

1. Product and company identification

Product identifier

Trade name: 86T3 - Dupligel

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

General use: Forming-material for modeling for orthopedic procedures.
Reserved for industrial and professional use.

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, elastic

Color: pink

Odor: weak, sweetish

Classification: This material is classified as not hazardous.

Regulatory status

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

Hazards not otherwise classified

see section 11: Toxicological information

3. Composition / Information on ingredients

Chemical characterization: A mixture of Glycerol (CAS 56-81-5, <10 %), water and polysaccharide (CAS 9002-18-0)

Additional information: The maximum workplace exposure limits are, where necessary, listed in section 8.

4. First aid measures

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

Following skin contact: Remove residues with soap and water. After contact with molten product, cool skin area rapidly with cold 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.
In case of troubles or persistent symptoms, consult an ophthalmologist.
If burned by hot product, quench immediately with cold tap water.
Subsequently consult an ophthalmologist.

After swallowing: Never give anything by mouth to an unconscious person. Rinse mouth. Do not induce vomiting without medical assistance. In case of accident or unwellness consult a doctor.

Most important symptoms/effects, acute and delayed

After contact with skin: In case of heating: risk of burns.

After eye contact:

Hot molten mass, liquid splashes: 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:

Co-ordinate fire-fighting measures to the fire surroundings.

Extinguishing media which must not be used for safety reasons:

Full water jet

Specific hazards arising from the chemical

Product is non-combustible.

Hazardous vapors may form during fires.

Protective equipment and precautions for firefighters:

Wear a self-contained breathing apparatus and chemical protective clothing.

Additional information:

Cool endangered containers with water spray and, if possible, remove from danger zone.
Use water spray jet to knock down vapors. Do not breathe fumes. Do not allow fire water to penetrate into surface or ground water.

6. Accidental release measures

Personal precautions:	Handle in accordance with good industrial hygiene and safety practice. Hot molten mass: Avoid contact with skin, eyes, and clothing. Do not breathe vapors. Protective gloves against thermic risks. Wear closely fitting protective glasses in case of splashes. Provide fresh air. Keep unprotected people away.
Environmental precautions:	Do not allow to penetrate into soil, waterbodies or drains.
Methods for clean-up:	Solid: Take up mechanically, placing in appropriate containers for disposal. Thoroughly clean surrounding area. Dispose of waste according to applicable legislation. Hot molten mass: Contain hot liquid after spilling and let it cool down (solidify); then collect mechanically.

7. Handling and storage

Handling

Advices on safe handling:	Handle in accordance with good industrial hygiene and safety practice. Hot molten mass: Provide adequate ventilation, and local exhaust as needed. Do not breathe vapors. Wear appropriate protective equipment.
Precautions against fire and explosion:	Take standard precautions to prevent fire.
Specific use(s)	Forming-material for modeling for orthopedic procedures

Storage

Requirements for storerooms and containers:	Keep container tightly closed and dry. Storage temperature: +5°C up to +30°C.
Hints on joint storage:	Keep away from food, drink and animal feedingstuffs.

8. Exposure controls / personal protection

Exposure guidelines

Occupational exposure limit values:

CAS No.	Designation	Type	Limit value
56-81-5	Glycerol	USA: OSHA: TWA USA: OSHA: TWA	15 mg/m ³ (total dust) 5 mg/m ³ (respirable fraction)

Engineering controls

Provide adequate ventilation.
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.
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Skin protection: Protective gloves according to OSHA Standard - 29 CFR: 1910.138 Glove material: Nitrile rubber
Breakthrough time: > 480 min.
Observe glove manufacturer's instructions concerning penetrability and breakthrough time.

Respiratory protection: Respiratory protection must be worn whenever the TLV (WEL) levels have been exceeded.
Use filter type A (= against vapors of organic substances).

General hygiene considerations:
Handle in accordance with good industrial hygiene and safety practice.
Wash hands before breaks and after work. When using do not eat, drink or smoke.

Environmental exposure controls

Refer to 6.: Section "Environmental precautions".

9. Physical and chemical properties

Information on basic physical and chemical properties

Appearance: Form: solid, elastic
Color: pink

Odor: weak, sweetish

Odor threshold: No data available

pH: 7

Melting point/freezing point: > 176 °F

Initial boiling point and boiling range: No data available

Flash point/flash point range: No data available

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: approx. 1.1 g/cm³

Water solubility: at 122 °F: soluble

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

Auto-ignition temperature: No data available

Thermal decomposition: No data available

Additional information: working temperature: 111.2 °F up to 125.6 °F
solidifying temperature: < 95 °F

10. Stability and reactivity

Reactivity: No data available

Chemical stability: Stable under recommended storage conditions.

Possibility of hazardous reactions: No hazardous reactions known.

Conditions to avoid: Keep away from heat.

Incompatible materials: No data available

Hazardous decomposition products:

Hazardous vapors may form during fires.

Thermal decomposition: No data available

11. Toxicological information

Toxicological tests

Acute toxicity: LD50 Rat, oral: Glycerol > 10,000 mg/kg
LD50 Rat, oral: Polysaccharide > 10,000 mg/kg

Toxicological effects: Acute toxicity (oral): Based on available data, the classification criteria are not met.
The product has not been tested. The statement is derived from the properties of the single components.

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

After contact with skin: In case of heating: risk of burns.

After eye contact:

Hot molten mass, liquid splashes: risk of burns.

12. Ecological information

Ecotoxicity

Further details: No data available

Mobility in soil

No data available

Persistence and degradability

Further details: Product is biodegradable.

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:

May be reused after remediation.

Dispose of waste according to applicable legislation.

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

Glycerol: TSCA Inventory: listed
Clean Air Act:
CAA SOCM Chemical: yes
NIOSH Recommendations:
Occupational Health Guideline: 0302

National regulations - U.S. State Regulations

Glycerol: Rhode Island Hazardous Substances:
listed
California Proposition 65 code: not listed
Massachusetts Haz. Substance codes: 2,4
Minnesota Haz. Substance:
Codes: A - Ratings: --
Pennsylvania Haz. Substance code: -
Washington Air Contaminant:
TWA: 10 mg

National regulations - Canada

Glycerol: DSL: listed

National regulations - Great Britain

Hazchem-Code: -

16. Other information

Hazard rating systems:



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

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
 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
 vPvB: Very persistent and very bioaccumulative
 WEL: Workplace Exposure Limit

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

Date of first version: 7/10/2008

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.