

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier****Sitran-OF**

Codensation-cured silicon

CAS No.: --
EG No.: --
INDEX No.: --
REACH No.: --**1.2. Relevant identified uses of the substance or mixture and uses advised against**Relevant identified uses: Impression silicone for orthopedics
Uses advised against: Other**1.3. Details of the supplier of the safety data sheet****Manufacturer**ERKODENT Erich Kopp GmbH
Siemensstrasse 3
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D 72285 PfalzgrafenweilerTelephone: +49 7445 8501 0
Telefax: +49 7445 8501-15**Supplier (manufacturer/importer/only representative/downstream user/distributor)**ERKODENT Erich Kopp GmbH
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1.4. Emergency telephone numberERKODENT Erich Kopp GmbH
Only available during office hours.

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SECTION 2: Hazards identification**2.1. Classification of the substance or mixture**

Regulation (EC) No 1272/2008: - No dangerous material! (!)

2.2. Label elements

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms: -

Signal word: -

Hazard statements: -

Precautionary statements: -

Hazardous component(s) for labelling
none

Special labelling of particular preparations:
none

2.3. Other hazards

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP]. The product does not have to be labelled according to guideline 67/548/EEC.

SECTION 3: Composition / information on ingredients

3.1. Substances

Mixtures

3.2. Mixtures

Mixture with, among others, the following ingredients and other non-hazardous admixtures

Composition/information on ingredients

Substance:	EC-no.:	CAS-No.:	INDEX no.:	REACH-no.:	Concentration:	Classification: EC 1272/2008 (CLP):
Dihydroxypolydimethyl siloxan		70131-67-8			50 - 60 %	-

(Full text of H- and EUH-phrases: see section 16.)

SECTION 4: First aid measures

4.1. Description of first aid measures

General information: No special measures are necessary.
Following inhalation: Provide fresh air. Seek medical attention if problems persist. Rinse mouth thoroughly with water.
Following skin contact: No special measures are necessary. Not an irritant.
After eye contact: Rinse immediately carefully and thoroughly with eye-bath or water.
After ingestion: Rinse mouth thoroughly with water. Rinse mouth immediately and drink plenty of water. Seek medical attention if problems persist.

4.2. Most important symptoms and effects, both acute and delayed

In all cases of doubt, or when symptoms persist, seek medical advice.

4.3. Indication of any immediate medical attention and special treatment needed

No information available.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media: Extinguishing powder. Carbon dioxide. alcohol resistant foam. Water spray.

Unsuitable extinguishing media: High power water jet.

5.2. Special hazards arising from the substance or mixture

No information available.

5.3. Advice for firefighters

General information

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

Special protective equipment for firefighters:

In case of fire: Wear self-contained breathing apparatus. Protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protection equipment. Special danger of slipping by leaking/spilling product.

6.2. Environmental precautions

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

6.3. Methods and material for containment and cleaning up

Take up mechanically, placing in appropriate containers for disposal.

6.4. Reference to other sections

Safe handling: see section 7 Personal protection equipment: see section 8 Disposal: see section 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advices on safe handling

When using do not eat, drink, smoke, sniff. Keep/Store only in original container.

Precautions against fire and explosion

No special measures are necessary.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed and dry.

Hints on joint storage

Conditions to avoid: UV-radiation/sunlight.

Storage class: 10-13

7.3. Specific end use(s)

Observe instructions for use.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limit value

Substance:	CAS-No.:		Source :	Occupational exposure limit value:[ppm]	Occupational exposure limit value:[mg/m³]	Limitation of exposure peaks:	Remark:
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Substance with a common (EC) occupational exposure limit value

Substance:	CAS-No.:		Source :	Occupational exposure limit value:[ppm]	Occupational exposure limit value:[mg/m³]	Limitation of exposure peaks:	Remark:
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DNEL-/PNEC-values

DNEL value

Substance:	CAS-No.:	DNEL/DMEL
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PNEC Value

Substance:	CAS-No.:	PNEC
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Remark:

none

8.2. Exposure controls

Occupational exposure controls

See section 7. No additional measures necessary.

General protection and hygiene measures

When using do not eat, drink, smoke, sniff. Wash hands before breaks and after work. Take off immediately all contaminated clothing.

Personal protection equipment

Minimum standard for preventive measures while handling with working materials are specified in the TRGS 500.

Respiratory protection

With correct and proper use, and under normal conditions, breathing protection is not required.

Hand protection

additional hand protection measures

Eye/face protection

Eye protection: not required.

Body protection

Protective clothing Minimum standard for preventive measures while handling with working materials are specified in the TRGS 500.

Environmental exposure controls

refer to chapter 7. No further action is necessary.

Consumer exposure controls

refer to chapter 7. No further action is necessary.

Exposure Scenario

none

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance:

Physical state:

Paste viscous

Colour:

whitish

Odour:

characteristically

Odour threshold: No data available

Safety relevant basis data

Parameter	Value	Unit	Remark
pH:			not determined
Melting point/freezing point:			not determined
Initial boiling point and boiling range:			not determined
Flash point:			not determined
Evaporation rate:			not applicable
Flammability (solid, gas):			not determined
Explosive properties:			not explosive.
Lower flammability or explosive limits:			not applicable
Upper flammability or explosive limits:			not applicable
Vapour pressure:			not applicable
Vapour density:			not applicable
Relative density:			not determined
Density:	approx.	1,2 g/cm ³	
Solubility(ies):	:		not determined
Water solubility:			not determined
Fat solubility:			not determined
Partition coefficient: n-octanol/water:			not determined
Auto-ignition temperature:			not determined
Decomposition temperature:			not determined
Viscosity:			not determined
Oxidising properties:			not determined
Solvent content:			not applicable

9.2. Other information

No information available.

SECTION 10: Stability and reactivity

10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

Polymerization.

10.4. Conditions to avoid

heat. UV-radiation/sunlight. frost.

10.5. Incompatible materials

Acids Base Oxidizing agents.

10.6. Hazardous decomposition products

none Hazardous decomposition products

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Data apply to the main component.

M-factor: --

Acute toxicity (dermal): --

Acute toxicity (oral): --

Acute toxicity (inhalative): --

Acute toxicity

Substance:	CAS-No.:	Toxicological information
Dihydroxypolydimethylsiloxan	70131-67-8	LD50 oral (rat) > 2000 mg/kg LD50 dermal > 2000 mg/kg

Skin corrosion/irritation

Not an irritant.

Serious eye damage/irritation

Not an irritant.

Respiratory or skin sensitisation

No known symptoms to date.

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

Carcinogenicity

Toxicological data are not available.

Germ cell mutagenicity

Toxicological data are not available.

Reproductive toxicity

Toxicological data are not available.

STOT-single exposure

Toxicological data are not available.

STOT-repeated exposure

Toxicological data are not available.

Aspiration hazard

none

SECTION 12: Ecological information

12.1. Toxicity

The information about ecology refers to the main components.

Ecotoxicity

Substance:	CAS-No.:	Ecotoxicity
Dihydroxypolydimethylsiloxan	70131-67-8	LC50 fish (96 h) > 100 mg/l LCO Daphnia (Daphnia sp.) 48 h > 100 mg/l EC50 Algae (72 h) > 100 mg/l

12.2. Persistence and degradability

There are no data available on the mixture itself.

12.3. Bioaccumulative potential

There are no data available on the mixture itself.

12.4. Mobility in soil

There are no data available on the mixture itself.

12.5. Results of PBT and vPvB assessment

The components in this formulation do not meet the criteria for classification as PBT or vPvB.

12.6. Other adverse effects

There are no data available on the mixture itself.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Appropriate disposal/Product:

Dispose of waste according to applicable legislation.

Appropriate disposal / Package:

Dispose of waste according to applicable legislation.

List of proposed waste codes/waste designations in accordance with EWC

Consult the appropriate local waste disposal expert about waste disposal.

Waste code product: -

Waste code packaging: --

SECTION 14: Transport information

14.1. UN number

UN No.: --

14.2. UN proper shipping name

ADR / RID

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IMDG / ICAO-TI / IATA-DGR

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14.3. Transport hazard class(es)

Hazard label(s):: --

Classification Code:

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14.4. Packing group

Packing Group: --

14.5. Environmental hazards

Labelling environmentally hazardous substances

ADR/RID / IMDG-Code / ICAO-TI / IATA-DGR: ☐ yes / ☒ no

Marine Pollutant: ☐ yes / ☒ no

14.6. Special precautions for user

Land transport (ADR/RID)

Transport category: --

Special provisions: --

Tunnel restriction code: --

Limited quantity (LQ): --

Sea transport (IMDG)

EmS-No: --

Special provisions: --

Limited quantity (LQ): --

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Remark: No dangerous good in sense of these transport regulations.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU legislation

Regulation (EC) No 166/2006 concerning the establishment of a European Pollutant Release and Transfer Register:

No information available.

Regulation (EC) No 1005/2009 on substance that deplete the ozone layer:

No information available.

Regulation (EC) No 648/2004 on detergents:

No information available.

Regulation (EC) No 850/2004 on persistent organic pollutants:

No information available.

Regulation (EU) No 649/2012 concerning the export and import of dangerous chemicals:

No information available.

Restrictions according to Title VIII of Regulation (EC) No 1907/2006:

No information available.

National regulations

Observe in addition any national regulations!

Restrictions of occupation

No information available.

Other regulations, restrictions and prohibition regulations

No information available.

15.2. Chemical Safety Assessment

A chemical safety assessment has been carried out for this substance: --

For this substance a chemical safety assessment has not been carried out.

SECTION 16: Other information

Relevant H- and EUH-phrases (Number and full text)

Hazard statements

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Training advice

none

Recommended restrictions of use

none

Further information

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

Documentation of changes

none

Key literature references and sources for data

Data arise from reference works and literature.

Abbreviations and acronyms

ZZZZ (AC: Artikelkategorie (Article Category))
ACGIH: Rat für Arbeitsschutz und Gefahrstoffe, Amerika (American Conference of Government Industrial Hygienists)
ADN: Europäisches Übereinkommen über die internationale Beförderung gefährlicher Güter auf Binnengewässern (Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures)
ADR: Europäisches Übereinkommen über die internationale Beförderung gefährlicher Güter auf der Straße (Accord européen relatif transport des marchandises dangereuses par route)
AGW: Arbeitsplatzgrenzwert
AOX: Adsorbierbare organisch gebundene Halogene (Adsorbable Organic halogen compounds)
Bw: Körpergewicht (Body weight)
CMR: Stoffe klassifiziert als Krebserzeugend, Mutagen oder Reproduktionstoxisch (Carcinogenic, Mutagenic, toxic for Reproduction)
CSR: Stoffsicherheitsbericht (Chemical Safety Report)
DIN: Deutsches Institut für Normung / Deutsche Industrienorm
DNEL: Grenzwert, unterhalb dessen der Stoff keine Wirkung ausübt (Derived No Effect Level)
DPD: Zubereitungsrichtlinie / Richtlinie 1999-45-EC (Dangerous Preparations Directive)
DSD: Stoffrichtlinie / Richtlinie 67-548-EC (Dangerous Substances Directive)
DU: Nachgeschalteter Anwender (Downstream User)
EC50: Wirksame Konzentration 50% (Effective Concentration 50%)
ECHA: Europäische Chemikalienagentur
EN: Europäische Norm
EWC/EWL: Europäischer Abfallartenkatalog (European Waste Catalogue)
IATA: Verband für den internationalen Lufttransport (International Air Transport Association)
IBC: Großpackmittel (Intermediate Bulk Container)
ICAO: Internationale Zivilluftfahrt-Organisation (International Civil Aviation Organization)
IMDG Code: Gefahrgutvorschriften für den internationalen Seetransport (International Maritime Dangerous Goods Code)
IMO: Internationale Seeschiffahrts-Organisation (International Maritime Organization)
ISO: Internationale Normungsorganisation (International Standards Organisation)
LC50: Lethale (Tödliche) Konzentration 50%
LD50: Lethale (Tödliche) Dosis 50%
LEV: Lokale Absaugung (Local exhaust ventilation)
MAK: Maximale Arbeitsplatzkonzentration – DFG
n.a.: nicht anwendbar
n.b.: nicht bestimmt
OEL: Arbeitsplatzgrenzwert (Occupational Exposure Limit)
PBT: persistent, bioakkumulierbar, giftig (persistent, bioaccumulative, toxic)
PNEC: Abgeschätzte Nicht-Effekt-Konzentration (Predicted No Effect Concentration)
PPE/PSA: Persönliche Schutzausrüstung (Personal Protective Equipment)
REACH: Registrierung, Bewertung und Zulassung von Chemikalien (Registration, Evaluation and Authorization of Chemicals)
RID: Gefahrgutvorschriften für den Transport mit der Eisenbahn (Règlement International concernant le transport de marchandises dangereuses par chemin de fer)
STEL: Grenzwert für Kurzzeiteexposition (Short-term Exposure Limit)
SVHC: Stoff sehr hoher Besorgnis (Substance of Very High Concern)
TLV: Arbeitsplatzgrenzwert (Threshold Limit Value)
VOC: Flüchtige organische Kohlenwasserstoffe (Volatile Organic Compounds)
vPvB: sehr persistent, sehr bioakkumulierbar (very persistent, very bioaccumulative)
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