in accordance with 29 CFR 1910.1200 and ANSI standard Z400.1-2010

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ottobock. 85P11/21/31 - Chlorosil, Component A

Material number 085P11/21/31=A

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1. Product and company identification

Product identifier

| Trade name: | 85P11/21/31 - Chlorosil, Component A This safety data sheet pertains to the following products: Article No. 85P11: Chlorosil, Component A = yellow-brown Article No. 85P21: Chlorosil, Component A = colorless up to yellowish Article No. 85P31: Chlorosil, Component A = yellow-brown | | |
|---|---|--|--|
| Relevant identified uses of the substance or mixture and uses advised against | | | |
| General use: | Component A for HTV - Silicone, rollable, 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) 954-2304 (7 AM - 3 PM, Mountain Time),

Max-Näder-Straße 15 Duderstadt

Dept. responsible for information:

Additional information:

Telephone: Telefax:

Emergency phone number

Germany

CHEMTREC, Telephone: +1 (800) 424-9300

Email: USRegulatory@ottobock.com

2. Hazards identification

Emergency overview

| Appearance: | Physical state at 68 °F and 101.3 kPa: solid | |
|-----------------|---|--|
| | Color: refer to section 1 | |
| Odor: | No data available | |
| Classification: | This material is classified as not hazardous. | |

+1 (801) 956-2400

+1 (801) 956-2401

Quality Department,

Corporate headquarters:

Ottobock SE & Co. KGaA

Regulatory status

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

Hazards not otherwise classified

see section 11: Toxicological information

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3. Composition / Information on ingredients

Chemical characterization: crepe rubber, Silicone

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

4. First aid measures

Move victim to fresh air. Seek medical attention. In case of inhalation:

- After contact with skin, wash immediately with soap and plenty of water. Take off Following skin contact: contaminated clothing and wash it before reuse. Seek medical attention.
- After eye contact: Immediately flush eves with plenty of flowing water for 10 to 15 minutes holding evelids apart. Remove contact lenses, if present and easy to do. Continue rinsing. In case of troubles or persistent symptoms, consult an opthalmologist.
- Do not induce vomiting. Rinse mouth thoroughly with water. Never give anything by mouth After swallowing: to an unconscious person. Seek medical attention.

Most important symptoms/effects, acute and delayed

After eye contact: Dust contact with the eyes can lead to mechanical irritation.

Information to physician

Treat symptomatically.

5. Fire fighting measures

Flash point/flash point range:

not applicable

Auto-ignition temperature: No data available

Suitable extinguishing media:

Water spray jet, alcohol resistant 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

This product can generate small amounts of formaldehyde at approximately 150 °C and above in the presence of air. In case of fire may be liberated: silicon dioxide, hydrocarbons, carbon monoxide and carbon dioxide. Protective equipment and precautions for firefighters: Wear a self-contained breathing apparatus and chemical protective clothing. Additional information: Keep containers cool with water spray until well after the fire is out. Move undamaged containers from immediate hazard area if it can be done safely.

| 6. Accidental release measures | | |
|--------------------------------|---|--|
| Personal precautions: | Provide fresh air. Wear appropriate protective equipment. Avoid generation of dust. Do not breathe dust. Take off contaminated clothing and wash it before reuse. | |
| 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. | |

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Handling

Advices on safe handling: Avoid contact with eyes. Wear appropriate protective equipment. Avoid generation of dust. Do not breathe dust. Have eye wash bottle or eye rinse ready at work place. When using do not eat, drink or smoke. Take off contaminated clothing and wash it before reuse.

7. Handling and storage

Storage

Requirements for storerooms and containers:

Keep container in a well-ventilated place. Protect from excessive heat.

Do not store together with strong oxidizing agents. Hints on joint storage:

8. Exposure controls / personal protection

Exposure guidelines

Occupational exposure limit values:

| CAS No. | Designation | Туре | Limit value |
|-----------|-----------------|---|---------------------------------|
| 7631-86-9 | Silicon dioxide | USA: NIOSH: TWA USA: OSHA: TWA USA: OSHA: TWA | 6 mg/m³ 20 mppcf 80 mg/m³ |

Engineering controls

Ensure adequate ventilation, especially in confined areas. See also information in chapter 7, section storage.

Personal protection equipment (PPE)

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9. Physical and chemical properties

Information on basic physical and chemical properties

| Appearance: | Physical state at 68 °F and 101.3 kPa: solid Color: refer to section 1 |
|-----------------|--|
| Odor: | No data available |
| Odor threshold: | No data available |

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| pH value: | not applicable |
|--|---|
| Melting point/freezing point: | No data available |
| Initial boiling point and boiling range: | not applicable |
| Flash point/flash point range: | not applicable |
| Evaporation rate: | No data available |
| Flammability: | No data available |
| Explosion limits: | No data available |
| Vapor pressure: | not applicable |
| Vapor density: | No data available |
| Density: | 1.1 - 1.2 g/cm³ |
| Water solubility: | insoluble |
| Partition coefficient: n-octanol/water: | No data available |
| Auto-ignition temperature: | No data available |
| Thermal decomposition: | Protect from direct exposure to sunlight and temperatures exceeding 302 °F. |
| Explosive properties: | Product is not explosive. |
| Oxidizing characteristics: | not oxidising |

10 Stability and reactivity

| To. Stability and reactivity | | |
|-----------------------------------|---|--|
| Reactivity: | No data available | |
| Chemical stability: | Stable under recommended storage conditions. | |
| Possibility of hazardous r | eactions No hazardous reaction when handled and stored according to provisions. | |
| Conditions to avoid: | Protect from direct exposure to sunlight and temperatures exceeding 302 °F. Protect from excessive heat. | |
| Incompatible materials: | Strong oxidizing agents | |
| Hazardous decomposition products: | | |
| | This product can generate small amounts of formaldehyde at approximately 150 °C and above in the presence of air. | |
| Thormal docomposition: | Protect from direct expensive to cuplight and temperatures expending 202 °E | |

Thermal decomposition: Protect from direct exposure to sunlight and temperatures exceeding 302 °F.

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11. Toxicological information

Toxicological tests

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| 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: Based on available data, the classification criteria are not met. |
| | Serious eye damage/irritation: Based on available data, the classification criteria are not met. |
| | Sensitisation to the respiratory tract: Based on available data, the classification criteria are not met. |
| | Skin sensitisation: Based on available data, the classification criteria are not met. |
| | Germ cell mutagenicity/Genotoxicity: Based on available data, the classification criteria are not met. |
| | Carcinogenicity: Based on available data, the classification criteria are not met. |
| | Reproductive toxicity: Based on available data, the classification criteria are not met. |
| | Effects on or via lactation: Lack of data. |
| | Specific target organ toxicity (single exposure): Based on available data, the classification criteria are not met. |
| | Specific target organ toxicity (repeated exposure): Based on available data, the classification criteria are not met. |
| | Aspiration hazard: Based on available data, the classification criteria are not met. |
| | |

Symptoms

After eye contact: Dust contact with the eyes can lead to mechanical irritation.

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): <3%

General information:

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

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13. Disposal considerations

Product

Incinerate according to applicable local, state and federal regulations.

Contaminated packaging

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Recommendation:

Recommendation:

Dispose of waste according to applicable legislation. Non-contaminated packages may be recycled.

14. Transport information

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

Product: TSCA: All ingredients are listed or need not be listed. Silicon dioxide: Carcinogen Status: IARC Rating: Group 3 OSHA Carcinogen: not listed NTP Rating: not listed **NIOSH Recommendations:** Occupational Health Guideline: 0552

National regulations - Canada

DSL: All ingredients are listed or need not be listed.

National regulations - Great Britain

Hazchem-Code:

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| | 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 |
| Reason of change: Date of first version: | Changes in section 1.3: Corporate headquarters 1/17/2007 |



Department issuing data sheet

see section 1: Dept. responsible for information Contact person:

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.