

EC safety data sheet

Trade name: Tensocold Pack

Product no.: 47423-01

Current version : 6.0.0, issued: 18.10.2016

Replaced version: 5.0.0, issued: 19.11.2015

Region: GB

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

1.1 Product identifier

Trade name

Tensocold Pack

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

Relevant identified uses of the substance or mixture

Cold Pack

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
Scientific & Regulatory Affairs
Tel. +49 40 4909-5765

Advice on Safety Data Sheet

sdb_info@umco.de

1.4 Emergency telephone number

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

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification information

This product is in the sense of article 3 of the Regulation (EC) 1907/2006 (REACH) an article and not subject to the labelling obligations according to:

- Art. 1, Regulation (EC) 1272/2008 (CLP).

To provide a safety data sheet is not mandatory for articles according to art. 31 of the Regulation (EC) 1907/2006 (REACH) and is done on a voluntary basis.

2.2 Label elements

Not relevant

Labelling information

The product is a medicine product according European Medical Device Directive 43/92/EEC and therefore not hazardous according regulation (EC) No 1272/2008.

2.3 Other hazards

This safety data sheet describes widely the hazards the chemical, that is contained as a substance in bags, may present. If used and handled properly, this substance will not be released.

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable. The product is not a substance.

3.2 Mixtures

Chemical characterization

The product consists of urea and water.

EC safety data sheet

Trade name: Tensocold Pack

Product no.: 47423-01

Current version : 6.0.0, issued: 18.10.2016

Replaced version: 5.0.0, issued: 19.11.2015

Region: GB

Hazardous ingredients

This product does not contain substances to be mentioned according to EU Regulation No 1907/2006 (REACH), annex II.

Additional ingredients

No	Substance name	Additional information	
	CAS / EC / Index / REACH no	Classification (EC) 1272/2008 (CLP)	Concentration %
1	urea		
	57-13-6 200-315-5 - 01-2119463277-33	-	< 100.00 % -b.w.

SECTION 4: First aid measures

4.1 Description of first aid measures

After inhalation

Fresh air. Get medical attention if pain still persists.

After skin contact

Wash off with soap and water.

After eye contact

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

After ingestion

Drink plenty of water. By continuous complaints consult a physician.

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

None

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Water; Carbon dioxide; Foam

Unsuitable extinguishing media

Foam

5.2 Special hazards arising from the substance or mixture

In the event of fire, the following can be released: Carbon monoxide (CO); Nitrogen oxides (NOx)

5.3 Advice for firefighters

Appropriate breathing apparatus may be required. Cool endangered containers with water spray jet.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

No special measures necessary.

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. kieselguhr).

EC safety data sheet

Trade name: Tensocold Pack

Product no.: 47423-01

Current version : 6.0.0, issued: 18.10.2016

Replaced version: 5.0.0, issued: 19.11.2015

Region: GB

6.4 Reference to other sections

No data available.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling

No special measures necessary.

General protective and hygiene measures

Observe the usual precautions when handling chemicals.

Advice on protection against fire and explosion

No special measures necessary.

7.2 Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions

Always keep in containers of same material as the original one. See also instructions on the label. Avoid heating and direct sunlight. Storage: cool and dry

Requirements for storage rooms and vessels

No special measures required.

Advice on storage assembly

Do not store with combustible materials. Do not store together with oxidizing agents. Do not store together with acids.

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

No special measures required. In case of accidental release, use suitable respiratory protection equipment.

Eye / face protection

Safety glasses recommended

Hand protection

Protective gloves (recommended)

Environmental exposure controls

No data available.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Form/Colour
crystalline
white

Odour
characteristic

EC safety data sheet

Trade name: Tensocold Pack

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Region: GB

Odour threshold			
No data available			
pH value			
No data available			
Boiling point / boiling range			
No data available			
Melting point / melting range			
Value		133	°C
Reference substance	urea		
Decomposition point / decomposition range			
No data available			
Flash point			
No data available			
Auto-ignition temperature			
No data available			
Oxidising properties			
No data available			
Explosive properties			
No data available			
Flammability (solid, gas)			
No data available			
Lower flammability or explosive limits			
No data available			
Upper flammability or explosive limits			
No data available			
Vapour pressure			
No data available			
Vapour density			
No data available			
Evaporation rate			
No data available			
Relative density			
No data available			
Density			
No data available			
Solubility in water			
No data available			
Solubility(ies)			
No data available			
Partition coefficient: n-octanol/water			
No	Substance name	CAS no.	EC no.
1	urea	57-13-6	200-315-5
	log Pow	<	-1.73
	Reference temperature		20 °C
	Method	92/69/EEC, A.8	
	Source	ECHA	

EC safety data sheet

Trade name: Tensocold Pack

Product no.: 47423-01

Current version : 6.0.0, issued: 18.10.2016

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Viscosity

No data available

9.2 Other information

Other information

No data available.

SECTION 10: Stability and reactivity

10.1 Reactivity

No data available.

10.2 Chemical stability

Stable if stored and handled properly.

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

None, if handled according to intended use.

10.5 Incompatible materials

organic materials; Oxidizing agents; Acids; Alkalies

10.6 Hazardous decomposition products

None, if handled according to intended use.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute oral toxicity

No	Substance name	CAS no.	EC no.
1	urea	57-13-6	200-315-5
	LD50		14300 mg/kg bodyweight
	Species	rat	
	Method	OECD 401	
	Source	ECHA	

Acute dermal toxicity

No data available

Acute inhalational toxicity

No data available

Skin corrosion/irritation

No	Substance name	CAS no.	EC no.
1	urea	57-13-6	200-315-5
	Species	rabbit	
	Method	OECD 404	
	Source	ECHA	
	Evaluation	non-irritant	

Serious eye damage/irritation

No	Substance name	CAS no.	EC no.
1	urea	57-13-6	200-315-5
	Species	rabbit	
	Method	OECD 405	
	Source	ECHA	
	Evaluation	non-irritant	

EC safety data sheet

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Respiratory or skin sensitisation			
No	Substance name	CAS no.	EC no.
1	urea	57-13-6	200-315-5
Route of exposure		Skin	
Species		Human	
Source		ECHA	
Evaluation		non-sensitizing	

Germ cell mutagenicity			
No	Substance name	CAS no.	EC no.
1	urea	57-13-6	200-315-5
Source		ECHA	
Evaluation/classification		Based on available data, the classification criteria are not met.	

Reproduction toxicity			
No data available			

Carcinogenicity			
No	Substance name	CAS no.	EC no.
1	urea	57-13-6	200-315-5
Source		ECHA	
Evaluation/classification		Based on available data, the classification criteria are not met.	

STOT-single exposure			
No data available			

STOT-repeated exposure			
No	Substance name	CAS no.	EC no.
1	urea	57-13-6	200-315-5
Route of exposure		dermal	
Source		ECHA	
Evaluation/classification		Based on available data, the classification criteria are not met.	

Aspiration hazard			
No data available			

Other information			
Take the precautions customary when handling chemicals.			

SECTION 12: Ecological information

12.1 Toxicity

Toxicity to fish (acute)			
No	Substance name	CAS no.	EC no.
1	urea	57-13-6	200-315-5
LC50		>	6810 mg/l
Duration of exposure			96 h
Species		Leuciscus idus	
Source		ECHA	

Toxicity to fish (chronic)			
No	Substance name	CAS no.	EC no.
1	urea	57-13-6	200-315-5
NOEC			200 mg/l
Duration of exposure			7 day(s)
Species		Gambusia affinis	
Source		ECHA	

EC safety data sheet

Trade name: Tensocold Pack

Product no.: 47423-01

Current version : 6.0.0, issued: 18.10.2016

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Toxicity to Daphnia (acute)			
No	Substance name	CAS no.	EC no.
1	urea	57-13-6	200-315-5
EC50	>	10000	mg/l
Duration of exposure		24	h
Species	Daphnia magna		
Method	DIN 38412 Part 11		
Source	ECHA		

Toxicity to Daphnia (chronic)			
No data available			

Toxicity to algae (acute)			
No	Substance name	CAS no.	EC no.
1	urea	57-13-6	200-315-5
EC50		16949	mg/l
Duration of exposure		24	h
Species	Euglena gracilis		
Source	ECHA		

Toxicity to algae (chronic)			
No	Substance name	CAS no.	EC no.
1	urea	57-13-6	200-315-5
EC10		47	mg/l
Duration of exposure		8	day(s)
Species	Microcystis aeruginosa (blue alge)		
Source	ECHA		

Bacteria toxicity			
No	Substance name	CAS no.	EC no.
1	urea	57-13-6	200-315-5
Duration of exposure		29	mg/l
Species		72	h
Source	Entosiphon sulcatum		
	ECHA		

12.2 Persistence and degradability

Biodegradability			
No	Substance name	CAS no.	EC no.
1	urea	57-13-6	200-315-5
Type	DOC decrease		
Value		96	%
Duration		16	day(s)
Method	OECD 302 B		
Source	ECHA		
Evaluation	readily biodegradable		

12.3 Bioaccumulative potential

Partition coefficient: n-octanol/water			
No	Substance name	CAS no.	EC no.
1	urea	57-13-6	200-315-5
log Pow	<	-1.73	
Reference temperature		20	°C
Method	92/69/EEC, A.8		
Source	ECHA		

EC safety data sheet

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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

Other information

The product should not be allowed to enter drains or water courses.

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

Packaging that cannot be cleaned should be disposed off as product waste.

SECTION 14: Transport information

14.1 Transport ADR/RID/ADN

The product is not subject to ADR/RID/ADN regulations.

14.2 Transport IMDG

The product is not subject to IMDG regulations.

14.3 Transport ICAO-TI / IATA

The product is not subject to ICAO-TI / IATA regulations.

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

EC safety data sheet

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Product no.: 47423-01

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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 article 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

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

Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances

This product is not subject to Part 1 or 2 of Annex I.

15.2 Chemical safety assessment

No data available.

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.

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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