1. IDENTICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

1.1 Product Names: Niltac™ Sting Free Medical Adhesive Remover, TR101, 50 mL Aerosol
Sensi-Care Sting Free Adhesive Releaser, 50 mL Aerosol

1.2 Product Use: Medical adhesive remover.

1.3 Manufacturer/Supplier:
ConvaTec Limited
First Avenue
Deeside Industrial Park
Deeside, Flintshire
CH5 2NU
United Kingdom

Customer Helpline:
Clinical Helpline numbers:
Stoma Care UK: 0800 289 2548 or Republic of Ireland: 1800 721 721
Wound Care UK: 0800 289 738 or Republic of Ireland: 1800 946 938
Customer Service: +44 (0) 1244 284 882

Contact (email address):
Clinical Helpline:
Stoma Care: stoma.webcare@convatec.com
Wound Care: wound.webcare@convatec.com
Customer Service: uk.customerservice@convatec.com

1.4 In Case of Emergency Call: CHEMTREC Europe: +1 703 527 3887
National Poisons Information Service (NPIS): 0870 600 6266 (UK only)

SDS Date of Preparation/Revision: June 1, 2015

2. HAZARDS IDENTIFICATION

2.1 Classification of the Substance or Mixture

EU Classification (1272/2008):	Aerosol Category 1 (H222, H229), Aquatic Acute Category 1 (H400), Aquatic Chronic Category 2 (H411)
EU Classification (1999/45/EC):	F, R11 Highly Flammable N, R50 Very toxic to aquatic organisms
US OSHA Classification (29CFR1910.1200):	Flammable Aerosol Category 1, Gas Under Pressure: Compressed Gas
GHS Classification:	Aerosol Category 1 (H222, H229), Aquatic Acute Category 1 (H400), Aquatic Chronic Category 2 (H411)

2.2 CLP Label Elements: Medical devices in finished state intended for the final user are not subject to the CLP.

Danger
H222 Extremely flammable aerosol.
H229 Pressurised container. May burst if heated.
P102 Keep out of reach of children.
P210 Keep away from heat, sparks, open flames and hot surfaces. 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: None identified

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixture

Component	CAS Number/ EINECS Number	Amount	EU Classification (67/548/EEC)	EU/GHS Classification (1272/2008)
Hexamethyldisiloxane	107-46-0 203-492-7	90-100%	F R11 N R50	Flamm Liq 2 (H225) Aquatic Acute 1 (H400) Aquatic Chronic 2 (H411)
HFC 134a (1,1,1,2-tetrafluoroethane)	811-97-2 212-377-0	<10%	Not Hazardous	Gas Under Pressure: Compressed Gas (H280)

Refer to Section 16 for Full Text of EU/GHS Classes and R Phrases/H Statements

4. FIRST AID MEASURES

4.1 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.

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

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

5. FIRE FIGHTING MEASURES

5.1 Extinguishing Media: Use water spray, carbon dioxide, dry chemical or foam to extinguish. Not known to be incompatible with any media.
5.2 Special Hazards Arising from the Substance or Mixture: 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.

5.3 Advice 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

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

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

6.3 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.

6.4 Reference to Other Sections:
Refer to Section 13 for disposal information and Section 8 for protective equipment.

7. HANDLING AND STORAGE

7.1 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.

7.2 **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.

7.3 Specific end use(s):
Industrial uses: None identified
Professional uses: For medical use.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:

Chemical Name	US OEL	EU IOEL	UK OEL	DFG MAK	Biological Limit Value
Hexamethyldisiloxane	None Established	None Established	None Established	None Established	None Established
HFC 134a (1,1,1,2-tetrafluoroethane)	1000 ppm TWA AIHA WEEL	None Established	1000 ppm TWA	1000 ppm TWA 8000 ppm STEL	None Established

DNEL: None established
PNEC: None Established

8.2 Exposure Controls:
Recommended Monitoring Procedures: None identified.

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

Personal Protective Measurers

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

9.1 Information on basic 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

9.2 Other Information: None

10. STABILITY AND REACTIVITY

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

10.2 Chemical Stability: Stable.

10.3 Possibility of Hazardous Reactions: None known.

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

10.5 Incompatible Materials: Avoid strong oxidizing and reducing agents.

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

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

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 $\geq$ 567,000 ppm/4hr.

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.

12. ECOLOGICAL INFORMATION

12.1 Toxicity: 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.

12.2 Persistence and degradability: Hexamethyldisiloxane is not readily biodegradable.

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

12.4 Mobility in Soil: No data available.

12.5 Results of PBT and vPvB assessment: Not PBT or vPvB.

12.6 Other Adverse Effects: None known.

13. DISPOSAL CONSIDERATIONS

13.1 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

	14.1 UN Number	14.2 UN Proper Shipping Name	14.3 Hazard Class(es)	14.4 Packing Group	14.5 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

14.6 Special Precautions for User: None identified.

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

15. REGULATORY INFORMATION

15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

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 deminimus 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

Effective Date: June 1, 2015

Supersedes Date: 8 August, 2014

Full text of Classification abbreviations used in Section 2 and 3:
F - Highly Flammable
N - Dangerous for the Environment
R11- Highly Flammable
R50 - Very toxic to aquatic organisms.
Flamm Liq 2 - Flammable Liquid Category 2
Aquatic Acute 1- Aquatic Toxicity Acute Category 1
Aquatic Chronic 2 - Aquatic Toxicity Chronic Category 2
H222 - Extremely flammable aerosol.
H225 - Highly flammable liquid and vapor
H229 - Pressurized container: may burst if heated.
H280 - Contains gas under pressure; may explode if heated.
H400 - Very toxic to aquatic life.
H411 - Toxic to aquatic life with long lasting effects.

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

HISTORY PAGE

VERSION:	1.0	**CR:**	015907	**ORIGINATOR:**	D. Miles
COMMENTS: This is part of an umbrella CR for SDS21-027-EU and SDS21-034-EU. This is the original safety data sheet for Niltac™ Sting Free Medical Adhesive Remover (50 ml) and Sensi-Care Sting Free Adhesive Releaser (50 ml).					
VERSION:	2.0	**CR:**	017728	**ORIGINATOR:**	D. Miles
COMMENTS: This is part of an umbrella CR for SDS21-027-EU and SDS21-034-EU. Safety data sheet has been updated. Section 1, included stoma care helpline and contact numbers for Republic of Ireland. Section 2, included P phrase, 'P102-Keep out of reach of children' in accordance with CLP Regulation (EC) No. 1272/2008 4th ATP for Aerosols. Section 3 and 8, originally written in error, corrected the propellant gas by replacing nitrogen with HCF 134a (1,1,1,2-tetrafluoroethane), CAS/EINECS numbers and control parameters were corrected accordingly.					

SIGNATURE PAGE

Document ID:	SDS21-027-EU
Version:	2.0,Effective,CURRENT

Signed by	Justification	Date & Time
Sara J Peers	Change Control Approval	7/13/2015 5:32:08 AM
Mark I Cresswell	Quality Approval	7/13/2015 5:46:37 AM
David Parsons	Technical Approval	7/13/2015 5:54:41 AM
Stephen Cottrill	Change Control Approval	7/13/2015 7:19:12 AM
Keith Godfrey	Management Approval	7/13/2015 12:45:28 PM
Desiree Miles	Author Approval	7/17/2015 9:31:38 AM
Kimberley Peters	Technical Approval	7/22/2015 12:28:02 PM
Sara J Peers	Change Control Approval	8/11/2015 10:03:42 AM