

according to 29 CFR 1910.1200 and ANSI standard Z400.1-2010

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1. Product and company identification

Product identifier

Trade name: 2/4Rx - Titan Articles

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

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

USA

W/W/W www.ottobockus.com Telephone: +1 (801) 956-2400 +1 (801) 956-2401 Telefax:

Department responsible for information:

Quality Department,

Telephone: +1 (801) 954-2304 (7 AM – 3 PM, Mountain Time),

Email: USRegulatory@ottobock.com

This safety data sheet pertains to the following products: Additional information:

> 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)

Corporate headquarters: Ottobock SE & Co. KGaA Max-Näder-Straße 15

Duderstadt Germany

Emergency phone number

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

2. Hazards identification

Emergency overview

Appearance: Form: solid

Color: gray

Odor: odorless

Classification: This substance is classified as not hazardous.

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Regulatory status

This material is not considered hazardous by the U.S. OSHA Hazard Communication Standard (29 CFR 1910.1200).

Hazards not otherwise classified

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.

see section 11: Toxicological information

3. Composition / Information on ingredients

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.

Titanium-dust: Following skin contact:

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 opthalmologist.

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

Do not induce vomiting. Seek medical attention.

Most important symptoms/effects, acute and delayed

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

Flash point/flash point range:

No data available

Auto-ignition temperature: Titanium-dust: approx. 480.2 °F (249 °C)

Titanium-in pieces: approx. 2199.2 °F (1204 °C)



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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

Avoid generation of dust. Do not breathe dust. Personal precautions:

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 for clean-up: Metal parts/dust:

Take up mechanically, placing in appropriate containers for disposal.

Avoid generation of dust.

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

7. Handling and storage

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.

Storage

Requirements for storerooms and containers:

Store in a dry place.



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8. Exposure controls / personal protection

Exposure guidelines

Occupational exposure limit values:

Туре	Limit value	
USA: ACGIH: TWA	10 mg/m³ (Dust limit value, inhalable fraction)	
USA: ACGIH: TWA	3 mg/m³ (Dust limit value, respirable fraction)	
USA: OSHA: TWA	15 mg/m³ (Dust limit value, inhalable fraction)	
USA: OSHA: TWA	5 mg/m³ (Dust limit value, respirable fraction)	

Engineering controls

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

See also information in chapter 7, section storage.

Personal protection equipment (PPE)

Eye/face 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.

Skin protection: For mechanical processing: Wear suitable protective clothing.

For mechanical processing:

Protective gloves according to OSHA Standard - 29 CFR: 1910.138.

Observe glove manufacturer's instructions concerning penetrability and breakthrough time.

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.

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.

9. Physical and chemical properties

Information on basic physical and chemical properties

Appearance: Form: solid

Color: gray

odorless Odor:

Odor threshold: No data available

pH value: No data available

3034.4 - 3050.6 °F (1668 - 1677 °C) Melting point/freezing point: Initial boiling point and boiling range: 5900 - 6332 °F (3260 - 3500 °C)

Flash point/flash point range: No data available Evaporation rate: No data available Flammability: No data available

Explosion limits: LEL (Lower Explosion Limit): Titanium-dust, dry: approx. 50g/m³



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Vapor pressure: No data available No data available Vapor density:

4.5 g/cm3 Density: insoluble Water solubility:

No data available Partition coefficient: n-octanol/water:

Titanium-dust: approx. 480.2 °F (249 °C) Auto-ignition temperature:

Titanium-in pieces: approx. 2199.2 °F (1204 °C)

Thermal decomposition: No data available

No data available Additional information:

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

Thermal decomposition: No data available

11. Toxicological information

Toxicological tests

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.

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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

Mobility in soil

No data available

Persistence and degradability

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

substances.

Additional ecological information

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

13. Disposal considerations

Product

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

14. Transport information

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

Refer to 29 CFR Part 1910 subpart q - Welding, Cutting, Brazing 1910.252.

Titanium: TSCA listed

with Qualisys SUMDAT printed by Otto Bock, Utah



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National regulations - Great Britain

Hazchem-Code:

16. Other information

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

Changes in section 1.3: Corporate headquarters Reason of change:

8/6/2008 Date of first version:

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.

