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

1.1 Product Names: Allkare™ Adhesive Remover Wipe
Convacare™ Adhesive Remover Wipe

1.2 Product Use: Adhesive remover

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

Customer Helpline:
Clinical Helpline number(s)
Wound Care UK: 0800 289 738 or Republic of Ireland: 1800 946 938
Stoma Care UK: 0800 282 254 or Republic of Ireland: 1800 721 721
Customer Service: +44 (0) 1244 284 882

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

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2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture
Classification according to Regulation (EC) No 1272/2008

GHS02 flame

Flammable solid
Additional information:
According to Regulation EU 1272/2008;
Article 1.5 a; Medicinal products for human use, as defined in Directive 2001/83/EC in their final state and intended for the final user, are exempted for both classification and labelling according to this Regulation
Article 1.5 b; Medicinal products for veterinary use, as defined in Directive 2001/82/EC in their final state and intended for the final user, are exempted for both classification and labelling according to this Regulation.

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Article 1.5 d; Medical devices as defined in Directives 90/385/EEC and 93/42/EEC, which are invasive or used in direct physical contact with the human body, and in Directive 98/79/EC, are exempted for both classification and labelling according to this Regulation.

2.2 Label elements
Labelling according to Regulation (EC) No 1272/2008 The product is classified and labelled according to the CLP regulation.
Hazard pictograms

GHS02

Signal word Warning
Hazard statements
H228 Flammable Solid
Precautionary statements

P101	If medical advice is needed, have product container and label at hand.
P102	Keep out of reach of children
P103	Read label before use
P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P280	Wear Protective gloves/protective clothing/eye protection/face protection
P240	Ground/bond container and receiving equipment.
P233	Keep container tightly closed
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 for extinction: CO_2, powder or water spray.
P403+P235	Store in a well-ventilated place, keep cool.
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.

Additional information:
According to Regulation EU 1272/2008;
Article 1.5 a; Medicinal products for human use, as defined in Directive 2001/83/EC in their final state and intended for the final user, are exempted for both classification and labelling according to this Regulation.
Article 1.5 b; Medicinal products for veterinary use, as defined in Directive 2001/82/EC in their final state and intended for the final user, are exempted for both classification and labelling according to this Regulation.
Article 1.5 d; Medical devices as defined in Directives 90/385/EEC and 93/42/EEC, which are invasive or used in direct physical contact with the human body, and in Directive 98/79/EC, are exempted for both classification and labelling according to this Regulation.

2.3 Other hazards
Physical / chemical hazards: THE PRODUCT IS FLAMMABLE!
Results of PBT and vPvB assessment
PBT:
Does not meet specific criteria detailed in Annex XIII of Regulation 1907/2006 and the substance is not considered as a PBT.
vPvB:
Does not meet specific criteria detailed in Annex XIII of Regulation 1907/2006 and the substance is not considered as a vPvB.

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3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Mixtures
Description: Medical device

Dangerous components: Not applicable.
Additional information:
All the percentages given are percentages by weight unless stated otherwise.
For the wording of the listed risk phrases refer to section 16

4. FIRST AID MEASURES

4.1 Description of first aid measures
General information: In case of doubt or when symptoms persist, always call a doctor.
After inhalation:
Supply fresh air; consult doctor in case of complaints.
After skin contact:
Remove contaminated clothing and shoes.
Wash with water and soap.
Seek immediate medical advice if symptoms occur.
After eye contact:
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
Do not rub the eyes. Flush eyes with clean water.
Remove contact lenses.
After swallowing:
Do not induce vomiting; call for medical help immediately.
Rinse mouth with clean water.

4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
4.3 Indication of any immediate medical attention and special treatment needed
For specialist advice physicians should contact the anti-poison control centre.

5. FIRE FIGHTING MEASURES

5.1 Extinguishing media
Suitable extinguishing agents: CO_2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
For safety reasons unsuitable extinguishing agents: Water with full jet
5.2 Special hazards arising from the substance or mixture Formation of toxic gases is possible during heating or in case of fire.
5.3 Advice for fire-fighters
Protective equipment:
Standard protective clothing for fire-fighters.
Wear self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures Keep away from ignition sources.
6.2 Environmental precautions: No special measures required.
6.3 Methods and material for containment and cleaning up:
Shut off leaks if without risk.

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If possible dike the spill with inert material.
Dispose contaminated material as waste according to item 13.

6.4 Reference to other sections
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling Keep away from heat and direct sunlight.
Information about fire - and explosion protection:
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.

7.2 Conditions for safe storage, including any incompatibilities
Storage:
Requirements to be met by storerooms and receptacles:
Store in a cool, dry, well ventilated place.
Comply with national regulations.
Information about storage in one common storage facility: No special measures required.
Further information about storage conditions: Keep container tightly sealed.

7.3 Specific end use(s) No further relevant information available.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Additional information about design of technical facilities: No further data; see item 7.

8.1 Control parameters
Ingredients with limit values that require monitoring at the workplace:
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
Additional information:
The lists valid during the making of this safety data sheet were used as basis to compile the above information.

8.2 Exposure controls
Personal protective equipment:
General protective and hygienic measures: The usual precautionary measures are to be adhered to when handling chemicals.
Respiratory protection: Not required.
Protection of hands: Optional.
Eye protection: Not required.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties
General Information
Appearance:

Form:	Homogeneous liquid on a non-woven substrate.
Colour:	Colourless.
Odour:	Scented.
Odour threshold:	Not determined.

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pH-value:	Not determined.
Change in condition	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.
Flash point:	< 60 °C
Flammability (solid, gaseous):	Not applicable.
Ignition temperature:	
Decomposition temperature:	Not determined.
Self-igniting:	Product is not self-igniting.
Danger of explosion:	Product does not present an explosion hazard.
Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
Vapour pressure:	Not determined.
Density:	Not determined.
Relative density:	Not determined.
Vapour density:	Not determined.
Evaporation rate:	Not determined.
Solubility in/Miscibility with water:	Not miscible or difficult to mix.
Partition coefficient (n-octanol/water):	Not determined.
Viscosity:	
Dynamic:	Not determined.
	Not applicable.
Kinematic:	Not determined.
9.2 Other information	No further relevant information available.

10. STABILITY AND REACTIVITY

10.1 Reactivity No further relevant information available.
10.2 Chemical stability
Thermal decomposition / conditions to be avoided: No decomposition if used and stored according to specifications.
10.3 Possibility of hazardous reactions No dangerous reactions known.
10.4 Conditions to avoid No further relevant information available.
10.5 Incompatible materials: No further relevant information available.
10.6 Hazardous decomposition products: Formation of toxic gases is possible during heating or in case of fire.

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects
Acute toxicity
Available data: Based on available data acute toxic effects are not expected.
Primary irritant effect:
Skin corrosion/irritation No irritant effect.
Serious eye damage/irritation No irritating effect.
Respiratory tract: Not applicable.
Ingestion: Not applicable.

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Respiratory or skin sensitisation No sensitising effects known.
Specific Target Organ Toxicity (STOT) single exposure: Not applicable.
Specific Target Organ Toxicity (STOT) repeated exposure: Not applicable.
CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
Product is not considered to be carcinogenic, mutagenic or reprotoxic.

12. ECOLOGICAL INFORMATION

12.1 Toxicity
Aquatic toxicity: No further relevant information available.
12.2 Persistence and degradability No further relevant information available.
12.3 Bioaccumulative potential No further relevant information available.
12.4 Mobility in soil No further relevant information available.
Additional ecological information:
General notes: Generally not hazardous for water
12.5 Results of PBT and vPvB assessment
PBT:
Does not meet the specific criteria detailed in Annex XIII of Regulation 1907/2006 and the substance is not considered as a PBT.
vPvB:
Does not meet the specific criteria detailed in Annex XIII of Regulation 1907/2006 and the substance is not considered as a vPvB.
12.6 Other adverse effects No further relevant information available.

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods
Recommendation Disposal must be made according to local regulations.

Uncleaned packaging:
Recommendation: Disposal must be made according to local regulations

14. TRANSPORT INFORMATION

Allkare™ Adhesive Remover Wipe
Convacare™ Adhesive Remover Wipe
Are not regulated for transport as per the following references.
IATA Special provision A146
ADR Special Provision 216
IMDG Special Provision 216

15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
European regulations: No further relevant information available.
Cosmetic Products; EC Regulation 1223/2009:
According to this Regulation a safety assessment is carried out and is available for relevant authorities.
15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

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16. OTHER INFORMATION

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

Abbreviations and acronyms:
NOEC: No Observed Effect Concentration
IC50: Inhibition Concentration, 50 percent
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
ATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)

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HISTORY PAGE

VERSION:	1.0	**CR:**	017803	**ORIGINATOR:**	Jackie Collings
COMMENTS: This is the first version of this document. This product safety data sheet was written according to 1907/2006/EC, Article 31.					
VERSION:	2.0	**CR:**	018640	**ORIGINATOR:**	D. Miles
COMMENTS: This is an umbrella CR for SDS12-024-EU, SDS12-025-EU, SDS21-033-EU, SDS21-029-EU and SDS21-028-EU. Safety data sheets were updated to reflect the description of the products as flammable solids. Section 1, updated helpline details. Section 2, Hazard Statement was changed from H225 (highly flammable liquid with vapour) to H228 (Flammable solids) and Signal Word changed from Danger to Warning. Section 14, UN number was changed from 1993 to 3175 describing the product as *solids containing flammable liquid*. Subsections within Section 14 were updated accordingly.					
VERSION:	3.0	**CR:**	020052	**ORIGINATOR:**	Julian Fairhurst/ Jackie Collings
COMMENTS: This is an umbrella CR for SDS12-024-EU, SDS12-025-EU, SDS21-029-EU and SDS21-028-EU. Section 14 amended following review against requirements within IATA, IMDG and ADR. Change advised by external DGSA consultant.					

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SIGNATURE PAGE

Document ID:	SDS12-024-EU
Version:	3.0,Effective,CURRENT

Signed by	Justification	Date & Time
Desiree Miles	Technical Approval	2/17/2016 7:31:58 AM
Mark I Cresswell	Quality Approval	2/8/2016 4:07:55 AM
Keith Godfrey	Management Approval	2/5/2016 12:41:24 PM
Stephen Cottrill	Change Control Approval	2/5/2016 12:16:44 PM
Gwen A Lawrence	Change Control Approval	2/5/2016 10:28:58 AM
Jackie Collings	Quality Approval	2/5/2016 9:56:40 AM
Sara J Peers	Change Control Approval	2/5/2016 9:35:30 AM