SECTION 1 - PRODUCTION IDENTIFICATION

Product Name : Inspradez C 50 Haemodialysis Machine Disinfectant

Company Identification :Inspramed Medikal Sanayi Ve Ticaret Anonim Şirketi
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Class Identification : Classification according to Medical Device Directive 93/42/EEC Class 2-b Rule 15. Non-Sterile Product

GMDN Code : 47631

SECTION 2 - COMPOSITION AND INGREDIENT INFORMATION

Component	CAS#	Approx. W/V%
Citric Acid Monohydrate	5949-29-1	50 %
Purified Water	7732-18-5	Enough Quantity

SECTION 3 - USAGE AND CHARACTERISTIC

Inspradez products are used in hemodialysis machines for disinfection and descaling processes.
Inspradez C 50 Hemodialysis Machine Disinfectants are taken by a proportional automatic pipette system of the hemodialysis machine and connected to the disinfectant connector. These provide descaling at 37 ° C and disinfection at 60 ° C. The detailed washing and disinfection procedure is provided from the dialysis machine manufacturer's disinfection description.

Appearance : Clear
Physical State : Liquid
Odor : None
Hazard of Products : Corrosive

SECTION 4 - HAZARDS IDENTIFICATION

Physico-chemical hazards : No specific hazards are known.
Health : See R-phrases.
Environment : No specific hazards are known.
Other risks : May be harmful if swallowed. Inhalation of vapors may cause irritation to respiratory tract.
Risk Symbol **:** Irritant
R-phrases : R 36: Irritating to eyes.
R 38: Irritating to skin.

SECTION 5 - FIRST AID MEASURES

General Information **:** Change soaked clothing.
Inhalation **:** Ensure supply fresh air. In the event of symptoms refer to medical treatment.

Ingestion **:** Do not induce vomiting unless directed to do so by medical personal. Get medical attention if symptoms appear.

Skin Contact **:** In case of contact, immediately flush skin with plenty of water. Get medical attention.

Eye Contact **:** Check for remove if any contact lenses. In case of contact immediately flush eyes with plenty of water for at least 15 minutes.

Potential Health Effects
Carcinogenic Effects **:** Not available
Mutagenic Effects **:** Not available
Teratogenic Effects **:** Not available
Developmental Toxicity **:** Not available

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

Personal precautions **:** Ensure adequate ventilation.

Small Spill **:** Use appropriate tools to dispose of the spilled amount if any. Finish the process by cleaning the contaminated surface with water and dispose of according to local and regional authority requirements.

Large Spill : Stop leak if without risk. Do not get water inside warehouse. Do not touch spilled material use water spray to reduce vapours.

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 Machine Disinfectants 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

For handling open containers, use of the following protective equipment is recommended:

Technical Controls : Provide sufficient ventilation by caring about the other technical controls to keep airborne levels under the recommended exposure limits.

Personnel Protection : Avoid contact with eyes and skin.

Hygiene Measures : Wash hands before breaks and after work. Use appropriate gloves.

SECTION 10 - PHYSICAL AND CHEMICAL PROPERTIES

Colour	: Colorless
Odour	: Odorless
pH-value	: 1- 2
pH-value, 1%	: ~2,5 (10%lg)
Boiling point [°C]	: Not determined
Flash point [°C]	: Not applicable
Flammability [°C]	: Not applicable
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Combustible properties	: No
Density [g/ml]	:1,172 g/mL (24°C)
Solubility in water	: Soluble, complete
Melting point [°C]	: Not determined

SECTION 11 - STABILITY AND REACTIVITY DATA

Stability : Stable
Corrosivity : Corrosive in presence aluminium, of zinc, of copper.
Hazardous Polymerization : Will not occur
Incompatibility : Reactive with oxidizing agents, reducing agents, metals, alkalis
Hazardous Decomposition : No hazardous decomposition products known.
Contains to Avoid : Incompatibles

SECTION 12 - TOXICOLOGY INFORMATION

General remarks : No toxicological data are available. The product was classified on the basis of its content.
Cytotoxicity : It is not toxic on CCL 81(Vero).
Acute oral toxicity : Not determined
Irritant effect on eye : Not determined
Irritant effect on skin : Not determined.
Sensitization : Not determined

SECTION 13 - ECOLOGICAL INFORMATION

Behaviour in environment compartments : Not determinated.
Behaviour in sewage plant : Not determinated
Biological degradability : Not determinated,
Contains compounds of 76/464/EC : Not applicable
Environmental Fate : No information found all ingredients.
General information : Ecological data are not available
Fish toxicity : Not determined
Bacterial toxicity : Not determined
Chemical oxygen demand : Not determined
Daphnia toxicity : Not determined

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 international plane, sea and land transportation according to IATA, IMDG and ADR.

SECTION 16 - REGULATORY INFORMATION

This Product is not classified as an Hazardous Material. This product is corrosive on the metal, aluminium. Do not contact with eyes.

SECTION 17 - OTHER INFORMATION

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.

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