

## 1. Identification

### Product identifier

Trade name: 28Uxx - AFOs

This safety data sheet pertains to the following products:

Article No. 28U9: AFO Orthosis

Article No. 28U15: Blank Heel PLS

Article No. 28U16: Rigid Heel PLS

Article No. 28U17: Semi Rigid Heel PLS

Article No. 28U18: Blank Heel PLS

Article No. 28U20: Articulating AFO - Free Motion

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

General use: Article for orthopedic procedures

### Details of the supplier of the safety data sheet

Company name: Otto Bock Health Care

Street/POB-No.: 3820 W. Great Lakes Drive

Zip code, city: Salt Lake City, UT 84120

USA

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Telephone: +1 (801) 956-2400

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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 telephone number

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

## 2. Hazard identification

### Classification of the substance or mixture

Article not subject to hazard labelling or classification.

### Label elements

not applicable

### Other hazards

Processing by heating can produce vapors. 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.

In case of heating: risk of burns.

## 3. Composition/information on ingredients

### Substances

Chemical characterization: Thermoplastic-Polyolefins (PE / PP)

## 4. First aid measures

General information: For mechanical processing: dust formation.  
In case of heating: development of gas/vapor possible.

In case of inhalation: When vapors form:  
Provide fresh air. Seek medical treatment in case of troubles.

Following skin contact: Remove residues with water.  
If burned by hot product, quench immediately with cold tap water.  
Do not peel solidified product off the skin. Immediately get medical attention.

After eye contact: In the case of the formation of dust / When vapors form:  
Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart.  
In case of troubles or persistent symptoms, consult an ophthalmologist.

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

In case of heating: risk of burns.

### Information to physician

Treat symptomatically.

## 5. Fire-fighting measures

### Suitable (and unsuitable) extinguishing media

Suitable extinguishing media:

Water spray jet, foam, dry chemical powder, carbon dioxide.

Extinguishing media which must not be used for safety reasons:

Full water jet

### Specific hazards arising from the chemical

In case of fire may be liberated: carbon black, compounds of low molecular weight (of PE or PP), carbon monoxide and carbon dioxide.

### Protective equipment and precautions for firefighters

Wear self-contained breathing apparatus.

## 6. Accidental release measures

### Personal precautions, protective equipment and emergency procedures

In case of development of vapors or dust:

Provide fresh air. Do not inhale vapors or dust particles. Wear protective equipment.

Environmental precautions:

Discharge into the environment must be avoided.

### Methods and material for containment and cleaning up

Methods for clean-up: Take up mechanically, placing in appropriate containers for disposal.

## 7. Handling and storage

### Precautions for safe handling

Advices on safe handling: Make sure that the processing machines are well equipped with suction and ventilation systems.

If necessary: With the formation of dust, use a dust mask.

In case of development of vapors or dust:

Provide fresh air. Do not inhale vapors or dust particles. Wear protective equipment.

### Conditions for safe storage, including any incompatibilities

Requirements for storerooms and containers:

Keep container dry.

Protect from: UV-radiation/sunlight

## 8. Exposure controls/personal protection

### Control parameters

Occupational exposure limit values:

Type	Limit value
USA: ACGIH: TWA	10 mg/m <sup>3</sup> (Dust limit value, inhalable fraction)
USA: ACGIH: TWA	3 mg/m <sup>3</sup> (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> (Dust limit value, respirable fraction)

### Appropriate engineering controls

Provide adequate ventilation, and local exhaust as needed.

### Personal protection equipment (PPE)

Respiratory protection: For mechanical processing: particulates filter  
OSHA Standard - 29 CFR: 1910.134 or ANSI Z88.2

Hand protection: If necessary:  
Protective gloves against thermic risks.  
For machine processing:  
Protective gloves against mechanical risks.  
OSHA Standard - 29 CFR: 1910.138  
Observe glove manufacturer's instructions concerning penetrability and breakthrough time.

Eye protection: For mechanical processing: tightly sealed goggles according to OSHA Standard - 29 CFR: 1910.133 or ANSI Z87.1-2010.

General hygiene considerations:

Avoid generation of dust.

Wash hands before breaks and after work.

In case of heating: Do not breathe vapors.

Work place should be equipped with a shower and an eye rinsing apparatus..

### Environmental exposure controls

Refer to 6.: Section "Environmental precautions".

## 9. Physical and chemical properties

### Information on basic physical and chemical properties

Physical state at 68 °F and 101.3 kPa	Form: solid
Color:	whitish
Odor:	odorless
Odor threshold:	No data available
Melting point/freezing point:	No data available
Initial boiling point and boiling range:	No data available
Flammability:	662 - 680 °F
Explosion limits:	No data available
Flash point/flash point range:	No data available
Evaporation rate:	No data available
Auto-ignition temperature:	No data available
Decomposition temperature:	> 300 °C
pH:	No data available
Viscosity:	No data available
Water solubility:	insoluble
Partition coefficient: n-octanol/water:	No data available
Vapor pressure:	No data available
Density:	0.90 - 0.96 g/cm <sup>3</sup>
Vapor density:	No data available
Particle characteristics:	Not applicable

### Additional information

Additional information: No data available

## 10. Stability and reactivity

Reactivity: refer to section 10.3

Chemical stability: Can be stored in any dry place.

Possibility of hazardous reactions:

No dangerous reactions are known.

Conditions to avoid: Avoid temperatures exceeding Processing temperature °C.  
(Processing temperature refer to section 9: Physical and chemical properties)

Incompatible materials: No data available

Hazardous decomposition products:  
In case of fire may be liberated: carbon black, compounds of low molecular weight (of PE or PP), carbon monoxide and carbon dioxide.

## 11. Toxicological information

### Information on toxicological effects

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

In case of inhalation: In case of heating: risk of burns.  
After contact with skin: In case of heating: risk of burns.  
After eye contact: Dust: mild irritant

## 12. Ecological information

### Ecotoxicity

Further details: No data available

### Persistence and degradability

Further details: Product is not biodegradable.

### Bioaccumulative potential

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

### Mobility in soil

No data available

### Other adverse effects

General information: Discharge into the environment must be avoided.

## 13. Disposal considerations

### Waste treatment methods

#### Product

Recommendation: If recycling is not possible, dispose of according to local waste laws and regulations (information requirements of authorities).

#### Package

Recommendation: Dispose of waste according to applicable legislation.  
Non-contaminated packages may be recycled.

## 14. Transport information

### UN number

DOT, IMDG, IATA-DGR: not applicable

### UN proper shipping name

DOT, IMDG, IATA-DGR: Not restricted

### Transport hazard class(es)

DOT, IMDG, IATA-DGR: not applicable

### Packing group

DOT, IMDG, IATA-DGR: not applicable

### Environmental hazards

Marine pollutant: no

### Transport in bulk according to IMO instruments

No data available

### Special precautions for user

#### 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

No data available

### Further regulations, limitations and legal requirements

No data available

## 16. Other information

Revision date: 12/17/2025

Date of first version: 5/30/2008

Reason of change: General revision: Safety Data Sheet according to Hazardous Products Regulations (HPR) 2022

General revision: Safety Data Sheet according to HCS 2024 (29 CFR 1910.1200)

Hazard rating systems:



NFPA Hazard Rating:

Health: 0 (Minimal)

Fire: 1 (Slight)

Reactivity: 0 (Minimal)

HMIS Version III Rating:

Health: 0 (Minimal)

Flammability: 1 (Slight)

Physical Hazard: 0 (Minimal)

Personal Protection: X = Consult your supervisor

HEALTH	0
FLAMMABILITY	1
PHYSICAL HAZARD	0
	X

Abbreviations and acronyms:

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

DOT: Department of Transportation's Safety Regulations (USA)

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

OSHA: Occupational Safety and Health Administration

PBT: Persistent, bioaccumulative and toxic

PNEC: Predicted no-effect concentration

TRGS: Technical Rules for Hazardous Substances

TSCA: Toxic Substance Control Act

UV: Ultraviolet

vPvB: Very persistent and very bioaccumulative

### Department issuing data sheet

Contact person: see section 1: Department responsible for information



# SAFETY DATA SHEET

according to HCS 2024 (29 CFR 1910.1200)

## 28Uxx - AFOs

Material number 028Uxx

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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.