

1. Product and company 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

Postal Code, city: Salt Lake City, UT 84120

USA

WWW: 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

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

Color: whitish

Odor: odorless

Classification: Article not subject to hazard labelling or classification.

Regulatory status

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

Hazards not otherwise classified

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.
see section 11: Toxicological information

3. Composition / Information on ingredients

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

Flash point/flash point range:	No data available
Auto-ignition temperature:	No data available
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: 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 for clean-up: Take up mechanically, placing in appropriate containers for disposal.

7. Handling and storage

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.

Specific use(s) Article for orthopedic procedures

Storage

Requirements for storerooms and containers:
Keep container dry.
Protect from: UV-radiation/sunlight

8. Exposure controls / personal protection

Exposure guidelines

Occupational exposure limit values:

Type	Limit value
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)

Engineering controls

Provide adequate ventilation, and local exhaust as needed.
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.

Skin 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.

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

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

Appearance: Form: solid
Color: whitish

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: No data available

Evaporation rate: No data available

Flammability: 662 - 680 °F

Explosion limits: No data available

Vapor pressure: No data available

Vapor density: No data available

Density: 0.90 - 0.96 g/cm³

Water solubility: insoluble

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

Auto-ignition temperature: No data available

Thermal decomposition: > 300 °C

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.

Thermal decomposition: > 300 °C

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

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

Mobility in soil

No data available

Persistence and degradability

Further details: Product is not biodegradable.

Additional ecological information

Volatile organic compounds (VOC):

0 % by weight

General information: Discharge into the environment must be avoided.

13. Disposal considerations

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

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

No data available

National regulations - Great Britain

Hazchem-Code: -

16. Other information

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:

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
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
TRGS: Technical Rules for Hazardous Substances
TSCA: Toxic Substance Control Act
UV: Ultraviolet
vPvB: Very persistent and very bioaccumulative

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

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SAFETY DATA SHEET

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

28Uxx - AFOs

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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.