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 (Triticum aestivum) corn (Zea Mays)	Seeds	Farmed	Europe
Vegetable oils, fatty acids	Palm (Elaeis guineensis), coconut (Cocos nucifera), rapeseed (Brassica napus)	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.

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 1-5%.

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. The potential presence of technically unavoidable traces of CMR substances is covered by the provision of Article 17 of Regulation (EC) No 1223/2009.

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 of 10 June 2022 on the definition of nanomaterial (2022/C 229/01), French Decree n° 2012-232 of 17 February 2012 , Art. 2 and the definition of Nanomaterial of the Cosmetic Regulation (EC) No 1223/2009, Art. 2, 1, (k), for not meeting the parameters of the previous definitions.

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
-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) 2023/915 of 25 April 2023, 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.

Based on Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants and based on the information supplied to us concerning the raw materials and the knowledge of the manufacturing

process, neither the prohibited substances listed in the Annex I, nor of the restricted substances listed in Annexes II, III or IV are expected to be present in

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
- 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).

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. (Regulation 1169/2011/EU of 25 October 2011 on the provision of food information to consumers, amending Directive 2000/13/EC - Annex II substances or products causing allergies and intolerances -).
- Cosmetic allergens: Based on the Regulation (EC) 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, Annex III, Commission Regulation (EU) 2023/1545 of 26 July 2023 amending Regulation (EC) No 1223/2009 of the European Parliament and of the Council as regards labelling of fragrance allergens in cosmetic products, the analysis of a representative batch of MONTANOV 68 failed to detect any of the 58 analyzable allergens quoted in the extended list, meaning that all dosages are mainly below 1.5 ppm (6 ppm for Benzyl salicylate, 10 ppm for Farnesol E,E) according to the GC-

MS/MS method used. Allergens such as natural extracts are not expected, as they are not used at any stage in the manufacturing process.

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 on11 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 (AIIC): 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): All CAS numbers used for this country are listed or exempted. ISHL compliance should be ensured by the importer.

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.

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)	Please refer to chemical regulatory status conclusion
	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	Please refer to chemical regulatory status conclusion
	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 -鲸蜡硬脂基葡糖苷	Cosmetic Supervision and Administration Regulation (CSAR) Safety and technical standard for cosmetics IECIC list 2021	Yes
Europe	INCI: -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	Quasi Drug: Pharmaceutical Affairs Law of Japan (PAL)	Yes

	Cetostearate- Cetostearyl Alcohol		
South Korea	INCI (Korean translation): - 세테아릴알코올 - 세테아릴글루코사이드	Classical cosmetic: Cosmetic Act 17250 Safety Standard for Cosmetics	Yes
	QD monograph n°: /	Cosmeceutical/ Quasi Drug according to the definition of functional cosmetics in the Korean Cosmetics Act	listed in JSQI
UK	INCI PCPC: -Cetearyl Alcohol -Cetearyl Glucoside	Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019	Yes
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 refer to Statement US OTC

To the best of the supplier 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