



# SAFETY DATA SHEET

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

## 16/17x - Stainless Steel, contains Nickel < 1%

Material number 016/17x

Revision date: 9/24/2024  
Version: 8.4  
Replaces version: 8.3  
Language: en-US  
Date of print: 9/2/2025

Page: 1 of 8

## 1. Product and company identification

### Product identifier

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

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

### 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

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

### Emergency phone number

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

Transport:

CONSULTANK Lutz Harder GmbH (Contract QUALI003)

Telephone: +49 (0)178-4337434 (from USA: 01149 178 4337434)

## 2. Hazards identification

### Emergency overview

Appearance: Form: solid, in pieces

Color: silver gray

Odor: odorless

Classification: Article not subject to hazard labelling or classification.

## 16/17x - Stainless Steel, contains Nickel < 1%

Material number 016/17x

Page: 2 of 8

### Regulatory status

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

### 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:<br>Move victim to fresh air. Seek medical attention.   |
| Following skin contact: | Refined steel-dust:<br>Wash with plenty of water. Change contaminated clothing.  |
| After eye contact:      | Refined steel-dust:<br>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.<br>Refined steel-dust:<br>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

## 16/17x - Stainless Steel, contains Nickel < 1%

Material number 016/17x

Page: 3 of 8

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.

## 16/17x - Stainless Steel, contains Nickel < 1%

Material number 016/17x

Page: 4 of 8

### 8. Exposure controls / personal protection

#### Exposure guidelines

Occupational exposure limit values:

| CAS No.   | Designation                                    | Type            | Limit value  |
|-----------|--|-----------------|--|
| 7440-02-0 | 16/17x - Stainless Steel, contains Nickel < 1% | USA: ACGIH: TWA | 10 mg/m <sup>3</sup><br>(Dust limit value, inhalable fraction) |
|           |  | USA: ACGIH: TWA | 3 mg/m <sup>3</sup><br>(Dust limit value, respirable fraction) |
|           |  | USA: OSHA: TWA  | 15 mg/m <sup>3</sup> (Dust limit value, total dust)            |
|           |  | USA: OSHA: TWA  | 5 mg/m <sup>3</sup><br>(Dust limit value, respirable fraction) |
|           | Nickel   | USA: ACGIH: TWA | 1.5 mg/m <sup>3</sup> (metal, inhalable fraction)              |
|           |  | USA: IDLH: TWA  | 10 Ni/m <sup>3</sup>   |
|           |  | USA: NIOSH: TWA | 0.015 mg/m <sup>3</sup>  |
|           |  | USA: OSHA: TWA  | 1 mg/m <sup>3</sup><br>(metal and insoluble compounds)         |
|           |  | USA: OSHA: TWA  | 1 mg/m <sup>3</sup><br>(metal and soluble compounds)           |
|           |  |                 |  |

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.

#### Environmental exposure controls

Refer to 6.: Section "Environmental precautions".

## 16/17x - Stainless Steel, contains Nickel < 1%

Material number 016/17x

Page: 5 of 8

### 9. Physical and chemical properties

#### Information on basic physical and chemical properties

|  |  |
|--|--|
| Appearance:                              | Form: solid, in pieces<br>Color: silver gray |
| Odor:                                    | odorless                                     |
| Odor threshold:                          | No data available                            |
| pH:                                      | 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  |

## 16/17x - Stainless Steel, contains Nickel < 1%

Material number 016/17x

Page: 6 of 8

## 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.



# SAFETY DATA SHEET

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

**16/17x - Stainless Steel, contains  
Nickel < 1%**

Material number 016/17x

Revision date: 9/24/2024  
Version: 8.4  
Replaces version: 8.3  
Language: en-US  
Date of print: 9/2/2025

Page: 7 of 8

## 13. Disposal considerations

### Product

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

## 14. Transport information

### UN number

ADR/RID, IMDG, IATA-DGR:

not applicable

### UN proper shipping name

ADR/RID, IMDG, IATA-DGR:

Not restricted

### Transport hazard class(es)

ADR/RID, IMDG, IATA-DGR:

not applicable

### Packing group

ADR/RID, IMDG, IATA-DGR:

not applicable

### Environmental hazards

Marine pollutant:

no

### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

No data available

### 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

Nickel: California Proposition 65: cancer

### National regulations - Canada

Nickel: DSL: 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)

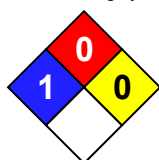
HMIS Version III Rating:

Health: 1 (Slight)

Flammability: 0 (Minimal)

Physical Hazard: 0 (Minimal)

Personal Protection: X = Consult your supervisor



|                 |   |
|-----------------|---|
| HEALTH          | 1 |
| FLAMMABILITY    | 0 |
| PHYSICAL HAZARD | 0 |
|                 | X |

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  
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  
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  
RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail  
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

Reason of change: General revision

Date of first version: 11/26/2008

### 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.