

Product Code: OLIO157
Trade name: MINK-FREE OIL
INCI composition: VEGETABLE OIL 99.7%; TOCOPHEROL 0.3%.
CAS: 68956-68-3 / 119-13-1
EC: 273-313-5 / 204-299-0

REGULATORY DOSSIER

MADE IN *Italy*
This is the Country where the product underwent its last, qualitatively substantial and/or economically justified transformation.

REACH Registration Number *Exempt (mixture)*
This product and its component ingredients are in compliance with EC Reg.1907/2006 and its subsequent amendments.

SUBSTANCES OF VERY HIGH CONCERN *Absent*
as defined in EC Reg.1907/2006, Art. 57 and its subsequent amendments.
This product does not contain intentionally added SVHCs listed on EC Reg.1907/2006, Annex XIV and its subsequent amendments, neither on latest SVHCs Candidate List issued by European CHemicals Agency.
This product respects restrictions eventually prescribed in EC Reg.1907/2006, Annex XVII and its subsequent amendments.
It may occur the non-intended presence of a small quantity of substance(s), stemming from impurities of natural or synthetic ingredients, the manufacturing process, storage, migration from packaging, which is(are) technically unavoidable in good manufacturing practice.

COSMETIC ALLERGENS *Does not contain cosmetic allergens*
as listed in EU Reg. 1223/2009, Annex III and its subsequent amendments.

NATURAL INDEX / NATURAL ORIGIN INDEX *I_{NO} = 1.00 (natural derived ingredient)*
calculated according to ISO 16128.

CHEMICAL SYNTHETIZED *No*
This product does not derive from and/or is not composed by artificially synthesized compounds

RAW MATERIAL ORIGIN *Vegetable*
intended as the origin of sourcing pool from which the major part of product constituents derived from.
It does not apply to intentionally added water. It may be declared as vegetable or animal or petrochemical.

BSE/TSE *BSE/TSE risk free*
In compliance with EU Reg. 2016/429, CE Reg. 999/2001 and their subsequent amendments.

ORGANIC INDEX / ORGANIC ORIGIN INDEX *I_o = I_{oo} = 0.00 (non-organic ingredient)*
calculated according to ISO 16128. If Index is not equal to zero, Organic Certificate may be downloaded from esperis.it.

V.O.C (Volatile Organic Compounds) *Absent*
as defined in EU Directive 2010/75, Art.3.

PRESERVATIVES *Present*
All preservatives present in this product are eventually declared; if any, they are listed as permitted on EU Reg. 1223/2009, Annex V and its subsequent amendments.

COLORANTS AND DYES *Absent*
All colorants and dyes present in this product are eventually declared; if any, they are listed as permitted on EU Reg. 1223/2009, Annex IV and its subsequent amendments.

TOTAL N-NITROSAMINE CONTENT *≤50 µg/kg*
This product and its components ingredients do not contain nitrosonium ion precursors, hydrazine derivatives, nitrite salts nor other nitrosating agents.

GENETICALLY MODIFIED ORGANISMS *Does not contain G.M.O.*
As defined in EC Directive 1829/2003, 1830/2003 and their subsequent amendments.
This product and its components ingredients are not G.M.O., neither they are manufactured using raw materials and/or processing aids derived from genetically modified sources.

MICROBEADS *Absent*
intended as any solid plastic particles less than 5 millimeters in size, not soluble in water, created with the intention of being used to exfoliate or cleanse the human body.

GLUTEN CONTENT *≤20 mg/kg*
as defined in EU Commission Implementing Reg. 828/2014 and its subsequent amendments.

ELEMENTAL IMPURITIES *≤20 mg/kg*
expressed as the sum of the content of arsenic, cadmium, chromium (VI), mercury, lead. It is not likely to be present: tin, tantalum and tungsten, their ores, and gold originating from conflict-affected and high-risk areas.

NANOMATERIALS

Absent

intended as any insoluble or biopersistent material, intentionally manufactured, having one or more dimensions measuring from 1 to 100 nm.

PERSISTENT ORGANIC POLLUTANTS (POPs) *Absent*

as listed in EU Reg. 2019/1021, Annex I and its subsequent amendments.

IFRA CERTIFICATE

Does not apply

The International FRAGRANCE Association Certificate is available only for fragrances, intended as intentional mixture of substances to be directly included in a finished consumer product to impart an odor/flavour.
IFRA Standards may not apply for some raw materials (i.e. essential oils).

PALM OIL CONTENT

Palm oil free

intended as crude or refined oil, extracted from palm trees belonging to genus *Elaeis*, in its pure or derivate forms. This product does not contain palm oil and it is not certified by Roundtable on Sustainable Palm Oil (RSPO) neither by other Organisations.

IMPURITIES PROFILE

The following substances are not likely to be present in product and its component ingredients:

acrylamide (CAS 79-06-1); alkylphenols (various CAS); aluminum and its salts (various CAS); amidoamines (various CAS); asbestos fibers (various CAS); boric acid and its salts (various CAS); Carcinogenic, Mutagenic, Reprotoxic (CMR) substances listed in EC Reg. 1272/2008, Annex VI, and its subsequent amendments (various CAS); cyclopentasiloxane (D₅, CAS 541-02-6); cyclotetrasiloxane (D₄, CAS 556-67-2); dichloroacetic acid (DCA, CAS 79-43-6); diethylene glycol (CAS 111-46-6); dimethylaminopropylamine (DMAPA, CAS 109-55-7); Endocrine Disruptors (various CAS) as listed in EC Reg.1907/2006, Annex XIV; ethanalamides (various CAS); ethylene oxide (CAS 75-21-8); fatty acid dialkylamides and dialkanolamides (various CAS); formaldehyde (CAS 50-00-0); formaldehyde releasing agents (various CAS); glycol ethers (intended as alkyl ethers of ethylene glycol or propylene glycol, various CAS); hormones (various CAS); lactose (CAS 63-42-3); melamine (CAS 108-78-1); methylchloroisothiazolinone (CMIT, CAS 26172-55-4); methylisothiazolinone (MIT, CAS 2682-20-4); mineral oils (various CAS); monochloroacetic acid (MCA, CAS 79-11-8); parabens (intended as 4-hydroxybenzoic acid and its salts and esters, various CAS); PerFluoroAlkyl and PolyFluoroAlkyl Substances (PFAS, various CAS); Persistent, Bioaccumulative and Toxic (PBT) substances (various CAS) as defined in EC Reg.1907/2006, Art. 57 and its subsequent amendments; phthalates (intended as esters of benzene-1,2-dicarboxylic acid, various CAS); Polycyclic Aromatic Hydrocarbons (PAHs, various CAS); polyethoxylated alkylphenols (various CAS); polyethoxylated polymers (various CAS); pyrrolizidine alkaloids (necine bases, various CAS); very Persistent, very Bioaccumulable (vPvB) substances (various CAS) as defined in EC Reg.1907/2006, Art. 57 and its subsequent amendments; other substances listed in EC Reg. 1223/2009, Annex II.

It may occur the non-intended presence of a small quantity of substance(s), stemming from impurities of natural or synthetic ingredients, the manufacturing process, storage, migration from packaging, which is(are) technically unavoidable in good manufacturing practice.

USE RESTRICTIONS

This product complies with EC Reg. 1223/2009.

To the best of our knowledge, no use restrictions are prescribed for the intended usage by any law in force in European Union. Please note, it is customer's duty to make sure to follow other local administration laws.

FOOD ALLERGENS

This product does not contain, intended in pure or derivative form: crustacean, egg, fish, milk, peanut, soy, tree nuts, cereals with gluten, sulphur dioxide, sulphites, buckwheat, celery, lupin, molluscan, mustard, sesame, bee pollen, propolis, beef, chicken, latex, mango, peach, pork, royal jelly, tomato.

This product is manufactured and/or manipulated in a facility that could employ, intended in pure or derivative form, one or more of food cited above.

PESTICIDE RESIDUES

This product and its component ingredients do not contain pesticides residues.

MYCOTOXINS CONTENT

This product and its component ingredients do not contain mycotoxins residues.

VEGAN STATUS

The manufacturer verifies that raw materials of animal origin was not included or used directly or indirectly during the manufacturing process.

No animal nor animal-derived materials, processing aids and/or enzymes from animal sources, or cultures from animal products are used in this manufacture.

For "animals" are intended multicellular, eukaryotic organisms that belong to biological kingdom *Animalia*.

It can be excluded cross-contamination with the raw material from animal origin ingredient.

There are documented in-place cleaning procedures for multipurpose processing lines.

NO TEST ON ANIMALS

This product and its component ingredients respect the Cruelty Free International Leaping Bunny Standards, as well as Human Cosmetics Standards, since 11th march 2013.

For this product and its component ingredients Esperis S.p.A. has been never carried out tests on animals, and/or requested for their execution by third parties, for cosmetic and/or non-cosmetic purposes.

ANTI-DOPING DECLARATION

This product and its component ingredients are not listed by World Anti-Doping Agency (WADA) on latest available List of Prohibited Substances and Methods.

RESIDUAL SOLVENTS

This product complies with the latest available version of Q3C Guidelines for Residual Solvents issued by International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

HALAL STATUS

The manufacturer verifies that this product does not contain components and/or derivatives of animal origin, nor Khamr, nor Genetically Modified Organisms.

There are documented in-place cleaning procedures, applied before production in order to eliminate all eventual traces of substances of animal origin and/or containing Khamr from equipment, tools, dispensers and trolleys (carts) used in the production, filling and packaging involved.

During production, filling, packaging, storage and transport, this product and its component ingredients are completely separated from any substance of animal origin and/or containing Khamr.

This product is not certified by any Halal Authority.

KOSHER STATUS

The manufacturer verifies that this product does not contain components and/or derivatives from following sources: animal, carmine, dairy, fish, seafood, gelatin, grape.

There are documented in-place cleaning procedures, applied before production in order to eliminate all eventual traces of above mentioned sources from equipment, tools, dispensers and trolleys (carts) used in the production, filling and packaging involved.

In their manufacturing plant, this product and its component ingredients are completely separated from any substance of above mentioned sources. However this plant may contain material(s) derived from animal, gelatin, grape.

This product is not certified by any Kosher Authority.

CALIFORNIA PROPOSITION 65/1986

This product and its component ingredients have not been added to the list of chemicals recognized by the State of California as cancerogenic or reprotoxic, according to the Safe Drinking Water and Toxic Enforcement Act of 1986 (California Proposition 65/1986).

IRRADIATION DECLARATION

This product and its component ingredients have not been exposed to ionising radiation for preservative purpose.

CONVENTION ON BIOLOGICAL DIVERSITY

This product and its component ingredients respect the Convention on Biological Diversity (CBD). Vegetable and/or animal sources eventually employed in their manufacture are in accord with CBD and its subsequent amendments, protocols and plans; these comprise Nagoya Protocol on Access and Benefit Sharing (ABS) and Cartagena Protocol on Biosafety to the Convention on Biological Diversity.

CITES DECLARATION

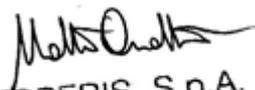
This product and its component ingredients respect the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES). Vegetable and/or animal sources eventually employed in their manufacture are not listed by CITES as endangered species.

DISCLAIMER NOTES

- a) This product is sold only for industrial, cosmetic use; not for food, food supplement nor pharmaceutical use.
- b) Only the corresponding, current Material Safety Data Sheet is authoritative for any safety assessments.
- c) The declarations and indications in this file are not representative for packaging materials.
- d) Some declarations are fully or partially based on information not verified directly by Esperis S.p.A.
- e) Some parameters may be analysed with tests not carried out over every batch.
- f) Some parameters may be reasonably estimated by considering the whole manufacturing cycle, and therefore not directly tested.
- g) The declarations and indications in this file do not absolve the customer from the duty to verify them.
- h) The disclosures in this regulatory dossier, which would be accurate in their drafting, are for information purposes only and do not constitute legally binding statements.
- i) The customer is responsible for the appropriate, safe and legal use, processing and handling of the product.
- j) Esperis S.p.A. shall promptly notify the customer after any change about the nature of this regulatory dossier, which shall therefore be considered valid until further notice.

Milano, 24th March 2023

Dr. Quattrini Matteo
Q.A. & Regulatory Manager
Esperis S.p.A.



ESPERIS S.p.A.
Via A. Binda, 29
20143 MILANO
C.F. e P. IVA 00729840157