

Product Regulatory Information

VIVAPUR® CS (grade) FM

INCI: *Microcrystalline Cellulose*

PRODUCT REGULATORY INFORMATIONⁱ

Additives

VIVAPUR® CS (grade) FM is free of any additive. It is neither preserved nor blended, flavoured, coloured, stabilized or diluted by any additive.

Aflatoxins

According to our knowledge VIVAPUR® CS (grade) FM is not affected by aflatoxins because the product does not contain any ingredients possibly contaminated by aflatoxins.

Allergens / Fragrances

VIVAPUR® CS (grade) FM is not made from and does not come in contact with the 26 potentially sensitizing fragrance ingredients in Annex III to Regulation (EC) No. 1223/2009 and its modifications during the manufacturing and packaging process.

Present	Absent	Allergen (Directive 2000/13/EC et seqq.) (FALCPA for USA)
	X	Cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains) and products thereof
	X	Crustaceans and products thereof
	X	Eggs and products thereof
	X	Fish and products thereof
	X	Peanuts and products thereof
	x	Soybeans and products thereof
	X	Milk and products thereof (including lactose)
	X	Nuts i.e. Almond (<i>Amygdalus communis</i>), Hazelnut (<i>Corylus avellana</i>), Walnut (<i>Juglans regia</i>), Cashew (<i>Anacardium occidentale</i>), Pecan nut (<i>Carya illinoensis</i>), Brazil nut (<i>Bertholletia excelsa</i>), Pistachio nut (<i>Pistacia vera</i>), Macadamia nut and Queensland nut (<i>Macadamia ternifolia</i>) and products thereof
	X	Celery and products thereof
	X	Mustard and products thereof
	X	Sesame seeds and products thereof
	X	Sulphur dioxide and sulphites at concentrations of more than 10 mg / kg or 10 mg / litre expressed as SO ₂
	X	Lupines and products thereof
	X	Molluscs and products thereof

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BSE

VIVAPUR® CS (grade) FM is not made from and does not come into contact with products of human or animal origin. VIVAPUR® CS (grade) FM and its starting materials do not come into contact with material of Bovine, Ovine, or Caprine origin during the manufacturing process. Therefore, VIVAPUR® CS (grade) FM is free of any rich forms of Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathy (TSE).

California Proposition 65

VIVAPUR® CS (grade) FM is tested for lead on a periodic basis using AAS/ICP-MS. The detection limit is 0.2 ppm. Results are typically less than the detection limit. This information is intended to be used as a foundation of understanding upon which additional testing may be necessary. The data provided is for informational purposes only and is not meant to be a guarantee or specification. VIVAPUR® CS (grade) FM complies with the California AG Protocol for lead under Proposition 65.

CITES

VIVAPUR® CS (grade) FM is in compliance with the Convention on International Trade in Endangered Species of Wild Fauna and Flora and Regulation (EC) No 407/2009. This certification is based on our knowledge of the ingredients.

Composition list

CAS No	EINECS / ELINCS No	Chemical name	%
9004-34-6	232-674-9	Microcrystalline Cellulose	100

CMR

VIVAPUR® CS (grade) FM does not contain substances which are classified as Carcinogenic, Mutagenic or toxic to Reproduction.

Country of manufacture

VIVAPUR® CS (grade) FM is manufactured in Germany.

Dioxin

VIVAPUR® CS (grade) FM does not contain any dioxins.

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Food Compliance

VIVAPUR® CS (grade) FM, Microcrystalline Cellulose, meets all specifications described by the “Cellulose Gel” Monograph of the Food Chemical Codex and the European food regulations described under E 460 (i), current editions.

VIVAPUR® CS (grade) FM complies with the Commission Directive 2008/84/EC laying down specific purity criteria on food additives other than colours and sweeteners.

The raw materials used to manufacture VIVAPUR® CS (grade) FM are in compliance with the Codex Alimentarius.

Therefore VIVAPUR® CS (grade) FM can be used as a food additive as far as the directive does not exclude the use for special food groups.

Formaldehyde

VIVAPUR® CS (grade) FM does not contain any formaldehyde.

Glycol Ethers

VIVAPUR® CS (grade) FM and its raw materials are not produced using glycol ethers.

GMO

Information for customers whose products comply with the European Union’s food and feed regulations:

There is no labeling requirement for VIVAPUR® CS (grade) FM according to the European Union Regulation on genetically modified food and feed (EU 1829/2003) and European Union Regulation concerning traceability and labeling of food and feed products produced from genetically modified organisms (EU 1830/2003).

GMP

GMP requirements for cosmetic products according to 1223/2009/EC have no mandatory character for ingredients of cosmetic products in the European Union. There is no regulatory GMP guideline or directive that applies for ingredients of cosmetic products. The Quality Management System of the manufacturing site is based on ISO 9001 and refers to i.e. DIN EN ISO 22716 or other applicable GMP guidelines.

Heavy Metals

VIVAPUR® CS (grade) FM does not exceed any applicable statutory limits for heavy metals in cosmetic products.

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Irradiation

There is no irradiation associated with the manufacture, packaging, or storage of VIVAPUR® CS (grade) FM including the raw materials and the packaging materials.

Material origin

VIVAPUR® CS (grade) FM is pure microcrystalline cellulose, cellulose of plant origin. It is produced from cellulose pulp originated from wood.

Melamine

VIVAPUR® CS (grade) FM does not contain any melamine.

Microplastics

According to the definition of “microplastics” of the European Chemicals Agency (ECHA), Annex XV restriction report (Proposal for a restriction) Substance name (S): intentionally added microplastics of 20 March 2019, we hereby confirm that VIVAPUR® CS (grade) FM does not contain “microplastics”.

Nagoya Protocol

VIVAPUR® CS (grade) FM (countries of raw material origin) is in compliance with REGULATION (EU) No 511/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union.

Nanoparticles

According to the definition of “nanomaterials” of the EU REGULATION (EU) No 1223/2009 of the EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30th November 2009 on cosmetic products we hereby confirm that VIVAPUR® CS (grade) FM does not contain “nanomaterial”. Nanomaterial means an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm. According to the RECOMMENDATION of the 18th October 2011 (EU) No 2011/696 a nanomaterial should have not less than 50 % of the particles in the described size distribution.

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National Inventory Status

Country	Inventory	Yes	No	Inventory No.
Australia	Listed in AICS	✓		CAS-No.
Canada	Listed in DSL	✓		CAS-No.
China	Listed in IECSC	✓		CAS-No.
EC	Listed in EINECS	✓		232-674-9
Japan	Listed in METI	✓		CAS-No.
Korea	Listed in KECI	✓		KE-05339
New Zealand	Listed in NZIoC	✓		CAS-No.
Philippines	Listed in PICS	✓		CAS-No.
Taiwan	Listed in NECI	✓		CAS-No.
USA	Listed in TSCA	✓		CAS-No.
	Listed in CAS	✓		9004-34-6

Nitrosamines

VIVAPUR® CS (grade) FM does not contain any nitrosamines.

NOAEL

A “No observed adverse effect level” is not defined for VIVAPUR® CS (grade) FM.

Palm oil and palm derivatives

VIVAPUR® CS (grade) FM, raw material, manufacturing process and product do not contain palm oil or palm derivatives.

Pesticides

VIVAPUR® CS (grade) FM does not contain any pesticides.

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Phthalates

Phthalates can be excluded by origin and raw materials, manufacturing process and facilities.

Residual solvents

VIVAPUR® CS (grade) FM does not contain any class 1, class 2 or class 3 solvents listed in CPMP/ICH/283/95.

Sulfites

VIVAPUR® CS (grade) FM does not contain any sulfites according to Directive 2000/13/EC et seqq.

SVHC

VIVAPUR® CS (grade) FM or its ingredients are not listed by the ECHA as “Substance of very high concern”.

Test on animals

VIVAPUR® CS (grade) FM has not been tested on animals and no animal testing is planned.

Vegan/Vegetarian

VIVAPUR® CS (grade) FM does not contain any ingredients of animal origin.

Based on our knowledge of ingredients and manufacturing process we further certify that VIVAPUR® CS (grade) FM is suitable for consumption by lacto vegetarians, ovo vegetarians, lacto-ovo vegetarians and vegans.

VOC

VIVAPUR® CS (grade) FM is produced without Volatile Organic Compounds.

ⁱ Disclaimer:

To the best of our knowledge, the information contained herein is accurate and reliable as of the date of publication; however, we do not assume any liability whatsoever for the accuracy and completeness of the above information.

VIVAPUR® CS (grade) FM is not a cosmetic product in the sense of 1223/2009/EC. It is within the responsibility of the producer of a cosmetic product to proof the suitability of an ingredient for the final application.