

1. Identification

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)

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

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

Details of the supplier of the safety data sheet

Company name: Otto Bock Health Care
Street/POB-No.: 3820 W. Great Lakes Drive
Zip code, city: Salt Lake City, UT 84120
USA

WWW: www.ottobockus.com

Telephone: +1 (801) 956-2400

Telefax: +1 (801) 956-2401

Department responsible for information:
Quality Department,
Telephone: +1 (801) 954-2304 (7 AM – 3 PM, Mountain Time),
Email: USRegulatory@ottobock.com

Additional information: Corporate headquarters:
Ottobock SE & Co. KGaA
Max-Näder-Straße 15
Duderstadt
Germany

Emergency telephone number

CHEMTREC, Telephone: +1 (800) 424-9300

2. Hazard identification

Classification of the substance or mixture

Article not subject to hazard labelling or classification.

Label elements

not applicable

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.

3. Composition/information on ingredients

Substances

Chemical characterization: Article of Titanium

4. 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: Ingestion is not considered a possible route of exposure.
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.

Most important symptoms/effects, acute and delayed

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

Information to physician

Treat symptomatically.

5. Fire-fighting measures

Suitable (and unsuitable) 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.

Specific hazards arising from the chemical

Titanium-dust: Danger of dust explosion.

Titanium-dust, burning:

After contact with water: Danger of explosion!

6. Accidental release measures

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.

Environmental precautions:

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

Methods and material for containment and cleaning up

Methods for clean-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.

7. Handling and storage

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.

Conditions for safe storage, including any incompatibilities

Requirements for storerooms and containers:

Store in a dry place.

8. Exposure controls/personal protection

Control parameters

Occupational exposure limit values:

Type	Limit value
USA: ACGIH: TWA	10 mg/m ³ (Dust limit value, inhalable fraction)
USA: ACGIH: TWA	3 mg/m ³ (Dust limit value, respirable fraction)
USA: OSHA: TWA	15 mg/m ³ (Dust limit value, total dust)
USA: OSHA: TWA	5 mg/m ³ (Dust limit value, respirable fraction)

Appropriate engineering controls

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

Personal protection equipment (PPE)

Respiratory protection:	For mechanical processing: Respiratory protection must be worn whenever the TLV (WEL) levels have been exceeded. Particulates filter P2 according to OSHA Standard - 29 CFR: 1910.134 or ANSI Z88.2.
Hand protection:	For mechanical processing: Protective gloves according to OSHA Standard - 29 CFR: 1910.138. Observe glove manufacturer's instructions concerning penetrability and breakthrough time.
Eye protection:	For mechanical processing: Tightly sealed safety glasses according to OSHA Standard - 29 CFR: 1910.133 or ANSI Z87.1-2003. or face protection shield.
Body protection:	For mechanical processing: Wear suitable protective clothing.
General hygiene considerations:	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.: Section "Environmental precautions".

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state at 68 °F and 101.3 kPa	Form: solid
Color:	gray
Odor:	odorless
Odor threshold:	No data available
Melting point/freezing point:	3034.4 - 3050.6 °F
Initial boiling point and boiling range:	5900 - 6332 °F
Flammability:	No data available
Explosion limits:	LEL (Lower Explosion Limit): Titanium-dust, dry: approx. 50g/m ³
Flash point/flash point range:	No data available
Evaporation rate:	No data available
Auto-ignition temperature:	Titanium-dust: approx. 480.2 °F Titanium-in pieces: approx. 2199.2 °F
Decomposition temperature:	No data available
pH:	No data available
Viscosity:	No data available
Water solubility:	insoluble
Partition coefficient: n-octanol/water:	No data available
Vapor pressure:	No data available
Density:	4.5 g/cm ³

Vapor density: No data available

Particle characteristics: Not applicable

Additional information

Additional information: No data available

10. Stability and reactivity

Reactivity: No data available

Chemical stability: Product is stable under normal storage conditions.

Possibility of hazardous reactions:
Titanium-dust: Danger of dust explosion.

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.

Incompatible materials: For mechanical processing:
Strong oxidizing agents, strong reducing agents

11. Toxicological information

Information on toxicological effects

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.

Symptoms

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

12. Ecological information

Ecotoxicity

Further details: No data available

Persistence and degradability

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

Bioaccumulative potential

Partition coefficient: n-octanol/water:

No data available

Mobility in soil

No data available

Other adverse effects

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

13. Disposal considerations

Waste treatment methods

Product

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

14. Transport information

UN number

DOT, IMDG, IATA-DGR: not applicable

UN proper shipping name

DOT, IMDG, IATA-DGR: Not restricted

Transport hazard class(es)

DOT, IMDG, IATA-DGR: not applicable

Packing group

DOT, IMDG, IATA-DGR: not applicable

Environmental hazards

Marine pollutant: no

Transport in bulk according to IMO instruments

No data available

Special precautions for user

USA: Department of Transportation (DOT)

Proper shipping name: Not restricted

Sea transport (IMDG)

Proper shipping name: Not restricted

Marine pollutant: no

Air transport (IATA)

Proper shipping name: Not restricted

Further information

No dangerous good in sense of these transport regulations.

15. Regulatory information

National regulations - U.S. Federal Regulations

This product is an article as defined by TSCA regulations, and is exempt from TSCA inventory listing requirements.

National regulations - U.S. State Regulations

No data available

Further regulations, limitations and legal requirements

No data available

16. Other information

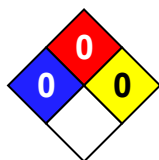
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Reason of change: General revision: Safety Data Sheet according to Hazardous Products Regulations (HPR) 2022

General revision: Safety Data Sheet according to HCS 2024 (29 CFR 1910.1200)

Hazard rating systems:



NFPA Hazard Rating:

Health: 0 (Minimal)

Fire: 0 (Minimal)

Reactivity: 0 (Minimal)

HMIS Version III Rating:

Health: 0 (Minimal)

Flammability: 0 (Minimal)

Physical Hazard: 0 (Minimal)

Personal Protection: X = Consult your supervisor

HEALTH	0
FLAMMABILITY	0
PHYSICAL HAZARD	0
	X

Abbreviations and acronyms:

AS/NZS: Australian Standards/New Zealand Standards
 CAS: Chemical Abstracts Service
 CFR: Code of Federal Regulations
 CLP: Classification, Labelling and Packaging
 DMEL: Derived minimal effect level
 DNEL: Derived no-effect level
 DOT: Department of Transportation's Safety Regulations (USA)
 EC: European Community
 EmS: Emergency Response Procedures for Ships Carrying Dangerous Goods
 EN: European Standard
 EQ: Excepted quantities
 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
 IMO: International Maritime Organization
 LEL: Lower Explosion Limit
 MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships
 OEL: Occupational Exposure Limit Value
 OSHA: Occupational Safety and Health Administration
 PBT: Persistent, bioaccumulative and toxic
 PNEC: Predicted no-effect concentration
 TLV: Threshold Limit Value
 TRGS: Technical Rules for Hazardous Substances
 TSCA: Toxic Substance Control Act
 vPvB: Very persistent and very bioaccumulative
 WEL: Workplace Exposure Limit

Department issuing data sheet

Contact person: see section 1: Department responsible for information

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.