

1. Product and company identification

Product identifier

Trade name: 85Z1-8 - Pigmisil Colour pastes

This safety data sheet pertains to the following products:

Article No. 85Z1: Pigmisil = white

Article No. 85Z2: Pigmisil = skin-colored

Article No. 85Z3: Pigmisil = yellow

Article No. 85Z4: Pigmisil = blue

Article No. 85Z5: Pigmisil = red

Article No. 85Z6: Pigmisil = black

Article No. 85Z7: Pigmisil = rust

Article No. 85Z8: Pigmisil = buffalo brown

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

General use: Pigment paste for orthopedic procedures.
For industrial purposes 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: pasty

Color: Refer to section 1

Odor: Odorless

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

Special danger of slipping by leaking/spilling product.
see section 11: Toxicological information

3. Composition / Information on ingredients

Chemical characterization: Pigment paste

Polydimethylsiloxane and pigment

Additional information: The product does not contain dangerous substances above limits that need to be mentioned in this section according to applicable legislation.

4. First aid measures

General information: If medical advice is needed, have product container or label at hand.

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

Following skin contact: Remove mechanically with cloth or paper. Rinse skin with water. Take off contaminated clothing and wash it before reuse.
Consult a doctor if skin irritation persists.

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. In case of troubles or persistent symptoms, consult an ophthalmologist.

After swallowing: Never give anything by mouth to an unconscious person. Do not induce vomiting without medical assistance. Rinse mouth with water. Seek medical attention.

Most important symptoms/effects, acute and delayed

No data available

Information to physician

Treat symptomatically.

5. Fire fighting measures

Flash point/flash point range:

> 392 °F (ISO 2592)

Auto-ignition temperature: > 482 °F

Suitable extinguishing media:

Water spray jet, alcohol resistant foam, dry chemical powder, carbon dioxide, Sand

Extinguishing media which must not be used for safety reasons:

Full water jet.

Specific hazards arising from the chemical

May form dangerous gases and vapors in case of fire.

Furthermore, there may develop: carbon monoxide and carbon dioxide.

Protective equipment and precautions for firefighters:

Wear self-contained breathing apparatus and protective clothing to protect skin and eyes.

Additional information:

Seal off endangered area. 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:

Provide fresh air. Avoid contact with skin, eyes, and clothing. Wear appropriate protective equipment. Take off contaminated clothing and wash it before reuse. Keep unprotected people away.

Environmental precautions:

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

Methods for clean-up:

Take up mechanically, placing in appropriate containers for disposal. Final cleaning. Dispose of waste according to applicable legislation.

Additional information:

Special danger of slipping by leaking/spilling product.

7. Handling and storage

Handling

Advices on safe handling:

Handle in accordance with good industrial hygiene and safety practice. Provide adequate ventilation, and local exhaust as needed. Avoid contact with skin, eyes, and clothing. Wear appropriate protective equipment. When using do not eat, drink or smoke. Wash hands before breaks and after work. Have eye wash bottle or eye rinse ready at work place.

Precautions against fire and explosion:

Take standard precautions to prevent fire.

Storage

Requirements for storerooms and containers:

Keep container tightly closed and in a well-ventilated place.
Keep container dry. Do not drop, drag or bang the container. Store material away from heat sources and open fires.

Hints on joint storage:

Keep away from food, drink and animal feedingstuffs.

8. Exposure controls / personal protection

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.

Skin protection:

Recommended: Wear suitable protective clothing.

Protective gloves according to OSHA Standard - 29 CFR: 1910.138.

Glove material:

Nitrile rubber - Layer thickness: > 0.1 mm

Butyl caoutchouc (butyl rubber) - Layer thickness: > 0.3 mm

Breakthrough time: > 480 min.

Observe glove manufacturer's instructions concerning penetrability and breakthrough time.

Respiratory protection: Respiratory protection is not necessary if room is well ventilated.

General hygiene considerations:

Avoid contact with skin, eyes, and clothing. Wear appropriate protective equipment. Have eye wash bottle or eye rinse ready at work place. When using do not eat, drink or smoke. Wash hands before breaks and after work.

Environmental exposure controls

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

9. Physical and chemical properties

Information on basic physical and chemical properties

Appearance:	Physical state at 68 °F and 101.3 kPa: liquid Form: pasty Color: Refer to section 1
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:	> 392 °F (ISO 2592)
Evaporation rate:	No data available
Flammability:	This material is combustible, but will not ignite readily.
Explosion limits:	No data available
Vapor pressure:	No data available
Vapor density:	No data available
Density:	at 73.4 °F: 1.39 g/mL (DIN 53479)
Water solubility:	Insoluble
Partition coefficient: n-octanol/water:	No data available
Auto-ignition temperature:	> 482 °F
Thermal decomposition:	Measurements taken at temperatures exceeding 302 °F have revealed that a small quantity of formaldehyde splits off through oxidative decomposition.
Viscosity, dynamic:	at 73.4 °F: 120,000 mPa*s
Ignition temperature:	> 482 °F (DIN 51794)

10. Stability and reactivity

Reactivity: Refer to subsection "Possibility of hazardous reactions".

Chemical stability: Stable under recommended storage conditions.

Possibility of hazardous reactions:

No dangerous reactions are known.

Conditions to avoid:

No data available

Incompatible materials:

No data available

Hazardous decomposition products:

No hazardous decomposition products when regulations for storage and handling are observed.

Thermal decomposition:

Measurements taken at temperatures exceeding 302 °F have revealed that a small quantity of formaldehyde splits off through oxidative decomposition.

11. Toxicological information

Toxicological tests

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): Based on available data, the classification criteria are not met.

Acute toxicity (dermal): Based on available data, the classification criteria are not met.

Acute toxicity (inhalative): Based on available data, the classification criteria are not met.

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: Based on available data, the classification criteria are not met.

12. Ecological information

Ecotoxicity

Further details:

No data available

Mobility in soil

For the silicone component: insoluble (water)

Persistence and degradability

Further details:

For the silicone component: Product is not biodegradable. Separation by sedimentation.

Additional ecological information

Volatile organic compounds (VOC):

< 0.1 % by weight

General information:

Do not allow to enter into ground-water, surface water or drains.

13. Disposal considerations

Product

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

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

TSCA: At least one ingredient of the mixture is not publicly/actively listed.

National regulations - U.S. State Regulations

No data available

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: B

HEALTH	0
FLAMMABILITY	1
PHYSICAL HAZARD	0
B	

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
 DIN: German Institute for Standardization
 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
 ISO: International Organization for Standardization
 MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships
 MFSU: Manufacture, formulation, supply and use
 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
 vPvB: Very persistent and very bioaccumulative

Reason of change:

Changes in section 2: Endocrine disrupting properties
 Changes in section 3: Additional information
 Changes in section 9: Physical and chemical properties
 Changes in section 11: Toxicological information
 Changes in section 12: Ecological information
 Changes in section 15: Regulatory information
 General revision

Date of first version:

4/26/2007

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.