

1. IDENTIFICATION 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)

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.

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.

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: CO₂, 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.

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.

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.

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 (carcinogenicity, 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.

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)

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 <i>solids containing flammable liquid</i> . 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.					

Document was approved per CR-020052

SIGNATURE PAGE

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Mark I Cresswell	Quality Approval	2/8/2016 4:07:55 AM
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