

	SAFETY DATA SHEET According to Regulation (EC) N° 1907/2006 – N° 453/2010	Creation date: 30/10/2014
	microINR EasyControl	Revision date: 30/10/2014 (Version 1)

SECTION 1: IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY

1.1. Product identifier

Product name: **microINR EasyControl**

Product code: **EKA0005UU**

Identification of the product: **Kit including:**

PRODUCT A: Calcium Chloride (CAS N° 10043-52-4) <95%

PRODUCT B: Human Citrated Plasma (containing Sodium Omadine 40% CAS N° 3811-73-2 <0.05%)

1.2. Relevant identified uses of the mixture and uses advised against

For in vitro diagnostic use.

1.3. Details of the supplier of the safety data sheet

iLine Microsystems S.L.

Paseo Mikeletegi, 69

20009 DONOSTIA (Guipúzcoa) SPAIN

Tel. 0034 943005651

Fax: 0034 943005651

MSDS information: info@ilinemicrosystems.com



1.4. Emergency telephone number:

Tel. 0034 94 300 56 51 (Company: iLine Microsystems S.L.)

Office hours:

- From Monday to Thursday: 8:00-18:00 horas
- Friday: 8:00-15:00 horas

Tel: 0034 91 562 04 20 INTCF (Instituto Nacional de Toxicología y Ciencias Forenses-Spain) (24h/365 days)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

2.1.1. Classification according to Regulation (EC) No 1272/2008 [CLP]

The kit consists of separated products A and B:

Classification according to Regulation (EC) No 1272/2008 [CLP]	
PRODUCT A (Calcium Chloride solution)	PRODUCT B (Human citrated Plasma)
Eye Irrit. 2, H319	Acute Tox. Oral, Categ. 4, H302 Acute Tox. Dermal, Categ. 4, H312 Acute Tox. Inhalation, Categ. 4, H332

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	Skin irritation Categ. 2, H315 Aquatic Acute Tox. Categ. 1, H400
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2.1.2 Classification according to Directive 67/548/EEC (see SECTION 16 for full text of risk phrases)

Classification according to Directive 67/548/EEC	
PRODUCT A (Calcium Chloride solution)	PRODUCT B (Human citrated Plasma)
Irritant, Xi, R36	Harmful, Xn, R20/21/22 Irritant, Xi, R38 Dangerous for the environment, N, R50

2.1.3. Additional information

For full text of R-phrases and Hazard- and EU Hazard-statements: see SECTION 16.

2.2. Label elements

Labelling according to Regulation (EC) No 1272/2008 [CLP]

Labelling according to Regulation (EC) No 1272/2008 [CLP]	
PRODUCT A (Calcium Chloride solution)	PRODUCT B (Human citrated Plasma)
Hazard pictograms:  GHS07 Signal Word: WARNING Hazard Statements: H319 Causes serious eye irritation Precautionary statements P264 Wash thoroughly after handling P280 Wear protective gloves/protective clothing/eye protection/face protection. 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.	Not classified according to Regulation 1272/2008/EC

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2.3. Other hazards

Easycontrol microINR Kit is not considered chemically hazardous but contains human plasma which must be treated as a potential biohazard.

Easycontrol microINR Kit does not meet the criteria for PBT or vPvB according to Regulation (EC) No 1907/2006, Annex XIII.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

No substances fulfill the criteria set forth in Annex II, part A, of the REACH Regulation (EC) No.1907/2006.

3.2. Mixtures

The kit consists of separated products A and B.

PRODUCT A (Calcium Chloride solution)

CAS No.	CE No.	INDEX No.	REACH Registration No.	% weight	Name	Classification according to 67/548/EEC	Classification according to Regulation (EC) No 1278/2008 (CLP).
10043-52-4	233-140-8	603-002-00-5	-	<95%	Calcium Chloride solution anhydrous	X, R36	Eye Irrit. 2, H319

PRODUCT B (Human citrated Plasma containing Sodium Omadine 40%)

CAS No.	CE No.	INDEX No.	REACH Registration No.	% weight	Name	Classification according to 67/548/EEC	Classification according to Regulation (EC) No 1278/2008 (CLP).
3811-73-2	223-296-5	011-005-00-2	-	<0.05%	Sodium Omadine 40%	X _n , R20/21/22 X _i , R38 N, R50	Acute Tox. 4, H302 Acute Tox. 4, H312 Acute Tox. 4, H332 Skin irritant. 2, H315 Aquatic Acute Tox. 1, H400

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SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

	PRODUCT A (Calcium Chloride solution)	PRODUCT B (Human citrated Plasma)
Potential Health effects:	None	Any contact with the substances contained in the product is susceptible biohazard, regardless of the contact pathway.
General notes:	Never provide drink or induce vomiting in the event of loss of consciousness.	Never provide drink or induce vomiting in the event of loss of consciousness.
Following inhalation:	Take the person out into the fresh air.	Take the person out in the fresh air. Seek medical attention if adverse symptoms appear.
Following skin contact:	Wash with plenty of water. Remove contaminated clothing.	Wash the contaminated area with soap or mild detergent and rinse with abundant water. Remove contaminated clothing.
Following eye contact:	Wash with plenty of water, keeping eyelids open. In the event of irritation, seek medical assistance.	Wash with plenty water or saline, keeping eyelids open. In the event of irritation. Seek medical attention if adverse symptoms appear.
Following ingestion:	Drink large amounts of water. Seek medical assistance	If the person is conscious, rinse mouth with water. Seek medical attention if adverse symptoms appear.
Self-protection of the first aider:	None	None

4.2. Most important symptoms and effects, both acute and delayed

	PRODUCT A (Calcium Chloride solution)	PRODUCT B (Human citrated Plasma)
Signs and symptoms:	May be harmful if swallowed. May cause eyes, skin and respiratory irritation. May cause sensitization by inhalation or skin contact.	May cause eyes, skin and respiratory tract irritation.
Potential chronic effects:	Not expected.	Not expected.
Conditions aggravated by prolonged exposure:	Not expected. People with respiratory system problems, may be more susceptible to irritating effects.	Not expected. People with respiratory system problems, may be more susceptible to irritating effects.

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4.3. Indication of any immediate medical attention and special treatment needed

	PRODUCT A (Calcium Chloride solution)	PRODUCT B (Human citrated Plasma)
Specific and immediate treatment	No data available.	No data available.
Information for the doctor	No data available.	No data available.

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media

	PRODUCT A (Calcium Chloride solution)	PRODUCT B (Human citrated Plasma)
Suitable extinguishing media	Use extinguishing media appropriate for surrounding fire.	Water spray, foam, CO ₂ and dry chemicals.
Unsuitable extinguishing media	No data available.	No data available.

5.2. Special hazards arising from the substance or mixture

	PRODUCT A (Calcium Chloride solution)	PRODUCT B (Human citrated Plasma)
Special hazards arising from the substance or mixture	Non-combustible.	Thermal decomposition or combustion may generate hazardous fumes (Ex.: CO _x , NO _x , SO _x).

5.3. Advice for firefighters

	PRODUCT A (Calcium Chloride solution)	PRODUCT B (Human citrated Plasma)
Advice for firefighters	If necessary, wear self-contained breathing apparatus for firefighting.	Self-contained breathing apparatus, protective clothing fire.

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SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

	PRODUCT A (Calcium Chloride solution)	PRODUCT B (Human citrated Plasma)
For non-emergency personnel	Use personal protective equipment. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Evacuate personnel to safety areas.	Protective clothing, latex or vinyl gloves.
For emergency responders	Not expected.	Fire fighters will be equipped with suitable personal protective equipment.

6.2. Environmental precautions

	PRODUCT A (Calcium Chloride solution)	PRODUCT B (Human citrated Plasma)
Environmental precautions	Contact local authorities in case of environmental pollution. Avoid pollution of the soil, water, supplies and drains.	Contact local authorities in case of environmental pollution. Avoid pollution of the soil, water, supplies and drains.

6.3. Methods and material for containment and cleaning up

	PRODUCT A (Calcium Chloride solution)	PRODUCT B (Human citrated Plasma)
Methods and material for containment and cleaning up	Contain the spilled liquid, and either pump back into original container or cover with sand or clay-type substance for absorption. Spilled material may cause a slipping hazard.	Collect up dry and deposit in waste containers for subsequent elimination in accordance with current legislation. Clean any remains with plenty of water.

6.4. Reference to other sections

See sections 8 and 13.

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SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

	PRODUCT A (Calcium Chloride solution)	PRODUCT B (Human citrated Plasma)
Handling Procedures	Avoid skin and eye contact and breathing vapors or mists.	Wear suitable protective clothing, gloves and eye protection. Do not eat, drink or smoke when using the product.
Advice on general occupational hygiene	Wash thoroughly after handling. Wash contaminated clothing before reuse.	Wash hands with soap and water after use.

7.2. Conditions for safe storage, including any incompatibilities

	PRODUCT A (Calcium Chloride solution)	PRODUCT B (Human citrated Plasma)
Ventilation	Dry atmosphere.	Provide sufficient ventilation in all workplaces.
Special precautions	No special indications.	Avoid dispersal in the environment.
Recommended temperature	Room temperature.	Store at 2-8°C.
Humidity, light and other environmental factors	No special indications.	Avoid exposure to light and keep away from sources of heat and incompatible materials.
Containers	Store in a tightly closed container away from incompatible materials.	Keep containers tightly closed and properly labelled. Keep containers away from food and drinks.

7.3. Specific end use(s)

	PRODUCT A (Calcium Chloride solution)	PRODUCT B (Human citrated Plasma)
Specific end use(s)	No specific.	For in vitro diagnostic use. During and after using the product, it should be considered as potential biohazard material.

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Limit values for Exposure:

TLV/TWA: not available

TLV/STEL: not available

Substance Calcium Chloride
CAS No 10043-52-4
OES (UK) 10 mg/m³

Substance	Sodium Omadine
CAS No	3811-73-2
OEL (Germany)	MAK 1 mg/m ³ (inhalable)
OEL (Switzerland)	MAK-week 1 mg/m ³ , KZG-week 2 mg/m ³ (skin)

Biological limits:

Not available

8.2. Exposure controls

8.2.1 Appropriate engineering controls

No special indications

8.2.2 Personal protection equipment

	PRODUCT A (Calcium Chloride solution)	PRODUCT B (Human citrated Plasma)
Eye protection	Use suitable goggles	Use suitable goggles
Hand protection	Use suitable gloves	Use suitable gloves
Body protection	Protective clothing, rubber or polythene gloves.	Protective clothing, rubber or polythene gloves.
Respiratory protection	Respirator protection not generally required. For misty conditions, wear NIOSH approved mist respirator.	Respirator protection is not required. If the risk assessment considers necessary the use of PPE it will be necessary use appropriate masks with appropriate filter.
Individual hygiene measures	Remove contaminated clothing. Use suitable work clothing. Wash hands and face before breaks and when the job is done.	Remove contaminated clothing. Use suitable work clothing. Wash hands and face before breaks and when the job is done.
Thermal risks	Not applicable.	Not applicable.

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8.2.3 Environmental exposure controls

	PRODUCT A (Calcium Chloride solution)	PRODUCT B (Human citrated Plasma)
Environmental exposure controls	Fulfill the commitments under local environmental protection legislation.	Fulfill the commitments under local environmental protection legislation.
Environmental protection	Avoid any release into the environment.	Avoid any release into the environment.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Properties	PRODUCT A (Calcium Chloride solution)	PRODUCT B (Human citrated Plasma)
General information:		
Appearance:	Liquid	Powder, cake
Colour:	Clear	Off white
Odour:	Odorless	Odorless
Important health, safety and environmental information:		
pH:	Not available	Not available
Melting point/Freezing point:	Not available	Not available
Boiling point/boiling range:	Not available	Not available
Flash point:	Not available	Not available
Evaporation rate:	Not available	Not available
Lower/upper flammability limits:	Not available	Not available
Lower/upper explosive limits:	Not available	Not available
Vapor pressure:	Not available	Not available
Vapor density:	Not available	Not available
Relative density:	Not available	Not available
Water solubility:	Not available	Miscible
Partition coefficient n-octanol/water:	Not available	Not available
Auto-flammability temperature:	Not available	Not available
Decomposition point/decomposition range:	Not available	Not available
Viscosity:	Not available	Not available
Explosive properties:	Not available	Not available
Oxidising properties:	Not available	Not available

9.2. Other information

No data available.

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SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

	PRODUCT A (Calcium Chloride solution)	PRODUCT B (Human citrated Plasma)
Reactivity	The product is stable under normal temperatures and pressures.	The product is stable until the expiration date shown on the box and on the labels when stored at 2-8°C.

10.2. Chemical stability

	PRODUCT A (Calcium Chloride solution)	PRODUCT B (Human citrated Plasma)
Chemical stability	Does not occur polymerization under normal temperatures and pressures.	The product is stable under normal conditions. No hazardous decomposition products are expected. Conditions which should be avoided: Keep away from sources of heat, light and moisture.

10.3. Possibility of hazardous reactions

	PRODUCT A (Calcium Chloride solution)	PRODUCT B (Human citrated Plasma)
Possibility of hazardous reactions	No data available.	Thermal decomposition or combustion may generate hazardous fumes (for example. CO _x , NO _x , SO _x , Na ₂ O, HCL).

10.4. Conditions to avoid

	PRODUCT A (Calcium Chloride solution)	PRODUCT B (Human citrated Plasma)
Conditions to avoid	Humidity.	Keep away from heat, humidity and light.

10.5. Incompatible materials

	PRODUCT A (Calcium Chloride solution)	PRODUCT B (Human citrated Plasma)
Incompatible materials	Strong oxidizing agents.	Oxidizing and reducing agents.

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10.6. Hazardous decomposition products

	PRODUCT A (Calcium Chloride solution)	PRODUCT B (Human citrated Plasma)
Hazardous decomposition products	No specific data.	Thermal decomposition or combustion may generate hazardous fumes (for example. CO _x , NO _x , SO _x , Na ₂ O, HCL).

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

	PRODUCT A (Calcium Chloride solution)	PRODUCT B (Human citrated Plasma)
Acute toxicity	LD ₅₀ Oral (rat): 1000-4179 mg/Kg	LD ₅₀ Oral (rat): 1500 mg/Kg related to Sodium Omadine
	LD ₅₀ Dermal (rat): 2630 mg/Kg	LD ₅₀ Dermal (rat): 1800 mg/Kg related to Sodium Omadine
	LC ₅₀ Inhalation (rat): Not available	LC ₅₀ Inhalation (rat): 1.08 mg/l/4h related to Sodium Omadine
Skin corrosion/skin irritation:	Not irritating to skin	Not irritating to skin
Serious eye damage/irritation	Irritating to eye	Not irritating to eye
Respiratory or skin sensitization	Not sensitizing	Not sensitizing
Germ cell mutagenicity	No data available	No data available
Carcinogenicity	No data available	No data available
Reproductive toxicity	No data available	No data available
STOT-single exposure	No data available	No data available
STOT-repeated exposure	No data available	No data available
Aspiration hazard	No data available	No data available
Other information	No data available	No data available

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

	PRODUCT A (Calcium Chloride solution)	PRODUCT B (Human citrated Plasma)
Crustacea	Daphnia magna: EC ₅₀ (48 h) water flea Daphnia: 144 mg/l	Daphnia magna: EC ₅₀ (48 h) water flea Daphnia: 0.022 mg/l related to Sodium Omadine
Fish	Fish: LC ₅₀ (96 h): 0.7 mg/l	Fish: LC ₅₀ (96 h): 0.0073-8.6 mg/l related to Sodium Omadine

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Algae/aquatic plants	Algae: EC ₅₀ (72h): No data available	Algae: EC ₅₀ (72h): No data available
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12.2. Persistence and degradability

No data available

12.3. Bioaccumulative potential

No data available

12.4. Mobility in soil

No data available

12.5. Results of PBT and vPvB assessment

microINR EasyControl Kit does not meet the criteria for PBT or vPvB according to Regulation (EC) No 1907/2006, Annex XIII.

12.6. Other adverse effects

No data available

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

	PRODUCT A (Calcium Chloride solution)	PRODUCT B (Human citrated Plasma)
13.1.1. Product / Packaging disposal	Disposal according to national or local regulations	Disposal according to national or local regulations
13.1.2. Waste treatment-relevant information	Contaminated containers and packaging of dangerous substances or preparations must be treated in the same manner as the actual products contained in them. European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste.	Take into consideration the national regulations in accordance to the elimination of waste and comply with local and EU waste recycling. The waste generated by the use of the product, product rest or waste product of accidental spills should be managed under the provisions of national and local regulations.
13.1.3. Sewage disposal-relevant information	No data available.	No data available.
13.1.4. Other disposal recommendations	No data available.	No data available.

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SECTION 14: TRANSPORT INFORMATION

14.1. UN number

Product A and B are not classified in accordance with international regulations relating to the transport of dangerous goods (RID, ADR, ADNR, IMDG, IATA, OACI, RID)

14.2. UN proper shipping name

Product A and B are not classified in accordance with international regulations relating to the transport of dangerous goods (RID, ADR, ADNR, IMDG, IATA, OACI, RID)

14.3. Transport hazard class (es)

Product A and B are not classified in accordance with international regulations relating to the transport of dangerous goods (RID, ADR, ADNR, IMDG, IATA, OACI, RID)

14.4. Packaging group

Product A and B are not classified in accordance with international regulations relating to the transport of dangerous goods (RID, ADR, ADNR, IMDG, IATA, OACI, RID)

14.5. Environmental hazards

Product A and B are not classified in accordance with international regulations relating to the transport of dangerous goods (RID, ADR, ADNR, IMDG, IATA, OACI, RID)

14.6. Special precautions for user

Product A and B are not classified in accordance with international regulations relating to the transport of dangerous goods (RID, ADR, ADNR, IMDG, IATA, OACI, RID)

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable

SECTION 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Not specific.

15.2. Chemical safety assessment

Not applicable

SECTION 16: OTHER INFORMATION

This safety data sheet has been developed in accordance with Annex II-Guide for the preparation of Material Safety Data Sheets of Regulation (EC) No. 1907/2006.

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Indication of changes

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Abbreviations and acronyms:

OEL: Occupational Exposure Limit

OES: Occupational Exposure Standard

TLV/TWA: Threshold Limit Value – Time Weighted Average

TLV/STEL: Threshold Limit Value – Short-Term Exposure Limit

MAK: Maximale Arbeitsplatz-Konzentration (maximum workplace concentration)

PBT: Persistent Bioaccumulative Toxic

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road

IMDG: International Maritime Dangerous Goods

IATA: International Air Transport Association

ICAO: International Civil Aviation Organization

RID: Regulations Concerning the International Transport of Dangerous Goods by Rail

Title for H and R indications mentioned in section 3:

Directive 67/548/EC and Directive 1999/45/EC:

R36 Irritating to eyes

R20/21/22 Harmful by inhalation, in contact with skin and if swallowed

R38 Irritating to skin

R50 Very toxic to aquatic organisms

Regulation 1272/2008 (CLP):

H302 Causes serious eye irritation

H312 Harmful in contact with skin

H319 Causes serious eye irritation

H332 Harmful if inhaled

H315 Causes skin irritation

H400 Very toxic to aquatic life

Training advice

Not available

Further information

For in vitro diagnostic use.

During and after using the product, it should be considered as potential biohazard material.

The above information represents the best information currently available for us. However this reagent may present unknown hazards and should be used with caution. Independent professional opinions regarding the risk or exposure to this solution are responsibility of the user.