

## 1. Product and company identification

### Product identifier

Trade name: 16/17x - Stainless Steel, contains Nickel < 1%

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

General use: Refined steel-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  
Postal Code, city: Salt Lake City, UT 84120  
USA

WWW: [www.ottobockus.com](http://www.ottobockus.com)

Telephone: +1 (801) 956-2400

Telefax: +1 (801) 956-2401

Dept. responsible for information:

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

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

16Y29 - Bar  
17F34 - Limited Motion Ankle Joints for Children  
17F35 - Stainless Steel Caliper Plate  
17F47 - Dorsiflexion-Assist Ankle Joints for Children  
17F53 - Ankle Joints for Children

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, in pieces

Color: silver gray

Odor: odorless

Classification: This material is classified as not hazardous.

### Regulatory status

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

**Hazards not otherwise classified**

Contains Nickel: May cause sensitisation especially in sensitive humans.  
 For mechanical processing:  
 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.  
 Nickel-Powder:  
 May cause an allergic skin reaction. Suspected of causing cancer. Causes damage to organs through prolonged or repeated exposure. Harmful to aquatic life with long lasting effects.  
 see section 11: Toxicological information

**3. Composition / Information on ingredients**

Chemical characterization: Article of steel, stainless, contains: < 0,3% Nickel (bound in the product)

**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: Refined steel-dust:  
 Wash with plenty of water. Change contaminated clothing.

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.

**Most important symptoms/effects, acute and delayed**

Contains Nickel: May cause sensitisation especially in sensitive humans.  
 For mechanical processing:  
 Formation of potentially hazardous splinters.  
 Dust: May cause irritations.  
 Nickel-Powder: May cause an allergic skin reaction.

**Information to physician**

Treat symptomatically.

**5. Fire fighting measures**

Flash point/flash point range:  
 not combustible

Auto-ignition temperature: No data available

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

**Specific hazards arising from the chemical**

None known. Product is non-combustible.

## 6. Accidental release measures

**Personal precautions:** 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.

**Environmental precautions:** Discharge into the environment must be avoided.

**Methods for clean-up:** **Metal parts/dust:**  
 Take up mechanically, placing in appropriate containers for disposal.

## 7. Handling and storage

### Handling

**Advices on safe handling:** For mechanical processing:  
 Avoid respiration of swarf. Wear appropriate protective equipment.  
 Provide adequate ventilation. Avoid contact with skin and eyes.

### Storage

**Requirements for storerooms and containers:**  
 Store in a dry place.

## 8. Exposure controls / personal protection

### Exposure guidelines

Occupational exposure limit values:

CAS No.	Designation	Type	Limit value
	16/17x - Stainless Steel, contains Nickel < 1%	USA: ACGIH: TWA	10 mg/m <sup>3</sup>
		USA: ACGIH: TWA	3 mg/m <sup>3</sup>
		USA: OSHA: TWA	15 mg/m <sup>3</sup>
		USA: OSHA: TWA	5 mg/m <sup>3</sup>
7440-02-0	Nickel	USA: ACGIH: TWA	1.5 mg/m <sup>3</sup>
		USA: NIOSH: TWA	0.015 mg/m <sup>3</sup>
		USA: OSHA: TWA	1 mg/m <sup>3</sup>

**Additional information:** Nickel: bound in the product

### 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 goggles according to OSHA Standard - 29 CFR: 1910.133 or ANSI Z87.1-2010 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.  
 Glove material: nitrile rubber-Breakthrough time: 480 min.

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. Avoid contact with skin and eyes.  
 Wash hands before breaks and after work.  
 Provide a conveniently located eye rinse station. Change contaminated clothing.

## 9. Physical and chemical properties

### Information on basic physical and chemical properties

Appearance:	Form: solid, in pieces Color: silver gray
Odor:	odorless
Odor threshold:	No data available
pH value:	No data available
Melting point/freezing point:	No data available
Initial boiling point and boiling range:	No data available
Flash point/flash point range:	not combustible
Evaporation rate:	No data available
Flammability:	No data available
Explosion limits:	No data available
Vapor pressure:	No data available
Vapor density:	No data available
Density:	No data available
Water solubility:	insoluble
Partition coefficient: n-octanol/water:	No data available
Auto-ignition temperature:	No data available
Thermal decomposition:	No data available
Additional information:	No data available

## 10. Stability and reactivity

Reactivity:	No data available
Chemical stability:	Stable under recommended storage conditions.
Possibility of hazardous reactions	No hazardous reaction when handled and stored according to provisions.
Conditions to avoid:	No data available
Incompatible materials:	No data available

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.

### Symptoms

Contains Nickel: May cause sensitisation especially in sensitive humans.  
Nickel-Powder:  
May cause an allergic skin reaction. Suspected of causing cancer. Causes damage to organs through prolonged or repeated exposure.  
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

Aquatic toxicity: Nickel-dust: Harmful to aquatic life with long lasting effects.

### 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: Discharge into the environment must be avoided.

### 13. Disposal considerations

**Product**

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

### 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**

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

Refined steel: formation of Dust and glass-fibers, NFPA/HMIS: H1  
Refer to 29 CFR Part 1910 subpart q - Welding, Cutting, Brazing 1910.252.  
TSCA: listedNickel: TSCA Inventory: listed  
TSCA HPVC: not listed  
Carcinogen Status:  
IARC Rating: Group 2B  
OSHA Carcinogen: not listed  
NTP Rating: listed  
Clean Water Act:  
Priority Pollutant: yes  
Other Environmental Laws:  
CERCLA: RQ 100\* lbs.  
RCRA Groundwater Monitoring: Methods 6010, 7520 / PQL 50, 400  
SARA Title III Section 313, Toxic Release: Conc. 0.1% / Threshold Standard  
NIOSH Recommendations:  
Occupational Health Guideline: 0445\***National regulations - U.S. State Regulations**Nickel: California Proposition 65:  
cancer  
Rhode Island HSL: listed**National regulations - Great Britain**

Hazchem-Code: -

**16. Other information**

Text for labeling: Contains Nickel. May produce an allergic reaction.

Hazard rating systems: NFPA Hazard Rating:



Health: 1 (Slight)

Fire: 0 (Minimal)

Reactivity: 0 (Minimal)

HMIS Version III Rating:

Health: 1 (Slight)

Flammability: 0 (Minimal)

Physical Hazard: 0 (Minimal)

Personal Protection: X = Consult your supervisor

HEALTH	1
FLAMMABILITY	0
PHYSICAL HAZARD	0
	X

Reason of change: Changes in section 1.3: Corporate headquarters

Date of first version: 11/26/2008

**Department issuing data sheet**

Contact person: see section 1: Dept. 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.