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
Dept. 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

2. Hazards identification

Emergency overview

Appearance: Form: liquid, 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) and SIMDUT in Canada.

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	Content	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 applicable

4. First aid measures

General information: Take off immediately all contaminated clothing. Wash contaminated clothing prior to re-use.

In case of inhalation: Move victim to fresh air; if necessary, provide artificial respiration or oxygen. Seek 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. Subsequently seek the immediate attention of an ophthalmologist.

After swallowing: Do not induce vomiting. Immediately get medical attention.

Most important symptoms/effects, acute and delayed

Irritant. May cause damage to organs through prolonged or repeated exposure.
In case of inhalation:
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
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: May cause an allergic skin reaction.
symptoms: redness, oedema (swelling), skin rash.

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.
decomposition products: 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 extinguih 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: Wear a self-contained breathing apparatus and chemical protective clothing.
Do not breathe vapors.
Avoid contact with skin and eyes.
Wear suitable protective clothing.

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

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.

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.

Specific use(s): Elastomer for orthopedic procedures.

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	NIOSH: Ceiling	0.2 mg/m³; 0.02 ppm
		OSHA: Ceiling	0.2 mg/m³; 0.02 ppm
		USA: ACGIH: TWA	0.005 ppm
		USA: NIOSH: TWA	0.05 mg/m³; 0.005 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:
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 immediately all contaminated clothing. Wash contaminated clothing prior to re-use.

9. Physical and chemical properties

Information on basic physical and chemical properties

Appearance:	Form: liquid, viscous Color: amber
Odor:	characteristic, mild
Odor threshold:	No data available
pH value:	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 10.3

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:
decomposition products: Isocyanates, nitrogen oxides (NOx), 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: 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:
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
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: May cause an allergic skin reaction.
symptoms: redness, oedema (swelling), skin rash.

12. Ecological information

Ecotoxicity

Aquatic toxicity: 4,4'-Methylenediphenyl diisocyanate:
Algae toxicity: IC50 Desmodesmus subspicatus: 1,5 mg/ l/72 h.
Daphnia toxicity: EC50 Daphnia magna: 0,35 mg/l/24 h.

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.

Contaminated packaging

Recommendation: Dispose of waste according to applicable legislation.

14. Transport information

USA: Department of Transportation (DOT)

Identification number: NA3082
Proper shipping name: NA 3082, UN 13082, Hazardous waste, liquid, n.o.s.
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

Further information

No dangerous good in sense of these transport regulations.

15. Regulatory information

National regulations - U.S. Federal Regulations

4,4'-Methylenediphenyl diisocyanate:
TSCA Inventory: listed
TSCA HPVC: not listed
Carcinogen Status:
IARC Rating: Group 3
OSHA Carcinogen: not listed
NTP Rating: not listed
Clean Air Act:
Hazardous Air Pollutants: Code XOV
SOCMI 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: listed - Flags: XU

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 - Great Britain

Hazchem-Code: -

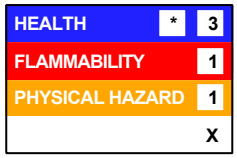
16. Other information

Text for labeling: Contains 50 - 75 % 4,4'-Methylenediphenyl diisocyanate, 20 % Polyurethane prepolymer of MDI and PEP. Safety data sheet available on request.

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



Reason of change: Changes in section 1.3: Corporate headquarters

Date of first version: 11/10/2001

Department issuing data sheet

Contact person: see section 1: Dept. 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.