Safety Data Sheet

In compliance with 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Revision Date: February 17, 2021

SECTION 1. IDENTIFICATION

1.1 Product identifier:

Pharma 200 USP
Pharma 400 USP
Pharma 700 USP

1.2 Synonyms: Talc, steatite, soapstone, hydrous magnesium silicate

1.3 Identified uses: Functional mineral for use in pharmaceutical applications, etc.

1.4 Supplier:

- Company name: **Magris Talc USA, Inc.**
- Address: 17509 Van Road
  Houston, TX 77049
  USA
- Tel: +1 281-272-7200
- Fax: +1 281-456-7816
- E-mail: regulatory@magristalc.com
- Website: www.magristalc.com

1.5 Emergency telephone number:

Emergency phone number: +1 303-623-5716
Available outside office hours: Yes

SECTION 2. HAZARD IDENTIFICATION

2.1 GHS Classification: No classification

2.2 Label elements:

- GHS Pictogram None
- Signal word None
- Hazard statement None
- Precautionary statements None

Repeated and prolonged exposure to large amounts of talc dust can cause lung injury (pneumoconiosis). Risk of injury is dependent on the duration and level of exposure.

SECTION 3. COMPOSITION / INFORMATION ON INGREDIENTS

The above-mentioned products are a natural association of talc, chlorite, magnesite and dolomite.

Main constituents	CAS Number	EC Number	Amount (%)	Classification
Talc (hydrous magnesium silicate)	14807-96-6	238-877-9	> 96	No

Chlorite	1318-59-8	215-285-9	< 3	No
Dolomite	16389-88-1	240-440-2	< 1	No
Magnesite	546-93-0	208-915-9	< 1	No

The specific percentages of composition of the ingredients are being withheld as a trade secret.

SECTION 4. FIRST-AID MEASURES

Description of first aid measures:

Inhalation: Remove to fresh air.
Ingestion: Drink plenty of water. Never give liquid to an unconscious person.
Eye contact: Immediately rinse with water for several minutes.
Skin contact: Wash skin thoroughly with soap and water.

SECTION 5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media: All extinguishing media can be used.

5.2 Special hazards arising from the substance or mixture: The product is not flammable, combustible or explosive. No hazardous thermal decomposition.

5.3 Advice for fire-fighters: No specific fire-fighting protection is required. Use an extinguishing agent suitable for the surrounding fire.

SECTION 6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures: Use proper respiratory and personal protective equipment. MSHA/NIOSH or OSHA/NIOSH approved respirator recommended. Spilled materials may cause slippery conditions when wet. Care should be exercised when walking on spills on floor or concrete pads.

6.2 Methods and material for containment and cleaning up: Dry product should be cleaned with a shovel or vacuum cleaner while wearing the personal protective equipment described above. Do not discharge into drains, watercourses or onto the ground. Washing the floor with water is not recommended since it may cause the floor to become slippery. However, if talc is already wet, and only in this case, the floor should be thoroughly flushed with water to remove all slipperiness.

SECTION 7. HANDLING AND STORAGE

7.1 Precautions for safe handing: Minimize dust generation and accumulation. If excessive dust is generated, provide adequate ventilation and use proper respiratory and personal protective equipment.

7.2 Conditions for safe storage: Keep the product dry and in closed containers. Store it in a cool and well-ventilated space.

SECTION 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters: Follow workplace regulatory exposure limits for all types of airborne dust (e.g. total dust, respirable dust, and respirable crystalline silica dust). In the U.S., the ACGIH OEL (Occupational Exposure Limit) for talc containing no asbestos fibers and less than 1% crystalline silica is 2 mg/m3 respirable fraction measured as an 8-hour TWA (Time Weighted Average). The OSHA exposure limit for talc is 20 mppcf Permissible Exposure Limit (PEL) TWA. For the equivalent limits in other countries, please

consult a competent occupational hygienist or the local regulatory authority.

8.2 Appropriate engineering controls: Use exhaust ventilation, if required, to maintain dust concentration below recommended exposure limits.

8.3 Personal protection measures:

(a) Eye protection: Wear side shield safety glasses.

(b) Hand protection: Rubber gloves are recommended for prolonged exposure.

(c) Respiratory protection: If a respirator is required, use of a MSHA/NIOSH or OSHA/NIOSH approved respirator is recommended.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Appearance: White or off white to light grey

9.2 Odor: Odorless

9.3 pH: 9–9.5 (suspension of 10% talc in water)

9.4 Melting point: >1300°C

9.5 Flammability (solid, gas): Not flammable

9.6 Upper/lower flammability or explosive limits: Not explosive. Limits do not apply.

9.7 Relative density: 2.58–2.83 g/cm^3

9.8 Solubility (ies):

Solubility in water: Negligible

Solubility in hydrofluoric acid: Yes

9.9 Decomposition temperature: >1000°C

9.10 Explosive properties: Not explosive

9.11 Oxidizing properties: Non-oxidizing

SECTION 10. STABILITY AND REACTIVITY

10.1 Reactivity: Inert, not reactive

10.2 Chemical stability: Chemically stable

10.3 Possibility of hazardous reactions: No hazardous reaction

10.4 Conditions to avoid: None

10.5 Incompatible materials: None known

10.6 Hazardous decomposition products: None

SECTION 11. TOXICOLOGICAL INFORMATION

Carcinogenic Status:

IARC: In 2006, IARC concluded that inhaled talc not containing asbestos or asbestiform fibers is not classifiable as a human carcinogen (Group 3). IARC ruled that there is limited evidence that the use of talc-based body powder for perineal dusting is a possible risk factor for ovarian cancer (Group 2B). This is not a route of exposure relevant to workers and applies only to one specific use of talc.

OSHA: Not listed

ACGIH: A4 – not classified as a human carcinogen

WHMIS 2015 Classification: Specific Target Organ Toxicity – Repeated Exposure – Category 1 (STOT RE1)

NTP: Not listed

SECTION 12. ECOLOGICAL INFORMATION

12.1 Aquatic Toxicity: No known effects

12.2 Persistence and degradability: This product is an inorganic substance and therefore is not considered biodegradable.

12.3 Bioaccumulative potential: Not relevant

12.4 Mobility in soil: Negligible

12.5 Other adverse effects: No specific adverse effects known

SECTION 13. DISPOSAL CONSIDERATIONS

13.1 Waste disposal information: Talc is not considered a hazardous waste as defined by the US EPA RCRA (40 CFR 261) regulations. Observe all applicable federal, state and local regulations when handling, storing or disposing of this substance.

13.2 Disposal of packaging: Where possible, recycling is preferable to disposal. Recycling and disposal of packaging should be carried out by an authorized waste management company in compliance with local regulations. Responsibility for proper waste disposal lies with the owner of the waste.

SECTION 14. TRANSPORT INFORMATION

14.1 US Department of Transportation (DOT): No classification assigned

14.2 Canadian Transportation of Dangerous Goods: No classification assigned

14.3 Land Transport – ADR/RID: No classification assigned

14.4 Air Transport – IATA/ICAO: No classification assigned

14.5 Maritime Transport – IMDG: No classification assigned

14.6 Harmonized Tariff Code: Talc – crushed or powdered. 2526.20.00 (stat suffix 00).

14.7 EPA TSCA 12(B) Export Notification: Not listed

SECTION 15. REGULATORY INFORMATION

15.1 International regulations:

Industrial Safety and Health Law: This product does not contain harmful or controlled hazardous substances under ISHL. It contains <1% crystalline silica.

Toxic Chemical Control Act: This product does not contain chemical substances regulated as toxic, observational, restricted or banned under TCCA.

Dangerous Substance Management Law: This product does not contain chemical substances

regulated under DSML.

Waste Management Law: Dispose of this product in accordance with the waste treatment standards prescribed in Waste Management Law.

15.2 Other regulations based on domestic or foreign laws: The following inventories have been investigated as to the publicly available portion of the lists:

MINERAL	CAS No.	EINECS (EU)	AIIC (Australia)	CEPA (DSL/NDSL) (Canada)	KECI Korean Gazette No. (Korea)	ENCS/ISHL (Japan)
Talc	14807-96-6	238-877-9	Yes	Yes (DSL)	KE-32773	(1)-468

MINERAL	IECSC (China)	PICCS (Philippines)	TSCA (USA)	Swiss ID No. (Switzerland)	NZIoC (New Zealand)	CSNN (Taiwan)
Talc	Yes	Yes	Yes	G-6939	Yes	Yes

Regarding regulatory inventories, talc is considered to be a "naturally occurring substance with variable composition". Talc ore contains variable amounts of associated minerals, such as magnesite, dolomite, and chlorite. In the interest of full disclosure, we list these associated minerals on our SDSs, however from a regulatory perspective, the product supplied is considered to be "talc" (CAS # 14807-96-6). Specifically, according to the Toxic Substances Control Act (TSCA), talc meets the definition of a "Naturally Occurring Substance", with unknown or variable composition, complex reaction product or biological material (UVCB Substance).

15.3 Chemical safety assessment: Exempted from REACH registration in accordance with Annex V.7

15.4 Other pertinent classifications/regulations:

California Safe Drinking Water and Toxic Enforcement Act (California PROP 65) Status:

CALIFORNIA REQUIRED STATEMENT

WARNING: Talc is not listed, however the product supplied can expose you to chemicals including crystalline silica (airborne particles of respirable size) which has been identified by the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov .

State Right-To-Know: Talc is listed in Illinois, Massachusetts, New Jersey, Pennsylvania and Florida.

Clean Air Act – Ozone depleting chemicals (ODC): None

CONEG Approved Packaging: Yes

National Fire Protection Association (NFPA) Ratings (0-4 scale):

Health = 0
Fire = 0
Reactivity = 0

National Paint and Coating Association (NPCA) – Hazardous Material Identification System (HMIS)

Health: 1* (chronic potential)
Flammability: 0
Physical: 0
Personal protection: dust respirator, safety glasses or goggles, gloves

SECTION 16. OTHER INFORMATION

16.1 Date of last revision: February 17, 2021

Revision comments: Updated with Magris Talc branding. Updated section 15.2 to reflect UVCB

regulatory status.

Date of previous revision: November 13, 2018

16.2 References and sources:

1. Baan, R, Straif K, Secretan B, Ghissassi FE and Cogliano V. (2006), On behalf of the WHO International Agency for Research on cancer Monograph Working Group. Carcinogenicity of carbon black, titanium dioxide and talc. The Lancet Oncology. 7:295-296.
2. Wild, P.; "Lung cancer risk and talc not containing asbestiform fibers: a review of the epidemiological evidence". Occup. Environ. Med. 2006; 63, 4-9.
3. Cohrssen, B. and Powell C.H. (2001). Talc. In Patty's Toxicology, 5th ed., Bingham, E., Cohrssen, B., and Powell, C.H., eds., John Wiley & Sons, Inc. NY. pp. 519-538.
4. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans Volume 93 (2010) Carbon Black, Titanium Dioxide, and Talc.
5. Wild, P. and coll; „Effects of talc dust on respiratory health: results of a longitudinal survey of 378 French and Austrian talc workers", Occup. Environ. Med. 2008; 65, 261-267.
6. USEPA 1992. Health Assessment Document for Talc, Environmental Criteria and Assessment Office, Office of Health and Environmental Assessment, U.S. Environmental Protection Agency, Research Triangle Park, NC. EPA 600/8-91/217, March 1992.
7. P. Leophonte and coll. "La pathologie respiratoire chronique des travailleurs du talc", Rev. Fr. Mal. Resp., 1980, 8, 43-45
8. S. Endo-Capron and coll. "In vitro response of rat pleural mesothelial cells to talc samples in genotoxicity assays (sister chromatid exchanges and DNA repair)" Toxic in vitro, 1993, 7, 7-14.
9. P. Wild, M. Refregier, G. Auburtin, B. Carton, JJ. Moulin "Survey of the respiratory health of the workers of a talc producing factory", Occup. Environ. Med. 1995, 52, 470-477.
10. P. Wild and coll. "A cohort mortality and nested case-control study of French and Austrian talc workers" Occup. Environ. Med 2002, 59, 98-105.
11. M. Coggiola and coll. "An Update of a Mortality Study of Talc Miners and Millers in Italy", Am. J Indust. Med. 2003, 44, 63-69

Notice to reader:

This safety data sheet complements the technical data sheets but does not replace them. The information it contains is based on our present knowledge of the product on the date indicated. It is given in good faith. Users should be warned about the risks associated with using the product for a different purpose than that for which it was developed, and particularly for uses for which we are not qualified to give advice.

These regulatory prescriptions are provided with a view to helping users meet their obligations when using this product. This list should not be considered exhaustive and does not exempt users from ensuring that they are not required to comply with any further prescriptions other than those mentioned above concerning product possession and handling for which they are solely responsible.

Only the original English version is authoritative.
