

## 1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION

### 1.1 Identification of the substance or preparation

Name: Montanov 68

Bulk code: 6627

Internal code: 405520

### 1.2 Synonyms

No information available.

## 2. DESCRIPTION

Appearance: Granules

Colour: Yellowish white

Country of manufacture: France

Origin: Plant-based

Origin of raw materials:

STARTING MATERIALS	BOTANICAL NAME**	PART OF PLANT	WILD/FARMED	GEOGRAPHIC SOURCE
Glucose	Wheat ( <i>Triticum aestivum</i> ) corn ( <i>Zea Mays</i> )	Seeds	Farmed	Europe
Vegetable oils, fatty acids	Palm ( <i>Elaeis guineensis</i> ), coconut ( <i>Cocos nucifera</i> ), rapeseed ( <i>Brassica napus</i> )	Pulp, palm kernels, seeds	Farmed and wild	Asia (palm, coconut) Europe (rapeseed)

\*\* With palm oil or palm kernels, the palm oil equivalence is 0.96.

The palm equivalence refers to the maximum quantity of palm used in production, per kg of commercial product. This value takes into account losses during the process. With PKO/CNO of mixed origins, the manufacturer has opted to maximise the value by considering the entire supply as coming from PKO. To make your own estimation of the PKO amount, we refer you to the ISTA Mielke statistical reference, giving a ratio of 68/32 for the production of PKO/CNO throughout the world.

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### 3. COMPOSITION/INFORMATION ON COMPONENTS

INCI: Cetearyl Alcohol (and) Cetearyl Glucoside

Components INCI name (USA)	Components Common name	CAS	Function	Concentration range (%)
Cetearyl Alcohol	Alcohols, C16-18	67762-27-0	Emulsifier	75-85
Cetearyl Glucoside	C16 Glucoside and C18 Glucoside	246159-33-1 (or 5549-27-8 and 27836-65-3)	Emulsifier	15-25
Water	Aqua	7732-18-5	Residual raw material	0-1
Glucose	D-glucose	50-99-7	Residual raw material	0-1

**Method of production:** The product is manufactured via a glycosylation (esterification) reaction between glucose and fatty alcohols, as per the Emil Fischer reaction, followed by a filtration and cooling process.

### 4. PHYSICO-CHEMICAL DATA

For more information see the analysis report.

**Solubility:** The product is miscible in oil and insoluble in water.

### 5. PROPERTIES/USES

Cosmetic use.

Emulsifier.

### 6. DOSAGE

The recommended usage dose is 0.5-5%.

## 7. REMARKS

### **STORAGE:**

Store at room temperature, in a cool, dry place, away from sunlight, in a tightly closed container.

The documentation available related to the product's regulatory compliance is included below.

### **BSE/TSE:**

The product has not been manufactured using animal- or human-based materials nor has it come into contact with any animal- or human-based materials during the manufacturing process. As such, this Product is not affected by BSE (bovine spongiform encephalopathy) or TSE (transmissible spongiform encephalopathy), or related regulations.

### **GMOs:**

Based on the raw materials used and the manufacturing process, the product does not contain any GMOs, as described in Article 2(2) of Directive (EC) 2001/18, or a substance "produced from GMOs", as per the description from Article 2(10) of Regulation (EC) 1829/2003 and Article 3(2) of Regulation (EC) 1830/2003.

### **CMR:**

Based on the information on the raw materials and the manufacturing process, the substances that comply with the CMR criteria, as per Annex VI of Regulation (EC) 1272/2008, are not expected to be present. The product is compliant with the provisions of Article 15 of Regulation (EC) 1223/2009 on CMR substances, as amended.

### **SVHC:**

The product does not contain any substances identified as SVHCs (Substances of Very High Concern), as referred to in the candidate list published by the ECHA within the context of the REACH Regulation (Regulation (EC) 1907/2006), above 0.1% w/w.

### **NANOMATERIALS:**

The product is not considered a nanomaterial, as per the definitions in Commission Recommendations (EC) 2011/696/EU or French Decree 2012-232.

### **MICROPLASTICS:**

The product are not synthetic polymer microparticles (or microplastics) or do not contain any synthetic polymer microparticles according to the Commission Regulation (EU) 2023/2055 of 25 September 2023.

**VOCs:**

None of the product components are considered as VOCs, as per the definition in SR 814.018. Furthermore, none of the substances listed in Annex 1 (Art 2, a) of SR 814.018 are expected to be present in the final product above the 3% threshold established in Article 8 for tax exemption.

**RADIATION:**

The product is not sterilised or decontaminated.

The product is not subjected to ionising radiation nor does it contain any components that have been subjected to ionising radiation, as per Directives (EC) 1999/2 and 1999/3.

**PESTICIDES:**

The starting raw materials comply with Regulation (EC) 2005/396 of the European Parliament and of the Council and of Ph. Eur. 2.8.13.

**PRESERVATIVES/COLOURANTS/ADDITIVES:**

The product does not contain any additives, whether it be preservatives, solubilising agents or anything else.

**RESIDUAL SOLVENTS:**

Based on the raw materials and manufacturing process, none of the solvents listed in ICH Q3C Guideline (class 1, 2 or 3) are expected to be present in the final product.

**CONTAMINANTS/IMPURITIES:**

Based on the raw materials used and the manufacturing process, the following substances are not used intentionally in the manufacturing process and are not expected to be present in the final product:

- Acetone
- Acrylamide
- Alkanolamines (MEA, DEA, TEA)
- Alkylphenol and alkylphenol ethoxylates
- Antibiotics
- Antineoplastic agents
- Asbestos
- BHT, BHA
- 1,4-butanediol
- Camphor and derivatives
- Diethylene glycol
- 1,4-Dioxane
- Ethanol
- Ethylene oxide
- Eucalyptol

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- Formaldehyde
- Glycol ethers
- Glycidol
- Growth promoter
- Hormones
- Substances listed by the IARC and NTP
- Isopropyl alcohol
- Lactose
- Latex
- 3-MPCD
- Melamine
- Menthol
- Methanol
- Methyl ethyl ketone
- Drugs
- Nitrosamines
- Parabens
- Per- and polyfluoroalkyl substances (PFAS)
- Phenol
- Phthalates
- Polycyclic aromatic hydrocarbons (PAHs)
- Psychotropic agents
- Residual metal catalysts
- Secondary alkyl and alkanolamines and their salts
- Silicone
- Steroids
- Terpenes

Based on Commission Regulation (EC) 1881/2006 of 19 December 2006, which establishes maximum levels for certain contaminants in food products, and amendments thereto, the product is not expected to contain nitrates, mycotoxins (including aflatoxins, 3-MCPD, dioxins and PCBs), PAHs, melamine and analogues, plant toxins or glycidol/glycidyl fatty acid esters.

**HEAVY METALS:**

The product may contain the following impurities, which derive from the manufacturing process and are technically inevitable:

- Lead < 5 ppm
- Cadmium < 1 ppm
- Mercury < 0.3 ppm
- Arsenic < 1 ppm
- Nickel < 5 ppm

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- Chromium < 1 ppm
- Cobalt < 5 ppm
- Antimony < 5 ppm
- Silver < 1 ppm
- Copper < 5 ppm

**CONFLICT MINERALS:**

Conflict materials, such as those defined in the Dodd-Frank Wall Street Reform and the Consumer Protection Law, are not added intentionally as components in the manufacture of the product.

**CALIFORNIA PROPOSITION 65:**

Based on the information regarding the raw materials and manufacturing process, no substance listed in Proposition 65 of the State Law on Control of Toxins and Drinkable Water is expected to be present (aside from any that may be indicated in the impurity table).

**NAGOYA:**

The product does not fall under the national category of Access and Benefit Sharing legislation related to the implementation of the Nagoya Protocol for the following reasons:

- It has not been developed using a genetic resource as defined in the Nagoya Protocol and in the related national legislation
- It has been developed using a genetic resource from a country where there was no access law at the time when the genetic resource was accessed and used.

The product is not included in the scope of application of Regulation (EU) 511/2014.

**ALLERGENS:**

- **Food allergens:** Based on the information regarding the raw materials and manufacturing process, the product does not need to be labelled, as per Article 21 of Regulation 1169/2011, Annex II.
- **Cosmetic allergens:** Based on the information regarding raw materials and the manufacturing process, none of the fragrance allergens listed in Annex III of Regulation (EU) 1223/2009 (Annex III) are expected to be present.

**HALAL:**

The product is HALAL certified.

**KOSHER:**

The product is suitable for kosher use, but it is not certified:

The product:

- Is not animal-based and does not contain animal-based components.
- Is not made with grape or wine and does not contain any grape or wine components.

No animal-based products, wine or grapes were present during the product manufacturing process.

**VEGAN/VEGETARIAN:**

The product is suitable\* for vegan/vegetarian use:

- It is not manufactured with animal-based raw materials
- It is not produced using animal-based processing aids
- It does not come into direct contact with animal-based materials at any stage of the manufacturing process

\*“Suitable” means that there is no independent certification available for the product and the suitability conclusion results from the manufacturer’s approval of the criteria expressly mentioned below the statement.

**ANIMAL TESTING:**

The product is not tested on animals in terms of Regulation (EC) 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products - Chapter V - Art. 18. The animal testing ban requirements of Article 18 (1) were made fully applicable to cosmetic ingredients on 11 March 2013.

**PALM OIL/RSPO:**

The product is certified for RSPO (mass balance certified standard)  
BVC-RSPO-1-1972708497

**CITES:**

The product does not contain any of the substances listed in the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) or the IUCN Red List.

**ECOCERT:**

The product is approved by ECOCERT.

**COSMOS:**

The product is approved by COSMOS:  
CPAI: 100% / PPAI: 0% / NNI: 0% / PeMo: 0%

**NATRUE:**

The product is approved by NATRUE.  
Natural: 0.10% / Derived natural : 99.6% / Water: 0.30%

**ISO 16128:**

The product has the following properties:

Natural index: -

Natural origin index: -

Natural content (%): 0.1

Natural origin content (%): 100

**REACH:**

COUNTRY OR REGION	IDENTIFIER UNDER SPECIFIC REGULATION		STATUS UNDER SPECIFIC REGULATION
	CHEMICAL NAME	IDENTIFICATION NUMBER	
Europe (REACH)	Acetalization product between glucose and C16/18(even numbered)-alcohol	EC: 927-870-2 CAS: /	Registered Id: 01-2119382604-36-0000 Seppic status: Manufacturer
Korea (K-REACH)	/	/	Excluded Pharmaceutical, food and cosmetic uses are out of the scope
Turkey (KKDIK)	Acetalization product between glucose and C16/18(even numbered)-alcohol	EC: 927-870-2 CAS: /	Pre-registered: Id: 05-0000215394-03-0000
United Kingdom (UK-REACH)	Acetalization product between glucose and C16/18(even numbered)-alcohol	EC: 927-870-2 CAS: /	Notified Id: UK-20-4249203941-9-0000

**Other regulations:**

Australia (AIC): Authorised. Usage restrictions: see assessment conditions.

Canada (DSL/NDSL/R-ICL): Authorised. Usage restrictions: only for the uses covered by the Food and Drug Act.

China (IECSC): Authorised. All the CAS numbers used for this country are listed or exempt.

Japan (ENCS): Authorised. Usage restrictions: only for pharmaceutical, food or cosmetic use. ISHL: the importer has to guarantee compliance.

New Zealand (NZIoC): Authorised. All the CAS numbers used for this country are listed, exempt or non-hazardous.

The Philippines (PICCS): Authorised. All the CAS numbers used for this country are listed or exempt.

Taiwan (TCSI): Authorised. All the CAS numbers used for this country are listed or exempt.

The United States (TSCA): Authorised. Usage restrictions: only for the uses covered by the Food and Drug Act.





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Type of document:

TECHNICAL DATA SHEET

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**COSMETICS REGULATIONS:**

COUNTRY / ZONE	IDENTIFIER	REGULATION / TEXT OF REFERENCE	COMPLIANCE (RESTRICTION)
Australia	INCI PCPC: -Cetearyl Alcohol -Cetearyl Glucoside	Classical cosmetic: Industrial Chemicals (notification and Assessment) Act 2019  Schedules (Poisons Standard)	Yes
	AAN: -Cetearyl Alcohol -Cetearyl Glucoside	Therapeutic Good: Therapeutic Goods Act 1989	Yes (as excipient): restrictions of use may apply
Canada	INCI PCPC: -Cetearyl Alcohol -Cetearyl Glucoside	Classical cosmetic: The Food and Drug Act, Cosmetic Regulations (C.R.C., ch. 869)  Cosmetic Ingredient Hotlist	Yes
	NHP ingredient Database: -Cetearyl Alcohol -Cetearyl Glucoside	Natural Health Product & Non-prescription Drugs: Category IV Monographs & Natural Health Products regulation (SOR/2003-196)	Yes (as excipient): restrictions of use may apply
China	INCI (Chinese translation): -鲸蜡硬脂醇 -鲸蜡硬脂基葡萄糖苷	Cosmetic Supervision and Administration Regulation (CSAR)  Safety and technical standard for cosmetics  IECIC list 2021	Yes
Europe	INCI COSING: -Cetearyl Alcohol -Cetearyl Glucoside	Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.	Yes
Japan	INCI (PCPC Japanese translation): -セテアリルアルコール -セテアリルグルコシド	Classical cosmetic: Japanese Standards of Cosmetics (Notification No.331 of 2000)	Yes
	QD monograph n°: 51 Ingredient code: 523141 Ingredient name: Glucose Cetostearate Cetostearyl Alcohol	Quasi Drug: Pharmaceutical Affairs Law of Japan (PAL)	Yes
South Korea	INCI (Korean translation): -세테아릴알코올 -세테아릴글루코사이드	Classical cosmetic: Cosmetic Act 17250  Safety Standard for Cosmetics	Yes
	QD monograph n°: No data available on QD monograph	Cosmeceutical/ Quasi Drug according to the definition of functional cosmetics in the Korean Cosmetics Act	Yes (listed in JSQI)
USA	INCI PCPC: -Cetearyl Alcohol -Cetearyl Glucoside	Classical cosmetic: Federal Food, Drug and Cosmetic (FD&C) Act. 21 CFR 700 to 740	Yes
	UNII: -2DMT128M1S -09FUA47KNA	OTC: 21 CFR Part 3xx - OVER-THE-COUNTER DRUG PRODUCTS	Please ask your usual contact for information



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To the best of our knowledge, the Product also complies with local cosmetics regulations in the following countries / geographical areas:

Andean Community - CAN

ASEAN

CACM

Gulf countries

Hong Kong

India

Mercosur

Morocco

New Zealand

Taiwan

Russia

Saudi Arabia

**TARIFF ITEM NUMBER:**

34021300