



DESCRIPTION OF PRODUCT GROUP AND TREE

Ürün Grubu ve Ağacı

DOCUMENT NO :CE-CART-03
ISSUE DATE :22.10.2019
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DESCRIPTION OF THE DEVICE

Hemodialysis solution is a solution used in the treatment of acute and chronic renal insufficiency during the hemodialysis process. The hemodialysis solution is used in combination with the hemodialysis machine to remove blood waste.

Hemodialysis solution (dialysate) is an aqueous solution without organic components (with the exception of acetate and glucose added to correct acidity in the blood) with an electrochemical composition similar to that of normal human extracellular fluid. Dialysis is prepared by mixing purified water with concentrated electrolytes and other dissolved substances, depending on the physiological needs of the patient.

The dialysis solution, or dialysate, assists the hemodialysis machine in controlling a safe rate of fluid removal from the body by restoring some of the necessary water and mineral substances, such as sodium (salt) and potassium, during the treatment process. The solution can be adjusted to accommodate the patient and their body's specific blood composition.(7)

Insprasol Haemodialysis Acid and Basic Concentrate, Inspracart Haemodialysis Sodium Bicarbonate Cartridge and Insprabag Haemodialysis Sodium Bicarbonate Bag are produced for treatment of chronic renal failure patients. Our products are major component of system which is designed by ultra purified dialysis water system component to prevent inflammation due to treatment. The electrolyte concentrations in solution is restore plasma levels to clinically desired concentrations or maintain plasma levels at the desired concentration.

Product description can be see table below.

PRODUCT DESCRIPTION	INSPRACART
Device Presentation	Polypropylene
pH	7.0-8.0
Sterile/ Nonsterile	Non-sterile
Appearance	White
Physical State	Powder
Odor	None



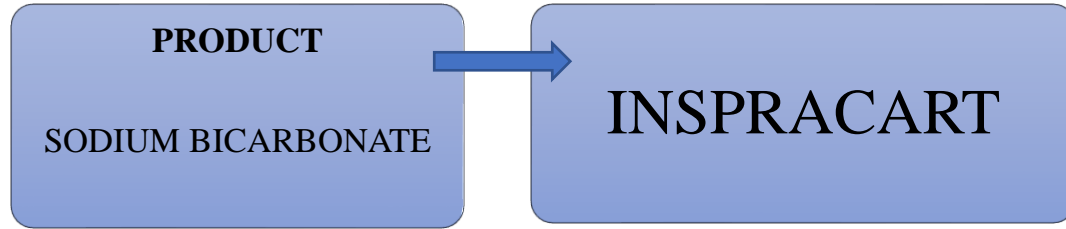
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Radioactivity	N/A
How the Device Achieves Its Intended Purpose	The Inspracart cartridge is a polypropylene container with sodium bicarbonate which enables on-line production of liquid bicarbonate concentrate. After taking an Acid in solution is used as an alkalizing buffer to normalize acid-base balance.
Principles of Operation	Use a component only in combination with haemodialysis acid concentrate Using programme and dilution rate with bicarbonate and water is regulated by haemodialysis machine specification and patients treatment requirements.
Materials Used in the Product	Sodium Bicarbonate
Incorporation with a Medicinal Substance	N/A

1. INSPRACART HAEMODIALYSIS SODIUM BICARBONATE CARTRIDGE PRODUCT TREE









2.PRODUCT GROUP NAMES, PRODUCT CODES

2.1 INSPRACART HAEMODIALYSIS SODIUM BICARBONATE CARTRIDGE

PRODUCT NAME	SODIUM BICARBONATE (Grams)
INSPRACART	550
INSPRACART	650
INSPRACART	720
INSPRACART	750
INSPRACART	760
INSPRACART	850
INSPRACART	920
INSPRACART	960

STRUCTURE OF PRODUCTION SUBSTANCES

INSPRACART HEMODIALYSIS SODIUM BICARBONATE CARTRIDGE

SODIUM BICARBONATE	BODY Polypropylene	COVER Polypropylene	STOPPER LDPE	COVER FILTER Polypropylene	BODY FILTER Polypropylene
					
Reference amount*	1 pcs	1 pcs	2 pcs	1 pcs	1 pcs

*Inspracart is available for 550g,650g,720g,750g,760g,850g,920g,960g. All sizes include 100% Sodium Bicarbonate.



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CHARACTERISTIC OF SODIUM BICARBONATE

Commercial Name : Sodium Hydrogen Carbonate

CAS# : 144-55-8

Characteristic : Its structure is white, crystal powder, be soluble in water, not be soluble in alcohol. When heated it has been drsyt ructure, in solution it is turned to sodium carbonate.

Description : Sodium bicarbonate is not included for NaHCO₃ less than 99.0 % more than 101 %.

Substance	Properties
Sodium Bicarbonate $\text{Na}^+ \text{ } ^-\text{O}-\text{C}-\text{OH}$ $\quad \quad \quad \parallel$ $\quad \quad \quad \text{O}$	<ul style="list-style-type: none">- Molar mass : 84.0066 g mol⁻¹- Appearance : White crystals- Physical state : Powder- Odor : Odorless- Density : 2.20 g/cm³- Melting Point : 50°C (decomposes to sodium bicarbonate)- Solubility : water, acetone, methanol, ethanol



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CHARACTERISTIC OF *POLYPROPYLENE* MATERIAL

Commercial Name of Material : SABIC QR6711K

PROPERTIES	UNIT	VALUE ⁽¹⁾	ASTM METHOD
Resin Properties			
Melt Flow Rate @230°C & 2.16 kg load	g/10 min.	45	D 1238
Density @ 23°C	Kg/m ³	905	D 792
Mechanical Properties⁽²⁾			
Tensile Strength @ Yield	MPa	28	D 638
Tensile Elongation @ Yield	%	13	D 638
Flexural Modulus (1% Secant)	MPa	1150	D 790A
Notched Izod Impact Strength @ 23°C	J/m	56	D 256
Rockwell Hardness, R-Scale	-	85	D 785
Thermal Properties⁽²⁾			
Vicat Softening Point	°C	124	D 1525B
Heat Deflection Temperature @ 455 KPa	°C	71	D 648

(1) Typical values; not to be construed as specification limits.

(2) Based on injection molded specimens.

*Body

*Cover

are made with *polypropylene* (SABIC QR6711K) material.



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*Cover filter

CHARACTERISTIC OF LDPE (Low Density Polyethylene) MATERIAL

Commercial Name of Material : PETILEN F2-12

PROPERTIES	UNIT	TYPICAL VALUE*	ASTM METHOD
Resin Properties			
Melt Flow Rate (190°C/2.16 kg)	g/10 min	2,5	D 1238
Density, 23°C	g/cm ³	0,920	D 1505
Melting Point (DSC)	°C	110	D 3418
Film Properties**			
Tensile Strength at Yield, MD	MPa	11	D 882
Tensile Strength at Yield, TD	MPa	10	D 882
Tensile Strength at Break, MD	MPa	23	D 882
Tensile Strength at Break, TD	MPa	17	D 882
Elongation at Break, MD	%	>200	D 882
Elongation at Break, TD	%	>500	D 882
Tear Strength, MD	cN	330	D 1922
Tear Strength, TD	cN	240	D 1922
Dart Drop Impact, F50	g	120	D1709A
Coefficient of Friction	-	<0,2	D 1894
Optical Properties			
Haze	%	6,3	D 1003
Gloss, 45°	GU	77	D 2457
Thermal Properties			
Vicat Softening Point, 10 N	°C	92	D1525



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(*) These are typical properties only and are not to be construed as specifications. Customers should confirm results by their own tests.

(**) Film properties are measured on 35 µm blown film, Blow up ratio (BUR) 2.5:1, melt temperature -170°C.

MD: Machine Direction, TD: Transverse Direction

Stopper is made with *polyethylene* (PETILEN F2-12) material.

CHARACTERISTIC OF *BODY FILTER*

Commercial Name of Material : IS 77660

Material	Polypropylene, XM-13163
Property	Hydrophobic
Color	Natural (white)
Melting point/range	120 to 170 °C DIN 53765 DSC 2010
Ignition temperature	>360°C
Density	0,4-0,61 g/cm ³ @ 20°C ISO 1183-1
Pore volume	>25%
Flash	≤ 0,7 mm A
Embedded Contamination	≤ ø 0,6 mm
Strength Test	50-110 N (PA 03-14)
Airflow	600-2500 l/h @ 20 mbar (PA 02-03)

Body filter is made with *polypropylene* (IS 77660) material.