SAFETY DATA SHEET
GEM® SYSTEM EVALUATOR 2

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CO: 460788
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IDENTIFICATION OF THE PRODUCT AND OF THE COMPANY

Identification of the product

Product Name: **GEM® SYSTEM EVALUATOR 2**

Product Number: **00025000102**

Use of the product: For in vitro diagnostic use

Company identification:

MANUFACTURER:
Instrumentation Laboratory Co.
180 Hartwell Road,
Bedford, MA 01730-2443 (USA)
Tel. +1 800 678 0710
Fax +1 781 863 9928

DISTRIBUTOR EU:
Via Leonardo da Vinci, 36
20877 Roncello (MB), Italy

DISTRIBUTOR US/CANADA:
Instrumentation Laboratory Co.
526 Route 303
Orangeburg, New York 10962 (USA)

E-mail address of the competent person: infosds@mail.ilww.it

Emergency phone: +44 (0) 3700 492 795
+1 215 207 0061 (USA and Canada)

INFORMATION ON COMPOSITION/HAZARD OF THE PRODUCT

P/N	Mixture name	Mixture classification According to Hazard Communication Standard, 29 CFR 1910.1200 (HCS) Hazardous Product Regulation HPR (WHMIS 2015)	Mixture classification According to 1272/2008/EC Regulation	Kit configuration
00025000102	**GEM System Evaluator 2**	**Not classified**	**Not classified**	**10 x 1.8 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 SDS are in accordance with Annex II of the Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) and its subsequent amendments, in accordance with Hazard Communication Standard (HCS), 29 CFR 1910.1200 (HazCom 2012) as recommended by US OSHA, and in accordance with Hazardous Product Regulation HPR (WHMIS 2015) as recommended by Health Canada (HC).

Prepared by: Chemsafe Srl

SECTION 1. IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY

1.1 Identification of the mixture

Product Name: **GEM SYSTEM EVALUATOR 2**

Product Number: **00025000102**

1.2 Use of the mixture:

Relevant use: For in vitro diagnostic use.

Uses advised against: There are no specific uses advised against.

1.3 Company identification:

MANUFACTURER:
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180 Hartwell Road,
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SECTION 2. HAZARDS IDENTIFICATION

2.1 Classification of the mixture:
This product is not hazardous according to Regulation (EC) No 1272/2008, according to OSHA 29 CFR 1910.1200 and to Hazardous Product Regulation HPR (WHMIS 2015).
Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

according to Regulation (EC) No 1272/2008 and according to Hazard Communication Standard, 29 CFR 1910.1200 (HCS) and Hazardous Product Regulation HPR (WHMIS 2015):

Hazard class	*Hazard category*	*Hazard statement*
Not classified		
		For exposure limits see ch. 8

Potential adverse physicochemical, human health and environmental effects *(see also ch. 9-12)*

Under normal conditions of use, the mixture does not cause adverse effects to the environment.

2.2 Label elements, according to Regulation (EC) No 1272/2008 and according to Hazard Communication Standard, 29 CFR 1910.1200 (HCS) and Hazardous Product Regulation HPR (WHMIS 2015):

Hazard pictogram(s):	**None**
Signal word(s):	**None**
Hazard statement(s):	**None**
Precautionary statement(s):	**None**
Other labeling details:	**Up to 1.8% of the mixture consists of component of unknown acute toxicity (inhalation) for the human health.**

Safety precautions: Use the product in accordance with the Good Laboratory Practice.
Avoid inhalation or contact with skin. Wear suitable protective clothing, gloves and eye/face protection.
Do not let the product enter drainage system, surface and ground-water or soil. Do not empty into drains.

2.3 Other hazards (which do not results in the classification)

The mixture does not meet the criteria for PBT or vPvB.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Composition: aqueous solution containing organic and inorganic components.

3.1 Hazardous components:

Name	EINECS/ ELINCS n°	CAS n°	Conc. % w/w*	Classification 29 CFR 1910.1200 (HCS) HPR (WHMIS2015)	Classification 1272/2008/EC
Calcium chloride dihydrate *Index N. (Annex VI of CLP Reg.) 017-013-00-2*	233-140-8 (as Calcium chloride anhydrous)	10035-04-8 (10043-52-4 as Calcium chloride anhydr.)	< 0.03%	Serious Eye damage/ Eye Irritation, cat.2A	Eye Irrit. 2 , H319
Gentamicin, sulfate (salt)	215-778-9	1405-41-0	< 0.03%	Skin Sensitization 1 Sensitization - Respiratory, 1 Reproductive Toxicity, 1B	Skin Sens. 1, H317 Resp. Sens. 1, H334 Repro. 1B, H360
2-octyl-2H-isothiazol-3-one (OIT) *Index N. (Annex VI of CLP Reg.) 613-112-00-5*	247-761-7	26350-20-1	< 0.003%	Acute Toxicity – Inhalation, cat. 2 Acute Toxicity – Dermal, cat. 3 Acute Toxicity –Oral, cat. 4 Skin Corrosion/Irritation, cat. 1B Sensitization - Skin, cat. 1 Aquatic Acute, cat. 1** Aquatic Chronic, cat. 1**	Acute Tox. 2, H330 Acute Tox. 3 (*), H311 Acute Tox. 4 (*), H302 Skin Corr. 1B, H314 Skin Sens. 1, H317 Aquatic Acute 1, H400 (M= 100) Aquatic Chronic 1, H410 (M= 10) *Specific concentr. limits:* *Skin Sens. 1; H317: C ≥ 0,05 %*
Sodium lactate	200-772-0	72-17-3	≤ 0.01%	Eye damage/Eye Irritation, cat. 2B	Eye Irrit. 2, H319
Propane-1,2-diol	200-338-0	57-55-6	≤0.003%	Not classified	Not classified

For exposure limits see ch. 8, for hazard statements text see ch. 16.
**** a range may be indicated, considering batch-to batch variation.***
*****Environmental classification according to Reg. N. 1272/2008 (EC) and subsequent amendments.***

The mixture contains one substance listed in the Hazardous Substance Lists and/or evaluated for carcinogenicity by IARC, NTP, OSHA: propane-1,2-diol. See Section 11 and 15.

SECTION 4. FIRST AID MEASURES

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

Contact with 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.

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.

4.2 Most important symptoms and effects (acute and delayed)

Acute: Inhalation: May cause irritation.
Skin: May be irritant for skin.
Eyes: May cause irritation.
Ingestion: May be harmful.

Delayed: Delayed symptoms and effects are not known.

4.3 Indication of any immediate medical attention and special treatment needed

Medical monitoring: Not foreseen.

Antidotes, if known: Not known.

SECTION 5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Water spray or regular foam, CO2, dry powder.

Unsuitable extinguishing media: Not known.

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products: Thermal decomposition or combustion may generate toxic and hazardous fumes of COx, NOx, Na2O, SOx, HCl, HF.

5.3 Advice for firefighters

Protective actions: Water jets can be used successfully to cool containers exposed to the fire and disperse fumes.

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

SECTION 6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel: Remove the ignition and heat sources, provide sufficient ventilation and evacuate the area. Respiratory protection: is not required. Where risk assessment shows air-purifying respirators are appropriate, use masks with approved filter. Suitable protective clothing, rubber or polythene gloves, rubber shoes, safety glasses.

For emergency responders: Wear appropriate protective equipment (see Section 8) to minimize exposure to the product.

6.2 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.

6.3 Methods and material for containment and cleaning up Collect spilled material in containers. Where appropriate, moisten to prevent the dispersion of dust, absorb with inert materials and wash the area with plenty of water. Send to the storage waiting for disposal procedures.

6.4 Reference to other sections See also section 8 and 13.

SECTION 7. HANDLING AND STORAGE

7.1 Precautions for safe handling Handle in a well ventilated place, and away from sparks and flames - sources of ignition. Keep the mixture away from drains, surface or ground waters. Avoid contact with incompatible materials. Wear suitable Personal Protection Equipment (see section 8).
Do not eat, drink and smoke in the working areas. Wash hands with soap and water after handling the mixture. Remove contaminated clothing and protective equipment before entering eating areas.

7.2 Conditions for safe storage, incompatibilities Recommended temperature: store at 2 -8°C. Avoid light exposure and keep away from heat sources. Room ventilation: well ventilated workplace. Keep containers tightly closed and labelled with the name of the product. Avoid environmental release.
Keep away from food and drinks.

7.3 Specific end use *GEM System Evaluator 2* is intended for in vitro diagnostic use. Use the product in accordance with the Good Laboratory Practice.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Community/National occupational exposure limit values:

	Limit value – 8 hours	*Limit value – short term**
2-octyl-2H-isothiazol-3-one		
Austria	0,05 mg/m³ - inhalable aerosol	0,05 mg/m³ - inhalable aerosol
Germany (AGS)	0,05 mg/m³ - inhalable aerosol	0,1 mg/m³ - inhalable aerosol [(a)]
Germany (DFG)	0,05 mg/m³ - inhalable aerosol	0,1 mg/m³ - inhalable aerosol
Switzerland	0,05 mg/m³ - inhalable aerosol	0,1 mg/m³ - inhalable aerosol

TLV/TWA (Rohm and Haas): 0.2 mg/m^3 for 2-octyl-2H-isothiazol-3-one [(3)]

TLV/STEL (Rohm and Haas): 0.6 mg/m^3 for 2-octyl-2H-isothiazol-3-one [(3)]

(a) 15 minutes average value

Calcium chloride(1)
Canada – Ontario: Occupational exposure limit (OEL) for calcium chloride of 5 mg/m3 has been established by the Ministry of Labour

Community/National biological exposure limit values: not available

DNEL Values (components):

Component	***Route of exposure***	*Workers*				*Consumers*			
		Acute effects		*Chronic effects*		*Acute effects*		*Chronic effects*	
		local	*systemic*	*local*	*systemic*	*local*	*systemic*	*local*	*systemic*
Calcium chloride anhydrous (2)	*Oral (mg/(mg/kg bw/day*	-	-	-	-	-	-	-	-
	Dermal (mg/kg bw/day)	-	-	-	-	-	-	-	-
	Inhalation (mg/m3)	*10*	-	*5*	-	***5***	-	2.5	-

PNEC Values (components): not available

Recommended monitoring procedures:

The measurement of substances at the workplace must be carried out with standardized methods (e.g. EN 689:1997: Workplace atmospheres. Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy; EN 482:2006: Workplace atmospheres - General requirements for the performance of procedures for the measurement of chemical agents) or, failing that, with appropriate methods.

8.2 Exposure controls

8. 2. 1. Appropriate engineering controls

Appropriate risk management measures, that must be adopted at the workplace, have to be selected and applied, following the risks assessment carried out by the employer, in connection with his working activity (in according with Directive 98/24/EEC).
If the results of this evaluation show that the general and collective prevention measures are not sufficient to reduce the risk, and if you cannot prevent exposure to the mixture by other means, adequate personal protective equipment must be adopted, complying with the relevant technical EN standards.

8.2.2. Individual protection measures, such as Personal Protective Equipment (PPE)

Respiratory protection:	Respiratory protection is not required. Where risk assessment shows air-purifying respirators are appropriate, use masks with approved filter. Use only devices approved by the Competent Authorities such as NIOSH (USA) and CEN (EU).
Skin protection:	Protective clothing, rubber gloves.
Eye protection:	Safety glasses.
Hand protection:	Protective gloves.
Other protective systems:	Personal protective equipment (PPE) useful for reducing individual exposure.

8.2.3.Environmental exposure controls

Avoid any release into the environment.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

	Value	**Related to**
Appearance:	Liquid	
Odor:	Not available	
Color:	Dark pink	
pH:	Not available	Mixture
Flammability:	Aqueous solution, not expected to be flammable	
Explosive properties:	Aqueous solution, not expected to be explosive	
Oxidizing properties:	Aqueous solution, not expected to have oxidizing properties	
Density:	Not available	
Solubility:	Not available	
Water Solubility:	Miscible	Mixture
Melting point/range:	Liquid, not applicable	

9.2 Other information Not available

SECTION 10. STABILITY AND REACTIVITY

10.1	**Reactivity**	This mixture is considered not reactive under the normal conditions of the usage.
10.2	**Chemical stability**	The product is stable until the expiration date shown on the box and on the labels when stored at 2 - 8°C.
10.3	**Possibility of hazardous reactions**	Not foreseen.
10.4	**Conditions to avoid:**	Keep out from heat and light.
10.5	**Incompatible materials**	Strong oxidising agents, strong bases, strong acids.
10.6	**Hazardous decomposition products:**	Thermal decomposition or combustion may include toxic and hazardous fumes of COx, NOx, Na2O, SOx, HCl, HF.

SECTION 11. TOXICOLOGICAL INFORMATION

The health effects of the product have not been thoroughly investigated. Data on toxicological effects of the hazardous ingredients are provided bellow.

11.1 Information on toxicological effects

Symptoms and effects for each route of exposure:

Dermal:	May cause skin irritation.
Ingestion:	May cause breathlessness, tachycardia, nausea, vomiting, headache, restlessness and diarrhea.
Inhalation:	May cause irritation to the mucous membranes and upper respiratory tract.
Contact with eyes:	May cause eye irritation.

Toxicokinetic effects (Absorption, Distribution, Metabolism, Excretion):

Calcium chloride : is easily dissociated into calcium and chloride ions in water. The absorption, the distribution and the excretion of the ions in animals are regulated separately. Both ions are essential constituents of the body of all animals. (1)

2-octyl-2H-isothiazol-3-one (OIT): is regarded as rapidly resorbable via the skin. After oral administration of the substance to test animals, systemic effects point to a high resorption rate. A very rapid and effective absorption via the respiratory tract can be assumed on the basis of very pronounced resorptive-toxic effects observed in animal experiments on the consequences of inhalation of the substance. (4)

Sodium lactate: The lactate is metabolised into bicarbonate, mainly in the liver, and produces an alkalinising effect on the plasma.

Acute toxicity	**Value**	**m.u.**	**Effects**		**Related to**
Oral:	LD50 (rat) =3,798 - 4,179 LD50 (rabbit) = 500 – 1,000	mg/Kg	The acute oral toxicity is attributed to the severe irritating property of the original substance or its high-concentration solutions to the gastrointestinal tract.	(1)	Calcium chloride
	LD50 (rat) = 350 - 800	mg/Kg		(4)	OIT
	LD50 (rat) > 5,000	mg/Kg		(12)	Sodium lactate
	LD50 (rat) > 5,000	mg/Kg	Somnolence (general depressed activity)	(9)	Gentamicin sulphate (salt)
Dermal:	LD50 (rabbit) > 5,000	mg/Kg		(1)	Calcium chloride
	LD50 (rat) > 2,000	mg/Kg	Read across from lactic acid	(13)	Sodium lactate
	LD50 (rabbit) = 311	mg/Kg		(4)	OIT
	Occlusive application of doses ≥ 291 mg OIT/kg bw in the form of a 45% solution in propylene glycol over a period of 24 hours caused skin injuries and systemic effects (apathy, ataxia, weakness, paralysis of the posterior limbs) that, in the case of higher doses, resulted in the death of all animals within one or two days.			(4)	OIT
Inhalation:	LC50 (rat) > 40	mg/m3/4h		(1)	Calcium chloride
	LC50 > 7.94	mg/L	Read across from lactic acid	(13)	Sodium lactate
	LC50 (rat) = 586	mg/m^3		(4)	OIT

Other data: not available

Corrosion/Irritation

Skin Corrosion/Irritation

Calcium chloride: is not irritating for the skin. (1)

Sodium lactate: not irritating or minimally irritating.(12)

OIT is corrosive to the skin. (5)

Serious eye damage/ irritation

OIT: A 0.1 ml of a 45% solution in propylene glycol caused strong irritations to corrosions on rabbit eyes, to the conjunctiva, the cornea and the iris. Immediate rinsing after application had only a minor influence on the extent and the persistence (>14 days) of the injuries. A 5% solution caused reversible corneal turbidities. (4)

Sodium lactate: minimal to mild irritation in some tests with cosmertic products.(12) Lactic Acid was found to be nonirritating to moderately irritating in ocular tests.(14)

Sensitization:

Skin sensitization:

Calcium chloride: Due to lack of data the classification is not possible.

OIT is responsible for several cases of occupational allergic contact dermatitis, mostly among paint manufacturers. (5)

Sodium lactate: not sensitizer in a Human Repeat Insult Patch Test (RIPT) with application of a cream containing 1% Sodium lactate. (12)

Gentamicin sulphate causes photosensitivity. Exposure to light can result in allergic reactions that cause dermatologic lesions, which can vary from sunburn-like responses to edematous, vesciculated lesions, or bullae. (10)

Respiratory sensitization:

Gentamicin sulphate may cause allergic respiratory reactions.(10)

CMR effects

Germ cell mutagenicity;

Calcium chloride: Genetic toxicity of calcium chloride was negative in the bacterial mutation tests and the mammalian chromosome aberration test. (1)

Sodium lactate: negative results in some in vitro tests (Ames test, chromosomal aberration). (12)

OIT : was found to be negative in the reverse mutation assay with Ames Salmonella, in a mouse bone marrow chromosomal aberration test, and in a mammalian cell in culture gene mutation assay. OIT is not mutagenic in activated and non-activated conditions and there is no evidence of genotoxic effect.(5)

Reproductive toxicity:

Calcium chloride: No reproductive toxicity study has been reported. A developmental toxicity study equivalent to an OECD Guideline Study reveals no toxic effects on dams or fetuses at doses up to 189 mg/kg bw/day (mice), 176 mg/kg bw/day (rats) and 169 mg/kg bw/day (rabbits). (1)

Gentamicin sulfate is known to the State of California to cause developmental toxicity, classified under the generic class of Aminoglycosides.
There is some evidence from animal testing that exposure to gentamicin may result in toxic effects to the unborn baby. In utero aminoglycosides-induced nephrotoxicity in rat neonates. Pregnant Wistar females were treated with gentamicin during two periods of pregnancy covering organogenesis and the beginning of nephrogenesis. It is concluded that the developing kidney can be altered after treating pregnant mothers with aminoglycosides. This model of in utero-indiced nephrotoxicity is dose-dependent. (11)

Carcinogenesis:

Substances listed in the National Toxicology Program (NTP) Report on Carcinogens, in the International Agency for Research on Cancer (IARC) Monographs or found to be potential carcinogen by OSHA:

Substance	*OSHA*	*IARC*	*NTP*
No component listed			

Sodium lactate: In studies examining the carcinogenic potential of Lactic Acid in rabbits and Calcium Lactate in rats, no significant positive effects were observed.(12)

OIT: An 18-month carcinogenicity mouse bioassay is available, but this negative study was found to be inadequate by both U.S. EPA (2007b) and CDPR (2001). (6)

STOT –single exposure

OIT: a NOAEL of 5.95 mg/kg/day was selected from a 90-day dermal toxicity study in rats based on systemic effects (decreases in HGB, GCT, RBC, albumin, and total protein and a decrease in body weight gain in 7 male rats). Not expected to cause any additional significant adverse effects (5)(7)

STOT – repeated exposure

Calcium chloride: A study for repeated dose oral toxicity in rats shows no adverse effect of calcium chloride on rats fed 20 mg CaCl2/g diet (comparable to 1000 mg/kg bw/day or more) for 12 months.(1)

Sodium lactate: In subchronic dermal testing, no significant findings of toxicity were observed with application of cosmetic formulations containing 0.10 of 60% aq. Sodium Lactate. (12)

Aspiration hazards Not available.

Other information: Not available.

Reasons for the lack of classification:
Where the mixture resulted in a non-classification, this may be due to the availability of data which does not impose a classification for that specific end-point, or due to lack of data, or due to availability of inconclusive data or data which are not sufficient to get a classification as for the criteria adopted in Regulations mentioned in this data sheet.

SECTION 12. ECOLOGICAL INFORMATION

The environmental effects of the product have not been thoroughly investigated. Data on toxicological effects of the hazardous ingredients are provided bellow.

12.1 Toxicity	species, media, units, test duration and test conditions.		Related to
Acute toxicity with fish:	LC50 *Pimephales promelas*= 4,630 mg/l/96 hours	(1)	Calcium chloride
	LC50 > 100 mg/l/96 hours (read across from lactic acid)	(13)	Sodium lactate
	LC50 Oncorhyncus mykiss = 0.047 mg/l/96 hours	(5)	OIT 98.5%
Chronic toxicity with fish:	NOEC = 0.0085 mg/l/35 day	(8)	OIT
Acute toxicity with crustaceans:	EC50 Daphnia magna = 1062 mg/L/48 hr	(1)	Calcium chloride
	EC50 > 100 mg/l/48 hours (read across from lactic acid)	(13)	Sodium lactate
	EC50 = 0.107 mg/L/48 hr	(5)	OIT 96%
Chronic toxicity with crustaceans:	The chronic toxicity study with Daphnia magna shows that a 16% impairment of reproduction (EC16) is caused at the concentration of 320 mg/L.	(1)	Calcium chloride
	NOAEC *Daphnia magna* = 0.074 mg/l/21 day	(5)	OIT 98.5%
Acute toxicity with algae:	EC50 Selenastrum capricornutum = 2,900 mg/l/72 h	(1)	Calcium chloride
	EC50 Selenastrum capricornutum = 0.004 mg/l/72 hours	(3)	OIT
	EC50 > 2.8 g/l/72 hours; NOEC = 1.52 g/l/72h nominal concentration (read across from lactic acid)	(13)	Sodium lactate
	EC50 (120-hour) = 0.015 mg/l (growth inhibition)	(5)	OIT 99.2%
Chronic toxicity with algae:	Not available		
Toxicity data on soil micro- and macroorganisms	Not available		
Toxicity data on birds, bees and plants:	LD50 Colinus virginianus = 346 mg/kg. Duration 21 day.	(8)	OIT

12.2 Persistency and degradability:

OIT: is stable and persistent in water under abiotic conditions with a half-life of greater than 30 days, and is not likely to be persistent in air. Microbial degradation occurs in soil within 120 days (U.S. EPA, 2007c). (6)

Sodium lactate is not suspected to be persistent.

Once emitted into the environment, calcium chloride which has a high water solubility, will dissociate into the calcium and the chloride anion. The calcium ion may bind to soil particulate or may form stable inorganic salts with sulphate and carbonate ions.

12.3 Bioaccumulation potential:

OIT: Bioaccumulation: BCF = 15. Octanol/water partition coefficient: Log Kow = 3.42. OIT is not likely to bioaccumulate in various aquatic organisms. (6)

Sodium lactate is not suspected to be bioaccumulative.

Considering its dissociation properties, *Calcium chloride* per se is not expected to accumulate in living organisms.

12.4 Mobility in soil:

OIT: is immobile in soil and binds strongly to top soil surfaces.(6)

The chloride ion is mobile in soil and eventually drains into surface water because it is readily dissolved in water.

12.5 Results of PBT and vPvB assessment Chemical Safety Report and PBT assessment: not performed.

12.6 Other toxic effects: Not available.

SECTION 13. DISPOSAL CONSIDERATION

National laws on disposal must be considered, local and UE requirements for wastes recycling must be respected.

13.1 Waste treatment methods

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 in accordance with ADR/RID, IMDG, IATA and DOT regulations.

SECTION 15. REGULATORY INFORMATION

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

EU Regulations

- Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (Official Journal L 183 , 29/06/1989 P. 0001 – 0008) and following amendment and National reinforcements.
- Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to the personal protective equipment.
- Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) Official Journal L 131 , 05/05/1998 P. 0011 – 0023.
- Council Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.
- Commission Regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH).
- Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December on classification, labelling and packaging of substances and mixtures 2008 (and subsequent amendments and supplements).

Restriction of use: none
Substance(s) under authorization: none

US Federal Regulations:

State	*Components listed*	*Note*
Massachusetts	No component listed	-
New York	No component listed	-
New Jersey	Propylene glycol	-
Pennsylvania	Propylene glycol	-

California Prop. 65

Ingredient name	*Cancer*	*Reproductive*	*NSRL or MADL (µg/day)*
No component listed			

Clean Water Act (CWA) 307	No component listed
Clean Air Act Section 112(b) Hazardous Air Pollutants (HAPs)	No component listed
Clean Air Act Section 602 Class I Substances	No component listed
Clean Air Act Section 602 Class II Substances	No component listed
DEA List I Chemicals (Precursor Chemicals)	No component listed
DEA List II Chemicals (Essential Chemicals)	No component listed

EPA List of Lists

Regulatory Name	*CAS No./SARA/ 313 Category Code* [I]	*SARA/ EPCRA 302 EHS TPQ* [II]	*SARA/ EPCRA 304 EHS RQ* [III]	*CERCLA RQ* [IV]	*SARA/EPCRA 313 TRI* [V]	*RCRA Code* [VI]	*CAA 112(r) RMP TQ* [VII]
No component listed							

[I] **SARA/313 Category Code:** Emergency Planning and Community Right-to Know Act Section 313 Category Code
[II] **SARA/EPCRA 302 EHS TPQ:** Extremely Hazardous Substance Threshold Planning Quantity (Emergency Planning and Community Right-to Know Act Section 302 Category Code)
[III] **SARA/EPCRA 304 EHS RQ:** Extremely Hazardous Substance Reportable Quantity (Emergency Planning and Community Right-to Know Act Section 304 Category Code)
[IV] **CERCLA RQ:** Reportable Quantity (Comprehensive Environmental Response, Compensation, and Liability Act)
[V] **SARA/EPCRA 313 TRI:** Toxics Release Inventory (Emergency Planning and Community Right-to Know Act Section 313 Category Code)
[VI] **RCRA Code:** Resource Conservation and Recovery Act Code
[VII] **CAA 112(r) RMP TQ:** Risk Management Plan Threshold Quantity (Clean Air Act Section 112(r)

United States Inventory (TSCA 8b): All components are listed or exempted.

Canada Domestic Substances List (DSL): All components are listed or exempted.

15.2 Chemical safety assessment: A chemical safety assessment has not been carried out for the mixture by the supplier.

SECTION 16. OTHER INFORMATION

Revisions:

- Edition n. 01, dated 11/10/2010.
- Revision n. 01, dated 03/10/2012.
- Revision n. 02, dated 11/25/2015. Main changes are in sections 2 to16, adapting the SDS format and contents to Hazard Communication Standard (HCS), 29 CFR 1910.1200 (HazCom 2012), Hazardous Product Regulation HPR (WHMIS 2015), and Regulation (EU) 2015/830 of 28 May 2015.

Acronyms:

ACGIH: American Conference of Governmental Industrial Hygienists
AIHA: American Industrial Hygiene Association
ADR: Agreement concerning the carriage of dangerous goods by Road
BCF: Bioaccumulative factor
BEI : Biological Esposure Indices
CAS: Chemical Abstract Service (division of the American Chemical Society
CLP: Classification, Labeling and Packaging
DNEL: Derived No-Effect Levels
EC50: the effect concentration associated with 50% response.
EINECS: European Inventory of Existing Commercial Substances
EPA: US Environmental Protection Agency
IARC: International Agency for Research on Cancer
IATA: International Air Transport Association Code
IMDG: International Maritime Dangerous Goods Code
LC50: Lethal Concentration to 50 % of a test population
LD50: Lethal Dose to 50% of a test population (Median Lethal Dose)
LOEL: Lowest Observed Effect Level
MADL: Maximum Allowable Daily (or Dose) Level
NOAEL: No Observed Adverse Effect Level)
NOEC: no observed effect concentration, means the test concentration immediately below the lowest tested concentration with statistically significant adverse effect.
NSRL: National Science Research Laboratory
NTP: National Toxicology Program
OEL: Occupational Exposure Limit
OSHA: Occupational Safety and Health Administration
PPE : Personal protective Equipment
PBT: Persistent, Bioaccumulative and Toxic substances
PNEC: Predicted No Effect Concentration
RID: Regulation concerning the International carriage of Dangerous goods by rail
TLV/TWA: Threshold Limit Value/Threshold Weighted Average
vPvB: very Persistent, very Bioaccumulative

WEEL: Workplace Environmental Exposure Level (air concentration of agents in a healthy worker's breathing zone)

Information related to the Regulation EC/1272/2008:

Hazard statement(s):
H302: Harmful if swallowed.
H314: Causes severe skin burns and eye damage.
H317: May cause an allergic skin reaction.
H319: Causes serious eye irritation.
H330: Fatal if inhaled.
H311: Toxic in contact with skin.
H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H360: May damage fertility or the unborn child.
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.

Information on workers training: Follow National requirements to ensure protection of human health and the environment.

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 and according to Hazard Communication Standard, 29 CFR 1910.1200 (HCS), and according to HPR (WHMIS 2015) :

Classification:	*Classification procedure*
Not classified	-

The contained information in this SDS are in accordance with Annex II of the COMMISSION REGULATION (EU) No 1907/2006 (REACH) and its subsequent amendments, in accordance with Hazard Communication Standard (HCS), 29 CFR 1910.1200 (HazCom 2012) as recommended by US OSHA, and in accordance with Hazardous Product Regulation HPR (WHMIS 2015) as recommended by Health Canada (HC).

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