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### **SECTION 1 - PRODUCTION IDENTIFICATION**

**Product Name** : Inspracart Hemodialysis Sodium Bicarbonate Cartrige

**Company Identification**: Inspramed Medikal Sanayi Ve Ticaret Anonim Şirketi

Serbest Bölge, 8.Cad., No:29, 38070 Melikgazi

Kayseri / TÜRKİYE

Telephone: +90 352 3114210 Fax: +90 352 311 4220

**Classification** : Medical Device Directive 93/42/EEC, ANNEX II(Excluding Section

4), CLASS II B, Rule 3, Non-Sterile Product

**GMDN Code** : 35849

#### SECTION 2 - COMPOSITION AND INGREDIENT INFORMATION

For 100 g Sodium Bicarbonate (NaHCO<sub>3</sub>)

Component	CAS#	Na (mmol)	HCO <sub>3</sub> (mmol)
Sodium Bicarbonate	144-55-8	1190	1190

#### SECTION 3 - USAGE AND CHARACTERISTIC

Inspracart Haemodialysis Sodium Bicarbonate Cartridge is used for haemodialysis treatment by diluting suitably with acidic concentrate and purified water. Diluted haemodialysis solution is used for replacing of electrolytes with toxic and liquid materials in blood via dialyzer (semi-permeable membrane) without direct contact with blood. By this way, the electrolyte balance is provided.

Inspracart cartridge has a polypropylene container with sodium bicarbonate which enables just-in-time production of liquid bicarbonate concentrate. When attached to a special holder, water passes through the Inspracart cartridge, thus producing a saturated bicarbonate solution, ready for use. This concentrated solution is proportioned in dialysis machine. Each 84-gram sodium bicarbonate of Inspracart allows to obtain 25-28 liters diluted basic solution.

Appearance : White Physical State : Powder Odor : None

**Hazards of Product**: Non-Hazardous

#### **SECTION 4 - HAZARDS IDENTIFICATION**



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**Potential Health Effects** 

Inhalation: Non-HazardousIngestion: Non-HazardousSkin Contact: Non-IrritationEye Contact: Non-Irritation

#### **SECTION 5 - FIRST AID MEASURES**

Inhalation: Non-HazardousIngestion: Non-Hazardous

**Eyes And Skin**: If irritation should occur to eyes or abraded skin, wash with some amounts of water.

#### SECTION 6 - FIRE AND EXPLOSION HAZARD DATA

Flash Point : N/A
Flammable Limits : N/A
Extinguishing Media : N/A

**Unusual Fire and Explosion Hazards**: Does not support combustion.

#### **SECTION 7 - ACCIDENTAL RELEASE MEASURES**

Remove spillage from the environment. Dispose of product and packaging in accordance with local conditions.

#### **SECTION 8 - HANDLING AND STORAGE**

**General Handling**: Keep products closed in original packages when not in use. Store in a dry area

between 5-30°C...

**Ventilation** :Use with adequate ventilation in storage and transport areas. Ventilation, temperature

and humidity controls should be made regularly.

#### SECTION 9 - EXPOSURE CONTROLS / PERSONAL PROTECTION

Eyewear : Not required, but recommend to be worn. Gloves : Not required, but recommend to be worn.

Clothing : Not required.
Respirator : Not required.

### **SECTION 10 - PHYSICAL AND CHEMICAL PROPERTIES**



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Physical state : Powder
Appearance : White, crystals

**pH** (as a concentrate) : 7.0 - 8.0 (when mixed)

**Solubility** : In water, acetone, methanol, and ethanol

Odor : Odorless
Molecular Weight : 84,0066 g mol<sup>-1</sup>
Density : 2.20 g/cm<sup>3</sup>

**Melting Point** : 50°C (sodium decomposes from bicarbonate)

## **SECTION 11 - STABILITY AND REACTIVITY DATA**

**Stability** : Stable **Incompatibility Materials** : Acids

**Hazardous Polymerization** : Will not occur **Hazardous Decomposition** : Will not occur

**Conditions to Avoid** : None

#### **SECTION 12 - TOXICOLOGY INFORMATION**

Sodium Bicarbonate Powder as a product was tested and determined not to be toxic to humans

#### **SECTION 13 - ECOLOGICAL INFORMATION**

**Environmental Fate** : Not hazardous. **Environmental Toxicity** : Will not occur.

### **SECTION 14 - DISPOSAL CONSIDERATIONS**

Dispose of the product and its packaging according to local conditions.

### **SECTION 15 - TRANSPORT INFORMATION**

This product is not classified as dangerous goods and appropriate to transport by international plane, sea and land transportation according to IATA, IMDG and ADR.

#### **SECTION 16 - REGULATORY INFORMATION**



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Status : Not Regulated

**D.O.T. Hazard Class**: None

OSHA : Not hazardous under 29 CFR 1910.1200

**RCRA** : Not a hazardous material by listing or characteristic

## **SECTION 17 - OTHER INFORMATION**

NFPA Ratings **HMIS Ratings** Flammability Flammability : 0 : 0 Health : 0 Health : 0 Reactivity : 0 Reactivity : 0 Specific Hazard: None **PPE** : B

The information contained in this document is prepared by Inspramed Medikal Sanayi Ve Ticaret Anonim Şirketi. It is the product user's obligation to determine safe conditions for usage of this material, and Inspramed will not be responsible for damages resulting from usage of this information.

Prepared By : Inspramed Medikal Sanayi ve Ticaret Anonim Şirketi

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