

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

1.1 Product identifier

Trade name: 2/4/xRx - Stainless Steel

This safety data sheet pertains to the following products:

2R3 - Tube Adapter
 2R45 - Adjustment Tube Adaptor
 2R45=S - Tube Adapter
 2R76, R77 - Internal Tube Adaptor
 4R39 - Torsion Adaptor
 7U2, 7U5, 7U10 - Orthopedic Steel Knee Joint Bars, medium duty
 7U27, 7U30, 7U32, 7U33, 7U42 - Stainless Steel Knee Joint Bars, light duty
 7U43 - Orthopedic Steel Knee Joint Bars, light duty
 7U46, 7U53, 7U54 - Stainless Steel Knee Joint Bars, light duty
 16X4 - Elbow Joints
 16X12, 16X13 - Elbow Joint Set With Draw Lock
 16X14 - Elbow Joint Set Without Lock
 17B5, 17B7, 17B87 - Lower Side Bar
 17B4, 17B6, 17B86 - Upper Side Bar
 17B38, 17B40 - Stainless Steel System Side Bar Set
 17B84 - Stainless Steel System Rounded Side Bar Set
 17B95, 17B96 - Stainless Steel Knee Joint With Wedge Lock and Pull-Release Cable
 17H28, 17H29 - Stainless Steel Hip Joint For Children
 17K29 - Stainless Steel Knee Joints For Children
 17K32 - Stainless Steel Limited Motion Knee Joints For Children
 17K33 - Stainless Steel Free-Motion Offset Knee Joints For Children
 17K34 - Stainless Steel Knee Joints With Swiss Lock for Children
 17M10-S, 17M11 - Posterior Free Joints (Steel)
 17M20=16, 17M20=20 - Option Ring Lock - Stainless Steel
 17M20=C - Duchenne Stirrup
 17M30=13, 17M31=13 - Bale Lock
 17M100 - Push Lock Hinge - Stainless Steel

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

General use: Refined steel-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

Telefax: +49 (0)5527 72330

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.

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 steel, stainless

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: Wash with plenty of water.

After eye contact: Refined steel-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.
Refined steel-dust:
Rinse mouth and drink large quantities of water. Seek medical attention if problems persist.

4.2 Most important symptoms and effects, both acute and delayed

In case of eye contact / in case of inhalation, Dust: 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: Use extinguishing material as appropriate for the surrounding area.

5.2 Special hazards arising from the substance or mixture

Product is non-combustible.

5.3 Advice for firefighters

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Avoid generation of dust. Provide adequate ventilation.

In the case of the formation of dust: Wear protective equipment. Do not breathe dust. Avoid contact with skin and eyes.

6.2 Environmental precautions

Discharge into the environment must be avoided.

6.3 Methods and material for containment and cleaning up

Metal parts/dust:

Take up mechanically, placing in appropriate containers for disposal.

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.

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 Chemically resistant glove according to EN 374,

Glove material nitrile rubber-Breakthrough time 480 min.

and Protective gloves against mechanical risks according to EN 388.

Eye protection:

For mechanical processing:

Tightly sealed goggles according to BS EN ISO 16321-1:2022 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.
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, in pieces
Colour:	silver grey
Odour:	odourless
Odour threshold:	No data available
Melting point/freezing point:	No data available
Initial boiling point and boiling range:	No data available
Flammability:	No data available
Upper/lower flammability or explosive limits:	No data available
Flash point/flash point range:	not combustible
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:	No data available
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:	No data available
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

No hazardous reaction when handled and stored according to provisions.

10.4 Conditions to avoid

No data available

10.5 Incompatible materials

No data available

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.

General remarks

For mechanical processing:
Formation of potentially hazardous splinters.
Refined steel-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: Discharge into the environment must be avoided.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Waste key number: 16 01 17 = ferrous metal

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

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: 28/10/2008

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
- CFR: Code of Federal Regulations
- 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
- 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
- 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.