



MATERIAL SAFETY DATA SHEET

DOCUMENT NO :MSDS-05
ISSUE DATE :18.02.2019
REVISION DATE/NO :04.01.2021/02
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SECTION 1 - PRODUCTION IDENTIFICATION

Product Name : Inspracart Hemodialysis Sodium Bicarbonate Cartridge

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_3)

Component	CAS#	Na (mmol)	HCO_3 (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

INSPRAMED MEDİKAL SANAYİ VE TİCARET A.Ş.
Serbest Bölge., 8. Cadde , No: 29 , Melikgazi, KAYSERİ / TÜRKİYE
Tel: +90 352 311 42 10 Fax: +90 352 311 42 20
www.inspramed.com.tr



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Potential Health Effects

Inhalation : Non-Hazardous
Ingestion : Non-Hazardous
Skin Contact : Non- Irritation
Eye Contact : Non- Irritation

SECTION 5 - FIRST AID MEASURES

Inhalation : Non-Hazardous
Ingestion : 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⁻¹
Density : 2.20 g/cm³
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

Flammability : 0
Health : 0
Reactivity : 0
Specific Hazard : None

HMIS Ratings

Flammability : 0
Health : 0
Reactivity : 0
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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