



Safety Data Sheet

(in compliance with Regulation (EC) 1907/2006,
Regulation (EC) 1272/2008 and Regulation (EC) 453/2010)

Version : 2.3
Revision date: 30.5.2017
Date of previous issue: 19.2.2015

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

1.1 Product identifier

Microtalc Pharma

REACH Registr. n°: Exempted in accordance with Annex V.7

Trade names:

MICROTALC PHARMA 8 MICROTALC PHARMA 30
MICROTALC PHARMA 15 MICROTALC PHARMA 50

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

Pharmaceutical applications.

1.3 Details of the supplier of the safety data sheet

Company Name: Mondo Minerals B.V.
Address: Kajuitweg 8
1041 AR Amsterdam
Phone N°: +31 (0)20 448 7448
Fax N°: +31 (0)20 448 7437
E-mail of responsible person for SDS:
info@mondominerals.com

1.4 Emergency telephone number

Emergency telephone number: +31 (0)20 448 7448
Available outside office hours? Yes No

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

This product does not meet the criteria for classification as hazardous as defined in the Regulation EC 1272/2008. This product should be handled with care to avoid dust generation.

Regulation EC 1272/2008: No classification.

2.2 Label elements

Label element according to Regulation (EC) No 1272/2008

Pictogram: none
Signal Word: none
Hazard statement: none
Precautionary statements: none

2.2 Other hazards

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 Main constituent

Microtalc Pharma is a natural association of talc, chlorite, dolomite and magnesite.

Main constituents

Name	CAS	EINECS	%wt/wt	Classification EC 1272/2008:
Talc	14807-96-6	238-877-9	>94	No classification
Chlorite	1318-59-8	215-285-9	}6	No classification
Dolomite	16389-88-1	240-440-2		No classification
Magnesite	546-93-0	208-915-9		No classification

This product does not contain detectable amounts of asbestos fibres as defined by the US Occupational Safety and Health Administration (OSHA) and the European Directive 2009/148/EC, when analysed by conventional methods. This statement is based upon verification by certified independent laboratories.

For use in foodstuff, pharmaceutical or cosmetics please contact your agent.

3.2 Impurities

This product does not contain any classified impurity.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Eye contact: Rinse with copious quantities of water and seek medical attention if irritation persists.

Inhalation: No special first aid measures. Remove to fresh air and get medical attention in case of serious respiratory problems.

Ingestion: No first-aid measure required.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms of acute accidental exposure would be non-specific and similar to those of a massive inhalation of any dust without toxic effects. These symptoms may include coughing, expectoration, sneezing, and difficulty in breathing due to upper respiratory tract irritation.

4.3 Indication of any immediate medical attention and special treatment needed

No specific actions are required.

SECTION 5: FIREFIGHTING 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 firefighters

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

Avoid airborne dust generation. If the generation of dust is likely, personal protective equipment should be worn in compliance with national legislation.

6.2 Environmental precautions

No special requirements.

Contain spillage and clean up as indicated below.

6.3 Methods and material for containment and cleaning up

Dry product should be cleaned with a shovel or vacuum cleaner while wearing personal protective equipment in compliance with national legislation. 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.

6.4 Reference to other sections

See sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Avoid airborne dust generation. Provide appropriate exhaust ventilation at places where airborne dust is generated. In case of insufficient ventilation, wear suitable respiratory protective equipment. Handle packaged products carefully to prevent accidental bursting. If you require advice on safe handling techniques, please contact your supplier or check the Good Practice Guide referred to in section 16.

7.2 Conditions for safe storage, including any incompatibilities

Technical measures/Precautions: Keep the product dry and in closed containers.

7.3 Specific end use(s)

If you require advice on specific uses, please contact your supplier or check the Good Practice Guide referred to in section 16.

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). About OEL (Occupational Exposure Limits) for talc: see section 15.1.

8.2 Exposure controls

8.2.1 Appropriate engineering controls

Minimise airborne dust generation. Use process enclosures, local exhaust ventilation or other engineering controls to keep airborne levels below specified exposure limits. If user operations generate dust, fumes or

mist, use ventilation to keep exposure to airborne particles below the exposure limit. Apply organisational measures, e.g. by isolating personnel from dusty areas. Remove and wash soiled clothing.

8.2.2 Individual protection measures, such as personal protective equipment

Eye/face protection:	Wear safety glasses with side-shields in circumstances where there is a risk of dust generation which could lead to mechanical irritation of the eye.
Skin protection:	No specific requirement. For hands, see below.
Hand protection:	Protective gloves are not necessary but recommended for those prone to skin irritation or dryness.
Respiratory protection:	In case of prolonged exposure to airborne dust concentrations, wear a respiratory protective equipment that complies with the requirements of European or national legislation.

8.2.3 Environmental exposure controls

Avoid wind dispersal.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance :	solid
Color	White, off white to light grey powder.
Odour:	odourless
Odour threshold:	Not relevant
pH:	9 (pH should be measured, generally, at 10% wt in water dispersion)
Melting point/freezing point:	> 1300 °C
Flammability (solid, gas):	Non flammable
Upper/lower flammability or explosive limits:	Not explosive. Limits do not apply
Relative density	2,75 g/cm ³
Solubility(ies):	
Solubility in water:	negligible
Solubility in hydrofluoric acid:	Yes
Auto-ignition Temperature:	Not relevant
Decomposition temperature:	> 1000 °C
Explosive properties:	Not explosive.
Oxidising properties:	Not oxidizing

9.2 Other information

No other information.

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 reactions.

10.4 Conditions to avoid

Not relevant

10.5 Incompatible materials

None known.

10.6 Hazardous decomposition products

Not relevant.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Information on the likely route of exposure:

Inhalation is the primary route of exposure. Repeated and prolonged exposure to large amount of talc dust might induce a mild pneumoconiosis. This is caused by lung overload exposure, a non specific particle effect, rather than a specific intrinsic fibrogenic activity of talc.

Acute toxicity:	Based on available data, the classification criteria are not met.
Skin corrosion/irritation:	Based on available data, the classification criteria are not met
Serious eye damage/irritation:	Based on available data, the classification criteria are not met
Respiratory or skin sensitisation:	Based on available data, the classification criteria are not met
Germ cell mutagenicity:	Based on available data, the classification criteria are not met
Carcinogenicity:	Based on available data, the classification criteria are not met
Reproductive toxicity:	No data are available on this product.
STOT-single exposure:	Based on available data, the classification criteria are not met
STOT-repeated exposure:	Based on available data, the classification criteria are not met
Aspiration hazard:	Based on available data, the classification criteria are not met.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

No data are available on this product.

No specific adverse effect known

12.2 Persistence and degradability

No data are available on this product.

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 Results of PBT and vPvB assessment

Not relevant.

12.6 Other adverse effects

No specific adverse effects known.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

§Waste from residues/unused products: Where possible, recycling is preferable to disposal. Can be disposed of in compliance with local regulations.

Packaging: Dust formation from residues in packaging should be avoided and suitable worker protection assured.

Store used packaging in enclosed receptacles.

The re-use of packaging is not recommended. Recycling and disposal of packaging should be carried out by an authorised waste management company.

Recycling and disposal of packaging should be carried out in compliance with local regulations.

SECTION 14: TRANSPORT INFORMATION

14.1 UN number

Not relevant.

14.2 UN proper shipping name

Not relevant

14.3 Transport hazard class(es)

ADR: Not classified.

IMDG: Not classified.

ICAO/IATA: Not classified.

RID: Not classified.

14.4 Packing group

Not relevant.

14.5 Environmental hazards

Not relevant.

14.6 Special precautions for user

No special precautions.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not relevant.

SECTION 15: REGULATORY INFORMATION

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

National legislation/requirements:

Workplace Exposure Limits (WEL) for talc: Austria 5 mg/m³, Belgium 2 mg/m³, Bulgaria 3 mg/m³, Czech Republic 2 mg/m³, Denmark 5 mg/m³, Finland 2 mg/m³, France 5 mg/m³, Germany 2 mg/m³, Greece 2 mg/m³, Hungary 2 mg/m³, Ireland 0,8 mg/m³, Italy 2 mg/m³, Lithuania 1 mg/m³, Luxembourg 2 mg/m³, Netherlands 0,25 mg/m³, Norway 2 mg/m³, Poland 1 mg/m³, Portugal 2 mg/m³, Romania 2 mg/m³, Slovakia 2 mg/m³, Slovenia 2 mg/m³, Spain 2 mg/m³, Sweden 1 mg/m³, Switzerland 2 mg/m³, UK 1 mg/m³

International legislation/requirements:

Industrial Safety and Health Law: This product does not contain harmful or controlled hazardous substances under ISHL. Contains silica requiring workplace environmental monitoring.

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: Ensure to dispose of in accordance with the waste treatment standards prescribed in Waste Management Law.

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	EINECS (EU)	AICS (Australia)	CEPA (DSL/ NDSL) (Canada)	KECI Korean Gazette No. (Korea)	ENCS/IS HL/MITI (Japan)	IECSC (China)	PICCS (Philippines)	TSCA (USA)	SWISS ID No. (Switzerland)	NZIoC (New Zealand)
Talc	14807-96-6	238-877-9	Yes	Yes (DSL)	KE-32773	Yes	Yes	Yes	Yes	G-6939	Yes
Chlorite	1318-59-8	215-285-9	No	Yes (DSL)	KE-05489	Yes	Yes	Yes	Yes	No	Yes
Dolomite	16389-88-1	240-440-2	Yes	Yes (DSL)	KE-13036	Yes	Yes	Yes	Yes	G-8431	Yes
Magnesite	546-93-0	208-915-9	Yes	Yes (DSL)	KE-22686	Yes	Yes	Yes	Yes	G-7477	Yes

15.2 Chemical safety assessment

Exempted from REACH Registration in accordance with Annex V.7.

SECTION 16: OTHER INFORMATION

16.1 Indication of the changes made to the previous version of the SDS.

Date of previous issue: 18.4.2013

Revision Details:

~~Microtalc Pharma 5~~

updating of old regulations

16.2 References and sources

1. Baan, R, Straif K, Secretan B, Ghissassi FE and Coglianò 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 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.
5. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans Volume 93 (2010), Carbon Black, Titanium Dioxide and Talc
6. WILD, P. et 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.
7. 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.

Third party materials

This material 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.