



SAFETY DATA SHEET

according to WHMIS 2015 and ANSI Z400.1-2010

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

Material number 016/17x

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

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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

Recommended use and restrictions on use

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

Initial supplier identifier

Company name: Otto Bock HealthCare Canada Ltd.

Street/POB-No.: 5470 Harvester Road

Postal Code, city: Burlington, ON L7L 5N5, CA
Canada

WWW: www.ottobock.ca

E-mail: info.canada@ottobock.com

Telephone: (800) 665-3327

Telefax: (800) 463-3659

Department responsible for information:

Mark Agro, Telephone: (800) 665-3327 (9 am - 5 pm)

Additional information:

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

Emergency phone number

COLLECT, Telephone: (613) 996-6666

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 labeling or classification.

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Regulatory status

This material is not considered hazardous by the U.S. OSHA Hazard Communication Standard (29 CFR 1910.1200) and WHMIS 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 characterisation: 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:	Ingestion is not considered a possible route of exposure. Refined steel-dust: Rinse mouth and drink large quantities of water. Seek medical attention if problems persist.

Most important symptoms and effects, both 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

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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.

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8. Exposure controls / personal protection

Exposure guidelines

Occupational exposure limit values:

CAS No.	Designation	Type	Limit value
16/17x - Stainless Steel, contains Nickel < 1%		Canada: OEL 8 hour	10 mg/m ³ (Dust limit value, inhalable fraction)
		Canada: OEL 8 hour	3 mg/m ³ (Dust limit value, respirable fraction)
		Canada: OEL TWA	10 mg/m ³ (Dust limit value, inhalable fraction)
		Canada: OEL TWA	3 mg/m ³ (Dust limit value, respirable fraction)
		Canada: VEMP	10 mg/m ³ (total dust)
		Canada: VEMP	3 mg/m ³ (total dust, respirable fraction)
		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)
		Canada: OEL 8 hour	1.5 mg/m ³ (metal)
		Canada: OEL TWA	0.05 mg/m ³ (compounds, insoluble)
		Canada: OEL TWA	0.05 mg/m ³ (compounds, soluble)
		Canada: OEL TWA	1 mg/m ³ (metal, inhalable fraction)
7440-02-0 Nickel		Canada: VEMP	1.5 mg/m ³ (inhalable fraction)
		USA: ACGIH: TWA	1.5 mg/m ³ (metal, inhalable fraction)
		USA: IDLH: TWA	10 Ni/m ³
		USA: NIOSH: TWA	0.015 mg/m ³
		USA: OSHA: TWA	1 mg/m ³ (metal and insoluble compounds)
		USA: OSHA: TWA	1 mg/m ³ (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.

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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".

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:	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.

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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.



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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

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

Canada: Transportation of Dangerous Goods (TDG)

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.

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15. Regulatory information

National regulations - Canada

Nickel: DSL: listed

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 - EC member states

Further regulations, limitations and legal requirements:

Nickel-restrictions on use: Regulation (EU) No 1907/2006, annex VII, 27

16. Other information

Text for labeling:

Hazard rating systems:



Contains Nickel. May produce an allergic reaction.

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



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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
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
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
WHMIS: Workplace Hazardous Materials Information System

Reason of change: Changes in section 8: Occupational exposure limit values

Date of first version: 26/11/2008

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.