

1. Product and company identification

Product identifier

Trade name: SL=P071-A - Footshell Foam Kit Part A

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

General use: Elastomer for orthopedic procedures.
For use in industrial installations and professional treatment only.

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: Physical state at 68 °F and 101.3 kPa: liquid
Form: viscous
Color: amber
Odor: characteristic, mild
Classification: Acute Toxicity - inhalative - Category 4. Skin Irritation - Category 2. Eye Irritation - Category 2A. Respiratory Sensitizer - Category 1. Sensitization - skin - Category 1. Carcinogenicity - Category 2. Specific Target Organ Toxicity (Single Exposure) - Category 3. Specific Target Organ Toxicity (Repeated Exposure) - Category 2.

Hazard symbols:



Signal word:

Danger

Hazard statements:

Causes skin irritation.
May cause an allergic skin reaction.
Causes serious eye irritation.
Harmful if inhaled.
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May cause respiratory irritation.
Suspected of causing cancer.
May cause damage to organs through prolonged or repeated exposure.

Precautionary statements:

Obtain special instructions before use.
Do not breathe dust/fume/gas/mist/vapors/spray.
Use only outdoors or in a well-ventilated area.
Wear protective gloves/protective clothing/eye protection/face protection.
Store locked up.
Dispose of contents/container to hazardous or special waste collection point.

Regulatory status

This material is considered hazardous by the U.S. OSHA Hazard Communication Standard (29 CFR 1910.1200).

Hazards not otherwise classified

Contact with water liberates carbon dioxide. Do not re-seal contaminated containers as pressure buildup may rupture.
see section 11: Toxicological information

3. Composition / Information on ingredients

Relevant ingredients:

CAS No.	Designation	Concentration	Classification
CAS 101-68-8	4,4'-Methylenediphenyl diisocyanate	50 - 75 %	Acute Toxicity - inhalative - Category 4. Skin Irritation - Category 2. Eye Irritation - Category 2A. Respiratory Sensitizer - Category 1. Sensitization - skin - Category 1. Carcinogenicity - Category 2. Specific Target Organ Toxicity (Single Exposure) - Category 3. Specific Target Organ Toxicity (Repeated Exposure) - Category 2.
CAS 68092-58-0	Polyurethane prepolymer of MDI and PEP	20 %	not classified

4. First aid measures

General information:	First aider: Pay attention to self-protection! If medical advice is needed, have product container or label at hand. Take off contaminated clothing and wash it before reuse.
In case of inhalation:	Move victim to fresh air; if necessary, provide artificial respiration or oxygen. Immediately get medical attention.
Following skin contact:	After contact with skin, wash immediately with soap and plenty of water. Seek medical treatment in case of troubles.
After eye contact:	Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart. Remove contact lenses, if present and easy to do. Continue rinsing. Subsequently seek the immediate attention of an ophthalmologist.
After swallowing:	Rinse mouth immediately and drink plenty of water. Never give anything by mouth to an unconscious person. Do not induce vomiting. Immediately get medical attention.

Most important symptoms/effects, acute and delayed

Harmful if inhaled. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Causes skin irritation. May cause an allergic skin reaction. Causes serious eye irritation. May cause respiratory irritation. May cause damage to organs through prolonged or repeated exposure.

Information to physician

Treat symptomatically. No specific antidote exists.
Symptoms of poisoning may develop several hours following exposure. Victim should be under medical observation for at least 24 hours after exposure.

5. Fire fighting measures

Flash point/flash point range:	> 399.2 °F (PMCC)
Auto-ignition temperature:	No data available
Suitable extinguishing media:	Extinguishing powder, Additionally: carbon dioxide, foam, water spray jet.

Specific hazards arising from the chemical

Contact with water liberates carbon dioxide.
May form dangerous gases and vapors in case of fire.
Furthermore, there may develop: Isocyanates, nitrogen oxides (NOx), hydrogen cyanide, carbon monoxide and carbon dioxide.

Protective equipment and precautions for firefighters:	Wear a self-contained breathing apparatus and chemical protective clothing.
Additional information:	If water is used to extinguish fire, the use of large doses is needed, as the reaction between water and hot isocyanates may be vigorous. Do not re-seal contaminated containers as pressure buildup may rupture.

6. Accidental release measures

Personal precautions:	Avoid exposure. If possible, eliminate leakage. Provide adequate ventilation. Wear appropriate protective equipment. Take off contaminated clothing and wash it before reuse. Do not breathe vapors. Avoid contact with skin and eyes.
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Environmental precautions:

Do not allow to penetrate into soil, waterbodies or drains. If necessary, notify appropriate authorities.

Methods for clean-up:

Soak up with absorbent materials such as sand, siliceus earth, acid- or universal binder.
Store in special closed containers and dispose of according to ordinance.
Keep container in a well-ventilated place.
Neutralization: Ammonia solution (8%) and Surfactants (2%).
Allow to rest for 48 hours, letting developing CO2 escape.

7. Handling and storage

Handling

Advices on safe handling:

Use local exhaust. Do not breathe vapors.
Avoid contact with skin and eyes.
Wear suitable protective clothing.
Use caution when opening containers under pressure.
Obtain special instructions before use.
Wash hands before breaks and after work.
When using do not eat, drink or smoke.
Safety shower and eye wash station should be easily accessible to the work area. Take off contaminated clothing and wash it before reuse.

Precautions against fire and explosion:

Contact with water liberates carbon dioxide. Do not re-seal contaminated containers as pressure buildup may rupture.
Protect from moisture contamination.
In case of warming: Danger of bursting container.

Storage

Requirements for storerooms and containers:

Keep containers tightly closed and at a temperature between 68 °F and 86 °F.
Avoid temperatures exceeding 149 °F.
Store under protective gas (nitrogen). Protect from frost.

Hints on joint storage:

Keep away from food, drink and animal feedingstuffs.
Reacts with water, acids, bases, metals and surface active materials.

Further details:

Protect from heat and direct sunlight.

8. Exposure controls / personal protection

Exposure guidelines

Occupational exposure limit values:

CAS No.	Designation	Type	Limit value
101-68-8	4,4'-Methylenediphenyl diisocyanate	USA: ACGIH: TWA	0.005 ppm
		USA: NIOSH: Ceiling	0.2 mg/m ³ ; 0.02 ppm
		USA: NIOSH: TWA	0.05 mg/m ³ ; 0.005 ppm
		USA: OSHA: Ceiling	0.2 mg/m ³ ; 0.02 ppm

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: Tightly sealed goggles according to OSHA Standard - 29 CFR: 1910.133 or ANSI Z87.1-2010.
- Skin protection: protective gloves according to OSHA Standard - 29 CFR: 1910.138.
Glove material: butyl caoutchouc (butyl rubber) - Layer thickness: 0.7 mm
Breakthrough time: >120 min.
Observe glove manufacturer's instructions concerning penetrability and breakthrough time. Observe glove manufacturer's instructions concerning penetrability and breakthrough time.
- Respiratory protection: When vapors form, use respiratory protection.
Use filter type A (= against vapors of organic substances) according to OSHA Standard - 29 CFR: 1910.134 or ANSI Z88.2.
- General hygiene considerations:
Obtain special instructions before use. Do not breathe vapors.
Wash hands before breaks and after work.
When using do not eat, drink or smoke.
Safety shower and eye wash station should be easily accessible to the work area.
Persons working with this product should not wear contact lenses.
Take off contaminated clothing and wash it before reuse.

Environmental exposure controls

Refer to 6.: Section "Environmental precautions".

9. Physical and chemical properties

Information on basic physical and chemical properties

- Appearance: Physical state at 68 °F and 101.3 kPa: liquid
Form: viscous
Color: amber
- Odor: characteristic, mild
- Odor threshold: No data available
- pH: No data available
- Melting point/freezing point: No data available
- Initial boiling point and boiling range: 406.04 °F
- Flash point/flash point range: > 399.2 °F (PMCC)
- Evaporation rate: No data available
- Flammability: No data available
- Explosion limits: No data available
- Vapor pressure: at 77 °F: ≤ 0.00013 hPa
- Vapor density: No data available
- Density: 1.23 g/mL
- Water solubility: reacts with water
- Partition coefficient: n-octanol/water: No data available

Auto-ignition temperature: No data available
Thermal decomposition: >120.2 °F: Reactions with water.
>347 °F: Reactions with strong bases.
Additional information: No data available

10. Stability and reactivity

Reactivity: Refer to subsection "Possibility of hazardous reactions".
Chemical stability: Hygroscopic (Keep container tightly closed in a cool place.)
Shelf life of this product is 6 months from date of manufacturing.
Possibility of hazardous reactions:
Danger of polymerization
Contact with water liberates carbon dioxide.
In case of warming: Danger of bursting container.
Conditions to avoid: Protect from heat and direct sunlight.
Avoid temperatures exceeding 149 °F.
Do not re-seal contaminated containers as pressure buildup may rupture.
Incompatible materials: Reacts with water, acids, bases, metals and surface active materials.
Hazardous decomposition products:
Isocyanates, nitrogen oxides (NO_x), hydrogen cyanide, carbon monoxide and carbon dioxide.
Thermal decomposition: >120.2 °F: Reactions with water.
>347 °F: Reactions with strong bases.

11. Toxicological information

Toxicological tests

Acute toxicity: LC50 Rat, inhalative: 434 mg/m³/4h

Toxicological effects: The statements are derived from the properties of the single components. No toxicological data is available for the product as such.

Acute toxicity (oral): Lack of data.

Acute toxicity (dermal): Lack of data.

Acute toxicity (inhalative): Acute Toxicity - inhalative - Category 4 = Harmful if inhaled.

Skin corrosion/irritation: Skin Irritation - Category 2 = Causes skin irritation.

Serious eye damage/irritation: Eye Irritation - Category 2A = Causes serious eye irritation.

Sensitisation to the respiratory tract: Respiratory Sensitizer - Category 1 = May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Skin sensitisation: Sensitization - skin - Category 1 = May cause an allergic skin reaction.

Germ cell mutagenicity/Genotoxicity: Lack of data.

Carcinogenicity: Carcinogenicity - Category 2 = Suspected of causing cancer.

Reproductive toxicity: Lack of data.

Effects on or via lactation: Lack of data.

Specific target organ toxicity (single exposure): Specific Target Organ Toxicity (Single Exposure) - Category 3 = May cause respiratory irritation.

Specific target organ toxicity (repeated exposure): Specific Target Organ Toxicity (Repeated Exposure) - Category 2 = May cause damage to organs through prolonged or repeated exposure.

Aspiration hazard: Lack of data.

Following skin contact: May stain the skin.

Symptoms

Irritant. May cause damage to organs through prolonged or repeated exposure.

In case of inhalation:
Prolonged exposure to high concentrations may irritate respiratory system, cause headaches, dizziness and effects of the central nervous system. Pulmonary edema is possible. (It is possible that exposure to TDI-MDI may cause impairment of lung function.)

In case of ingestion: Irritant.

After contact with skin:
symptoms: redness, oedema (swelling), skin rash.

After eye contact: Upon direct contact with eyes may cause burning, tearing, redness.

12. Ecological information

Ecotoxicity

Further details: No data available

Mobility in soil

No data available

Persistence and degradability

Further details: No data available

Additional ecological information

Volatile organic compounds (VOC):

0 % by weight

General information:

Do not allow to penetrate into soil, waterbodies or drains.

13. Disposal considerations

Product

Recommendation: Incinerate as hazardous waste according to applicable local, state, and federal regulations.

Package

Recommendation: Dispose of waste according to applicable legislation.

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:

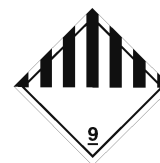
no

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

No data available

USA: Department of Transportation (DOT)

Identification number: NA3082
Proper shipping name: NA 3082, hazardous waste, liquid, n.o.s.
(4,4'-Methylenediphenyl diisocyanate)
Hazard class or Division: 9
Packing Group: III
Labels: 9
Symbols: D G
Special Provisions: IB3, T2, TP1
Packaging – Exceptions: 155
Packaging – Non-bulk: 203
Packaging – Bulk: 241
Quantity limitations – Passenger aircraft / rail: No limit
Quantity limitations – Cargo only: No limit
Vessel stowage – Location: A



Sea transport (IMDG)

Proper shipping name: Not restricted
Marine pollutant: no

Air transport (IATA)

Proper shipping name: Not restricted

15. Regulatory information

National regulations - U.S. Federal Regulations

4,4'-Methylenediphenyl diisocyanate: TSCA Inventory: listed
Carcinogen Status:
IARC Rating: Group 3
OSHA Carcinogen: not listed
NTP Rating: not listed
Clean Air Act:
CAA Hazardous Air Pollutants: yes
CAA SOCM Chemical: yes
Other Environmental Laws:
CERCLA: RQ 5000 lbs.
SARA Title III - Section 313, Toxic Release: Conc. 1.0% /
Threshold Standard
NIOSH Recommendations:
Occupational Health Guideline: 0413

Polyurethane prepolymer of MDI and PEP: TSCA Inventory: listed

National regulations - U.S. State Regulations

4,4'-Methylenediphenyl diisocyanate: California Proposition 65 code: -
Delaware Air Quality Management List:
DRQ: 5000 - RQ State: Federal Regulations Apply
Idaho Air Pollutant List:
Title 585: -, Title 586: -
Main Hazardous Air Pollutants:
Me 2005: HAP - Hap Rpt: 200
Massachusetts Haz. Substance codes: 2,4 F8 F9
Minnesota Haz. Substance:
Codes: ANO - Ratings: 12.36 - Status: Air Pollutant
New York List of Hazardous Substances:
RQ-Air: 1 - RQ-Land: 1 - Note: No Note Associated with this chemical.
Pennsylvania Haz. Substance code: E
Washington Air Contaminant:
Ceiling: 0,02 ppm - 0,2 mg

National regulations - Canada

4,4'-Methylenediphenyl diisocyanate: DSL: listed
Polyurethane prepolymer of MDI and PEP: DSL: listed

National regulations - Great Britain

Hazchem-Code: -

16. Other information

Text for labeling:

Contains 50 - 75 % 4,4'-Methylenediphenyl diisocyanate, 20 % Polyurethane prepolymer of MDI and PEP.

Hazard rating systems:



NFPA Hazard Rating:

Health: 3 (Serious)

Fire: 1 (Slight)

Reactivity: 1 (Slight)

HMIS Version III Rating:

Health: 3 (Serious) - Chronic effects

Flammability: 1 (Slight)

Physical Hazard: 1 (Slight)

Personal Protection: X = Consult your supervisor

HEALTH	*	3
FLAMMABILITY		1
PHYSICAL HAZARD		1
X		



SAFETY DATA SHEET

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

SL=P071-A - Footshell Foam Kit Part A

Material number SL=P071-A

Revision date: 9/13/2024
Version: 9.3
Replaces version: 9.2
Language: en-US
Date of print: 9/2/2025

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Abbreviations and acronyms:

Acute Toxicity: Acute toxicity
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
Carcinogenicity: Carcinogenicity
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
Eye Irritation: Eye irritation
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
LC50: Median lethal concentration
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
Respiratory Sensitizer: Sensitisation to the respiratory tract
RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail
Sensitization - skin: Skin sensitisation
Skin Irritation: Skin irritation
STOT RE: Specific target organ toxicity - repeated exposure
STOT SE: Specific target organ toxicity - single exposure
TRGS: Technical Rules for Hazardous Substances
vPvB: Very persistent and very bioaccumulative

Reason of change: Changes in section 2: EUH204

Date of first version: 11/10/2001

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.