% Granular	OUV3-3B863CF	Pareve	Ⓤ Symbol required.
• 50-06384 Coenzyme Q10 RODI	OUV3-A118E79	Pareve	Ⓤ Symbol required.
• 50-06600 CaroCare Nat. BC 20% V	OUV3-E57CCB4	Pareve	Ⓤ Symbol required.
• 50-06805 Genistein S Pure	OUV3-459A965	Pareve	Ⓤ Symbol required.
• 50-07143 PEPTOPRO	OUD3-3E25A07	Dairy	Ⓤ-D Symbol required.
• 50-07550 Sodium Ascorbate	OUV3-2BBB7EF	Pareve	Ⓤ Symbol required.
• 50-07569 Calcium Ascorbate	OUV3-173B14B	Pareve	Ⓤ Symbol required.

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DSM Nutritional Products, & Its Affiliates (3341) (continued)

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Product Name	UKD-ID	Status	Certification Requirements
Brand: DSM Nutritional Products (continued)			
• 50-07577 Ascorbic Acid 90% Granulation	OUD3-7BC499F	Dairy	Ⓤ-D Symbol required.
• 50-07747 Ascorbic Acid 95% Granulation	OUV3-0EEEFF7	Pareve	Ⓤ Symbol required.
• 50-07771 B-Carotene N-Crystalline	OUV3-771E19C	Pareve	Ⓤ Symbol required.
• 50-08247 Food Powder - Type C/OU	OUV2-B4EEA86	Pareve Fish	Symbol not required. Letter Required
• 50-08271 Resveratol-Resvida	OUV3-1937679	Pareve	Ⓤ Symbol required.
• 50-08409 B-CAROTENE 15% LCS, OFFEN	OUV3-8275AE2	Pareve	Ⓤ Symbol required.
• 50-08611 B2 Universal Fine Powder	OUV2-A188BDE	Pareve	Symbol not required. Letter Required
• 50-08646 Dry Vitamin A Palmitate 250 S/N	OUV3-6EB7FE9	Pareve	Ⓤ Symbol required.
• 50-08735 B-Carotene 30% FS	OUV3-654CD21	Pareve	Ⓤ Symbol required.
• 50-08999 Dry Vitamin E 50% CWS/S	OUV3-AC635A3	Pareve	Ⓤ Symbol required.
• 50-09219 Apocarotenal 10% CWS/S	OUV3-F72731A	Pareve	Ⓤ Symbol required.

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DSM Nutritional Products, & Its Affiliates (3341) (continued)

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Product Name	UKD-ID	Status	Certification Requirements
Brand: DSM Nutritional Products (continued)			
• 50-09227 TEAVIGO	OUV3-EFBD0CB	Pareve	Ⓤ Symbol required.
• 50-09278 Vitamine D3 Pure Crist	OUW3-7CB1C23	Pareve	Ⓤ Symbol required. Certified for Passover and year-round use.
• 50-09421 Dry Vitamin A Acetate 325 CWS/F	OUV3-B2594D9	Pareve	Ⓤ Symbol required.
• 50-09456 FloraGLO Lutein 10% VG TabGrade	OUV3-2C98161	Pareve	Ⓤ Symbol required.
• 50-09464 Flora GLO Lutein 5% VG Granules	OUV3-2942AD8	Pareve	Ⓤ Symbol required.
• 50-09472 FloraGlo Lutein 20% Liquid in Safflower Oil	OUV3-B314AF9	Pareve	Ⓤ Symbol required.
• 50-09510 Riboflavin B2 ROCOAT® Fine Powder	OUV2-370612D	Pareve	Symbol not required. Letter Required
• 50-09553 INSUVITAL	OUD3-C9ED20D	Dairy	Ⓤ-D Symbol required.
• 50-09723 FloraGlo Lutein 5% Liquid in Corn Oil	OUV3-B28A925	Pareve	Ⓤ Symbol required.
• 50-09731 FloraGlo Lutein 20% Liquid in Corn Oil	OUV3-9C86484	Pareve	Ⓤ Symbol required.
• 50-09766 Ascorbic Acid Ultrafine Powder	OUV3-D8438F9	Pareve	Ⓤ Symbol required.

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DSM Nutritional Products, & Its Affiliates (3341) (continued)

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Product Name	UKD-ID	Status	Certification Requirements
Brand: DSM Nutritional Products (continued)			
• 50-09855 Dry Vitamin D3 100 CWS/AM	OUV3-E899E50	Pareve	Ⓤ Symbol required.
• 50-09863 Dry Vitamin A Palmitate Type 250 CWS/F	OUV3-8DB33F8	Pareve Fish	Ⓤ-Fish Symbol required.
• 50-09871 Dry Vitamin E Acetate 700 CWS/S NS	OUV3-34F16D6	Pareve	Ⓤ Symbol required.
• 50-09901 Dry Vitamin D3 100 INF	OUV3-63CDDD4	Pareve	Ⓤ Symbol required.
• 50-10152 B-Carotene 10% CWS	OUV3-6775FE1	Pareve	Ⓤ Symbol required.
• 50-10187 Dry Vitamin E Acetate 500 NS	OUV3-B9ADBA5	Pareve	Ⓤ Symbol required.
• 50-10322 Ascorbic Acid 97% Granular	OUV3-1DD1584	Pareve	Ⓤ Symbol required.
• 50-10330 Dry Vitamin A Acetate 325 CWS/A	OUV3-4146173	Pareve	Ⓤ Symbol required.
• 50-10446 Dry Vitamin A Palmitate 50	OUV3-C27CE6C	Pareve	Ⓤ Symbol required.
• 50-10462 ROPUFA® '15' N-3 Emulsion MultiVit K	OUD2-79D710E	Dairy Fish	Symbol not required. Letter Required
• 50-10675 Bonistein	OUV3-12BF9FC	Pareve	Ⓤ Symbol required.

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DSM Nutritional Products, & Its Affiliates (3341) (continued)

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Product Name	UKD-ID	Status	Certification Requirements
Brand: DSM Nutritional Products (continued)			
• 50-10756 ROPUFA® '30' N-3 EPA Oil K	OUV2-8A29037	Pareve Fish	Symbol not required. Letter Required
• 50-10764 ROPUFA® '30' N-3 EPA Oil K	OUV2-5BA9690	Pareve Fish	Symbol not required. Letter Required
• 50-10810 Niacinamide USP Powder *04-09634 was the former product code.*	OUW3-64B12C5	Pareve	Ⓤ Symbol required. Certified for Passover and year-round use.
• 50-10837 Niacin	OUV3-17B5984	Pareve	Ⓤ Symbol required.
• 50-10888 ROPUFA® '15' N-3 Emulsion K	OUD2-CA0220C	Dairy Fish	Symbol not required. Letter Required
• 50-10934 CaroCare Nat. BC 10% CWS Star	OUV3-22FDD64	Pareve	Ⓤ Symbol required.
• 50-10950 Dry Vitamin D3 100 SD/S, Offen	OUV3-70BB050	Pareve	Ⓤ Symbol required.

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DSM Nutritional Products, & Its Affiliates (3341) (continued)

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Product Name	UKD-ID	Status	Certification Requirements
Brand: DSM Nutritional Products (continued)			
• 50-10977 ROPUFA® '15' N-3 Emulsion LV K	OUD2-BEC0292	Dairy Fish	Symbol not required. Letter Required
• 50-11108 resVida TM	OUV3-28CF889	Pareve	Ⓤ Symbol required.
• 50-11140 B-Carotene 1% CWS/M INF, Offen	OUV3-9751D9F	Pareve	Ⓤ Symbol required.
• 50-11205 Dry Vitamin K1 5% SD INF, Offen	OUV3-6D8B970	Pareve	Ⓤ Symbol required.
• 50-11213 Dry Vitamin E 50% CWS/S INF, Offen	OUV3-E06C146	Pareve	Ⓤ Symbol required.
• 50-11256 B-Carotene 5% EM K	OUV2-55C59E7	Pareve	Symbol not required. Letter Required
• 50-11331 Dry Vitamin A Acetate 325 SD INF, Offen	OUV3-400F761	Pareve	Ⓤ Symbol required.
• 50-11477 Dry Vitamin D3 100 CWS/AM	OUV3-DAD23E3	Pareve	Ⓤ Symbol required.
• 50-11507 Dry Vitamin D3 100 CWS/AM BULK	OUV3-857605E	Pareve	Ⓤ Symbol required.
• 50-11523 Ascorbic Acid 95% Granulation	OUV3-1D0E19D	Pareve	Ⓤ Symbol required.
• 50-11531 Ascorbic Acid 90% Granulation	OUD3-37E0AA7	Dairy	Ⓤ-D Symbol required.

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Product Name	UKD-ID	Status	Certification Requirements
Brand: DSM Nutritional Products (continued)			
• 50-11558 Vitamin A Palmitate 1.0 MIU/g and Vitamin D3 100'000 IU/g (Tocopherol)	OUV3-121A9AF	Pareve	Ⓤ Symbol required.
• 50-11574 Vitamin D3 1.0 MIU/g	OUV3-130EB25	Pareve	Ⓤ Symbol required.
• 50-11590 geniVida™ TG	OUV2-C61769A	Pareve	Symbol not required. Letter Required
• 50-11604 geniVida	OUV3-CEAC66E	Pareve	Ⓤ Symbol required.
• 50-11647 resVidalTG	OUV2-FCFB081	Pareve	Symbol not required. Letter Required
• 50-11655 D-Biotine	OUV3-4A36E9C	Pareve	Ⓤ Symbol required.
• 50-11868 Floraglo Lutein 10%CWS/S-TG	OUV3-06A3459	Pareve	Ⓤ Symbol required.
• 50-11876 FloraGLO® Lutein 20% SAF	OUV3-D3A7D73	Pareve	Ⓤ Symbol required.
• 50-11892 Dry Vitamin E 700 NS, Offen	OUV3-C4ADEE4	Pareve	Ⓤ Symbol required.
• 50-11906 resVida TM	OUV3-E013603	Pareve	Ⓤ Symbol required.

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Product Name	UKD-ID	Status	Certification Requirements
Brand: DSM Nutritional Products (continued)			
• 50-11914 ROPUFA® '10' N-3 EPA Powder S/SD K	OUV2-1BCAAAE	Pareve Fish	Symbol not required. Letter Required
• 50-11922 ROPUFA® '30' N-3 INF Oil K	OUV2-1D41116	Pareve Fish	Symbol not required. Letter Required
• 50-11930 ROPUFA® '10' N-3 INF S-SD K	OUV2-D01E9E0	Pareve	Symbol not required. Letter Required
• 50-12066 FLORAGLO LUTEIN 5% CWS/S-TG, BULK	OUV3-D729D15	Pareve	Ⓤ Symbol required.
• 50-12120 CaroCare® Nat BC 1% CWS-M	OUV3-498FC8E	Pareve	Ⓤ Symbol required.
• 50-12295 Vitamin D3 techn. approx. 10 MIU/g R	OUV3-8BB1D80	Pareve	Ⓤ Symbol required.
• 50-12368 PLACEBO '10' N-3/6 DHA/ARA POWDER, BULK	OUV3-97A4425	Pareve	Ⓤ-Fish Symbol required.
• 50-12511 Vitamin B12 1% SD, BULK	OUV3-FC6A8AD	Pareve	Ⓤ Symbol required.
• 50-12538 B-CAROTENE 10% EMULSION RED	OUV3-71D10F4	Pareve	Ⓤ Symbol required.

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DSM Nutritional Products, & Its Affiliates (3341) (continued)

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Product Name	UKD-ID	Status	Certification Requirements
Brand: DSM Nutritional Products (continued)			
• 50-12597 DRY VITAMIN E 50% CWS/S	OUV2-4070AA7	Pareve	Symbol not required. Letter Required
8 lots: WB02110011-18 (DOM: Feb '11), 2 lots: WB01110009-10 (DOM 1/15/11), 2 lots: WB01110007-8 (DOM 1/8/11), 3 lots: WB08100004-6 are Kosher-Pareve.			
• 50-12627 VITAMIN D3 15 Mio IU in Petrolether	OUV3-DDF70C0	Pareve	Ⓤ Symbol required.
• 50-12643 Liquid Vitamin D3 (in corn oil)	OUV3-ECCDDC1	Pareve	Ⓤ Symbol required.
• 50-12686 FLORAGLO(R) LUTEIN 5% CWS, BULK	OUV3-0E6BCCD	Pareve	Ⓤ Symbol required.
• 50-12724 Fruitflow®I	OUV3-7A95664	Pareve	Ⓤ Symbol required.
• 50-12732 Bitrit-1 - Type A	OUV3-6CF3E04	Pareve	Ⓤ Symbol required.
• 51-13000 FABULESS DE, BULK	OUV3-8BA06E1	Pareve	Ⓤ Symbol required.
• 51-14000 Fabuless DE	OUV2-5F455D6	Pareve	Symbol not required. Letter Required
Brand: Internal DSM Use			

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Product Name	UKD-ID	Status	Certification Requirements
Brand: Internal DSM Use (continued)			
• 04-20662 Vit A Acetate Crystalline 2,8	OUV2-DA2B19F	Pareve	Symbol not required.
• 04-21049 Vitamin E Alpha Tocopherol Technical Grade	OUW2-400BEFF	Pareve	Symbol not required. Certified for Passover and year-round use.
• 50-03571 Tocopherol technical	OUV2-C5342F6	Pareve	Symbol not required.
• 50-10969 Riboflavin for RPH	OUV2-DCABA4C	Pareve	Symbol not required.
• 50-12716 FloraGLO® Lutein 3% Milled	OUV2-DA84980	Pareve	Symbol not required.

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مجلس العلماء الإندونيسي

MAJELIS ULAMA INDONESIA
THE INDONESIAN COUNCIL OF ULAMA

شهادة حلال
SERTIFIKAT HALAL - HALAL CERTIFICATE

No : 00180055730810 الرقم :

قرر مجلس العلماء الإندونيسي - بعد الاختبارات والبحوث - بأن المنتجات الغذائية أو الأدوية أو مستحضرات التجميل المبين اسمها أدناه **حلال** حسب متطلبات الشريعة الإسلامية.

Majelis Ulama Indonesia (MUI), setelah melakukan pengujian dan pembahasan, menetapkan bahwa produk pangan, obat-obatan, atau kosmetika yang disebutkan namanya di bawah ini adalah **HALAL** menurut Syari'at Islam.

*The Indonesian Council of Ulama, after examining, inspecting/auditing and discussing the ingredients, has declared that the undermentioned food, drug and cosmetic products as **HALAL** according to the Islamic Law.*

Jenis Produk *Type of Product*	: AS ATTACHED	نوع المنتجات :
Nama Produk *Name of Product*	: AS ATTACHED	اسم المنتجات :
Nama Perusahaan *Name of Company*	: DSM NUTRITIONAL PRODUCTS LTD	اسم الشركة :
Alamat Perusahaan *Company's Address*	: PO BOX 2676 Bldg 241/655 CH 4002 BASEL SWITZERLAND	عنوان الشركة :
Dikeluarkan di Jakarta pada *Issued in Jakarta on*	: AUGUST 04, 2010	أصدرت هذه الشهادة بجاكرتا في:
Berlaku sampai dengan *Valid until*	: AUGUST 03, 2012	وصالحة إلى :

مادامت تركيبات المواد المشار إليها وعملية إنتاجها مطابقة على الشكل الذي قرره قسم الإفتاء بالمجلس.

selama bahan-bahan dan proses produksinya masih sesuai dengan keputusan Komisi Fatwa MUI.

as long as the ingredients, and production processes are in accordance to the decree of Fatwa Commission of the Indonesian Council of Ulama.

رئيس قسم الإفتاء بالمجلس

KETUA KOMISI FATWA MUI
HEAD OF THE FATWA COMISSION OF MUI

Dr. K.H.M. ANWAR IBRAHIM

مدير لجنة البحوث في الأطعمة والأدوية ومستحضرات التجميل بالمجلس

DIREKTUR LEMBAGA PENGKAJIAN PANGAN, OBAT-OBATAN DAN KOSMETIKA (LP POM) MUI,
DIRECTOR OF THE ASSESSMENT INSTITUTE FOR FOODS, DRUGS AND COSMETICS OF MUI

Ir. LUKMANUL HAKIM MSi

الرئيس العام للمجلس

KETUA UMUM MUI,
CHAIRMAN OF MUI

DR. K.H. M.A. SAHAL MAHFUDH

بسم الله الرحمن الرحيم

مجلس العلماء الإندونيسي

MAJELIS ULAMA INDONESIA

THE INDONESIAN COUNCIL OF ULAMA

مرفقة لشهادة الحلال

LAMPIRAN SERTIFIKAT HALAL

THE ATTACHMENT OF HALAL CERTIFICATE

No : 00180055730810 الرقم

Nama Perusahaan *Company Name*	: DSM Nutritional Products Ltd	اسم الشركة
Nama Pabrik *Factory Name*	: DSM Nutritional Products Ltd	اسم المصنع
Alamat Pabrik *Factory Address*	: 1 Boulevard D'alsace Village Neuf BP 170 F-68305 Saint Louis Cedex France	عنوان المصنع
Kelompok Produk *Product Groups*	: Vitamin and Mineral	مجموعة المنتجات
Jenis Produk *Product Type*	: Vitamin	نوع المنتجات
Nama Produk *Product Name*	: (Table)	اسم المنتجات

1	Beta carotene 30% FS (0427233)
2	Beta carotene 30% FS/SF (5000238)
3	Beta Carotene 10% EM Red (5003024)
4	Beta Carotene 5 % EM (0427292)
5	Beta Carotene 5% EM K (5011256)
6	Lutein 20% FS (5000742)
7	FloraGlo a FloraGLO® Lutein 20% SAF (5011876)
8	Redivivo (Lycopene) 10% FS(5000203)
9	Carocare Nat.Beta Carotene 30% S (5000476)
10	Optisharp (zeaxhantin)20% FS (5002001)
11	Riboflavin 5 Fosfat Sodium (0421413)
12	D Biotin (0417459)

Berlaku sampai dengan *Valid until* : August 03, 2012 : وصالحة إلى

Dikeluarkan di Jakarta pada *Issued in Jakarta on* : August 04, 2010 : أصدرت هذه الشهادة بجاكرتا في

مدير لجنة البحوث في الأطعمة والأدوية
ومستحضرات التجميل بالمجلس

DIREKTUR LEMBAGA PENGKAJIAN PANGAN, OBAT-OBATAN DAN KOSMETIKA (LP POM) MUI,
DIRECTOR OF THE ASSESSMENT INSTITUTE FOR FOODS, DRUGS AND COSMETICS OF MUI

MAJELIS ULAMA INDONESIA LP-POM

H. LUKMANUL HAKIM MSi

بسم الله الرحمن الرحيم

مجلس العلماء الإندونيسي

MAJELIS ULAMA INDONESIA

THE INDONESIAN COUNCIL OF ULAMA

مرفقة لشهادة الحلال

LAMPIRAN SERTIFIKAT HALAL

THE ATTACHMENT OF HALAL CERTIFICATE

No : 00180055730810 الرقم

Nama Perusahaan *Company Name*	: DSM Nutritional Products Ltd	اسم الشركة
Nama Pabrik *Factory Name*	: DSM Nutritional Products Ltd	اسم المصنع
Alamat Pabrik *Factory Address*	: 1 Boulevard D'alsace Village Neuf BP 170 F-68305 Saint Louis Cedex France	عنوان المصنع
Kelompok Produk *Product Groups*	: Vitamin and Mineral	مجموعة المنتجات
Jenis Produk *Product Type*	: Vitamin	نوع المنتجات
Nama Produk *Product Name*	: (Table)	اسم المنتجات

13	STAY –C50 (5000858)
14	Ronoxan A (0442534)
15	Apocarotenal 20% S (0480932)

Berlaku sampai dengan : August 03, 2012 : وصالحة إلى
Valid until

Dikeluarkan di Jakarta pada : August 04, 2010 : أصدرت هذه الشهادة بجاكرتا في
Issued in Jakarta on

مديرلجنة البحوث في الأطعمة والأدوية
ومستحضرات التجميل بالمجلس

DIREKTUR LEMBAGA PENGKAJIAN PANGAN, OBAT-OBATAN DAN KOSMETIKA (LP POM) MUI,
DIRECTOR OF THE ASSESSMENT INSTITUTE FOR FOODS, DRUGS AND COSMETICS OF MUI

Ir. LUKMANUL HAKIM MSi

بسم الله الرحمن الرحيم

مجلس العلماء الإندونيسي

MAJELIS ULAMA INDONESIA

THE INDONESIAN COUNCIL OF ULAMA

مرفقة لشهادة الحلال

LAMPIRAN SERTIFIKAT HALAL

THE ATTACHMENT OF HALAL CERTIFICATE

No : 00180055730810 الرقم

Nama Perusahaan *Company Name*	DSM Nutritional Products Ltd	اسم الشركة
Nama Pabrik *Factory Name*	DSM Nutritional Products Ltd	اسم المصنع
Alamat Pabrik *Factory Address*	Emil Barell Str 3 D 79639 Grenzach Wyhhlen Germany	عنوان المصنع
Kelompok Produk *Product Groups*	Vitamin and Mineral	مجموعة المنتجات
Jenis Produk *Product Type*	Vitamin	نوع المنتجات
Nama Produk *Product Name*	(Table)	اسم المنتجات

1	Teavigo (5009227)
2	Thiamine Hydrochloride (0413038)
3	Thiamine Mononitrate (0418943)
4	Riboflavin Tablet Grade (0470295)
5	Riboflavin Universal (0470406)
6	B2 Universal Fine Powder (5008611)
7	Pyridoxine Hydrocloride (0411604)
8	Ascorbyl Palmitate (0418595)
9	Phytantriol (0429082)

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Nama Pabrik *Factory Name*	DSM Nutritional Products Ltd	اسم المصنع
Alamat Pabrik *Factory Address*	Dalry Ayshire KA24 5 JJ Scotland UK	عنوان المصنع
Kelompok Produk *Product Groups*	Vitamin and Mineral	مجموعة المنتجات
Jenis Produk *Product Type*	Vitamin	نوع المنتجات
Nama Produk *Product Name*	(Table)	اسم المنتجات

1	Calcium Ascorbate (0419443)
2	Calcium D-Pantothenate (0412678)
3	D-Panthenol (0413852)
4	D-Panthenol 75 L (0416118)
5	Ascorbic Acid (0408050)
6	Ascorbic Acid Fine Powder (0422460)
7	Ascorbic Acid Ultra Fine Powder (0408107)
8	Ascorbic Acid Ultra Fine Powder (5009766)
9	Ascorbic Acid Fine Granular (0408093)
10	Coated Ascorbic Acid Type EC (0425117)
11	Coated Ascorbic Acid Type FC (0440809)
12	Coated Ascorbic Acid Type SC (0432210)

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Nama Pabrik *Factory Name*	: DSM Nutritional Products Ltd	اسم المصنع
Alamat Pabrik *Factory Address*	: Dalry Ayshire KA24 5 JJ Scotland UK	عنوان المصنع
Kelompok Produk *Product Groups*	: Vitamin and Mineral	مجموعة المنتجات
Jenis Produk *Product Type*	: Vitamin	نوع المنتجات
Nama Produk *Product Name*	: (Table)	اسم المنتجات

13	Sodium Ascorbate Crystalline (0408174)
14	Sodium Ascorbate 250 (5006201)
15	Ethyl Panthenol (0483575)

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MAJELIS ULAMA INDONESIA LP-POM MUI

Ir. LUKMANUL HAKIM MSi

بِسْمِ اللهِ الرَّحْمٰنِ الرَّحِيْمِ

مَجْلِسُ العُلَمَاءِ الإِنْدُونِيْسِيُّ

MAJELIS ULAMA INDONESIA

THE INDONESIAN COUNCIL OF ULAMA

مرفقة لشهادة الحلال

LAMPIRAN SERTIFIKAT HALAL

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Nama Perusahaan *Company Name*	DSM Nutritional Products Ltd	اسم الشركة
Nama Pabrik *Factory Name*	DSM Nutritional Products Ltd	اسم المصنع
Alamat Pabrik *Factory Address*	Hauptstrasse 4, CH-4334 Sisseln, Switzerland	عنوان المصنع
Kelompok Produk *Product Groups*	Vitamin and Mineral	مجموعة المنتجات
Jenis Produk *Product Type*	Vitamin	نوع المنتجات
Nama Produk *Product Name*	(Table)	اسم المنتجات

1	B carotene 10 % B 0434833
2	B Carotene 10% CWS 5010152
3	B Carotene 10% CWS 0434825
4	B Carotene 10% CWS/S 0489999
5	Beta Carotene 7% CWS (0482285
6	Beta carotene 1% CWS (0434523)
7	Beta carotene 10% EM Yellow (5002427)
8	Beta Carotene 1% CWS/M (5003741)
9	Beta Carotene 3% CWS/M(5003636)
10	10.Beta Carotene 10% CWS Star (5005221)
11	Beta Tab 20% S (5004004)
12	Apocarotenal 10% WS/N (0487376)

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MAJELIS ULAMA INDONESIA
LP-POM

Ir. LUKMANUL HAKIM MSi

Gedung Majelis Ulama Indonesia Jl. Proklamasi No. 51, Lt. III, Menteng, Jakarta Pusat Telp. : 391.8890, 31902666, Fax. : 391.8915

بسم الله الرحمن الرحيم

مجلس العلماء الإندونيسي

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Alamat Pabrik *Factory Address*	Hauptstrasse 4, CH-4334 Sisseln, Switzerland	عنوان المصنع
Kelompok Produk *Product Groups*	Vitamin and Mineral	مجموعة المنتجات
Jenis Produk *Product Type*	Vitamin	نوع المنتجات
Nama Produk *Product Name*	(Table)	اسم المنتجات

13	Apocarotenal 1% CWS (0434620)
14	Apocarotenal 1% CWS/M (5006317)
15	Apocarotenal 1% CWS/S (5009219)
16	Canthaxanthin 10% CWS/N (0486906)
17	Canthaxanthin 10% CWS/S (5005256)
18	Lutein 5% CWS (5000343)
19	Lutein 5% CWS/S-TG (5005213)
20	Redivivo (Lycopene) 10% WS (0481041
21	Redivivo (Lycopene) 10% CWS/S-TG (5003792)
22	Carocare Nat.Beta Carotene 20% V (5006600)
23	Carocare Nat.Beta Carotene 10% CWS Star(5010934)
24	CH-4334 Sisseln, Switzerland

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Jenis Produk *Product Type*	Vitamin	نوع المنتجات
Nama Produk *Product Name*	(Table)	اسم المنتجات

25	All Q (Coenzyme Q10) Plus (5005809)
26	Optisharp (zeaxanthin) 5% CWS/S-TG (5003563)
27	Bonistein (5010675)
28	Bonistein S (5007259)
29	Vitamin A Acetate 2.3 MIU (BH/BHT) (0423009)
30	Vitamin A Acetate 1.5 MIU/g **(tocopherol)**
31	Vitamin A Palmitate 1.7.MIU/g (BHA/BHT) (0424013)
32	Vitamin A Palmitate 1.7.MIU/g (toco) (0418579)
33	Vitamin A Palmitate 1.7.MIU/g (w/o stabilizer) (0424005)
34	Vitamin A palmitate /M 1.0 MIU/g (BHA/BHT)(0420603)
35	Vitamin A Palmitate 1.0 MIU/g (toco) (0431400)
36	Vitamin A Palmitate/M 1.0 MIU/g (5008530)

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Hj LUKMANUL HAKIM MSi

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Jenis Produk *Product Type*	: Vitamin	نوع المنتجات
Nama Produk *Product Name*	: (Table)	اسم المنتجات

37	Vitamin A Palmitate 1.0 MIU/g +Vit D3 100.000 IU/G (0442623)
38	Dry Vitamin A Acetate Type 325 CWS/F (0436305)
39	Dry Vitamin A Acetate Type 325 CWS/A (5010330)
40	Dry Vitamin A Acetate Type 250 CWS/S (0429716)
41	Dry Vitamin A Palmitate Type 250 CWS/**F**
42	Dry Vitamin A Palmitate 250 S/N (5000718)
43	Vitamin A Water Miscible Type 100 (0421316)
44	Vitamin A+D3 Water Miscible Type 100/20 (0422010)
45	Vitamin D3 1.0 MIU/g (0419133)
46	Dry Vitamin D3 type 100 CWS/AM (5003652)
47	Dry Vitamin D3 100 SD/S (5005043)
48	Vitamin K1 (0435015)

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M.U.I

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Kelompok Produk *Product Groups*	Vitamin and Mineral	مجموعة المنتجات
Jenis Produk *Product Type*	Vitamin	نوع المنتجات
Nama Produk *Product Name*	(Table)	اسم المنتجات

49	Dry Vitamin K1 5% S.D (0434922)
50	DL-alpha-Tocopherol
51	DL-alpha-Tocopheryl Acetate
52	dry Vitamin E 50% type CWS/F (0437239)
53	Dry Vitamin E 50% CWS/S (5001129)
54	Dry Vitamin E 15% CC (5001285)
55	Vitamin B12.0.1% WS (0429090)
56	Vitamin B12 0.1% WS/N (0483125)
57	Folic acid (0417823)
58	Folic acid food grade (5004357)
59	Ropufa 10 n 3 Food powder S/S.d (5000351)
60	Ropufa 10 n 3 INF powder S/S.D (5006392)

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Jenis Produk *Product Type*	Vitamin	نوع المنتجات
Nama Produk *Product Name*	(Table)	اسم المنتجات

61	Ropufa 75 n 3 EE oil (5008441)
62	Ropufa 30 n 3 Food oil (5008360)
63	Ropufa 30 n 3 EPA oil (5009596)
64	Ropufa 30 n 3 INF Oil (5009537)
65	Dry Vitamin A Acetate, Type 250 CWS/A – 0429716

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LP-POM

LUKMANUL HAKIM MSi

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NSF International

789 N. Dixboro Road, Ann Arbor, Michigan 48105
(800) 673-6275

INDEPENDENTLY REGISTERED NSF GMP
Manufacturing Facility

Kemin Health, L.C.

2100 Maury Street
Des Moines, IA 50317 USA

has been assessed by NSF International and found to be in compliance with:

GMP Requirements in NSF/ANSI Standard 173, Section 8

DIETARY SUPPLEMENTS

Certificate Date:	February 17, 2011
Certification Number:	C0029220D
Initial Certification:	December 02, 2009

Ed Wyszumiala, General Manager
Dietary Supplements

NSF International

789 N. Dixboro Road, Ann Arbor, Michigan 48105
(800) 673-6275

Manufacturing Facility

Kemin Health, L.C.

2111 East 17th Street
Des Moines, IA 50316 USA

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DIETARY SUPPLEMENTS

Certificate Date: February 17, 2011
Certification Number: C0029219D
Initial Certification: December 02, 2009

Ed Wyszumiala, General Manager
Dietary Supplements

POST IN CONSPICUOUS PLACE ***NONTRANSFERABLE***

STATE OF IOWA

IOWA DEPARTMENT OF INSPECTIONS AND APPEALS

DES MOINES

FEE $ 337.50 PROCESSING PLANTS LICENSE NO.FP00-0000173

KEMIN INDUSTRIES INC
KEMIN INDUSTRIES, INC
2100 MAURY ST
DES MOINES, IA 50317

THE AFORESAID, HAVING DEPOSITED THE REQUIRED FEE, IS HEREBY GRANTED THE ABOVE LICENSE PURSUANT TO CHAPTER 137F, CODE OF IOWA. THIS LICENSE SHALL REMAIN IN FULL FORCE FROM THE DATE OF ISSUE UNTIL ITS EXPIRATION DATE, UNLESS REVOKED OR SUSPENDED FOR CAUSE BY THE DIRECTOR OF INSPECTIONS AND APPEALS FOR NONCOMPLIANCE WITH CHAPTER137F, CODE OF IOWA OR RULES PROMULGATED PURSUANT THERETO.

- LICENSE FOR FOLLOWING LOCATION -

2100 MAURY ST
DES MOINES, IA 50317

DATE OF ISSUE April 26, 2011
EXPIRATION DATE May 09, 2012

Rodney A. Roberts

DIRECTOR

SEAL OF IOWA STATE DEPARTMENT OF INSPECTIONS AND APPEALS

This license issued by:

Iowa Department of Inspections & Appeals
FOOD & CONSUMER SAFETY BUREAU
LUCAS BLDG - 321 E 12TH ST
DES MOINES, IA 50319
Phone: (515)281-6538
Email: terri.duden@dia.iowa.gov
Web Site: http://dia.iowa.gov/food

POST IN CONSPICUOUS PLACE ***NONTRANSFERABLE***

STATE OF IOWA

IOWA DEPARTMENT OF INSPECTIONS AND APPEALS

DES MOINES

FEE $ 337.50 PROCESSING PLANTS LICENSE NO.FP00-0000172

KEMIN HEALTH
KEMIN FOODS LC
600 E COURT AVENUE, SUITE A
DES MOINES, IA 50309

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- LICENSE FOR FOLLOWING LOCATION -

2111 E 17TH, SUITE A
DES MOINES, IA 50316

DATE OF ISSUE April 13, 2011
EXPIRATION DATE May 06, 2012

Rodney A. Roberts

DIRECTOR

SEAL OF IOWA STATE DEPARTMENT OF INSPECTIONS AND APPEALS

This license issued by:

Iowa Department of Inspections & Appeals
FOOD & CONSUMER SAFETY BUREAU
LUCAS BLDG - 321 E 12TH ST
DES MOINES, IA 50319
Phone: (515)281-6538
Email: terri.duden@dia.iowa.gov
Web Site: http://dia.iowa.gov/food

Certificate

SQS herewith certifies that the company named below has a management system which meets the requirements of the normative base specified below.

DSM Nutritional Products Ltd.
CH-4303 Kaiseraugst

Certified area

Division worldwide,
Details mentioned in Appendix

Field of activity

Manufacturing and Distribution
of Vitamins and Fine Chemicals,
Fats and Oils, Carotenoids,
Vitamin and Mineral Premixes,
Food / Nutritional / Microbiological Additives,
Substances derived from nature and
synthetic nature-identical Substances

Normative base

ISO 9001:2008 Quality Management System

Swiss Association for Quality and
Management Systems SQS
Bernstrasse 103, CH-3052 Zollikofen
Issue date: July 1, 2010

This SQS Certificate is valid up to
and including June 30, 2013
Scope number 12
Registration number 10780

X. Edelmann, President SQS

T. Zahner, Managing Director SQS

SCESm 001

Swiss Made

Partner of IQNet

APPENDIX to the SQS-Certificate, Registration number 10780

DSM Nutritional Products Ltd.

The SQS-Certificate mentioned includes all global and local processes of the Division worldwide of DSM Nutritional Products in Headquarters, all Sites/Sales Organizations,
Human Nutrition and Health Premix Units and Animal Nutrition and Health Premix Units, detailed as follows:

Unit of Worldwide Division	Country	Location	Reg. No.	Certificate	
				Standard	Valid until
Headquarters					
DSM Nutritional Products Ltd., Headquarters Kaiseraugst	Switzerland	Kaiseraugst	10780	ISO 9001:2008	30.06.2013
M & T Sites					
DSM Nutritional Products Inc.	USA	Belvidere / NJ	22314	ISO 9001:2008 ISO 14001:2004	30.06.2013
DSM Nutritional Products Inc.	USA	Freeport / TX	21230	ISO 9001:2008 ISO 14001:2004	30.06.2013
DSM Nutritional Products (UK) Ltd.	UK	Dalry / Scotland	22427 31743 37218	ISO 9001:2008 ISO 14001:2004 FAMI-QS FSSC 22000	30.06.2013 30.06.2013 06.06.2013
DSM Nutritional Products GmbH	Germany	Grenzach-Wyhlen	31643 31644	ISO 9001:2008 ISO 14001:2004 FAMI-QS	30.06.2013 11.07.2011
DSM Nutritional Products AG	Switzerland	Lalden	10750	ISO 9001:2008 ISO 14001:2004	30.06.2013
DSM Nutritional Products AG	Switzerland	Sisseln	10694 31538	ISO 9001:2008 ISO 14001:2004 FAMI-QS	30.06.2013 19.06.2011
DSM Nutritional Products France SAS	France	Saint-Louis / Village-Neuf	20963 31598	ISO 9001:2008 ISO 14001:2004 FAMI-QS	30.06.2013 03.07.2011
DSM Vitamins (Shanghai) Ltd.	PRC China	Xinghuo	22689 33381	ISO 9001:2008 ISO 14001:2004 ISO 22000:2005 FAMI-QS	30.06.2013 18.02.2013
DSM Fine Chemicals (Shanghai) Ltd.	PRC China	Xinghuo "Teavigo"	22690	ISO 9001:2008 ISO 14001:2004 ISO 22000:2005	30.06.2013
DSM Nutritional Products AG	Switzerland	Gland	33949 33950	ISO 9001:2008 ISO 14001:2004 FAMI-QS	30.06.2013 25.07.2013
DSM Nutritional Products AG, Zweigniederlassung Pentapharm	Switzerland	Basel / Aesch	11179 34091	ISO 9001:2008 ISO 13485:2003	07.08.2012 07.08.2012
DSM Nutritional Products, Inc.	USA	Naperville / IL	10780	ISO 9001:2008	30.06.2013

APPENDIX to the SQS-Certificate, Registration number 10780

DSM Nutritional Products Ltd.

Unit of Worldwide Division	Country	Location	Reg. No.	Certificate	
				Standard	Valid until
Distribution Centers					
DSM Nutritional Products Nederland B.V.	Holland	Venlo	10780	ISO 9001:2008	30.06.2013
DSM Nutritional Products, Inc	USA	Belvidere / NJ	10780	ISO 9001:2008	30.06.2013
DSM Nutritional Products Asia Pacific Pte Ltd	Singapore	Singapore	10780	ISO 9001:2008	30.06.2013
Global Marketing & Sales Organisations / Area Centers					
DSM Nutritional Products Europe Ltd.	Switzerland	Basel SBB	10780 32297	ISO 9001:2008 FAMI-QS	30.06.2013 09.02.2012
DSM Nutritional Products Inc.	USA	Parsippany / NJ	10780	ISO 9001:2008	30.06.2010
DSM Nutritional Products Latin America	Brazil	São Paulo	10780	ISO 9001:2008	30.06.2013
DSM Nutritional Products Asia Pacific Pte. Ltd.	PRC China	Shanghai, Zhangjiang Tower	10780	ISO 9001:2008	30.06.2013
DSM China Ltd.	PRC China	Shanghai, Zhangjiang Tower	10780	ISO 9001:2008	30.06.2013
Human Nutrition and Health Premix Units					
DSM Produtos Nutricionais Brasil Ltda.	Brazil	São Paulo	10780	ISO 9001:2008	30.06.2013
DSM Nutritional Products Inc.	USA	Belvidere / NJ	10780	ISO 9001:2008	30.06.2013
DSM Nutritional Products Colombia S.A.	Colombia	Bogotá	10780	ISO 9001:2008	30.06.2013
DSM Nutritional Products México, S.A. de C.V.	Mexico	El Salto / Jalisco	10780	ISO 9001:2008	30.06.2013
DSM Nutritional Products Asia Pacific Pte. Ltd.	Singapore	Singapore	10780 37274	ISO 9001:2008 FSSC 22000	30.06.2013 01.05.2013
DSM Nutritional Products France SAS	France	Saint-Louis / Village-Neuf	36953	FSSC 22000	30.06.2013
DSM Nutritional Products South Africa (Pty) Ltd.	South Africa	Isando	10780	ISO 9001:2008	30.06.2013
Animal Nutrition and Health Premix Units					
DSM Nutritional Products Argentina S.A.	Argentina	Buenos Aires	10780	ISO 9001:2008	30.06.2013
DSM Nutritional Products Australia Pty Ltd.	Australia	Wagga Wagga	10780	ISO 9001:2008	30.06.2013
DSM Nutritional Products NV	Belgium	Deinze	10780 31096	ISO 9001:2008 FAMI-QS	30.06.2013 19.04.2011
DSM Produtos Nutricionais Brasil Ltda.	Brazil	São Paulo	10780	ISO 9001:2008	30.06.2008
DSM Nutritional Products Canada Inc.	Canada	Cambridge, Ayr	10780 32827	ISO 9001:2008 FAMI-QS	30.06.2013 01.10.2012
DSM Nutritional Products Canada Inc.	Canada	High River	10780	ISO 9001:2008	30.06.2013
DSM Nutritional Products Chile S.A.	Chile	Puerto Montt	10780	ISO 9001:2008	30.06.2013
DSM Nutritional Products Colombia S.A.	Colombia	Bogotá	10780	ISO 9001:2008	30.06.2013
DSM Nutritional Products Costa Rica S.A.	Costa Rica	Heredia	10780	ISO 9001:2008	30.06.2013
DSM Nutritional Products Ecuador S.A.	Ecuador	Quito	10780	ISO 9001:2008	30.06.2013
DSM Nutritional Products (UK) Ltd.	UK	Heanor	10780 31097	ISO 9001:2008 FAMI-QS	30.06.2013 19.04.2011

APPENDIX to the SQS-Certificate, Registration number 10780

DSM Nutritional Products Ltd.

Unit of Worldwide Division	Country	Location	Reg. No.	Certificate	
				Standard	Valid until
Animal Nutrition and Health Premix Units					
DSM Nutritional Products Hellas Ltd.	Greece	Inofita (plant) Maroussi (office)	10780 31820	ISO 9001:2008 FAMI-QS	30.06.2013 10.11.2011
DSM Nutritional Products Guatemala S.A.	Guatemala	Villa Nueva	10780	ISO 9001:2008	30.06.2013
DSM Nutritional Products Hungary Kft.	Hungary	Újhartyán	10780 31703	ISO 9001:2008 FAMI-QS	30.06.2013 26.07.2011
DSM Nutritional Products (UK) Ltd.	Ireland	Belfast	10780 31098	ISO 9001:2008 FAMI-QS	30.06.2013 19.04.2011
Istituto delle Vitamine SpA	Italy	Segrate / Milano	10780 30953	ISO 9001:2008 FAMI-QS	30.06.2013 06.02.2011
DSM Nutrition Japan K.K.	Japan	Fukuroi-Shizuoka	10780	ISO 9001:2008	30.06.2013
DSM Nutrition Korea Ltd	South Korea	Poseung	10780	ISO 9001:2008	30.06.2013
DSM Nutritional Products México, S.A. de C.V.	Mexico	El Salto / Jalisco	10780	ISO 9001:2008	30.06.2013
DSM Nutritional Products Peru S.A.	Peru	San Borja (Lima)	10780	ISO 9001:2008	30.06.2013
DSM Nutritional Products Sp. z o.o.	Poland	Mszczonów	10780 31704	ISO 9001:2008 FAMI-QS	30.06.2013 26.07.2011
DSM Nutritional Products South Africa (Pty) Ltd.	South Africa	Germiston	10780	ISO 9001:2008	30.06.2013
DSM Nutritional Products Iberia S.A.	Spain	Alcalà de Henares (Madrid)	10780 31817	ISO 9001:2008 FAMI-QS	30.06.2013 28.11.2011
DSM Nutritional Products Taiwan Ltd.	Taiwan	Hsinchu	10780	ISO 9001:2008	30.06.2013
Rovithai Ltd	Thailand	Chon Buri	10780	ISO 9001:2008	30.06.2013
DSM Besin Maddeleri Ltd. Sti.	Turkey	Istanbul / Gebze	10780 32209	ISO 9001:2008 FAMI-QS	30.06.2013 22.12.2011
DSM Nutritional Products Uruguay S.A.	Uruguay	Montevideo	10780	ISO 9001:2008	30.06.2013
DSM Nutritional Products, Inc.	USA	Pendergrass	10780	ISO 9001:2008	30.06.2013
DSM Nutritional Products, Inc.	USA	Fort Worth	10780	ISO 9001:2008	30.06.2013
DSM Nutritional Products, Inc.	USA	Ames	10780	ISO 9001:2008	30.06.2013
DSM Nutritional Products Venezuela S.A.	Venezuela	La Victoria (Caracas)	10780	ISO 9001:2008	30.06.2013
DSM Nutritional Products Vietnam Ltd.	Vietnam	Ho Chi Minh City	10780	ISO 9001:2008	30.06.2013
Vitamins (Hunan) Ltd.	PRC China	Hunan	10780	ISO 9001:2008	30.06.2013
Vitamins (Shangdong) Ltd.	PRC China	Shandong	10780	ISO 9001:2008	30.06.2013
Vitamins (Changchun) Ltd	PRC China	Changchun	10780	ISO 9001:2008	30.06.2013
DSM entities					
DSM Food Specialties (Shanghai) Ltd.	PRC China	Xinghuo	34267	ISO 9001:2008 ISO 14001:2004 ISO 22000:2005	30.06.2013
DSM Composite Resins (Shanghai) Co. Ltd.	PRC China	Xinghuo	35137	ISO 9001:2008 ISO 14001:2004	30.06.2013

Appendix C

Product Labels

1. Infant formula product containing Lutein (USP) (**CBI deleted**)
2. Food/Beverage product containing Lutein (USP) (**CBI deleted**)
3. Dietary supplement containing Lutein (USP)
4. FloraGLO® Lutein 5% Corn Oil Sample Label
5. FloraGLO® Lutein 5% VG Granules Sample Label
6. FloraGLO® Lutein 10% VG TabGrade™ Sample Label
7. FloraGLO® Lutein 20% Liquid in Corn Oil Sample Label
8. FloraGLO® Lutein 20% Liquid in Safflower Oil Sample Label
9. FloraGLO® Crystalline Lutein Sample Label
10. FloraGLO® Lutein 20% FS Sample Label
11. FloraGLO® Lutein 20% SAF Sample Label

Bausch & Lomb

Ocuvite®

Eye Vitamin & Mineral Supplement

Adult 50+

50 SOFT GELS

Bausch & Lomb

Ocuvite®

Eye Vitamin & Mineral Supplement

Adult 50+

Keep out of reach of children

Store at room temperature

FOR MORE INFORMATION, CALL 1-800-553-5340

Ocuvite Adult 50+ – the vitamin and mineral supplement that may help keep eyes healthy.*

Recent studies indicate proper nutrition is critical to maintaining eye health. As we age, our eyes may not get enough nutrition through diet alone.

Ocuvite Adult 50+ contains 150 mg of Omega-3 and 6 mg of Lutein, antioxidants vitamins C and E essential to the health of your eyes.* The leading multi-vitamins contain only a fraction of the amounts found to be beneficial.

* These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Bausch & Lomb –
Committed to research and leadership in ocular nutritionals

FloraGLO® LUTEIN ® FloraGlo is a registered trademark of Kemin Industries, Inc.

DO NOT USE IF SEAL UNDER CLOSURE IS BROKEN

Order No.: AB46530N

Bausch & Lomb

Ocuvite®

Eye Vitamin & Mineral Supplement

Adult 50+
Age-adjusted Formula

- Advanced Eye Nutrition
- 6 mg Lutein and 150 mg of Omega-3

50
Easy to swallow Soft Gels

#1 BRAND RECOMMENDED BY EYE CARE PROFESSIONALS

Supplement Facts

Serving Size: 1 soft gel
Servings per container: 50

Amount per Serving	1 Soft Gel	% of Daily Value
Vitamin C (ascorbic acid)	150 mg	250%
Vitamin E (d-alpha tocopherol)	30 IU	100%
Zinc (as zinc oxide)	9 mg	60%
Copper (as cupric oxide)	1 mg	50%
Lutein	6 mg	+
Omega-3	150 mg	+

+ Daily Value not established

Other Ingredients: Gelatin, Fish Oil (anchovy, sardine), Glycerin, Yellow Beeswax, Silicon Dioxide, Soy Lecithin (Contains peanut oil), Caramel Color, Titanium Dioxide, Blue 2 Lake, Yellow #6, Yellow 6 Lake, Red #40, Red 40 Lake.

Marketed by:
Bausch & Lomb Incorporated, Rochester, NY 14609

Directions for use: Take 1 Soft Gel daily, in the morning taken with food. Do not exceed the dose indicated without seeking medical advice.

2009-07
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(S) V-NN 0282049.0000 p

DSM

V 001

Ⓤ FloraGLO® Lutein 5% Corn Oil

K1

0001

Suspension of micro-crystalline lutein in corn oil. Contains minimum 5% lutein (E161b*).

Ingredients:
Lutein (extract from Tagetes erecta), corn oil.

Caution:
For manufacturing, processing or repacking. Not for retail sale. Store in a cool, dry place. Keep package closed. Prior to use, heat unopened container in a water bath to 40°C, shake/stir it gently. Once opened, use contents quickly.

FloraGLO® is a trademark of Kemin Industries, Inc.

*E161b is the resp. European food additive number.
1 lb = 0.4535 kg

Suspensión de luteina micro-cristalino en aceite de maíz. Contiene un mínimo de 5% de luteína (E161b).

Ingredientes:
Luteína (sacar de Tagetes erecta), aceite de maíz.

Atención:
Para uso industrial no para venta directa. Almacenar cerrado en lugar seco y fresco. Antes de abrir, calentar el envase en baño maria a 40°C, agitese con cuidado. Una vez abierto utilicese rápidamente.

Suspension de lutéine micro-cristallisée dans de l'huile de maïs. Contient au minimum 5% de lutéine (E161b).

Ingrédients:
Lutéine (extrait de Tagetes erecta), huile de maïs.

Remarque:
Destiné à l'utilisation industrielle et non à la vente au détail. Conserver fermé au sec et au frais. Avant utilisation, chauffer au bain-marie le récipient fermé à 40°C, agiter soigneusement. A utiliser rapidement après ouverture de l'emballage.

Sospensione micro-cristallina di luteina in olio di mais. Contiene minimo 5% di luteina (E161b).

Ingredienti:
Luteina (estrarre da Tagetes erecta), olio di mais.

Avviso:
Da impiegare unicamente ai fini della produzione. Esclusa la vendita al dettaglio. Conservare chiuso in luogo asciutto e fresco. Prima dell'uso, scaldare il recipiente chiuso a bagno maria fino a 40°C. Agitare leggermente. Dopo l'apertura utilizzare il contenuto rapidamente.

Suspension von mikrokristallinem Lutein in Maisöl. Enthält mind. 5% Lutein (E161b).

Zusammensetzung:
Lutein (Extrakt von Tagetes erecta), Maisöl.

Hinweis:
Nur für die Weiterverarbeitung bestimmt, nicht für den Verkauf im Einzelhandel. In geschlossenem Behälter kühl und trocken lagern. Vor Gebrauch Behälter ungeöffnet in einem Wasserbad auf 40°C erwärmen und vorsichtig schütteln. Angebrochene Verpackung kurzfristig aufbrauchen.

Code 5009723189

Lot 0712100538

Manufactured for:
DSM Nutritional Products Ltd , Site Sisseln
Hauptstrasse 4, CH-4334 Sisseln, Switzerland

for sale by:
DSM affiliates & authorized distributors
Made in U.S.A.

DSM Nutritional Products Ltd., Wurmisweg 576, CH-4303 Kaiseraugst, Switzerland, +41 61 688 33 33

DSM Nutritional Products Europe Ltd., Klünenfeldstrasse 22,Muttenz,CH-4127 Birsfelden, Switzerland, +41 61 68 71777
DSM Nutritional Products Nederland BV, Global Distribution Centre (alpha NL 30341), Columbusweg 24, NL-5928 LC Venlo, Netherlands, +31 (77) 389 44 00
DSM Nutritional Products Asia Pacific Pte.Ltd.,78 Shenton Way #21-00,MCL Building,Singapore 079120,+65 63256200
DSM China Ltd, Ocean Tower 22F, 550 Yan An East Road, Shanghai 200001, P.R.China, +86 21 3310 4988
DSM Produtos Nutricionais Brasil Ltda.,Av.Eng.Bilings 1729-Predio 9,05321-900 São Paulo,SP Brasil,+55113719-4566
DSM Nutritional Products, Inc., 45 Waterview Blvd, Parsippany NJ 07054-1298, USA, +1 800 528 0189

Manufacturing Date: / Fecha de fabricación: / Date de fabrication: / Data di produzione: / Herstellungs-Datum:	Best use before: / Fecha de caducidad: / A utiliser avant: / Data di scadenza: / Mindestens haltbar:	Net weight: / Peso neto: / Poids net: / Peso netto: / Nettogewicht:
12.2007	12.2008	6x5 lb

(S) V-NN 0282049.0000 p

DSM V 001

© FloraGLO® Lutein 5% VG Granules

0001

Contains minimum 5% Lutein (E161b*).

Ingredients:
Lutein (extract from Tagetes erecta),sucrose, tapioca starch.

Caution:
For manufacturing, processing or repacking. Not for retail sale. Store in a cool, dry place. Keep package closed. Once opened, use contents quickly.

FloraGLO® is a trademark of Komin Industries, Inc.

*E161b is the resp. European food additive number.

Contiene un mínimo de 5% de luteína (E161b).

Ingredientes:
Luteína (sacar de Tagetes erecta),sacarosa, almidón de tapioca.

Atención:
Para uso industrial no para venta directa. Almacenar cerrado en lugar seco y fresco. Una vez abierto utilícese rápidamente.

Contient au minimum 5% de lutéine (E161b).

Ingrédients:
Lutéine (extrait de Tagetes erecta), saccharose, amidon de tapioca.

Remarque:
Destiné à l'utilisation industrielle et non à la vente au détail. Conserver fermé au sec et au frais. A utiliser rapidement après ouverture de l'emballage.

Contiene minimo 5% di luteina (E161b).

Ingredienti:
Luteina (estrarre da Tagetes erecta), saccarosio, amido di tapioca.

Avviso:
Da impiegare unicamente ai fini della produzione. Esclusa la vendita al dettaglio. Conservare chiuso in luogo asciutto e fresco. Dopo l'apertura utilizzare il contenuto rapidamente.

Enthält mind. 5% Lutein (E161b).

Zusammensetzung:
Lutein (Extrakt von Tagetes erecta), Saccharose, Tapiokastärke.

Hinweis:
Nur für die Weiterverarbeitung bestimmt, nicht für den Verkauf im Einzelhandel. In geschlossenem Behälter kühl und trocken lagern. Angebrochene Verpackung kurzfristig aufbrauchen.

5009464298

0802102225

Code

Lot

Manufactured for:
DSM Nutritional Products Ltd., Site Sisseln
Hauptstrasse 4, CH-4334 Sisseln, Switzerland

for sale by:
DSM affiliates & authorized distributors
Made in U.S.A.

DSM Nutritional Products Ltd., Wurmisweg 576, CH-4303 Kaiseraugst, Switzerland, +41 61 688 33 33

DSM Nutritional Products Europe Ltd., Klunenfeldstrasse 22,Muttenz,CH-4127 Birsfelden, Switzerland, +41 61 68 71777
DSM Nutritional Products Nederland BV, Global Distribution Centre (alpha NL 30341), Columbusweg 24, NL-5928 LC Venlo, Netherlands, +31 (77) 389 44 00
DSM Nutritional Products Asia Pacific Pte Ltd.,78 Shenton Way #21-00,MCL Building,Singapore 079120,+65 63256200
DSM China Ltd. Ocean Tower 22F, 550 Yan An East Road, Shanghai 200001, P.R.China, +86 21 3310 4999
DSM Produtos Nutricionais Brasil Ltda.,Av.Eng.Billings 1729-Predio 9,05321-900 São Paulo,SP Brasil,+55113719-4566
DSM Nutritional Products, Inc., 45 Waterview Blvd, Parsippany NJ 07054-1298, USA, +1 800 526 0189

Manufacturing Date: / Fecha de fabricación: / Date de fabrication: / Data di produzione: / Herstellungs-Datum:	Best use before: / Fecha de caducidad: / A utiliser avant: / Data di scadenza: / Mindestens haltbar:	Net weight: / Peso neto: / Poids net: / Peso netto: / Nettogewicht:
02.2008	02.2010	25 kg

(S) V-NN 0282049.0000 p

DSM

V 001

© FloraGLO® Lutein 10% VG TabGrade™

0001

KH PP

Contains minimum 10% Lutein (E161b*).

Ingredients:
Lutein (extract from Tagetes erecta), sucrose, tapioca starch.

Caution:
For manufacturing, processing or repacking. Not for retail sale. Store in a cool, dry place. Keep package closed. Once opened, use contents quickly.

FloraGLO® is a trademark of Kemin Industries, Inc.

*E161b is the resp. European food additive number.

Contiene un mínimo de 10% de luteína (E161b).

Ingredientes:
Luteína (sacar de Tagetes erecta),sacarosa, almidón de tapioca.

Atención:
Para uso industrial no para venta directa. Almacenar cerrado en lugar seco y fresco. Una vez abierto utilícese rápidamente.

Contient au minimum 10% de lutéine (E161b).

Ingrédients:
Lutéine (extrait de Tagetes erecta), saccharose, amidon de tapioca.

Remarque:
Destiné à l'utilisation industrielle et non à la vente au détail. Conserver fermé au sec et au frais. A utiliser rapidement après ouverture de l'emballage.

Contiene minimo 10% di luteina (E161b).

Ingredienti:
Luteina (estrarre da Tagetes erecta), saccarosio, amido di tapioca.

Avviso:
Da impiegare unicamente ai fini della produzione. Esclusa la vendita al dettaglio. Conservare chiuso in luogo asciutto e fresco. Dopo l'apertura utilizzare il contenuto rapidamente.

Enthält mind. 10% Lutein (E161b).

Zusammensetzung:
Lutein (Extrakt von Tagetes erecta), Saccharose, Tapiokastärke.

Hinweis:
Nur für die Weiterverarbeitung bestimmt, nicht für den Verkauf im Einzelhandel. In geschlossenem Behälter kühl und trocken lagern. Angebrochene Verpackung kurzfristig aufbrauchen.

5009456298

0706100676

Code

Lot

Manufactured for:
DSM Nutritional Products Ltd., Site Sisseln
Hauptstrasse 4, CH-4334 Sisseln, Switzerland

for sale by:
DSM affiliates & authorized distributors
Made in U.S.A.

DSM Nutritional Products Ltd., Wurmisweg 576, CH-4303 Kaiseraugst, Switzerland, +41 61 969 33 33
DSM Nutritional Products Europe Ltd., Kliznenfeldstrasse 22,Muttenz,CH-4127 Birsfelden, Switzerland, +41 61 69 71777
DSM Nutritional Products Nederland BV, Global Distribution Centre (alpha NL 30341), Columbusweg 24, NL-5928 LC Venlo, Netherlands, +31 (77) 389 44 00
DSM Nutritional Products Asia Pacific Pte Ltd ,79 Shenton Way #21-00,MCL Building,Singapore 079120,+65 63256200
DSM China Ltd, Ocean Tower 22F, 550 Yan An East Road, Shanghai 200001, P.R.China, +86 21 3310 4988
DSM Produtos Nutricionais Brasil Ltda ,Av. Eng.Billings 1729-Predio 9,05321-900 São Paulo,SP Brasil,+55113719-4566
DSM Nutritional Products, Inc., 45 Waterview Blvd, Parsippany NJ 07054-1298, USA, +1 800 526 0189

Manufacturing Date: / Fecha de fabricación: / Date de fabrication: / Data di produzione: / Herstellungs-Datum:	Best use before: / Fecha de caducidad: / A utiliser avant: / Data di scadenza: / Mindestens haltbar:	Net weight: / Peso neto: / Poids net: / Peso netto: / Nettogewicht:
06.2007	06.2009	25 kg

(S) V-N\N 0282049.0000 p

DSM V 001

Ⓤ FloraGLO® Lutein 20% Corn Oil

0001

KM

Sùspension of micro-crystalline lutein in corn oil. Contains minimum 20% lutein (E161b*).

Ingredients:
Lutein (extract from Tagetes erecta), corn oil.

Caution:
For manufacturing, processing or repacking. Not for retail sale. Store in a cool, dry place. Keep package closed. Prior to use, heat unopened container in a water bath to 40°C, shake/stir it gently. Once opened, use contents quickly.

FloraGLO® is a trademark of Kemin Industries, Inc.

*E161b is the resp. European food additive number.

Suspensión de luteina micro-cristalino en aceite de maíz. Contiene un mínimo de 20% de luteína (E161b).

Ingredientes:
Luteína (sacar de Tagetes erecta), aceite de maíz.

Atención:
Para uso industrial no para venta directa. Almacenar cerrado en lugar seco y fresco. Antes de abrir, calentar el envase en baño maria a 40°C, agitese con cuidado. Una vez abierto utilícese rápidamente.

Suspension de lutéine micro-cristallisée dans de l'huile de maïs. Contient au minimum 20% de lutéine (E161b).

Ingrédients:
Lutéine (extrait de Tagetes erecta), huile de maïs.

Remarque:
Destiné à l'utilisation industrielle et non à la vente au détail. Conserver fermé au sec et au frais. Avant utilisation, chauffer au bain-marie le récipient fermé à 40°C, agiter soigneusement. A utiliser rapidement après ouverture de l'emballage.

Sospensione micro-cristallina di luteina in olio di mais. Contiene minimo 20% di luteina (E161b).

Ingredienti:
Luteina (estrarre da Tagetes erecta), olio di mais.

Avviso:
Da impiegare unicamente ai fini cella produzione. Esclusa la vendita al dettaglio. Conservare chiuso in luogo asciutto e fresco. Prima dell'uso, scaldare il recipiente chiuso a bagno maria fino a 40°C. Agitare leggermente. Dopo l'apertura utilizzare il contenuto rapidamente.

Suspension von mikrokristallinem Lutein in Maisöl. Enthält mind. 20% Lutein (E161b).

Zusammensetzung:
Lutein (Extrakt von Tagetes erecta), Maisöl.

Hinweis:
Nur für die Weiterverarbeitung bestimmt, nicht für den Verkauf im Einzelhandel. In geschlossenem Behälter kühl und trocken lagern. Vor Gebrauch Behälter ungeöffnet in einem Wasserbad auf 40°C erwärmen und vorsichtig schütteln. Angebrochene Verpackung kurzfristig aufbrauchen.

Code 5009731298

Lot 0712104735

Manufactured for:
DSM Nutritional Products Ltd., Site Sisseln
Hauptstrasse 4, CH-4334 Sisseln, Switzerland

for sale by:
DSM affiliates & authorized distributors
Made in U.S.A.

DSM Nutritional Products Ltd., Wurmisweg 576, CH-4303 Kaiseraugst, Switzerland, +41 61 689 33 33
DSM Nutritional Products Europe Ltd., Klünenfeldstrasse 22,Muttenz,CH-4127 Birsfelden, Switzerland, +41 61 68 71777
DSM Nutritional Products Nederland BV, Global Distribution Centre (alpha NL 30341), Columbusweg 24, NL-5928 LC Venlo, Netherlands, +31 (77) 389 44 00
DSM Nutritional Products Asia Pacific Pte.Ltd.,78 Shenton Way #21-00,MCL Building,Singapore 079120,+65 63256200
DSM China Ltd, Ocean Tower 22F, 550 Yan An East Road, Shanghai 200001, P.R.China, +86 21 3310 4988
DSM Produtos Nutricionais Brasil Ltda.,Av.Eng.Billings 1729-Predio 9,05321-900 São Paulo,SP Brasil,+55113719-4566
DSM Nutritional Products, Inc., 45 Waterview Blvd, Parsippany NJ 07054-1298, USA, +1 800 526 0189

Manufacturing Date: / Fecha de fabricación: / Date de fabrication: / Data di produzione: / Herstellungs-Datum:	Best use before: / Fecha de caducidad: / A utiliser avant: / Data di scadenza: / Mindestens haltbar:	Net weight: / Peso neto: / Poids net: / Peso netto: / Nettogewicht:
12.2007	12.2009	25 kg

(S) V-NN 0282049.0000 p

DSM V 001

Ⓤ FloraGLO® Lutein 20% Safflower Oil

KH PRINT

0001

Suspension of micro-crystalline lutein in safflower oil. Contains minimum 20% lutein (E161b*).

Ingredients:
Lutein (extract from Tagetes erecta), safflower oil.

Caution:
For manufacturing, processing or repacking. Not for retail sale. Store in a cool, dry place. Keep package closed. Prior to use, heat unopened container in a water bath to 40°C, shake/stir it gently. Once opened, use contents quickly.

FloraGLO® is a trademark of Kemin Industries, Inc.

*E161b is the resp. European food additive number.

Suspensión de luteina micro-cristalino en aceite de cártamo. Contiene un mínimo de 20% de luteína (E161b).

Ingredientes:
Luteína (sacar de Tagetes erecta), aceite de cártamo.

Atención:
Para uso industrial no para venta directa. Almacenar cerrado en lugar seco y fresco. Antes de abrir, calentar el envase en baño maria a 40°C, agitese con cuidado. Una vez abierto utilícese rápidamente.

Suspension de lutéine micro-cristallisée dans de l'huile de carthame. Contient au minimum 20% de lutéine (E161b).

Ingrédients:
Lutéine (extrait de Tagetes erecta), huile de carthame.

Remarque:
Destiné à l'utilisation industrielle et non à la vente au détail. Conserver fermé au sec et au frais. Avant utilisation, chauffer au bain-marie le récipient fermé à 40°C, agiter soigneusement. À utiliser rapidement après ouverture de l'emballage.

Sospensione micro-cristallina di luteina in olio di cartamo. Contiene minimo 20% di luteina (E161b).

Ingredienti:
Luteina (estrarre da Tagetes erecta), olio di cartamo.

Avviso:
Da impiegare unicamente ai fini della produzione. Esclusa la vendita al dettaglio. Conservare chiuso in luogo asciutto e fresco. Prima dell'uso, scaldare il recipiente chiuso a bagno maria fino a 40°C. Agitare leggermente. Dopo l'apertura utilizzare il contenuto rapidamente.

Suspension von mikrokristallinem Lutein in Färberdistelöl. Enthält mind. 20% Lutein (E161b).

Zusammensetzung:
Lutein (Extrakt von Tagetes erecta), Färberdistelöl.

Hinweis:
Nur für die Weiterverarbeitung bestimmt, nicht für den Verkauf im Einzelhandel. In geschlossenem Behälter kühl und trocken lagern. Vor Gebrauch Behälter ungeöffnet in einem Wasserbad auf 40°C erwärmen und vorsichtig schütteln. Angebrochene Verpackung kurzfristig aufbrauchen.

Code 5009472298

Lot 0802100399

Manufactured for:
DSM Nutritional Products Ltd , Site Sisseln
Hauptstrasse 4, CH-4334 Sisseln, Switzerland

for sale by:
DSM affiliates & authorized distributors
Made in U.S.A.

DSM Nutritional Products Ltd., Wurmisweg 576, CH-4303 Kaiseraugst, Switzerland, +41 61 688 33 33

DSM Nutritional Products Europe Ltd., Klingenfeldstrasse 22,Muttenz,CH-4127 Birsfelden, Switzerland, +41 61 68 71777
DSM Nutritional Products Nederland BV, Global Distribution Centre (alpha NL 30341), Columbusweg 24, NL-5928 LC Venlo, Netherlands, +31 (77) 389 44 00
DSM Nutritional Products Asia Pacific Pte.Ltd.,78 Shenton Way #21-00,MCL Building,Singapore 079120,+65 63256200
DSM China Ltd, Ocean Tower 22F, 550 Yan An East Road, Shanghai 200001, P.R.China, +86 21 3310 4988
DSM Produtos Nutricionais Brasil Ltda.,Av Eng.Billings 1729-Predio 9,05321-900 São Paulo,SP Brasil,+55113719-4566
DSM Nutritional Products, Inc., 45 Waterview Blvd, Parsippany NJ 07054-1298, USA, +1 800 5280189

Manufacturing Date: / Fecha de fabricación: / Date de fabrication: / Data di produzione: / Herstellungs-Datum:	Best use before: / Fecha de caducidad: / A utiliser avant: / Data di scadenza: / Mindestens haltbar:	Net weight: / Peso neto: / Poids net: / Peso netto: / Nettogewicht:
02.2008	01.2010	25 kg

FloraGLO® LUTEIN

KEMIN®

Crystalline Dry

DSM Product: 0489263344

PRODUCT 080187-20-WW

A dietary ingredient composed of crystalline lutein obtained from marigold oleoresin, which is extracted from marigold flowers.

DIRECTIONS:

Store at room temperature in a dry and odor-free environment. Shelf life is a minimum of 1 year in unopened containers.

INGREDIENTS:

Lutein and Zeaxanthin

Manufactured under the following patents: U.S. RE40,912 E, RE40,931 E, RE40,938 E, and 5,648,564, Canada 2,239,971, Japan 2,790,212 and 3,190,686, Australia 700,719, Austria E191475, Belgium 0904258 and 0672655, Denmark 0672655, France 0904258 and 0672655, Germany 69516031 and 69620258, Ireland 0904258 and 0672655, Israel 124987, Italy 0672655, Korea 214430, Netherlands 0672655, New Zealand 319,825, Mexico 205122, Portugal 0672655, Spain 2147261, Sweden 95300273, Switzerland 0904258 and 0672655, and United Kingdom 0904258 and 0672655.

LOT NO. 0123456789

MFG. DATE: JUN 10

The manufacturer makes no warranties, expressed or implied, concerning this product or its use, which extend beyond the description on the face hereof. All statements made concerning this product apply only when used as directed.

FOR MANUFACTURING USE.

TAKE TIME

OBSERVE LABEL DIRECTIONS

Manufactured by:

KEMIN HEALTH, L.C.
DES MOINES, IOWA U.S.A. 50317

NET WT. 20 KG (44.09 LB)

HALAL

030102

001

DSM

V 007

© Lutein 20% FS

0003

Lutein 20% FS

Suspension of micro-crystalline lutein in vegetable oil. Contains minimum 20% lutein (E161b*).

Ingredients:
Lutein, corn oil, dl-alpha-tocopherol.

Caution:

For manufacturing, processing or repacking. Not for retail sale. Store in a cool, dry place. Keep package closed. Prior to use, heat unopened container in a water bath to 40°C, shake/stir it gently. Once opened, use contents quickly. Sealed under nitrogen.

*E161b is the resp. European food additive number.

Luteina 20% FS

Suspensión de luteina micro-cristalino en aceite vegetal. Contiene un mínimo de 20% de luteina (E161b).

Ingredientes:
Luteina, aceite de maíz, dl-alfa-tocoferol.

Atención:

Para uso industrial no para venta directa. Almacenar cerrado en lugar seco y fresco. Antes de abrir, calentar el envase en baño maria a 40°C, agitese con cuidado. Una vez abierto utilícese rápidamente. Envasado en atmósfera de nitrógeno.

Lutéine 20% FS

Suspension de lutéine micro-cristallisé dans de l'huile végetale. Contient au minimum 20% de lutéine (E161b).

Ingrédients:
Lutéine, huile de maïs, dl-alpha-tocophérol.

Remarque:

Destiné à l'utilisation industrielle et non à la vente au détail. Conserver fermé au sec et au frais. Avant utilisation, chauffer au bain-marie le récipient fermé à 40°C, agiter soigneusement. A utiliser rapidement après ouverture de l'emballage. Sous atmosphère d'azote.

Luteina 20% FS

Sospensione micro-cristallina di luteina in olio vegetale. Contiene minimo 20% di luteina (E161b).

Ingredienti:
Luteina, olio di mais, dl-alfa-tocoferolo.

Avviso:

Da impiegare unicamente ai fini della produzione. Esclusa la vendita al dettaglio. Conservare chiuso in luogo asciutto e fresco. Prima dell'uso, scaldare il recipiente chiuso a bagno maria fino a 40°C. Agitare leggermente. Dopo l'apertura utilizzare il contenuto rapidamente. Sigillato sotto azoto.

Lutein 20% FS

Suspension von mikrokristallinem Lutein in Pflanzenöl. Enthält mind. 20% Lutein (E161b).

Zusammensetzung:
Lutein, Maisöl, dl-alpha-Tocopherol.

Hinweis:

Nur für die Weiterverarbeitung bestimmt, nicht für den Verkauf im Einzelhandel. In geschlossenem Behälter kühl und trocken lagern. Vor Gebrauch Behälter ungeöffnet in einem Wasserbad auf 40°C erwärmen und vorsichtig schütteln. Angebrochene Verpackung kurzfristig aufbrauchen. Mit Stickstoff begast.

Code 5000742694

Lot WA03292005

XPL0058103

Further processed by:
DSM Nutritional Products France SAS
1 boulevard d'Alsace,
F-68128 Village Neuf, France
for sale by:
DSM affiliates & authorized distributors
Made in U.S.A.

DSM Nutritional Products Ltd., Wurmisweg 576, CH-4303 Kaiseraugst, Switzerland, +41 61 688 33 33

DSM Nutritional Products Europe Ltd.,Klünenfeldstrasse 22,Muttenz,CH-4127 Birsfelden,Switzerland, +41 61 68 71777
DSM Nutritional Products Nederland BV, Global Distribution Centre (alpha NL 30341), Columbusweg 24, NL-5902 RJ Venlo, Netherlands, +31 (77) 389 44 00
DSM Nutritional Products Asia Pacific Pte.Ltd.,78 Shenton Way #21-00,MCL Building,Singapore 079120,+65 63256200
DSM China Ltd, Ocean Tower 22F, 550 Yan An East Road, Shanghai 200001, P.R.C., +86 21 3310 4988
DSM Produtos Nutricionais Brasil Ltda.,Av.Eng.Billings 1729-Predio 9,05321-900 São Paulo,SP Brasil,+55113719-4566
DSM Nutritional Products, Inc., 45 Waterview Blvd, Parsippany NJ 07054-1298, USA, +1 800 526 0189

Manufacturing date: / Fecha de fabricación: / Date de fabrication: / Data di produzione: / Herstellungs-Datum:	Best use before: / Fecha de caducidad: / A utiliser avant: / Data di scadenza: / Mindestens haltbar:	Net weight: / Peso neto: / Poids net: / Peso netto: / Nettogewicht:
03.2005	09.2006	5 kg

DSM

V 003

© FloraGLO®Lutein 20% SAF

00001

Suspension of microcrystalline lutein in vegetable oil. Contains minimum 20% lutein (E161b*).

Ingredients:
Lutein (JECFA) (extract from Tagetes erecta), safflower oil, dl-alpha- tocopherol.

Caution:
For manufacturing, processing or repacking. Not for retail sale. Store in a cool, dry place. Keep package closed. Prior to use, heat unopened container in a water bath to 40°C, shake/stir it gently. Once opened, use contents quickly.

FloraGLO® is a trademark of Kemin Industries, Inc

*For food, E161b is the resp. European food additive number.

Suspensión de luteina micro-cristalina en aceite vegetal. Contiene un mínimo de 20% de luteína (E161b*).

Ingredientes:
Luteína (JECFA) (sacar de Tagetes erecta), aceite de cártamo, dl-alfa-tocoferol.

Atención:
Para uso industrial no para venta directa. Almacenar cerrado en lugar seco y fresco. Antes de abrir, calentar el envase en baño maria a 40°C, agitese con cuidado. Una vez abierto utilícese rápidamente.

*Destinado a la alimentación, E161b es el resp. Número Europeo de aditivo alimentario.

Suspension de lutéine micro-cristallisé dans de l'huile végetale. Contient au minimum 20% de lutéine (E161b*).

Ingrédients:
Lutéine (JECFA) (extrait de Tagetes erecta), huile de carthame, dl-alpha-tocophérol.

Remarque:
Destiné à l'utilisation industrielle et non à la vente au détail. Conserver fermé au sec et au frais. Avant utilisation, chauffer au bain-marie le récipient fermé à 40°C, agiter soigneusement. A utiliser rapidement après ouverture de l'emballage.

*Pour denrées alimentaires, E161b correspond à la numérotation Européenne des additifs alimentaires.

Sospensione micro-cristallina di luteina in olio vegetale. Contiene minimo 20% di luteina (E161b*).

Ingredienti:
Luteina (JECFA) (estrarre da Tagetes erecta), olio di cartamo, dl-alfa-tocoferolo.

Avviso:
Da impiegare unicamente ai fini della produzione. Esclusa la vendita al dettaglio. Conservare chiuso in luogo asciutto e fresco. Prima dell'uso, scaldare il recipiente chiuso a bagno maria fino a 40°C. Agitare leggermente. Dopo l'apertura utilizzare il contenuto rapidamente.

*Per alimenti, il numero rispettivo per gli additivi alimentari in Europa è E161b.

Suspension von mikrokristallinem Lutein in Pflanzenöl. Enthält mind. 20% Lutein (E161b*).

Zusammensetzung:
Lutein (JECFA) (Extrakt von Tagetes erecta), Färberdistelöl, dl-alpha-Tocopherol.

Hinweis:
Nur für die Weiterverarbeitung bestimmt, nicht für den Verkauf im Einzelhandel. In geschlossenem Behälter kühl und trocken lagern. Vor Gebrauch Behälter ungeöffnet in einem Wasserbad auf 40°C erwärmen und vorsichtig schütteln. Angebrochene Verpackung kurzfristig aufbrauchen.

* Für Lebensmittel, E161b ist die Europäische Zusatzstoffnummer.

Code 5011876635

Lot EXAMPLE

Further processed by:
DSM Nutritional Products France SAS
1 boulevard d'Alsace,
F-68128 Village Neuf, France

for sale by:
DSM affiliates & authorized distributors
Made in: **U.S.A.**

DSM Nutritional Products Ltd.,P.O.Box2676,4002 Basel,Switzerland,+41 618158888 Emergency N° +41 628662314
DSM Nutritional Products Europe Ltd., P.O. Box 2676, 4002 Basel, Switzerland, +41 61 815 77 77
DSM Nutritional Products Nederland BV, Global Distribution Centre (alpha NL 30341), Columbusweg 24, NL-5928 LC Venlo, Netherlands, +31 (77) 389 44 00
DSM Nutritional Products Asia Pacific Pte Ltd, 2 Havelock Road #04-01,2HR,Singapore 059763,+65 66326500
DSM(China)Ltd.,No.476,Li Bing Road,Zhangjiang High-TechPark,Pudong Area,Shanghai201203,PRC,+862161418188
DSM Produtos Nutricionais Brasil Ltda.,Av.Eng.Billings 1729-Predio 9,05321-900 São Paulo,SP Brasil,+55113719-4566
DSM Nutritional Products, Inc., 45 Waterview Blvd, Parsippany NJ 07054-1298, USA, +1 800 526 0189

Manufacturing date:	Best use before:	Net weight:
Date de fabrication:	A utiliser avant:	Poids net:
Fecha de fabricación:	Fecha de caducidad:	Peso neto:
Data di produzione:	Data di scadenza:	Peso netto:
Herstellungs-Datum:	Mindestens haltbar:	Nettogewicht:
30-DEC-2010	**29-DEC-2013**	**20kg**

(01) 97613221081770 (17) 131229 (3102) 002000 (10) EXAMPLE

Appendix D

MSDS

1. FloraGLO® Lutein 5% Liquid in Corn Oil MSDS
2. FloraGLO® Lutein 5% VG Granules MSDS
3. FloraGLO® Lutein 10% VG TabGrade™ MSDS
4. FloraGLO® Lutein 20% Liquid in Corn Oil MSDS
5. FloraGLO® Lutein 20% Liquid in Safflower Oil MSDS
6. FloraGLO® Crystalline Lutein MSDS
7. FloraGLO® Lutein 20% FS MSDS
8. FloraGLO® Lutein 20% SAF MSDS

KEMIN INSPIRED MOLECULAR SOLUTIONS™

Material Safety Data Sheet

Kemin Health, L.C. suggests the customer receiving this Material Safety Data Sheet (MSDS) to study the information provided carefully to become aware of the hazards, if any, of the product involved. In the interest of safety, you should: (1) Notify your employees, agents, contractors of the information on this sheet and (2) furnish a copy to each of your customers to inform their employees and customers as well.

I. GENERAL INFORMATION

TRADE NAME FloraGLO® Lutein 5% Liquid in Corn Oil	CHEMICAL FAMILY Carotenoids
PROPER DOT SHIPPING NAME None	DOT HAZARD CLASSIFICATION N/A
MANUFACTURER Kemin Health, L.C.	MANUFACTURER PHONE NUMBER 866.536.4666
ADDRESS 2100 Maury Street, Bldg. 3	CITY/STATE/ZIP Des Moines, Iowa 50317

II. INGREDIENTS

PRINCIPAL COMPONENTS	CAS NUMBER	PERCENT	THRESHOLD LIMIT VALUE
Corn Oil	8001-30-7	N/A	N/A
Lutein & Zeaxanthin	127-40-2	N/A	N/A

III. PHYSICAL DATA

COLOR & STATE:	Red-orange Liquid	ODOR:	Slightly oily
VISCOSITY:	120 cps at 50 rpm	SOLUBILITY IN WATER:	N/A
VAPOR PRESSURE:	N/A	SPECIFIC GRAVITY:	0.92-0.93
VAPOR DENSITY:	N/A	PERCENT VOLATILE:	less than 3%
EVAPORATION RATE:	N/A	pH:	9.0-10.0

IV. FIRE & EXPLOSION HAZARD DATA

FLASH POINT (TEST METHOD):	(620-630ºF) Tag Closed Cup ASTM D56-79
FLAMMABLE LIMITS:	LEL: N/A UEL: N/A
EXTINGUISHING MEDIA:	Use foam, CO_2, or dry chemical extinguishing media.
SPECIAL FIRE FIGHTING PROCEDURES:	Avoid contact with hot oil. Wear protective clothing.
UNUSUAL FIRE & EXPLOSION HAZARDS:	None

V. HEALTH HAZARD DATA

EYE CONTACT:	Flush eyes with water at least 15 minutes. Consult a physician.
SKIN CONTACT:	May cause discoloration of skin. Wash with soap and water.
INHALATION:	Handle in well ventilated area. Move to fresh air.
INGESTION:	Safe when ingested in reasonable quantities.

VI. REACTIVITY DATA			
STABILITY:	Unstable.....☐ Stable.....☑	CONDITIONS TO AVOID:	N/A
INCOMPATIBILITY:	None	MATERIALS TO AVOID:	N/A
HAZARDOUS POLYMERIZATION:	May Occur ....☐ Not Occur.....☑	CONDITIONS TO AVOID:	N/A
HAZARDOUS DECOMPOSITION PRODUCTS:	None		

VII: ENVIRONMENTAL PROTECTION PROCEDURES	
SPILL RESPONSE:	Prevent entry into sewers and waterways. Absorb oil mixture with inert material and dispose properly.
WASTE DISPOSAL:	Dispose in accordance with federal, state, and local regulations.

VIII: SPECIAL PROTECTION INFORMATION	
EYE PROTECTION: Goggles recommended.	SKIN PROTECTION: Avoid prolonged exposure. Rubber gloves recommended.
RESPIRATORY INFORMATION: Use a NIOSH approved respirator.	VENTILATION RECOMMENDED Local exhaust recommended.
	OTHER PROTECTION: N/A

IX. SPECIAL PRECAUTIONS
OTHER PRECAUTIONS: N/A

ISSUE DATE:	01Dec12	SUPERSEDES:	NEW

We believe that the information contained herein is current as of the date of this Material Data Safety Sheet. Since the use of this information and the conditions of the use of the product are not under the control of Kemin Health, L.C., it is the user's obligation to determine conditions of safe use of the product. The data contained above are not to be taken as a warranty or representation for which Kemin Health, L.C. assumes legal responsibility. They are offered only for your consideration and verification.

KEMIN INSPIRED MOLECULAR SOLUTIONS™

Material Safety Data Sheet

Kemin Health, L.C. suggests the customer receiving this Material Safety Data Sheet (MSDS) to study the information provided carefully to become aware of the hazards, if any, of the product involved. In the interest of safety, you should: (1) Notify your employees, agents, contractors of the information on this sheet and (2) furnish a copy to each of your customers to inform their employees and customers as well.

I. GENERAL INFORMATION

TRADE NAME FloraGLO® Lutein 5% VG Granules	CHEMICAL FAMILY Xanthophyll
PROPER DOT SHIPPING NAME None	DOT HAZARD CLASSIFICATION N/A
MANUFACTURER Kemin Health, L.C.	MANUFACTURER PHONE NUMBER 866.536.4666
ADDRESS 2100 Maury Street, Bldg. 3	CITY/STATE/ZIP Des Moines, Iowa 50317

II. INGREDIENTS

PRINCIPAL COMPONENTS	CAS NUMBER	PERCENT	THRESHOLD LIMIT VALUE
Sucrose	57-50-1	~70	N/A
Modified Food Starch	N/A	~21	N/A
Lutein & Zeaxanthin	127-40-2	~9	N/A

III. PHYSICAL DATA

COLOR & STATE:	Orange-Red, Solid	ODOR:	Bland
VISCOSITY:	N/A	SOLUBILITY IN WATER:	1 g/100 ml cold water. 10 g/100 ml hot water. Partially soluble in organic solvents
VAPOR PRESSURE:	N/A	SPECIFIC GRAVITY:	1.0 g/ml
VAPOR DENSITY:	N/A	PERCENT VOLATILE:	N/A
EVAPORATION RATE:	N/A	pH:	N/A

IV. FIRE & EXPLOSION HAZARD DATA

FLASH POINT (TEST METHOD):	(>300ºC) Tag Closed Cup ASTM D56-79
FLAMMABLE LIMITS:	LEL: N/A UEL: N/A
EXTINGUISHING MEDIA:	Use foam, CO_2, or dry chemical extinguishing media.
SPECIAL FIRE FIGHTING PROCEDURES:	Wear protective clothing with self-contained breathing apparatus.
UNUSUAL FIRE & EXPLOSION HAZARDS:	None

V. HEALTH HAZARD DATA

EYE CONTACT:	Flush eyes with water at least 15 minutes. Consult a physician.
SKIN CONTACT:	May cause discoloration of skin. Wash with soap and water.
INHALATION:	Handle in well ventilated area. Immediately move to fresh air.
INGESTION:	Safe when ingested in reasonable quantities.

VI. REACTIVITY DATA			
STABILITY:	Unstable.....☐ Stable.....☑	CONDITIONS TO AVOID:	N/A
INCOMPATIBILITY:	None	MATERIALS TO AVOID:	N/A
HAZARDOUS POLYMERIZATION:	May Occur ☐ Not Occur…☑	CONDITIONS TO AVOID:	N/A
HAZARDOUS DECOMPOSITION PRODUCTS:	None		

VII: ENVIRONMENTAL PROTECTION PROCEDURES	
SPILL RESPONSE:	Sweep or vacuum up granules.
WASTE DISPOSAL:	Dispose in accordance with federal, state, and local regulations.

VIII: SPECIAL PROTECTION INFORMATION	
EYE PROTECTION: Goggles recommended.	SKIN PROTECTION: Avoid prolonged exposure. Rubber gloves recommended.
RESPIRATORY INFORMATION: Use a NIOSH approved respirator.	VENTILATION RECOMMENDED Local exhaust recommended.
	OTHER PROTECTION: N/A

IX. SPECIAL PRECAUTIONS	
HANDLING:	N/A
STORAGE:	N/A
OTHER:	N/A

X. TRANSPORTATION DATA AND ADDITIONAL INFORMATION
N/A

XI. KEY FOR ACRONYMS
N/A

ISSUE DATE:	10Jun02	SUPERSEDES:	04Feb20

We believe that the information contained herein is current as of the date of this Material Data Safety Sheet. Since the use of this information and the conditions of the use of the product are not under the control of Kemin Health, L.C., it is the user's obligation to determine conditions of safe use of the product. The data contained above are not to be taken as a warranty or representation for which Kemin Health, L.C. assumes legal responsibility. They are offered only for your consideration and verification.

KEMIN INSPIRED MOLECULAR SOLUTIONS™

Material Safety Data Sheet

Kemin Health, L.C. suggests the customer receiving this Material Safety Data Sheet (MSDS) to study the information provided carefully to become aware of the hazards, if any, of the product involved. In the interest of safety, you should: (1) Notify your employees, agents, contractors of the information on this sheet and (2) furnish a copy to each of your customers to inform their employees and customers as well.

I. GENERAL INFORMATION	
TRADE NAME FloraGLO® Lutein 10% VG TabGrade™	CHEMICAL FAMILY Xanthophyll
PROPER DOT SHIPPING NAME None	DOT HAZARD CLASSIFICATION N/A
MANUFACTURER Kemin Health, L.C.	MANUFACTURER PHONE NUMBER 866.536.4666
ADDRESS 2100 Maury Street, Bldg. 3	CITY/STATE/ZIP Des Moines, IA 50317

II. INGREDIENTS			
PRINCIPAL COMPONENTS	CAS NUMBER	PERCENT	THRESHOLD LIMIT VALUE
Sucrose	57-50-1	~56	N/A
Modified Food Starch	N/A	~27	N/A
Lutein	127-40-2	~17	N/A

III. PHYSICAL/ CHEMICAL DATA			
COLOR & STATE:	Red-Orange, Solid	ODOR:	Bland
VISCOSITY:	N/A	SOLUBILITY IN WATER:	1 g/100 ml cold water. 10 g/100 ml hot water. Partially soluble in organic solvents
VAPOR PRESSURE:	N/A	SPECIFIC GRAVITY:	1.0 g/ml
VAPOR DENSITY:	N/A	PERCENT VOLATILE:	N/A
EVAPORATION RATE:	N/A	pH:	N/A

IV. FIRE & EXPLOSION HAZARD DATA	
FLASH POINT (TEST METHOD):	(>300ºC) Tag Closed Cup ASTM D56-79
FLAMMABLE LIMITS:	LEL: N/A UEL: N/A
EXTINGUISHING MEDIA:	Use foam, CO_2, or dry chemical extinguishing media.
SPECIAL FIRE FIGHTING PROCEDURES:	Wear protective clothing with self-contained breathing apparatus.
UNUSUAL FIRE & EXPLOSION HAZARDS:	None

V. HEALTH HAZARD DATA	
EYE CONTACT:	Flush eyes with water at least 15 minutes. Consult a physician.
SKIN CONTACT:	May cause discoloration of skin. Wash with soap and water.
INHALATION:	Handle in well ventilated area. Immediately move to fresh air.
INGESTION:	Safe when ingested in reasonable quantities.

VI. REACTIVITY DATA			
STABILITY:	Unstable..... ☐ Stable..... ☑	CONDITIONS TO AVOID:	N/A
INCOMPATIBILITY:	None	MATERIALS TO AVOID:	N/A
HAZARDOUS POLYMERIZATION:	May Occur .... ☐ Not Occur..... ☑	CONDITIONS TO AVOID:	N/A
HAZARDOUS DECOMPOSITION PRODUCTS:	None		

VII: ENVIRONMENTAL PROTECTION PROCEDURES	
SPILL RESPONSE:	Sweep or vacuum up granules.
WASTE DISPOSAL:	Dispose in accordance with federal, state, and local regulations.

VIII: SPECIAL PROTECTION INFORMATION	
EYE PROTECTION: Goggles recommended.	SKIN PROTECTION: Avoid prolonged exposure. Rubber gloves recommended.
RESPIRATORY INFORMATION: Use a NIOSH approved respirator.	VENTILATION RECOMMENDED Local exhaust recommended.
	OTHER PROTECTION: N/A

IX. SPECIAL PRECAUTIONS	
HANDLING:	N/A
STORAGE:	N/A
OTHER:	N/A

X. TRANSPORTATION DATA AND ADDITIONAL INFORMATION
N/A

XI. KEY FOR ACRONYMS
N/A

ISSUE DATE:	10Jun02	SUPERSEDES:	06Apr21

We believe that the information contained herein is current as of the date of this Material Data Safety Sheet. Since the use of this information and the conditions of the use of the product are not under the control of Kemin Health, L.C., it is the user's obligation to determine conditions of safe use of the product. The data contained above are not to be taken as a warranty or representation for which Kemin Health, L.C. assumes legal responsibility. They are offered only for your consideration and verification.

KEMIN INSPIRED MOLECULAR SOLUTIONS™

Material Safety Data Sheet

Kemin Health, L.C. suggests the customer receiving this Material Safety Data Sheet (MSDS) to study the information provided carefully to become aware of the hazards, if any, of the product involved. In the interest of safety, you should: (1) Notify your employees, agents, contractors of the information on this sheet and (2) furnish a copy to each of your customers to inform their employees and customers as well.

I. GENERAL INFORMATION

TRADE NAME FloraGLO® Lutein 20% Liquid in Corn Oil	CHEMICAL FAMILY Carotenoids
PROPER DOT SHIPPING NAME None	DOT HAZARD CLASSIFICATION N/A
MANUFACTURER Kemin Health, L.C.	MANUFACTURER PHONE NUMBER (866.536.4666
ADDRESS 2100 Maury Street, Bldg. 3	CITY/STATE/ZIP Des Moines, Iowa 50317

II. INGREDIENTS

PRINCIPAL COMPONENTS	CAS NUMBER	PERCENT	THRESHOLD LIMIT VALUE
Corn Oil	8001-30-7	N/A	N/A
Lutein & Zeaxanthin	127-40-2	N/A	N/A

III. PHYSICAL DATA

COLOR & STATE:	Orange Liquid	ODOR:	Slightly oily
VAPOR PRESSURE:	N/A	SPECIFIC GRAVITY:	0.93-0.95
VAPOR DENSITY:	N/A	PERCENT VOLATILE:	less than 3%
EVAPORATION RATE:	N/A	pH:	9.0-10.0
SOLUBILITY IN WATER:	N/A		

IV. FIRE & EXPLOSION HAZARD DATA

FLASH POINT (TEST METHOD):	(620-630°F) Tag Closed Cup ASTM D56-79
FLAMMABLE LIMITS:	LEL: N/A UEL: N/A
EXTINGUISHING MEDIA:	Use foam, CO_2, or dry chemical extinguishing media.
SPECIAL FIRE FIGHTING PROCEDURES:	Avoid contact with hot oil. Wear protective clothing.
UNUSUAL FIRE & EXPLOSION HAZARDS:	None

V. HEALTH HAZARD DATA

EYE CONTACT:	Flush eyes with water at least 15 minutes. Consult a physician.
SKIN CONTACT:	May cause discoloration of skin. Wash with soap and water.
INHALATION:	Handle in well ventilated area. Immediately move to fresh air.
INGESTION:	Safe when ingested in reasonable quantities.

VI. REACTIVITY DATA		
STABILITY:	Unstable.....☐ Stable.....☑	CONDITIONS TO AVOID: N/A
INCOMPATIBILITY:	None	MATERIALS TO AVOID: N/A
HAZARDOUS POLYMERIZATION:	May Occur ....☐ Not Occur.....☑	CONDITIONS TO AVOID: N/A
HAZARDOUS DECOMPOSITION PRODUCTS:	None	

VII: ENVIRONMENTAL PROTECTION PROCEDURES	
SPILL RESPONSE:	Prevent entry into sewers and waterways. Absorb the oil mixture with inert material and dispose properly.
WASTE DISPOSAL:	Dispose in accordance with federal, state, and local regulations.

VIII: SPECIAL PROTECTION INFORMATION	
EYE PROTECTION: Goggles recommended.	SKIN PROTECTION: Avoid prolonged exposure. Rubber gloves recommended.
RESPIRATORY INFORMATION: Use a NIOSH approved respirator.	VENTILATION RECOMMENDED Local exhaust recommended.
	OTHER PROTECTION: N/A

IX. SPECIAL PRECAUTIONS
OTHER PRECAUTIONS: N/A

ISSUE DATE:	02Jan10	SUPERSEDES:	NEW

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KEMIN INSPIRED MOLECULAR SOLUTIONS™

Material Safety Data Sheet

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I. GENERAL INFORMATION

TRADE NAME FloraGLO® Lutein 20% Liquid in Safflower Oil	CHEMICAL FAMILY Carotenoids
PROPER DOT SHIPPING NAME None	DOT HAZARD CLASSIFICATION N/A
MANUFACTURER Kemin Health, L.C.	MANUFACTURER PHONE NUMBER 866.536.4666
ADDRESS 2100 Maury Street, Bldg. 3	CITY/STATE/ZIP Des Moines, Iowa 50317

II. INGREDIENTS

PRINCIPAL COMPONENTS	CAS NUMBER	PERCENT	THRESHOLD LIMIT VALUE
Safflower Oil	8001-23-8	N/A	N/A
Lutein & Zeaxanthin	127-40-2	N/A	N/A

III. PHYSICAL DATA

COLOR & STATE:	Orange Liquid	ODOR:	Slightly oily
VAPOR PRESSURE:	N/A	SPECIFIC GRAVITY:	0.93-0.95
VAPOR DENSITY:	N/A	PERCENT VOLATILE:	less than 3%
EVAPORATION RATE:	N/A	pH:	9.0-10.0
SOLUBILITY IN WATER:	N/A		

IV. FIRE & EXPLOSION HAZARD DATA

FLASH POINT (TEST METHOD):	(620-630°F) Tag Closed Cup ASTM D56-79
FLAMMABLE LIMITS:	LEL: N/A UEL: N/A
EXTINGUISHING MEDIA:	Use foam, CO_2, or dry chemical extinguishing media.
SPECIAL FIRE FIGHTING PROCEDURES:	Avoid contact with hot oil. Wear protective clothing.
UNUSUAL FIRE & EXPLOSION HAZARDS:	None

V. HEALTH HAZARD DATA

EYE CONTACT:	Flush eyes with water at least 15 minutes. Consult a physician.
SKIN CONTACT:	May cause discoloration of skin. Wash with soap and water.
INHALATION:	Handle in well ventilated area. Immediately move to fresh air.
INGESTION:	Safe when ingested in reasonable quantities.

VI. REACTIVITY DATA		
STABILITY:	Unstable.....☐ Stable.....☑	CONDITIONS TO AVOID: N/A
INCOMPATIBILITY:	None	MATERIALS TO AVOID: N/A
HAZARDOUS POLYMERIZATION:	May Occur ....☐ Not Occur.....☑	CONDITIONS TO AVOID: N/A
HAZARDOUS DECOMPOSITION PRODUCTS:	None	

VII: ENVIRONMENTAL PROTECTION PROCEDURES	
SPILL RESPONSE:	Prevent entry into sewers and waterways. Absorb the oil mixture with inert material and dispose properly.
WASTE DISPOSAL:	Dispose in accordance with federal, state, and local regulations.

VIII: SPECIAL PROTECTION INFORMATION	
EYE PROTECTION: Goggles recommended.	SKIN PROTECTION: Avoid prolonged exposure. Rubber gloves recommended.
RESPIRATORY INFORMATION: Use a NIOSH approved respirator.	VENTILATION RECOMMENDED Local exhaust recommended.
	OTHER PROTECTION: N/A

IX. SPECIAL PRECAUTIONS
OTHER PRECAUTIONS: N/A

ISSUE DATE:	02Jan10	SUPERSEDES:	NEW

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KEMIN INSPIRED MOLECULAR SOLUTIONS™

Material Safety Data Sheet

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I. GENERAL INFORMATION	
TRADE NAME FloraGLO® Crystalline Lutein	CHEMICAL FAMILY Xanthophylls
PROPER DOT SHIPPING NAME None	DOT HAZARD CLASSIFICATION N/A
MANUFACTURER Kemin Health, L.C.	MANUFACTURER PHONE NUMBER 866.536.4666
ADDRESS 2100 Maury Street, Bldg. 3	CITY/STATE/ZIP Des Moines, Iowa 50317

II. INGREDIENTS			
PRINCIPAL COMPONENTS	CAS NUMBER	PERCENT	THRESHOLD LIMIT VALUE
Lutein Zeaxanthin	127-40-2 144-68-3	N/A N/A	N/A N/A

III. PHYSICAL DATA			
COLOR & STATE:	Deep Orange Powder		
MELTING POINT:	177-178°C	SOLUBILITY:	In Ethyl Alcohol
VAPOR DENSITY:	N/A	BULK DENSITY:	0.35 – 0.40 g/ml

IV. FIRE & EXPLOSION HAZARD DATA	
FLASH POINT (TEST METHOD): N/A	
FLAMMABLE LIMITS:	LEL: N/A UEL: N/A
EXTINGUISHING MEDIA:	Water spray, carbon dioxide, dry chemical powder or appropriate foam.
SPECIAL FIRE FIGHTING PROCEDURES:	Wear a self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.
UNUSUAL FIRE & EXPLOSION HAZARDS:	This material can burn if heated in a confined area

V. HEALTH HAZARD DATA	
EYE CONTACT:	Flush eyes with water at least 15 minutes. Consult a physician.
SKIN CONTACT:	May cause discoloration of skin. Wash with soap and water.
INHALATION:	Handle in well ventilated area. Immediately move to fresh air. If not breathing give artifical respiration. If breathing is difficult, give oxygen.
INGESTION:	If swallowed, wash mouth out with water provided the person is conscious. May cause upset stomach.
EMERGENCY FIRST AID:	Whenever first aid is required, it should be given immediately. Prompt treatment may greatly decrease the severity of the effect.

VI. REACTIVITY DATA			
STABILITY:	Unstable.....☐ Stable.....☑	CONDITIONS TO AVOID:	Heat Air
INCOMPATIBILITY:	None	MATERIALS TO AVOID:	Acids Strong oxidizing agent
HAZARDOUS POLYMERIZATION: HAZARDOUS DECOMPOSITION PRODUCTS:	May Occur ....☐ Not Occur.....☑ Toxic Fumes of: Carbon Monoxide Carbon Dioxide	CONDITIONS TO AVOID:	N/A

VII: ENVIRONMENTAL PROTECTION PROCEDURES	
WASTE DISPOSAL:	Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber. Observe all federal, state and local environmental regulations.

VIII: SPECIAL PROTECTION INFORMATION	
EYE PROTECTION: Chemical safety goggles. Avoid contact with eyes.	SKIN PROTECTION: Compatible chemical resistant gloves. Avoid contact with skin. Contact will cause temporary skin discoloration.
RESPIRATORY INFORMATION: Use a NIOSH/MSHA approved respirator. Avoid inhalation.	VENTILATION RECOMMENDED Mechanical exhaust required.
	OTHER PROTECTION: Safety shower and eye bath.

IX. HANDLING AND STORAGE
Keep container closed when not in use. Store in a cool, dark area. Do not expose to sunlight. Wash thoroughly After handling. Avoid prolonged or repeated exposure. Wash contaminated clothing before reuse.

X. TOXICITY
None known

ISSUE DATE:	08Jun04	SUPERSEDES:	03Feb13

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SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name	:	Lutein 20% FS
Product Use Description	:	Ingredient for capsules and/or tablets For the fortification of foods
Company	:	DSM Nutritional Products 45 Waterview Blvd Parsippany NJ 07054-1298
Telephone	:	(908) 475-7373
Telefax	:	(908) 475-7406
Emergency telephone number	:	Emergency # 1-800-424-9300 (24 HR CHEMTREC)

SECTION 2. HAZARDS IDENTIFICATION

Emergency Overview

Form: viscous, oily liquid, Colour: red,

OSHA Hazards : MILD SKIN IRRITANT
MILD EYE IRRITANT

Carcinogenicity:

IARC No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

NTP No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

ACGIH No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Brief description of the product : Mixture (preparation) containing active ingredient and auxiliary substances

Hazardous components

Component	CAS-No.	Weight percent
β,ε-carotene-3,3'-diol	127-40-2	20 - 25
(3R,3'R)-β,β-carotene-3,3'-diol	144-68-3	1 - 2
3,4-dihydro-2,5,7,8-	10191-41-0	1 - 5

tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-ol (dl-α-tocopherol)		

SECTION 4. FIRST AID MEASURES

First aid procedures

General advice : No hazards which require special first aid measures.

Inhalation : Move to fresh air in case of accidental inhalation of dust or fumes from overheating or combustion.
If symptoms persist, call a physician.

Skin contact : Take off contaminated clothing and shoes immediately.
Wash off with soap and plenty of water.

Eye contact : Flush eyes with water as a precaution.
Remove contact lenses.
Protect unharmed eye.
Keep eye wide open while rinsing.

Ingestion : Rinse mouth with water and drink afterwards plenty of water.
Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.

SECTION 5. FIRE-FIGHTING MEASURES

Flammable properties

Flash point : > 392 °F (> 200 °C)

Fire fighting

Suitable extinguishing media : Dry chemical
Alcohol-resistant foam
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media : High volume water jet

Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

Protective equipment and precautions for firefighters

Special protective equipment for fire-fighters : In the event of fire, wear self-contained breathing apparatus.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Environmental precautions : No special environmental precautions required.
Try to prevent the material from entering drains or water courses.

Methods for containment / Methods for cleaning up : Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Handling

Handling : For personal protection see section 8.
No special handling advice required.

Advice on protection against fire and explosion : Take precautionary measures against static discharges.

Storage

Requirements for storage areas and containers : Protect against light.

Keep container tightly closed and dry.

Advice on common storage : No special restrictions on storage with other products.

Storage temperature : < 59 °F (< 15 °C)

Other data : No decomposition if stored and applied as directed.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

Components	CAS-No.	Value	Control parameters	Update	Basis
β,ε-carotene-3,3'-diol	127-40-2	TWA	1 mg/m3		DSM Internal Limit
(3R,3'R)-β,β-carotene-3,3'-diol	144-68-3	TWA	1 mg/m3		DSM Internal Limit

Engineering measures

For technical measures see section 7.

Personal protective equipment

Eye protection : Safety glasses

Hand protection : Glove material: for example nitrile rubber

Skin and body protection : Protective suit

Respiratory protection	:	No personal respiratory protective equipment normally required.
Hygiene measures	:	General industrial hygiene practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Form	:	viscous, oily liquid
Colour	:	red

Safety data

Flash point	:	> 200 °C
Water solubility	:	insoluble
Solubility in other solvents	:	Oils and fats: slightly soluble

SECTION 10. STABILITY AND REACTIVITY

Conditions to avoid	:	Heat.
Materials to avoid	:	Strong acids and strong bases Strong oxidizing agents
Thermal decomposition	:	no data available
Hazardous reactions	:	Stable under recommended storage conditions.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute oral toxicity	:	LD50 (rat): > 5,000 mg/kg (calculated from LD50 of components)
Skin irritation	:	Prolonged skin contact may cause skin irritation.
Eye irritation 3,4-dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-ol	:	Mild eye irritation (rabbit, Draize Test) temporary redness
Sensitisation	:	Did not cause sensitization. (mouse, Local Lymph Node Assay (LLNA), OECD Test Guideline 429) Tested with a similar product containing 1.5% dl-alpha-tocopherol.

SECTION 12. ECOLOGICAL INFORMATION

Biodegradability

β,ε-carotene-3,3'-diol	:	Not readily biodegradable. Test performed using a similar product.
(3R,3'R)-β,β-carotene-3,3'-diol	:	Not readily biodegradable. 2 % (28 d) (OECD Test Guideline 301B)
3,4-dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-ol	:	Not readily biodegradable. 8 % (28 d) (OECD Test Guideline 301F)

Further information on ecology

Additional ecological information	:	There is no data available for this product.

SECTION 13. DISPOSAL CONSIDERATIONS

Further information	:	Offer surplus and non-recyclable solutions to a licensed disposal company. User must determine if any wastes generated exhibit hazardous characteristics as per 40 CFR Part 261 or other national / local legislation.
Contaminated packaging	:	Empty containers should be taken to an approved waste handling site for recycling or disposal.

SECTION 14. TRANSPORT INFORMATION

DOT
Not dangerous goods

TDG
Not dangerous goods

IATA
Not dangerous goods

IMDG
Not dangerous goods

RID
Not dangerous goods

Not classified as dangerous in the meaning of transport regulations.

SECTION 15. REGULATORY INFORMATION

OSHA Hazards : Mild skin irritant, Mild eye irritant
SARA 311/312 Hazards : Acute Health Hazard

EPCRA - EMERGENCY PLANNING COMMUNITY RIGHT - TO – KNOW

SARA 302 Reportable Quantity : SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.
SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.
Clean Air Act
Ozone-Depletion Potential : This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).
This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

Pennsylvania Right To Know Components :	Corn oil	8001-30-7
	beta,epsilon-carotene-3,3'-diol	127-40-2
New Jersey Right To Know Components :	Corn oil	8001-30-7
	beta,epsilon-carotene-3,3'-diol	127-40-2
	(3R,3'R)-beta,beta-carotene-3,3'-diol	144-68-3
	3,4-dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-ol	10191-41-0

The components of this product are reported in the following inventories:

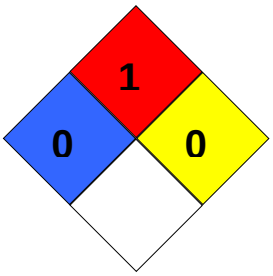
TSCA	Not On TSCA Inventory	
	(3R,3'R)-beta,beta-carotene-3,3'-diol	144-68-3
DSL	This product contains the following components that are not on the Canadian DSL nor NDSL lists.	
	(3R,3'R)-beta,beta-carotene-3,3'-diol	144-68-3
	beta,epsilon-carotene-3,3'-diol	127-40-2

SECTION 16. OTHER INFORMATION

Further information

HMIS Classification : Health hazard: 1
Flammability: 1
Physical hazards: 0

NFPA Classification : Health hazard: 0
Fire Hazard: 1
Reactivity Hazard: 0



The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

E-mail address : sds.nutritionalproducts@dsm.com
Responsible/issuing person

Definitions: ACGIH = American Conference of Governmental Industrial Hygienists. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act. CFR = Code of Federal Regulations. CPR = Controlled Products Regulations. DSL = Canadian Domestic Substance List. DOT = Department of Transportation. EINECS = European Inventory of New and Existing Chemical Substances. EPA = Environmental Protection Agency. HCS = Hazardous Communication Standard. HEPA = High Efficiency Particulate Air. HMIS = Hazardous Material Identification System. IARC = International Agency for Research on Cancer. IATA = International Air Transport Association. IMDG = International Maritime Dangerous Good. NFPA = National Fire Protection Association. NIOSH = National Institute of Occupational Safety and Health. NJTSR = New Jersey Trade Secret Registry. NTP = National Toxicology Program. OSHA = Occupational Safety and Health Administration. SARA = Superfund Amendments and Reauthorization Act. TDG = Transportation of Dangerous Goods. TLV = Threshold Limit Value. TSCA = Toxic Substance Control Act. WHMIS = Workplace Hazardous Materials Information System.

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name	:	FloraGLO® Lutein 20% Safflower Oil
Product Use Description	:	Ingredient for capsules and/or tablets For the fortification of foods
Company	:	DSM Nutritional Products, Inc. 45 Waterview Blvd Parsippany NJ 07054-1298
Telephone	:	(973) 257-1063
Telefax	:	(973) 257-8615
Emergency telephone	:	(800) 424-9300 (24 Hr CHEMTREC)

SECTION 2. HAZARDS IDENTIFICATION

Emergency Overview

Form: oily liquid, Colour: orange - red,

Experience with human exposure

Skin contact : Remarks: May cause skin discolorations.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Brief description of the product : Mixture (preparation) containing active ingredients and auxiliary substances

Hazardous components

WHMIS hazardous composition: No ingredients are hazardous according to the CPR criteria.

Further ingredients

Component	CAS-No.	Weight percent
β,ε-carotene-3,3'-diol	127-40-2	10 - 30
(3R,3'R)-β,β-carotene-3,3'-diol	144-68-3	1 - 5

SECTION 4. FIRST AID MEASURES

First aid procedures

General advice : No hazards which require special first aid measures.

Inhalation : Move to fresh air in case of accidental inhalation of dust or fumes from overheating or combustion.

If symptoms persist, call a physician.

Skin contact	:	Take off contaminated clothing and shoes immediately. Wash off with soap and plenty of water.
Eye contact	:	Flush eyes with water as a precaution. Remove contact lenses. Protect unharmed eye. Keep eye wide open while rinsing.
Ingestion	:	Clean mouth with water and drink afterwards plenty of water. Do not give milk or alcoholic beverages. Never give anything by mouth to an unconscious person.

SECTION 5. FIRE-FIGHTING MEASURES

Flammable properties

Flash point	:	> 212 °F (> 100 °C)

Fire fighting

Suitable extinguishing media	:	Dry chemical Alcohol-resistant foam Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable extinguishing media	:	High volume water jet
Further information	:	Collect contaminated fire extinguishing water separately. This must not be discharged into drains. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

Protective equipment and precautions for firefighters

Special protective equipment for fire-fighters	:	In the event of fire, wear self-contained breathing apparatus.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Environmental precautions	:	Try to prevent the material from entering drains or water courses. No special environmental precautions required.
Methods for containment / Methods for cleaning up	:	Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Handling

Handling	:	For personal protection see section 8. No special handling advice required.
Advice on protection against	:	Take precautionary measures against static discharges.

fire and explosion

Storage

Requirements for storage areas and containers : Keep container tightly closed and dry.

Protect against light.

Advice on common storage : No special restrictions on storage with other products.

Storage temperature : 61 - 81 °F (16 - 27 °C)

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

Components	CAS-No.	Value	Control parameters	Update	Basis
β,ε-carotene-3,3'-diol	127-40-2	TWA	1 mg/m3		DSM Internal Limit
(3R,3'R)-β,β-carotene-3,3'-diol	144-68-3	TWA	1 mg/m3		DSM Internal Limit

Engineering measures

For technical measures see section 7.

Personal protective equipment

Eye protection : Safety glasses

Hand protection : For prolonged or repeated contact use protective gloves. for example nitrile rubber

Skin and body protection : Protective suit

Respiratory protection : No personal respiratory protective equipment normally required.
In case of mist, spray or aerosol exposure wear suitable personal respiratory protection and protective suit.

Hygiene measures : General industrial hygiene practice.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Form : oily liquid

Colour : orange - red

Safety data

Flash point	:	> 100 °C
Solubility in other solvents	:	Oils and fats: slightly soluble

10. STABILITY AND REACTIVITY

Conditions to avoid	:	Heat.
Materials to avoid	:	Strong acids and strong bases Strong oxidizing agents
Thermal decomposition	:	no data available
Hazardous reactions	:	Stable under recommended storage conditions.

11. TOXICOLOGICAL INFORMATION

Skin irritation	:	Prolonged skin contact may cause skin irritation.
Experience with human exposure: Skin contact	:	May cause skin discolorations.

12. ECOLOGICAL INFORMATION

Further information on ecology

Additional ecological information	:	There is no data available for this product.

SECTION 13. DISPOSAL CONSIDERATIONS

Further information	:	Offer surplus and non-recyclable solutions to a licensed disposal company.
Contaminated packaging	:	Empty containers should be taken to an approved waste handling site for recycling or disposal.

SECTION 14. TRANSPORT INFORMATION

DOT
Not dangerous goods

TDG
Not dangerous goods

IATA
Not dangerous goods

IMDG

Not dangerous goods

RID
Not dangerous goods

Not classified as dangerous in the meaning of transport regulations.

SECTION 15. REGULATORY INFORMATION

WHMIS Classification : Not Rated

The components of this product are reported in the following inventories:

TSCA	On TSCA Inventory
DSL	This product contains the following components listed on the Canadian NDSL list. All other components are on the Canadian DSL list.
	β,ε-carotene-3,3'-diol 127-40-2

This product has been classified according to the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

SECTION 16. OTHER INFORMATION

Further information

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

E-mail address : sds.nutritionalproducts@dsm.com
Responsible/issuing person

Definitions: ACGIH = American Conference of Governmental Industrial Hygienists. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act. CFR = Code of Federal Regulations. CPR = Controlled Products Regulations. DSL = Canadian Domestic Substance List. DOT = Department of Transportation. EINECS = European Inventory of New and Existing Chemical Substances. EPA = Environmental Protection Agency. HCS = Hazardous Communication Standard. HEPA = High Efficiency Particulate Air. HMIS = Hazardous Material Identification System. IARC = International Agency for Research on Cancer. IATA = International Air Transport Association. IMDG = International Maritime Dangerous Good. NFPA = National Fire Protection Association. NIOSH = National Institute of Occupational Safety and Health. NJTSR = New Jersey Trade Secret Registry. NTP = National Toxicology Program. OSHA = Occupational Safety and Health Administration. SARA = Superfund Amendments and Reauthorization Act. TDG = Transportation of Dangerous Goods. TLV = Threshold Limit Value. TSCA = Toxic Substance Control Act. WHMIS = Workplace Hazardous Materials Information System.

Appendix E

Information on the Safety of FloraGLO Crystalline Lutein for Use in Food and Infant Formula (**CBI deleted**)

APPENDIX E

CBI Deleted-Sections 1-6: Pages 1-46

7. References

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Appendix F

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Research Bibliography

APPENDIX F

BIBLIOGRAPHY OF SCIENTIFIC LITERATURE REGARDING LUTEIN

I. LUTEIN'S ROLE IN EYE HEALTH

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II. LUTEIN'S ROLE IN WOMEN'S AND INFANT'S HEALTH

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III. LUTEIN'S ROLE IN SKIN HEALTH

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Appendix G

Confidential Manufacturing Information

(**CBI Deleted**)