

85P11/21/31 - Chlorosil, Component A

Material number 085P11/21/31=A

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1 Identification

Product identifier

Trade name: 85P11/21/31 - Chlorosil, Component A

Other means of identification

This safety data sheet pertains to the following products:
Article No. 85P11: Chlorosil, Component A = yellow-brown
Article No. 85P21: Chlorosil, Component A = translucent
Article No. 85P31: Chlorosil, Component A = translucent

Recommended use and restrictions on use

General use: Component A for HTV - Silicone, rollable, for orthopedic procedures

Initial supplier identifier

Company name: Otto Bock HealthCare Canada Ltd.

Street/POB-No.: 5470 Harvester Road

Postal code, city: Burlington, ON L7L 5N5, CA

Canada

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Department responsible for information:

Mark Agro, Telephone: (800) 665-3327 (9 am - 5 pm)

Additional information:

Corporate headquarters:
Ottobock SE & Co. KGaA
Max-Näder-Straße 15
Duderstadt
Germany

Emergency telephone number

COLLECT, Telephone: (613) 996-6666

2 Hazard identification

Classification

Reproductive toxicity 2 Suspected of damaging fertility.

Information elements

Symbols:



Signal word:

Warning

Hazard statements:

Suspected of damaging fertility.

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Precautionary statements:

Obtain special instructions before use.
Wear protective gloves/protective clothing/eye protection/face protection.
IF exposed or concerned: Get medical advice/attention.
Store locked up.
Dispose of contents/container to hazardous or special waste collection point.

Other hazards known to the supplier with respect to the product

This product can generate small amounts of formaldehyde at approximately 150 °C and above in the presence of air.

3 Composition/Information on ingredients

Mixture

Chemical name: Crepe rubber, Silicone

Hazardous ingredients:

CAS No.	Designation	Content	Classification
CAS 556-67-2	Octamethylcyclotetrasiloxane	0.1 - < 1 %	Flammable Liquid 3. Reproductive toxicity 2. Aquatic toxicity - chronic 1 (M-factor = 10).
CAS 540-97-6	Dodecamethylcyclohexasiloxane	< 1 %	not classified
CAS 541-02-6	Decamethylcyclopentasiloxane	< 1 %	not classified

The actual concentration or concentration range is withheld as a trade secret.

4 First-aid measures

Description of necessary first-aid measures

General information: First aider: Pay attention to self-protection! If medical advice is needed, have product container or label at hand.

In case of inhalation: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. Seek medical attention if problems persist.

In case of swallowing: Do not induce vomiting. Rinse mouth immediately and drink plenty of water. Never give anything by mouth to an unconscious person. Seek medical attention.

In case of skin contact: Immediately clean with water and soap followed by thorough rinsing. In case of skin reactions, consult a physician. Take off contaminated clothing and wash it before reuse.

In case of 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.

Most important symptoms and effects, whether acute or delayed

In case of inhalation:
Inhaling can lead to irritations of the respiratory tract and mucous membrane.
In case of ingestion: Constipation
After eye contact:
Dust contact with the eyes can lead to mechanical irritation. When vapours form: Irritation and redness may occur.

Indication of immediate medical attention and special treatment needed, if necessary

Treat symptomatically.

5 Fire-fighting measures

Suitable and unsuitable extinguishing media

Suitable extinguishing media:

Water spray jet, alcohol resistant foam, dry extinguishing powder, carbon dioxide.

Unsuitable extinguishing media:

Full water jet.

Specific hazards arising from the product

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 oxides, carbon monoxide and carbon dioxide.

Special protective equipment and precautions for fire-fighters

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.
Do not allow water used to extinguish fire to enter drains, ground or waterways. Fire residuals and contaminated extinguishing water must be disposed of in accordance with the regulations of the local authorities.

6 Accidental release measures

Personal precautions, protective equipment and emergency procedures

Provide adequate ventilation. If possible, eliminate leakage. Avoid exposure.
Wear appropriate protective equipment. Keep unprotected people away. Avoid generation of dust. Avoid breathing dust.
Avoid contact with the substance. Take off contaminated clothing and wash it before reuse.

Environmental precautions:

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

Methods and material for containment and cleaning up

Take up mechanically, placing in appropriate containers for disposal.

7 Handling and storage

Precautions for safe handling

Advices on safe handling: Obtain special instructions before use. Provide adequate ventilation, and local exhaust as needed. Avoid contact with skin and eyes. Avoid contact during pregnancy/while nursing. Wear appropriate protective equipment. Avoid generation of dust. Avoid breathing dust. Have eye wash bottle or eye rinse ready at work place. Do not eat, drink or smoke when using this product. Wash hands thoroughly after handling. Take off contaminated clothing and wash it before reuse.

Precautions against fire and explosion:

Keep away from sources of ignition - No smoking.

Conditions for safe storage, including any incompatibilities

Requirements for storerooms and containers:

Keep container tightly closed and in a well-ventilated place.
Keep container dry. Keep only in the original container.
Protect from heat and direct sunlight.
Store containers in upright position.

Hints on joint storage:

Do not store together with strong oxidizing agents.
Keep away from food, drink and animal feedingstuffs.

8 Exposure controls/Personal protection

Control parameters

Occupational exposure limit values:

Type	Limit value
Canada: Alberta, OEL 8 hour	10 mg/m ³ (Dust limit value, inhalable fraction)
Canada: Alberta, OEL 8 hour	3 mg/m ³ (Dust limit value, respirable fraction)
Canada: BC, OEL TWA	10 mg/m ³ (Dust limit value, inhalable fraction)
Canada: BC, OEL TWA	3 mg/m ³ (Dust limit value, respirable fraction)
Canada: Québec, VEMP	10 mg/m ³ (total dust)
Canada: Québec, VEMP	3 mg/m ³ (total dust, respirable fraction)

Appropriate engineering controls

Provide for good ventilation or exhaust system or work with completely self-contained equipment.

Individual protection measures, such as personal protective equipment

Respiratory protection: Respiratory protection must be worn whenever the TLV (WEL) levels have been exceeded. Recommendation: Use combination filter type A/P2 according to OSHA Standard - 29 CFR: 1910.134 or ANSI Z88.2. The filter class must be suitable for the maximum contaminant concentration (gas/vapour/aerosol/particulates) that may arise when handling the product.

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Hand protection:	Protective gloves according to OSHA Standard - 29 CFR: 1910.138. Glove material: Neoprene, Nitrile rubber, Polyvinyl chloride Layer thickness: > 0.35 mm Observe glove manufacturer's instructions concerning penetrability and breakthrough time.
Eye protection:	Tightly sealed goggles according to OSHA Standard - 29 CFR: 1910.133 or ANSI Z87.1-2010.
Body protection:	Wear suitable protective clothing.
General hygiene considerations:	Obtain special instructions before use. Avoid contact with skin and eyes. Avoid contact during pregnancy/while nursing. Avoid generation of dust. Avoid breathing dust. Have eye wash bottle or eye rinse ready at work place. Do not eat, drink or smoke when using this product. Wash hands thoroughly after handling. 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

Physical state at 20 °C and 101.3 kPa	solid
Colour:	Form: crepe rubber refer to section 1
Odour:	Characteristic
Odour threshold:	No data available
Melting point and freezing point:	No data available
Boiling point or initial boiling point and boiling range:	Not applicable
Flammability:	This material is combustible, but will not ignite readily.
Lower and upper explosion limit or lower and upper flammability limit:	No data available
Flash point/flash point range:	Not applicable
Evaporation rate:	Not applicable
Auto-ignition temperature:	Incapable of spontaneous heating
Decomposition temperature:	No data available
pH:	Not applicable
Kinematic viscosity:	Not applicable
Dynamic viscosity:	Not applicable
Solubility:	No data available

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Partition coefficient — n-octanol/water:	at 22 °C: 6.98 log P(o/w) (Octamethylcyclotetrasiloxane) Based on the n-octanol/water partition coefficient accumulation in organisms is possible. at 24 °C: 8.87 log P(o/w) (Dodecamethylcyclohexasiloxane) Based on the n-octanol/water partition coefficient accumulation in organisms is possible. at 25 °C: 8.07 log P(o/w) (Decamethylcyclopentasiloxane) Based on the n-octanol/water partition coefficient accumulation in organisms is possible.
Vapour pressure:	Not applicable
Density and/or relative density	1.2 g/cm ³
Vapour density:	No data available
Particle characteristics:	No data available

Additional information

Explosive properties:	Product is not explosive.
Oxidizing characteristics:	Not oxidising

10 Stability and reactivity

Reactivity:	Refer to subsection "Possibility of hazardous reactions".
Chemical stability:	Stable under recommended storage conditions.
Possibility of hazardous reactions:	No hazardous reaction when handled and stored according to provisions.
Conditions to avoid:	Protect from direct exposure to sunlight and temperatures exceeding 150 °C. 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.

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11 Toxicological information

Information on the likely routes of exposure

No data available

Health hazard information

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

ATE > 5,000 mg/kg

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

ATE > 2,000 mg/kg

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: Reproductive toxicity 2 = Suspected of damaging fertility.

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.

Other information:

Information about Dodecamethylcyclohexasiloxane (CAS 208-762-8):

LD50 Rat, oral: > 2,000 mg/kg

LD50 Rat, dermal: > 2,000 mg/kg

Information about Decamethylcyclopentasiloxane (CAS 541-02-6):

LD50 Rat, oral: > 5,000 mg/kg

LD50 Rabbit, dermal: > 2,000 mg/kg

LC50 Rat, inhalative (dusts/mist): 8.67 mg/L/4h

Information about Octamethylcyclotetrasiloxane (CAS 556-67-2):

LD50 Rat, oral: > 4,800 mg/kg

LD50 Rat, dermal: > 2,375 mg/kg

LC50 Rat, inhalative (dusts/mist): 36 mg/L/4h

Symptoms

In case of inhalation:

Inhaling can lead to irritations of the respiratory tract and mucous membrane.

In case of ingestion: Constipation

After eye contact:

Dust contact with the eyes can lead to mechanical irritation. When vapours form: Irritation and redness may occur.

12 Ecological information

Ecotoxicity

Aquatic toxicity:

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

Based on testing of comparable products: The estimated maximum aqueous concentration of octamethylcyclotetrasiloxane (D4) from migration to water from the product as supplied is below the D4 established no-effect threshold (< 0.0079 mg/L) for aquatic organisms.

Information about Dodecamethylcyclohexasiloxane (CAS 208-762-8):

Algae toxicity:

EC50 *Pseudokirchneriella subcapitata* (green algae): > 2 µg/L/72h

Daphnia toxicity:

NOEC *Daphnia magna* (Big water flea): ≥ 4.6 µg/L/21d

Information about Decamethylcyclopentasiloxane (CAS 541-02-6):

Algae toxicity:

EC50 *Pseudokirchneriella subcapitata* (green algae): >12 µg/L/96h

NOEC *Pseudokirchneriella subcapitata* (green algae): ≥ 12 µg/L/96h

Daphnia toxicity:

EC50 *Daphnia magna* (Big water flea): > 2.9 µg/L/48h

NOEC *Daphnia magna* (Big water flea): ≥ 15 µg/L/21d

Fish toxicity:

LC50 *Oncorhynchus mykiss*: > 16 µg/L/96h

NOEC *Oncorhynchus mykiss*: ≥ 14 µg/L/90d

Information about Octamethylcyclotetrasiloxane (CAS 556-67-2):

Algae toxicity:

EC50 *Pseudokirchneriella subcapitata* (green algae): > 22 µg/L/96h

Daphnia toxicity:

EC50 *Daphnia magna* (Big water flea): > 15 µg/L/48h

NOEC *Daphnia magna* (Big water flea): ≥ 15 µg/L/21d

Fish toxicity:

LC50 *Oncorhynchus mykiss*: > 22 µg/L/96h

NOEC *Oncorhynchus mykiss*: ≥ 4.4 µg/L/93d

Persistence and degradability

Further details:

Information about Dodecamethylcyclohexasiloxane (CAS 208-762-8):

Biodegradation: 4.47%/28 d (OECD 310). Product is biodegradable with difficulty.

Information about Decamethylcyclopentasiloxane (CAS 541-02-6):

Biodegradation: 0.14 %/28 d (OECD 310). Product is biodegradable with difficulty.

Information about Octamethylcyclotetrasiloxane (CAS 556-67-2):

Biodegradation: 3.7 %/28 d (OECD 310). Product is biodegradable with difficulty.

Hydrolysis, Half-life time: 69.3 - 144 h (pH 7, 24.6 °C, OECD 111)

Bioaccumulative potential

Partition coefficient — n-octanol/water:

at 22 °C: 6.98 log P(o/w) (Octamethylcyclotetrasiloxane)

Based on the n-octanol/water partition coefficient accumulation in organisms is possible.

at 24 °C: 8.87 log P(o/w) (Dodecamethylcyclohexasiloxane)

Based on the n-octanol/water partition coefficient accumulation in organisms is possible.

at 25 °C: 8.07 log P(o/w) (Decamethylcyclopentasiloxane)

Based on the n-octanol/water partition coefficient accumulation in organisms is possible.

Mobility in soil

Information about Dodecamethylcyclohexasiloxane (CAS 208-762-8):

pOC: 0 - 50

Information about Decamethylcyclopentasiloxane (CAS 541-02-6):

pOC: > 5,000

Koc: > 5,000 (estimated)

Information about Octamethylcyclotetrasiloxane (CAS 556-67-2):

pOC: > 5,000

Other adverse effects

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

13 Disposal considerations

Waste treatment methods

Product

Recommendation: 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

TDG, IMDG, IATA-DGR: not applicable

UN proper shipping name

TDG, IMDG, IATA-DGR: Not restricted

Transport hazard class

TDG, IMDG, IATA-DGR: not applicable

Packing group

TDG, IMDG, IATA-DGR: not applicable

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Environmental hazards

Marine pollutant: no

Special precautions in connection with transport or conveyance either within or outside the premises

Canada: Transportation of Dangerous Goods (TDG)

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 - Canada

Octamethylcyclotetrasiloxane: DSL: listed
CEPA Schedule 1: listed

Dodecamethylcyclohexasiloxane: DSL: listed

Decamethylcyclopentasiloxane: DSL: listed

Further regulations, limitations and legal requirements

No data available

16 Other information

Revision date: 17/12/2025

Date of first version: 17/1/2007

Reason of change: General revision: Safety Data Sheet according to Hazardous Products Regulations (HPR) 2022

Abbreviations and acronyms:

Aquatic toxicity - chronic: Hazardous to the aquatic environment - chronic
AS/NZS: Australian Standards/New Zealand Standards
ATE: Acute toxicity estimate
CAS: Chemical Abstracts Service
CEPA: Canadian Environmental Protection Act
CFR: Code of Federal Regulations
CLP: Classification, Labelling and Packaging
DMEL: Derived minimal effect level
DNEL: Derived no-effect level
DSL: Domestic Substances List
EC: European Community
EC50: Effective Concentration 50%
EmS: Emergency Response Procedures for Ships Carrying Dangerous Goods
EN: European Standard

SAFETY DATA SHEET

according to Hazardous Products Regulations (HPR) 2022

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EQ: Excepted quantities
Flammable Liquid: Flammable liquid
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
LD50: Lethal dose 50%
log P(o/w): Partition coefficient: octanol/water
MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships
M-factor: Multiplication factor
NOEC: No Observed Effect Concentration
OECD: Organisation for Economic Co-operation and Development
OEL: Occupational Exposure Limit Value
OSHA: Occupational Safety and Health Administration
PBT: Persistent, bioaccumulative and toxic
PNEC: Predicted no-effect concentration
REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals
Reproductive toxicity: Reproductive toxicity
SVHC: Substance of very high concern
TDG: Transportation of Dangerous Goods Regulation in Canada
TLV: Threshold Limit Value
TRGS: Technical Rules for Hazardous Substances
vPvB: Very persistent and very bioaccumulative
WEL: Workplace Exposure Limit

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.