

## 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 = 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  
WWW: www.ottobock.ca  
E-mail: info.canada@ottobock.com  
Telephone: (800) 665-3327  
Telefax: (800) 463-3659

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 phone number

COLLECT, Telephone: (613) 996-6666  
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 20 °C and 101.3 kPa: solid  
Form: crepe rubber  
Color: refer to section 1  
Odor: Characteristic  
Classification: Reproductive toxicity 2.

Hazard symbols:



Signal word:

**Warning**

Hazard statements:

Suspected of damaging fertility.

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.

## Regulatory status

This material is considered hazardous by the WHMIS in Canada.

## Hazards not otherwise classified

This product can generate small amounts of formaldehyde at approximately 150 °C and above in the presence of air.  
see section 11: Toxicological information

## 3. Composition / Information on ingredients

Chemical characterisation: Crepe rubber, Silicone

Relevant ingredients:

CAS No.	Designation	Concentration	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

## 4. 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.
Following 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.
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:	Do not induce vomiting. Rinse mouth immediately and drink plenty of water. Never give anything by mouth to an unconscious person. Seek medical attention.

### Most important symptoms and effects, both acute and 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 vapors form: Irritation and redness may occur.

### Information to physician

Treat symptomatically.

## 5. Fire fighting measures

Flash point/flash point range:

Not applicable

Auto-ignition temperature: Incapable of spontaneous heating

Suitable extinguishing media:

Water spray jet, alcohol resistant foam, dry extinguishing 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 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:

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 for clean-up:

Take up mechanically, placing in appropriate containers for disposal.

## 7. Handling and storage

### 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.

### Storage

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

### Exposure guidelines

Occupational exposure limit values:

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

### Engineering controls

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

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: Wear suitable protective clothing.

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.

**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/vapor/aerosol/particulates) that may arise when handling the product.

**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

Appearance:	Physical state at 20 °C and 101.3 kPa: solid Form: crepe rubber Color: refer to section 1
Odor:	Characteristic
Odor threshold:	No data available
pH:	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:	Not applicable
Flammability:	This material is combustible, but will not ignite readily.
Explosion limits:	No data available
Vapor pressure:	Not applicable
Vapor density:	No data available
Density:	1.2 g/cm <sup>3</sup>
Solubility:	No data available
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.
Auto-ignition temperature:	Incapable of spontaneous heating
Thermal decomposition:	No data available
Viscosity, dynamic:	Not applicable
Viscosity, kinematic:	Not applicable

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.

Thermal decomposition: No data available

## 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.  
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.

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Component A**

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## Other information:

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

LD50 Rat, oral: &gt; 2,000 mg/kg

LD50 Rat, dermal: &gt; 2,000 mg/kg

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

LD50 Rat, oral: &gt; 5,000 mg/kg

LD50 Rabbit, dermal: &gt; 2,000 mg/kg

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

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

LD50 Rat, oral: &gt; 4,800 mg/kg

LD50 Rat, dermal: &gt; 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 vapors 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):  $\geq 4.6$  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):  $\geq 12$  µg/L/96h

Daphnia toxicity:

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

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

Fish toxicity:

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

NOEC *Oncorhynchus mykiss*:  $\geq 14$  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):  $\geq 15$  µg/L/21d

Fish toxicity:

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

NOEC *Oncorhynchus mykiss*:  $\geq 4.4$  µg/L/93d

### 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:  $> 5,000$



### 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)

### Additional ecological information

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

## 13. Disposal considerations

#### 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

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

#### 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  
Dodecamethylcyclohexasiloxane: DSL: listed  
Decamethylcyclopentasiloxane: DSL: listed

## 16. Other information

Text for labeling:

Contains 0.1 - < 1 % Octamethylcyclotetrasiloxane, < 1 %  
Dodecamethylcyclohexasiloxane, < 1 % Decamethylcyclopentasiloxane.

Hazard rating systems:



NFPA Hazard Rating:

Health: 3 (Serious)  
Fire: 1 (Slight)  
Reactivity: 0 (Minimal)

HMIS Version III Rating:

Health: 3 (Serious) - Chronic effects  
Flammability: 1 (Slight)  
Physical Hazard: 0 (Minimal)  
Personal Protection: X = Consult your supervisor

HEALTH	*	3
FLAMMABILITY		1
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  
Aquatic toxicity - chronic: Hazardous to the aquatic environment - chronic  
AS/NZS: Australian Standards/New Zealand Standards  
ATE: Acute toxicity estimate  
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  
EC50: Effective Concentration 50%  
EmS: Emergency Response Procedures for Ships Carrying Dangerous Goods  
EN: European Standard  
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%



# SAFETY DATA SHEET

according to WHMIS 2015 and ANSI Z400.1-2010

## 85P11/21/31 - Chlorosil, Component A

Material number 085P11/21/31=A

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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  
RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail  
SVHC: Substance of very high concern  
TLV: Threshold Limit Value  
TRGS: Technical Rules for Hazardous Substances  
vPvB: Very persistent and very bioaccumulative  
WEL: Workplace Exposure Limit  
WHMIS: Workplace Hazardous Materials Information System

Reason of change: Changes in section 3: Concentration details  
Changes in section 7-8: Personal protective measures  
Changes in section 9: Physical and chemical properties  
Changes in section 11: Toxicological information  
Changes in section 12: ecological information

Date of first version: 17/1/2007

### 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.