SAFETY DATA SHEET
GEM® PREMIER 3500 PAK WITH IQM®

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IDENTIFICATION OF THE PRODUCT AND OF THE COMPANY

Identification of the product

Product Name: **GEM® PREMIER 3500 PAK WITH IQM®**

Product Number: **00026403584, 00026407584, 00026307584, 00026407587, 00026307587, 00026307589, 00026315084, 00026315087, 00026315089, 00026330084, 00026330087, 00026330089, 00026345084, 00026345087, 00026345089, 00026360084, 00026360087, 00026360089**

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 (US)

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
-	**GEM 3500 A Solution**	**Hazardous to the aquatic environment, Cat. 3**	**Aquatic chronic 3, H412**	**95 ml**
-	**GEM 3500 B Solution**	**Hazardous to the aquatic environment, Cat. 3**	**Aquatic chronic 3, H412**	**965 ml**
-	**GEM 3500 C Solution**	**Sensitization – Skin, Cat. 1**	**Not Classified**	**85 ml**
-	**Reference Solution**	**Serious eye damage/eye irritation, Cat. 1** **Hazardous to the aquatic environment, Cat. 3**	**Eye Irrit. 1, H318** **Aquatic chronic 3, H412**	**131 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 3500 A SOLUTION**

Product Number: **NOT APPLICABLE**

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:
Instrumentation Laboratory Co.
180 Hartwell Road,
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1.4 Emergency phone: +44 (0) 3700 492 795
+1 215 207 0061 (USA and Canada)

SECTION 2. HAZARDS IDENTIFICATION

2.1 Classification of the mixture:
This product is hazardous according to Regulations (EC) No 1272/2008, OSHA 29 CFR 1910.1200 and 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:

Hazard class	*Hazard category*	*Hazard statement*
HAZARDOUS TO THE AQUATIC ENVIRONMENT	**Cat. 3**	**Harmful to aquatic life with long lasting effects.** (H412)
		For exposure limits see section 8.

According to Hazard Communication Standard, 29 CFR 1910.1200 (HCS), and according to Hazardous Product Regulation HPR (WHMIS 2015):

Hazard class	*Hazard category*	*Hazard statement*
HAZARDOUS TO THE AQUATIC ENVIRONMENT**	**Cat. 3**	**Harmful to aquatic life with long lasting effects.**
		For exposure limits see ch. 8.

*****Environmental classification according to Reg. N. 1272/2008 (EC) and subsequent amendments.***

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

Under normal conditions of use, the mixture does not cause adverse effects to humans.
The product is harmful to aquatic life with long lasting effects.

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

Hazard pictogram(s):	None
Signal word(s):	None
Hazard statement(s):	**Harmful to aquatic life with long lasting effects.** (H412)**
Precautionary statement(s):	**Avoid release to the environment.** (P273) **Dispose of contents/container in accordance with local/regional/national/international regulation.** (P501)
Other labeling details:	**Up to 2.7% of the mixture consists of component of unknown acute toxicity (dermal, inhalation) for the human health and unknown hazard to the aquatic environment.**

*****Environmental classification and labeling according to Reg. N. 1272/2008 (EC) and subsequent amendments.***

Safety precautions: Use the product in accordance with the Good Laboratory Practice.
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 (WHMIS 2015)	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.)	< 0.05 %	Eye damage/irritation, cat. 2	Eye Irrit. 2, H319
2-Methyl-4-isothiazolin-3-one hydrochloride (Methylisothiazolinone hydrochloride) **(***)**	247-499-3	26172-54-3	< 0.05 %	Acute Toxicity – Oral, cat.3 Acute Toxicity – Dermal, cat.3 Acute Toxicity – Inhalation, cat.3 Skin Corrosion/Irritation, cat. 1B Sensitization – Skin, cat. 1 Aquatic Acute, cat. 1** Aquatic Chronic, cat. 1 **	Acute Tox. 3, H331 Acute Tox. 3, H311 Acute Tox. 3, H301 Skin Corr. 1B, H314 Skin Sens. 1, H317 Aquatic Acute 1, H400 (M=100) Aquatic Chronic 1, H410 (M=10)

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.***

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. Do not induce vomiting. Get medical advice if adverse symptoms appear.

Inhalation exposure: If inhaled, move person to fresh air. If breathing is difficult, oxygen should be administered. Get medical advice if adverse symptoms appear.

Contact with skin: Remove immediately contaminated clothes and shoes. Wash immediately affected area with soap or mild detergent and plenty of water until the removal of the mixture (15-20 minutes). Get medical advice if adverse symptoms appear.

Contact with eyes: Wash immediately with plenty of water or normal saline for at least 15 minutes. 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, CO_2, 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, SOx, HCl.

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. Equipment must be conformed with the national/international standards and used in highest condition of protection on the basis of the information reported in the previous sub-sections.

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 Soak up with inert absorbent material, and clean with plenty of water. Collect spilled material in containers. 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 sparkles 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 15-25°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 *Calibration Solution A* 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:

Calcium chloride: Canada – Ontario: Occupational exposure limit (OEL) for calcium chloride of 5 mg/m^3 has been established by the Ministry of Labor.

Community/National biological exposure limit values: Not established.

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 anhydr. (13)	*Oral (mg/(mg/kg bw/day*								
	Dermal (mg/kg bw/day)								
	Inhalation (mg/m³)	*10*		*5*		*5*		2.5	

PNEC values (components): not available

The measurement of substances at the workplace must be carried out with standardized methods 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. 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 national/international 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:	Odorless	
Color:	colorless	
pH:	not available	
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 15 – 25 °C.

10.3 Possibility of hazardous reactions Keep away from heat and light.

10.4 Conditions to avoid: Strong oxidizing agents, strong bases, strong acids.

10.5 Incompatible materials Thermal decomposition or combustion may include toxic and hazardous fumes of CO_x, NO_x, SO_x, HCl.

10.6 Hazardous decomposition products: Keep away from heat and light.

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. (12)

2-methyl-3(2H)-isothiazolone (Methylisothiazolinone) and 5-chloro-2-methyl-4-isothiazolin-3-one (Methylchoroisothiazolinone): both are readily excreted in the urine and feces following oral administration. (1)

Acute toxicity	Value	m.u.	Effects		Related to
Oral:	LD50 (male rat) = 235 LD50 (male rat) = 183	mg/Kg mg/Kg		(2)	Methylisothiazolinone
	LD50 (rat) = 53-60	mg/Kg		(3)	5-Chloro-2-methyl-4-isothiazolin-3-one
	Isothiazolinones are moderately to highly toxic by oral administration. The major signs of toxicity were severe gastric irritation, lethargy, and ataxia. (3)				
	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.	(12)	Calcium chloride
Dermal:	LD50 (rat) = 242	mg/Kg		(2)	Methylisothiazolinone
	LD50 (rabbit) > 5,000	mg/Kg		(12)	Calcium chloride
Inhalation:	The LC50 values of Methylisothiazolinone and Methylchoroisothiazolinone reported in rats range from 0.2 -1.4 mg/l aerosols. Major signs of acute toxicity following inhalation are pulmonary congestion and edema, marked dyspnea, salivation, and hemorrhage.			(1)	Methylisothiazolinone
	LC50 (rat) = 0.33	mg/l/4h	aerosol exposure	(2)	Methylisothiazolinone
	LC50 (rat) > 40	$mg/m^3/4$ h		(12)	Calcium chloride
Other data:	Not available.				

Corrosion/Irritation

Skin Corrosion/Irritation: *Methylisothiazolinone* was severely irritating to the skin of rabbit (4) and is corrosive to the skin when applied undiluted. (5) *5-chloro-2-methyl-4-isothiazolin-3-one* was corrosive to rabbit skin. (9)

Calcium chloride is not irritating for the skin. (12)

Serious eye damage/ irritation: *Methylisothiazolinone* was corrosive to the eyes of rabbit. (4)
5-chloro-2-methyl-4-isothiazolin-3-one was highly irritating to rabbit eyes. (9)

Calcium chloride is irritating for the eyes. (12)

Sensitization:

Skin sensitization: *Methylisothiazolinone* produced skin sensitization effects in several animal and human studies. Although the potency of these effects varied across the studies, skin sensitization was sufficiently noted across all the studies to support the classification (SCCS, 2009; CIR, 2010; Lundov et al., 2011; Yazar et al., 2011; Boyapati et al., 2013; Cahill et al., 2014; SCCS, 2013; Lammintausta et al., 2014). (2)
5-chloro-2-methyl-4-isothiazolin-3-one caused dermal sensitization in guinea pig. (9)

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

Respiratory sensitization: Not available.

CMR effects

Germ cell mutagenicity; *3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):* negative in a Chromosomal aberration test. (6)
The specific mutagenicity studies on *Methylisothiazolinone* and *5-chloro-2-methyl-4-isothiazolin-3-one* demonstrated that only the last one possesses a mutagenic potential. (7) Based on the weight of evidence from the available in vitro and in vivo genotoxicity studies, Methylisothiazolinone is not considered to be genotoxic. (2)

Calcium chloride: Genetic toxicity of calcium chloride was negative in the bacterial mutation tests and the mammalian chromosome aberration test. (12)

Reproductive toxicity: *Methylisothiazolinone* was not found to be fetotoxic, embryotoxic, or teratogenic in rats. The maternal toxicity NOEL is 10 mg/kg/day. (2)(4)

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). (12)

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			

Carcinogenicity studies with *Methylisothiazolinone* resulted in no significant effects. The Agency's Office of Pesticide Program Health Effects Division RfD Peer Review Committee classified Methylisothiazolinone as a Group D carcinogen. (4)
Based on the weight of evidence from the available carcinogenicity study for the analogue chemical—3:1 mixture of methylchloroisothiazolinone and methylisothiazolinone (CAS No. 55965-84-9), in which there was no evidence of carcinogenicity, the chemical is not likely to be a carcinogen. (2)

STOT –single exposure Not available.

STOT – repeated exposure Based on the available data, *Methylisothiazolinone* is not considered to cause serious damage to health from repeated oral, dermal and inhalation exposure.(2)

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.(12)

Aspiration hazards Not available.

Other information: *Methylisothiazolinone:* no evidence of neurotoxicity was observed in vivo in the repeat dose or reproductive and developmental animal studies. (2)

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 = 0.07 mg/l/96 hours	(4)	Methylisothiazolinone
	LC50 *Brachydanio rerio* = 0.27 mg/l/96 hr, (static test, presumably nominal concentrations, poorly documented test)	(10)	(CIT/MIT) (3:1)*
	LC50 *Pimephales promelas* = 4,630 mg/l/96 hours	(12)	Calcium chloride
Chronic toxicity with fish:	NOEC *Oncorhynchus mykiss* = 0.05 mg/l/14d, (flow-through test, nominal concentrations, 13-17°C, pH 7.6-8.0)	(10)	(CIT/MIT) (3:1)*

Acute toxicity with crustaceans:	EC50 daphnia magna = 0.18 mg/l/48 hours	(4)	Methylisothiazolinone
	EC50 *Daphnia magna* = 0.18 mg/l/48h (static test, nominal concentrations, 21°C, pH 7.1-7.6)	(10)	(CIT/MIT) (3:1)*
	EC50 *Daphnia magna* = 1062 mg/L/48 hr	(12)	Calcium chloride
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.	(12)	Calcium chloride
	NOEC = 0.10 mg/l/ 21 d, *Daphnia magna*, (flow-through test, nominal concentration, 19.6°C, pH 8.3)	(10)	(CIT/MIT) (3:1)*
Acute toxicity with algae:	EC50 = 0.0094 mg/l/72	(10)	(CIT/MIT) (3:1)*
	EC_{50} *Selenastrum capricornutum* = 2900 mg/L/72 hours (biomass)	(12)	Calcium chloride
Chronic toxicity with algae:	NOEC = 0.005 mg/l, Selenastrum capricornutum (estimated concentrations based on measurements, 24°C,pH 7.5 - 7.8)	(10)	(CIT/MIT) (3:1)*
Toxicity data on soil micro- and macroorganisms	EC50 = 4.5 mg/l/3hr (respiration inhibition of activated sludge)	(10)	(CIT/MIT) (3:1)*
Toxicity data on birds, bees and plants:			

12.2 Persistency and degradability: *Methylisothiazolinone* and *Methylchloroisothiazolinone* are not readily biodegradable and have not been proven to be degradable under anaerobic conditions.(11)

The methods for determining the biological degradability are not applicable to inorganic substances. 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: The high water-solubility and the low log Kow values determined for *Methylisothiazolinone* (MIT) and 1.15% *5-chloro-2-methyl-4-isothiazolin-3-one* (CIT) (0.4 and -0.5, respectively) indicate a low potential for bioaccumulation of both substances. (3)

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

12.4 Mobility in soil: *Methylisothiazolinone* is very volatile. (4) It does not bind to soil or sediment.(8)
5-Chloro-2-methyl-4-isothiazolin-3-one is expected to be very mobile in soil. (4)

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 Not performed.

12.6 Other toxic effects: Not available.

**(CIT/MIT) (3:1) is the Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1)*

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.
- 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).
- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices.

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	No component listed	-
Pennsylvania	No component listed	-

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] [I] **SARA/EPCRA 302 EHS TPQ:** Extremely Hazardous Substance Threshold Planning Quantity (Emergency Planning and Community Right-to Know Act Section 302 Category Code)
[III] [I] **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] [I] **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.

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 03/11/2010.
- Revision n. 01, dated 07/13/2010.
- Revision n. 02, dated 11/11/2011.
- Revision n. 03, dated 03/06/2012.
- Revision n. 04, dated 06/22/2012.
- Revision n. 05, dated 10/13/2015. 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.
- Revision n. 06, dated 2022-11-01. Main change is in Section 15, updating the Directive 98/79/EC reference to Regulation (EU) 2017/746.

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

CDPR: California Department of Pesticide Regulation

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):

H331: Toxic if inhaled.

H301: Toxic if swallowed.

H311: Toxic in contact with skin.

H314: Causes severe skin burns and eye damage.

H317: May cause an allergic skin reaction.

H319: Causes serious eye irritation.

H400: Very toxic to aquatic life.

H410: Very toxic to aquatic life with long lasting effects.

H412: Harmful 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, according to Hazard Communication Standard, 29 CFR 1910.1200 (HCS), and according to HPR (WHMIS 2015) :

Classification:	*Classification procedure*
Harmful to aquatic life with long lasting effects. (H412)	**Calculation method**

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).

Bibliographic references:

(1) Health effects of selected chemicals 2. Kathon and 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-isothiazolin-3-one

(2) National Industrial Chemicals Notification & Assessment Scheme (http://www.nicnas.gov.au), Inventory multi-tiered assessment and prioritisation (imap) human health TIER II ASSESSMENT FOR 3-ISOTHIAZOLONE, 2-METHYL, CAS NUMBER: 2682-20-4

(3) Environmental Project No. 615 2001 Miljøprojekt, Environmental and Health Assessment of Substances in Household Detergents and Cosmetic Detergent Products

(4) United States Environmental Protection Agency, Prevention, Pesticides, And Toxic Substances, EPA738-R-98-012, October 1998 - Reregistration Eligibility Decision (RED) Methylisothiazolinone

(5) The Scientific Committee on Cosmetic Products and Non-Food products intended for consumers, Opinion concerning Methylisothiazolinone, COLIPA n° P94, Adopted by the SCCNFP during the 23rd plenary meeting of 18 March 2003

(6) National Library of Medicine, Genetic Toxicology for CAS 26172-54-3.

(7) Gestis Substance database, 2-Methyl-4-isothiazolin-3-one, ZVG 570030

(8) The Dow Chemical Company, Product Safety Assessment DOW™ Methylisothiazolinone (MIT) Antimicrobial Products, Created: December 17, 2010

(9) IUCLID data set for, 5-Chloro-2-methyl-4-isothiazolin-3-one,18-feb-2000.

(10) Kemikaali, Data bank of environmental properties of chemicals, Chloro/methylisothiazolinone = CMI/MI, CAS-number : 55965-84-9

(11) Survey of liquid hand soaps, including health and environmental assessments, available at http://www2.mst.dk/common/Udgivramme/Frame.asp?http://www2.mst.dk/udgiv/publications/2006/87-7052-062-3/html/kap08_eng.htm

(12) Calcium Chloride, SIDS Initial Assessment Report For SIAM 15 Boston, USA 22-25th October 2002

(13) Calcium chloride anh., Registration dossier, available at: http://apps.echa.europa.eu/registered/data/dossiers/DISS-9eb43f6f-23a1-5205-e044-00144f67d031/AGGR-dc2ba8fd-c7fc-402e-906e-b6cd0864ad5e_DISS-9eb43f6f-23a1-5205-e044-00144f67d031.html#AGGR-dc2ba8fd-c7fc-402e-906e-b6cd0864ad5e

(***) After bibliographic research, the information about 3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1) are limited. Toxicological and eco-toxicological data for 2-Methyl-3(2H)-isothiazolone and 5-Chloro-2-methyl-4-isothiazolin-3-one are considered valid also for 3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1) due to the similarity of the three molecules.

SECTION 1. IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY

1.1 Identification of the mixture

Product Name: **GEM 3500 B SOLUTION**

Product Number: **NOT APPLICABLE**

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:
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 (US)

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

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

SECTION 2. HAZARDS IDENTIFICATION

2.1 Classification of the mixture:
This product is hazardous according to Regulations (EC) No 1272/2008, OSHA 29 CFR 1910.1200 and 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:

Hazard class	*Hazard category*	*Hazard statement*
HAZARDOUS TO THE AQUATIC ENVIRONMENT	**Cat. 3**	**Harmful to aquatic life with long lasting effects.** (H412)
		For exposure limits see section 8.

According to Hazard Communication Standard, 29 CFR 1910.1200 (HCS), and according to Hazardous Product Regulation HPR (WHMIS 2015):

Hazard class	*Hazard category*	*Hazard statement*
HAZARDOUS TO THE AQUATIC ENVIRONMENT**	**Cat. 3**	**Harmful to aquatic life with long lasting effects.**
		For exposure limits see ch. 8.

***Environmental classification according to Reg. N. 1272/2008 (EC) and subsequent amendments*.

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

Under normal conditions of use, the mixture does not cause adverse effects to humans.
The product is harmful to aquatic life with long lasting effects.

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

Hazard pictogram(s):	None
Signal word(s):	None
Hazard statement(s):	**Harmful to aquatic life with long lasting effects.** (H412)**
Precautionary statement(s):	**Avoid release to the environment.** (P273) **Dispose of contents/container in accordance with local/regional/national/international regulation.** (P501)
Other labeling details:	**Up to 2.4% of the mixture consists of component of unknown acute toxicity (dermal, inhalation) for the human health.**

***Environmental classification and labeling according to Reg. N. 1272/2008 (EC) and subsequent amendments*

Safety precautions: Use the product in accordance with the Good Laboratory Practice.
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 (WHMIS 2015)	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.)	< 0.05 %	Eye damage/irritation, cat. 2	Eye Irrit. 2, H319
2-Methyl-4-isothiazolin-3-one hydrochloride (Methylisothiazolinone hydrochloride) **(***)**	247-499-3	26172-54-3	< 0.05 %	Acute Toxicity – Oral, cat.3 Acute Toxicity – Dermal, cat.3 Acute Toxicity – Inhalation, cat.3 Skin Corrosion/Irritation, cat. 1B Sensitization – Skin, cat. 1 Aquatic Acute, cat. 1** Aquatic Chronic, cat. 1 **	Acute Tox. 3, H331 Acute Tox. 3, H311 Acute Tox. 3, H301 Skin Corr. 1B, H314 Skin Sens. 1, H317 Aquatic Acute 1, H400 (M=100) Aquatic Chronic 1, H410 (M=10)

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.***

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. Do not induce vomiting. Get medical advice if adverse symptoms appear.

Inhalation exposure: If inhaled, move person to fresh air. If breathing is difficult, oxygen should be administered. Get medical advice if adverse symptoms appear.

Contact with skin: Remove immediately contaminated clothes and shoes. Wash immediately affected area with soap or mild detergent and plenty of water until the removal of the mixture (15-20 minutes). Get medical advice if adverse symptoms appear.

Contact with eyes: Wash immediately with plenty of water or normal saline for at least 15 minutes. 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, CO_2, 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, SOx, HCl.

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. Equipment must be conformed with the national/international standards and used in highest condition of protection on the basis of the information reported in the previous sub-sections.

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 Soak up with inert absorbent material, and clean with plenty of water. Collect spilled material in containers. 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 sparkles 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 15-25°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 *Calibration Solution B* 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:

Calcium chloride: Canada – Ontario: Occupational exposure limit (OEL) for calcium chloride of 5 mg/m^3 has been established by the Ministry of Labor.

Community/National biological exposure limit values: Not established.

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 anhydr. (13)	*Oral (mg/(mg/kg bw/day*								
	Dermal (mg/kg bw/day)								
	Inhalation (mg/m³)	*10*		*5*		*5*		2.5	

PNEC values (components): not available

The measurement of substances at the workplace must be carried out with standardized methods 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. 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 national/international 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:	Odorless	
Color:	colorless	
pH:	not available	
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 15 – 25 °C.

10.3 Possibility of hazardous reactions Keep away from heat and light.

10.4 Conditions to avoid: Strong oxidizing agents, strong bases, strong acids.

10.5 Incompatible materials Thermal decomposition or combustion may include toxic and hazardous fumes of CO_x, NO_x, SO_x, HCl.

10.6 Hazardous decomposition products: Keep away from heat and light.

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. (12)

2-methyl-3(2H)-isothiazolone (Methylisothiazolinone) and 5-chloro-2-methyl-4-isothiazolin-3-one (Methylchoroisothiazolinone): both are readily excreted in the urine and feces following oral administration. (1)

Acute toxicity	Value	m.u.	Effects		Related to
Oral:	LD50 (male rat) = 235 LD50 (male rat) = 183	mg/Kg mg/Kg		(2)	Methylisothiazolinone
	LD50 (rat) = 53-60	mg/Kg		(3)	5-Chloro-2-methyl-4-isothiazolin-3-one
	Isothiazolinones are moderately to highly toxic by oral administration. The major signs of toxicity were severe gastric irritation, lethargy, and ataxia. (3)				
	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.	(12)	Calcium chloride
Dermal:	LD50 (rat) = 242	mg/Kg		(2)	Methylisothiazolinone
	LD50 (rabbit) > 5,000	mg/Kg		(12)	Calcium chloride
Inhalation:	The LC50 values of Methylisothiazolinone and Methylchoroisothiazolinone reported in rats range from 0.2 -1.4 mg/l aerosols. Major signs of acute toxicity following inhalation are pulmonary congestion and edema, marked dyspnea, salivation, and hemorrhage.			(1)	Methylisothiazolinone
	LC50 (rat) = 0.33	mg/l/4h	aerosol exposure	(2)	Methylisothiazolinone
	LC50 (rat) > 40	mg/m³/4h		(12)	Calcium chloride
Other data:	Not available.				

Corrosion/Irritation

Skin Corrosion/Irritation: *Methylisothiazolinone* was severely irritating to the skin of rabbit (4) and is corrosive to the skin when applied undiluted. (5) *5-chloro-2-methyl-4-isothiazolin-3-one* was corrosive to rabbit skin. (9)

Calcium chloride is not irritating for the skin. (12)

Serious eye damage/ irritation: *Methylisothiazolinone* was corrosive to the eyes of rabbit. (4)
5-chloro-2-methyl-4-isothiazolin-3-one was highly irritating to rabbit eyes. (9)

Calcium chloride is irritating for the eyes. (12)

Sensitization:

Skin sensitization: *Methylisothiazolinone* produced skin sensitization effects in several animal and human studies. Although the potency of these effects varied across the studies, skin sensitization was sufficiently noted across all the studies to support the classification (SCCS, 2009; CIR, 2010; Lundov et al., 2011; Yazar et al., 2011; Boyapati et al., 2013; Cahill et al., 2014; SCCS, 2013; Lammintausta et al., 2014). [2]
5-chloro-2-methyl-4-isothiazolin-3-one caused dermal sensitization in guinea pig. [9]

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

Respiratory sensitization: Not available.

CMR effects

Germ cell mutagenicity; *3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):* negative in a Chromosomal aberration test. [6]
The specific mutagenicity studies on *Methylisothiazolinone* and *5-chloro-2-methyl-4-isothiazolin-3-one* demonstrated that only the last one possesses a mutagenic potential. [7] Based on the weight of evidence from the available in vitro and in vivo genotoxicity studies, Methylisothiazolinone is not considered to be genotoxic. [2]

Calcium chloride: Genetic toxicity of calcium chloride was negative in the bacterial mutation tests and the mammalian chromosome aberration test. [12]

Reproductive toxicity: *Methylisothiazolinone* was not found to be fetotoxic, embryotoxic, or teratogenic in rats. The maternal toxicity NOEL is 10 mg/kg/day. [2][4]

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). [12]

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			

Carcinogenicity studies with *Methylisothiazolinone* resulted in no significant effects. The Agency's Office of Pesticide Program Health Effects Division RfD Peer Review Committee classified Methylisothiazolinone as a Group D carcinogen. [4]
Based on the weight of evidence from the available carcinogenicity study for the analogue chemical—3:1 mixture of methylchloroisothiazolinone and methylisothiazolinone (CAS No. 55965-84-9), in which there was no evidence of carcinogenicity, the chemical is not likely to be a carcinogen. [2]

STOT –single exposure Not available.

STOT – repeated exposure Based on the available data, *Methylisothiazolinone* is not considered to cause serious damage to health from repeated oral, dermal and inhalation exposure.[2]

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.[12]

Aspiration hazards Not available.

Other information: *Methylisothiazolinone:* no evidence of neurotoxicity was observed in vivo in the repeat dose or reproductive and developmental animal studies. [2]

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 = 0.07 mg/l/96 hours	[4]	Methylisothiazolinone
		LC50 *Brachydanio rerio* = 0.27 mg/l/96 hr, (static test, presumably nominal concentrations, poorly documented test)	[10]	(CIT/MIT) (3:1)*
		LC50 *Pimephales promelas* = 4,630 mg/l/96 hours	[12]	Calcium chloride

Chronic toxicity with fish:	NOEC *Oncorhynchus mykiss* = 0.05 mg/l/14d, (flow-through test, nominal concentrations, 13-17°C, pH 7.6-8.0)	(10)	(CIT/MIT) (3:1)*
Acute toxicity with crustaceans:	EC50 daphnia magna = 0.18 mg/l/48 hours	(4)	Methylisothiazolinone
	EC50 *Daphnia magna* = 0.18 mg/l/48h (static test, nominal concentrations, 21°C, pH 7.1-7.6)	(10)	(CIT/MIT) (3:1)*
	EC50 *Daphnia magna* = 1062 mg/L/48 hr	(12)	Calcium chloride
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.	(12)	Calcium chloride
	NOEC = 0.10 mg/l/ 21 d, *Daphnia magna*, (flow-through test, nominal concentration, 19.6°C, pH 8.3)	(10)	(CIT/MIT) (3:1)*
Acute toxicity with algae:	EC50 = 0.0094 mg/l/72	(10)	(CIT/MIT) (3:1)*
	EC_{50} *Selenastrum capricornutum* = 2900 mg/L/72 hours (biomass)	(12)	Calcium chloride
Chronic toxicity with algae:	NOEC = 0.005 mg/l, Selenastrum capricornutum (estimated concentrations based on measurements, 24°C,pH 7.5 - 7.8)	(10)	(CIT/MIT) (3:1)*
Toxicity data on soil micro- and macroorganisms	EC50 = 4.5 mg/l/3hr (respiration inhibition of activated sludge)	(10)	(CIT/MIT) (3:1)*
Toxicity data on birds, bees and plants:	Not available.		

12.2 Persistency and degradability:

Methylisothiazolinone and *Methylchloroisothiazolinone* are not readily biodegradable and have not been proven to be degradable under anaerobic conditions.(11)

The methods for determining the biological degradability are not applicable to inorganic substances. 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:

The high water-solubility and the low log Kow values determined for *Methylisothiazolinone* (MIT) and 1.15% *5-chloro-2-methyl-4-isothiazolin-3-one* (CIT) (0.4 and -0.5, respectively) indicate a low potential for bioaccumulation of both substances. (3)

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

12.4 Mobility in soil:

Methylisothiazolinone is very volatile. (4) It does not bind to soil or sediment.(8)
5-Chloro-2-methyl-4-isothiazolin-3-one is expected to be very mobile in soil. (4)

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

Not performed.

12.6 Other toxic effects:

Not available.

**(CIT/MIT) (3:1) is the Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1)*

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.
- 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).
- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices.

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	No component listed	-
Pennsylvania	No component listed	-

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] [I] **SARA/EPCRA 302 EHS TPQ:** Extremely Hazardous Substance Threshold Planning Quantity (Emergency Planning and Community Right-to Know Act Section 302 Category Code)
[III] [I] **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] [I] **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**.**

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 03/11/2010.
- Revision n. 01, dated 07/13/2010.
- Revision n. 02, dated 11/11/2011.
- Revision n. 03, dated 03/06/2012.
- Revision n. 04, dated 06/22/2012.
- Revision n. 05, dated 10/13/2015. 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.
- Revision n. 06, dated 2022-11-01. Main change is in Section 15, updating the Directive 98/79/EC reference to Regulation (EU) 2017/746.

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

CDPR: California Department of Pesticide Regulation

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):

H331: Toxic if inhaled.

H301: Toxic if swallowed.

H311: Toxic in contact with skin.

H314: Causes severe skin burns and eye damage.

H317: May cause an allergic skin reaction.

H319: Causes serious eye irritation.

H400: Very toxic to aquatic life.

H410: Very toxic to aquatic life with long lasting effects.

H412: Harmful 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, according to Hazard Communication Standard, 29 CFR 1910.1200 (HCS), and according to HPR (WHMIS 2015) :

Classification:	*Classification procedure*
Harmful to aquatic life with long lasting effects. (H412)	**Calculation method**

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).

Bibliographic references:

(1) Health effects of selected chemicals 2. Kathon and 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-isothiazolin-3-one

(2) National Industrial Chemicals Notification & Assessment Scheme (http://www.nicnas.gov.au), Inventory multi-tiered assessment and prioritization (imap) human health TIER II ASSESSMENT FOR 3-ISOTHIAZOLONE, 2-METHYL, CAS NUMBER: 2682-20-4

(3) Environmental Project No. 615 2001 Miljøprojekt, Environmental and Health Assessment of Substances in Household Detergents and Cosmetic Detergent Products

(4) United States Environmental Protection Agency, Prevention, Pesticides, And Toxic Substances, EPA738-R-98-012, October 1998 - Reregistration Eligibility Decision (RED) Methylisothiazolinone

(5) The Scientific Committee on Cosmetic Products and Non-Food products intended for consumers, Opinion concerning Methylisothiazolinone, COLIPA n° P94, Adopted by the SCCNFP during the 23rd plenary meeting of 18 March 2003

(6) National Library of Medicine, Genetic Toxicology for CAS 26172-54-3.

(7) Gestis Substance database, 2-Methyl-4-isothiazolin-3-one, ZVG 570030

(8) The Dow Chemical Company, Product Safety Assessment DOW™ Methylisothiazolinone (MIT) Antimicrobial Products, Created: December 17, 2010

(9) IUCLID data set for, 5-Chloro-2-methyl-4-isothiazolin-3-one,18-feb-2000.

(10) Kemikaali, Data bank of environmental properties of chemicals, Chloro/methylisothiazolinone = CMI/MI, CAS-number : 55965-84-9

(11) Survey of liquid hand soaps, including health and environmental assessments, available at http://www2.mst.dk/common/Udgivramme/Frame.asp?http://www2.mst.dk/udgiv/publications/2006/87-7052-062-3/html/kap08_eng.htm

(12) Calcium Chloride, SIDS Initial Assessment Report For SIAM 15 Boston, USA 22-25th October 2002

(13) Calcium chloride anh., Registration dossier, available at: http://apps.echa.europa.eu/registered/data/dossiers/DISS-9eb43f6f-23a1-5205-e044-00144f67d031/AGGR-dc2ba8fd-c7fc-402e-906e-b6cd0864ad5e_DISS-9eb43f6f-23a1-5205-e044-00144f67d031.html#AGGR-dc2ba8fd-c7fc-402e-906e-b6cd0864ad5e

(***) After bibliographic research, the information about 3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1) are limited. Toxicological and eco-toxicological data for 2-Methyl-3(2H)-isothiazolone and 5-Chloro-2-methyl-4-isothiazolin-3-one are considered valid also for 3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1) due to the similarity of the three molecules.

SECTION 1. IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY

1.1 Identification of the mixture

Product Name: **GEM 3500 C SOLUTION**

Product Number: **NOT APPLICABLE**

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:
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 (US)

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

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

SECTION 2. HAZARDS IDENTIFICATION

2.1 Classification of the mixture:
This product is not hazardous according to Regulation (EC) No 1272/2008, and hazardous 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:

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

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

Hazard class	*Hazard category*	*Hazard statement*
SENSITIZATION - SKIN	**Cat. 1**	**May cause an allergic skin reaction.**
		For exposure limits see ch. 8.

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

Contains m-Phenylendiamine. May produce an allergic reaction.
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

Hazard pictogram(s):	**none**
Signal word(s):	**none**
Hazard statement(s):	**none**
Precautionary statement(s):	**none**
Other labeling details:	**Contains m-Phenylendiamine. May produce an allergic reaction.** (EUH208)
	Up to 1.9% of the mixture consists of component of unknown acute toxicity (oral, dermal, inhalation) for the human health and for unknown hazard to the aquatic environment.

According to Hazard Communication Standard, 29 CFR 1910.1200 (HCS) and Hazardous Product Regulation HPR (WHMIS 2015):

Hazard pictogram(s):	
Signal word(s):	**Warning**
Hazard statement(s):	**May cause an allergic skin reaction.** (H317)
Precautionary statement(s):	**Avoid breathing vapors/spray**. (P261) **Wear protective gloves.** (P208) **IF ON SKIN: Wash with plenty of water**. (P302 + P352) **If skin irritation or a rash occurs: Get medical advice/attention**. (P333 + P313)
Other labeling details:	**Contains m-Phenylendiamine.**
	Up to 1.9% of the mixture consists of component of unknown acute toxicity (oral, dermal, inhalation) for the human health and unknown hazard to the aquatic environment.

Safety precautions: Use the product in accordance with the Good Laboratory Practice.
Avoid 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 buffered 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
m-Phenylendiamine *Index N. (Annex VI of CLP Reg.) 612-147-00-3)*	203-584-7	108-45-2	< 0.2%	Mutagenicity, cat. 2 Acute Toxicity – Oral, cat. 3 Acute Toxicity – Dermal, cat. 4 Acute Toxicity – Inhalation, cat. 4 Eye Damage/Irritation, cat. 2A Sensitisation – Skin, cat. 1 Aquatic Acute, cat. 1** Aquatic Chronic, cat.1**	Muta. 2, H341 Acute Tox. 3, H301 Acute Tox. 4, H311 Acute Tox. 4, H331 Eye Irrit. 2, H319 Skin Sens. 1, H317 Aquatic Acute 1, H400 (M=1) Aquatic Chronic 1, H410 (M=1)
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 substance(s) listed in the Hazardous Substance Lists and/or evaluated for carcinogenicity by IARC, NTP, OSHA: m-Phenylendiamine. 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 immediately (show the SDS or the label were possible).

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:	Contains m-Phenylendiamine. **May cause an allergic skin reaction.** Ingestion may cause irritation to the gastrointestinal mucous membranes. Inhalation of the product may cause irritation to the mucous membranes and upper respiratory tract.
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, CO_2, 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 CO_x, NO_x, SO_x, HCl.

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. Equipment must be conformed with national/international standards and used in highest condition of protection on the basis of the information reported in the previous sub-sections.

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 sparkles 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 15 – 25 °C. 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	*Calibration Solution C* is intended for in vitro diagnostic use. Avoid contact with skin. 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****
m-Phenylenediamine[5]		
Australia	0,1 mg/m³	
Belgium	0,1 mg/m³	
Canada - Ontario	0,1 mg/m³	
Canada - Quebec	0,1 mg/m³	
Denmark	0,1 mg/m³	0,2 mg/m³
New Zealand	0,1 mg/m³	
Spain	0,1 mg/m³	
Switzerland	0,1 mg/m³	

m-Phenylenediamine [6]**:** TLV-TWA (ACGIH): 0.1 mg/m3 for m-Phenylendiamine (Note: A4 – not classifiable as a human carcinogen).

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*
m-Phenylenediamine (2)	*Oral (mg/(mg/kg bw/day*								0.06
	Dermal (mg/kg bw/day)		0.49 µg/cm²		0.12		0.25 µg/cm²		0.06
	Inhalation (mg/m³)				0.24				0.03

PNEC Values (components): **m-Phenylenediamine** (2)

PNEC aqua (freshwater) 0.001 mg/L

PNEC aqua (marine water) = 0.0001 mg/L

PNEC aqua (intermittent releases) = 0.046 mg/L

PNEC STP =1 mg/L

PNEC sediment (marine water) = 0.00041 mg/kg

PNEC sediment (fresh water) = 0.0041

PNEC soil = 0.0002 mg/kg soil

Recommended monitoring procedures:

The measurement of substances at the workplace must be carried out with standardized methods 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. 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 national/international 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:	odorless	
Color:	colorless	
pH:	Not available	
Flammability:	Aqueous solution, not expected to be flammable	
Explosive properties:	Aqueous solution, not expected to be explosive	
Oxidizing properties:	Aqueous solution, not expected to be oxidant	
Density:	not available	
Solubility:	Not available	
Water Solubility:	miscible	Mixture
Melting point/range:	Liquid, not applicable	

9.2 Other information

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 15-25°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 oxidizing agents.
10.6 Hazardous decomposition products:	Thermal decomposition or combustion may include toxic and hazardous fumes of CO_x, NO_x, SO_x, HCl.

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 irritation. May cause an allergic skin reaction.
Ingestion:	may cause irritation to the gastrointestinal mucous membranes.
Inhalation:	inhalation of the product may cause irritation to the mucous membranes and upper respiratory tract
Contact with eyes:	may cause irritation.

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

m-Phenylenediamine: The percutaneous absorption of m-phenylenediamine has been demonstrated in dogs and rats. Resorption of the substance, applied in the form of hydrochloride, was confirmed for humans, but not quantified. m-Phenylendiamine is metabolized in the liver. It is partially ring-hydroxylated in the mammalian organism and relatively rapidly eliminated with the urine in N-acetylated condition. The following three urinary metabolites were also identified: N-acetyl-1,3-diaminobenzene, N,N'-diacetyl-2,4-diaminophenol, and N,N'-diacetyl-1,3-diaminobenzene. [4][7][8]

Acute toxicity	Value	m.u.	Effects		Related to
Oral:	LD50 (rat) = 280	mg/Kg		[1]	m-Phenylendiamine
Dermal:	LD50 (rabbit) = 1,500	mg/Kg		[1]	m-Phenylendiamine
Inhalation:	IC50 (rat) = 3.2	mg/L/4h		[7]	m-Phenylendiamine

Other data: Not available

Corrosion/Irritation

Skin Corrosion/Irritation: *m-Phenylendiamine* was a mild skin irritant. (2)

Serious eye damage/ irritation: In a study on rabbit 100µL of *m-Phenylendiamine* produced severe eye irritation to eyes. (3)

Sensitization:

Skin sensitization: At three concentrations, 2%, 5%, and 10% m-Phenylendiamine is a sensitizing agent in the LLNA assay. (2)

Respiratory sensitization: Data not available

CMR effects

Germ cell mutagenicity: *m-Phenylendiamine :* In most of the Ames mutagenicity assays, m-phenylenediamine was mutagenic to Salmonella typhimurium strains with, but not without, metabolic activation. In human lymphocyte cultures, m-phenylenediamine was classified as a borderline mutagen in the chromosomal aberrations assay and was not mutagenic in the cytogenetics assay (with or without metabolic activation). Positive and negative responses were also noted in a variety of other in vitro and in vivo mutagenicity tests. (7)

Reproductive toxicity: *m-Phenylendiamine :* In teratogenicity studies, the m-phenylenediamine was administered by gavage to Sprague-Dawley rats on days 6 through 15 of gestation at doses of 45, 90, and 180 mg/kg. A significant reduction in mean maternal weight gain was noted at the highest dose level, but no teratogenic effects were noted. (4) Based on the available data, the chemical is not considered to have reproductive or developmental toxicity.

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*
m-Phenylendiamine	-	Group 3 - Not classifiable as to its carcinogenicity to humans.	-

m-Phenylendiamine: In the studies carried out to date, m-phenylenediamine was not carcinogenic after oral administration; when the substance was administered by subcutaneous injection, tumours developed at the injection site. (10) The substance is classified in Group 3 by the International Agency for Research on Cancer (IARC). Equivocal tumorigenic agent by RTECS criteria. (3)

STOT –single exposure Not available

STOT – repeated exposure *m-Phenylenediamine*: The data available are not sufficient to make a conclusion about the carcinogenicity of the chemical. In a subchronic (90-day) oral toxicity study involving groups of 20 rats, the no-effect level was 6 mg mphenylenediamine/kg body weight. At histopathologic examination, degenerative lesions in the liver were observed only in the 18-mg/kg/day dose group. There was no indication of toxic injury to the kidneys. m-Phenylenediamine was not neurotoxic when administered orally to rats at doses of up to 20 mg/kg for 90 days. (2)(7)

Aspiration hazards Not available

Other information: m-phenylenediamine was classified as inactive, i.e., no endocrine disruption activity. (7)

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 (*Oncorhynchus mykiss*) = 512 mg/l/96 hours	(2)	m-Phenylendiamine
		LC50 = 5,7 mg/l/48 h	(9)	m-Phenylendiamine
	Chronic toxicity with fish:	Not available		
	Acute toxicity with crustaceans:	LC50 (*Gammarus fasciatus*)= 7.8 mg/L/48h	(2)	m-Phenylendiamine
		EC50 = 5,9 mg/l/48 h	(9)	m-Phenylendiamine

	Chronic toxicity with crustaceans:	NOEC (*Daphnia magna*), reproduction = 0.05 mg/L/21 d NOEC (*Daphnia magna*), growth = 0.19 mg/L/21 d	(2)	m-Phenylendiamine
		NOEC = 0,32 mg/l/21 day	(9)	m-Phenylendiamine
	Acute toxicity with algae:	EC50 (*Selenastrum capricornutum*)= 2.87 mg/l/96 hours NOEC = 0.915 mg/l/96 hours		m-Phenylendiamine
	Chronic toxicity with algae:	Reproduction (number of young/day and total young produced) was the most sensitive indicator of the toxicity of the test substance to Daphnia magna, where the NOEL was determined to be 0.2 mg/L. A NOEL for growth of 1.5 mg/L was determined. Survival was the least sensitive indicator. The Maximum Allowable Toxicant Concentration (MATC) is between 0.2 and 0.4 mg/L.	(10)	m-Phenylendiamine
	Toxicity data on soil micro- and macroorganisms	Not available		
	Toxicity data on birds, bees and plants:	Not available		
12.2	**Persistency and degradability:**	*m-Phenylendiamine* was observed to degrade 60% after 5 days at concentration levels of 25 to 30 ppm using an acclimated activated sludge inoculum. However at 50 ppm the substance was reported to be toxic to 3 unacclimated activated sludges. Soil microflora did not cleave the benzene ring of m-Phenylendiamine in 64 days. m-Phenylendiamine, present at an initial concn of 100 mg/l, reached 2% of its theoretical BOD in 4 weeks using an activated sludge inoculum. (4)		
12.3	**Bioaccumulation potential:**	log Pow: -0.3 for m-Phenylendiamine. (2) On the basis of log Pow values a bioaccumulation potential is not expected for m-Phenylendiamine. An BCF value of 0.33 was calculated for m-Phenylendiamine, using an estimated log Kow of –0.3. BCF values of 1.3 to 4.6 and <1.6 to 24 that were measured for 1,3-benzenediamine in carp at 2 and 0.2 mg/l respectively, suggest that bioconcentration of m-Phenylendiamine in aquatic organisms is low.(4)		
12.4	**Mobility in soil:**	The Koc of m-Phenylendiamine, estimated as ≈16, using a measured log Kow of –0.3, suggests that the substance is expected to have very high mobility in soil. (4)		
12.5	**Results of PBT and vPvB 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.
- 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).
- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices.

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

US Federal Regulations:

State	*Components listed*	*Note*
Massachusetts	m-PHENYLENEDIAMINE	-
New York	-	-
New Jersey	m-PHENYLENEDIAMINE	-
Pennsylvania	-	-

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]*
1,3-Phenylenediamine	108-45-2	-	-	-	313	-	-

[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**.**

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 03/11/2010.
- Revision n. 01, dated 07/13/2010.
- Revision n. 02, dated 11/11/2011.
- Revision n. 03, dated 03/06/2012.
- Revision n. 04, dated 06/22/2012.
- Revision n. 05, dated 10/13/2015. 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.
- Revision n. 06, dated 2022-11-01. Main change is in Section 15, updating the Directive 98/79/EC reference to Regulation (EU) 2017/746.

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):

H301 : Toxic if swallowed.
H311 : Toxic in contact with skin.
H317 : May cause an allergic skin reaction.
H319 : Causes serious eye irritation.
H331 : Toxic if inhaled.
H341 : Suspected of causing genetic defects.
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:

Classification according to Regulation (EC) 1272/2008	*Classification procedure*
Not classified	**-**

Classification according to 29 CFR 1910.1200 (HCS) and to HPR (WHMIS 2015)	*Classification procedure*
Skin sens. 1, H317	**Cut-off method**

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).

Bibliographic references:

(1) m-Phenylenediamine, ChemIDplus Lite

(2) m-Phenylenediamine, ECHA dossier online. Available: http://apps.echa.europa.eu/registered/data/dossiers/DISS-abd20f18-e36b-3946-e044-00144f67d249/DISS-abd20f18-e36b-3946-e044-00144f67d249_DISS-abd20f18-e36b-3946-e044-00144f67d249.html

(3) National Institute for Occupational Safety and Health, m-Phenylenediamine, RTECS SS7700000

(4) HSDB , m-Phenylenediamine, CAS 108-45-2

(5) GESTIS Database

(6) ACGIH, TLVs and BEIs based on the Documentation of the Threshold Limit Values for Chemical Substances and Physical Agents & Biological Exposure Indices, 2012

(7) Safety Assessment of m-Phenylenediamine and m-Phenylenediamine Sulfate as Used in Cosmetics, CIR EXPERT PANEL MEETING DECEMBER 10-11, 2012

(8) Gestis Substance Database, m-Phenylenediamine

(9) Scheda di Dati di Sicurezza secondo l'Allegato II del Regolamento 1907/2006 (REACh), m-fenilendiamina, Versione: 1.1 Data di emissione: 29/10/2014

(10) http://www.epa.gov/oppt/chemtest/pubs/pda.pdf

SECTION 1. IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY

1.1 Identification of the mixture

Product Name: **REFERENCE SOLUTION**

Product Number: **NOT APPLICABLE**

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:
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 (US)

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

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

SECTION 2. HAZARDS IDENTIFICATION

2.1 Classification of the mixture:
This product is hazardous according to Regulation (EC) No 1272/2008, according to OSHA 29 CFR 1910.1200, and according 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:

Hazard class	*Hazard category*	*Hazard statement*
SERIOUS EYE DAMAGE/EYE IRRITATION	**Cat. 1**	**Causes serious eye damage.** (H318)
HAZARDOUS TO THE AQUATIC ENVIRONMENT	**Cat. 3**	**Harmful to aquatic life with long lasting effects.** (H412)
		For exposure limits see ch. 8.

According to Hazard Communication Standard, 29 CFR 1910.1200 (HCS), and according to Hazardous Product Regulation HPR (WHMIS 2015):

Hazard class	*Hazard category*	*Hazard statement*
SERIOUS EYE DAMAGE/EYE IRRITATION	**Cat.1**	**Causes serious eye damage.**
HAZARDOUS TO THE AQUATIC ENVIRONMENT**	**Cat. 3**	**Harmful to aquatic life with long lasting effects.**
		For exposure limits see ch. 8.

***Environmental classification according to Reg. N. 1272/2008 (EC) and subsequent amendments*.

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

The product causes serious eye damage.
The product is harmful to aquatic life with long lasting effects.

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

Hazard pictogram(s):	
Signal word(s):	**Danger**

Hazard statement(s):	**Causes serious eye damage.** (H318) **Harmful to aquatic life with long lasting effects.** (H412)**
Precautionary statement(s):	**Wear protective gloves/protective clothing/eye protection/face protection.** (P280) **IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.** (P305 + P351 + P338) **Immediately call a POISON CENTER or doctor/physician.** (P310) **Avoid release to the environment.** (P273) **Dispose of contents/container in accordance with local/regional/national/international regulation.** (P501)
Other labeling details:	**Contains: Polyethylene glycol dodecyl ether**.
	Up to 3.4% of the mixture consists of component of unknown acute toxicity (inhalation) for the human health.

*****Environmental classification and labeling according to Reg. N. 1272/2008 (EC) and subsequent amendments.***

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: liquid 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 (WHMIS 2015)	Classification 1272/2008/EC
Glycerin	200-289-5	56-81-5	< 50%	Not classified	Not classified
Potassium nitrate	231-818-8	7757-79-1	< 8.0%	Oxidizing Solid, cat. 3	Ox. Sol. 3, H272
Polyethylene glycol dodecyl ether (Brij 35)	500-002-6	9002-92-0	< 8.0%	Acute Toxicity - Oral, cat.4 Eye Damage/Irritation, cat. 1	Acute Tox 4, H302 Eye Dam. 1, H318
Silver nitrate *Index N. (Annex VI of CLP Reg.)* *047-001-00-2*	231-853-9	7761-88-8	< 0.01%	Oxidizing Solid, cat. 2 Skin Corrosion/ Irritation, cat 1B Aquatic Acute, cat. 1** Aquatic Chronic, cat 1**	Ox. Sol. 2, H272 Skin Corr. 1B, H314 Aquatic Acute 1, H400 (M=1000) Aquatic Chronic 1, H410 (M=100)

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 substances listed in the Hazardous Substance Lists and/or evaluated for carcinogenicity by IARC, NTP, OSHA: Potassium nitrate, Glycerol, Silver nitrate. 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. Do not induce vomiting. Get medical advice if adverse symptoms appear.

Inhalation exposure: If inhaled, move person to fresh air. If breathing is difficult, oxygen should be administered. Get medical advice if adverse symptoms appear.

Contact with skin: Remove immediately contaminated clothes and shoes. Wash immediately affected area with soap or mild detergent and plenty of water until the removal of the mixture (15-20 minutes). Get medical advice if adverse symptoms appear.

Contact with eyes: Wash immediately with plenty of water or normal saline for at least 15 minutes. Keep eyelid open with the finger. Get medical advice immediately (show the SDS or the label were possible).

4.2 Most important symptoms and effects (acute and delayed)

Acute:	Inhalation: May cause irritation. Skin : May be irritant for skin. Eyes: causes serious eye damage. 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:	Based on the assessment of risk of hazardous chemical agents, the competent person will settle the appropriate medical surveillance protocol, in accordance with the national/Community legislation, in order to protect the health status of the workers.
Antidotes, if known:	Not known.

SECTION 5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Water spray or regular foam, CO_2, 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.

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. Equipment must be conformed with national/international standards and used in highest condition of protection on the basis of the information reported in the previous sub-sections.

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 sparkles 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 at15-25°C. Avoid light exposure and keep away from heat sources. Room ventilation: well ventilated workplace. Keep containers tightly closed and labeled with the name of the product. Avoid environmental release. Keep away from food and drinks.
7.3 Specific end use	*Reference Solution* is intended for in vitro diagnostic use. Avoid contact with eyes. 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****
Silver, soluble compounds (as Ag) [1]		
Australia	0,01 mg/m³	
France	0,01 mg/m³	
Italy	0,01 mg/m³	
Sweden	0,1 mg/m³	
The Netherlands	0,01 mg/m³	
Canada - Ontario	0,01 mg/m³	
USA NIOSH	0,01 mg/m³	
UK	0,01 mg/m³	
Silver compounds (as Ag) [1]		
Austria	0,01 – inhalable aerosol	0,1 – inhalable aerosol
Belgium	0,01 mg/m³	
Germany (AGS)	0,01 mg/m³ – inhalable aerosol	0,02 mg/m³–inhalable aerosol[a]
Germany (DFG)	0,01 mg/m³ – inhalable aerosol	0,02 mg/m³– inhalable aerosol
New Zealand	0,01 mg/m³	
Poland	0,05 mg/m³	
Spain	0,01 mg/m³	
Switzerland	0,01 mg/m³ – inhalable aerosol	0,02 mg/m³– inhalable aerosol
Canada - Ontario	0,01 mg/m³	
USA-OSHA	0,01 mg/m³	
Silver, soluble compounds (as Ag) total dust [1]		
Austria	0,01 mg/m³ – inhalable aerosol	
Canada - Quebec	0,01 mg/m³– inhalable aerosol	
Denmark	0,01 mg/m³– inhalable aerosol	0,02 mg/m³– inhalable aerosol
European Union	0,01 mg/m³ – inhalable aerosol	
France	0,01 mg/m³	
Hungary	0,01 mg/m³	
Poland	0,05 mg/m³	
Sweden	0,01 mg/m³	
Silver, metallic [1]		
Australia	0.1 mg/m³	
Austria	0,01 mg/m³– inhalable aerosol	
Belgium	0,1 mg/m³	
Denmark	0,01 mg/m³– inhalable aerosol	0,02 mg/m³
European Union	0,1 mg/m³ – inhalable aerosol	
France	0,1 mg/m³	
Germany (AGS)	0,1 mg/m³ – inhalable aerosol	0,8 mg/m³–inhalable aerosol[a]
Germany (DFG)	0,1 mg/m³ – inhalable aerosol	0,8 mg/m³– inhalable aerosol
Hungary	0,1 mg/m³	0,4 mg/m³

Ireland	0,1 mg/m³	
Italy	0,1 mg/m³	
New Zealand	0,1 mg/m³	
Poland	0,05 mg/m³	
Spain	0,1 mg/m³	
Sweden	0,1 mg/m³	
Switzerland	0,1 mg/m³ – inhalable aerosol	0,8 mg/m³– inhalable aerosol
The Netherlands	0,1 mg/m³	

Silver, soluble compounds, as Ag [2]**:** TWA = 0.01 mg/m³
Silver, metal, dust and fume [2] TWA = 0,1 mg/m³

[a] *15 minutes average value;*

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*
Potassium nitrate [3]	*Oral (mg/kg bw/day)*								12.5
	Dermal (mg/kg bw/day)				20.8				12.5
	Inhalation (mg/m3)				36.7				10.9
Silver nitrate [5]	*Oral (mg/kg bw/day)*								0.02
	Dermal (mg/kg bw/day)								
	Inhalation (mg/m3)				0.016				0.0063

PNEC Values (components): **Potassium nitrate** [3]
PNEC aqua (freshwater) = 0.45 mg/L
PNEC aqua (marine water) = 0.045 mg/L
PNEC aqua (intermittent releases) = 4.5 mg/L
PNEC STP =18 mg/L

Sopdium nitrate [5]
PNEC aqua (freshwater) = 0.04 µg/L
PNEC aqua (marine water) = 0.86 µg/L
PNEC STP =0.025 mg/L
PNEC sediment (marine water) = 438.13 mg/kg
PNEC sediment (fresh water) = 438.13 mg/kg
PNEC soil = 1.41 mg/hg soil dw

Recommended monitoring procedures:

The measurement of substances at the workplace must be carried out with standardized methods 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. 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 national/international 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:	not available	
pH:	not available	
Flammability:	not available	
Explosive properties:	not available	
Oxidizing properties:	not available	
Density:	not available	
Solubility:	not available	
Water Solubility:	miscible	Mixture
Melting point/range:	Liquid, not applicable	

9.2 Other information

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 15 - 25°C.
10.3 Possibility of hazardous reactions	Not foreseen.
10.4 Conditions to avoid:	Keep out from heat and light.
10.5 Incompatible materials	Oxidising agents, reducing agents, strong acid agents, strong basic agents.
10.6 Hazardous decomposition products:	Thermal decomposition or combustion may include toxic and hazardous fumes of COx, NOx.

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 irritation.
Ingestion:	Ingestion may cause irritation to the gastrointestinal mucous membranes.
Inhalation:	Inhalation of the product may cause irritation to respiratory ways.
Contact with eyes:	Causes serious eye irritation.

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

Potassium nitrate: After uptake into biological systems, the salts in the nitrate category will dissociate directly into nitrate ion and the corresponding cations, i.e. sodium, potassium and calcium. The cations will enter the body electrolyte pool, and are not expected to play a significant toxicological role at low doses. Animal studies indicated that after intestinal absorption, ammonium ions are converted to urea in the liver, and subsequently excreted in urine (within 6 hours). After ingestion of nitrate, it will be partly reduced to nitrite in the saliva in the mouth (and the gastro-intestinal tract) in humans and nitrite is less efficiently absorbed in the rat than in humans. In humans most of ingested nitrate is excreted via the urine (65-75%). ADME data were not available for sodium nitrate or ammonium nitrate. [4]

Silver, as Ag nitrate, is absorbed from the respiratory and the gastrointestinal tracts. Absorption through the intact skin is of no physiological significance, however, some absorption through mucous membranes of the nose and throat probably occurs. Long-term retention takes place in the liver, kidneys, spleen, bone marrow, lungs, muscles and skin. The deposits in the organs are limited to the connective tissue. Elimination occurs slowly, chiefly after biliary secretion with the faeces, whereas small amounts are excreted with the urine.[6]

In rats, *alcohol ethoxylates* are readily absorbed in the gastrointestinal tract and rapidly excreted via the urine and faeces after oral application. Alcohol ethoxylates penetrate poorly through human skin and clearly less readily than through rat skin. The alkyl chain length appears to have an impact on the metabolism. AEs with longer alkyl chains are excreted at a higher proportion into expired air and less in urine. Also, ethoxy chain length impacts the proportions excreted via the urine, the faeces and the expired air with more being excreted via the faeces and expired in the air with longer ethoxy chain length. (10)

Acute toxicity	**Value**	**m.u.**	**Effects**		**Related to**
Oral:	LD50 (rat) = 3,750	mg/Kg		(3)	Potassium nitrate
	LD50 (rat) = 1,173	mg/Kg		(7)	Silver Nitrate
	LD50 (rat) = 1,000	mg/Kg		(20)	Brij 35
Dermal:	LD50 (rat) > 5,000	mg/Kg		(4)	Potassium nitrate
	LD50 (rat) > 2,000	mg/Kg		(5)	Silver
	LD50 (rabbit) > 2,000	mg/Kg		(10)	*alcohol ethoxylates*
Inhalation:	No mortality, no lesion of pathological significance were observed at the maximum achievable breathing zone concentration (0.527 mg/L air). The acute median lethal concentration (LC50) of potassium nitrate was found to be greater than 0.527 mg/L air.			(3)	Potassium nitrate
	Alcohol ethoxylates are considered to be of low acute inhalation toxicity to rats with LC50 values exceeding the saturated vapour concentration in air.			(10)	Polyethylene glycol dodecyl ether
Other data:	Potassium nitrate is fatal to humans at an oral dose of 214-500 mg/kg bw. (4)				

Corrosion/Irritation

Skin Corrosion/Irritation

Potassium nitrate: not irritating to rabbit skin (read across from ammonium nitrate). (3)

Silver nitrate dusts and solutions cause irritative to severely corrosive effects on mucosa and skin. (8) silver nitrate was corrosive in an OECD Guideline 431: In vitro Skin Corrosion: Human Skin Model Test (2004). (5)

Polyethylene glycol dodecyl ether: in a closed patch test, it was harmful to the blood vessel of the dermal layer but had little effect on the epidermal layer.(11) Alcohol ethoxylates with varying carbon chain lengths and ethoxylation degree were found to be slightly to severely irritating to skin in rabbits and rats. In humans, AEs are less irritating to skin than in animals. Neat applications of a range AEs in a 4h human patch test did not warrant these chemicals to be classified as skin irritants under EU legislation. (10)

Serious eye damage/ irritation

Potassium nitrate: not irritating in an OECD guideline 437 "Bovine corneal opacity and permeability (BCOP) test.(3)

Silver nitrate: was highly irritating to rabbit in an in vivo test.(5) Crystals that entered the eyes can cause severe inflammations and profound injuries in the surrounding tissues. Solutions of 5-50% silver nitrate cause severe eye damage, and some cases entail permanent corneal turbidities. (6)(8)

Polyethylene glycol dodecyl ether: Alcohol ethoxylates range from mildly to severely irritating to rabbit eyes. The available information suggest that concentrated solutions containing AEs at concentrations above 1% may be moderately to severely irritating to eyes. (10) In a Draize test, *Brij* produced severe irritation to eyes of rabbit (24h). (12)

Sensitization:

Skin sensitization:

Potassium nitrate: not sensitizing (read across from supporting substance). (3)

Silver nitrate: no signs of a significant sensitizing potential. (8)

Polyethylene glycol dodecyl ether: Based on a weight of evidence approach and considering quality criteria in evaluating the studies, alcohol ethoxylates are not considered to be skin sensitizers.(10)

Respiratory sensitization: Not available

CMR effects

Germ cell mutagenicity;

Potassium nitrate: The nitrate category members are not considered genotoxic in vitro. (4)

Silver nitrate: based on the available data the criteria for classification are not satisfied.

Brij 35 was negative in vitro (Ames test, Chromosomal aberration, Mouse lymphoma test). (13)(14) In all available in vitro and in vivo genotoxicity assays, there was no indication of genetic toxicity of broad range of structurally different alcohol ethoxylates. Most of the studies were performed in accordance with GLP and following OECD guideline methodologies. (10)

Reproductive toxicity:

Potassium nitrate: In an OECD TG 422 reproductive/developmental toxicity screening study, rats were exposed to 1, 250, 750 and 1,500 mg/kg bw/day potassium nitrate. The NOAEL for reproduction and developmental toxicity was 1,500 mg/kg bw/d based on the absence of adverse effects. Based on the available data, members of the nitrate category are not considered reproductive or developmental toxicants. (4)

Silver nitrate: Based on the existing information, it is not known whether silver causes developmental toxicity in humans. The existing evidence does not point to a strong effect of silver on reproduction. However, no multigeneration reproductive studies were located, and therefore a firm conclusion regarding reproductive toxicity cannot be made. (9)

Based on the available information from two 2-generation studies, there was no evidence that exposure to *alcohol ethoxylates* caused reproductive toxicity. (10)

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*
The components of the mixture are not listed.			

Potassium nitrate: Nitrates taken up in food may be implicated in the formation of N-nitroso compounds that are known mutagens and/or carcinogens. However, no data indicating carcinogenicity of nitrate category members were available. No positive relationship has been found between cancer incidence and nitrate intake in several epidemiological studies. (4)

Silver nitrate: Even after many years in which SN was utilized as therapeutic agent there are no signs of a carcinogenic potential.(8) Predominantly negative genotoxicity studies and the lack of reports of cancer associated with silver in humans, despite long-standing and varied usage, suggest that silver does not cause cancer. (9)

Polyethylene glycol dodecyl ether: On the basis of the available information it can be concluded that alcohol ethoxylates are not carcinogenic. This assessment is further supported by the absence of any mutagenic or genotoxic activity of this compound class. (10)

STOT –single exposure

Silver nitrate: The inhalation of dusts might cause acute irritations of the respiratory tract, and also possible lung damage. However, it is assumed that the relevant concentrations are much higher than those that cause rapid discolorations of the eyes and the nasal mucosa.(8)

STOT – repeated exposure

Potassium nitrate: In an OECD TG 422 study, rats were exposed to 0, 250, 750 and 1,500 mg/kg bw/day potassium nitrate via the oral route for 28 days. The NOAEL was 1,500 mg/kg bw/d based on the absence of adverse effects. (4)

Silver nitrate: The predominant effect of exposure to silver in humans is the development of a characteristic, irreversible pigmentation of the skin, called argyria. Exposure to silver has been observed to result in the deposit of silver in neurons of the central nervous system. However, this effect is not known to be toxic. Neurological effects attributable to silver have not been reported in humans nor have existing case or occupational studies. No human studies were located that indicate that exposure to silver or silver compounds will affect the cardiovascular system or blood counts.
Silver nitrate and/or silver oxide have been reported to cause upper and lower respiratory tract irritation in humans when inhaled. However, these effects are likely to be related to the caustic properties of the compound, not to the presence of silver. (9)

The NOAEL of *alcohol ethoxylates* for systemic toxicity was established to be 50 mg/kg bw/d on the basis of a well conducted 2-year oral feeding study in rats with C12-13AE6.5. The effects were restricted to changes in organ weights with no histopathological organ changes with the exception of liver hypertrophy (indicative of an adaptive response to metabolism rather than a toxic effect).(10)

Aspiration hazards

Not available.

Other information:

Occupational studies weakly suggest that impairment of vision, gastrointestinal distress, or renal histopathology may result from chronic exposure to silver in humans. (9)

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 (96 h) > 98.9 mg/L (No mortality or sublethal effects)	(3)	Potassium nitrate
	LC50 (96 h) = 1.2 µg Ag/l/96 h	(5)	Silver nitrate
Chronic toxicity with fish:	28 day EC10 = 0.39 µg Ag/l 28 day NOEC = 130 µg Ag/l	(5)	Silver nitrate
Acute toxicity with crustaceans:	EC50 = 490 mg/L/48 h (300 mg NO3/L)	(3)	Potassium nitrate
	EC50 = 0.22 µg Ag/l48 h	(5)	Silver nitrate
Chronic toxicity with crustaceans:	12 day NOEC > 245 < 408 mg/L	(3)	Potassium nitrate
	21 day NOEC = 2.6 µg Ag/l 28 day NOEC = 19 µg Ag/l	(5)	Silver nitrate
Acute toxicity with algae:	EC10 = 0.443 µg Ag/l/96 h EC50 = 9.6 µg Ag/l/96 h	(5)	Silver nitrate
Chronic toxicity with algae:	EC50 >1700 mg/L/10 day (growth rate)	(3)	Potassium nitrate
	14 day NOEC = 1.2 µg Ag/l	(5)	Silver nitrate
Toxicity data on soil micro- and macroorganisms	Not available.		
Toxicity data on birds, bees and plants:	Not available.		

12.2 Persistency and degradability:

Potassium nitrate: The nitrate salts are soluble in water and dissociate into the nitrate ion and the corresponding cations in biological fluids and aquatic environments. (4)

Polyethylene glycol dodecyl ether **:** is readily biodegradable. (11)

12.3 Bioaccumulation potential:

Potassium nitrate: As nitrates are biodegradable and very soluble in water, they are not expected to bioaccumulate in aquatic organisms. (4)

*Polyethylene glycol dodecyl ether***:** An estimated BCF of 81 suggests the potential for bioconcentration in aquatic organisms is moderate. (11)

12.4 Mobility in soil:

*Polyethylene glycol dodecyl ether***:** If released to soil, is expected to have high mobility based upon an estimated Koc of 150. (11)

12.5 Results of PBT and vPvB assessment

Chemical Safety Report and PBT assessment: not performed.

12.6 Other toxic effects:

Nitrates can have indirect and long-term effects on ecosystems, e.g. eutrophication. (4)

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. Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

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.
- 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).
- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices.

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

US Federal Regulations:

State	*Components listed*	*Note*
Massachusetts	Glycerin Potassium nitrate Silver nitrate	No note No note No note
New York	Silver nitrate	No note
New Jersey	Glycerin Potassium nitrate Silver nitrate	No note No note No note
Pennsylvania	Glycerin Potassium nitrate Silver nitrate	No note No note No note

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]*
Silver nitrate	7761-88-8	-	-	1	313c	-	-

[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.

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 03/11/2010.
- Revision n. 01, dated 07/13/2010.
- Revision n. 02, dated 11/11/2011.
- Revision n. 03, dated 03/06/2012.
- Revision n. 04, dated 06/22/2012.
- Revision n. 05, dated 10/13/2015. 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.
- Revision n. 06, dated 2022-11-01. Main change is in Section 15, updating the Directive 98/79/EC reference to Regulation (EU) 2017/746.

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 Exposure 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.

H318: Causes serious eye damage.

H272: May intensify fire; oxidiser.

H400: Very toxic to aquatic life.

H410: Very toxic to aquatic life with long lasting effects.

H412: Harmful 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, according to Hazard Communication Standard, 29 CFR 1910.1200 (HCS), and to HPR (WHMIS 2015) :

Classification:	*Classification procedure*
Causes serious eye damage. (H318) **Harmful to aquatic life with long lasting effects.** (H412)	**Calculation method**

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).

Bibliographic references:

(1) GESTIS International Limit Values, available on http://limitvalue.ifa.dguv.de/WebForm_ueliste.aspx

(2) ACGIH, TLVs and BEIs based on the Documentation of the Threshold Limit Values for Chemical Substances and Physical Agents & Biological Exposure Indices, 2012

(3) Potassium Nitrate, Registration Dossier, ECHA, http://apps.echa.europa.eu/registered/data/dossiers/DISS-9ec15aa2-7274-0156-e044-00144f67d031/DISS-9ec15aa2-7274-0156-e044-00144f67d031_DISS-9ec15aa2-7274-0156-e044-00144f67d031.html

(4) SIAM 25, 17-18 October 2007, SIDS INITIAL ASSESSMENT PROFILE, Nitrates category

(5) Silver Nitrate, Registration Dossier, ECHA http://apps.echa.europa.eu/registered/data/dossiers/DISS-98786238-3657-1bb4-e044-00144f67d031/DISS-98786238-3657-1bb4-e044-00144f67d031_DISS-98786238-3657-1bb4-e044-00144f67d031.html

(6) HSDB, Silver Nitrate, Full record display

(7) ChemIDplus, A TOXNET DATABASE, Silver nitrate, Full record

(8) Gestis Substance Database, Silver Nitrate, ZVG 3720

(9) http://www.atsdr.cdc.gov/toxprofiles/tp146-c2.pdf

(10) Human & Environmental Risk Assessment on ingredients of European household cleaning products, Alcohol Ethoxylates, Version 2.0
September 2009

(11) HSDB Hazardous Substances Databank, DODECYL ALCOHOL, ETHOXYLATED

(12) BIOFAX Industrial Bio-Test Laboratories, Inc., Data Sheets. Vol. 9-4/1970

(13) SUZUKI,S, ATAI,H AND HATAKEYAMA,Y; Mutagenicity test on polidocanol; JITCHUKEN ZENRINSHO KENKYUHO 15(1):1-9, 1989

(14) NTP database search application, Ethoxylated dodecyl alcohol