



Regulatory summary of Olivatis® 15C

INCI NAME:

Olive Oil PEG-8 Esters

COMPOSITION BREAKDOWN

INCI NAME	CAS N.	EC N.	REACH STATUS	FUNCTION	%
Olive Oil PEG-8 Esters	103819-46-1	n/a	Exempt from registration (Polymer)	Emulsifier Surfactant	100%

SOURCE OF ORIGIN OF COMPONENTS

INCI NAME	SOURCE OF ORIGIN	PLACE OF ORIGIN
Olive Oil PEG-8 Esters	Vegetable (Olive oil from olive fruit, glycerin)	European Union

MICROBIOLOGICAL SPECIFICATIONS

Total Aerobic Count < 100 CFU /g
Yeasts and moulds < 10 CFU /g

TOXICOLOGICAL DATA

EYE IRRITATION:

Not irritant

In vitro testing: OECD Guidelines for The Testing of Chemicals: TG N° 439-Adopted 28 July 2015

SKIN IRRITATION:

Not Irritant

In Vitro Skin Irritation: Reconstructed Human Epidermis Test Method Ref. OECD Guidelines for The Testing of Chemicals: TG N° 439 - Adopted 28 July 2015

Safety of the ingredient has been assessed by CIR on Amended Safety Assessment of PEGylated Oils as Used in Cosmetics (International Journal of Toxicology 2014, Vol. 33(Supplement 4) 13S-39S)



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INVENTORY STATUS

EU

Olive Oil PEG-8 Esters

Listed (polymer)

USA (TSCA)

Olive Oil PEG-8 Esters

Listed (polymer)

AUSTRALIA (AICS)

Olive Oil PEG-8 Esters

Listed (polymer)

CHINA

Olive Oil PEG-8 Esters

NMPA registration number: 002514-04015-8278

JAPAN

Olive Oil PEG-8 Esters

Listed (polymer)

KOREA

Olive Oil PEG-8 Esters

Listed (polymer)

PHILIPPINES

Olive Oil PEG-8 Esters

Listed (polymer)

ADDITIVES (CHEMICAL SUBSTANCES INTENTIONALLY ADDED)

Olivatis® 15C does not contain any of the following additives: solvents, preservatives, antioxidants, stabilizers, formaldehyde and formaldehyde donors, and phthalates.



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IMPURITIES	
Animal derivatives:	free
Chlorinated solvents:	free
Dichloroacetic acid:	free
Diethylene glycol, propylene glycol, ethylene glycol:	free
Dimethyl sulphate:	free
Ethanol and other alcohols with boiling point <150 °C:	free
Ethylene oxide:	max. 1,0 ppm
Fragrance allergens (Reg. EC 1223/2009):	free
Free amines:	free
GMO:	free
Gluten:	free
Lactose:	free
Latex:	not expected to be present in the product on the ground of the information on the raw materials used in the manufacturing process.
Monochloroacetic acid:	free
Mycotoxins:	complies with limits of Regulation CE 1881/2006 for vegetal oils
Nitrosamines:	free
Organic solvents:	free
Palm Oil/Palm kernel and derivatives:	free
Pesticides:	complies with the regulatory requirements for limits for pesticides used in agriculture: <0,05 ppm
Petrolatum:	free
Phthalates:	free
Polycyclic aromatic hydrocarbon (PAH):	free
Propylene oxide:	free
P-Toluene sulfonic acid:	free
Siloxanes:	free
Total heavy metals (As, Pb, Cd, Sb, Hg, Ni, Cr (VI)):	max. 10 ppm
VOC:	not expected to be present in the product on the ground of the manufacturing process and raw materials used.
1,4-dioxane:	max. 10 ppm (10,0 mg/kg)



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CMR SUBSTANCES

Olivatis® 15C may contain the following substances classified as carcinogenic, mutagenic, or toxic for reproduction (CMR substances) by the European commission:

- Ethylene oxide (CAS 75-21-8): maximum 1,0 mg/kg
- Dioxane (CAS 123-91-1) maximum 10,0 mg/kg

CONVENTION ON INTERNATIONAL TRADE IN ENDANGERED SPECIES (CITES)

The production of Olivatis® 15C does not involve raw materials obtained from species protected by the CITES convention.

NANOMATERIALS

Olivatis® 15C does not contain nanomaterials as defined by Regulation EC 1223/2009.

MICROPLASTICS

Olivatis® 15C does not contain microplastics as defined by ECHA 2019 draft.

BSE/TSE

Olivatis® 15C is produced entirely from materials of vegetal and synthetic origin which are therefore free from human or any other animal derived materials including bovine products. Furthermore, no animal derived component is used in the manufacturing or handling processes of Olivatis® 15C. As such, this material can be declared free of Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathy (TSE).

GAMMA RAYS AND OTHER RADIATION TREATMENT

Olivatis® 15C is not subjected to any treatment with ionizing radiation.

REGULATORY COMPLIANCE FOR COSMETICS

- Olivatis® 15C complies with Reg. EC 1223/2009. Olivatis® 15C is not prohibited (Annex II) or limited (Annex III) for the use in cosmetics by Regulation EC 1223/2009.
- ISO 16128: Olivatis® 15C has a natural origin index of 0.



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NAGOYA PROTOCOL

Olivatis® 15C falls outside the scope of Nagoya protocol regulation.

CONFLICT MINERALS

Olivatis® 15C does not involve any conflict minerals as defined under US conflict minerals Trade Act (Coltan, Tantalum; Cassiterite, Gold, Wolframite or their derivatives).

The production of Olivatis® 15C does not involve any other mineral and its derivatives determined by the US Secretary of State to be financing conflict in the Democratic Republic of Congo or adjoining countries (Angola, Congo, Central African Rep. Sudan, Uganda Rwanda, Burundi, Tanzania, Zambia).

ANIMAL TESTING

Olivatis® 15C has not been tested on animals by Medolla Speciality Chemicals, its subsidiaries or other companies on its behalf.

HALAL

Olivatis® 15C is not produced from unlawful or forbidden substances under Halal rules. No unlawful or forbidden material under Halal rules is used or added during manufacturing or packaging.

KOSHER

Olivatis® 15C is not produced from unlawful or forbidden substances under Kosher rules. No unlawful or forbidden material under Kosher rules is used or added during manufacturing or packaging.

VEGAN SUITABILITY

Olivatis® 15C is produced entirely from materials of vegetal and synthetic origin and is therefore free from any animal derived materials. Therefore, Olivatis® 15C is suitable for the manufacture of vegan products.



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CALIFORNIA PROPOSITION 65

Olivatis® 15C may contain the following substances listed in California Prop. 65 Regulation:

- Ethylene oxide (CAS 75-21-8: maximum 1,0 mg/kg)

MANUFACTURING PLACE

Italy

SHELF LIFE

24 months (last day of the month)