

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name: 519L5 - Silicone Parting Agent Spray

This safety data sheet pertains to the following products:

519L5 = Silikon-Trennmittel

UFI: 2G10-S0JC-000G-2EVG

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

General use: Release agent and lubricating agent, for orthopaedic procedures.
Reserved for industrial and professional use.

1.3 Details of the supplier of the safety data sheet

Company name: Ottobock SE & Co. KGaA

Street/POB-No.: Max-Näder-Straße 15

Postal Code, city: 37115 Duderstadt

Germany

E-mail: export@ottobock.de

Telephone: +49 (0)5527 848-0

Telefax: +49 (0)5527 72330

Department responsible for information:

Arbeitssicherheit, Telephone: 05527-848-0, e-mail: Arbeitssicherheit@ottobock.de

Only available during office hours.

1.4 Emergency telephone number

GIZ-Nord, Germany, Telephone: +49 (0)551-19240

Transport:

CONSULTANK Lutz Harder GmbH (Contract QUALI003)

Telephone: +49 (0)178-4337434 (from USA: 01149 178 4337434)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to EC regulation 1272/2008 (CLP)

Aerosol 1; H222; H229 Extremely flammable aerosol. Pressurised container: May burst if heated.

2.2 Label elements

Labelling (CLP)



Signal word: **Danger**

Hazard statements: H222 Extremely flammable aerosol.
H229 Pressurised container: May burst if heated.

Precautionary statements: P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P211 Do not spray on an open flame or other ignition source.

P251 Do not pierce or burn, even after use.

P410+P412 Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122 °F.

2.3 Other hazards

Inhaling can lead to irritations of the respiratory tract and mucous membrane. Higher doses may lead to a narcotic effect.

Propellant:

Contact with the product can cause cold burns or frostbite.

Heating will lead to pressure increase: Danger of bursting and explosion. Vapours can form explosive mixtures with air.

Endocrine disrupting properties, Results of PBT and vPvB assessment:

No data available

SECTION 3: Composition/information on ingredients

3.1 Substances: not applicable

3.2 Mixtures

Chemical characterisation: Polydimethylsiloxane and propellant

Hazardous ingredients:

Identifiers	Designation Classification	Content
EC No. 203-448-7 CAS 106-97-8	n-Butane, <0,1% 1,3-Butadiene Flam. Gas 1; H220. Press. Gas (Liq.); H280.	>= 50 %
EC No. 200-827-9 CAS 74-98-6	Propane Flam. Gas 1; H220. Press. Gas (Comp.); H280.	5 - 10 %

Full text of H- and EUH-statements: see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

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

In case of inhalation: Move victim to fresh air. If breathing becomes irregular or ceases, apply rescue breathing or artificial respiration immediately, where required supply oxygen.
Seek medical aid in case of troubles.

Following skin contact: After contact with skin, wash immediately with soap and plenty of water. Take off contaminated clothing and wash it before reuse.
Cover frostbitten skin with sterile tissue.
Seek medical aid in case of troubles.

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. Seek medical attention if irritation persists.

4.2 Most important symptoms and effects, both acute and delayed

Inhalation causes narcotic effects/intoxication.

In case of prolonged exposure: Nausea, drowsiness, headache, agitation, fatigue, dizziness, unconsciousness.

In case of high vapour concentrations: CNS disorders, unconsciousness.

Even short-term inhalation of larger quantities of gas may cause death. Risk of suffocation!

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: Water spray jet, foam, carbon dioxide, extinguishing powder

Extinguishing media which must not be used for safety reasons:

Full water jet

5.2 Special hazards arising from the substance or mixture

Extremely flammable aerosol. Pressurised container: May burst if heated. Vapours form explosive mixtures with air.

In case of fire may be liberated: silicon dioxide, carbon monoxide and carbon dioxide.

5.3 Advice for firefighters

Special protective equipment for firefighters:

Wear self-contained positive pressure breathing apparatus and full firefighting protective clothing.

Additional information:

Heating causes rise in pressure with risk of bursting.

Fight fire from a safe distance.

Cool endangered containers with water spray and, if possible, remove from danger zone.

Do not allow fire water to penetrate into surface or ground water.

Fire residuals and contaminated extinguishing water must be disposed of in accordance with the regulations of the local authorities.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Eliminate all ignition sources if safe to do so. Provide adequate ventilation.

Wear appropriate protective equipment. Take off contaminated clothing and wash it before reuse. Keep unprotected people away.

Do not breathe spray. Avoid contact with skin and eyes.

Be aware that gases can spread at ground level (heavier than air) and pay attention to the wind direction.

6.2 Environmental precautions

Do not allow to enter soil, sewage, water bodies, lower level rooms or pits.

Gas/vapour is heavier than air and can accumulate in closed spaces, particularly on the ground/in lower level areas.

Suppress gases/vapours/mists with water spray jet.

6.3 Methods and material for containment and cleaning up

Isolate leaked material using non-flammable absorption agent (e.g. sand, earth, vermiculit, diatomaceous earth) and collect it for disposal in appropriate containers in accordance with the local regulations (see section 13).

Thoroughly clean surrounding area.

In case of greater quantities: Collect mechanically (use only explosion-proof equipment when pumping out).

Additional information:

Special danger of slipping by leaking/spilling product.

6.4 Reference to other sections

Refer additionally to section 8 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advices on safe handling: Provide adequate ventilation, and local exhaust as needed. Do not breathe spray. Do not get in eyes, on skin, or on clothing. Wear appropriate protective equipment.
Do not eat, drink or smoke when using this product. Wash hands thoroughly after handling.
Take off contaminated clothing and wash it before reuse.
Guarantee sufficient ventilation during and after use, in order to prevent vapour accumulation.
When handling large quantities, supply emergency spray.

Precautions against fire and explosion: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Do not pierce or burn, even after use. Do not spray on an open flame or other ignition source.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storerooms and containers: Keep container tightly closed in a cool, well-ventilated place.
Keep container dry.
Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122 °F.
Store containers in upright position.

Hints on joint storage: Keep away from combustible material. Keep away from combustible materials.
Keep away from food, drink and animal feedingstuffs.

7.3 Specific end use(s)

No information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Additional information: Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Provide good ventilation and/or an exhaust system in the work area.
Explosion protection required.
See also information in chapter 7, section storage.

Personal protection equipment

Occupational exposure controls

Respiratory protection: Respiratory protection must be worn whenever the WEL levels have been exceeded.
The filter class must be suitable for the maximum contaminant concentration (gas/vapour/aerosol/particulates) that may arise when handling the product. If the concentration is exceeded, self-contained breathing apparatus must be used.

Hand protection: Recommendation: Protective gloves according to BS EN 374.
Glove material: butyl caoutchouc (butyl rubber) - Breakthrough time: 480 min.
Observe glove manufacturer's instructions concerning penetrability and breakthrough time.

Eye protection: Tightly sealed goggles according to BS EN ISO 16321-1:2022.

Body protection: Flame retardant, antistatic and chemical resistant protective clothing.

General protection and hygiene measures:

Do not spray on an open flame or other ignition source. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
 Do not pierce or burn, even after use. Provide adequate ventilation, and local exhaust as needed.
 Do not breathe spray. Do not get in eyes, on skin, or on clothing.
 Do not eat, drink or smoke when using this product. Wash hands thoroughly after handling.
 Take off contaminated clothing and wash it before reuse.
 Guarantee sufficient ventilation during and after use, in order to prevent vapour accumulation.
 When handling large quantities, supply emergency spray.

Environmental exposure controls

Refer to "6.2 Environmental precautions".

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state at 20 °C and 101.3 kPa	liquid
Colour:	Form: Aerosol colourless
Odour:	characteristic
Odour threshold:	No data available
Melting point/freezing point:	> -138 °C (n-Butane)
Initial boiling point and boiling range:	No data available
Flammability:	Extremely flammable aerosol.
Upper/lower flammability or explosive limits:	LEL (Lower Explosion Limit): 1.50 Vol-% UEL (Upper Explosive Limit): 15.00 Vol-%
Flash point/flash point range:	-60 °C (n-Butane)
Auto-ignition temperature:	365 °C (n-Butane)
Decomposition temperature:	> 250°C (Polydimethylsiloxane)
pH:	No data available
Viscosity, kinematic:	No data available
Water solubility:	at 20 °C: practically insoluble
Partition coefficient: n-octanol/water:	No data available
Vapour pressure:	at 20 °C: 2,700 hPa at 50 °C: 7,300 hPa
Density:	at 20 °C: 0.6 g/mL
Vapour density:	No data available
Particle characteristics:	Not applicable

9.2 Other information

Explosive properties:	Vapours can form explosive mixtures with air.
Oxidizing characteristics:	No data available
Auto-ignition temperature:	No data available
Evaporation rate:	No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Extremely flammable aerosol.
 Vapours can form explosive mixtures with air.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

Pressurised container: May burst if heated.

10.4 Conditions to avoid

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Do not pierce or burn, even after use. Do not spray on an open flame or other ignition source. Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122 °F.

10.5 Incompatible materials

Reacts violently with strong oxidizing agents.

10.6 Hazardous decomposition products

For the silicone component:

Measurements taken at temperatures exceeding 150 °C have revealed that a small quantity of formaldehyde splits off through oxidative decomposition.

Thermal decomposition: > 250°C (Polydimethylsiloxane)

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity:

LD50 Rat, oral: > 5,000 mg/kg (Literature)

LD50 Rat, dermal: > 2,008 mg/kg (ext. test report)

Toxicological effects:

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): Lack of data.

Skin corrosion/irritation: Based on available data, the classification criteria are not met. Not an irritant (Rabbit; ext. test report)

Serious eye damage/irritation: Based on available data, the classification criteria are not met.

Mild irritant (Rabbit; ext. test report)

Sensitisation to the respiratory tract: Lack of data.

Skin sensitisation: Based on available data, the classification criteria are not met. Not sensitising (Method Magnusson-Klingmann, Guinea pig - ext. test report)

Germ cell mutagenicity/Genotoxicity: Based on available data, the classification criteria are not met.

No mutagenity, after different in-vitro studies. (OECD 471)

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

Rat, oral, NOAEL: >= 1000 mg/kg (Polydimethylsiloxane)

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

Rabbit, oral, NOAEL: >= 1000 mg/kg (Polydimethylsiloxane)

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.

11.2 Information on other hazards

Endocrine disrupting properties: No data available

Symptoms

In case of inhalation: Information about n-Butane: Inhalation causes narcotic effects/intoxication.

In case of prolonged exposure: Nausea, drowsiness, headache, agitation, fatigue, dizziness, unconsciousness.

In case of high vapour concentrations: CNS disorders, unconsciousness.

Even short-term inhalation of larger quantities of gas may cause death. Risk of suffocation!

After contact with skin:

In case of spraying: Contact with the product can cause cold burns or frostbite.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity: According to experience to date, toxicity to fish is not expected.

12.2 Persistence and degradability

Further details: For the silicone component:
Product is not biodegradable. Polydimethylsiloxane are to a certain extent partly degradable through abiotic processes.

Effects in sewage plants: According to current data, no harmful effects are expected with release to sewage treatment facility.

12.3 Bioaccumulative potential

Partition coefficient: n-octanol/water:
No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

No data available

12.6 Endocrine disrupting properties

No data available

12.7 Other adverse effects

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

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Waste key number: 16 05 04* = Gases in pressure containers (including halons) containing hazardous substances/Aerosol

* = Evidence for disposal must be provided.

Recommendation: Special waste. Dispose of waste according to applicable legislation.

Do not open with force or incinerate, even when empty.

Do not dispose of with household waste.

Package

Waste key number: 15 01 10* = packaging containing residues of or contaminated by dangerous substances

* = Evidence for disposal must be provided.

Recommendation: Empty carefully and completely, if possible.
 Dispose of waste according to applicable legislation. Handle contaminated packages in the same way as the substance itself.
 Handle empty containers with care. Incineration may cause explosion.

SECTION 14: Transport information

14.1 UN number or ID number

ADR/RID, ADN, IMDG, IATA-DGR:

UN 1950

14.2 UN proper shipping name

ADR/RID, ADN, IMDG: UN 1950, AEROSOLS

IATA-DGR: UN 1950, AEROSOLS, FLAMMABLE

14.3 Transport hazard class(es)

ADR/RID, ADN: Class 2, Code: 5F

IMDG: Class 2.1, Subrisk -

IATA-DGR: Class 2.1



14.4 Packing group

ADR/RID, ADN, IATA-DGR: not applicable

IMDG: -

14.5 Environmental hazards

Dangerous for the environment: Substance/mixture is not environmentally hazardous according to the criteria of the UN model regulations.

Marine pollutant - IMDG: no

14.6 Special precautions for user

Land transport (ADR/RID)

Warning board: RID: Kemmler-number 23, UN number UN 1950

Hazard label: 2.1

Special Provisions: 190 327 344 625

Limited quantities: 1 L

EQ: E0

Package - Instructions: P207 LP200

Package - Special Provisions: PP87 RR6 L2

Special provisions for packing together: MP9

Tunnel restriction code: D

Inland waterway craft (ADN)

Hazard label: 2.1

Special Provisions: 190 327 344 625

Limited quantities: 1 L

EQ: E0

Equipment necessary: PP - EP - A

ventilation: VE01, VE04

Sea transport (IMDG)

EmS:	F-D, S-U
Special Provisions:	63 190 277 327 344 381 959
Limited quantities:	1000 mL
Excepted quantities:	E0
Package - Instructions:	P207, LP200
Package - Provisions:	PP87, L2
IBC - Instructions:	-
IBC - Provisions:	-
Tank instructions - IMO:	-
Tank instructions - UN:	-
Tank instructions - Provisions:	-
Stowage and handling:	SW1 SW22
Segregation:	SG69
Properties and observations:	-
Segregation group:	none

Air transport (IATA)

Hazard label:	Flamm. gas
Excepted Quantity Code:	E0
Passenger and Cargo Aircraft: Ltd.Qty.:	Pack.Instr. Y203 - Max. Net Qty/Pkg. 30 kg G
Passenger and Cargo Aircraft:	Pack.Instr. 203 - Max. Net Qty/Pkg. 75 kg
Cargo Aircraft only:	Pack.Instr. 203 - Max. Net Qty/Pkg. 150 kg
Special Provisions:	A145 A167 A802
Emergency Response Guide-Code (ERG):	10L

14.7 Maritime transport in bulk according to IMO instruments

No data available

SECTION 15: Regulatory information

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

National regulations - EC member states

Volatile organic compounds (VOC):

91.6 % by weight (= 218g/400ml)

Further regulations, limitations and legal requirements:

Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances
[Seveso-III-Directive]

Physical hazards: Code P3a, Quantity threshold 150 000 kg / 500 000 kg

Use restriction according to REACH annex XVII, no.: 3, 40, 75

Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances
[Seveso-III-Directive]: P3a

15.2 Chemical Safety Assessment

For this mixture a chemical safety assessment is not required.

SECTION 16: Other information

Wording of the H-phrases under paragraph 2 and 3:

H220 = Extremely flammable gas.

H222 = Extremely flammable aerosol.

H229 = Pressurised container: May burst if heated.

H280 = Contains gas under pressure; may explode if heated.

Reason of change: General revision

Date of first version: 12/8/1994

Department issuing data sheet: **see section 1: Department responsible for information**

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
- Aerosol: Aerosol
- AS/NZS: Australian Standards/New Zealand Standards
- CAS: Chemical Abstracts Service
- CFR: Code of Federal Regulations
- CLP: Classification, Labelling and Packaging
- CNS: Central Nervous System
- DMEL: Derived minimal effect level
- DNEL: Derived no-effect level
- EC: European Community
- EN: European Standard
- EQ: Excepted quantities
- EU: European Union
- Flam. Gas: Flammable gases
- 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
- LD50: Lethal dose 50%
- LEL: Lower Explosion Limit
- MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships
- OEL: Occupational Exposure Limit Value
- OSHA: Occupational Safety and Health Administration
- PBT: Persistent, bioaccumulative and toxic
- PNEC: Predicted no-effect concentration
- Press. Gas: Gases under pressure
- REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals
- RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail
- TLV: Threshold Limit Value
- TRGS: Technical Rules for Hazardous Substances
- UN: United Nations
- vPvB: Very persistent and very bioaccumulative
- WEL: Workplace Exposure Limit

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.