Entropic® Biodegradable Microspheres

INCI Name: 3-Hydroxybutyrate/3-Hydroxyhexanoate Copolymer

PRODUCT INFORMATION

Composition Statement

INCI NAME	CAS#	%	Origin
3-Hydroxybutyrate/3-Hydroxyhexanoate Copolymer	147398-31-0	100	Plant (Vegetable oil)

Animal Testing Statement: This product has not been the subject of animal testing for cosmetic purposes by or on behalf of this company.

BSE-Status: This product does not contain any material derived from tissues included on the list of Specified Risk Materials laid down in Decision 97/534/EC concerning transmissible bovine spongiform encephalopathy (BSE). Subsequent directives 97/1/EC, 98/16/EC and 2000/6/EC are also contemplated.

California Proposition 65: This product is not listed by the State of California as a substance that may cause cancer or other reproductive harm, according to the latest updated list. No impurities present or expected are listed on Prop 65.

Nanomaterials: This product is not classified as a nanomaterial in accordance with the definition of nanomaterial in accordance with EU legislation set out in the 2011 European Commission recommendation (2011/696/EU) and the definition proposed by the Cosmetic Regulations (EC) No. 1223/2009 (Chapter I, Article 2).

Microplastic particles: This product is not classified as microplastic particles according to the definition proposed by the ECHA (European Chemicals Agency), and also does not contain intentionally added microplastic particles or release intentional or unintentionally microplastic particles into the environment.

VOC (Volatile Organic Compounds): This product is not classified as a VOC.

Palm Oil / Palm Kernel Oil: This product is not derived from and does not contain Palm Oil or Palm Kernel Oil. This can be considered Palm free.

CITES: This product is not affected by the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES).

Nagoya Protocol: This product is not affected by the Nagoya Protocol as the source materials are commodities sourced from within the US.

Natural Origin Index: In accordance with ISO 16128, the NOI for this material is 1.

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ALLERGENS

Cosmetic allergens: The raw materials and production system used ensure that this product does not contain any of the substances considered allergenic by current European cosmetics legislation.

Food Allergens: According to the European Parliament and Council Regulation (EU) No. 1169/2011, the following substances have been identified as main responsible for food allergies or intolerances.

Cereals containing gluten (namely: wheat, rye, barley, oats, spelled, kamut or their crossbred varieties)	No
Crustaceans	No
Eggs	No
Fish	No
Peanuts	No
Soybeans	Yes
Milk (Including lactose)	No
Nuts, namely almonds, hazelnuts, walnuts, cashews, pecans, Brazil nuts, pistachios, macadamia nuts or Australian nut	No
Celery	No
Mustard	No
Sesame	No
Sulfur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/liter expressed as SO2.	No
Lupin	No
Molluscs	No

Gluten: This product is not derived from any plant material which could contain gluten and as such can be considered gluten-free.

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IMPURITIES

Entropic® Biodegradable Microspheres does not contain any of the following impurities.

1,4 dioxane: The 1,4 dioxane content is not analyzed on this product. However, according to the raw materials used and the manufacturing process, the presence of 1,4 dioxane in this product is not expected to be found.

Phthalates: This product does not contain phthalates such as Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP), Diisobutyl phthalate (DIBP), Diethylhexyl phthalate (DEHP), Diisononyl phthalate (DINP), Di-n-octyl phthalate (DNOP), Diisodecyl phthalate (DIDP) and Diethyl phthalate (DEP).

CMRs: This product does not contain any material classified as carcinogenic, mutagenic or toxic for reproduction in accordance with Annex VI of Regulation (EC) No. 1272/2008 and its latest updates, therefore the presence of substance classified as CMR in this product is not expected to be found, and the eventual presence of traces of these substances would be technically unavoidable following the Good Manufacturing Practices.

PFAS: This product does not contain perfluoroalkyl substances (PFAS, PFOS, PFOAs).

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REULATORY INFORMATION

Country/Area	Inventory	Remarks
US	FDA	No FDA or state restrictions
	TSCA	Not listed.
EU	Annexes	Not restricted by any Annex. Complies with (EC) No. 1223/2009
	REACH	Exempt from REACH (polymer)
Canada	HOTLIST	Not present. No restrictions.
	DSL / NDSL	Individual importer subject to 1000 kg import limit per year.
China	IECSC	**Listed:** 3-羟基丁酸酯与 3-羟基己酸酯的聚合 物
	IECIC	Not listed. New Cosmetic Ingredient Registration to be initiated following 3 years of market safety (2029).
Mercosur Markets		Not restricted
Mexico		Not restricted
ASEAN Markets		Not restricted
ANDEAN Markets		Not restricted
Australia	AICIS	Not listed. Exempt from registration as Polymers of Low Concern (PLC)

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