

Product Information

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

Product:

Origin:

1. Product composition

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

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2. Product allergen labeling

United States (FALCPA)	Yes	No	Comments
Milk		X	
Eggs		X	
Fish		X	
Crustacean shellfish		X	
Tree nuts (Almond, Brazil nut, Butternut, Cashew, Chestnut, Coconut, Filbert/hazelnut, Ginkgo 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)		X	
Peanuts		X	
Soybeans		X	Mixed tocopherols: highly refined and deodorized oil with no measurable protein ²
Allergen labeling required (USA)		X	
Allergen statement (USA)	X		
Canada (FDA / CPLA)	Yes	No	Comments
Milk		X	
Eggs		X	
Fish		X	
Shellfish		X	
Crustaceans		X	
Tree nuts (Almonds, Brazil nuts, Cashews, Hazelnuts, Macadamia nuts, Pecans, Pine nuts, Pistachios and Walnuts)		X	
Wheat (Triticum sp.)		X	
Peanuts		X	
Soybeans		X	Mixed tocopherols: highly refined and deodorized oil with no measurable protein ²

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Canada (FDA / CPLA)	Yes	No	Comments
Sulfites > 10 ppm SO ₂ (Potassium bisulfite / metabisulfite; Sodium sulfite/bisulfite /dithionate/ metabisulfite; Sulfur dioxide; Sulfurous acid)		X	
Sesame seeds		X	
Mustard seeds		X	
Gluten protein (Oat, Barley, Rye, Triticale, Wheat, Kamut, Spelt)		X	
Allergen labelling required (Canada)		X	
Allergen statement (Canada)	X		
Other sensitizers and constituents - FAQ	Yes	No	Comments
Corn (maize) or corn derivatives		X	
Fruit or fruit derivatives		X	
Yeast or yeast derivatives		X	
Artificial color / colorants (dyes)		X	
Artificial flavor		X	
Artificial preservatives	X		Ascorbyl palmitate
MSG (Monosodium Glutamate)		X	
Sweeteners (artificial or natural)		X	
Salt		X	
Celery		X	
Sugar alcohols		X	
Phosphoric acid		X	

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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 & 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
PAH statement (Polycyclic Aromatic Hydrocarbons)	X		
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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Suitability in organic food	Yes	No	Comments
Permitted for use in organic food		X	

Packaging Material	Yes	No	Comments
Traceability of packaging materials	X		
Compliance of packaging materials	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. Compliance confirmations for products used as active pharmaceutical ingredient in drugs

Compliance	Yes	No	Comments
CFR-Reference			not applicable
GMO statement			not applicable
BSE/TSE statement			not applicable
Heavy metals statement			not applicable
Residual solvents statement (ICH)			not applicable
Microbiology statement			not applicable

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5. Product suitability

Diet suitability	Yes	No	Comments
Vegans	X		
Vegetarians	X		

Kosher / Halal status	Yes	No	Comments
Kosher certificate	X		
Halal certificate	X		

¹ highly refined oils are exempt from allergen labeling

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