

MATERIAL SAFETY DATA SHEET

EASYLYTE SOLUTIONS PACK, NA⁺/K⁺/Li⁺

FILE NO.: 2122-A
MSDS DATE: 30/09/13

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: EASYLYTE SOLUTIONS PACK NA⁺/K⁺/Li⁺
SYNONYMS: N/A
PRODUCT CODES: 2122, L2122, F2122

MANUFACTURER: Medica Corporation
DIVISION: USA
ADDRESS: 5 Oak Park Dr., Bedford, MA 01730 USA

EMERGENCY PHONE: 781-275-4892
OTHER CALLS: 781-275-4892
FAX PHONE: 781-275-2731
EMAIL: pmakris@medicacorp.com

PRODUCT USE: Solution for in-vitro diagnostic use

SECTION 2: COMPOSITION/INFORMATION ON INGREDIENTS

<u>P/N</u>	<u>Mixture Name</u>	<u>Mixture Classification</u> According to 67/548/EEC and 1999/45/EEC Directives	<u>Mixture Classification</u> According to 1272/2008/EC Regulation	<u>Kit Configuration</u>
2122, L2122, or F2122	EasyLyte Solutions Pack - NA⁺/K⁺/Li⁺ Standard A Solution Standard B Solution Wash Solution	 Not Classified Not Classified Xi; R36/R38	 Not Classified Not Classified Skin Irritant 2, H315 Eye Irritant 2, H319	 800mL 180mL 80mL

SECTION 2 NOTES: 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.

MATERIAL SAFETY DATA SHEET

EASYLYTE SOLUTIONS PACK, NA⁺/K⁺/Li⁺

FILE NO.: 2122-A
MSDS DATE: 30/09/13

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: STANDARD A SOLUTION
SYNONYMS: N/A
PRODUCT CODES: NOT APPLICABLE

MANUFACTURER: Medica Corporation
DIVISION: USA
ADDRESS: 5 Oak Park Dr., Bedford, MA 01730 USA

EMERGENCY PHONE: 781-275-4892
OTHER CALLS: 781-275-4892
FAX PHONE: 781-275-2731
EMAIL: pmakris@medicacorp.com

PRODUCT USE: Solution for in-vitro diagnostic use

SECTION 2: HAZARD IDENTIFICATION

2.1 MIXTURE CLASSIFICATION

CLASSIFIED: NOT DANGEROUS According to 67/548/EEC and 1999/45/EEC Directives

CLASSIFIED: NOT HAZARDOUS According to 1272/2008/EC Regulation

2.2 POTENTIAL HEALTH AND ENVIRONMENTAL EFFECTS

INGESTION: MAY BE HARMFUL IF SWALLOWED

INHALATION: MAY CAUSE IRRITATION

SKIN CONTACT: MAY CAUSE IRRITATION

EYE CONTACT: MAY CAUSE IRRITATION

SENSITIZATION: MAY CAUSE SENSITIZATION BY INHALATION OR SKIN CONTACT

ENVIRONMENTAL EXPOSURE: MIGHT CAUSE ADVERSE EFFECTS FOR THE ENVIRONMENT

SECTION 3: COMPOSITION/INGREDIENTS

COMPOSITION: LIQUID CONTAINING ORGANIC AND INORGANIC COMPONENTS

3.1 HAZARDOUS COMPONENTS:

<u>NAME</u>	<u>EINECS/ELINCS NO.</u>	<u>CAS NO.</u>	<u>CONC. % W/W</u>	<u>CLASSIFICATION</u> <u>67/548/EEC</u>	<u>CLASSIFICATION</u> <u>1272/2008/EEC</u>
LITHIUM CHLORIDE	231-212-3	7447-41-8	< 0.01%	Xi, R36/R38	Eye Irrit. 2, H319 Skin Irrit. 2, H315

For exposure limits see ch. 8, for phrases R and hazard statements text see ch. 16

SECTION 4: FIRST AID MEASURES

EYES: Wash immediately with plenty of water or normal saline. Keep eyelid open with the finger. Get medical advice if adverse symptoms appear.

SKIN: Remove contaminated clothes and shoes. Wash affected area with soap or mild detergent and plenty of water. Get medical advice if adverse symptoms appear.

INGESTION: If swallowed rinse mouth with plenty of water provided person is conscious. Get medical advice if adverse symptoms appear.

INHALATION: If inhaled, move person to fresh air. Get medical advice if adverse symptoms appear.

SECTION 5: FIRE-FIGHTING MEASURES

Suitable extinguishing means: Water spray or regular foam, CO2, 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 (including COx, NOx, HCl, Na2O).

Equipment for self-protection: (fire fighters): Self-contained breathing apparatus, flame and chemical resistant clothing, boots, gloves.

SECTION 6: ACCIDENTAL RELEASE MEASURES

ACCIDENTAL RELEASE MEASURES:

Personal precautions: Suitable protective clothing, rubber or polythene gloves, rubber shoes, safety glasses.

Environmental precautions: Do not let the product enter drainage system, surface and ground-water or soil. Contact local authorities in case of environmental release. Do not empty into drains.

Cleaning procedure to recover spilled material: Soak up with inert absorbent material, and clean with plenty of water. Send to the storage waiting for disposal procedures.

SECTION 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 Section 8) Avoid environmental release.

Recommended temperature: Store at 18 – 25 °C.

Humidity, light and other environmental factors: Avoid light exposure and keep away from heat sources and non compatible materials.

Containers: Keep containers tightly closed and labeled with the name of the product.

Other storage precautions: Keep away from food and drinks.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 EXPOSURE LIMIT VALUES

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

8.2 EXPOSURE CONTROLS

Respiratory protection: Respiratory protection is not required. Where risk assessment shows air-purifying respirators are appropriate, use masks with approved filter.

Skin protection: Protective clothing, rubber or polythene gloves.

Eye protection: Safety glasses.

Hand protection: Rubber or polythene gloves.

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

Environmental protection: Avoid any release into the environment.

MATERIAL SAFETY DATA SHEET

EASYLYTE SOLUTIONS PACK, $\text{Na}^+/\text{K}^+/\text{Li}^+$

FILE NO.: 2122-A
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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 GENERAL INFORMATION

Appearance: Liquid
Odor: Odorless
Color: Colorless

9.2 IMPORTANT HEALTH, SAFETY AND ENVIRONMENTAL INFORMATION

	VALUE	RELATED TO
pH:	7.4 at 25° C	Mixture
Boiling point/range:	not available	
Flash point:	not available	
Vapor pressure:	not available	
Density:	1.0 g/cm ³ at 25° C	Mixture
Solubility:	not available	
Water Solubility:	Completely miscible	Mixture
Viscosity:	not available	
Vapor density:	not available	
Evaporation rate:	not available	
Melting point/range:	not available	

SECTION 10: STABILITY AND REACTIVITY

STABILITY: The product is stable until the expiration date shown on the box and on the labels when stored at 18 - 25°C.

- 10.1** Conditions to avoid: Keep away from heat and light.
- 10.2** Materials to avoid: Strong oxidizing agents, strong bases, strong acids.
- 10.3** Hazardous decomposition products: Thermal decomposition or combustion may include toxic and hazardous fumes (including CO_x , NO_x , HCl, Na_2O).

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 TOXICOKINETIC EFFECTS (ADME)

Absorption: In a study employing human volunteers exposed to lithium chloride in spa water at concentrations of 40 ppm for 20 minutes/day, five days/week for two consecutive weeks, it was concluded that lithium is not absorbed through the skin during spa use. Li^+ is absorbed readily and almost completely from the gastrointestinal tract and may also be absorbed via the lungs. Complete absorption occurs in about 8 hours, with peak concentration in plasma occurring 2-4 hours after an oral dose. ⁽¹⁾

Distribution: Li^+ initially is distributed in the extra cellular fluid and then gradually accumulates in various tissues (with higher levels in kidney, thyroid, and bone). The ion does not bind appreciably to plasma proteins. ⁽¹⁾

Metabolism: Lithium is not metabolized or bioaccumulated in mammals. ⁽²⁾

Excretion: Approximately 95% of a single dose of Li^+ is eliminated in the urine, less than 1% in the feces, and 4 - 5% in the sweat. Lithium crosses the placenta and is excreted in breast milk, breast milk levels being approximately 50% of that of maternal serum. ⁽¹⁾

11.2 ACUTE TOXICITY

	VALUE	M.U.	EFFECTS	RELATED TO
Oral:	LD50 (rat) = 526 - 840	mg/Kg		Lithium chloride
Dermal:	LD50 (rat) = 1,488	mg/Kg		Lithium chloride
Inhalation:	LC50 (rat) = not available	mg/ml/4h		
Other data:	LDLo human = 200	mg/Kg/3 day	Somnolence, muscle weakness, muscle contraction or spasticity	Lithium chloride

MATERIAL SAFETY DATA SHEET

EASYLYTE SOLUTIONS PACK, $\text{Na}^+/\text{K}^+/\text{Li}^+$

FILE NO.: 2122-A
MSDS DATE: 30/09/13

11.3 IRRITATION

Skin: Lithium chloride was found to be irritating in the rabbit acute toxicity testing of the skin.
Eye: Lithium chloride was moderately irritating in the Draize test in rabbit eyes when dosed at 0.10 g. (1)
Inhalation: not available

11.4 SENSITIZATION:

Skin sensitization: not available
Sensitization by inhalation: not available

11.5 PROLONGED EXPOSURE TOXICITY: Prolonged absorption of Lithium chloride may affect electrolyte balance and impair kidney function; dehydration, weight loss, skin effects, and thyroid disturbances have been reported. Chronic exposure to lithium salts may cause drowsiness, visual abnormalities, weakness, ringing in the ears, and muscle tremors, mental confusion. Target organs of Lithium chloride: thyroid, cardiovascular system, kidneys, central nervous system. (2)

11.6 CMR

EFFECTS

RELATED TO

Mutagenicity:	Ames test: Negative (1) Mouse lymphoma: not available Chromosomal aberration: When administered to mice at 0.21 - 21.25 mg/kg bw, Lithium chloride induced chromosomal aberrations, but not sister chromatid exchanges. (1)	Lithium chloride Lithium chloride
Micronucleus test:	not available	
Teratogenesis:	When administered intraperitoneal to rats, Lithium chloride produced effects on fertility (effects on mating performance, post implantation mortality, abortion, effects on litter size), effects on embryo, fetus or newborn (fetal death, physical biochemical or metabolic effects on newborn), specific developmental abnormalities (craniofacial). (1) In studies in mice, observed offspring developmental toxicity was a consequence of maternal exposure to lithium salts and breast feeding. (1)	
Carcinogenesis:	not available	

SECTION 12: ECOLOGICAL INFORMATION

12.1	ECOTOXICOLOGY	VALUE	M.U.	RELATED TO
	Acute toxicity with fish:	LC50 Ptychocheilus lucius = 17	mg/l/96 hours (4)	Lithium chloride
	Acute toxicity with Daphnia Magna:	EC50 = not available	mg/l/48 hours	
	Acute toxicity with algae:	EC50 = not available	mg/l/72 hours	
12.2	MOBILITY:	Lithium chloride is soluble and dissociates in aqueous environment. Lithium ion occurs naturally in soil, water and air. Its stability in soil and water is based on the fact that lithium ion can not be further degraded. (2)		
12.3	PERSISTENCY AND DEGRADABILITY:	Lithium chloride exists as the inorganic ions of lithium and chloride. (2) Lithium is not regarded as having adverse effects on the environment. (5)		
12.4	BIOACCUMULATION POTENTIAL:	Lithium is mainly found on ion form in the environment and is not expected to bioaccumulate. (5)		
12.5	EVALUATION PBT RESULT:	not available		
12.6	OTHER TOXIC EFFECTS:	not available		

SECTION 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

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SECTION 14: TRANSPORT INFORMATION

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

SECTION 15: REGULATORY INFORMATION

	According to 67/548/EEC and 1999/45/EEC Directives Not classified as dangerous	According to 1272/2008/EC Regulation Not classified as hazardous
Classification:		
Labeling symbols: (signal word)	None	None
Labeling risk phrases: (hazard statements)	None	None
Labeling safety phrases: (precautionary statements)	None	None

Regulatory information on labeling according to 67/548/EEC, to 1999/45/EEC Directive and to 1272/2008 Regulation (EC)(European reinforcement of GHS), and according to their following amendments/atp.

Other labeling details:	≈1.2 % percent of this mixture consist of ingredient(s) of unknown toxicity for health and aquatic environment.
Safety precautions:	Wear suitable protective clothing, gloves and eye/face protection.
Authorization:	no
Restriction:	no

SECTION 16: OTHER INFORMATION

Phrases R:	R36/38: Irritating to eyes and skin.
Hazard Statements:	H319: Causes serious eye irritation. H315: Causes skin irritation.

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.

Bibliographic references:

- (1) Hazardous Substances Data Bank (HSDB), Lithium chloride, HSN: 4281.
- (2) IUCLID data set for Lithium Chloride, 19-feb-2000.
- (3) National Institute for Occupational Safety and Health, Lithium Chloride, RTECS n. OJ5950000, The Registry of Toxic Effects of Chemical Substances.
- (4) Sigma Aldrich, Lithium chloride, MSDS, Revision date: 15.07.2007.
- (5) <http://www2.mst.dk/Udgiv/publications>, Datasheet for the 11 metals, Danish Environmental Protection Agency, Lithium.

MATERIAL SAFETY DATA SHEET

EASLYTE SOLUTIONS PACK, $\text{Na}^+/\text{K}^+/\text{Li}^+$

FILE NO.: 2122-A
MSDS DATE: 30/09/13

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: STANDARD B SOLUTION
SYNONYMS: N/A
PRODUCT CODES: NOT APPLICABLE

MANUFACTURER: Medica Corporation
DIVISION: USA
ADDRESS: 5 Oak Park Dr., Bedford, MA 01730 USA

EMERGENCY PHONE: 781-275-4892
OTHER CALLS: 781-275-4892
FAX PHONE: 781-275-2731
EMAIL: pmakris@medicacorp.com

PRODUCT USE: Solution for in-vitro diagnostic use

SECTION 2: HAZARD IDENTIFICATION

2.1 MIXTURE CLASSIFICATION

CLASSIFIED: NOT DANGEROUS According to 67/548/EEC and 1999/45/EEC Directives
CLASSIFIED: NOT HAZARDOUS According to 1272/2008/EC Regulation

2.2 POTENTIAL HEALTH AND ENVIRONMENTAL EFFECTS

INGESTION: MAY BE HARMFUL IF SWALLOWED
INHALATION: MAY CAUSE IRRITATION
SKIN CONTACT: MAY CAUSE IRRITATION
EYE CONTACT: MAY CAUSE IRRITATION
SENSITIZATION: MAY CAUSE SENSITIZATION BY INHALATION OR SKIN CONTACT
ENVIRONMENTAL EXPOSURE: MIGHT CAUSE ADVERSE EFFECTS FOR THE ENVIRONMENT

SECTION 3: COMPOSITION/INGREDIENTS

COMPOSITION: LIQUID CONTAINING ORGANIC AND INORGANIC COMPONENTS

3.1 HAZARDOUS COMPONENTS:

<u>NAME</u>	<u>EINECS/ELINCS NO.</u>	<u>CAS NO.</u>	<u>CONC. % W/W</u>	<u>CLASSIFICATION</u> <u>67/548/EEC</u>	<u>CLASSIFICATION</u> <u>1272/2008/EEC</u>
LITHIUM CHLORIDE	231-212-3	7447-41-8	< 0.01%	Xi, R36/R38	Eye Irrit. 2, H319 Skin Irrit. 2, H315

For exposure limits see ch. 8, for phrases R and hazard statements text see ch. 16

SECTION 4: FIRST AID MEASURES

EYES: Wash immediately with plenty of water or normal saline. Keep eyelid open with the finger. Get medical advice if adverse symptoms appear.

SKIN: Remove contaminated clothes and shoes. Wash affected area with soap or mild detergent and plenty of water. Get medical advice if adverse symptoms appear.

INGESTION: If swallowed rinse mouth with plenty of water provided person is conscious. Get medical advice if adverse symptoms appear.

INHALATION: If inhaled, move person to fresh air. Get medical advice if adverse symptoms appear.

MATERIAL SAFETY DATA SHEET

EASYLYTE SOLUTIONS PACK, $\text{Na}^+/\text{K}^+/\text{Li}^+$

FILE NO.: 2122-A
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SECTION 5: FIRE-FIGHTING MEASURES

Suitable extinguishing means: Water spray or regular foam, CO₂, 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 (including CO_x, NO_x, HCl, Na₂O).

Equipment for self-protection: (fire fighters): Self-contained breathing apparatus, flame and chemical resistant clothing, boots, gloves.

SECTION 6: ACCIDENTAL RELEASE MEASURES

ACCIDENTAL RELEASE MEASURES:

Personal precautions: Suitable protective clothing, rubber or polythene gloves, rubber shoes, safety glasses.

Environmental precautions: Do not let the product enter drainage system, surface and ground-water or soil. Contact local authorities in case of environmental release. Do not empty into drains.

Cleaning procedure to recover spilled material: Soak up with inert absorbent material, and clean with plenty of water. Send to the storage waiting for disposal procedures.

SECTION 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.

7.2 STORAGE

Room ventilation: Well ventilated workplace.

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

Recommended temperature: Store at 18 – 25 °C.

Humidity, light and other environmental factors: Avoid light exposure and keep away from heat sources and non compatible materials.

Containers: Keep containers tightly closed and labeled with the name of the product.

Other storage precautions: Keep away from food and drinks.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 EXPOSURE LIMIT VALUES

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

8.2 EXPOSURE CONTROLS

Respiratory protection: Respiratory protection is not required. Where risk assessment shows air-purifying respirators are appropriate, use masks with approved filter.

Skin protection: Protective clothing, rubber or polythene gloves.

Eye protection: Safety glasses.

Hand protection: Rubber or polythene gloves.

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

Environmental protection: Avoid any release into the environment.

MATERIAL SAFETY DATA SHEET

EASYLYTE SOLUTIONS PACK, $\text{Na}^+/\text{K}^+/\text{Li}^+$

FILE NO.: 2122-A
MSDS DATE: 30/09/13

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 GENERAL INFORMATION

Appearance: Liquid
Odor: Odorless
Color: Colorless

9.2 IMPORTANT HEALTH, SAFETY AND ENVIRONMENTAL INFORMATION

	VALUE	RELATED TO
pH:	7.4 at 25° C	Mixture
Boiling point/range:	not available	
Flash point:	not available	
Vapor pressure:	not available	
Density:	1.0 g/cm ³ at 25° C	Mixture
Solubility:	not available	
Water Solubility:	Completely miscible	Mixture
Viscosity:	not available	
Vapor density:	not available	
Evaporation rate:	not available	
Melting point/range:	not available	

SECTION 10: STABILITY AND REACTIVITY

STABILITY: The product is stable until the expiration date shown on the box and on the labels when stored at 18 - 25°C.

- 10.1** Conditions to avoid: Keep away from heat and light.
- 10.2** Materials to avoid: Strong oxidizing agents, strong bases, strong acids.
- 10.3** Hazardous decomposition products: Thermal decomposition or combustion may include toxic and hazardous fumes (including CO_x , NO_x , HCl , Na_2O).

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 TOXICOKINETIC EFFECTS (ADME)

Absorption: In a study employing human volunteers exposed to lithium chloride in spa water at concentrations of 40 ppm for 20 minutes/day, five days/week for two consecutive weeks, it was concluded that lithium is not absorbed through the skin during spa use. Li^+ is absorbed readily and almost completely from the gastrointestinal tract and may also be absorbed via the lungs. Complete absorption occurs in about 8 hours, with peak concentration in plasma occurring 2-4 hours after an oral dose. ⁽¹⁾

Distribution: Li^+ initially is distributed in the extra cellular fluid and then gradually accumulates in various tissues (with higher levels in kidney, thyroid, and bone). The ion does not bind appreciably to plasma proteins. ⁽¹⁾

Metabolism: Lithium is not metabolized or bioaccumulated in mammals. ⁽²⁾

Excretion: Approximately 95% of a single dose of Li^+ is eliminated in the urine, less than 1% in the feces, and 4 - 5% in the sweat. Lithium crosses the placenta and is excreted in breast milk, breast milk levels being approximately 50% of that of maternal serum. ⁽¹⁾

11.2 ACUTE TOXICITY

	VALUE	M.U.	EFFECTS	RELATED TO
Oral:	LD50 (rat) = 526 - 840	mg/Kg		Lithium chloride
Dermal:	LD50 (rat) = 1,488	mg/Kg		Lithium chloride
Inhalation:	LC50 (rat) = not available	mg/ml/4h		
Other data:	LDLo human = 200	mg/Kg/3 day	Somnolence, muscle weakness, muscle contraction or spasticity	Lithium chloride

MATERIAL SAFETY DATA SHEET

EASYLYTE SOLUTIONS PACK, $\text{Na}^+/\text{K}^+/\text{Li}^+$

FILE NO.: 2122-A
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11.3 IRRITATION

Skin: Lithium chloride was found to be irritating in the rabbit acute toxicity testing of the skin.
Eye: Lithium chloride was moderately irritating in the Draize test in rabbit eyes when dosed at 0.10 g. (1)
Inhalation: not available

11.4 SENSITIZATION:

Skin sensitization: not available
Sensitization by inhalation: not available

11.5 PROLONGED EXPOSURE TOXICITY: Prolonged absorption of Lithium chloride may affect electrolyte balance and impair kidney function; dehydration, weight loss, skin effects, and thyroid disturbances have been reported. Chronic exposure to lithium salts may cause drowsiness, visual abnormalities, weakness, ringing in the ears, and muscle tremors, mental confusion. Target organs of Lithium chloride: thyroid, cardiovascular system, kidneys, central nervous system. (2)

11.6 CMR

EFFECTS

RELATED TO

Mutagenicity: Ames test: Negative (1)
Mouse lymphoma: not available
Chromosomal aberration: When administered to mice at 0.21 - 21.25 mg/kg Lithium chloride induced chromosomal aberrations, but not sister chromatid exchanges. (1)
Lithium chloride

Micronucleus test: not available

Teratogenesis: When administered intraperitoneal to rats, Lithium chloride produced effects on fertility (effects on mating performance, post implantation mortality, abortion, effects on litter size), effects on embryo, fetus or newborn (fetal death, physical biochemical or metabolic effects on newborn), specific developmental abnormalities (craniofacial). (1) In studies in mice, observed offspring developmental toxicity was a consequence of maternal exposure to lithium salts and breast feeding. (1)

Carcinogenesis: not available

SECTION 12: ECOLOGICAL INFORMATION

12.1	ECOTOXICOLOGY	VALUE	M.U.	RELATED TO
	Acute toxicity with fish:	LC50 <i>Ptychocheilus lucius</i> = 17	mg/l/96 hours (4)	Lithium chloride
	Acute toxicity with <i>Daphnia</i> Magna:	EC50 = not available	mg/l/48 hours	
	Acute toxicity with algae:	EC50 = not available	mg/l/72 hours	
12.2	MOBILITY:	Lithium chloride is soluble and dissociates in aqueous environment. Lithium ion occurs naturally in soil, water and air. Its stability in soil and water is based on the fact that lithium ion can not be further degraded. (2)		
12.3	PERSISTENCY AND DEGRADABILITY:	Lithium chloride exists as the inorganic ions of lithium and chloride. (2) Lithium is not regarded as having adverse effects on the environment. (5)		
12.4	BIOACCUMULATION POTENTIAL:	Lithium is mainly found on ion form in the environment and is not expected to bioaccumulate. (5)		
12.5	EVALUATION PBT RESULT:	not available		
12.6	OTHER TOXIC EFFECTS:	not available		

SECTION 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

SECTION 14: TRANSPORT INFORMATION

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

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FILE NO.: 2122-A
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SECTION 15: REGULATORY INFORMATION

	According to 67/548/EEC and 1999/45/EEC Directives	According to 1272/2008/EC Regulation
Classification:	Not classified as dangerous	Not classified as hazardous
Labeling symbols: (signal word)	None	None
Labeling risk phrases: (hazard statements)	None	None
Labeling safety phrases: (precautionary statements)	None	None

Regulatory information on labeling according to 67/548/EEC, to 1999/45/EEC Directive and to 1272/2008 Regulation (EC)(European reinforcement of GHS), and according to their following amendments/atp.

Other labeling details:	≈1.2 % percent of this mixture consist of ingredient(s) of unknown toxicity for health and aquatic environment.
Safety precautions:	Wear suitable protective clothing, gloves and eye/face protection.
Authorization:	no
Restriction:	no

SECTION 16: OTHER INFORMATION

Phrases R:	R36/38: Irritating to eyes and skin.
Hazard Statements:	H319: Causes serious eye irritation. H315: Causes skin irritation.

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.

Bibliographic references:

- (1) Hazardous Substances Data Bank (HSDB), Lithium chloride, HSN: 4281.
- (2) IUCLID data set for Lithium Chloride, 19-feb-2000.
- (3) National Institute for Occupational Safety and Health, Lithium Chloride, RTECS n. OJ5950000, The Registry of Toxic Effects of Chemical Substances.
- (4) Sigma Aldrich, Lithium chloride, MSDS, Revision date: 15.07.2007.
- (5) <http://www2.mst.dk/Udgiv/publications>, Datasheet for the 11 metals, Danish Environmental Protection Agency, Lithium.

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EASLYTE SOLUTIONS PACK, $\text{Na}^+/\text{K}^+/\text{Li}^+$

FILE NO.: 2122-A
MSDS DATE: 30/09/13

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: WASH SOLUTION
SYNONYMS: N/A
PRODUCT CODES: NOT APPLICABLE

MANUFACTURER: Medica Corporation
DIVISION: USA
ADDRESS: 5 Oak Park Dr., Bedford, MA 01730 USA

EMERGENCY PHONE: 781-275-4892
OTHER CALLS: 781-275-4892
FAX PHONE: 781-275-2731
EMAIL: pmakris@medicacorp.com

PRODUCT USE: Solution for in-vitro diagnostic use

SECTION 2: HAZARD IDENTIFICATION

2.1 MIXTURE CLASSIFICATION

CLASSIFIED: Xi, R36/R38 According to 67/548/EEC and 1999/45/EEC Directives

CLASSIFIED: Skin Irrit. 2, H315 – Eye Irrit. 2, H319 According to 1272/2008/EC Regulation

2.2 POTENTIAL HEALTH AND ENVIRONMENTAL EFFECTS

INGESTION: MAY BE HARMFUL IF SWALLOWED

INHALATION: MAY CAUSE IRRITATION

SKIN CONTACT: CAUSES IRRITATION

EYE CONTACT: CAUSES SERIOUS EYE IRRITATION

SENSITIZATION: MAY CAUSE SENSITIZATION BY INHALATION OR SKIN CONTACT

ENVIRONMENTAL EXPOSURE: MIGHT CAUSE ADVERSE EFFECTS FOR THE ENVIRONMENT

SECTION 3: COMPOSITION/INGREDIENTS

COMPOSITION: LIQUID CONTAINING ORGANIC AND INORGANIC COMPONENTS

3.1 HAZARDOUS COMPONENTS:

<u>NAME</u>	<u>EINECS/ELINCS NO.</u>	<u>CAS NO.</u>	<u>CONC. % W/W</u>	<u>CLASSIFICATION</u> <u>67/548/EEC</u>	<u>CLASSIFICATION</u> <u>1272/2008/EEC</u>
AMMONIUM HYDROGEN BIFLOURIDE; AMMONIUM BIFLOURIDE	215-676-4	1341-49-7	< 1.0%	Xi ; R36/38: 0.1% ≤ C < 1%	Skin Irrit. 2, H315: 0.1% ≤ C < 1% Eye Irrit. 2, H319: 0.1% ≤ C < 1%

For exposure limits see ch. 8, for phrases R and hazard statements text see ch. 16

SECTION 4: FIRST AID MEASURES

EYES: Wash immediately with plenty of water or normal saline. Keep eyelid open with the finger. Get medical advice if adverse symptoms appear.

SKIN: Remove contaminated clothes and shoes. Wash affected area with soap or mild detergent and plenty of water. Get medical advice if adverse symptoms appear.

INGESTION: If swallowed rinse mouth with plenty of water provided person is conscious. Get medical advice if adverse symptoms appear.

INHALATION: If inhaled, move person to fresh air. Get medical advice if adverse symptoms appear.

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SECTION 5: FIRE-FIGHTING MEASURES

Suitable extinguishing means:	Water spray or regular foam, CO ₂ , 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 (including NO _x , HF)
Equipment for self-protection: (fire fighters):	Self-contained breathing apparatus, flame and chemical resistant clothing, boots, gloves.

SECTION 6: ACCIDENTAL RELEASE MEASURES

ACCIDENTAL RELEASE MEASURES:

Personal precautions:	Suitable protective clothing, rubber or polythene gloves, rubber shoes, safety glasses.
Environmental precautions:	Do not let the product enter drainage system, surface and ground-water or soil. Contact local authorities in case of environmental release. Do not empty into drains.
Cleaning procedure to recover spilled material:	Soak up with inert absorbent material, and clean with plenty of water. Send to the storage waiting for disposal procedures.

SECTION 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 Section 8)	Avoid environmental release.
Recommended temperature:	Store at 18 – 25 °C.
Humidity, light and other environmental factors:	Avoid light exposure and keep away from heat sources and non compatible materials.
Containers:	Keep containers tightly closed and labeled with the name of the product.
Other storage precautions:	Keep away from food and drinks.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 EXPOSURE LIMIT VALUES

TLV/TWA: not available	MAK (DE): 2.5 mg/m ³ for fluorides, measured as F (1)
TLV /STEL: not available	TLV (US): 2.5 mg/m ³ as fluorides (1)

8.2 EXPOSURE CONTROLS

Respiratory protection:	Respiratory protection is not required. Where risk assessment shows air-purifying respirators are appropriate, use masks with approved filter.
Skin protection:	Protective clothing, rubber or polythene gloves.
Eye protection:	Safety glasses.
Hand protection:	Rubber or polythene gloves.
Other protective systems:	Personal protective equipment (PPE) useful for reducing individual exposure.
Environmental protection:	Avoid any release into the environment.

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 GENERAL INFORMATION

Appearance: Liquid
Odor: Odorless
Color: Colorless

9.2 IMPORTANT HEALTH, SAFETY AND ENVIRONMENTAL INFORMATION

	VALUE	RELATED TO
pH:	4.0 at 25° C	Mixture
Boiling point/range:	not available	
Flash point:	not available	
Vapor pressure:	not available	
Density:	1.0 at 25° C	Mixture
Solubility:	Completely miscible	
Water Solubility:	not available	Mixture
Viscosity:	not available	
Vapor density:	not available	
Evaporation rate:	not available	
Melting point/range:	not available	

SECTION 10: STABILITY AND REACTIVITY

STABILITY: The product is stable until the expiration date shown on the box and on the labels when stored at 18 - 25°C.

- 10.1** Conditions to avoid: Keep away from heat and light.
- 10.2** Materials to avoid: oxidizing agents, reducing agents, strong bases, strong acids.
- 10.3** Hazardous decomposition products: Thermal decomposition or combustion may include toxic and hazardous fumes (including NO_x, HF).

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 TOXICOKINETIC EFFECTS (ADME)

Absorption: Fluorides are absorbed from gastro-intestinal tract, lung, and skin. (2)
Distribution: Absorbed fluoride is distributed throughout the tissues of the body by the blood. There is no evidence that it is concentrated in any tissues except bone, thyroid, aorta, and perhaps kidney. Fluoride is preponderantly deposited in the skeleton and teeth, and the degree of skeletal storage is related to intake and age. (2)
Metabolism: Fluoride exchanges with hydroxyl radicals of hydroxyapatite (the inorganic constituent of bone) to form fluorohydroxyapatite. (2)
Excretion: Major route of excretion of fluorides is by way of kidneys. About 90% of fluoride ion filtered by glomerulus is reabsorbed by renal tubules. Fluorides are also excreted in small amount by sweat glands, lactating breast, and gastro-intestinal tract. Under certain conditions perspiration may be an important route of fluoride excretion. Fecal elimination is up to 10%.

Biological half-life of fluorides is about 2-9 hours. (2)

11.2 ACUTE TOXICITY

	VALUE	M.U.	EFFECTS	RELATED TO
Oral:	LD50 (rat) = 130	mg/Kg		Ammonium Biflouride
Dermal:	LD50 (rat) = not available	mg/Kg		
Inhalation:	not available	mg/Kg		
Other data:	Typical symptoms of acute toxicity induced by fluorides are reduction or loss of appetite, local or general congestion, and sub-mucosal hemorrhages of the gastrointestinal tract.			Fluorides

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11.3 IRRITATION

Skin: Fluoride ions, once separated from either HF or fluoride salts, penetrate deep into tissues, causing burning at sites deeper than the original exposure site. The process of tissue destruction can continue for days. (2)

Eye: Ocular exposure to fluorides can result in serious eye injury. (2)

Inhalation: When exposure is through inhalation, fluorides can cause severe chemical burns to the respiratory system. Inhalation can result in difficulty breathing (dyspnea), bronchospasms, chemical pneumonitis, pulmonary edema, airway obstruction, and tracheobronchitis. (2)

11.4 SENSITIZATION:

Skin sensitization: not available

Sensitization by inhalation: not available

11.5 PROLONGED EXPOSURE TOXICITY: Several animal studies have examined the chronic toxicity of ingested fluoride; the observed effects included bone alterations in rats, mice, and mink, intestinal damage in rabbits, hematological effects in rabbits, immunological effects in rabbits, and male reproductive effects in rabbits. (2) Chronic exposure of cattle to fluoride added to their ration caused symptoms of dental and skeletal fluorosis. (2) In humans, intake of more than 6 mg/day results in fluorosis. Symptoms are weight loss, anemia, weakness, general ill health, stiffness of joints. (2)

11.6 CMR

EFFECTS

RELATED TO

Mutagenicity:	Ames test: Negative ⁽¹⁾ Mouse lymphoma: not available Chromosomal aberration: not available Micronucleus test: not available	Ammonium Bifluoride
Teratogenesis: Carcinogenesis:	not available The carcinogenicity of fluoride has been assessed in a number of human studies of communities with fluoridated water or naturally high levels of fluoride in the drinking water. Although some human studies have found positive results, particularly for bone cancer, the majority of the studies have not found significant increases in cancer risk.	

SECTION 12: ECOLOGICAL INFORMATION

12.1 ECOTOXICOLOGY

	VALUE	M.U.	RELATED TO
Acute toxicity with fish:	LC0=237	mg/l/96 hours ⁽⁴⁾	Ammonium Bifluoride
Acute toxicity with Daphnia Magna:	EC50 = not available	mg/l/48 hours	
Acute toxicity with algae:	EC50 = not available	mg/l/72 hours	

12.2 MOBILITY:

not available

12.3 PERSISTENCY AND DEGRADABILITY:

In water, ammonium bifluoride is completely dissociated, and its environmental fate and pathways are related to the dissociation products (ammonia and hydrofluoric acid). (1)

12.4 BIOACCUMULATION POTENTIAL:

not available

12.5 EVALUATION PBT RESULT:

not available

12.6 OTHER TOXIC EFFECTS:

not available

SECTION 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

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SECTION 14: TRANSPORT INFORMATION

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

SECTION 15: REGULATORY INFORMATION

Regulatory information on labeling according to 67/548/EEC, to 1999/45/EEC Directive and to 1272/2008 Regulation (EC)(European reinforcement of GHS), and according to their following amendments/atp.

	According to 67/548/EEC and 1999/45/EEC Directives	According to 1272/2008/EC Regulation
Classification:	Xi, R36/38	Skin Irrit. 2, H315 Eye Irrit. 2, H319
Labeling symbols: (signal word)		
Labeling risk phrases: (hazard statements)	Xi - Irritant R36/38: Irritating to eye and skin.	Warning H315: Causes skin irritation. H319: Causes serious eye irritation. P280: Wear protective gloves/protective clothing/eye protection/face protection. P302+P352: IF ON SKIN: Wash with plenty of soap and water. P332+P313: If skin irritation occurs: Get medical advice/attention. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313: If eye irritation persists: Get medical advice/attention. P362: Take off contaminated clothing and wash before reuse.
Labeling safety phrases: (precautionary statements)	S24/25: Avoid contact with skin and eyes. S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.	
Other labeling details:	None	
Safety precautions:	Wear suitable protective clothing, gloves and eye/face protection.	
Authorization:	no	
Restriction:	no	

SECTION 16: OTHER INFORMATION

Phrases R: R36/R38 Irritating to eye and skin
Hazard Statements: H315; Causes skin irritation
H319; Causes serious eye irritation

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.

Bibliographic references:

- (1) IUCLID file for CAS 1341-49-7.
 - (2) HSDB dataset for CAS 1341-49-7.
- (*) Classification in Annex I of Dir 67/548/EEC and in Annex VI of the 1272/2008/EC Regulation