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SECTION 1 - PRODUCTION IDENTIFICATION

Product Name :Insprasol Haemodialysis Acid Concentrate

Company Identification :Inspramed Medikal Sanayi ve Ticaret Anonim Sirketi

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

Component	CAS#	Expression in (mmol/L)	Expression in (mEq/L)
Sodium Chloride	7647-14-5	80-110	80-110
Potassium Chloride	7447-40-7	0-3	0-3
Calcium Chloride	10035-04-8	0-2	0-2
Magnesium Chloride	7791-18-6	0-1.2	0-2.4
Acetic Acid	64-19-7	2.5-10	2.5-10
Total Chloride	-	90-120	90-120
Dextrose/Glucose	14431-43-7	0-12	-

Dilution Ratio	Acid:Bicarbonate:Water	Product Description
35 X	1:1.225:32.775	
36.83 X	36.83 X 1:1.83:34	
45 X	1:1.575:42.425	Dialysate Acid Concentrate Liquid
45 X	1:1.755:42.245	



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SECTION 3 - USAGE AND CHARACTERISTIC

Insprasol acid concentrate is formulated to be used with a three stream haemodialysis machine calibrated to. Insprasol Acid Concentrate is used for haemodialysis treatment by diluting suitably with basic concentrate and purified water. Diluted haemodialysis solution is used for replacing electrolytes with toxic and liquid materials in blood via dialyzer (semi-permeable membrane) without direct contact with blood. In this way, the electrolyte balance is provided.

Appearance : Clear
Physical State : Liquid
Odor : Vinegar
Hazards of Product : Corrosive

SECTION 4 - HAZARDS IDENTIFICATION

Potential Health Effects

Inhalation: Effects from inhalation may cause mild irritation to the upper respiratory tract.

Symptoms may include sneezing, sore throat or runny nose.

Ingestion : Swallowing may cause burns of mouth, throat and stomach. Symptoms may include

bleeding, vomiting or diarrhea.

Skin Contact : Contact with skin can cause irritation.

Eye Contact : Causes irritation of eyes.

SECTION 5 - FIRST AID MEASURES

Inhalation : Remove patient to fresh air. Contact a physician.

Ingestion: If swallowed, drink large amounts of water. Do not attempt to induce vomiting.

Eyes and Skin : Check for remove if any contact lenses. In case of contact immediately flush eyes with plenty of water for at least 15 minutes. If burn or irritation has occurred seek

medical attention. If clothing is contaminated, remove clothing, wash skin and wash

clothing before reusing.

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

Avoid eye or skin contact. Ventilate area from of leak or spill; move leaking containers to well ventilated area with spill containment Improperly spilled into the environment may cause soil and water contamination. Do not



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allow to enter sewers / surface water / groundwater. If possible, collect acidic liquid in a suitable container and use suitable cleaners to facilitate cleaning. Methods for cleaning may include chemical materials, vacuum components, or other suitable tools.

SECTION 8 - HANDLING AND STORAGE

General Handling : Keep container closed when not in use. Store in a dry area between 5-30 °C. Store

unused product in original closed container. Avoid inhalation if leakage is observed. Do

not use Acidic Concentrates that have frozen, opened and leaked.

Storage: Use with adequate ventilation in storage and transport areas. The warehouse should be

cleaned regularly; ventilation, temperature and humidity controls should be made.

SECTION 9 - EXPOSURE CONTROLS / PERSONAL PROTECTION

Eyewear: Use safety glasses or goggles. A face shield should be worn when splashes are likely.

Gloves : Protective gloves should be worn.

Clothing :A protective apron should be worn when splashes are likely. Rubber boots should be used in

case spilling.

Mask :It is recommended that people use masks if the air pollution is above the allowed levels.

SECTION 10 - PHYSICAL AND CHEMICAL PROPERTIES

Physical state : Liquid
Appearance : Clear
pH (as a concentrate) : 2 - 3
Solubility in Water : Complete
Odor : As vinegar

Molecular Weight : ND
Boiling Point (760mmHg) : ND
Freezing Point : ND
Specific Gravity(24°C) : 1.10-1.25

Vapor Density (air=1) : 1
Melting Point : ND

SECTION 11 - STABILITY AND REACTIVITY DATA

Stability : Stable

Incompatibility : Lithium, bromine trifluoride, strong alkalis such as sodium hydroxide

Hazardous PolymerizationHazardous DecompositionConditions to AvoidWill not occurWill not occurNone known



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SECTION 12 - TOXICOLOGY INFORMATION

None of the all have no ingredient any toxic substances.

SECTION 13 - ECOLOGICAL INFORMATION

Environmental Fate : No information found. **Environmental Toxicity** : No information found.

SECTION 14 - DISPOSAL CONSIDERATIONS

Dilute with water and flush to sewer if local ordinances allow, otherwise, all waste should be managed in an appropriate and approved waste disposal facility. Processing use or contamination of this product may change the waste management options. Dispose of container and unused contents in accordance with state and local requirements.

SECTION 15 - TRANSPORT INFORMATION

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

SECTION 16 - REGULATORY INFORMATION

This Product is not classified as a Hazardous Material.

SECTION 17 - OTHER INFORMATION

NFPA Ratings **HMIS Ratings** Flammability : 0 Flammability : 0 Health . 2 Health : 2 Reactivity : 0 Reactivity : 0 Specific Hazard: None **PPE** : B

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Prepared By : Inspramed Medikal Sanayi ve Ticaret Anonim Şirketi

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