



GUINAMA. Laboratory distributor of raw materials for the pharmaceutical and cosmetics industries.

Type of document:

TECHNICAL DATA SHEET

Review date:

11.11.2022

Version:

13.0

93533-TALC

1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION

1.1. Identification of the substance or preparation

Name: Talc

Bulk code: 93533

Internal code: 405148

1.2. Synonyms

Hydrous magnesium, steatite, soapstone, magnesium silicate hydrate.

2. DESCRIPTION

Appearance: Powder.

Colour: White.

Odour: Odourless.

Origin: Mineral. The source is natural talc deposits.

Geographical origin: France.

3. COMPOSITION/INFORMATION ON COMPONENTS

CAS: 14807-96-6

EINECS: 238-877-9

CI: 77 718

INCI: Talc

Molecular formula: $Mg_3Si_4O_{10}(OH)_2$

MW: 379.3 g/mol

Composition: Talc is produced from natural mineral deposits. As with all naturally occurring minerals, these talc grades are subject to natural variations in their composition. Therefore, clear identification based solely on chemical composition is not possible and they are considered UVCB substances (unknown or variable composition, complex reaction products or biological materials). There may be trace metals and other natural minerals, which are included in the UVCB definition.

The product may contain crystalline silica as an impurity. As with all naturally occurring mineral fillers, the mineralogical composition may vary, so the total amount of crystalline silica may also vary. Crystalline silica is potentially harmful if it enters the lung (inhalation), with only the "fine fraction" in the air being of concern. The fine fraction of crystalline silica (SWeRF – size-weighted relevant fine fraction) is determined using a method developed and adopted by the European mining industries. The value of the "fine fraction of crystalline silica" corresponds to the maximum content of crystalline silica, in the worst case, that may become respirable during handling and use of the product. "Respirable crystalline silica" (expressed in mg/m³) relates to the airborne dust in workplace atmospheres and depends on the conditions of handling and use. Therefore, the index of respirable crystalline silica cannot be determined in a bulk powder.



GUINAMA. Laboratory distributor of raw materials for the pharmaceutical and cosmetics industries.

Type of document:

TECHNICAL DATA SHEET

Review date:

11.11.2022

Version:

13.0

93533-TALC

Method of production: The extraction and selection techniques, associated with the homogenisation of the mineral inside the crude product silo, guarantee the homogeneity of the product in the long term, as well as its conformity with the product specifications.

4. PHYSICO-CHEMICAL DATA

For more information, see the analysis report.

Solubility: Practically insoluble in water and in dilute solutions of mineral acids and alkaline hydroxides.

Incompatibilities: Incompatible with quaternary ammonium compounds.

5. PROPERTIES/USES

Excipient for pharmaceutical use.

Food use.

The product is compliant with Commission Regulation 1129/2011 (EC) (talc is registered as a food additive as E553b (Annex II), with Commission Regulation 231/2012 (EC) and the Food Chemical Codex 10th edition.

6. DOSAGE

No information available.

7. REMARKS

STORAGE:

Store 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 does not contain any animal/human products and therefore cannot transmit bovine spongiform encephalopathy/transmissible spongiform encephalopathy (BSE/TSE).

GMOs:

The product is of mineral origin and does not contain any plant products. No GMOs are used in the manufacturing process and the product does not come into contact with GMOs in the manufacturing process.



GUINAMA. Laboratory distributor of raw materials for the pharmaceutical and cosmetics industries.

Type of document:

TECHNICAL DATA SHEET

Review date:

11.11.2022

Version:

13.0

93533-TALC

CMR substances:

The product is not classified as a CMR (carcinogenic, mutagenic or toxic for reproduction) substance and no substances classified as CMR (carcinogenic, mutagenic or toxic for reproduction) according to European Regulation (EC) No 1272/2008 (and subsequent amendments) are added to these grades during any stage of the production processes.

SVHC:

Although their presence is not analysed, to the best of our knowledge these products are not expected to contain more than 0.1% of any of the substances included in the Candidate List of Substances of Very High Concern (SVHC), as published on the ECHA website (<https://echa.europa.eu/candidate-list-table>) in accordance with Article 59 (10) of the REACH Regulation (Regulation (EC) No 1907/2006). This statement reflects the SVHC Candidate List valid at the date of the document.

NANOMATERIALS:

In 2011, the European Commission adopted the following definition of nanomaterials: "Nanomaterial" means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm.

This definition is a recommendation (2011/696/EU) used in different European regulations, including REACH and CLP, to harmonise how nanomaterials are defined in legal frameworks.

To the best of our knowledge and current evidence, talc does not fall within the definition of nanomaterial according to the current recommendation.

Talc is not required to be:

- registered under the Belgian Royal Decree of 27 May 2014;
- reported to the Danish Inventory of Nanoproducts;
- declared annually to ANSES in accordance with French Decree No 2012-232.

IRRADIATION:

The product has not undergone any type of ionising radiation.

RESIDUAL SOLVENTS:

The product does not contain residual solvents. No chemical additives, including solvents, are used or added during any stage of the talc production process. Therefore, these grades comply with the ICH Q3C (R8) guideline of the European Medicines Agency (Guideline for Residual Solvents - Effective date: 20 November 2021), and the general chapter of the US Pharmacopoeia <467>, which states that it is only necessary to test for solvents that are used or produced in the manufacture or purification of pharmaceutical substances, excipients or pharmaceutical products.

CALIFORNIA PROP 65:

Talc is not listed under "Proposition 65" of the California Safe Drinking Water and Toxic Enforcement Act. The chemicals listed in Proposition 65 are not deliberately added during the production process, and with the exception of small amounts of natural impurities, SiO₂/quartz crystalline silica (respirable



GUINAMA. Laboratory distributor of raw materials for the pharmaceutical and cosmetics industries.

Type of document:

TECHNICAL DATA SHEET

Review date:

11.11.2022

Version:

13.0

93533-TALC

airborne particles), the rest of the products such as arsenic, beryllium, cadmium, hexavalent chromium, mercury, lead and nickel, are not naturally found in it.

CONFLICT MINERALS:

The talc comes from deposits that are not located in conflict-affected regions such as the Democratic Republic of Congo or neighbouring countries. Raw materials are not sourced from these countries to produce it. In addition, the manufacturer does not have the above minerals in its portfolio, and these minerals are also not added to any talc mineral supplied.

IMPURITIES:

- **Dioxins/PCBs:** Dioxins and PCBs are below the maximum permissible limit set by the European Union. Therefore, it is considered that the product is not contaminated with dioxins, PCBs or the like. In addition, these are not intentionally added or used in the manufacturing process.
- **Metal catalysis:** The product is not derived from a catalysed or synthesis reaction, and thus no inorganic impurities can arise from the manufacturing process. Therefore, the metal catalyst and metal reagents, such as platinum (Pt), palladium (Pd), iridium (Ir), rhodium (Rh), ruthenium (Ru), osmium (Os), are not present. In addition, the only inorganic impurities that may be present are those from the minerals contained in the products.
- **ICHQ3D, ICHQ3A, ICHQ3B:** Elemental impurities are not intentionally added in the manufacturing process. However, because it is a natural, mineral product, it may have traces of metal elements as impurities. These are technically unavoidable.
- **Nitrosamines:** Although no specific tests are performed to measure traces of nitrosamines in talc, the presence thereof is not likely as talc is a fully naturally occurring mineral. Its typical chemical formula is $Mg_3Si_4O_{10}(OH)_2$ and, by nature, it does not contain nitroso (N=O) or related amino groups. Furthermore, no other starting materials, chemical reagents, solvents or catalysts are used in pharmaceutical-grade processing lines, and, to the best of our knowledge, no intermediates or degradants are formed during any stage of the talc processing. More specifically: sodium nitrite ($NaNO_2$) or other nitrites, in the presence of secondary or tertiary amines, are not used in talc processing lines.
- **Persistent organic pollutants (POPs):** Talc does not contain any of the substances listed in the Annexes to the Stockholm Convention (Annex A: Elimination, Annex B: Restriction, Annex C: Unintentional Production) and EU Regulation (EU) 2019/1021 on Persistent Organic Pollutants (Annex I: Prohibition of Manufacture, Marketing and Use, Annex II: Restriction of Manufacture, Marketing and Use, Annex III: Provisions on Emission Reduction, Annex IV: Provisions on Waste Management).
- Talc is derived from natural minerals that have only been physically processed. No other substance is intentionally added or used during any stage of the manufacturing process. Therefore, the product is not expected to contain any of the substances listed below, although no specific tests are performed to measure these substances. The following list is a non-exhaustive list of substances:
 - o Aflatoxins
 - o Alcohol
 - o Alkylphenol (AP) or alkylphenol ethoxylates (APEs)

93533-TALC

- Animal products
- Human products
- Anthraquinone
- Aromatic amines
- Aspartame
- Benzene
- Biocidal products (Regulation (EU) No 528/2012)
- Bisphenols (BPA, BPF and BPS) (Regulation (EU) No 321/2011)
- Commission Regulation (EU) 2018/213)
- CFCs (chlorofluorocarbons) - Colourants
- Dichloroacetic acid
- Dimethyl fumarate (Commission Decision 2009/251/EC
- Commission Regulation (EU) No 412/2012)
- Diethylene glycol (DEG)
- Endocrine disruptors
- Epoxy derivatives: BADGE, NOGE, BFDGE (Commission Regulation (EC) No 1895/2005)
- Ethylene oxide, 2-chloroethanol
- Flavourings or fragrances
- Fluorinated resin polymers
- Formaldehyde
- Genotoxic impurities
- Glutamic acid
- Gluten
- Glycol ethers (EGME, EGMEA, EGEE, EGEEA)
- Halogens and halogenated compounds
- Iodine
- Latex
- MBT Monobutyltin (MBT), Dibutyltin (DBT) and Tributyltin (TBT)
- Melamine
- Microplastics
- Mineral oil (MOSH/MOAH)
- Monoacetic acid
- Monomers or residual monomers
- Nitrosamines, N-nitrosamines/N-nitrosamides
- Octabromodiphenyl ether (octaBDE), Pentabromodiphenyl ether (pentaBDE)
- Ozone-depleting agents (Regulation (EC) No 1005/2009)
- Palm oil/fat
- Parabens
- Para-phenylenediamine
- Per- and polyfluoroalkyl substances (PFAS)
- Pesticides and herbicides
- Phthalates
- Plant products



GUINAMA. Laboratory distributor of raw materials for the pharmaceutical and cosmetics industries.

Type of document:

TECHNICAL DATA SHEET

Review date:

11.11.2022

Version:

13.0

93533-TALC

- Polychlorinated biphenyls (PCBs), Polychlorinated terphenyls (PCTs)
- Polycyclic aromatic hydrocarbons (PAHs)
- Polyvinyl chloride (PVC)
- Preservatives or antioxidants
- Silicone
- Solvents / Residual solvents
- Sucrose
- Volatile organic compounds (VOCs) / Semi-volatile organic compounds (SVOCs)

ALLERGENS:

Cosmetic allergens: Talc is not a substance that is likely to cause contact allergies and none of the allergens with reference numbers 67 to 92 listed in Annex III to Regulation (EC) No 1223/2009 are intentionally added during the manufacturing process. Therefore, although no specific tests are performed, the presence of these substances is not expected.

Food allergens: Talc is not a substance causing food allergies or intolerances, and none of the food allergens defined in Regulation (EU) No 1169/2011 and the US Food Allergen Labelling and Consumer Protection Act have been intentionally added. Therefore, although no specific tests are performed, the product is not expected to contain any of the specified known food allergens.

HALAL:

These grades of talc are derived from natural minerals. According to the FAO/WHO "General Guidelines for the Use of the Term Halal" (CAC/GL 24-1997), these grades of talc comply with Halal certification because:

- 1 - they do not consist of or contain anything which is considered to be unlawful
- 2 - they have not been prepared, processed, transported or stored using any appliance or facility that was not free from anything unlawful
- 3 - they have not been in direct contact with any product that fails to satisfy points 1 and 2 above in the course of preparation, processing, transportation or storage

KOSHER:

Talc is of mineral origin and comes from natural sources; no animal materials or alcohol are intentionally used or added in the course of preparation. The production equipment is not used to manufacture animal products or alcohol. Therefore, it is compliant with the specifications of the kosher certificate.

VEGETARIAN/VEGAN:

This product does not contain and has not been in contact with any animal ingredients or animal by-products; no animal ingredients or animal by-products are used in the manufacturing process. Therefore, this product is suitable for vegetarians/vegans.

93533-TALC

WADA (WORLD ANTI-DOPING AGENCY) LIST:

This product is made from natural talc minerals. They are not included in the WADA's list of prohibited substances and are not contaminated at any point in the process by any WADA-prohibited substance.

NUTRITIONAL COMPOSITION:

Talc has no nutritional value since it is not assimilated by the body when ingested.

INVENTORIES

Talc CAS Number: 14807-96-6			
Country	List / Inventory	Status	Remarks
Australia	Australian Inventory of Chemical Substances (AICS)	Listed	
Canada	Domestic Substances List (DSL); Liste intérieure des substances (LIS)	Listed	
Canada	Non-Domestic Substances List (NDSL); Liste extérieure des substances (LES)	Not listed	
China	Inventory of Existing Chemical Substances Produced or Imported in China (IECSC)	Listed	
Japan	Japanese Existing and New Chemical Substances (ENCS/CSCL/METI/MITI List)	Exempt (being a natural mineral)	
New Zealand	The New Zealand Inventory of Chemicals (NZIoC)	Listed	
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Listed	
South Korea	Korean Existing Chemicals List (KECI)	Listed	KE No.= KE- 32773
Taiwan	Taiwan Chemical Substances Inventory (TCSI)	Listed	
United States of America	Toxic Substances Control Act (TSCA) Inventory	Listed	ACTIVE

REACH:

Talc is exempt from registration in accordance with Article 2(7)(b) and Annex V.7 (Natural substances that are not chemically modified) of Regulation (EC) No 1907/2006 and its amendments.

REACH substances of concern: REACH authorisation list of substances of concern: Talc does not contain any substances subject to authorisation under REACH Annex XIV (Authorisation list) above 0.1% by weight or in concentrations sufficient to be classified as a hazard under criteria 1272/2008



GUINAMA. Laboratory distributor of raw materials for the pharmaceutical and cosmetics industries.

Type of document:

TECHNICAL DATA SHEET

Review date:

11.11.2022

Version:

13.0

93533-TALC

(CLP). The substances listed are not naturally found in talc and are not intentionally added during the production process.

REACH restricted substances: Talc does not contain any substances that are restricted under REACH Annex XVII (List of restricted substances) above 0.1% by weight or in concentrations sufficient to be classified as a hazard under criteria 1272/2008 (CLP). With the exception of natural impurities of arsenic, cadmium, lead, mercury and nickel, the listed substances are not naturally found in talc and are not intentionally added during the production process. Restriction conditions with regard to the indicated impurities are not relevant to any known use or listing. These substances are present as trace impurities at low levels of parts per million. No specific tests are carried out on talc for all the substances listed in Annexes XIV and XVII.

ANIMAL TESTS:

Talc has not been tested on animals for cosmetic purposes.

TARIFF ITEM NUMBER:

2526 20 00