Smith-Nephew

Safety Data Sheet

according to Federal Register / Vol. 89, No. 98 / Monday, May 20, 2024 / Rules and Regulations SDS Reference Number: CSSS-TCO-010-164886 Issue date: 2/7/2025 Revision date: 2/7/2025 Version: 1.0

| SECTION 1 Identification | |
|--|---|
| 1.1. Product identifier | |
| Product form Product name | : Mixture : CICA-CARE Silicone Gel |
| 1.2. Other means of identification | |
| No additional information available | |
| 1.3. Recommended use of the chemical and | I restrictions on use |
| Recommended use Restrictions on use | : Topical management of existing and new raised scars (hypertrophic/keloidal) : Not available |
| 1.4. Supplier's details | |
| Smith & Nephew Medical Ltd 101 Hessle Road Hull HU3 2BN United Kingdom T +44 (0)1482 225181 (24 Hours) | |
| 1.5. Emergency phone number | |
| Emergency number | : 1-800-424-9300 (Chemtrec 24 Hours) |
| SECTION 2 Hazard identification | |
| 2.1. Classification of the substance or mixt | ure |
| GHS US classification | |
| Flammable liquid, Category 2 Full text of H-statements: see section 16 | H225 Highly flammable liquid and vapour. |
| 2.2. Label elements | |
| GHS US labelling Hazard pictograms (GHS US) | |
| Signal word (GHS US) Hazard statements (GHS US) Precautionary statements (GHS US) | Danger H225 - Highly flammable liquid and vapour P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P233 - Keep container tightly closed. P240 - Ground/Bond container and receiving equipment. P241 - Use explosion-proof equipment. P242 - Use non-sparking tools. P243 - Take action to prevent static discharges. P280 - Wear protective gloves, protective clothing, eye protection, face protection, and hearing |
| 2/7/2025 (Revision date) | EN (English) 1/- |
| Document Number: 200773 Document Version: 07 | 9 Document Part: 000 Document Status: Released |

Safety Data Sheet

according to Federal Register / Vol. 89, No. 98 / Monday, May 20, 2024 / Rules and Regulations

protection.

P303+P361+P353 - If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

P370+P378 - In case of fire: Use dry powder, alcohol-resistant foam, carbon dioxide, sand to extinguish.

P403+P235 - Store in a well-ventilated place. Keep cool.

P501 - Dispose of contents and/or container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulations.

2.3. Hazards associated with known or reasonably anticipated uses

No additional information available

2.4. Hazards not otherwise classified

No additional information available

2.5. Unknown acute toxicity

No additional information available

SECTION 3 Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

| Name | Product identifier | % | GHS US classification |
|-----------------------------|--------------------|---------|-----------------------|
| Hexamethyldisiloxane ; HMDS | CAS-No.: 107-46-0 | 10 – 25 | Flam. Liq. 2, H225 |

Full text of hazard classes and H-statements : see section 16

SECTION 4 First-aid measures

| 4.1. Description of necessary first-aid measures | | |
|--|--|--|
| First-aid measures general | : If you feel unwell, seek medical advice. | |
| First-aid measures after inhalation | Remove person to fresh air and keep comfortable for breathing. If breathing is difficult, give oxygen. Call a poison center or a doctor if you feel unwell. | |
| First-aid measures after skin contact | : Rinse skin with water/shower. Take off immediately all contaminated clothing. If skin irritation or rash occurs: Get medical advice/attention. | |
| First-aid measures after eye contact | Rinse immediately with plenty of water. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. | |
| First-aid measures after ingestion | : Rinse mouth. Do not induce vomiting. Call a poison center or a doctor if you feel unwell. | |
| 4.2. Most important symptoms/effects | , acute and delayed | |
| Symptoms/effects after inhalation | : None under normal conditions. | |
| Symptoms/effects after skin contact | : None under normal conditions. | |
| Symptoms/effects after eye contact | : None under normal conditions. | |
| Symptoms/effects after ingestion | : None under normal conditions. | |

| 2/7/2025 (Revision date) |
|--------------------------|
| Document Number: |
| Document Version: |

2007739 07

EN (English) Document Part: **Document Status:**

000 Released

Safety Data Sheet

according to Federal Register / Vol. 89, No. 98 / Monday, May 20, 2024 / Rules and Regulations

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

Other medical advice or treatment

: Treat symptomatically.

| SECTION 5: Fire-fighting measures | | | |
|---|---|--|--|
| 5.1. Suitable (and unsuitable) extinguishing | g media | | |
| Suitable extinguishing media Unsuitable extinguishing media | Dry powder. Alcohol-resistant foam. Carbon dioxide. Sand.Do not use a heavy water stream. | | |
| 5.2. Specific hazards arising from the chem | nical | | |
| Fire hazard Explosion hazard Reactivity in case of fire Hazardous decomposition products in case of fire | Highly flammable liquid and vapour. No direct explosion hazard. On combustion, forms: carbon oxides (CO and CO2). Toxic fumes may be released. | | |
| 5.3. Special protective equipment and precautions for fire-fighters | | | |
| Firefighting instructions Protection during firefighting | Fight fire from safe distance and protected location. Do not enter fire area without proper protective equipment, including respiratory protection. Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing. | | |
| | | | |
| SECTION 6 Accidental release measure | es | | |

| 6.1. Personal precautions, protective equipm | ent and emergency procedures | | |
|--|--|--|--|
| General measures : | Stop leak if safe to do so. Notify authorities if product enters sewers or public waters. Absorb spillage to prevent material damage. | | |
| For non-emergency personnel | | | |
| Protective equipment : Emergency procedures : | Wear recommended personal protective equipment. Ventilate spillage area. No open flames, no sparks, and no smoking. Wear personal protective equipment. Evacuate personnel to a safe area. | | |
| For emergency responders | | | |
| Protective equipment : | Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection". | | |
| Emergency procedures : | Evacuate unnecessary personnel. Stop leak if safe to do so. | | |
| Environmental precautions : | Avoid release to the environment. | | |
| 6.2. Methods and materials for containment and cleaning up | | | |
| For containment : | Collect spillage. Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams. Stop leak without risks if possible. | | |
| Methods for cleaning up : | Take up liquid spill into absorbent material. Notify authorities if product enters sewers or public waters. | | |
| Other information : | Dispose of materials or solid residues at an authorized site. | | |
| For further information refer to section 13 | | | |

2007739 07 EN (English) Document Part: C Document Status: F

000 Released

Safety Data Sheet

| according to Federal Register / Vol. 89, No. 98 / Monday, May 20, 2024 / Rules and Regulations | | | |
|--|---|--|--|
| SECTION 7 Handling and storage | | | |
| 7.1. Precautions for safe handling | | | |
| Precautions for safe handling : | Ensure good ventilation of the work station. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Ground/bond container and receiving equipment. Use only non-sparking tools. Take precautionary measures against static discharge. Flammable vapours may accumulate in the container. Use explosion-proof equipment. Wear personal protective equipment. | | |
| Hygiene measures : | Do not eat, drink or smoke when using this product. Always wash hands after handling the product. | | |
| Additional hazards when processed : | Not expected to present a significant hazard under anticipated conditions of normal use. | | |
| 7.2. Conditions for safe storage, including inc | compatibilities | | |
| Technical measures:Storage conditions:Packaging materials: | Ground/bond container and receiving equipment. Store in a well-ventilated place. Keep cool. Keep container tightly closed. Store in a dry place. Store always product in container of same material as original container. | | |
| SECTION 8 Exposure controls/personal | protection | | |
| 8.1. Control parameters | | | |
| No additional information available | | | |
| 8.2. Appropriate engineering controls | | | |
| | Ensure good ventilation of the work station. Avoid release to the environment. | | |
| 8.3. Individual protection measures, such as personal protective equipment | | | |
| Personal protective equipment: Wear recommended personal protective equipment. | | | |
| Hand protection: | | | |
| Protective gloves | | | |
| Eye protection: | | | |
| Safety glasses | | | |
| Skin and body protection: | | | |

Wear suitable protective clothing

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

Personal protective equipment symbol(s):



2007739 07

EN (English) Document Part: 000 Document Status:

Released

Safety Data Sheet

according to Federal Register / Vol. 89, No. 98 / Monday, May 20, 2024 / Rules and Regulations

| SECTION 9 Physical and chemical properties | | |
|---|---|--|
| | | |
| 9.1. Basic physical and chemical propertie | 95 | |
| Physical state | : Liquid | |
| Appearance | : gel. | |
| Colour | : Colourless | |
| Odour | : odourless | |
| Odour threshold | : No data available | |
| pH | : No data available | |
| Melting point | : Not applicable | |
| Freezing point | : No data available | |
| Boiling point | : > 100 °C | |
| Flash point | : 7 °C | |
| Flammability (solid, gas) | : Not applicable. | |
| Vapour pressure | : No data available | |
| Relative vapour density at 20°C | : No data available | |
| Relative density | : 0.939 | |
| Solubility | : Water: Not miscible or difficult to mix | |
| Partition coefficient n-octanol/water (Log Pow) | : No data available | |
| Auto-ignition temperature | : No data available | |
| Decomposition temperature | : No data available | |
| Viscosity, kinematic | : No data available | |
| Explosive limits | : No data available | |
| Particle characteristics | : No data available | |

9.2. Data relevant with regard to physical hazard classes (supplemental)

No additional information available

SECTION 10 Stability and reactivity

10.1. Reactivity

Highly flammable liquid and vapour.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

Avoid contact with hot surfaces. Heat. No flames, no sparks. Eliminate all sources of ignition. Avoid high temperatures.

10.5. Incompatible materials

Strong oxidizing agents.

10.6. Hazardous decomposition products

On combustion, forms: carbon oxides (CO and CO2).

2/7/2025 (Revision date) Document Number: Document Version:

2007739 07 EN (English) Document Part: 00 Document Status: Re

000 Released

Safety Data Sheet

according to Federal Register / Vol. 89, No. 98 / Monday, May 20, 2024 / Rules and Regulations

| SECTION 11 Toxicological information | on |
|---|--|
| 11.1. Information on toxicological effects | S |
| Acute toxicity (oral) Acute toxicity (dermal) Acute toxicity (inhalation) | : Not classified : Not classified : Not classified |
| Hexamethyldisiloxane ; HMDS (107-46-0) | |
| LD50 oral rat | > 12.16 g/kg |
| LD50 dermal rat | > 2000 mg/kg |
| LC50 Inhalation - Rat | 106 mg/l/4h |
| Skin corrosion/irritation | : Not classified |
| Serious eye damage/irritation | : Not classified |
| Respiratory or skin sensitisation | : Not classified |
| Germ cell mutagenicity | : Not classified |
| Carcinogenicity | : Not classified |
| CICA-CARE Silicone Gel | |
| IARC group | Not applicable |
| National Toxicity Program (NTP) Status | Not applicable |
| Reproductive toxicity STOT-single exposure STOT-repeated exposure | Not classified Not classified Not classified |
| Aspiration hazard | : Not classified |
| Symptoms/effects after inhalation Symptoms/effects after skin contact | : None under normal conditions. : None under normal conditions. |
| Symptoms/effects after eye contact | : None under normal conditions. |
| Symptoms/effects after ingestion | : None under normal conditions. |

SECTION 12 Ecological information

| 12.1. Ecotoxicity | |
|--|---|
| Hazardous to the aquatic environment, short-term (acute) | Toxic to aquatic life. Harmful to aquatic life with long lasting effects. Toxic to aquatic life. Harmful to aquatic life with long lasting effects. |
| Hexamethyldisiloxane ; HMDS (107-46-0) | |
| LC50 96h - Fish [1] | 0.46 mg/l |
| EC50 48h - Crustacea [1] | 0.2 mg/l |
| NOEC chronic fish | 0.2 mg/l |
| NOEC chronic crustacea | 0.26 mg/l |
| 2/7/2025 (Revision date) Document Number: 2007739 Document Version: 07 | EN (English) 6/17 Document Part: 000 Document Status: Released |

Safety Data Sheet

according to Federal Register / Vol. 89, No. 98 / Monday, May 20, 2024 / Rules and Regulations

| 12.2. Persistence and degradability | | | |
|---------------------------------------|--------------------------|--|--|
| No additional information available | | | |
| 12.3. Bioaccumulative potential | | | |
| No additional information available | | | |
| 12.4. Mobility in soil | | | |
| No additional information available | | | |
| 12.5. Other adverse effects | | | |
| Ozone Fluorinated greenhouse gases | : Not classified : No | | |
| | | | |

| Regional waste regulation | : Disposal must be done according to official regulations. |
|--|---|
| Waste treatment methods | : Dispose of contents/container in accordance with licensed collector's sorting instructions. |
| Sewage disposal recommendations | : Disposal must be done according to official regulations. |
| Product/Packaging disposal recommendations | : Disposal must be done according to official regulations. |
| Additional information | : Flammable vapours may accumulate in the container. Do not re-use empty containers. |

SECTION 14 Transport information

In accordance with DOT / TDG / IMDG / IATA

| 14.1. UN Number | |
|--|--|
| UN-No.(DOT) UN-No. (TDG) UN-No. (IMDG) UN-No. (IATA) | : UN1993 : UN1993 : UN1993 : UN1993 |
| 14.2. UN Proper Shipping Name | |
| Proper Shipping Name (DOT) Proper Shipping Name (TDG) Proper Shipping Name (IMDG) Proper Shipping Name (IATA) | Flammable liquids, n.o.s. (Hexamethyldisiloxane) FLAMMABLE LIQUID, N.O.S. (Hexamethyldisiloxane) FLAMMABLE LIQUID, N.O.S. (Hexamethyldisiloxane) Flammable liquids, n.o.s. (Hexamethyldisiloxane) |
| 14.3. Transport hazard class(es) | |
| DOT Transport hazard class(es) (DOT) Hazard labels (DOT) | : 3 : 3 |

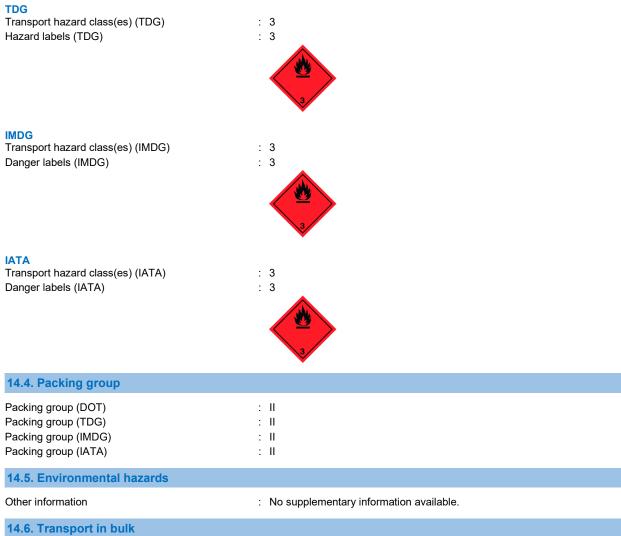
2/7/2025 (Revision date) Document Number: Document Version:

2007739 07 EN (English) Document Part: 000 Document Status: Rele

000 Released

Safety Data Sheet

according to Federal Register / Vol. 89, No. 98 / Monday, May 20, 2024 / Rules and Regulations



Not applicable

| 2/7/2025 (Revision date) | | EN (English) | | 8/11 |
|--------------------------|---------|------------------|----------|------|
| Document Number: | 2007739 | Document Part: | 000 | |
| Document Version: | 07 | Document Status: | Released | |

Safety Data Sheet

according to Federal Register / Vol. 89, No. 98 / Monday, May 20, 2024 / Rules and Regulations

14.7. Special precautions for user

| 2/7/2025 (Revision date) Document Number: 200773 | 9/11 99 Document Part: 000 |
|---|---|
| 2/7/2025 (Bevision date) | (3). (2) Despite subsection (1), the technical name for the following dangerous goods is not required to be shown on a shipping document or on a small means of containment when Canadian law for domestic transport or an international convention for international transport prohibits the disclosure of the technical name: (a) UN1544, ALKALOID SALTS, SOLID, N.O.S. or ALKALOIDS, SOLID, N.O.S; (b) UN1851, MEDICINE, LIQUID, TOXIC, N.O.S; (c) UN3140, ALKALOID SALTS, LIQUID, N.O.S. or ALKALOIDS, LIQUID, N.O.S; (d) UN3248, MEDICINE, LIQUID, FLAMMABLE, TOXIC, N.O.S; (e) UN3249, MEDICINE, SOLID, TOXIC, N.O.S. (f) Despite subsection (1), the technical name for the following dangerous goods is not required to be shown on a small means of containment: (a) UN2814, INFECTIOUS SUBSTANCE, AFFECTING HUMANS; or (b) UN2900, INFECTIOUS SUBSTANCE, AFFECTING ANIMALS,150 - An approved ERAP is required for the dangerous goods referred to in paragraph 7.2(1)(f) of Part 7 (Emergency Response Assistance Plan). |
| TDG UN-No. (TDG) TDG Special Provisions | UN1993 16 - (1) The technical name of at least one of the most dangerous substances that predominantly contributes to the danger or dangers posed by the dangerous goods must be shown, in parentheses, on the shipping document following the shipping name in accordance with clause 3.5(1)(c)(ii)(A). The technical name must also be shown, in parentheses, on a small means of containment or on a tag following the shipping name in accordance with subsections 4.11(2) and |
| CFR 175.75) DOT Vessel Stowage Location | : B - (i) The material may be stowed "on deck" or "under deck" on a cargo vessel and on a passenger vessel carrying a number of passengers limited to not more than the larger of 25 passengers, or one passenger per each 3 m of overall vessel length; and (ii) "On deck only" on passenger vessels in which the number of passengers specified in paragraph (k)(2)(i) of this section is exceeded. |
| CFR 173.27) DOT Quantity Limitations Cargo aircraft only (49 | : 60 L |
| DOT Packaging Exceptions (49 CFR 173.xxx) DOT Packaging Non Bulk (49 CFR 173.xxx) DOT Packaging Bulk (49 CFR 173.xxx) DOT Quantity Limitations Passenger aircraft/rail (49 | : 150 : 202 : 242 |
| DOT UN-No.(DOT) DOT Special Provisions (49 CFR 172.102) | UN1993 IB2 - Authorized IBCs: Metal (31A, 31B and 31N); Rigid plastics (31H1 and 31H2); Composite (31HZ1). Additional Requirement: Only liquids with a vapor pressure less than or equal to 110 kPa at 50 C (1.1 bar at 122 F), or 130 kPa at 55 C (1.3 bar at 131 F) are authorized. T7 - 4 178.274(d)(2) Normal |

07

Document Version:

Released

Document Status:

Safety Data Sheet

according to Federal Register / Vol. 89, No. 98 / Monday, May 20, 2024 / Rules and Regulations

| Explosive Limit and Limited Quantity Index | : 1L |
|--|---|
| Excepted quantities (TDG) | : E2 |
| Passenger Carrying Road Vehicle or Passenger | : 5L |
| Carrying Railway Vehicle Index | |
| Emergency Response Guide (ERG) Number | : 128 |
| IMDG | |
| Special provisions (IMDG) | : 274 |
| Limited quantities (IMDG) | : 1L |
| Excepted quantities (IMDG) | : E2 |
| Packing instructions (IMDG) | : P001 |
| IBC packing instructions (IMDG) | : IBC02 |
| Tank instructions (IMDG) | : T7 |
| Tank special provisions (IMDG) | : TP1, TP28, TP8 |
| EmS-No. (Fire) | : F-E - FIRE SCHEDULE Echo - NON-WATER-REACTIVE FLAMMABLE LIQUIDS |
| EmS-No. (Spillage) | : S-E - SPILLAGE SCHEDULE Echo - FLAMMABLE LIQUIDS, FLOATING ON WATER |
| Stowage category (IMDG) | : B |
| ΙΑΤΑ | |
| Special provisions (IATA) | : A3 |
| PCA Excepted quantities (IATA) | : E2 |
| PCA Limited quantities (IATA) | : Y341 |
| PCA limited quantity max net quantity (IATA) | : 1L |
| PCA packing instructions (IATA) | : 353 |
| PCA max net quantity (IATA) | : 5L |
| CAO packing instructions (IATA) | : 364 |
| CAO max net quantity (IATA) | : 60L |
| ERG code (IATA) | : 3H |

SECTION 15 Regulatory information

15.1. Federal regulations **CICA-CARE Silicone Gel** Physical hazard - Flammable (gases, aerosols, liquids, or solids) SARA Section 311/312 Hazard Classes Commercial status of components according to the United States Environmental Protection Agency's Toxic Substances Control Act (TSCA): Name CAS-No. Listing **Flags** Commercial status Hexamethyldisiloxane ; HMDS 107-46-0 Active Present 15.2. International regulations CANADA Hexamethyldisiloxane ; HMDS (107-46-0)

Listed on the Canadian DSL (Domestic Substances List)

EU-Regulations

No additional information available

2/7/2025 (Revision date) Document Number: Document Version:

2007739 07 EN (English) Document Part: 000 Document Status: Rele

000 Released

Safety Data Sheet

according to Federal Register / Vol. 89, No. 98 / Monday, May 20, 2024 / Rules and Regulations

| National regulations | | |
|--------------------------------------|---|--|
| Hexamethyldisiloxane ; HMDS | 107-46-0) | |
| Listed on INSQ (Mexican National Ir | antory of Chemical Substances) | |
| 15.3. State regulations | | |
| No additional information available | | |
| | | |
| SECTION 16 Other Informa | on | |
| according to Federal Register / Vol. | , No. 98 / Monday, May 20, 2024 / Rules and Regulations | |
| Revision date | : 2/7/2025 | |

| : | 2/7/2025 |
|---|----------|
| : | 2/7/2025 |

| Full text of hazard | I classes and H-statements |
|---------------------|---|
| H225 | Highly flammable liquid and vapour |
| H400 | Very toxic to aquatic life |
| H401 | Toxic to aquatic life |
| H411 | Toxic to aquatic life with long lasting effects |
| H412 | Harmful to aquatic life with long lasting effects |

Safety Data Sheet (SDS), USA

Issue date

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

| 11/11 | | EN (English) | | 2/7/2025 (Revision date) |
|-------|----------|------------------|---------|--------------------------|
| | 000 | Document Part: | 2007739 | Dòcument Number: |
| | Released | Document Status: | 07 | Document Version: |