

1. IDENTIFICATION OF THE MIXTURE AND THE COMPANY

1.1 Identification of the mixture

Product Name: **ISE Module Reagent Pack** Product Number: **5425-0000, 5425-0030, 5425-0057, 5425-0104**

1.2 Use of the Product: To calibrate and retain waste of ISE 4 Channel 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

Note:

The SDS does not address the hazards associated with the waste after use, which combines both mixtures listed as well as the biological fluids used during analysis. A BIOHAZARD label is provided to the end user that should be affixed to the solutions pack prior to use with the ISE 4 Channel Module.

Mixture name: Solution Pack ISE Module Na/K/Cl/Li	Mixture classification According to 67/548/EED and 1999/45/EEC directives	Mixture classification According to 1272/2008/EC regulation	Kit configuration
Standard A Solution	Not Classified	Not Classified	400 ml
Standard B Solution	Not Classified	Not Classified	300 ml

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.

1. IDENTIFICATION OF THE MIXTURE AND THE COMPANY

1.1 Identification of the mixture

Product Name: **Standard A** Product Number: **Part of 5425-0000, 5425-0030, 5425-0057, 5425-0104**

1.2 Use of the Product: To calibrate ISE 4 Channel 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
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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: Not applicable

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Hazardous/Non-Hazardous Components:

Name	EINECS/ ELINCS No.	CAS No.	Conc. % w/w	Classification 1272/2008/EC
Standard A Solution	Not listed	Not listed		Not Classified
Sodium chloride	231-598-3	7647-14-5	0.82%	Not listed
Potassium chloride	231-211-8	7447-40-7	<0.1%	Not listed
Lithium chloride	231-212-3	7447-4-8	<0.1%	Not listed
Goods Buffer	Not listed	Not listed	<1%	Not listed
Water		732-18-5	98%	Not listed

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: TLV (US): 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: Aqueous saline solution

Appearance: Liquid
 Odor: Odorless
 Color: Colorless

9.2 Important health, safety and environmental information

Value Related to pH: 7.5 at 25° C
 Boiling point/range: Not available
 .Flash point: Not available
 .Vapor pressure: Not available
 .Density: 1.0 g/cm³ 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

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: Not established
 Eye: Not established
 Inhalation: Not applicable

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:	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 standard A solution are not 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

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Revision Date: 2017/07/05

1. IDENTIFICATION OF THE MIXTURE AND THE COMPANY

1.1 Identification of the mixture

Product Name: **Standard B** Product Number: **Part of 5425-0000, 5425-0030, 5425-0057, 5425-0104**

1.2 Use of the Product: To calibrate the ISE 4 Channel Module.
For In-vitro diagnostic use.

1.3 Company identification:

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	Bedford MA 01730 USA
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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: Not applicable

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Hazardous/Non-Hazardous Components:

Name	EINECS/ ELINCS No.	CAS No.	Conc. % w/w	Classification 1272/2008/EC
Standard B Solution	Not listed	Not listed		Not Classified
Sodium chloride	231-598-3	7647-14-5	0.2%	Not listed
Potassium chloride	231-211-8	7447-40-7	<1%	Not listed
Lithium chloride	231-212-3	7447-4-8	<1%	Not listed
Goods Buffer	Not listed	Not listed	<0.1%	Not listed
			<1%	Not listed
Water		732-18-5	98%	Not listed

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: TLV (US): 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: Aqueous saline solution

Appearance: Liquid
Odor: Odorless
Color: Colorless

9.2 Important health, safety and environmental information

Value Related to pH: 6.8 at 25° C
Boiling point/range: Not available
Flash point: Not available
Vapor pressure: Not available
Density: 1.0 g/cm³ 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

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: Not established

Eye: Not established

Inhalation: Not applicable

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:	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 standard B solution are not 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.

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End of SDS