SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING.

1.1 Product identifier.

Product Name:	Talcum
Product Code:	93533
Chemical Name:	Talc (Mg3H2(SiO3)4)
CAS No:	14807-96-6
EC No:	238-877-9
Registration No:	01-2120140278-58-XXXX

1.2 Relevant identified uses of the substance or mixture and uses advised against.

pharmaceutical use
Oral use

Uses advised against:
Uses other than those recommended.
Functional mineral for use in paper, paints, ceramics, plastics, personal hygiene, etc.

1.3 Details of the supplier of the safety data sheet.

Company:	**GUINAMA S.L**
Address:	C/ Oslo Nº3
City:	46185 - La Pobla de Vallbona
Province:	Valencia
Telephone:	+34961869090 / 902119816
Fax:	+34961850352
E-mail:	ventas@guinama.com
Web:	www.guinama.com

1.4 Emergency telephone number: +34961869090 / 902119816 (Only available during office hours; Monday-Friday; 08:00-18:00)

SECTION 2: HAZARDS IDENTIFICATION.

2.1 Classification of the substance or mixture.
The product is not classified as hazardous within the meaning of Regulation (EC) No 1272/2008.

2.2 Label elements.
Este producto no esta clasificado como peligroso según el Reglamento CE 1272/2008.

2.3 Other hazards.

The substance is not PBT
The substance is not vPvB
Substance does not have endocrine disrupting properties.

The product may have the following additional risks:
Repeated and prolonged exposure to large amounts of talcum powder can cause lung damage (pneumoconiosis). The risk of injury depends on the duration and level of exposure. depending on the type of handling and use, airborne respirable crystalline silica may be generated. Prolonged or massive inhalation of respirable crystalline silica can cause pulmonary fibrosis, commonly known as silicosis. The main symptoms of silicosis are coughing and shortness of breath. Occupational exposure to respirable crystalline silica dust should be monitored and controlled. This product must be handled with care to avoid creating dust.
This product is an inorganic substance and does not meet the criteria for PBT or vPvB in accordance with Annex XIII of REACH.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS.

3.1 Substances.
UVCB (Substance of Unknown or Variable composition, Complex reaction products or Biological materials).

Identifiers	Name	Concentrate	(*)Classification - Regulation (EC) No 1272/2008

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			Classification	Specifics concentration limits and Acute toxicity estimate
CAS No: 14807-96-6 EC No: 238-877-9	Talc (Mg3H2(SiO3)4)	75 - 100 %	-	-

3.2 Mixtures.
Not applicable.

SECTION 4: FIRST AID MEASURES.

4.1 Description of first aid measures.
Due to the composition and type of the substances present in the product, no particular warnings are necessary.

Inhalation.
If breathing stops, seek emergency medical attention. Take the victim into open air; keep them warm and calm. If breathing is irregular or stops, perform artificial respiration.

Eye contact.
Remove contact lenses, if present and if it is easy to do. Wash eyes with plenty of clean and cool water for at least 10 minutes while pulling eyelids up, and seek medical assistance. Dont let the person to rub the affected eye.

Skin contact.
Remove contaminated clothing.

Ingestion.
Keep calm. NEVER induce vomiting.

4.2 Most important symptoms and effects, both acute and delayed.
No known acute or delayed effects from exposure to the product.

4.3 Indication of any immediate medical attention and special treatment needed.
In case of doubt or when symptoms of feeling unwell persist, get medical attention. Never administer anything orally to persons who are unconscious.

SECTION 5: FIREFIGHTING MEASURES.

5.1 Extinguishing media.
Suitable extinguishing media:
Extinguisher powder or CO2. In case of more serious fires, also alcohol-resistant foam and water spray.

Unsuitable extinguishing media:
Do not use a direct stream of water to extinguish. In the presence of electrical voltage, you cannot use water or foam as extinguishing media.

5.2 Special hazards arising from the substance or mixture.
Special risks.
Exposure to combustion or decomposition products can be harmful to your health.

5.3 Advice for firefighters.
Use water to cool tanks, cisterns, or containers close to the heat source or fire. Take wind direction into account.

Fire protection equipment.
According to the size of the fire, it may be necessary to use protective suits against the heat, individual breathing equipment, gloves, protective goggles or facemasks, and boots.

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SECTION 6: ACCIDENTAL RELEASE MEASURES.

6.1 Personal precautions, protective equipment and emergency procedures.
For exposure control and individual protection measures, see section 8.

6.2 Environmental precautions.
Product not classified as hazardous for the environment, avoid spillage as much as possible.

6.3 Methods and material for containment and cleaning up.
Contain and collect spillage with inert absorbent material (earth, sand, vermiculite, Kieselguhr...) and clean the area immediately with a suitable decontaminant.
Deposit waste in closed and suitable containers for disposal, in compliance with local and national regulations (see section 13).

6.4 Reference to other sections.
For exposure control and individual protection measures, see section 8.
For later elimination of waste, follow the recommendations under section 13.

SECTION 7: HANDLING AND STORAGE.

7.1 Precautions for safe handling.
Avoid generation of airborne dust. Ensure there is adequate exhaust ventilation where airborne dust is generated. In case of insufficient ventilation, wear suitable equipment for the protection of the respiratory tract. Handle packaged products carefully to avoid accidental breakage.

7.2 Conditions for safe storage, including any incompatibilities.
The product does not require special storage measures.As general storage measures, sources of heat, radiation, electricity and contact with food should be avoided.
Keep away from oxidising agents and from highly acidic or alkaline materials.
Store the containers between 15 and 25 º C, in a dry and well-ventilated place.
Store according to local legislation. Observe indications on the label. Once the containers are open, they must be carefully closed and placed vertically to prevent spills.

The product is not affected by Directive 2012/18/EU (SEVESO III).

7.3 Specific end use(s).
Not available.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION.

8.1 Control parameters.

The product does NOT contain substances with Professional Exposure Environmental Limit Values.The product does NOT contain substances with Biological Limit Values.
8.2 Exposure controls.

Measures of a technical nature:

Minimize the generation of airborne dust. Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne concentrations below specified exposure limits. If user operations generate dust, smoke, or mist, use ventilation to keep exposure to airborne particles below the exposure limit. Take organizational measures, such as separating dusty areas from areas frequented by staff. Dirty clothes must be removed and washed.
Eye Protection: Use eye protectors with a side shield when there is a risk of dust generation that can cause mechanical irritation of the eyes.
Skin Protection: No specific requirements.
Hand protection: The use of protective gloves is not necessary but their use is recommended for people prone to developing dryness or skin irritation.
Respiratory protection: In case of prolonged exposure to airborne dust concentrations, wear respiratory protection equipment that meets the requirements of European or national regulations. It is recommended to use a full mask or half mask with a filter against category 2 or 3 particles (FP2-FP3). Refer to EN 143: 2000- Respiratory protection equipment. Filters against particles.

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Environmental Exposure Controls: Avoid airborne dispersion.

Concentration:	**100 %**
Uses:	**pharmaceutical use** **Oral use**
Breathing protection:	
If the recommended technical measures are observed, no individual protection equipment is necessary.	
Hand protection:	
If the product is handled correctly, no individual protection equipment is necessary.	
Eye protection:	
If the product is handled correctly, no individual protection equipment is necessary.	
Skin protection:	
PPE:	Work footwear.
Characteristics:	«CE» marking, category II.
CEN standards:	EN ISO 13287, EN 20347
Maintenance:	This product adapts to the first user's foot shape. That is why, as well as for hygienic reasons, it should not be used by other people.
Observations:	Work footwear for professional use includes protection elements aimed at protecting users against any injury resulting from an accident

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES.

9.1 Information on basic physical and chemical properties.
Physical state: Solid - Dust
Colour: White, whitish or light gray
Odour: Odorless
Odour threshold: Not applicable
Melting point: >3000 ºC
Freezing point: Not applicable
Boiling point or initial boiling point and boiling range: Not applicable
Flammability: Not applicable (Not relevant for this type of product)
Lower explosion limit: Not applicable (Not relevant for this type of product)
Upper explosion limit: Not applicable (Not relevant for this type of product)
Flash point: Not applicable (Not relevant for this type of product)
Auto-ignition temperature: Not applicable (Not relevant for this type of product)
Decomposition temperature: > 1000 ºC
pH: 9-9.5 (10%)
Kinematic viscosity: Not applicable (Not relevant for this type of product)
Solubility: Water solubility: negligible. Solubility in hydrofluoric acid: Yes.
Hydrosolubility: Negligible
Liposolubility: Not available
Partition coefficient n-octanol/water (log value): Not applicable (Not relevant for this type of product)
Vapour pressure: Not applicable (Not relevant for this type of product)
Absolute density: Not available
Relative density: 2.58-2.83
Relative vapour density: Not applicable
Particle characteristics: Not available

9.2 Other information
Information with regard to physical hazard classes
Explosives:
Explosive properties: Not explosive
Oxidizing solids:
Oxidizing properties: Non-oxidizing

SECTION 10: STABILITY AND REACTIVITY.

10.1 Reactivity.
The product does not present hazards by their reactivity.

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10.2 Chemical stability.
Stable under the recommended handling and storage conditions (see section 7).

10.3 Possibility of hazardous reactions.
The product does not present possibility of hazardous reactions.

10.4 Conditions to avoid.
Avoid any improper handling.

10.5 Incompatible materials.
Keep away from oxidising agents and from highly alkaline or acidic materials in order to prevent exothermic reactions.

10.6 Hazardous decomposition products.
No decomposition if used for the intended uses.

SECTION 11: TOXICOLOGICAL INFORMATION.

11.1 Information on hazard classes as defined in Regulation (EC) Nº 1272/2008.
There are no tested data available on the product.

a) acute toxicity;
Talc is not very toxic
Oral LD50 > 5000 mg/kg bw (Weir, 1974)
Cutaneous: Data inconclusive for classification.
Inhalation: Inconclusive data for classification.

b) skin corrosion or irritation;
Talc is not a skin irritant (in vivo, OECD 404, rabbit)
Classification for irritation or corrosion is not warranted.

c) serious eye damage or eye irritation;
Inconclusive data for classification.

d) respiratory or skin sensitization;
LLNA (OECD 429, mouse): Talc does not cause skin sensitisation.

e) germ cell mutagenicity;
Talc is not mutagenic (OECD 471 and OECD 487 in vitro study results). From the strains tested, talc appears to have no mutagenic effect. Classification for mutagenicity is not warranted.

f) carcinogenicity;
Inhaled talc that does not contain asbestos fibers or asbestiform fibers is not classifiable as to its carcinogenicity (group 3), IARC monograph volume 93, 2010.
The IARC ruled that the evidence that the use of talc body powder for perineal dusting is a possible risk factor for ovarian cancer is limited (group 2B). This is not a relevant route of exposure for workers and is only applicable to a specific use of talc.
Classification as to carcinogenicity is not warranted.

g) reproductive toxicity;
Inconclusive data for classification.

h) specific target organ toxicity (STOT) - single exposure;
Inconclusive data for classification.

i) specific target organ toxicity (STOT) - repeated exposure;
Inconclusive data for classification.
Oral: 90-Day Subchronic Oral Toxicity (OECD 408, Rat): No mortality or relevant toxicological findings related to the test article have been observed. NOAEL > 1000mg/kg.
Inhalation: Classification for specific organ toxicity by inhalation at repeated dose exposure is not warranted. Probably all effects will be non-particle specific effects rather than mineral specific intrinsic fibrogenic activity.
Cutaneous: toxicity by the dermal route is not considered relevant.
Therefore, the classification of talc in terms of toxicity in case of prolonged exposure by oral route, by dermal route or inhalation is not justified.

j) aspiration hazard;

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Inconclusive data for classification.

11.2 Information on other hazards.
Endocrine disrupting properties
This product does not contain components with endocrine-disrupting properties with effects on human health.
Other information
There is no information available on other adverse health effects.

SECTION 12: ECOLOGICAL INFORMATION.

12.1 Toxicity.
No information is available regarding the ecotoxicity.

12.2 Persistence and degradability.
No information is available regarding the biodegradability
No information is available on the degradability
No information is available about persistence and degradability of the product.

12.3 Bioaccumulative potential.
No information is available regarding the bioaccumulation.

12.4 Mobility in soil.
No information is available about the mobility in soil.
The product must not be allowed to go into sewers or waterways.
Prevent penetration into the ground.

12.5 Results of PBT and vPvB assessment.
No information is available about the results of PBT and vPvB assessment of the product.

12.6 Endocrine disrupting properties.
This product doesn't contain components with environmental endocrine disrupting properties.

12.7 Other adverse effects.
The product is not affected by the Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer.
No information is available about other adverse effects for the environment.

SECTION 13: DISPOSAL CONSIDERATIONS.

13.1 Waste treatment methods.
Do not dump into sewers or waterways. Waste and empty containers must be handled and eliminated according to current, local/national legislation.
Follow the provisions of Directive 2008/98/EC regarding waste management.

SECTION 14: TRANSPORT INFORMATION.

Transportation is not dangerous. In case of road accident causing the product's spillage, proceed in accordance with point 6.

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14.1 UN number or ID number.
Transportation is not dangerous.

14.2 UN proper shipping name.
Description:
ADR/RID: Not classified as hazardous for transport.
IMDG: Not classified as hazardous for transport.
ICAO/IATA: Not classified as hazardous for transport.

14.3 Transport hazard class(es).
Transportation is not dangerous.

14.4 Packing group.
Transportation is not dangerous.

14.5 Environmental hazards.
Transportation is not dangerous.
Transport by ship, FEm – Emergency sheets (F – Fire, S - Spills): Not applicable.

14.6 Special precautions for user.
Transportation is not dangerous.

14.7 Maritime transport in bulk according to IMO instruments.
Not classified as hazardous for transport.

SECTION 15: REGULATORY INFORMATION.

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture.

The product is not affected by Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products.
The product is not affected by the procedure established Regulation (EU) No 649/2012, concerning the export and import of dangerous chemicals.

15.2 Chemical safety assessment.
No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

SECTION 16: OTHER INFORMATION.

Changes regarding to the previous version:

- Changes in the composition of the product (SECTION 3.2).

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Physical hazards	On basis of test data
Health hazards	Calculation method
Environmental hazards	Calculation method

It is recommended that the product only be employed for the purposes advised.

Information on the TSCA Inventory (Toxic Substances Control Act) USA:

CAS No	Name	State
14807-96-6	Talc (Mg3H2(SiO3)4)	Registered

Risk classification system NFPA 704:

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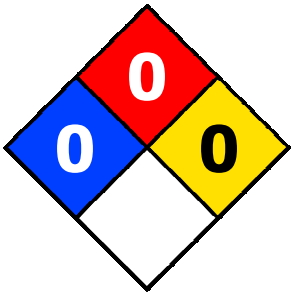

Health hazard: 0 (Normal Material)

Flammability: 0 (Will not burn)

Reactivity: 0 (Stable)

Abbreviations and acronyms used:
CEN: European Committee for Standardization.
PPE: Personal protection equipment.

Key literature references and sources for data:
http://eur-lex.europa.eu/homepage.html
http://echa.europa.eu/
Regulation (EU) 2020/878.
Regulation (EC) No 1907/2006.
Regulation (EC) No 1272/2008.

The information given in this Safety Data Sheet has been drafted in accordance with COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemical substances and mixtures (REACH).

The information in this Safety Data Sheet on the Preparation is based on current knowledge and on current EC and national laws, as far as the working conditions of the users is beyond our knowledge and control. The product must not be used for purposes other than those that are specified without first having written instructions on how to handle. It is always the responsibility of the user to take the appropriate measures in order to comply with the requirements established by current legislation. The information contained in this Safety Sheet only states a description of the safety requirements for the preparation, and it must not be considered as a guarantee of its properties.

-End of safety data sheet.-