

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name: 2/4Rx - Titan Articles

This safety data sheet pertains to the following products:

2R38 - Tube Adaptor

2R38=10 - Tube Adaptor

2R57 - Internal Tube Adaptor

2R58 - Internal Tube Adaptor

2R216 - SACH Shin Kit

2R217 - Single Axis Shin Kit

2R219 - Universal Tube Kit

4R52 - Tube Clamp Adaptor

7E7-T - Modular Single Axis Hip Joint (Titan)

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

General use: Titanium-Article for orthopaedic procedures
Reserved for industrial and professional use.

1.3 Details of the supplier of the safety data sheet

Company name: Ottobock SE & Co. KGaA

Street/POB-No.: Max-Näder-Straße 15

Postal Code, city: 37115 Duderstadt

Germany

E-mail: export@ottobock.de

Telephone: +49 (0)5527 848-0

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Department responsible for information:

Arbeitssicherheit, Telephone: 05527-848-0, e-mail: Arbeitssicherheit@ottobock.de

Only available during office hours.

1.4 Emergency telephone number

Telephone: +49 (0)5527 848-0

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to EC regulation 1272/2008 (CLP)

This substance is classified as not hazardous.

2.2 Label elements

Labelling (CLP)

Hazard statements: not applicable

Precautionary statements: not applicable

2.3 Other hazards

Processing, e.g. by cutting, sawing or grinding, can produce particles and dust. For risks which have to be observed thereby, see section 7: Handling, section 8: Exposure controls / personal protection and section 11: Toxicology.

Titanium-dust: Danger of dust explosion.

Endocrine disrupting properties, Results of PBT and vPvB assessment:

No data available

SECTION 3: Composition/information on ingredients

3.1 Substances

Chemical characterisation: Article of Titanium

SECTION 4: First aid measures

4.1 Description of first aid measures

In case of inhalation: In case of troubles after inhalation of dust:

Move victim to fresh air. Seek medical attention.

Following skin contact: Titanium-dust:

Wash with plenty of water. In case of troubles:

Take off immediately all contaminated clothing. Seek medical attention.

After eye contact: Titanium-dust:

With eyelids open, wash out eyes for several minutes under flowing water. In case of troubles or persistent symptoms, consult an ophthalmologist.

After swallowing:

Swallowing is not regarded as a possible way of exposition.

Titanium-dust:

If person is clearly conscious, have them drink two glasses of water to dilute ingested material.

Do not induce vomiting. Seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Dust:

In case of eye contact / in case of inhalation: May cause irritations.

Lung damage is possible in a chronic situation.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: Product is non-combustible. Extinguishing materials should therefore be selected according to surroundings.

Titanium-dust:

Extinguishing powder on the basis of NaCl or pulverized limestone.

In case of fire, use dry sand or fire extinguisher of fire class D. Never use water.

Extinguishing media which must not be used for safety reasons:

Titanium-dust:

Never extinguish with a halon or carbon dioxide extinguisher or water.

Not a foam extinguisher.

5.2 Special hazards arising from the substance or mixture

Titanium-dust: Danger of dust explosion.

Titanium-dust, burning:

After contact with water: Danger of explosion!

5.3 Advice for firefighters

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Avoid generation of dust. Do not breathe dust.

Provide adequate ventilation.

In the case of the formation of dust: Wear protective equipment. Avoid contact with skin and eyes.

6.2 Environmental precautions

Do not allow to penetrate into soil, waterbodies or drains.

6.3 Methods and material for containment and cleaning up

Metal parts/dust:

Take up mechanically, placing in appropriate containers for disposal.

Avoid generation of dust.

Additional information:

Titanium-dust: Eliminate all ignition sources if safe to do so.

6.4 Reference to other sections

Refer additionally to section 8 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advices on safe handling:

For mechanical processing:

Avoid respiration of swarf. Wear appropriate protective equipment.

Provide adequate ventilation. Keep workplace dry.

Precautions against fire and explosion:

For mechanical processing:

Avoid generation of dust. Danger of dust explosion.

Keep away from combustible material. Keep away from sources of ignition.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storerooms and containers:

Store in a dry place.

7.3 Specific end use(s)

No information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Additional information:

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Provide good ventilation and/or an exhaust system in the work area.

Personal protection equipment

Occupational exposure controls

Respiratory protection:	For mechanical processing: Respiratory protection must be worn whenever the WEL levels have been exceeded. Particulates filter P2 according to EN 143.
Hand protection:	For mechanical processing: combination Protective gloves against mechanical risks according to EN 388 and chemically resistant gloves according to EN 374 Observe glove manufacturer's instructions concerning penetrability and breakthrough time.
Eye protection:	For mechanical processing: Tightly sealed safety glasses according to EN 166 or face protection shield.
Body protection:	For mechanical processing: Wear suitable protective clothing.
General protection and hygiene measures:	For mechanical processing: Do not breathe dust. Keep workplace dry. Wash hands before breaks and after work. Provide a conveniently located eye rinse station.

Environmental exposure controls

Refer to "6.2 Environmental precautions".

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state at 20 °C and 101.3 kPa	Form: solid
Colour:	grey
Odour:	odourless
Odour threshold:	No data available
Melting point/freezing point:	1668 - 1677 °C
Initial boiling point and boiling range:	3260 - 3500 °C
Flammability:	No data available
Upper/lower flammability or explosive limits:	LEL (Lower Explosion Limit): Titanium-dust, dry: approx. 50g/m ³
Flash point/flash point range:	No data available
Decomposition temperature:	No data available
pH:	No data available
Viscosity, kinematic:	No data available
Water solubility:	insoluble
Partition coefficient: n-octanol/water:	No data available
Vapour pressure:	No data available
Density:	4.5 g/cm ³
Vapour density:	No data available
Particle characteristics:	Not applicable

9.2 Other information

Explosive properties:	No data available
Oxidizing characteristics:	No data available
Auto-ignition temperature:	Titanium-dust: approx. 249 °C Titanium-in pieces: approx. 1204 °C
Evaporation rate:	No data available
Additional information:	No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

refer to section 10.3

10.2 Chemical stability

Product is stable under normal storage conditions.

10.3 Possibility of hazardous reactions

Titanium-dust: Danger of dust explosion.

10.4 Conditions to avoid

For mechanical processing:
Avoid formation of dust/air mixtures because of explosion hazard.
Keep away from sources of ignition. Protect from excessive heat.
Protect from moisture contamination.

10.5 Incompatible materials

For mechanical processing:
Strong oxidizing agents, strong reducing agents

10.6 Hazardous decomposition products

Thermal decomposition: No data available

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Toxicological effects:

- Acute toxicity (oral): Lack of data.
- Acute toxicity (dermal): Lack of data.
- Acute toxicity (inhalative): Lack of data.
- Skin corrosion/irritation: Lack of data.
- Serious eye damage/irritation: Lack of data.
- Sensitisation to the respiratory tract: Lack of data.
- Skin sensitisation: Lack of data.
- Germ cell mutagenicity/Genotoxicity: Lack of data.
- Carcinogenicity: Lack of data.
- Reproductive toxicity: Lack of data.
- Effects on or via lactation: Lack of data.
- Specific target organ toxicity (single exposure): Lack of data.
- Specific target organ toxicity (repeated exposure): Lack of data.
- Aspiration hazard: Lack of data.

11.2 Information on other hazards

Endocrine disrupting properties: No data available

Symptoms

In case of inhalation: Dust: May cause irritations.
Lung damage is possible in a chronic situation.
After eye contact: Dust: May cause irritations.

SECTION 12: Ecological information

12.1 Toxicity

Further details: No data available

12.2 Persistence and degradability

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

12.3 Bioaccumulative potential

Partition coefficient: n-octanol/water:

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

No data available

12.6 Endocrine disrupting properties

No data available

12.7 Other adverse effects

General information: Do not allow to penetrate into soil, waterbodies or drains.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Waste key number: 16 01 18 = non-ferrous metal

Recommendation: Special waste. Dispose of waste according to applicable legislation.

SECTION 14: Transport information

14.1 UN number or ID number

ADR/RID, IMDG, IATA-DGR: not applicable

14.2 UN proper shipping name

ADR/RID, IMDG, IATA-DGR: Not restricted

14.3 Transport hazard class(es)

ADR/RID, IMDG, IATA-DGR: not applicable

14.4 Packing group

ADR/RID, IMDG, IATA-DGR: not applicable

14.5 Environmental hazards

Dangerous for the environment: Substance/mixture is not environmentally hazardous according to the criteria of the UN model regulations.

Marine pollutant: no

14.6 Special precautions for user

No dangerous good in sense of these transport regulations.

14.7 Maritime transport in bulk according to IMO instruments

No data available

SECTION 15: Regulatory information

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

National regulations - EC member states

Further regulations, limitations and legal requirements:

No data available

15.2 Chemical Safety Assessment

No data available

SECTION 16: Other information

Reason of change: General revision

Date of first version: 6/8/2008

Department issuing data sheet: see section 1: Department responsible for information

Abbreviations and acronyms:

- ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
- ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road
- AS/NZS: Australian Standards/New Zealand Standards
- CAS: Chemical Abstracts Service
- CLP: Classification, Labelling and Packaging
- DMEL: Derived minimal effect level
- DNEL: Derived no-effect level
- EC: European Community
- EN: European Standard
- EQ: Excepted quantities
- EU: European Union
- IATA: International Air Transport Association
- IATA-DGR: International Air Transport Association – Dangerous Goods Regulations
- IBC Code: International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
- IMDG Code: International Maritime Dangerous Goods Code
- LEL: Lower Explosion Limit
- MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships
- OEL: Occupational Exposure Limit Value
- PBT: Persistent, bioaccumulative and toxic
- PNEC: Predicted no-effect concentration
- REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals
- RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail
- TLV: Threshold Limit Value
- TRGS: Technical Rules for Hazardous Substances
- vPvB: Very persistent and very bioaccumulative
- WEL: Workplace Exposure Limit

The information in this data sheet has been established to our best knowledge and was up-to-date at time of revision. It does not represent a guarantee for the properties of the product described in terms of the legal warranty regulations.