



Material Safety Data Sheet
According to EU Regulation 1907/2006 in the current version

Date 2/9/2016
Version 2.0

TITANIUM DIOXIDE

1. Identification of the substance/preparation and the company

Trade name: Titanium dioxide
Utilization: Cosmetic ingredient
Supplier company: **Elemental SRL**, Piata Cazarmii no.15, 410188-Oradea, jud.Bihor, Romania
identification: Tel/Fax: +40259-436.755, office@elemental.eu
Emergency: RO: numar national pentru cazuri de urgenta: 021 3183606 Institutul de Sanatate Publica Bucuresti. International emergency number: +49 180 2273-112

2. Hazards Identification

- Classification of the substance or mixture
- Classification according to Regulation (EC) No 1272/2008: Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.
- Classification according to Directive 67/548/EEC or Directive 1999/45/EC: This substance is not classified as dangerous according to Directive 67/548/EEC.
- Classification system: The classification is according to the latest editions of the EU-lists, and extended by company and literature data.
- Labelling according to Regulation (EC) No 1272/2008:
Hazard pictograms: Void. Signal word: Void Hazard statements: Void Hazard description: Not applicable.
- Information concerning particular hazards for human and environment:
The product does not have to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version. Prevent formation of dust.
- GHS label elements: Void
- Other hazards:
- Results of PBT and vPvB assessment: Titanium dioxide is neither a PBT nor a vPvB substance.

3. Composition / Information on ingredients

- Formula: TiO₂
- CAS Number: 13463-67-7 • EINECS Number: 236-675-5
- Registration number: 01-2119489379-17-0000

4. First Aid

- General information: No special measures required. Do not inhale dust.
- After inhalation: Supply fresh air; consult doctor in case of complaints. Inhalation of dust may cause discomfort. Inhalation exposure to large amounts may cause a temporary drying effect or irritation of mucous membranes. Exposure to dust may lead to aggravation of pre-existing upper respiratory and lung diseases.
- After skin contact: Immediately wash with water and soap and rinse thoroughly. Prolonged contact may result in scaling/irritations due to drying of the skin and/or mechanical abrasion related to skin-to-clothing contact or skin-to-skin contact.
- After eye contact: Rinse opened eye for several minutes under running water.
- After swallowing: If symptoms persist consult doctor.

5. Fire-fighting Measures

- Suitable extinguishing agents: CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam. Non-flammable, non-explosive.
- Protective equipment: Wear fully protective suit.



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6. Accidental release measures:

- Personal precautions, protective equipment and emergency procedures:
Wear protective clothing.
- Environmental precautions:
Do not allow product to reach sewage system or any water course. Inform respective authorities in case of seepage into water course or sewage system.
- Methods and material for containment and cleaning up:
Dispose contaminated material as waste according to item 13. Pick up mechanically.

7. Handling and Storage

- Precautions for safe handling: Store in cool, dry place in tightly closed receptacles. Ensure good ventilation/exhaustion at the workplace. Open and handle receptacle with care. Prevent formation of dust. Wear suitable respiratory protective device when decanting larger quantities without extractor facilities.
- Information about fire - and explosion protection: Protect against electrostatic charges.
- Storage: T°:<25°C. Shelf life 10 years: After opening, product must be rechecked every year
- Requirements to be met by storerooms and receptacles: Store only in unopened original receptacles.
- Information about storage in one common storage facility: Not required.
- Further information about storage conditions: Caution when reopening receptacles with broken seal. Open receptacle only under localized extractor facilities. Store receptacle in a well ventilated area. Protect from humidity and water.

8. Exposure Controls and Personal Protection

- Ingredients with limit values that require monitoring at the workplace:
OEL-France : VME 10 mg/m³ - Janvier 1999 - ACGIH-TLV-TWA 10 mg/m³ - 2003 // OEL-UK : TWA 10 mg/m³ (total inhalable dust) Sept. 2000 TWA 4 mg/m³ (respirable dust) Sept.2000
- Additional information: The lists valid during the making were used as basis.
- Personal protective equipment:
- General protective and hygienic measures: The usual precautionary measures are to be adhered to when handling chemicals. Keep away from foodstuffs, beverages and feed.
- Respiratory protection: Use suitable respiratory protective device in case of insufficient ventilation.
- Recommended filter device for short term use: Filter P3
- Protection of hands: Protective gloves
- Material of gloves: Nitrile rubber, NBR
- Eye protection: Safety glasses
- Body protection: Use protective suit.



9. Physical and Chemical Properties

Appearance:	powder
Colour:	white
Solubility:	insoluble
Odour	odourless
pH	6,5-8,0 (1 : 10 watersuspension)
Melting point/ range	1843 (rutile)
Boiling point/ range	> 2500 °C
Flash point	Not Applicable



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Evaporation rate	Not Available
Upper/lower flammability or explosive limits	Not Available
Vapour density	Not Available
Vapour pressure (20°C)	Not Available
Density (20°C)	Not Available
Water solubility	Insoluble
Lipid solubility	Insoluble
Partition coefficient (n-octanol/water)	In accordance with Column 2 of REACH Annex VII, does not need to be conducted as the substance is inorganic.
Auto-ignition temperature	Not Available
Decomposition temperature	Not Available
Viscosity (20°C)	Not Available
Explosive properties	Not explosive. ST0
Oxidising properties	Not Available
Flammability (Solid, Gas)	Not Available
Volatile Organic compounds - VOCs	Not Available

10. Stability and Reactivity

- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- Hazardous decomposition products: No dangerous decomposition products known. Stable under recommended storage and handling conditions. In case of emissions into atmosphere the substance doesn't form toxic compounds.

11. Toxicological Information

- Acute toxicity:

Oral LD50 > 5000mg/kg bw - rat - OECD Guideline 425

Inhalation LC50 > 6.82mg/L 4 hours - rat - study was conducted according to methodology at that time - lit.

For acute inhalation toxicity there are two animal studies of which one has been performed according to OECD TG 403 and which shows no signs of acute toxicity after inhalation exposure to titanium dioxide. Several animal studies on acute oral exposure are available, conducted according to OECD guidelines 401, 420, 425 or according to state of the art methodology at that time. There are no reliable reports whatsoever on acute dermal toxicity in the public domain. However, the conduct of an acute dermal toxicity study is unjustified as inhalation of the substance is considered as major route of exposure and physicochemical properties and dermal absorption data of the substance do not suggest a significant rate of absorption through the skin. - lit.

- Irritation:

Not irritating. Titanium dioxide has been tested in three in vivo skin irritation and one eye irritation study. All tests show a negative response, thus titanium dioxide does not require classification either as skin or as eye irritant.

- Respiratory or skin sensitisation:

Not sensitising. Titanium dioxide has been tested in two different systems for sensitising properties. Both study types show a negative response, thus titanium dioxide does not require classification as sensitiser. - lit.

- Germ cell mutagenicity:

Negative. Titanium dioxide did not show a significant or dose-dependent increase in chromosome aberrations in the bone marrow of male mice via i. p. injection up to the maximum dose of 2500mg/kg bw 17 and 36 hours after dosing. Titanium dioxide did not show a significant or dose-dependent increase in micronucleated cells in the bone marrow of male mice via i. p. injection up to the maximum dose of 1500mg/kg bw 24 hours after dosing. None of the in vitro genotoxicity studies rated as reliable showed any effect in bacterial reverse mutation assays, in mammalian cell gene mutation tests (TK assay) or in mammalian cell chromosome aberration tests, thus supporting the negative findings in the in vivo tests as cited above. The classification criteria acc. to Regulation (EC) 1272/2008 as germ cell



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mutagen are also not met. - lit.

- Carcinogenicity:

Carcinogen rating for titanium dioxide is not warranted. Overall, the epidemiological evidence from well-conducted investigations has not shown that exposure to titanium dioxide is correlated to any detectable carcinogenic potential for humans. Titanium Dioxide is listed by IARC as possibly carcinogenic to humans (Group 2B). This listing is based on inadequate evidence of carcinogenicity in humans and sufficient evidence in experimental animals. - lit

- STOT-single exposure

The classification criteria acc. to regulation (EC) 1272/2008 as specific target organ toxicant (STOT) single exposure, oral are not met since no reversible or irreversible adverse health effects were observed immediately or delayed after exposure and no effects were observed at the guidance value, oral for a Category 1 classification of 300 mg/kg bw and at the guidance value, oral for a Category 2 classification of 2000 mg/kg bw. No classification required. The classification criteria acc. to regulation (EC) 1272/2008 as specific target organ toxicant (STOT) single exposure, inhalation dust/mist/fume are not met since no reversible or irreversible adverse health effects were observed immediately or delayed after exposure and no effects were observed at the guidance value, inhalation dust/mist/fume for a Category 1 classification of 1.0 mg/L/4h and at the guidance value, inhalation dust/mist/fume for a Category 2 classification of 5.0 mg/L/4h. Therefore, no classification is required. Finally, any category 3 classification should primarily be based on human data. It can be safely assumed that standard occupational hygiene measures provide a sufficient level of worker protection. - lit.

- Repeated dose toxicity:

Oral NOAEL: 3,500 mg/kg bw/day chronic rat. Inhalation NOAEC: 10 mg/m³ chronic rat

- STOT-repeated exposure:

The following observations have been made in experimental animals and in human epidemiological studies: No systemic toxicity was shown to result from chronic inhalation exposure in rats to high concentrations of cosmetic grade titanium dioxide. Particle overload is observed for insoluble particles whereby the rat is the most sensitive species studied, and species-specific differences are demonstrated in various mechanistic animal studies (Oberdörster, 1996). It has been demonstrated with reasonable certainty that lung overload conditions are not relevant for human health and, therefore, results based on these data do not justify classification. It has also been clearly demonstrated through epidemiological studies of titanium dioxide – exposed workers that there is no causal link between titanium dioxide exposure and the risk of non-malignant respiratory disease in humans. For the reasons presented above, no classification for specific target organ toxicant (STOT) repeated exposure, inhalation is required. - lit.

12. Ecological Information

- Persistence and degradability: The inert product is not biodegradable. According to column 2 from Annex VIII from the REACH regulation, a study on hydrolysis as function of the pH does not need to be conducted if the substance is highly insoluble in water.
- Bioaccumulative potential: Not considered as bioaccumulative.
- Aquatic toxicity: LCO > 1000 mg/l/48h (Leuciscus idus) - ECO > 3 mg/l/30j (Daphnia magna) - ECO > 10000 mg/l/24h (Pseudomonas fluorescens)
- Behaviour in sewage processing plants: The product can be mechanically separated.
- Mobility in soil: There is no evidence of mobility of this product
- Results of PBT and vPvB assessment: According to Annex XIII of regulation (EC) 1907/2006 a PBT and vPvB assessment shall not be conducted for titanium dioxide as inorganic substance.

13. Disposal Considerations

- Recommendation: Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- Uncleaned packaging:



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- Recommendation: Disposal must be made according to official regulations. Packaging may be reused or recycled after cleaning.

14. Transport Information

General recommendations:	Not dangerous product
UN no:	not classified
Road (ADR/RID):	not classified
Air (IATA/ICAO):	not classified
Sea (IMDG):	not classified
Special precautions for user:	See section 6-8
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC:	not applicable

15. Additional Regulatory Information

- Safety, health and environmental regulations/legislation specific for the substance EU regulation:
This product is not classified according to Directive 67/548/EC, Directive 1999/45/EC, Regulation (EC) No 1272/2008/15.2
- Chemical Safety Assessment: A chemical safety assessment has been carried out for the Titanium dioxide.

16. Other Information

- Abbreviations and acronyms:
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)
ICAO: International Civil Aviation Organization
ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO)
GHS: Globally Harmonized System of Classification and Labelling of Chemicals
CAS: Chemical Abstracts Service (division of the American Chemical Society)
LC50: Lethal concentration, 50 percent. LD50: Lethal dose, 50 percent

- Disclaimer:
This material safety data sheet does not constitute a guarantee of the properties of the product and is not a contractual legal report. The information is given in good faith on the basis of our best knowledge of the product at the indicated time. However, we cannot accept responsibility or liability for any consequences arising from its use, no warranty for correctness and completeness is given. We caution the users against the incurred possible risks when the product is used at other ends than the use for which it was initially planned. It is the user's responsibility during handling, storage and product use to consult the main regulatory texts in force regarding workers and environment protection.