

Quality & Regulatory Product Information

Omegia® Powder

Herewith we certify to the best of our knowledge / based on information provided by our previous vendors / based on knowledge of used raw materials and applied production processes.

General Product Information

Trade Name	Omegia® Powder
Type of Product	Botanical extract
INCI Name	Hippophae Rhamnoides Fruit Extract (and) Hippophae Rhamnoides Seed Oil (and) Maltodextrin
CAS no.	90106-68-6
EINECS no.	290-292-8(I)

Quality & Registration Status

Quality level (recommended use)	Technical Application, Cosmetic
REACH status	<i>Hippophae Rhamnoides</i> (Sea Buckthorn) Fruit Extract is exempted from REACH Registration Annex V Entry 7&8
Monograph (Ph. Eur., USP/NF)	Does not apply
Regulation EC/1223/2009 (cosmetic regulation)	Complies with
EU no. (food additives)	Does not apply
FDA status	Does not apply
Food chemical codex	Does not apply
Regulation EC/231/2012 (food additives purity criteria)	Does not apply
Regulation EC/258/97 (novel foods, novel food ingredients)	Does not apply
Regulation EC/10/2011 (on plastic materials and articles intended to come into contact with food)	Does not apply
BfR recommendation	Does not apply
Chemical inventory listing	EINECS, TSCA, AICS, DSL, IECIC, KECI, ENCS, NZIoC, PICCS
Colipa recommendation 14	Does not apply
Kosher	Kosher grade
Halal	Halal grade
CITES	Not affected by CITES

Raw Material & Manufacturing Information

Raw material origin (vegetable, animal, mineral, synthetic)	Vegetable
Parts used	Sea buckthorn fruit
Palm oil status	Does not apply
Suitable for vegetarians	Yes
Suitable for vegans	Yes
Country of origin	Tibetan Plateau, China
Nanomaterial	The product is not a / does not contain nanomaterial/s as defined under cosmetic regulation EC/1223/2009
Preservatives, antioxidants, other additives	Does not apply
GMO (Reg. EC/1829/2003 and EC/1830/2003)	Non-GMO certified

Microbiological safety	Total plate count \leq 1000CFU/g Total mold \leq 25CFU/g Total yeast \leq 25CFU/g Coliform: Negative/25g Salmonella: Negative/25g Staphylococcus aureus: Negative/25g
Irradiation (Dir. EC/1999/2 & amendments)	Has never been treated with ionizing radiation

Storage & Handling

Shelf life / Re-test period	36 months (if appropriate storage conditions are maintained)
Storing Conditions	Store in a cool, dry and dark place

Packaging

Packaging type	10kg per carton box
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By-products & Impurities

Allergens Fragrance allergens: Annex III, No. 67-92 of Regulation EC/1223/2009; Food allergens: Annex II of regulation EC/1169/2011 Other allergens	Not tested, but due to origin not to expect Free from Latex
CMR	Due to origin and production process not to expect
Pesticides	Free from pesticides
Heavy metals	Arsenic \leq 0.3ppm Lead \leq 0.5ppm Mercury \leq 0.01ppm Cadmium \leq 0.5ppm
Metal catalysts	Due to origin and production process not to expect
Phthalates	Due to origin and production process not to expect
Glycol ethers	Free of any glycol ethers
Dioxin, 3-MCPD, DMF (dimethyl formamide)	Due to origin and production process not to expect
Formaldehyde /Formaldehyde releaser	Free of formaldehyde or any type of formaldehyde releaser
Halogen organic compounds (AOX, EOX)	Free of AOX, EOX (below detection limits)
California proposition 65	Does not contain any contaminants or by-products known to the State of California to cause cancer or reproductive toxicity as listed under Proposition 65 State Drinking Water and Toxic Enforcement Act
Residual solvents	Free of any volatile impurity as defined in the USP Organic Volatile Impurities <467>
Other residual solvents	Free of any other residual solvents
VOC	Free of any VOC classified compound
Other impurities (especially mycotoxins, PAHs, Nitrosamines)	Due to origin and production process not to expect
BSE / TSE	Free of BSE / TSE
Ethanol	Ethanol is not used as raw material in the manufacturing of these products nor stored. We are not aware that in the manufacturing process ethanol can be introduced into the product

Safety & Environment

Toxicological data	No Observed Adverse Effect Level (NOAEL) of water extract of sea buckthorn berry in rats administered by gavage for 90 days at 100mg/kg body weight per day.
Biologically degradability	Biodegradable, soluble in water
Animal testing	Never tested on animals by /or on behalf of Puredia Corporation Limited

In general:

All our products are traceable by our batch number. Batch records list all raw materials used in the manufacture of our products. We hereby confirm that the above raw materials have not been the subject of animal testing or retesting for cosmetic purposes by or on behalf of our company since 2012.

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Every care has been taken to compile the above information accurately. To the best of our knowledge, it strictly complies with our best results. Since the analysis is intended to describe the product and the application of this information is beyond our control, we disclaim any liability incurred in connection with its application and use. The information contained herein does not imply any legally binding statement concerning the use or description of this product. We further disclaim any liability for changes that might occur due to ageing of the product or damage during transport and storage, and we recommend that the consumer always test the product prior to using it to establish its suitability for the intended application. All facts given in this document apply only to the pertinent Puredia product. Any transfer to similar generic market products is illegal. All market participants must know the specifics of manufacturing processes and potential contaminants and must ensure the safety of their product on their own.