

### 1. IDENTIFICATION OF THE MIXTURE AND THE COMPANY

#### 1.1 Identification of Product

Product Name: **ISE Module Cleaning Solution Kit**

Product Number: **5421**

1.2 Use of the product/Kit: Clean the fluid path of the ISE Module.  
For in vitro diagnostic use

#### 1.3 Company identification:

Address	<b>Medica Corporation</b>
	<b>5 Oak Park Drive</b>
	<b>Bedford MA 01730 USA</b>
Phone	<b>+1-800-777-5983 or +1-781-275-4892</b>
Email	<b>sds@medicacorp.com</b>
Website	<b>www.medicacorp.com</b>
FAX	<b>+1-781-275-2731</b>

Note:

The kit contains two separate compounds that must be combined prior to use. The SDS in the following pages refers to the combined mixture of the individual chemicals when mixed, stored and used per instructions of use.

A separate Safety Data Sheet is prepared for each of the two individual compounds, as outlined in the following pages.

### 2. HAZARDS IDENTIFICATION

#### 2.1 Hazard Classification (see also § 15)

Skin irritant 2

H315: Causes skin irritation

P264, P280 for prevention

P302+P352, P321, P332+P313, P362 for response

Eye irritant 2

H319: Causes serious eye irritation

P264, P280 for prevention

P305+P351+P338, P337+P313 for response

Respiratory Sensitivity 1

H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled

P261, P285 for prevention

P304+P341, P342+P311 for response

P501 for disposal

STOT SE 3 according to 1272/2008/EC and GHS Regulation

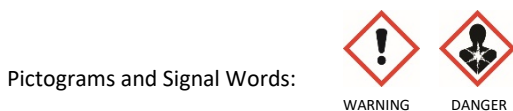
H335: May cause respiratory irritation

P261, P271 for prevention

P304+P340, P312 for response

P403+P233, P405 for storage

P501 for disposal



- 2.2 Hazards not otherwise classified: Not available
- 2.3 Mixture ingredients of unknown toxicity: Not applicable

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Composition: Pure powder. May be classified as hazardous as stated above (see §2).

Name	EINECS/ ELINCS No.	CAS no.	Conc. % w/v	Classification 1272/2008/EC
Pepsin	232-629-3	9001-75-6	5%	Skin Irritant 2, H315 Eye Irritant 2, H319 STOT SE 3, H335 Respiratory Sensitivity 1, H334
Daily Rinse/Cleaning Diluent	231-595-7	7647-01-0	95%	Skin Irritant 2, H315 Eye Irritant 2, H319

### 4. First Aid Measures

- Ingestion: If swallowed rinse mouth with plenty of water provided person is conscious. Get medical advice if adverse symptoms appear.
- Inhalation exposure: Move to a clean air environment and seek medical attention if adverse symptoms appear.
- Contact with skin: Remove contaminated clothes and shoes. Wash affected area with plenty of water. Get medical advice if adverse symptoms appear.
- Contact with eyes: Wash immediately with plenty of water. Get medical advice if adverse symptoms appear.

### 5. FIRE FIGHTING MEASURES

- Suitable extinguishing means: Water spray or regular foam, CO<sub>2</sub>, dry powder.
- Mean of extinguishing NOT to be used: Not known.
- Known hazards caused by combustion: Thermal decomposition or combustion may generate toxic and hazardous fumes.
- Equipment for self-protection: (fire fighters): Standard equipment

### 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions: Plastic gloves and safety glasses.
- Environmental precautions: No special requirements
- Cleaning procedure to recover spilled material: Soak up with inert absorbent material, and clean with plenty of water.

### 7. HANDLING AND STORAGE

#### 7.1 Handling

Handling procedures: Wear suitable protective clothing, gloves, eye protection. When use do not eat, drink or smoke. Provide sufficient ventilation in all work areas.

Work/Hygienic practices: Wash hands with soap and water after use.

#### 7.2 Storage

Room ventilation: Well ventilated workplace.

Special precautions: (see also § 8) Avoid environmental release.

Recommended temperature: Store at 4 – 8 °C.

Humidity, light and other environmental factors: Keep away from heat sources.

Containers: Keep individual bottles closed.

Other storage precautions: Keep away from food and drinks.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### 8.1 Exposure limit values

TLV/TWA: Not available

TLV/STEL: Not available

LV EU: Not available

#### 8.2 Personal Protective Equipment (PPE) and Handling

Respiratory protection: Normal room ventilation.

Skin protection: Protective clothing, rubber or polythene gloves.

Eye protection: Safety glasses.

Hand protection: Plastic gloves.

Other protective systems: Personal protective equipment (PPE) useful for reducing individual exposure.

Environmental protection: Avoid any release into the environment.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

#### 9.1 General information

Appearance: Liquid

Liquid Odor: Characteristic odor

Color: white to light yellow

### 9.2 Important health, safety and environmental information

Value Related to pH:	2.5 at 25° C
Boiling point/range:	Not available
Flash point:	Not available
Vapor pressure:	Not available
Density:	1.0 g/cm <sup>3</sup> at 25° C
Mixture Solubility:	Not available
Water Solubility:	Completely miscible
Mixture Viscosity:	Not available
Vapor density:	Not available
Evaporation rate:	Not available

### 9.3 Other information

Melting point/range:	Not available
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## 10. STABILITY AND REACTIVITY INFORMATION

Stability: The product is stable for 30 days after mixing individual components, when stored at 4 - 8°C.

10.1 Conditions to avoid: Keep away from heat, Strong oxidizing agents, strong bases

10.2 Reactivity: No known self-polymerization or self-decomposition when stored as recommended.

10.3 Hazardous decomposition products: Thermal decomposition or combustion may include toxic and hazardous fumes.

## 11. TOXICOLOGICAL INFORMATION

### 11.1 Toxicokinetic effects (ADME)

Absorption:	No data available
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11.2 Acute toxicity Value mu. No data available

### 11.3 Irritation (See §2)

Skin:	Causes irritation
Inhalation:	Not applicable
Eye:	Causes Eye irritation

### 11.4 Sensitization:

Skin sensitization:	Not available
Sensitization by inhalation:	Not available

### 11.5 Prolonged exposure toxicity:

Teratogenesis:	Not available
Carcinogenesis:	Not available

### 12. ECOLOGICAL INFORMATION

12.1 Ecotoxicology:	Not known
12.2 Mobility:	Not available
12.3 Persistency and degradability:	Not available
12.4 Bioaccumulation potential:	Not available
12.5 Evaluation PBT result:	Not available
12.6 Other toxic effects:	Not available

### 13. DISPOSAL CONSIDERATIONS

National laws on disposal must be considered, local and UE requirements for wastes recycling must be respected. Used waste product, surplus product or spillage products shall be disposed of in accordance with national, state and local laws.

### 14. TRANSPORT INFORMATION

Not classified for transport in accordance with ADR/RID, IMDG, IATA and DOT regulations.

### 15. REGULATORY INFORMATION

The active ingredients and all components of the enzyme preparation are listed on the TSCA Inventory.

### 16. OTHER INFORMATION

The contained information in this Safety Data Sheet (SDS) are in accordance with OSHA "Hazard Communication Standard" (HCS) under 29CFR 1910.1200(g) and EU Regulation No 1272/2008.

#### Bibliographic references:

OSHA BRIEF: Hazard Communication Standard: Safety Data Sheets

EC1272/2008

#### Disclaimer:

This document is intended only as a guide to appropriate precautionary handling of this product by a trained person, or supervised by a person trained in chemical handling. The product shall not be used for purposes different from those indicated in section 1, unless having received suitable written instructions on how to handle the material. Use the product in accordance with the Good Laboratory Practice. This document cannot describe all potential dangers of use or interaction with other chemicals or materials. It is the user's responsibility for the product's safe use, the product's suitability for the intended use and the product's safe disposal. No representation or warranties, either expressed or implied, of merchantability, fitness for a particular purpose or of any other nature are made hereunder with respect to the information set forth herein or to the product to which the information refers. The contained information in this MSDS are in accordance with Annex II of Regulation no.1907/2006 (REACH) and in accordance with ANSI "Standard for Hazardous Industrial Chemicals - Material Safety Data Sheets - Preparation" (ANSI Z400.1-2004) as recommended by US OSHA.

Revision Date: 2017/06/15

### 1. IDENTIFICATION OF THE MIXTURE AND THE COMPANY

#### 1.1 Identification of the mixture

Product Name: **Pepsin Powder** Product Number: **Part of Ref. No. 5421**

1.2 Use of the mixture: Protein cleaner to clean the fluid path of the ISE Module.  
For in vitro diagnostic use

#### 1.3 Company identification:

Address	Medica Corporation
	5 Oak Park Drive
	Bedford MA 01730 USA
Phone	+1-800-777-5983 or +1-781-275-4892
Email	sds@medicacorp.com
Website	www.medicacorp.com
FAX	+1-781-275-2731

### 2. HAZARDS IDENTIFICATION

#### 2.1 Hazard Classification (see also § 15)

Skin irritant 2

H315: Causes skin irritation

P264, P280 for prevention

P302+P352, P321, P332+P313, P362 for response

Eye irritant 2

H319: Causes serious eye irritation

P264, P280 for prevention

P305+P351+P338, P337+P313 for response

Respiratory Sensitivity 1

H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled

P261, P285 for prevention

P304+P341, P342+P311 for response

P501 for disposal

STOT SE 3 according to 1272/2008/EC and GHS Regulation

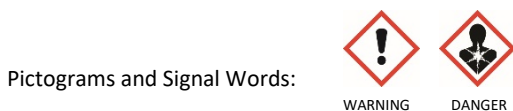
H335: May cause respiratory irritation

P261, P271 for prevention

P304+P340, P312 for response

P403+P233, P405 for storage

P501 for disposal



2.2 Hazards not otherwise classified: Not available

2.3 Mixture ingredients of unknown toxicity: Not applicable

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Name	EINECS/ELINCS No	CAS No.	Concentration	Hazard classification (see also §2)
Pepsin	232-629-3	9001-75-6	100% powder	Skin Irritant 2, H315 Eye Irritant 2, H319 Respiratory Sensitivity 1, H334 STOT SE 3, H335

### 4. First Aid Measures

- Ingestion:** If swallowed rinse mouth with plenty of water provided person is conscious. Get water to drink and get medical advice if adverse symptoms appear.
- Inhalation exposure:** Move to a clean air and seek medical attention if adverse symptoms appear.
- Contact with skin:** Remove contaminated clothes and shoes. Wash affected area with plenty of water. Get medical advice if adverse symptoms appear.
- Contact with eyes:** Wash immediately with plenty of water. Get medical advice if adverse symptoms appear.

### 5. FIRE FIGHTING MEASURES

**NFPA Ratings:** Health: 1 Flammability: 1 Reactivity: 0

Suitable extinguishing means: Water spray or regular foam, CO<sub>2</sub>, dry powder.

Mean of extinguishing NOT to be used: Not known.

Known hazards caused by combustion: Thermal decomposition or combustion may generate toxic and hazardous fumes.

Equipment for self-protection: Standard equipment

### 6. ACCIDENTAL RELEASE MEASURES

Clean up spills in a manner that does not disperse dust into the air. Use non-sparking tools and equipment. Reduce airborne dust and prevent scattering by moistening with water. Pick up spill for recovery or disposal and place in a closed container.

**Personal precautions:** Plastic gloves and safety glasses.

**Environmental precautions:** No special requirements

**Cleaning procedure to recover spilled material:** Soak up with inert absorbent material, and clean with plenty of water.

### 7. HANDLING AND STORAGE

#### 7.1 Handling

**Handling procedures:** Wear suitable protective clothing, gloves, eye protection. When use do not eat, drink or smoke. Provide sufficient ventilation in all work areas.

**Work/Hygienic practices:** Wash hands with soap and water after use.

### 7.2 Storage

Room ventilation:	Well ventilated workplace.
Special precautions: (see also § 8)	Avoid environmental release.
Recommended temperature:	Store refrigerated at 4 – 25 °C.
Humidity, light and other environmental factors:	Keep away from heat sources.
Containers:	Keep individual bottles tightly capped.
Other storage precautions:	Keep away from food and drinks.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### 8.1 Exposure limit values

TLV/TWA:	Not available
TLV/STEL:	Not available
LV EU:	Not available

### 8.2 Personal Protective Equipment (PPE) and Handling

Eye protection:	Safety glasses.
Hand protection:	Plastic gloves.
Other protective systems:	Personal protective equipment (PPE) useful for reducing individual exposure.
Environmental protection:	Avoid any release into the environment.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 General information Appearance: Powder

Powder Odor:	Characteristic odor
Color:	White to light yellow

### 9.2 Important health, safety and environmental information

Value Related to pH:	Not applicable
Boiling point/range:	Not applicable
Flash point:	Not applicable
Vapor pressure:	Not applicable
Density:	Not applicable
Water Solubility:	Completely miscible
Evaporation rate:	Not available

### 9.3 Other information

Melting point/range:	Not available
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### 10. STABILITY AND REACTIVITY INFORMATION

10.1 Stability: The product is stable until the expiration date shown on the box and on the labels when stored at 4 - 25°C.  
Pepsin powder is somewhat hygroscopic

10.1 Reactivity: No known self-polymerization or self-decomposition when stored as recommended.

10.3 Other: **Hazardous Decomposition Products:**  
Burning may produce carbon monoxide, carbon dioxide, nitrogen oxides.  
**Incompatibilities:**  
Tannin, alkalis, salts of heavy metals, strong oxidizers.  
**Conditions to Avoid:**  
Moisture, heat, flames, ignition sources and incompatibles.

### 11. TOXICOLOGICAL INFORMATION

No LD50/LC50 information found relating to normal routes of occupational exposure. Investigated as a mutagen.

---NTP Carcinogen---

Ingredient	Known	Anticipated	IARC Category
Pepsin A (9001-75-6)	No	No	None

#### 11.1 Toxicokinetic effects (ADME)

Absorption: No data available

11.2 Acute toxicity Value mu. No data available

#### 11.3 Irritation (See §2)

Skin: Causes irritation

Inhalation: Causes respiratory sensitivity

Eye: Causes Eye irritation

#### 11.4 Sensitization:

Skin sensitization: Not available

Sensitization by inhalation: Not available

#### 11.5 Prolonged exposure toxicity:

Micronucleus test: Not available

Teratogenesis: Not available

Carcinogenesis: Not available

### 12. ECOLOGICAL INFORMATION

12.1 Ecotoxicology:	Not known
12.2 Mobility:	Not available
12.3 Persistency and degradability:	Pepsin powder is readily biodegradable
12.4 Bioaccumulation potential:	Not available
12.5 Evaluation PBT result:	Not available
12.6 Other toxic effects:	Not available

### 13. DISPOSAL CONSIDERATIONS

No special disposal method is required. Used waste product, surplus product or spillage products shall be disposed of in accordance with national, state and local laws.

### 14. TRANSPORT INFORMATION

Not classified for transport in accordance with ADR/RID, IMDG, IATA and DOT regulations.

### 15. REGULATORY INFORMATION

The active ingredients and all components of the enzyme preparation are listed on the TSCA Inventory.

SARA 311/312: Acute: Yes , Chronic: No , Fire: No , Pressure: No , Reactivity: No (Pure / Solid)

### 16. OTHER INFORMATION

The contained information in this Safety Data Sheet (SDS) are in accordance with OSHA "Hazard Communication Standard" (HCS) under 29CFR 1910.1200(g) and EU Regulation No 1272/2008.

#### Bibliographic references:

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EC1272/2008

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Revision Date: 2017/06/15

### 1. IDENTIFICATION OF THE MIXTURE AND THE COMPANY

#### 1.1 Identification of the mixture

Product Name: **Daily Rinse/Cleaning Diluent**      Product Number: **Part of Ref. No. 5421**

#### 1.2 Use of the mixture: Activation of pepsin powder for cleaning the fluid path of the ISE Module.

For in vitro diagnostic use

#### 1.3 Company identification:

Address	Medica Corporation
	5 Oak Park Drive
	Bedford MA 01730 USA
Phone	+1-800-777-5983 or +1-781-275-4892
Email	sds@medicacorp.com
Website	www.medicacorp.com
FAX	+1-781-275-2731

### 2. HAZARDS IDENTIFICATION

2.1 Mixture classification (see also § 15)      Not Hazardous

2.2 Hazards not otherwise classified:      Not available

2.3 Mixture ingredients of unknown toxicity:      None

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Composition: Liquid containing inorganic components only.

#### 3.1 Hazardous Components:

Name	EINECS/ ELINCS No.	CAS No.	Conc. % w/w	Classification 1272/2008/EC
Hydrochloric Acid 0.2N	231-595-7	7647-01-0	0.73%	Not Classified
Water		732-18-5	99%	Not Classified

### 4. FIRST AID MEASURES

- Ingestion:**      If swallowed rinse mouth with plenty of water provided person is conscious. Get medical advice if adverse symptoms appear.
- Inhalation exposure:**      Not Applicable
- Contact with skin:**      Remove contaminated clothes and shoes. Wash affected area with plenty of water. Get medical advice if adverse symptoms appear.
- Contact with eyes:**      Wash immediately with plenty of water or normal saline. Keep eyelid open with the finger. Get medical advice if adverse symptoms appear.

### 5. FIRE FIGHTING MEASURES

Aqueous solution is not flammable.

Suitable extinguishing means: Use any means suitable for extinguishing surrounding fire.

Mean of extinguishing NOT to be used: Not applicable

Known hazards caused by combustion: Not considered to be a fire or explosion hazard.

Equipment for self-protection: Standard equipment.

### 6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Plastic gloves and safety glasses.

Environmental precautions: No special requirements

Cleaning procedure to recover spilled material: Soak up with inert absorbent material, and clean with plenty of water.

### 7. HANDLING AND STORAGE

#### 7.1 Handling

Handling procedures: Wear suitable protective clothing, gloves, eye protection. When use do not eat or drink.

Work/Hygienic practices: Wash hands with soap and water after use.

#### 7.2 Storage

Room ventilation: Well ventilated workplace.

Special precautions: (see also § 8) Avoid environmental release.

Recommended temperature: Store at 4 – 25 °C.

Humidity, light and other environmental factors: No limitations

Containers: Keep individual bottles closed tightly.

Other storage precautions: Keep away from food and drinks.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### 8.1 Exposure limit values

TLV/TWA: Not available

TLV/STEL: Not available

LV EU: Not available

#### 8.2 Personal Protective Equipment (PPE) and Handling

Eye protection: Safety glasses.

Hand protection: Plastic gloves.

Other protective systems: Personal protective equipment (PPE) useful for reducing individual exposure.

Environmental protection: Avoid any release into the environment.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

#### 9.1 General information Appearance: Aqueous solution

Appearance:	Liquid
Odor:	Odorless
Color:	Colorless

#### 9.2 Important health, safety and environmental information

Value Related to pH:	2 at 25° C
Boiling point/range:	Not available
Flash point:	Not available
Vapor pressure:	Not available
Density:	1.0 g/cm <sup>3</sup> at 25° C
Solubility:	Completely miscible
Water Solubility:	Completely miscible
Mixture Viscosity:	Not available
Vapor density:	Not available
Evaporation rate:	Not available

#### 9.3 Other information

Melting point/range:	Not available
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### 10. STABILITY AND REACTIVITY INFORMATION

Stability: The product is stable until the expiration date shown on the box and on the labels when stored at 4 - 25°C.

10.1 Conditions to avoid:	Not known.
10.2 Materials to avoid:	Strong oxidizing agents, strong bases, strong acids.
10.3 Hazardous decomposition products:	Not known.

### 11. TOXICOLOGICAL INFORMATION

#### 11.1 Toxicokinetic effects (ADME)

Absorption: No data available

11.2 Acute toxicity Value mu. No data available

#### 11.3 Irritation Skin:

Skin: May cause skin irritation

Eye: May cause eye irritation

Ingestion: Not known

#### 11.4 Sensitization:

Skin sensitization: Not available

Sensitization by inhalation: Not available

11.5 Prolonged exposure toxicity: Not available

### 12. ECOLOGICAL INFORMATION

12.1 Ecotoxicology: Not known

12.2 Mobility: Not available

12.3 Persistency and degradability: Not available

12.4 Bioaccumulation potential: Not available

12.5 Evaluation PBT results: Not available

12.6 Other toxic effects: Not available

### 13. DISPOSAL CONSIDERATIONS

National laws on disposal must be considered, local and UE requirements for wastes recycling must be respected. Used waste product, surplus product or spillage products shall be disposed of in accordance with national, state and local laws.

### 14. TRANSPORT INFORMATION

Not classified for transport in accordance with ADR/RID, IMDG, IATA and DOT regulations.

### 15. REGULATORY INFORMATION

The active ingredients and all components of the diluent solution are listed on the TSCA Inventory.

### 16. OTHER INFORMATION

The contained information in this Safety Data Sheet (SDS) are in accordance with OSHA "Hazard Communication Standard" (HCS) under 29CFR 1910.1200(g) and EU Regulation No 1272/2008.

**Bibliographic references:**

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EC1272/2008

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End of SDS