Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

TITANII DIOXIDUM

Publication: 12/04/2022
Revision: XX/XX/XXXX
Version: 00

MAGIS PHARMA

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

1.1 Product identifier

Product name:	Titanium dioxide Titanii dioxidum Titaandioxide Titane (dioxyde de) Titandioxid
N° CAS:	13463-67-7
N° EC:	236-675-5

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

Identified uses:	Active Pharmaceutical Ingredient or Excipient.

1.3 Details of the supplier of the safety data sheet

Company:	FAC SECUNDUM ARTEM NV Oostmalsebaan 1c (unit 5) 2960 Sint-Lenaarts Belgium
Telephone:	(+32) (0)3 457 11 76
Email:	info@magis-pharma.be
Web page:	www.magis-pharma.be

1.4 Emergency telephone number

Public utility foundation:	Belgisch Antigifcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antigifcentrum.be	www.centreantipoisons.be

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance/mixture

Classification according to (EC) n° 1272/2008

The product is not classified as hazardous according to the Regulation (EC) No 1272/2008 and the Council Directives 67/548/EEC and 1999/45/EEC. Therefore no obligation exists to issue a safety data sheet according to REACH Art. 31.

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):	Not applicable.
Signal word(s):	Not applicable.
Hazard statements:	Not applicable.
Precautionary statements:	Not applicable.
Additional applicable label elements:	Not applicable.

2.3 Other hazards

Not available.

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

TITANII DIOXIDUM

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Titanium dioxide
IUPAC name:	Dioxotitanium
Synonyms:	Rutile
	Anatase
	Titanium(IV) oxide
	Titanium white
	Titanium oxide (TiO_2)
N° CAS:	13463-67-7
N° EC:	236-675-5
Molecular Formula:	TiO_2
Content:	98.0 per cent to 100.5 per cent

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	No hazards which require special first aid measures.
After inhalation:	Move to fresh air.
	Give symptomatic treatment as necessary.
After skin contact:	Wash with soap and water.
After eye contact:	Wash with water or neutral eyewash solution.
After ingestion:	Do not induce vomiting.
	Give up to 200 ml of water.
	In case of persistent symptoms, consult a doctor.

4.2 Most important symptoms and effects, both acute and delayed

Not available.

4.3 Indication of any immediate medical attention and special treatment needed

Not available.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Not available.
Unsuitable extinguishing media:	No restrictions.

5.2 Special hazards arising from the substance/mixture

The product itself does not burn.
Product is inert, not flammable and incombustible.

5.3 Advice for firefighters

Surrounding fires:	Not available.
Protection against fire:	Not available.
Hazardous combustion products:	Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Avoid dust formation.

Ensure adequate ventilation.

For emergency responders

Avoid dust formation.

6.2 Environmental precautions

Avoid dust dispersion to the environment.

Dust may cause the surroundings to become white.

Prevent leakages from entering drains and ditches that lead to natural waterways.

6.3 Methods and material for containment and cleaning up

Use any suitable mechanical means (e.g. vacuum, sweeping), but avoid dusting during clean-up.

6.4 Reference to other sections

Not available.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Avoid dust formation during handling.
Personal protection:	In case of insufficient ventilation, wear suitable respiratory equipment.
Technical protective measures:	Provide appropriate exhaust ventilation at machinery and at places where dust can be generated.
Handling:	Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Not available.
Conditions for safe storage, including any incompatibilities:	Fire Precautions: The product is not flammable. Keep in a dry place. Incompatible products: No restrictions
Storage – away from:	Not available.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Substance	**Titanium dioxide**		**Dust, inhalable**		**Dust, respirable**	
CAS No.	13463-67-7					
	limit value - eight hours mg/m³	limit value - short term mg/m³	limit value - eight hours mg/m³	limit value - short term mg/m³	limit value - eight hours mg/m³	limit value - short term mg/m³
Austria			10	20	5	10
Belgium	10		10		3	
Canada – Québec	10					
Denmark	6 total dust	12 total dust	10	20		
European Union						
France	11 inhalable aerosol		10		5 respirable aerosol	
Germany (AGS)			10	20	3	6
Germany (DFG)			4		1.5	
Hungary			10		6	
Italy						
Japan						
Poland	10	30				
Spain	10 inhalable aerosol		10		3	
Sweden	5 inhalable aerosol		10		5	
Switzerland	3 respirable aerosol		10		3	
The Netherlands						
USA – OSHA	15 total dust		15		5	
United Kingdom	10 inhalable aerosol 4 respirable aerosol					

Remarks:			
	Austria		*STV 15 minutes average value
	France	*Bold type: Restrictive statutory limit values	*Bold type: Restrictive statutory limit values
	Germany (AGS)	*15 minutes average value, insoluble particulates	*15 minutes average value, insoluble particulates
	Germany (DFG)	*long term exposure level, insoluble particulates	*insoluble particulates

8.2 Exposure controls

Appropriate engineering control

None required. Industrial hygiene measures: Maintain exposures below applicable exposure limits.

Individual protection measures

Eye/face protection: The use of an approved dustproof goggles is recommended if the dust concentration is likely to exceed the occupational exposure limit.

Skin protection:	TiO_2 pigments are not irritant but as with all fine powders can adsorb moisture and natural oils from the surface of the skin during prolonged exposure. Prolonged exposure should be avoided by wearing suitable protective gloves and clothing.
Hand protection:	Prolonged exposure should be avoided by wearing suitable protective gloves and clothing.
Respiratory protection:	A respirator must be used if the dust concentration is likely to exceed the occupational exposure limit. At higher concentrations, wear particle filter DIN EN 143 - P2.
Thermal hazards:	Not determined.

Environmental exposure control

Not available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	White or almost white powder.
Odour:	None.
Odour threshold:	Not available.
pH:	Approx. 4 – 9
Melting/freezing point:	> 1 800 °C
Initial boiling point:	Not applicable.
Boiling range:	Not applicable.
Flash point:	Not flammable.
Evaporation rate:	Not available.
Flammability (solid/gas):	Not available.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not applicable.
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	It does not dissolve in dilute mineral acids but dissolves slowly in hot concentrated sulfuric acid.
Solubility in water:	Practically insoluble in water.
Partition coefficient (n-octanol/water):	Not applicable.
Auto-ignition temperature:	Not flammable.
Decomposition temperature:	Not available.
Viscosity:	Not applicable.
Explosive properties:	No danger of explosion.
Oxidising properties:	None.

9.2 Other information

Density: approx. 3.9 g/ml

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No special reactivity known.

10.2 Chemical stability

Stable under normal conditions of use.

10.3 Possibility of hazardous reactions

No hazardous reactions known.

10.4 Conditions to avoid

Stable under normal conditions of use.

10.5 Incompatible materials

None known.

10.6 Hazardous decomposition products

No hazardous decomposition products known.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Oral LD_{50} (rats): > 10 000 mg/kg Inhalative LC_{50} /4 hrs (Rat): > 6.8 mg/l
Skin corrosion/irritation:	Titanium dioxide is not irritating
Serious eye damage/irritation:	Titanium dioxide is not irritating
Respiratory/skin sensitisation:	No sensitisation known.
Germ cell mutagenicity:	Non genotoxic.
Carcinogenicity:	Not available.
Reproductive toxicity:	Not available.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
Other:	Health injuries are not known under normal use. Tumours produced in rats on inhalation of very high concentrations of titanium dioxide are believed to be the result of prolonged "lung overload" and are not considered relevant for humans.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Not available.
Skin contact:	Not available.

Inhalation:	Not available.
Ingestion:	Not available.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Aquatic toxicity: Fish LC_0 (*Leuciscus idus*, 48h): > 1000 mg/l

12.2 Persistence and degradability

Methods for the determination of biodegradability are not applicable to inorganic substances.

12.3 Bioaccumulative potential

The product is practically insoluble in water and not biodegradable.

12.4 Mobility in soil

Not available.

12.5 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 inorganic substances. Titanium dioxide is an inorganic substance, thus a PBT and vPvB assessment is not required.

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product: No hazardous waste according to European Directive 2000/532/EC. Place in an appropriate disposal facility in compliance with local and national regulations.

Contaminated packaging: Containers that cannot be cleaned must be treated as waste and disposed of in an approved industrial incineration facility. The empty and clean containers may be reused in conformity with regulations.

Cleanser: water.

SECTION 14: TRANSPORT INFORMATION

Transport information according to ADR/RID/IMDG/ICAO/IATA

14.1 UN Number

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	Not classified.

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	Not classified.

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	Not classified.

14.4 Packing group

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	Not classified.

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	Not classified.

14.6 Special precautions for user

Not available.

14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not available.

14.8 Additional transport information

The product is not classified as a hazardous material according to the ADR/RID, IMDG, IATA on the transport of dangerous or hazardous goods.

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:	Not applicable.
Risk phrases:	Not applicable.
Safety phrases:	Not applicable.

15.2 Chemical safety assessment

The substance has undergone a safety assessment.

SECTION 16: OTHER INFORMATION

16.1 Changes since the previous version

Not applicable.

16.2 Abbreviations and acronyms used

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS:	Chemical Abstracts Service (division of the American Chemical Society)
EC (number):	European Community (number)
IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization
IMDG:	International Maritime Code for Dangerous Goods
IUPAC:	International Union of Pure and Applied Chemistry
PBT:	Persistent, Bioaccumulative and Toxic substance
RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail
STOT:	Specific Target Organ Toxicity
UN (number):	United Nations (number)
vPvB:	very Persistent and very Bioaccumalative

16.3 Key literature references/sources for data

European Chemicals Agency.
https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/

16.4 Method of classification in case of mixture

Not applicable.

16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

16.6 Training advisement

Not available.

16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

This MSDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information has been compiled from sources considered to be dependable and is accurate to the best of the FSA NV's knowledge. However, the information is provided without any representation or warranty, expressed or implied regarding its accuracy or correctness. FSA NV cannot assume responsibility for adverse events which may occur in the use and/or misuse of this product and expressly disclaims liability for loss, damage and/or expense arising out of or in any way connected with the handling, storage, use and/or disposal of this product.

16.8 Department issuing MSDS

Quality Department
FAC SECUNDUM ARTEM NV
info@magis-pharma.be