



Safety Data Sheet

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

Version: 1

Revision date: 1st December 2010

Section 1. Identification of the Substance/preparation and of the Company undertaking

1.1 Product identifier

Talc in powder form

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

Synonyms: steatite, soapstone.

Trade names: **Talc 1656 USP/EP/JP – Talc 3355 USP/EP/JP - Talc 3355Dense USP/EP/JP**

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

Functional mineral for use in pharmaceutical, cosmetic and food industries.

1.3 Details of the supplier of the safety data sheet

- Company name: IMI Fabi S.p.A.
- Address: Via Nazionale 24 – 23010 Postalesio (So) - Italy
- Phone N°: +39 – 0342 490311
- Fax N°: +39 – 0342 490399
- E-mail of responsible person for SDS: mario.mondonico@imifabi.com

1.4 Emergency telephone number

Emergency phone number: +39 – 0342 490311

Available outside office hours: No

Section 2. Hazard Identification

2.1 Classification of the substance or mixture

These products do not meet the criteria defined in the Regulation EC 1272/2008 and in the Directive 67/548/EC. These products should be handled with care to avoid dust generation.

Classification EU (67/548/EC): No classification.

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

2.3 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.

IMI Fabi Talc 1656-3355-3355Dense - Safety Data Sheet

Section 3. Composition / Information on ingredients

Main constituents :

IMI Fabi Talc 1656-3355-3355Dense are natural associations of talc and chlorite.

Main constituents	EINECS	CAS.	Amount (%)
Talc	238-877-9	14807-96-6	98%
Chlorite	215-285-9	1318-59-8	2%

Impurities: These product do 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 measures required.

Skin contact: No special first aid measures necessary.

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 immediate medical attention and special treatment needed:

No specific actions are required.

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:

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 for others 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. For the national regulations about the Occupational Exposure Limit (OEL) of talc powder: 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, 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:

(a) Eye 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.

(b) Skin protection:

No specific requirement. For hands, see below.

(c) Hand protection:

Protective gloves are not necessary but recommended for those prone to skin irritation or dryness.

(d) Respiratory protection:

In case of prolonged overexposure to airborne dust concentrations, wear respiratory protective equipment that complies with the requirements of 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

(a) Appearance: Solid.

(b) Colour: White, off white to light grey powder.

(c) Odour: Odourless.

(d) Odour threshold: Not relevant.

(e) pH – suspension of 10% of talc in water: 8.5 – 9.0

(f) Melting point: >1300°C

(g) Flammability (solid, gas): Not flammable.

(h) Upper/lower flammability or explosive limits: Not explosive. Limits do not apply.

(j) Relative density: 2.7 - 2.8 g/cm³

(m) Solubility:

Solubility in water: Negligible.

Solubility in hydrofluoric acid: Yes.

(n) Auto-ignition temperature: Not applicable.

(o) Decomposition temperature: >950°C

(p) Explosive properties: Not explosive.

(t) Oxidising properties: Not oxidising.

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 reaction.

10.4 Conditions to avoid: None.

10.5 Incompatible materials: None known.

10.6 Hazardous decomposition products: None.

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.

- (a) **Acute toxicity:** Based on available data, the classification criteria are not met.
- (b) **Skin corrosion/irritation:** Based on available data, the classification criteria are not met.
- (c) **Serious eye damage/irritation:** Based on available data, the classification criteria are not met.
- (d) **Respiratory or skin sensitisation:** Based on available data, the classification criteria are not met.
- (e) **Germ cell mutagenicity:** Based on available data, the classification criteria are not met.
- (f) **Carcinogenicity:** Based on available data, the classification criteria are not met.
- (g) **Reproductive toxicity:** No data are available on this product.
- (h) **STOT – single exposure:** Based on available data, the classification criteria are not met.
- (i) **STOT – repeated exposure:** Based on available data, the classification criteria are not met.
- (j) **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 effects 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 residue/unused products

Where possible, recycling is preferable to disposal. Can be disposed of in compliance with local regulations.

13.2 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 authorized 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
 HS-code (Customs Tariff code): 252620 (TALC POWDER)

14.4 Packaging group: Not applicable.

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/legislations specific for the substance or mixture

National legislation/requirements: Occupational Exposure Limits (OEL) for talc powder, or where not considered, for a not specified inert powder: **Austria** 5 mg/m³, **Belgium** 2 mg/m³, **Bulgaria** mg/m³, **Czech Republic** 2 mg/m³, **Denmark** 5 mg/m³, **Finland** 5 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 <1% of respirable 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: 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 No.	EINECS (EU)	AICS (Australia)	CEPA (DSL/NDL) (Canada)	KECI Korean Gazette No. (Korea)	ENCS ISHL/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*	Not listed	Yes

Yes*: There exists a broad category for naturally occurring chemicals, so these minerals are covered by definition, but not specifically listed.

15.2 Chemical safety assessment

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

Section 16. Other Information

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

Date of previous issue: June 30, 2008

Revision details:

- Format updated with Regulation (EC) 453/2010
- Section 1: Emergency number added.
- Section 11: Complete toxicological overview given.
- Section 15: Regulatory information revised.
- Section 16: Additional references added.

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. 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.
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.

Notice to reader

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.

Only the original English version is authoritative.