

# EC safety data sheet

Trade name: Cutimed PROTECT Spray

Current version : 4.1.0, issued: 28.10.2016

Replaced version: 4.0.0, issued: 23.09.2016

Region: GB

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1 Product identifier

Trade name

**Cutimed PROTECT Spray**

### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses of the substance or mixture

Medical skin protection

Uses advised against

No data available.

### 1.3 Details of the supplier of the safety data sheet

Address

BSN medical GmbH  
Quickbornstraße 24  
D-20253 Hamburg

Telephone no. +49 40 4909-909  
Fax no. +49 40 4909-6666

Information provided by / telephone

BSN medical GmbH  
R&D Wound Care and Physiotherapy  
+ 49 (0)172 425 93 60

Advice on Safety Data Sheet

sdb\_info@umco.de

### 1.4 Emergency telephone number

For medical advice (in German and English):  
+49 (0)551 192 40 (Giftinformationszentrum Nord)  
only for Austria: +43 1 406 43 43 0

## SECTION 2: Hazards identification

### 2.1 Classification of the substance or mixture

Classification in accordance with Regulation (EC) No 1272/2008 (CLP)

Aquatic Acute 1; H400  
Aquatic Chronic 2; H411  
Flam. Liq. 2; H225

Classification information

This product is assessed and classified using the methods and criteria below referred to in Article 9 of Regulation (EC) n° 1272/2008:  
Physical hazards: determined through assessment data based on the methods or standards referred to in part 2 of Annex I to CLP  
Health hazards and environmental hazards: determined through toxicological and ecotoxicological assessment data based on the methods or standards referred to in Part 3, 4 and 5 of Annex I to CLP.

This product is a medical device in accordance with the European Medical Device Directive 43/92/EEC. Therefore, according to article 1, it is not subject to the provisions of Regulation (EC) No. 1272/2008.

### 2.2 Label elements

**Labelling according to Regulation (EC) No 1272/2008 (CLP Regulation)**

Hazard pictograms



GHS02



GHS09

Signal word

Danger

Hazard statements

H225  
H410

Highly flammable liquid and vapour.  
Very toxic to aquatic life with long lasting effects.

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## Precautionary statements

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.  
 P273 Avoid release to the environment.  
 P370+P378 In case of fire: Use water spray, carbon dioxide, dry chemical or foam to extinguish.  
 P391 Collect spillage.  
 P501 Dispose of contents/container to a facility in accordance with local/regional/national/international regulations.

## Labelling information

Since the CLP Regulation (EC no. 1272/2008), according to Article 1, not for Drugs and Medical Devices applies, this product is no labeling required. The classification and labeling information in this safety data sheet are for information only.

## 2.3 Other hazards

Vapours may cause drowsiness and dizziness.

## SECTION 3: Composition/information on ingredients

### 3.1 Substances

Not applicable. The product is not a substance.

### 3.2 Mixtures

#### Chemical characterization

Solution, filled as pump spray

#### Hazardous ingredients

No	Substance name		Additional information	
	CAS / EC / Index / REACH no	Classification (EC) 1272/2008 (CLP)	Concentration	%
1	hexamethyldisiloxane			
	107-46-0	Aquatic Acute 1; H400	< 100.00	% -b.w.
	203-492-7	Flam. Liq. 2; H225		
	-	Aquatic Chronic 2; H411		
	-			

Full Text for all H-phrases and EUH-phrases: pls. see section 16

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

#### General information

In case of persisting adverse effects, consult a physician. Remove contaminated clothing and shoes immediately, and launder thoroughly before reusing.

#### After inhalation

Remove affected person from the immediate area. Ensure supply of fresh air.

#### After skin contact

When in contact with the skin, clean with soap and water.

#### After eye contact

Separate eyelids, wash the eyes thoroughly with water (15 min.).

#### After ingestion

Call in a physician immediately and show him the Safety Data Sheet.

### 4.2 Most important symptoms and effects, both acute and delayed

No data available.

### 4.3 Indication of any immediate medical attention and special treatment needed

No data available.

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

#### Suitable extinguishing media

Extinguishing powder; Sand; Alcohol-resistant foam; Carbon dioxide

#### Unsuitable extinguishing media

Water

### 5.2 Special hazards arising from the substance or mixture

In the event of fire, the following can be released: Carbon monoxide (CO); Carbon dioxide (CO<sub>2</sub>)

### 5.3 Advice for firefighters

Use self-contained breathing apparatus. Cool endangered containers with water spray jet. Wear protective clothing. Suppress gases/vapours/mists with water spray jet.

## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

#### For non-emergency personnel

Refer to protective measures listed in sections 7 and 8. Avoid contact with skin, eyes and clothing. Ensure adequate ventilation. Keep away sources of ignition.

#### For emergency responders

No data available. Personal protective equipment (PPE) - see Section 8.

### 6.2 Environmental precautions

Do not discharge into the drains/surface waters/groundwater.

### 6.3 Methods and material for containment and cleaning up

Pick up with absorbent material (e.g., sand, kieselguhr, acid binder, universal binder, sawdust). Send in suitable containers for recovery or disposal.

### 6.4 Reference to other sections

No data available.

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

#### Advice on safe handling

Provide good ventilation at the work area (local exhaust ventilation, if necessary). If workplace exposure limits are exceeded, respiratory protection approved for this particular job must be worn. Product inherent handling risks must be minimised taking the appropriate measures for protection and preventive actions. The working process should be designed to rule out the release of hazardous substances or skin contact as far as possible by the state of the art.

#### General protective and hygiene measures

Do not eat, drink or smoke during work time. Keep away from foodstuffs and beverages. Avoid contact with eyes and skin. Remove soiled or soaked clothing immediately. Do not inhale vapours. Wash hands before breaks and after work.

#### Advice on protection against fire and explosion

Vapours can form an explosive mixture with air. Take precautionary measures against static charges. Keep away from sources of heat and ignition. Use explosion-proof equipment/fittings and non-sparking tools.

### 7.2 Conditions for safe storage, including any incompatibilities

#### Technical measures and storage conditions

Keep container tightly closed and dry in a cool, well-ventilated place. Protect from heat and direct sunlight.

#### Requirements for storage rooms and vessels

Containers which are opened must be carefully closed and kept upright to prevent leakage. Always keep in containers of same material as the original one.

#### Advice on storage assembly

Do not store together with: Oxidizing agents; Acids; Bases

### 7.3 Specific end use(s)

No data available.

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

No parameters available for monitoring.

### 8.2 Exposure controls

#### Appropriate engineering controls

No data available.

#### Personal protective equipment

##### Respiratory protection

If workplace exposure limits are exceeded, a respiration protection approved for this particular job must be worn. In case of aerosol and mist formation, take appropriate measures for breathing protection in the event workplace threshold values are not specified.

##### Eye / face protection

Safety glasses (EN 166)

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## Hand protection

Sufficient protection is given wearing suitable protective gloves checked according to i.e. EN 374, in the event of risk of skin contact with the product. Before use, the protective gloves should be tested in any case for its specific work-station suitability (i.e. mechanical resistance, product compatibility and antistatic properties). Adhere to the manufacturer's instructions and information relating to the use, storage, care and replacement of protective gloves. Protective gloves shall be replaced immediately when physically damaged or worn. Design operations thus to avoid permanent use of protective gloves.

## Other

Normal chemical work clothing.

## Environmental exposure controls

No data available.

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

<b>Form/Colour</b>			
liquid			
colourless			
<b>Odour</b>			
slight			
<b>Odour threshold</b>			
No data available			
<b>pH value</b>			
No data available			
<b>Boiling point / boiling range</b>			
Value	~	100	°C
<b>Melting point / melting range</b>			
Value	~	-68	°C
<b>Decomposition point / decomposition range</b>			
No data available			
<b>Flash point</b>			
Value		-1	°C
<b>Auto-ignition temperature</b>			
No data available			
<b>Oxidising properties</b>			
not oxidizing			
<b>Explosive properties</b>			
Product is explosive.			
<b>Flammability (solid, gas)</b>			
No data available			
<b>Lower flammability or explosive limits</b>			
Value		0.5	% vol
<b>Upper flammability or explosive limits</b>			
Value		21.8	% vol
<b>Vapour pressure</b>			
Value		20	hPa
Reference temperature		20	°C
Value		175	hPa
Reference temperature		50	°C
<b>Vapour density</b>			
No data available			
<b>Evaporation rate</b>			
No data available			
<b>Relative density</b>			
No data available			
<b>Density</b>			
Value	appr.	0.76	g/cm <sup>3</sup>
Reference temperature		20	°C

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<b>Solubility in water</b>	
Remarks	insoluble

<b>Solubility(ies)</b>	
No data available	

<b>Partition coefficient: n-octanol/water</b>	
No data available	

<b>Viscosity</b>	
No data available	

## 9.2 Other information

<b>Other information</b>	
The physical data is that of the main component/s.	

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

No data available.

### 10.2 Chemical stability

Stable under recommended storage and handling conditions (See section 7).

### 10.3 Possibility of hazardous reactions

Dangerous reactions are not to be expected when handling product according to its intended use.

### 10.4 Conditions to avoid

Heat, naked flames and other ignition sources.

### 10.5 Incompatible materials

Oxidizing agents; Acids; Bases

### 10.6 Hazardous decomposition products

None, if handled according to intended use.

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## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

<b>Acute oral toxicity</b>	No data available
<b>Acute dermal toxicity</b>	No data available
<b>Acute inhalational toxicity</b>	No data available
<b>Skin corrosion/irritation</b>	No data available
<b>Serious eye damage/irritation</b>	No data available
<b>Respiratory or skin sensitisation</b>	No data available
<b>Germ cell mutagenicity</b>	No data available
<b>Reproduction toxicity</b>	No data available
<b>Carcinogenicity</b>	No data available
<b>STOT-single exposure</b>	No data available
<b>STOT-repeated exposure</b>	No data available
<b>Aspiration hazard</b>	No data available
<b>Other information</b>	Take the precautions customary when handling chemicals.

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## SECTION 12: Ecological information

### 12.1 Toxicity

<b>Toxicity to fish (acute)</b>
No data available
<b>Toxicity to fish (chronic)</b>
No data available
<b>Toxicity to Daphnia (acute)</b>
No data available
<b>Toxicity to Daphnia (chronic)</b>
No data available
<b>Toxicity to algae (acute)</b>
No data available
<b>Toxicity to algae (chronic)</b>
No data available
<b>Bacteria toxicity</b>
No data available

### 12.2 Persistence and degradability

No data available.

### 12.3 Bioaccumulative potential

No data available.

### 12.4 Mobility in soil

No data available.

### 12.5 Results of PBT and vPvB assessment

No data available.

### 12.6 Other adverse effects

No data available.

### 12.7 Other information

<b>Other information</b>
Do not discharge product unmonitored into the environment.

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

#### Product

Allocation of a waste code number, according to the European Waste Catalogue, should be carried out in agreement with the regional waste disposal company.

#### Packaging

Contaminated packaging should be emptied as far as possible and after appropriate cleansing may be taken for reuse. Packaging that cannot be cleaned should be disposed of in agreement with the regional waste disposal company.

## SECTION 14: Transport information

### 14.1 Transport ADR/RID/ADN

Class	3
Classification code	F1
Packing group	II
Hazard identification no.	33
UN number	UN1993
Technical name	FLAMMABLE LIQUID, N.O.S.
Danger releasing substance	hexamethyldisiloxane
Special Provision 640	640D
Tunnel restriction code	D/E
Label	3
Environmentally hazardous substance mark	Symbol "fish and tree"

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## 14.2 Transport IMDG

Class	3
Packing group	II
UN number	UN1993
Proper shipping name	FLAMMABLE LIQUID, N.O.S.
Danger releasing substance	hexamethyldisiloxane
EmS	F-E+S-E
Label	3
Marine pollutant mark	Symbol "fish and tree"

## 14.3 Transport ICAO-TI / IATA

Class	3
Packing group	II
UN number	UN1993
Proper shipping name	Flammable liquid, n.o.s.
Danger releasing substance	hexamethyldisiloxane
Label	3

## 14.4 Other information

No data available.

## 14.5 Environmental hazards

Information on environmental hazards, if relevant, please see 14.1 - 14.3.

## 14.6 Special precautions for user

No data available.

## 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Not relevant

## SECTION 15: Regulatory information

### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

#### EU regulations

##### **Regulation (EC) No 1907/2006 (REACH) Annex XIV (List of substances subject to authorisation)**

According to the data available and/or specifications supplied by upstream suppliers, this product does not contain any substances considered as substances requiring authorisation as listed on Annex XIV of the REACH regulation (EC) 1907/2006.

##### **REACH candidate list of substances of very high concern (SVHC) for authorisation**

According to available data and the information provided by preliminary suppliers, the product does not contain substances that are considered substances meeting the criteria for inclusion in annex XIV (List of Substances Subject to Authorisation) as laid down in Article 57 and article 59 of REACH (EC) 1907/2006.

##### **Regulation (EC) No 1907/2006 (REACH) Annex XVII: RESTRICTIONS ON THE MANUFACTURE, PLACING ON THE MARKET AND USE OF CERTAIN DANGEROUS SUBSTANCES, PREPARATIONS AND ARTICLES**

The product is considered being subject to REACH regulation (EC) 1907/2006 annexe XVII.	No 3, 40
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##### **Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances**

This product is subject to Part I of Annex I, risk category:	E1, P5b
If the properties of the substance/product give rise to more than one classification, for the purposes of 2012/18/UE, the lowest qualifying quantities set out in Part 1 and Part 2 of Annex I shall apply.	

### 15.2 Chemical safety assessment

For this mixture a chemical safety assessment has not been carried out.

## SECTION 16: Other information

#### **Sources of key data used to compile the data sheet:**

Regulation (EC) No 1907/2006 (REACH), 1272/2008 (CLP) as amended in each case.  
 EC Directives 2000/39/EC, 2006/15/EC, 2009/161/EU  
 National Threshold Limit Values of the corresponding countries as amended in each case.  
 Transport regulations according to ADR, RID, IMDG, IATA as amended in each case.  
 The data sources used to determine physical, toxic and ecotoxic data, are indicated directly in the corresponding chapter.

#### **Full text of the H- and EUH- phrases drawn up in sections 2 and 3 (provided not already drawn up in these sections)**

H400	Very toxic to aquatic life.
H411	Toxic to aquatic life with long lasting effects.



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**Department issuing safety data sheet**

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This information is based on our present knowledge and experience.

The safety data sheet describes products with a view to safety requirements.

It does not however, constitute a guarantee for any specific product properties and shall not establish a legally valid contractual relationship.

Alterations/supplements:

Alterations to the previous edition are marked in the left-hand margin.

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