

Regulatory Product Documentation for Food/Dietary Supplements (USA/Canada)

Product: 5015295 life'sOmega[™] 60 (O55-O100)

Origin: Kingstree, SC (USA)

1.	Product	composition	

Source of active ingredient(s)	Yes	No	Comments
Synthetic		Χ	
Fermentation	Χ		Algal oil from Schizochytrium sp. (marine algae)
Vegetable		Χ	
Animal		Χ	
Mineral		Χ	
Authorisation of active ingredient(s) in US	Yes	No	Comments
GRAS affirmed	Χ		Self-affirmed GRAS, GRAS Notification 137
Permitted as food color additive		Χ	
Permitted as food additive		Χ	
Source of formulation ingredient(s)	Yes	No	Comments
Synthetic	Χ		Ascorbyl palmitate
Fermentation		Χ	
Vegetable	X		High oleic sunflower oil, mixed tocopherols, rosemary extract (as flavour)
Animal		Χ	
Mineral		Χ	



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2. Product allergen labeling

United States (FALCPA)	Yes	No	Comments
Milk		Х	
Eggs		Χ	
Fish		Χ	
Crustacean shellfish		Χ	
Tree nuts (Almond, Brazil nut, Butternut, Cashew, Chestnut, Coconut, Filbert/hazelnut, Gingko nut, Heartnut, Hickory nut, Lichee nut, Macadamia nut/Bush nut, Pecan, Pine nut/Pinon nut, Pistachio, Sheanut, Walnut)		X	
Wheat (Durum, Club, Spelt, Semolina, Einkorn, Emmer, Kamut, Triticale)		Χ	
Peanuts		Χ	
Soybeans		Χ	Mixed tocopherols: highly refined and deodorized oil with no measurable protein ²
Allergen labeling required (USA)		Χ	
Allergen statement (USA)	Χ		
Canada (FDA / CPLA)	Yes	No	Comments
Milk		Χ	
Eggs		Χ	
Fish		Χ	
Shellfish		Χ	
Crustaceans		Χ	
Tree nuts (Almonds, Brazil nuts, Cashews, Hazelnuts, Macadamia nuts, Pecans, Pine nuts, Pistachios and Walnuts)		Χ	
Wheat (Triticum sp.)		Χ	
Peanuts		Χ	
Soybeans		Χ	Mixed tocopherols: highly refined and deodorized oil with no measurable protein ²



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Canada (FDA / CPLA)		No	Comments	
Sulfites > 10 ppm SO2 (Potassium bisulfite / metabisulfite; Sodium sulfite/bisulfite / dithionate/ metabisulfite; Sulfur dioxide; Sulfurous acid)		Х		
Sesame seeds		Χ		
Mustard seeds		Χ		
Gluten protein (Oat, Barley, Rye, Triticale, Wheat, Kamut, Spelt)		Χ		
Allergen labelling required (Canada)		Χ		
Allergen statement (Canada)	Χ			
Other sensitizers and constituents - FAQ	Yes	No	Comments	
Corn (maize) or corn derivatives		Χ		
Fruit or fruit derivatives		Χ		
Yeast or yeast derivatives		Χ		
Artificial color / colorants (dyes)		Χ		
Artificial flavor		Χ		
Artificial preservatives	Χ		Ascorbyl palmitate	
MSG (Monosodium Glutamate)		Χ		
Sweeteners (artificial or natural)		Χ		
Salt		Χ		
Celery		Χ		
Sugar alcohols		Χ		
Phosphoric acid		Χ		



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3. Compliance confirmations for products used in food applications and dietary supplements

GMO Yes No Comments

GMO labelling required X

GMO statement X

GMO: Traceability and Labelling X

BSE/TSE Yes No Comments

BSE/TSE statement X

Contaminants Yes No Comments

Dioxin/PCB statement X

Heavy metals statement X See Product Data Sheet

Mycotoxins statement X

Residue levels of pesticides Yes No Comments

Pesticides statement X

Ionizing radiation Yes No Comments

Ionizing radiation statement X

Microbiological purity Yes No Comments

Microbiology statement X

Solvents Yes No Comments

Residual solvents X



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Traceability of packaging materials statement

Suitability in organic food	Voc	No	Comments
Suitability in organic 1000	res	NO	comments

Χ

Χ

Permitted for use in organic food

Packaging material	Yes	No	Comments

Compliance of packaging materials statement X

Treatment of pallets X

Absence of phthalates statement X

Absence of latex statement X

Other compliance confirmations Yes No Comments

Traceability of food ingredients X
Food Hygiene X
General policy on allergen cross contamination X

4. Product suitability

Diet suitability	Yes	No	Comments
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Vegans X
Vegetarians X

Kosher / Halal status Yes No Comments

Kosher certificate X
Halal certificate X

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¹ highly refined oils are exempt from allergen labeling