



Regulatory summary of Olivatis® 18

| | |
|------------|---------------------------------|
| INCI NAME: | Olive Oil Polyglyceryl-6 Esters |
| | Sodium Stearoyl Lactylate |
| | Cetearyl Alcohol |

COMPOSITION BREAKDOWN

| INCI NAME | CAS N. | EC N. | REACH STATUS | FUNCTION | % |
|---------------------------------|------------|-----------|------------------------------------------------------------------------------|--------------------------------|--------|
| Olive Oil Polyglyceryl-6 Esters | 85711-62-2 | 288-323-5 | Exempt from registration (Polymer) | Emulsifier | 45-55% |
| Sodium Stearoyl Lactylate | 25383-99-7 | 246-929-7 | 01-2120779437-39-XXXX (Medolla Speciality Chemicals is a downstream user) | Emulsifier | 20-30% |
| Cetearyl Alcohol | 67762-27-0 | 267-008-6 | 01-2120092297-47-XXXX (Medolla Speciality Chemicals is a downstream user) | Emulsifier - Consistency agent | 20-30% |

SOURCE OF ORIGIN OF COMPONENTS

| INCI NAME | SOURCE OF ORIGIN | PLACE OF ORIGIN |
|---------------------------------|----------------------------------------|-----------------|
| Olive Oil Polyglyceryl-6 Esters | Vegetable (Olive oil from olive fruit) | European Union |
| Cetearyl Alcohol | Vegetable (Palm) | European Union |
| Lactic Acid | Vegetable (Sucrose fermentation) | European Union |
| Stearic Acid | Vegetable (Olive) | European Union |



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MICROBIOLOGICAL SPECIFICATIONS

Total Aerobic Count < 100 CFU /g

Yeasts and moulds < 10 CFU /g

TOXICOLOGICAL DATA

EYE IRRITATION:

Not irritant

Reference:

OECD Guidelines for The Testing of Chemicals, Section 4: Test No. 492 - Adopted 14 June 2019

Reconstructed human Cornea-like Epithelium (RhCE) test method for identifying chemicals not requiring classification and labelling for eye irritation or serious eye damage

SKIN IRRITATION:

Not Irritant

Reference:

OECD Guidelines for The Testing of Chemicals: TG N° 439 Adopted: 18 June 2019

Corrected: 26 June 2020 (Annex 2) In Vitro Skin Irritation: Reconstructed Human Epidermis Test Method

DATA ON SINGLE SUBSTANCES OF THE MIXTURE:

Olive Oil Polyglyceryl-6 Esters:

CIR Safety Assessment of Polyglyceryl Fatty Acid Esters as used in cosmetics. Final report 14 November, 2016.

Sodium Stearoyl Lactylate:

CIR Safety Assessment of Alkanoyl Lactyl Lactate Salts as Used in Cosmetics final report Release Date: July 17, 2019

European Food Safety Authority. Scientific opinion on the re-evaluation of Sodium Stearoyl-2-Lactylate (E 481) and Calcium Stearoyl-2-Lactylate (E 482) as food additives. 2013. pp.1-35.

Cetearyl Alcohol:

Safety evaluation: Journal of the American college of toxicology vol 7 number 3 1988.



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INVENTORY STATUS

EU

| Olive Oil Polyglyceryl-6 Esters | Sodium Stearoyl Lactylate | Cetearyl Alcohol |
|---------------------------------|----------------------------|----------------------------|
| Listed EC number 288-323-5 | Listed EC number 246-929-7 | Listed EC number 267-008-6 |

USA (TSCA)

| Olive Oil Polyglyceryl-6 Esters | Sodium Stearoyl Lactylate | Cetearyl Alcohol |
|-----------------------------------------------------------------------------|---------------------------|------------------|
| Listed (Fats and Glyceridic oils vegetable esters with polyglycerol active) | Listed | Listed |

AUSTRALIA (AICS)

| Olive Oil Polyglyceryl-6 Esters | Sodium Stearoyl Lactylate | Cetearyl Alcohol |
|---------------------------------------------------------------------------------------------------------------------------|---------------------------|------------------|
| Listed under the entry "Fatty acids, C14-18 and C16-18 unsaturated, esters with polyglycerol". CAS Number: 118870-11-4 | Listed | Listed |

CHINA

| OLIVATIS 18 | NMPA registration number | 110995-04015-2857 |
|-------------|--------------------------|-------------------|
| | | |

JAPAN

| Olive Oil Polyglyceryl-6 Esters | Sodium Stearoyl Lactylate | Cetearyl Alcohol |
|---------------------------------|---------------------------|------------------|
| Listed | Listed | Listed |

KOREA

| Olive Oil Polyglyceryl-6 Esters | Sodium Stearoyl Lactylate | Cetearyl Alcohol |
|---------------------------------|---------------------------|------------------|
| Listed | Listed | Listed |

PHILIPPINES

| Olive Oil Polyglyceryl-6 Esters | Sodium Stearoyl Lactylate | Cetearyl Alcohol |
|---------------------------------|---------------------------|------------------|
| Listed | Listed | Listed |



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BIODEGRADABILITY

INCI NAME

| | |
|---------------------------------|---------------------------------------------------------------------------|
| Olive Oil Polyglyceryl-6 Esters | Readily Biodegradable (OECD 301B Test) |
| Sodium Stearoyl Lactylate | Readily Biodegradable Data From Literature (QSAR calculation (BIOWIN)) |
| Cetearyl Alcohol | Readily Biodegradable Data From Literature (OECD 301D Test) |

ADDITIVES (CHEMICAL SUBSTANCES INTENTIONALLY ADDED)

Olivatis® 18 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: | free |
| 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 |
| 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: | free |



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PHthalATES, CMR SUBSTANCES AND SVHC

Olivatis® 18 does not contain Phthalates and any substance classified carcinogenic, mutagenic, or toxic for reproduction (CMR substances) by the European commission above 0.001% threshold. **Olivatis® 18** does not contain substances identified of very-high concern by ECHA.

VOLATILE ORGANIC COMPOUNDS (VOC)

Not present.

GLYCOLS AND GLYCOL ETHERS

Olivatis® 18 does not contain alkyl diols (glycols) and ethers solvents (alkyl ethers of ethylene glycol or propylene glycol).

CONVENTION ON INTERNATIONAL TRADE IN ENDANGERED SPECIES (CITES)

The production of **Olivatis® 18** does not involve raw materials obtained from species protected by the CITES convention.

NANOMATERIALS

Olivatis® 18 does not contain nanomaterials as defined by Regulation EC 1223/2009.

MICROPLASTICS

Olivatis® 18 does not contain microplastics as defined by ECHA 2019 draft.

BSE/TSE

Olivatis® 18 is produced entirely from materials of vegetal 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® 18**. As such, this material can be declared free of Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathy (TSE).



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GAMMA RAYS AND OTHER RADIATION TREATMENT

Olivatis® 18 is not subjected to any treatment with ionizing radiation.

REGULATORY COMPLIANCE FOR COSMETICS

- Olivatis® 18 complies with Reg. EC 1223/2009. Olivatis® 18 is not prohibited (Annex II) or limited (Annex III) for the use in cosmetics by Regulation EC 1223/2009.
- ISO 16128: Olivatis® 18 has a natural origin index of 1.

NAGOYA PROTOCOL

Olivatis® 18 falls outside the scope of Nagoya protocol regulation.

CONFLICT MINERALS

Olivatis® 18 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® 18 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,

ANIMAL TESTING

Olivatis® 18 has not been tested on animals by Medolla Speciality Chemicals, its subsidiaries or other companies on its behalf.

HALAL

Olivatis® 18 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® 18 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.



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VEGAN SUITABILITY

Olivatis® 18 is produced entirely from materials of vegetal origin and is therefore free from any animal derived materials. Therefore, **Olivatis® 18** is suitable for the manufacture of vegan products.

CALIFORNIA PROPOSITION 65

Olivatis® 18 does not contain substances listed in California Prop. 65 Regulation.

MANUFACTURING PLACE

Italy

SHELF LIFE

24 months (last day of the month)