

1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product Names: Niltac™ Sting Free Medical Adhesive Remover, TR1015, 150 mL Aerosol (Sterile)
Sensi-Care® Sting Free Adhesive Releaser, 150 mL Aerosol (Sterile)

1.2 Product Use: Medical adhesive remover.

1.3 Manufacturer/Supplier: ConvaTec Inc.
211 American Avenue
Greensboro
North Carolina 27409
USA

Customer Helpline: Customer Interaction Centre: 1-800-422-8811
Monday – Friday 8.30am – 7.00pm ET

Contact (email address): cic@convatec.com

1.4 In Case of Emergency Call: CHEMTREC: 1-800-424-9300
Outside the US: +1 703-527-3887
National Poisons Control Centre: 1-800-222-1222

2. HAZARDS IDENTIFICATION

GHS/OSHA Hazcom 2012 Hazard Classification

Flammable Aerosol Category 1, Gas Under Pressure: Compressed Gas

Label Elements:

Note: This is a medical product whose labeling is regulated by the FDA in the US. Products labeled in accordance with FDA regulations are exempt from OSHA labeling. The labeling below will not appear on the actual product label.

Danger

Extremely flammable aerosol.

Contains gas under pressure; may explode if heated.

Keep away from heat, sparks, open flames and hot surfaces. No smoking.

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

Pressurized container: Do not pierce or burn, even after use.

Protect from sunlight. Do not expose to temperatures exceeding 50 °C/ 122 °F. Store in a well-ventilated place.

Other Hazards: None identified



3. COMPOSITION/INFORMATION ON INGREDIENTS

Component	CAS Number	Amount	NA GHS Classification
Hexamethyldisiloxane	107-46-0	90-100%	Flammable Liquid Category 2
Nitrogen	7727-37-9	<10%	Gas Under Pressure: Compressed Gas

4. FIRST AID MEASURES

Description of First Aid Measures

First Aid

Eyes: If eye contact occurs, flush eyes thoroughly with water. If irritation persists, seek medical attention.

Skin: No first aid should be needed. This product is intended for skin contact. For unintended contact, wash with water.

Ingestion: If swallowed, rinse mouth with water. Do not induce vomiting. Seek medical advice if symptoms develop.

Inhalation: Move to fresh air. If irritation or other symptoms develop, seek medical attention.

See Section 11 for more detailed information on health effects.

Most Important symptoms and effects, both acute and delayed: May cause mild eye irritation.

Indication of any immediate medical attention and special treatment needed: Immediate medical attention is not required.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use water spray, carbon dioxide, dry chemical or foam to extinguish. Not known to be incompatible with any media.

Specific Hazards Arising from the Chemical: This product is an extremely flammable aerosol. Keep the product away from sources of heat including direct sunlight. Heated containers may rupture, sometimes with violent force. Keep containers away from sources of electricity. Combustion products include carbon dioxide, carbon monoxide, silicon oxide.

Special Protective Equipment and Precautions for Fire-fighters: Wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemical products and all interior fires. Use shielding to protect from bursting containers.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures: Eliminate flames and other sources of ignition. Ventilate the area.

Environmental Precautions: Avoid contamination of water supplies and environmental releases. Report spills as required to authorities.

Methods and Material for Containment and Cleaning Up: Place leaking containers in a well-ventilated area in an open pail or other container to retain leaking liquid until the pressure has dissipated. Collect liquid with an inert absorbent and place in a suitable container for disposal.

7. HANDLING AND STORAGE

Precautions for Safe Handling:

Use in a well-ventilated area. Avoid contact with eyes. Keep product away from heat, sparks, flames and other sources of ignition. Heated containers may rupture, sometimes with violent force. Do not spray on or near open flames or hot surfaces. Do not puncture or incinerate container. Protect from sunlight. Do not expose to temperatures exceeding 50°C.

Conditions for Safe Storage, Including any Incompatibilities: Store in a cool, dry, well-ventilated place away from excessive heat and incompatible materials such as oxidizers. Do not store above 50°C.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure guidelines

Chemical Name	US Occupational Exposure Limit
Hexamethyldisiloxane	None Established
Nitrogen	None Established

Appropriate Engineering Controls: No special ventilation is required for normal handling and use.

Personal Protective Measures

Respiratory Protection: None required for normal use and if workplace concentrations of hazardous constituents are below recommended limits. If the exposure limit is exceeded, an approved respirator should be worn. Respirator selection and use should be based on contaminant type, form and concentration. Follow local regulations and good Industrial Hygiene practice.

Eye Protection: Follow facility requirements.

Skin Protection: None required.

Other protection: None required.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance and Odor: Colorless liquid in an aerosol container.

Solubility in Water:	Insoluble	Boiling Point:	99°C
Odor Threshold:	Not Determined	Partition Coefficient:	Log Kow 5.06
pH:	Not Applicable	Melting Point:	-66°C
Specific Gravity:	~1	Vapor Density:	Not Applicable
Evaporation Rate:	Not Determined	Vapor Pressure:	5.69 kPa @ 25°C
Flammability(solid/gas):	Aerosol is classified as extremely flammable	Flash Point:	-3°C
Explosive Limits:	Not Determined	Autoignition Temperature:	Not determined
Decomposition Temperature:	Not Determined	Viscosity:	Not determined
Explosive Properties:	Vapors may be explosive at high concentrations in air	Oxidizing Properties:	None

Other Information: None

10. STABILITY AND REACTIVITY

Reactivity: Not reactive under normal conditions of use and storage.

Chemical Stability: Stable.

Possibility of Hazardous Reactions: None known.

Conditions to Avoid: Avoid heat, sparks, flames and all other ignition sources. Avoid direct sunlight. Protect containers from damage.

Incompatible Materials: Avoid strong oxidizing and reducing agents.

Hazardous Decomposition Products: Products of combustion include carbon dioxide, carbon monoxide, silicon oxide.

11. TOXICOLOGICAL INFORMATION

Potential Health Hazards

Inhalation: Inhalation of vapors may be slightly irritating.

Skin Contact: None expected. Non-irritating to skin.

Eye Contact: None expected. Non-irritating to eyes.

Ingestion: No adverse effects are expected.

Chronic Health Effects: No adverse effects are expected.

Acute Toxicity Values: This product is not expected to be acutely toxic based on an evaluation of the component materials.

Hexamethyldisiloxane: LD50 oral rat >16 ml/kg; LD50 dermal rat >2000 mg/kg; LC50 inhalation rat 106 mg/L/4 hr HFC 134a (1,1,1,2-tetrafluoroethane): LD50 >=567,000 ppm/4 hr.

Skin corrosion/irritation: Non-irritating to rabbit skin.

Eye damage/ irritation: Non-irritating to rabbit eyes.

Respiratory Irritation: No irritation is expected.

Skin Sensitization: No adverse effects expected. Components are not sensitizers.

Respiratory Sensitization: No adverse effects expected. Components are not sensitizers.

Germ Cell Mutagenicity: This product is not expected to present a risk of genetic damage.

Carcinogenicity: None of the components is listed as a potential carcinogen by IARC, NTP, ACGIH or the EU CLP.

Developmental / Reproductive Toxicity: This product is not expected to present a risk of adverse reproductive or developmental toxicity. Studies with hexamethyldisiloxane did not show effects on fertility or development.

Specific Target Organ Toxicity (Single Exposure): No adverse effects of exposure are expected from normal use.

Specific Target Organ Toxicity (Repeated Exposure): No adverse effects of exposure are expected from normal use.

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12. ECOLOGICAL INFORMATION

Ecotoxicity Values: Hexamethyldisiloxane: LC50 fish (oncorhynchus mykiss) 3.02 mg/L/96 hr; NOEC daphnia magna 0.08 mg/L/21 d.; ErC50 Pseudokirchneriella subcapitata >0.55 mg/L/95 hr.

Persistence and degradability: Hexamethyldisiloxane is not readily biodegradable.

Bioaccumulative Potential: Hexamethyldisiloxane has experimentally derived BCFs of 776-2410 and a log Kow of 5.06 indicating that bioaccumulation is possible.

Mobility in Soil: No data available.

Other Adverse Effects: None known.

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods:

Dispose in accordance with all local, state and national regulations. Local regulations may be more stringent than regional and national requirements. It is the responsibility of the waste generator to determine the toxicity and physical characteristics of the material to determine the proper waste identification and disposal in compliance with applicable regulations.

14. TRANSPORT INFORMATION

	UN Number	UN Proper Shipping Name	Hazard Class(s)	Packing Group	Environmental Hazards
US DOT	UN1950	Aerosols	2.1	None	No
CANADIAN TDG	UN1950	Aerosols	2.1	None	No
EU ADR/RID	UN1950	Aerosols	2.1	None	Yes
IMDG	UN1950	Aerosols	2.1	None	Yes
IATA/ICAO	UN1950	Aerosols, flammable	2.1	None	No

Special Precautions for User: None identified

Transport in Bulk According to Annex III MARPOL 73/78 and the IBC Code: Not applicable.
Transported in packaged form only.

15. REGULATORY INFORMATION

INTERNATIONAL INVENTORIES

TSCA Status: This product is a medical device and not subject to TSCA.

Canadian Environmental Protection Act: This product is a medical device and not subject to chemical notification requirements.

EU REACH: This product is a medicinal and not subject to registration requirements.

Australian Inventory of Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

China Inventory of Existing Chemicals and Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

Japanese Existing and New Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

Korean Existing Chemicals List: This product is a medical device and not subject to chemical notification requirements.

Philippine Inventory of Chemicals and Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

New Zealand: This product is a medical device and not subject to chemical notification requirements

United States Regulations

EPA SARA Regulations:

SARA 311/312 Hazard Categories:

- Y – Fire Hazard
- Y – Sudden Release of Pressure
- N – Reactivity
- N – Acute Health
- N – Chronic Health

SARA 313: This contains the following chemicals above de minimus concentrations subject to the notification or reporting requirements of SARA 313: None

CERCLA Section 103: This product is not subject to release notification. However, states and local authorities may have more stringent requirements. Report releases if required by all local and national authorities.

California Proposition 65: This product is not known to contain chemicals regulated under California Proposition 65.

16. OTHER INFORMATION

Preparation Date: December 24, 2014

Supersedes Date: New SDS

This information is furnished without warranty, expressed or implied. It is accurate to the best knowledge of ConvaTec. The data on this sheet is related only to the specific product designated herein. ConvaTec assumes no legal responsibility for the use or reliance upon these data.

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HISTORY PAGE

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SIGNATURE PAGE

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