

Material Safety Data Sheet

according to the Commission Directive 91/155/EEC
and its two amendments: 93/112/EC & 2001/58/EC

LUZENAC PHARMA

1 - PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: LUZENAC PHARMA
USE OF THE PRODUCT: Functional mineral
SUPPLIER: LUZENAC EUROPE SAS
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2 - HAZARDS IDENTIFICATION

Talc presents the same hazards as other non-toxic dusts.

⇒ **INHALATION IS THE PRIMARY ROUTE OF ENTRY.**

Repeated and prolonged overexposure to large amounts of talc dust exceeding the occupational exposure limits (see attached annex) might induce a mild pneumoconiosis, called talcosis. Smoking and other chronic respiratory diseases may accelerate the onset of pneumoconiotic overloading. The observance of current national occupational exposure limits to prevent lung overloading provides an efficient protection and is therefore recommended.

Symptoms of **acute accidental exposure** would be non-specific and similar to those of a massive inhalation of any dust. These symptoms may include coughing, expectoration, sneezing, difficult breathing due to upper respiratory tract irritation.

⇒ Generally, no adverse effect is observed if applied to unbroken skin. Some subjects may complain of slight skin dryness.

⇒ Accidental direct contact with the eyes may cause, as most dusts, a temporary discomfort due to mechanical irritation.

3 - COMPOSITION / INFORMATION ON INGREDIENTS

SUBSTANCE: talc, concentration: $\geq 92\%$

SYNONYMS: soapstone, steatite, talcum, hydrated magnesium silicate

	<u>CAS Nr</u>	<u>EINECS Nr</u>	<u>Molecular formula</u>
Talc	14807-96-6	238-877-9	$\text{Mg}_3\text{Si}_4\text{O}_{10}(\text{OH})_2$

CHEMICAL FAMILY: silicates

ASSOCIATED MINERALS:

	<u>CAS Nr</u>	<u>EINECS Nr</u>	<u>Concentration</u>
Chlorite	1318-59-8	215-285-9	< 5%
Dolomite	16389-88-1	240-440-2	< 1%
Magnesite	13717-00-5	281-193-0	< 1%
Quartz	14808-60-7	238-878-4	< 0.5% (1)

(1): Fourier Transform Infra-Red analysis

LUZENAC PHARMA does not contain asbestos fibres as defined by the United States Occupational Safety and Health Administration (OSHA) and European Directive 83/477/EEC, when analysed by conventional methods. This statement is based upon verification by certified independent laboratories.

Epidemiological studies carried out on Luzenac workers and by some of our customers have shown that there is no risk of silicosis or lung cancer by inhalation of Luzenac talcs (LEOPHONTE, 1980, CATILINA, 1980, WILD, 1995, 2002, 2006 and COGGIOLA, 2003).

4 - FIRST-AID MEASURES

INHALATION

In the event of **acute overexposure**, if an irritation of the upper respiratory tract develops, move subject away from source of exposure and into fresh air. Treatment should be limited to the control of symptoms: coughing, expectoration, sneezing, difficult breathing.

In the event of **massive accidental inhalation**, seek medical assistance.

SKIN CONTACT

If the subject complains of dryness of the skin, apply ordinary skin moisturisers.

Broken skin exposed to talc dust should be cleansed with mild soap and water.

Irritation is uncommon, but if it develops and persists, seek medical advice.

EYE CONTACT

Direct contact can cause irritation. Wash the affected eye(s) copiously with clean water. If irritation or redness develops, seek medical assistance.

INGESTION

No adverse effects having been observed, no specific antidote is necessary.

5 - FIRE-FIGHTING MEASURES

NOT FLAMMABLE - NOT EXPLOSIVE

Extinguishing media: none required

Fire-fighting procedures: none required

6 - ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS

If the dust level exceeds the recommended occupational exposure limits (see attached annex), approved dust masks should be worn.

ENVIRONMENTAL PRECAUTIONS

No special precautions required.

METHODS FOR CLEANING UP

In the event of release onto working area floors, clean up with a shovel and/or vacuum cleaner and vacuum the residues.

If the product is clean and dry, it may be packed in a convenient container and disposed of.

It is not recommended to wash the floor with water since it would become extremely slippery. However, if the dispersed talc is already wet, and only in this case, the floor should be thoroughly flushed with water to remove all slipperiness.

7 - HANDLING AND STORAGE

HANDLING

Avoid generating dust in excess of the recommended occupational limits (see annex attached).

In the event of dust dispersion into the air in excess of the authorised levels, approved dust masks should be worn.

Keep all floors, work areas, stairs and handrails clean as surfaces covered with talc dust are liable to be slippery.

STORAGE

Avoid generation of dust.

Keep the product dry.

All normal packaging materials are recommended.

8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

ENGINEERING MEASURES

Ventilation / Exhaust: if necessary, install additional ventilation or exhaust systems in the work areas to maintain dust levels below the recommended occupational limits (see annex attached).

CONTROL PARAMETERS

Dust levels should be controlled according to national and local regulations. Recommended occupational exposure limits should be strictly applied, be they V.M.E., T.L.V., M.A.C. or M.A.K. values.

PERSONAL PROTECTIVE EQUIPMENT

- ◇ Respiratory protection: approved dust masks should be worn if the dust level exceeds the authorised limits.
- ◇ Hand protection: protective gloves are not necessary. They may be worn by workers prone to skin irritation or dryness.
- ◇ Eye protection: if necessary, safety goggles may be worn to prevent eye contact with large quantities of airborne dust.

9 - PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE:	solid presented in powder form
COLOUR:	white, off white to light grey
ODOUR:	none
pH:	suspension of 10 % talc in water: pH = 9
FLASH POINT:	none
EXPLOSIVE PROPERTIES:	not applicable
REAL DENSITY:	2.58 to 2.83
SOLUBILITY:	in water < 0.1%
MELTING TEMPERATURE:	> 1300 °C

10 - STABILITY AND REACTIVITY

Stable under normal conditions of temperature and pressure.

Possible hazardous reactions: none

Hazardous decomposition products: none

11 - TOXICOLOGICAL INFORMATION

No acute toxic effect has been observed; as indicated in the IARC (International Agency for Research on Cancer) monograph on talc: "...no acute mortality was observed in several species of animals following administration of high doses of talc by ingestion, inhalation or intratracheal, intrapleural, intraperitoneal or subcutaneous injection".

The IARC working group also evaluated the biological effects of talc and concluded, from the reviewed in vivo and in vitro studies, that there was *inadequate evidence* for the carcinogenicity or genotoxicity of talc to humans or experimental animals.

Toxicity tests on sister chromatid exchanges (SCEs) and on unscheduled DNA synthesis (UDS) (Endo-Capron, 1993) show that talc does not induce the enhancement of UDS or SCEs in treated cell cultures.

No teratological effect was observed in hamsters, rats, mice or rabbits following oral administration of talc (Food & Drug Research Laboratories, 1973).

Talc was not classified as a dangerous substance by the European Community, Meeting 29 of the Working Group "Classification and Labelling of Dangerous Substances" (C/M/R substances; Directive 79/831/EEC), Brussels 14-15 September, 1989.

Talc is not listed as a carcinogen by NTP (US National Toxicological Programme) and not regulated as a carcinogen by OSHA (US Occupational Safety and Health Administration).

12 - ECOLOGICAL INFORMATION**No known environmental effects.**

Trials carried out by the *Laboratoire Municipal de Bordeaux* on the acute toxicity of a product suspended in water (LD50), in compliance with French standard NF T 90-303, showed that talc had no adverse effect whatsoever on fish: no effect was shown in spite of a very high concentration of 100 g/l, i.e. 100 000 times the dose considered as toxic.

There is no reported ecotoxicity for this product, which is a widespread, naturally occurring substance.

13 - DISPOSAL CONSIDERATIONS

Talc is not considered as a hazardous waste and can be disposed of in the same way as any non-toxic waste. The disposal of packaging having contained talc requires no particular precautions. Dry product may be landfilled; wet talc may be sewerage if quantities are small and diluted enough to ensure that slurries or gels will not cause drain system blockage.

National or local regulations should be complied with when disposing of talc.

14 - TRANSPORT INFORMATION

NO LABELLING REQUIRED

◇ Land: talc is not listed in the ADR/RID (European Agreement on Dangerous Goods Transport by Road/International Regulation on Dangerous Goods Transport by Rail).

◇ Sea: talc is listed in Appendix C of the Code of Safe Practice for Solid Bulk Cargoes (BC Codes) of the International Maritime Dangerous Goods Code (IMDG). Appendix C is a list of bulk materials which cannot liquefy (= appendix A) or do not constitute a chemical risk (= appendix B). Bags should be positioned securely to avoid any sliding during transport.

Talc is not listed in the UN Classification (United Nations numbers are assigned to dangerous goods carried frequently).

15 - REGULATORY INFORMATION

Talc is not classified as a dangerous substance, therefore no special labelling is required. However, dust levels in work areas are regulated, and national and local regulations should be applied (see attached annex).

16 - OTHER INFORMATION

Bibliographical references:

P. LEOPHONTE et coll. "La pathologie respiratoire chronique des travailleurs du talc", Rev. Fr. Mal. Resp., 1980, 8, 43-45

P. CATILINA et coll. "Risques pulmonaires professionnels liés à l'utilisation du talc dans l'industrie du caoutchouc", Arch. Mal. Prof., 1980, 41, 363-368

IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans. Vol. 42. Silica and some silicates pp.185-224, International Agency for Research on Cancer, Lyon, France, 1987, 1 vol., 289 p.

S. ENDO-CAPRON et 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.

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.

P. WILD et coll. "A cohort mortality and nested case-control study of French and Austrian talc workers" Occup. Environ. Med 2002, 59, 98-105.

M. COGGIOLA et coll. "An Update of a Mortality Study of Talc Miners and Millers in Italy", Am. J Indust. Med. 2003, 44, 63-69

P. WILD, "Lung cancer risk and talc not containing asbestiform fibres: a review of the epidemiological evidence" Occup. Environ. Med. 2006; 63, 4-9.

Inventories

AUSTRALIA

AICS: Listed

CANADA

CEPA **DOMESTIC SUBSTANCE LIST (DSL)** Status: Listed

CEPA **NON-DOMESTIC SUBSTANCE LIST (NDSL)** Status: Not listed

CHINA

ICESC (CAS # 14807-96-6)

JAPAN

ENCS/MITI – Exempt – not required for natural minerals

KOREA

ECL Serial Nb 1-686

NEW ZEALAND

TSA: not listed

PHILIPPINES

PICCS: Listed

SWISS

Giftliste No: G-6939

USA

EPA TSCA Status: Listed (CAS # 14807-96-6)

EPA TSCA 12(B) Export Notification: Not listed

This material safety data sheet completes 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 the use of a 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: dusting of surgical gloves and pleural poudrage with talc (carried out under the medical doctor's responsibility).

These regulatory prescriptions are provided with a view to helping the user fulfil his/her obligations when using this product. This list should not be considered as exhaustive and does not discharge the user from ensuring that other obligations do not exist other than those mentioned above concerning product possession and handling for which he/she is solely responsible.

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Annex**THRESHOLD LIMIT VALUES
IN EUROPE AND THE UNITED STATES****AUSTRIA:**

Talc, total dust: 5 mg/m³ or 2000 particles/cm³.

*Maximale Arbeitsplatzkonzentrationen gesundheitsschädlicher Arbeitsstoffe
MAK-Werte 1986.*

Österreichischer Gewerkschaftsbund, Gewerkschaft der Chemiearbeiter.

BELGIUM:

Non fibrous talc: total dust, 10 mg/m³ – respirable dust, 2 mg/m³.

Arrêté Royal 10/08/98

DENMARK:

No specific regulations for talc.

Inert mineral, total dust: 10 mg/m³

Respirable dust: 5 mg/m³.

Direktoratet for Arbejdstilsynet At – anvisning nr 3.1.02 „Grænseværdier for stoffer og materialer“ Dec. 1996.

FINLAND:

Non fibrous talc: 5 mg/m³.

Ministry of Social Affairs and Health. Department for Occupational health & Safety.

Instructions n°25. 1981, rev. 1996

FRANCE:

No specific regulations for talc.

Total dust: 10 mg/m³.

Respirable dust: 5 mg/m³.

Article R-232-5-1 du Code du Travail - Décret n°84 -1093 du 7/12/84 - Circulaire du 9/5/85.

GERMANY:

Respirable dust: 1.5 mg/m³.

*Maximale Arbeitsplatzkonzentrationen - .Senatskommission zur Prüfung Gesundheitsschädlicher
Arbeitsstoffe der Deutschen Forschungsgemeinschaft. 39 Lieferung 2004.*

GREAT BRITAIN:

Respirable dust: 1 mg/m³ for an average working period of 8 hours

Total inhalable dust: 10 mg/m³

Health and Safety Executive Review 1995, published 1996

GREECE:

Non fibrous talc.

Respirable dust (<1% free crystalline silica): 3 mg/m³

Mining regulations (December 1984)

ITALY:

Non fibrous talc.

Total dust: 10 mg/m³.

Respirable dust: 2 mg/m³.

Associazione Italiana Degli Igienisti Industriali and ACGIH 1987.

NETHERLANDS:

Respirable dust: 0.25 mg/m³.

Asbestos free

SZW (*Sociale Zaken en Werkgelegenheid*), *UIT: Staatscourant 28/12/2006, n°252, p. 23*

NORWAY:

Talc, asbestos free: Total dust 10 mg/m³ and respirable dust 2 mg/m³.

Administrative normer for forurensninger i arbeidsatmosfären. 1996

PORTUGAL:

Non fibrous talc.

Total dust: 6 mg/m³ - Respirable dust: 3 mg/m³.

Direcção General da Qualidade 1982.

SPAIN:

Talc, (containing no asbestos fibres). Respirable dust: 2 mg/m³.

According to ACGIH recommendations. 1995/1996

SWEDEN:

Talc: total dust 2 mg/m³ and respirable dust 1 mg/m³

The National Board of Occupational Safety and Health 01/07/1997.

SWITZERLAND:

Total dust: 10 mg/m³

Respirable dust: 4 mg/m³.

Zulässige Werte am Arbeitsplatz Schweizerische Unfallversicherungsanstalt 1986.

U.S.A.:

Talc (asbestos free), respirable dust: 2 mg/m³.

Air contaminants - Permissible exposure limits - Titre 29 du Code of Federal Regulations – Part 1910-1000. 1996.