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| | Technical File: INSTANT COLD PACK Safety Data Sheet TENSOCOLD PACK | Pag. 1/5 REV 00 07/04/2015 |
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Technical Safety Data Sheet

REF AND NAME OF THE PRODUCT

| BIOSPORT REF | BSN REF | DESCRIPTION |
|--------------|----------|------------------------------|
| BS3011/BSN | 47423-01 | Tensocold pack cm 24x14,5 cm |

CHEMICAL NATURE OF THE PRODUCT

UREA in pearls / WATER

| <u>INCI Name</u> | <u>CAS No.:</u> | <u>EINECS No./EC No.:</u> |
|------------------|-----------------|---------------------------|
| UREA | 57-13-6 | 200-315-5 |
| AQUA | 7732-18-5 | 2317912 |

REACH REGISTRATION NUMBER OF UREA 01-2119463277-33-0017

PACKING OF THE OUTER POUCH

Pouches in PE/PA (Polyethylene + Polyamide) with pearls of urea and a pouch with water.

PACKING OF THE INNER POUCH

Pouches in PET with water inside.

PHYSICAL PROPERTIES OF THE UREA

- PM 60,056
- Chemical Formula CH₄N₂O
- Structural Formula NH₂CONH₂

COMPOSITION/INFORMATION ON UREA

| | |
|----------------------------|----------------------------|
| Substance/mixture : | Mono-constituent substance |
|----------------------------|----------------------------|

| Product / ingredient name | Identifiers | % | Classification 67/548/EEC | Classification Regulation (EC) No. 1272/2008 [CLP] | Type |
|---------------------------|---|-------------|------------------------------|--|------|
| urea | RRN: 01-2119463277-33 EC: 200-315-5 CAS : 57-13-6 | >=90 - <100 | Not classified. | Not classified. | [A] |

Type [A] Constituent [B] Impurity [C] Stabilizing additive

DETAILS OF THE MANUFACTURER OF PRODUCT

Biosport Italia Srl
 Via Enrico Fermi, 11
 35030 Veggiano (PD)
 Tel. 049-900 26 80 Fax 049- 900 26 81
 info@biosport.it – www.biosport.it

Safety Data Sheet TENSOCOLD PACK

EMERGENCY TELEPHONE NUMBER

National advisory body/Poison Center

Poison Center Hospital Niguarda Milan tel. +39- 02-66101029 24 hours

Manufacturer telephone no. + 39 049 900 26 80 working time.

WASTE CODE OF UREA

06 10 99

HAZARDOUS WASTE

Within the present knowledge of the supplier of urea, this product is not regarded as hazardous waste, as defined by EU Directive 2008/98/EC.

PRODUCT SPECIFICATIONS

| BIOSPORT REF | BSN REF | DESCRIPTION |
|--------------|----------|-------------------------------------|
| BS3011/BSN | 47423-01 | Instant cold pack BSN cm 24x14,5 cm |

BAR CODE

| | | | |
|--------------|-------|----------------|------------------|
| REF 47423-01 | EAN13 | 8013366 101573 | individual pouch |
| | EAN13 | 8013366 101580 | unit of 24 pcs |

POUCH WEIGHT

the weight of 1 pouch of cm 24x14,5 is as average g 320 +/-1,5%

LANGUAGES ON THE POUCH

German, English, French, Spanish, Dutch, Swedish, Norwegian, Danish, Finnish

CLASSIFICATION OF THE DEVICE AS PER DIRECTIVE 93/42/EEC

UMDC 10932 **UMDNS** cold packs **CND** M9001 **GMDN** 44147

The instant cold pack is a Medical Device Class IIa for rule 9 Annex IX. Active medical Device (see section 1, paragraph 1.4 of annex IX).

Product certified by the Notified Body KIWA CERMET

Certificate no. MED 31270

"DEVICES FOR HOT/COLD THERAPY" of Biosport Italia Srl.

USE

Instant cold pack for first aid purpose. The device is intended for a short term contact.

Within 24 hours (REF: EN ISO 10993-1).

Safety Data Sheet TENSOCOLD PACK

INSTANT COLD PACK

Caution: for protection against frostbite place a dressing between skin and cold pack.

For external use only. Do not puncture. Keep out of reach of children.

1. Hit the external pouch with a firm hand stroke so as to burst the small inner pouch of water;
2. Shake to mix the contents to get maximum cooling;
3. For single use only, dispose after use.

WARNING: Do not ingest: if accidentally ingested drink 1/2 liter of warm water, do not induce vomiting and consult a physician.

If solution contacts eyes, skin or open wound, rinse immediately with water for 15 minutes and call a physician. In the event of circulatory diseases and/or skin insensitivity use only under medical advice. Store at room temperature. Do not expose to heat.

Ingredients: urea-aqua.

LOT LOT NUMBER

The LOT number is fundamental for the traceability of the product.

Printing of the LOT no. on the pouch:

LOT 7 digits (from left to right):

- 1 digit – ending of year of production
 - 2 digits – week of production
 - 4 digits- vendor ID no. (BIOSPORT ITALIA SRL)
- YWW9707**



EXPIRY DATE

example **LOT** 5129707

The performances of the product are guaranteed for 5 years (60 months) from the production date if the storage conditions are observed: keep in a dry and cool place, at room temperature. Do not expose to heat.

- 4 numbers – year of expiring
- 2 numbers – month of expiring



+6 numbers

example:



2020-03

PACKAGE

24 Pcs per carton

48 cartons per Epal/Eur pallet

1152 Pcs per pallet

dimensions Epal/Eur pallet 80x120x120h

sizes of 1 carton : 19x38x25h

gross weight of 1 carton : Kg. 8,100

gross weight of cartons+ pallet : around Kg. 390 + around Kg. 15 of pallet

CLINICAL EVALUATION

Clinical evaluation on the Cold Therapy packs made by Doctor Paiaro Stefano and All. 6 (NB-MED 2.7/rec.3).

**Safety Data Sheet
TENSOCOLD PACK****SYMBOLS**

Manufacturer



Keep out of sunlight



Keep dry



Do not reuse



Bin Symbol



Other plastic recycle



Expiry Date



LOT number



Product code



Kiwa Cermet Notified Body number

MANUFACTURERBiosport Italia Srl
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Safety Data Sheet TENSOCOLD PACK

This is to certify that in our product there are not raw materials of Japanese origin and that these instant cold packs are manufactured in Italy.



To the best of our knowledge, the information provided in this Technical Safety Data Sheet is accurate as at the date of its issue. The information it contains is being given for safety guidance purposes and relates only to the specific material and uses described in it.

This revision cancels any previous.

Revisions are indicated with a line in front of new addition/changes.