SAFETY DATA SHEET
COATEST™ APC™ RESISTANCE V

Doc. ID: SDS00082312063_EN
Revision: 01
CO: 459894
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IDENTIFICATION OF THE PRODUCT AND OF THE COMPANY

Identification of the product

Product Name: **COATEST™ APC™ Resistance V**

Product Number: **0082312063**

Use of the product: For in vitro diagnostic use

Company identification:

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

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

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

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

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

INFORMATION ON COMPOSITION/HAZARD OF THE PRODUCT

P/N	Mixture name	Mixture classification According to Hazard Communication Standard, 29 CFR 1910.1200 (HCS) Hazardous Product Regulation HPR (WHMIS 2015)	Mixture classification According to 1272/2008/EC Regulation	Kit configuration
000H00527	$CaCl_2$	Not classified	Not classified	1 x 8 ml
000H01176	APTT Reagent	Not classified	Not classified	1 x 16 ml
000H01434	APC/ $CaCl_2$	Sensitization-Respiratory, cat. 1	Not classified	4 x 2 ml
000C00423	Control Plasma Level 1	Not classified	Not classified	1 x 1 ml
000H01444	Control plasma Level 2	Not classified	Not classified	1 x 1 ml
000H01450	V-DEF Plasma	Not classified	Not classified	4 x 4 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: **$CaCl_2$**

Product Number: **000H00527**

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.
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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 not 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, 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*
Not classified		
		For exposure limits see ch. 8

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

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

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):	None
Precautionary statement(s):	None
Other labeling details:	None

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

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

Warning:
The product contains bovine material. All donor animals were sourced from BSE-free herds. The cattle received ante- and post mortem health inspection by a veterinarian, and they were apparently free from infectious and contagious material. However, the material should be treated as potentially infectious.
Bovine serum albumin (BSA) might cause allergic skin reaction and/or allergy or asthma symptoms or breathing difficulties if inhaled.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Composition: Liquid containing organic and inorganic components, bovine source material.

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.)	< 0.4 %	Eye damage/irritation, cat. 2	Eye Irrit.2, H319
Tris Hydrochloride	214-684-5	1185-53-1	< 0.2%	Skin Corrosion/Irritation, cat.2 Eye damage/Eye Irritation, cat. 2B	Skin Irrit. 2, H315 Eye Irrit. 2, H319
Tris-Hydroxymethyl aminomethane (Tris Amino)	201-064-4	77-86-1	< 0.05%	Skin Corrosion/Irritation, cat.2	Skin Irrit. 2, H315
1,2-dibromo-2,4-dicyanobutane (MDBGN)	252-681-0	35691-65-7	< 0.015%	Acute Tox. – Oral, cat. 4 Skin Corrosion/Irritation, cat.2 Eye damage/irritation, cat. 1 Sensitization – Skin, cat.1 Aquatic Acute, cat 1**	Acute Tox. 4, H302 Skin Irrit. 2, H315 Eye Dam. 1, H318 Skin Sens. 1, H317 Aquatic Acute 1, H400 (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 one substance listed in the Hazardous Substance Lists and/or evaluated for carcinogenicity by IARC, NTP, OSHA: 1,2-dibromo-2,4-dicyanobutane. 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 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 to the mucous membranes and upper respiratory tract.
Skin : May be irritant for skin.
Eyes: May cause irritation.
Ingestion: may cause irritation to the gastrointestinal mucous membranes.

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, HCl, HF, HBr, 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 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 2-8°C. Avoid light exposure and keep away from heat sources. Room ventilation: well ventilated workplace. Keep containers tightly closed and labelled with the name of the product. Avoid environmental release.
Keep away from food and drinks.

7.3 Specific end use *$CaCl_2$* is intended for in vitro diagnostic use. The material contains bovine material, and should be treated as potentially infectious. Bovine serum albumin (BSA) might cause allergic skin reaction and/or allergy or asthma symptoms or breathing difficulties if inhaled. 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 [(1)]
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. [(3)]	*Oral (mg/(mg/kg bw/day*								
	Dermal (mg/kg bw/day)								
	Inhalation (mg/m^3)	*10*		*5*		*5*		2.5	

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:	Clear liquid	
Odor:	Not available	
Color:	Colorless	
pH:	7.4 – 7.6	Mixture
Flammability:	Aqueous solution, not expected to be flammable	
Explosive properties:	Aqueous solution, not expected to be explosive	
Oxidizing properties:	Aqueous solution, not expected to be oxidant	
Density:	Not available	
Solubility:	not available	
Water Solubility:	miscible	Mixture
Melting point/range:	Liquid, not applicable	

9.2 Other information

Miscibility	miscible

SECTION 10. STABILITY AND REACTIVITY

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

Ingestion: Ingestion may cause irritation to the gastrointestinal mucous membranes.

Inhalation: May cause irritation to the mucous membranes and upper respiratory tract.

Contact with eyes: May cause eye irritation.

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

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

Tris amino: is not metabolized appreciably and is eliminated by the kidneys. Ionized tromethamine is excreted by kidney, so the effect is that of excretion of hydrogen ions. Elimination of drug from body is entirely by renal excretion. It is not known whether tromethamine is distributed into human milk. (4)

1,2-dibromo-2,4-dicyanobutane (MDBGN) is readily absorbed following oral and dermal administration. Once inside the body, is rapidly metabolised to 2-MGN before eventually being eliminated from the body, mostly via urine. Debromination of MDBGN occurs prior to systemic distribution; therefore, tissue exposure to parent chemical is expected to be low. (10)

Acute toxicity	**Value**	**m.u.**	**Effects**		**Related to**
Oral:	LD50 (rat) > 3,000	mg/kg		(5)	Tris Amino
	LD50 (rat) =3,798 - 4,179 LD50 (rabbit)=500 – 1,000	mg/Kg	The acute oral toxicity is attributed to the severe irritating property of the original substance or its high-concentration solutions to the gastrointestinal tract.	(1)	Calcium chloride
	LD50 (rat) = 515 - 770	mg/Kg		(11)	1,2-dibromo-2,4-dicyanobutane
Dermal:	LD50 (rat) > 5,000	mg/kg		(6)	Tris Amino
	LD50 (rabbit) > 5,000	mg/Kg		(1)	Calcium chloride
	LD50 (rabbit) > 5,000	mg/Kg		(11)	1,2-dibromo-2,4-dicyanobutane
Inhalation:	LC50 (rat) > 40	mg/m^3/4h		(1)	Calcium chloride
	LC50 (rat) > 5,09 LC50 (rat) > 13	mg/l/4h		(12) (13)	1,2-dibromo-2,4-dicyanobutane

Corrosion/Irritation

Skin Corrosion/Irritation

Tris Amino: Tromethamine was a mild irritant to rabbits at 25% with a pH of 10.8. At 40%, tromethamine was not irritating. Intradermal injections of tromethamine were severely irritating to rabbits at pH 10.4 but were only mildly irritating at pH 7.4. The supporting substance 2-Amino-2-methyl-1-Propanol (AMP) was found to be irritating to rabbits, with burrowing lesions noted when applied to abraded skin sites; there was mild irritation noted when applied to unabraded skin.(5)

Tris Hydrochloride: irritant to skin (read across from Tris Amino).

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

1,2-dibromo-2,4-dicyanobutane (Technical 98%) was severe irritant to rabbit skin. (14)

Serious eye damage/ irritation

Tris Amino (100%) was not an ocular irritant when administered to rabbits. (5)

Tris Hydrochloride : mild eye irritant in rabbits. (17)

Calcium chloride is irritating for the eyes. (1)

1,2-dibromo-2,4-dicyanobutane : In pure form (98%) is a severe eye irritant. Instillation of 1,2-dibromo-2,4-dicyanobutane powder into the rabbit eye resulted in severe irritation, which persisted for at least 21 days post-instillation.(10)

Sensitization:

Skin sensitization:

Tris Amino: The supporting chemical AMP is not sensitizing to guinea pig skin. (5)

Tris Hydrochloride: Not a sensitizer in experimental animals. (8)

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

1,2-dibromo-2,4-dicyanobutane : is a skin sensitizer agent, based on in vivo and in vitro animal data, and based on human data. (10)(15)

Bovine serum albumin (BSA), which is present in bovine plasma, could develop allergic skin reactions in laboratory workers after dealing with BSA powder. Based on the available data, the criteria for classification are not satisfied.

Respiratory sensitization:

Bovine serum albumin (BSA), which is present in bovine plasma, could develop allergic reactions in laboratory workers after dealing with BSA powder. It is reported a case of occupational asthma and rhinitis in a laboratory worker caused by the inhalation of 100% BSA powder. The patient had a high serum-spercific IgE level to BSA, and experienced severe systemic reactions, including eye itching, conjunctivitis, rhinorrhea, nasal obstruction, sneezing, shortness of breath, bronchospasm and decreased blood pressure. It was suggested an IgE-mediated response as the pathogenic mechanism.(17) Based on the available data, the criteria for classification are not satisfied.

CMR effects

Germ cell mutagenicity;

Tris Amino: The supporting chemical, AMP, was not mutagenic to bacteria and mammalian cells in vitro, and did not induce micronuclei in mice in vivo.

Tris Hydrochloride: Ames test negative.(9)

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

1,2-dibromo-2,4-dicyanobutane: did not show evidence of mutagenic activity in a variety of in vitro and in vivo assays, except for one assay where increased frequencies of chromosomal aberrations in CHO cells were observed in an in vitro chromosomal aberration test. (10)(16)

Reproductive toxicity:

Tris Amino: In an oral gavage combined reproductive/developmental toxicity screening test in rats no effects on reproductive or developmental parameters were observed at the doses tested; the NOAEL for reproductive and developmental toxicity is 1000 mg/kg-day, the highest dose tested. (5)

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

1,2-dibromo-2,4-dicyanobutane: In a study in rats exposed to 1,2-dibromo-2,4-dicyanobutane, a NOAEL for developmental toxicity was determined to be 175 mg/kg bw. Available information suggests that the substance is neither a reproductive nor a developmental toxin at doses that are not associated with maternal toxicity. (1)(12)(16)

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			

Tris Amino: based on the available data, the substance is not carcinogenic. (7)

1,2-dibromo-2,4-dicyanobutane: Under the conditions of 2-year dermal studies there was no evidence of carcinogenic activity of 1,2-dibromo-2,4- dicyanobutane in male or female rats administered 2, 6, or 18 mg/kg. (10)(16)

STOT –single exposure Not available.

STOT – repeated exposure There are no documented long-term effects of *TRIS AMINO* treatment, and no serious side-effects on record that are directly attributed to treatment with the compound. (6)

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

1,2-dibromo-2,4-dicyanobutane : In long-term repeat feeding studies in animals, the observed effects were thyroid follicular cell hypertrophy, thyroid hyperplasia, increased pigmentation of the liver and spleen and increased extramedullary hematopoiesis when administered at high doses (4000 ppm) in dogs. Follow-up studies found no significant changes in levels of thyroid hormones. Repeated dermal application of 1,2-dibromo-2,4-dicyanobutane was associated with moderate to severe erythema and slight to moderate edema. (10)(16)

Aspiration hazards Not available.

Other information: Not available.

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

SECTION 12. ECOLOGICAL INFORMATION

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

12.1 Toxicity	**species, media, units, test duration and test conditions.**		**Related to**
Acute toxicity with fish:	LC50 *Leuciscus idus* > 10,000 mg/L/ 96-h	(5)	Tris Amino
	LC50 *Pimephales promelas*= 4,630 mg/l/96 hours	(1)	Calcium chloride
	LC50 *Salmo gairdneri* = 1.75 mg/l/96 hour	(12)	1,2-dibromo-2,4-dicyanobutane
Chronic toxicity with fish:	Not available		
Acute toxicity with crustaceans:	Water fleas (Daphnia magna) were exposed to AMP at unspecified concentrations for 48 hours. LC50 = 193 mg/L/48 h.	(4)	Tris Amino
	EC50 daphnia > 100 mg/l/48h	(9)	Tris HCl
	EC50 *Daphnia magna* = 1062 mg/L/48 hr	(1)	Calcium chloride
	EC50 *Daphnia magna* = 6.16 mg/L/48 hr	(12)	1,2-dibromo-2,4-dicyanobutane
Chronic toxicity with crustaceans:	The chronic toxicity study with Daphnia magna shows that a 16% impairment of reproduction (EC16) is caused at the concentration of 320 mg/L.	(1)	Calcium chloride
Acute toxicity with algae:	EC50 *Selenastrum capricornutum* >100 mg/L/ 96 h	(5)	Tris Amino
	EC_{50} *Selenastrum capricornutum* = 2900 mg/L/72 hours (biomass)	(1)	Calcium chloride
	EC50 *Selenastrum capricornutum* =0.15 mg/L/72 hours	(12)	1,2-dibromo-2,4-dicyanobutane
Chronic toxicity with algae:	Not available.		
Toxicity data on soil micro- and macroorganisms	Not available.		
Toxicity data on birds, bees and plants:	LD50 *Mallard Duck* = 1064 mg/kg	(14)	1,2-dibromo-2,4-dicyanobutane (98%)

12.2 Persistency and degradability:

Tris Amino is not readily biodegradable is expected to have moderate persistence. (4)

Tris Hydrochloride: readily biodegradable. (9)

1,2-dibromo-2,4-dicyanobutane is expected to degrade rapidly in aquatic environments. (14)

Once emitted into the environment, calcium chloride which hasa 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:

Tris-Hydroxymethyl aminomethane is expected to have low bioaccumulation potential. (4)

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

12.4 Mobility in soil:

Tris Amino is expected to have high mobility in soil. (5)

1,2-dibromo-2,4-dicyanobutane is expected to be very mobile and non-persistent in aquatic and soil environments. (14)

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.

SECTION 13. DISPOSAL CONSIDERATION

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

13.1 Waste treatment methods

Used waste product, surplus product or spillage products shall be disposed of in accordance with national, state and local laws.

SECTION 14. TRANSPORT INFORMATION

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

SECTION 15. REGULATORY INFORMATION

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

EU Regulations

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

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

US Federal Regulations:

State	*Components listed*	*Note*
Massachusetts	No component listed	
New York	No component listed	
New Jersey	*1,2-dibromo-2,4-dicyanobutane*	-
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]
1,2-dibromo-2,4-dicyanobutane	35691-65-7	-	-	-	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 02/02/2012.
- Revision n. 01, dated10/20/2015. Main changes are in sections 2 to16, adapting the SDS format and contents to Hazard Communication Standard (HCS), 29 CFR 1910.1200 (HazCom 2012), Hazardous Product Regulation HPR (WHMIS 2015), and Regulation (EU) 2015/830 of 28 May 2015.

Acronyms:

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

Information related to the Regulation EC/1272/2008:

Hazard statement(s): H315: Causes skin irritation.
H319: Causes serious eye irritation.
H302: Harmful if swallowed.
H317: May cause an allergic skin reaction.
H318: Causes serious eye damage.
H400: Very toxic to aquatic life.

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*
Not classified	-

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

Bibliographic references:

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

(2) ChemIDplus Lite, full records for CAS 302-95-4.

(3) 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

(4) HSDB Hazardous Substances Databank, Tromethamine

(5) Screening-Level Hazard Characterization, Sponsored chemical 2-Amino-2-hydroxymethyl-1,3-propanediol (TRIS AMINO) CASRN 77-86-1, U.S. Environmental Protection Agency, Hazard Characterization Document, September, 2014

(6) ECHA, Registration Dossier, Tromethamine, http://apps.echa.europa.eu/registered/data/dossiers/DISS-d7f60455-0965-1602-e044-00144f67d031/AGGR-932e53a4-4218-4161-b380-2c99a562941f_DISS-d7f60455-0965-1602-e044-00144f67d031.html#AGGR-932e53a4-4218-4161-b380-2c99a562941f

(7) TEST PLAN For Tris(hydroxymethy1)aminomethane (77-86-1) Submitted to the U.S. Environmental Protection Agency Under the High Production Volume (HPV) Chemicals Challenge Program The Dow Chemical Company Midland, Michigan, 48674

(8) Haz-Map, Tromethamine hydrochloride, available at http://hazmap.nlm.nih.gov/category-details?table=copytblagents&id=18456

(9) Sigma Aldrich, SDS for Tromethamine Hydrochloride, Version 5.0, revision date 17.10.2013

(10) Australian Government, Department of Health and Ageing, NICNAS Existing Chemicals Information Sheet, Methyldibromo Glutaronitrile, June 2009

(11) NTP Nomination History and Review, 1,2-dibromo-2,4-dicyanobutane, CAS No. 35691-65-7

(12) LANXESS, Material Safety Data Sheet for Tektamer 38LV

(13) Gestis Substance database, 1,2-Dibromo-2,4-dicyanobutane, ZVG 139996

(14) EPA R.E.D. Facts, DIBROMODICYANOBUTANE

(15) SCIENTIFIC COMMITTEE ON CONSUMER PRODUCTS, SCCP, Opinion on Methyldibromo glutaronitrile (sensitisation only), COLIPA n° P77, Adopted by the SCCP during the 3rd plenary meeting of 15 March 2005

(16) HSDB: 1,2-DIBROMO-2,4-DICYANOBUTANE, available at http://toxnet.nlm.nih.gov/cgi-bin/sis/search2/f?./temp/~tRCfcl:1

(17) http://e-aair.org - Allergy, Asthma and Immunology Research (AAIR) 2009, October, Occupational asthma caused by inhalation of bovine serum albumin powder, Case report

SECTION 1. IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY

1.1 Identification of the mixture

Product Name: **APTT Reagent**

Product Number: **000H01176**

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 (USA)

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 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, 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*
Not classified		
		For exposure limits see ch. 8

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

Contains 1,2-benzisothiazolin-3-one. May produce an allergic reaction in already sensitized individuals.
Under normal conditions of use, the mixture does not cause other adverse effects to humans or adverse effects to the environment.

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):	None
Precautionary statement(s):	None
Other labeling details:	**Contains 1,2-benzisothiazolin-3-one. May produce an allergic reaction.** (EUH208)
	Up to 20.85% of the mixture consists of component of unknown acute toxicity (oral, dermal, inhalation) for the human health and for the aquatic environment.

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: 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
Tris Hydrochloride	214-684-5	1185-53-1	< 0.3%	Skin Corrosion/Irritation, cat.2 Eye damage/Eye Irritation, cat. 2B	Skin Irrit. 2, H315 Eye Irrit. 2, H319
Tris-Hydroxymethyl aminomethane (Tris Amino)	201-064-4	77-86-1	< 0.03%	Skin Corrosion/Irritation, cat.2	Skin Irrit. 2, H315
1,2-benzisothiazolin-3-one (BIT) *Index N. (Annex VI of CLP Reg.): 613-088-00-6*	220-120-9	2634-33-5	≤ 0.008%	Acute Toxicity – Oral, cat. 4 Skin Corrosion/Irritation, cat.2 Eye damage/irritation, cat. 1 Sensitization – Skin, cat.1 Aquatic Acute, cat 1** Aquatic Chronic, cat. 3**	Acute Tox. 4 (*), H302 Skin Irrit. 2, H315 Eye Dam. 1, H318 Skin Sens. 1, H317 Aquatic Acute 1, H400 (M = 1) Aquatic Chronic 3, H412 *Specific Conc. Limits* Skin Sens. 1; H317: C ≥ 0,05 %
Sodium hydroxide *Index N. (Annex VI of CLP Reg.): 011-002-00-6*	215-185-5	1310-73-2	< 0.003%	Skin Corrosion/Irritation 1A	Skin Corr. 1A, H314 *Specific Conc. Limits* Skin Corr. 1A,H314: C ≥5% Skin Corr. 1B; H314: 2 % ≤ C < 5 % Skin Irrit. 2; H315: 0,5 % ≤ C < 2 % Eye Irrit. 2; H319: 0.5 % ≤ C < 2 %

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

The mixture contains one substance listed in the Hazardous Substance Lists and/or evaluated for carcinogenicity by IARC, NTP, OSHA: sodium hydroxide. 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 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: Skin : May be irritant for skin. Contains 1,2-benzisothiazolin-3-one. May produce an allergic reaction in already sensitised individuals.
Eyes: May cause irritation.
Inhalation: May cause irritation to the mucous membranes and upper respiratory tract.
Ingestion: may cause irritation to the gastrointestinal mucous membranes.

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, Na2O, SOx, HCl, HF, PxOy.

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 2-8°C. Avoid light exposure and keep away from heat sources. Room ventilation: well ventilated workplace. Keep containers tightly closed and labelled with the name of the product. Avoid environmental release.
Keep away from food and drinks.

7.3 Specific end use *APTT Reagent* is intended for in vitro diagnostic use. Contains 1,2-benzisothiazolin-3-one. May produce an allergic reaction in already sensitised individuals. 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:

Sodium hydroxide [7][8]	*Limit value – 8 hours*	*Limit value – short term*
Austria	2 mg/m³ - inhalable aerosol	4 mg/m³ - inhalable aerosol
Belgium	2 mg/m³	-
Denmark	2 mg/m³	2 mg/m³
France	2 mg/m³	
Hungary	2 mg/m³	2 mg/m³

New Zealand		2 mg/m³ - ceiling value
Poland	0.5 mg/m³	1 mg/m³
Spain	2 mg/m³	-
Sweden	1 mg/m³	2 mg/m³ - inhalable dust; ceiling value
Switzerland	2 mg/m³ - inhalable aerosol	2 mg/m³ - inhalable aerosol
United Kingdom	-	2 mg/m³
Canada – Québec	-	2 mg/m³ - ceiling value
Canada – Ontario	-	2 mg/m³ - ceiling value
USA – NIOSH	-	2 mg/m³ - ceiling value (15 min)
USA –OSHA	2 mg/m³	-

ACGIH: STEL 2 mg/m³ - ceiling value

NIOSH IDLH: 10 mg/m^3 for NaOH

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*
Sodium hydroxide (16)	*Oral (mg/(mg/kg bw/day*								
	Dermal (mg/kg bw/day)								
	Inhalation (mg/m3)			*1*				1	

PNEC values (components): *NaOH:* Because the buffer capacity, the pH and the fluctuation of the pH are very specific for a certain ecosystem it is not considered useful to derive a PNEC. (14)

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:	7.4 -7.6	Mixture
Flammability:	not available	

Explosive properties:	not available	
Oxidizing properties:	not available	
Density:	Not available	
Solubility:	not available	
Water Solubility:	miscible	Mixture
Melting point/range:	not available	

9.2 Other information

Miscibility	miscible

SECTION 10. STABILITY AND REACTIVITY

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

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. Contains 1,2-benzisothiazolin-3-one. May produce an allergic reaction in already sensitized individuals
Ingestion:	Ingestion may cause irritation to the gastrointestinal mucous membranes.
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):

Tris amino: is not metabolized appreciably and is eliminated by the kidneys. Ionized tromethamine is excreted by kidney, so the effect is that of excretion of hydrogen ions. Elimination of drug from body is entirely by renal excretion. It is not known whether tromethamine is distributed into human milk. [1]

1,2-benzisothiazolin-3-one (BIT): in animals is rapidly and completely metabolized. Neither the substance nor its metabolites do not accumulate in the liver and adipose tissue. The major metabolites are o-(methylsulfinyl)-benzamide and o-(methylsulphonyl)-benzamide. Elimination is within 24 hours and almost entirely through the urine.[9]

Sodium hydroxide: Alkalis penetrate skin slowly and act at the site of contact. Sodium is a normal constituent of the blood. Exposure to NaOH could potentially increase the pH of the blood. An excess of sodium is avoided through increased elimination which is directed by homeostatic mechanisms. The main excretion route of NaOH is via urine, small amounts were found in feces, sweat, tears, nasal mucous, saliva, and vaginal and urethral discharges. NaOH is not expected to be systemically available in the body under normal handling and use conditions. [13][14][15]

Acute toxicity	**Value**	**m.u.**	**Effects**		**Related to**
Oral:	LD50 (rat) > 3,000	mg/kg		[2]	Tris Amino
	LD50 (rat) = 670-1,200	mg/Kg		[9]	BIT
Dermal:	LD50 (rat) > 5,000	mg/kg		[3]	Tris Amino
	LD50 (rabbit) > 2,000	mg/Kg		[9]	BIT
Inhalation:	not available				
Other data:	*NaOH:* The existing animal and human data on acute toxicity show that NaOH has a local effect and that systemic effects are not to be expected.[15]				

Corrosion/Irritation

Skin Corrosion/Irritation

Tris Amino: Tromethamine was a mild irritant to rabbits at 25% with a pH of 10.8. At 40%, tromethamine was not irritating. Intradermal injections of tromethamine were severely irritating to rabbits at pH 10.4 but were only mildly irritating at pH 7.4. The supporting substance 2-Amino-2-methyl-1-Propanol (AMP) was found to be irritating to rabbits, with burrowing lesions noted when applied to abraded skin sites; there was mild irritation noted when applied to unabraded skin.(2)

Tris Hydrochloride: irritant to skin (read across from Tris Amino).

1,2-benzisothiazolin-3-one : According to a study conducted in rabbits BIT can be classified as a moderate irritant to skin.(10)

NaOH is highly irritating and highly corrosive for the skin. (14)

Serious eye damage/ irritation

Tris Amino (100%) was not an ocular irritant when administered to rabbits. (2)

Tris Hydrochloride : mild eye irritant in rabbits. (5)

1,2-benzisothiazolin-3-one : A study in rabbits classified the compound as a severe eye irritant. (10)

NaOH: even strongly diluted solutions still cause irritation and chemical burns. The available animal data on eye irritation revealed small differences in eye irritation levels. The non-irritant level was 0.2-1.0%, while the corrosive concentration was 1.2% or higher than 2%. There is a danger of blindness. (15)

Sensitization:

Skin sensitization:

Tris Amino: The supporting chemical AMP is not sensitizing to guinea pig skin. (2)

Tris Hydrochloride: Not a sensitizer in experimental animals. (5)

1,2-benzisothiazolin-3-one : A guinea pig maximization test classified BIT as a moderate contact sensitizer whilst the Buehler test classifies BIT as non-sensitizing. Literature data for the local lymph node assay support a classification of BIT as a moderate dermal sensitizer (EC3 2.3%). (In the context of occupational uses, benzisothiazolinone (BIT) is a well-documented contact allergen. (10)

NaOH is not considered to be a skin sensitizer. (14)

Respiratory sensitization:

CMR effects

Germ cell mutagenicity;

Tris Amino: The supporting chemical, AMP, was not mutagenic to bacteria and mammalian cells in vitro, and did not induce micronuclei in mice in vivo.

Tris Hydrochloride: Ames test negative.(6)

1,2-benzisothiazolin-3-one : The compound has been found to be clastogenic in mammalian cells treated *in vitro,* non-mutagenic *in vitro*, non clastogenic and DNA damaging *in vivo.* (10)

NaOH: Both the in vitro and the in vivo genetic toxicity test indicate no evidence for a mutagenic activity. (14)

Reproductive toxicity:

Tris Amino: In an oral gavage combined reproductive/developmental toxicity screening test in rats no effects on reproductive or developmental parameters were observed at the doses tested; the NOAEL for reproductive and developmental toxicity is 1000 mg/kg-day, the highest dose tested. (2)

1,2-benzisothiazolin-3-one : Studies on rats carried out to date did not indicate a reproductive toxic potential (foetal toxicity and teratogenicity) in the maternal-toxic dosage range. (9)

NaOH is not expected to be systemically available in the body under normal handling and use conditions and for this reason it can be stated that the substance will not reach the foetus nor reach male and female reproductive organs. (14)

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			

Tris Amino: based on the available data, the substance is not carcinogenic. (4)

1,2-benzisothiazolin-3-one : Based on its characteristics, BIT is unlikely to demonstrate a carcinogenic potential. (11)

NaOH: Following chemical burns due to alkalis, the incidence of the occurrence of esophageal tumors is increased by a factor between 1000 and 3000. However, the tumor formation is a consequence of massive tissue destruction and the regenerative processes which subsequently start and is not the result of a direct carcinogenic effect. If irritation is avoided, the formation of tumors is not to be expected. (15)

STOT –single exposure

1,2-benzisothiazolin-3-one : At room temperature, exposure to vapor is minimal due to low volatility. A single exposure is unlikely to be hazardous. Mist may cause severe irritation to the upper respiratory tract (nose and throat) and lungs. (11)

NaOH in the atmosphere causes irritation to the airways (in particular in the nose and throat). A concentration of 2 mg/m3 was reported to have produced distinct but not excessive irritation.

STOT – repeated exposure

There are no documented long-term effects of *TRIS AMINO* treatment, and no serious side-effects on record that are directly attributed to treatment with the compound. (3)

1,2-benzisothiazolin-3-one : A 90-day study on dogs that were administered gelatine capsules with different BIT levels (corresponding to 5; 20 or 50 mg of B per kg of body weight per day) revealed irritations in the gastrointestinal tract (vomiting, diarrhea), slight functional changes of the liver and slightly increased liver weights, but no pathological organ changes. The LOAEL was stated to be 50, and the NOAEL 5, mg per kg of body weight per day. (9)

NaOH: In studies in workplaces, irritation to the eyes, nose and throat as well as skin was reported. Animal experimental results also indicate possible chronic damage to the airways. (15)

Aspiration hazards

Not available.

Other information:

Not available.

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

SECTION 12. ECOLOGICAL INFORMATION

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

12.1 Toxicity	**species, media, units, test duration and test conditions.**		**Related to**
Acute toxicity with fish:	LC50 *Leuciscus idus* > 10,000 mg/L/ 96-h	(2)	Tris Amino
	LC50 Oncorhynchus mykiss = 1.9 mg a.i./L/96 h	(12)	1,2-benzisothiazolin-3-one
	LC50 *Gambusia affinis* = 125 mg/l/96 hours	(14)	NaOH
Chronic toxicity with fish:	MATC* (growth) *Pimephales promelas* = 0.41 mg a.i./L/33-day	(12)	1,2-benzisothiazolin-3-one
Acute toxicity with crustaceans:	Water fleas (Daphnia magna) were exposed to AMP at unspecified concentrations for 48 hours. LC50 = 193 mg/L/48 h.	(1)	Tris Amino
	EC50 daphnia > 100 mg/l/48h	(6)	Tris HCl
	EC50 Daphnia = 3.7 mg a.i./L/48h	(12)	1,2-benzisothiazolin-3-one
	LC50 *Ceriodaphnia cf dubia* = 40 mg/l/48 hours. The toxicity threshold concentration for Daphnia magna was reported to range from 40 to 240 mg/l.	(14)	NaOH
Chronic toxicity with crustaceans:	EC50 *Daphnia magna* = 3.8 mg a.i./L/ 21-day Flow-Through Life-Cycle	(12)	1,2-benzisothiazolin-3-one
Acute toxicity with algae:	EC50 *Selenastrum capricornutum* >100 mg/L/ 96 h	(2)	Tris Amino
	EC50 *Pseudokirchneriella subcapitata* = 0.38-0.98 mg a.i./L/96 h	(12)	1,2-benzisothiazolin-3-one
Chronic toxicity with algae:	Not available.		
Toxicity data on soil micro- and macroorganisms	LC50 Eisenia foetida = 278 mg a.i./L	(12)	1,2-benzisothiazolin-3-one
	EC50 Photobacterium phosphoreum = 22 mg/l/15 minutes	(14)	NaOH
Toxicity data on birds, bees and plants:	Six Terrestrial Plant Species: EC50s = 18.4-166 mg a.i./L/21-day	(12)	1,2-benzisothiazolin-3-one

12.2 Persistency and degradability:

Tris Amino is not readily biodegradable is expected to have moderate persistence. (1)

Tris Hydrochloride: readily biodegradable. (6)

1,2-benzisothiazolin-3-one: has a low volatility and is slightly soluble in water. Once introduced into the aquatic environment, BIT will have a tendency to remain in water. BIT is considered degradable and will not persist in the environment. Although the product is hydrolytically stable in water, it is susceptible to photo degradation in aquatic environments. (11)

NaOH : It is highly soluble in water and dissociates to sodium and hydroxide ions, with the effect of increasing pH and alkalinity. Na+ and OH- persist indefinitely in the environment with equilibrium between various forms of complexes and precipitates. (17)

12.3 Bioaccumulation potential: *Tris-Hydroxymethyl aminomethane* is expected to have low bioaccumulation potential. (1)

1,2-Benzisothiazolin-3-one: based on a Kow value of 20 at 25°C is unlikely to bioaccumulate in aquatic organisms. (12)

Considering its high water solubility, *NaOH* is not expected to bioconcentrate in organisms.

12.4 Mobility in soil: *Tris Amino* is expected to have high mobility in soil. (2)

1,2-Benzisothiazolin-3-one shows moderate to strong binding to soil sand it is not likely to migrate into the ground and there is low potential for ground water contamination. (12)

NaOH is very soluble and mobile in water. In soil, mobility depends directly on the importance of the liquid phase of the soil and the possibility to form metal hydroxo-complexes with metal solid species.(13)

12.5 Results of PBT and vPvB assessment Not performed.

12.6 Other toxic effects: Not available.

*** Maximum Acceptable Toxicant Concentrations (MATC) – An estimated value that represents the highest "no-effect" concentration of a specific substance within the range including the NOEC and LOEC.**

SECTION 13. DISPOSAL CONSIDERATION

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

13.1 Waste treatment methods

Used waste product, surplus product or spillage products shall be disposed of in accordance with national, state and local laws.

SECTION 14. TRANSPORT INFORMATION

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

SECTION 15. REGULATORY INFORMATION

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

EU Regulations

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

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

US Federal Regulations:

State	*Components listed*	*Note*
Massachusetts	Sodium hydroxide	-
New York	Sodium hydroxide	-
New Jersey	Sodium hydroxide	Corrosive
Pennsylvania	Sodium hydroxide	E - Substance is on the Environmental Hazard List

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]
Sodium Hydroxide	1310-73-2	-	-	1,000	-	-	-

[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 02/02/2012.
- Revision n. 01, dated 10/20/2015. Main changes are in sections 2 to16, adapting the SDS format and contents to Hazard Communication Standard (HCS), 29 CFR 1910.1200 (HazCom 2012), Hazardous Product Regulation HPR (WHMIS 2015), and Regulation (EU) 2015/830 of 28 May 2015.

Acronyms:

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

PBT: Persistent, Bioaccumulative and Toxic substances

PNEC: Predicted No Effect Concentration

RID: Regulation concerning the International carriage of Dangerous goods by rail

TLV/TWA: Threshold Limit Value/Threshold Weighted Average

vPvB: very Persistent, very Bioaccumulative

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

Information related to the Regulation EC/1272/2008:

Hazard statement(s):

H315: Causes skin irritation.

H319: Causes serious eye irritation.

H302: Harmful if swallowed.

H318: Causes serious eye damage

H317: May cause an allergic skin reaction.

H314: Causes severe skin burns and eye damage.

H400: Very toxic to aquatic life.

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*
Not classified	-

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

Bibliographic references:

(1) HSDB Hazardous Substances Databank, Tromethamine

(2) Screening-Level Hazard Characterization, Sponsored chemical 2-Amino-2-hydroxymethyl-1,3-propanediol (TRIS AMINO) CASRN 77-86-1, U.S. Environmental Protection Agency, Hazard Characterization Document, September, 2014

(3) ECHA, Registration Dossier, Tromethamine, http://apps.echa.europa.eu/registered/data/dossiers/DISS-d7f60455-0965-1602-e044-00144f67d031/AGGR-932e53a4-4218-4161-b380-2c99a562941f_DISS-d7f60455-0965-1602-e044-00144f67d031.html#AGGR-932e53a4-4218-4161-b380-2c99a562941f

(4) TEST PLAN For Tris(hydroxymethy1)aminomethane (77-86-1) Submitted to the U.S. Environmental Protection Agency Under the High Production Volume (HPV) Chemicals Challenge Program The Dow Chemical Company Midland, Michigan, 48674

(5) Haz-Map, Tromethamine hydrochloride, available at http://hazmap.nlm.nih.gov/category-details?table=copytblagents&id=18456

(6) Sigma Aldrich, SDS for Tromethamine Hydrochloride, Version 5.0, revision date 17.10.2013

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

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

(9) Gestis Substance database, 1,2-Benzisothiazol-3(2H)-one, ZVG 35240

(10) SCCS (Scientific Committee on Consumer Safety), Opinion on benzisothiazolinone, 26-27 June 2012

(11) Product Safety Assessment: 1,2-Benzisothiazol-3(2H)-one (BIT) The Dow Chemical Company, Created: December 4, 2012

(12) Environmental Assessment, FCN 001108, July 26, 2011, http://www.fda.gov/downloads/Food/FoodIngredientsPackaging/EnvironmentalDecisions/UCM287533.pdf

(13) IUCLID data set for Sodium hydroxide, 18-feb-2000.

(14) Sodium hydroxide, SIDS Initial Assessment Report For SIAM 14 Paris, 26-28 March 2002

(15) Sodium hydroxide, IFA, GESTIS Substance database , ZVG n. 1270

(16) Sodium hydroxide, ECHA, Registration dossier, available at http://echa.europa.eu/it/information-on-chemicals/registered-substances?p_p_id=registeredsubstances_WAR_regsubsportlet&_registeredsubstances_WAR_regsubsportlet_name-sc=&_registeredsubstances_WAR_regsubsportlet_ec-number-sc=1310-73-2&_registeredsubstances_WAR_regsubsportlet_cas-number-sc=1310-73-2&_registeredsubstances_WAR_regsubsportlet_sc=true&_registeredsubstances_WAR_regsubsportlet_do-search=

(17) Environmental and Health Assessment of Substances in Household Detergents and Cosmetic Detergent Products, available at http://eng.mst.dk/

SECTION 1. IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY

1.1 Identification of the mixture

Product Name: **APC/$CaCl_2$**

Product Number: **000H01434**

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 (USA)

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 classified as hazardous according to Regulation (EC) No 1272/2008.
Classified as hazardous according to 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*
Not classified		
		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*
Sensitization-Respiratory	**Cat.1**	**May cause allergy or asthma symptoms or breathing difficulties if inhaled.**
		For exposure limits see section 8.

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

Contains APC (Activated Protein C). May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Under normal conditions of use, the mixture does not cause other adverse effects to human health or 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 APC (Activated Protein C). May produce an allergic reaction.** (EUH208)
	Safety data sheet available on request. (EUH210)
	Up to 3.97% of the mixture consists of component of unknown acute toxicity (dermal, inhalation) for the human health and for the aquatic environment.

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

Hazard pictogram(s):	
Signal word(s):	**Danger**
Hazard statement(s):	**May cause allergy or asthma symptoms or breathing difficulties if inhaled. (H334)**
Precautionary statement(s):	**Avoid breathing dust/fume.(P261)** **If INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.(P304 + P340)** **If experiencing respiratory symptoms: Call a POISON CENTER doctor. (P342 + P311)** **Dispose of contents container in accordance with local/regional/national/international regulations. (P501)**
Other labeling details:	**Up to 3.97% of the mixture consists of component of unknown acute toxicity (dermal, inhalation) for the human health and for the aquatic environment.**

__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.

Warning:
The product contains bovine material. All donor animals were sourced from BSE-free herds. The cattle received ante- and post mortem health inspection by a veterinarian, and they were apparently free from infectious and contagious material. However, the material should be treated as potentially infectious.
Bovine serum albumin (BSA) might cause allergic skin reaction and/or allergy or asthma symptoms or breathing difficulties if inhaled.
This product contains human source material that tested non-reactive for HIV antibody, Hepatitis B Surface Antigen and Anti-HCV at the donor stage. This product, as with all human based specimens, should be handled with proper laboratory safety procedures to minimize the risk of transmission of infectious disease.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Composition: solid containing organic and inorganic components, bovine and human source material.

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 dehydrate *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.)	< 0.4%	Eye damage/irritation, cat. 2	Eye Irrit.2, H319
APC (Activated Protein C) *Index N. (Annex VI of CLP Reg.): 647-014-00-9 - proteases with the exception of those specified elsewhere in this Annex*	Not available	Not available	< 0.3%	Skin Corrosion/Irritation, cat. 2 Eye damage/Eye Irritation, cat. 2A Specific target organ Toxicity – Single Exposure, cat. 3 Sensitization-Respiratory, cat. 1	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335 Resp. Sens. 1, H334
Tris Hydrochloride	214-684-5	1185-53-1	< 0.2%	Skin Corrosion/Irritation, cat. 2 Eye damage/Eye Irritation, cat. 2B	Skin Irrit. 2, H315 Eye Irrit. 2, H319
Tris-Hydroxymethyl aminomethane (Tris Amino)	201-064-4	77-86-1	< 0.04%	Skin Corrosion/Irritation, cat. 2	Skin Irrit. 2, H315
Manganese Chloride Tetrahydrate	603-826-5	13446-34-9 (7773-01-5 as manganese chloride anh)	< 0.02%	Acute Tox. 4 – Oral Eye damage/Eye Irritation, cat. 1 Specific target organ Toxicity – Repeated Exposure, cat. 2 Aquatic Chronic , cat.2**	Acute Tox. 4, H302 Eye Dam.1, H318 STOT RE 2, H373 Aquatic Chronic 2 H411

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 does not contain substances listed in the Hazardous Substance Lists and/or evaluated for carcinogenicity by IARC, NTP, OSHA. 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 immediately (show the SDS or the label were possible).
Contact with skin:	Remove 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 to the mucous membranes and upper respiratory tract. Skin : May be irritant for skin. Eyes: May cause irritation. Ingestion: may cause irritation to the gastrointestinal mucous membranes. Contains APC (Activated Protein C). May cause allergy or asthma symptoms or breathing difficulties if inhaled. The product contains bovine albumin, that might cause allergic skin reaction and/or allergy or asthma symptoms or breathing difficulties if inhaled.
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, 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 2-8°C. Avoid light exposure and keep away from heat sources. Room ventilation: well ventilated workplace. Keep containers tightly closed and labelled with the name of the product. Avoid environmental release.
Keep away from food and drinks.

7.3 Specific end use

APC/$CaCl_2$ is intended for in vitro diagnostic use. Contains APC (Activated Protein C). May cause allergy or asthma symptoms or breathing difficulties if inhaled. The material contains human and bovine material, and should be treated as potentially infectious. Bovine serum albumin (BSA) might cause allergic skin reaction and/or allergy or asthma symptoms or breathing difficulties if inhaled. Avoid inhalation of dust/fume. 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 [(1)]
Canada – Ontario: Occupational exposure limit (OEL) for calcium chloride of 5 mg/m^3 has been established by the Ministry of Labor

Manganese and inorganic compounds (as Mn)[(20)]		***Limit value – 8 hours***	***Limit value – short term***
	Austria	0,5 mg/m^3 - inhalable aerosol	2 mg/m^3 - inhalable aerosol
	Belgium	0,2 mg/m^3	
	Denmark	0,2 mg/m^3	0,4 mg/m^3
	Finland	0,2 mg/m^3 – inhalable fraction 0.02 mg/m^3 - respirable fraction	
	Germany (AGS)	0,5 mg/m^3 - inhalable aerosol	
	Germany (DFG)	0.02 mg/m^3 - respirable aerosol 0,2 mg/m^3 - inhalable aerosol	0.16 mg/m^3 - respirable aerosol [(a)(c)] 1.6 mg/m^3 - inhalable aerosol[(b)(c)]
	Hungary	5 mg/m^3	20 mg/m^3
	Ireland	0,2 mg/m^3 – manganese fume	3 mg/m^3 – manganese fume [(c)]
	Latvia	0.1 mg/m^3 – welding aerosol	
	Poland	0.3 mg/m^3	
	Spain	0.2 mg/m^3	
	Sweden	0.2 mg/m^3 - total aerosol 0.1 – respirable fraction	
	Switzerland	0,5 mg/m^3 - inhalable aerosol	
	United Kingdom	0,5 mg/m^3	
	Canada - Ontario	0.2 mg/m^3	
	Canada- Quebec	5 mg/m^3	
	USA - NIOSH	1 mg/m^3	3 mg/m^3 [(c)]
	USA - OSHA		5 mg/m^3
	SCOEL: 8 hour TWA: 0.200 mg/m³ (inhalable fraction); 0.050 mg/m3 (respirable fraction)[(14)]		
Manganous chloride, anhydr. [(20)]	Finland	0,2 mg/m^3 – inhalable fraction, calculated as Mn 0.02 mg/m^3 - respirable fraction, calculated as Mn	

[(a)] permanganates: STV 0,02 mg/m³; [(b)] permanganates: STV 0,2 mg/m³; [(C)] 15 minutes average value; [(d)] Manganese and compounds as Mn.

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

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:	Lyophilized, solid	
Odor:	not available	
Color:	White	
pH:	7.4 – 7.6	Mixture
Flammability:	Not available	
Explosive properties:	Not available	
Oxidizing properties:	Not available	
Density:	Not available	
Solubility:	not available	
Water Solubility:	Soluble	Mixture
Melting point/range:	Liquid, not applicable	

9.2 Other information not available

SECTION 10. STABILITY AND REACTIVITY

10.1 Reactivity	This mixture is considered not reactive under the normal conditions of the usage.
10.2 Chemical stability	The product is stable until the expiration date shown on the box and on the labels when stored at 2 – 8 °C.
10.3 Possibility of hazardous reactions	Not foreseen.
10.4 Conditions to avoid:	Keep away from heat, water, humidity and light.
10.5 Incompatible materials	Strong oxidising agents.
10.6 Hazardous decomposition products:	Thermal decomposition or combustion may generate toxic and hazardous fumes of COx, HCl, 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:	Prolonged or repeated skin contact may cause irritation.
Contact with eyes:	May cause irritation.
Ingestion:	Ingestion may cause irritation to the gastrointestinal mucous membranes.
Inhalation:	Inhalation of the product may cause irritation to respiratory ways.
Other:	Contains APC (Activated Protein C). May cause allergy or asthma symptoms or breathing difficulties if inhaled. The product contains bovine albumin, that might cause allergic skin reaction and/or allergy or asthma symptoms or breathing difficulties if inhaled.

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

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

Tris amino: is not metabolized appreciably and is eliminated by the kidneys. Ionized tromethamine is excreted by kidney, so the effect is that of excretion of hydrogen ions. Elimination of drug from body is entirely by renal excretion. It is not known whether tromethamine is distributed into human milk. (4)

Manganese chloride was readily absorbed after oral gavage, intraperitoneal injection, or intratracheal instillation and distributed in brain tissue to varying degrees. While rodents are able to absorb manganese via the olfactory bulb with subsequent direct accumulation in the brain, this route has not been established in humans. The major route of manganese excretion is via the bile, although some excretion occurs in urine, milk, and sweat. (12)

Acute toxicity	**Value**	**m.u.**	**Effects**		**Related to**
Oral:	LD50 (rat) > 3,000	mg/kg		(5)	Tris Amino
	LD50 (rat) =3,798 - 4,179 LD50 (rabbit)=500 – 1,000	mg/Kg	The acute oral toxicity is attributed to the severe irritating property of the original substance or its high-concentration solutions to the gastrointestinal tract.	(1)	Calcium chloride
	LD50 (rat) = 1,484	mg/Kg		(10)	Manganese chloride tetrahydrate
Dermal:	LD50 (rat) > 5,000	mg/kg		(6)	Tris Amino
	LD50 (rabbit) > 5,000	mg/Kg		(1)	Calcium chloride
Inhalation:	LC50 (rat) > 40	$mg/m^3/4h$		(1)	Calcium chloride
Other data:	Not available.				

Corrosion/Irritation

Skin Corrosion/Irritation	*Tris Amino*: Tromethamine was a mild irritant to rabbits at 25% with a pH of 10.8. At 40%, tromethamine was not irritating. Intradermal injections of tromethamine were severely irritating to rabbits at pH 10.4 but were only mildly irritating at pH 7.4. The supporting substance 2-Amino-2-methyl-1-Propanol (AMP) was found to be irritating to rabbits, with burrowing lesions noted when applied to abraded skin sites; there was mild irritation noted when applied to unabraded skin.(5) *Tris Hydrochloride:* irritant to skin (read across from Tris Amino). *Calcium chloride* is not irritating for the skin. (1) *Manganese dichloride* is not a dermal irritant. (11)
Serious eye damage/ irritation	*Tris Amino (100%)* was not an ocular irritant when administered to rabbits. (5) *Tris Hydrochloride :* mild eye irritant in rabbits. *Calcium chloride* is irritating for the eyes. (1) *MnCl2:* was a severe irritant to the rabbit eyes in an in vivo test according to OECD Guideline 405. (11)

Sensitization:

Skin sensitization:

Tris Amino: The supporting chemical AMP is not sensitizing to guinea pig skin. (5)

Tris Hydrochloride: Not a sensitizer in experimental animals. (8)

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

Manganese dichloride is not a sensitizer. (11)

Bovine serum albumin (BSA), which is present in bovine plasma, could develop allergic skin reactions in laboratory workers after dealing with BSA powder. Based on the available data, the criteria for classification are not satisfied.

Respiratory sensitization:

Bovine serum albumin (BSA), which is present in bovine plasma, could develop allergic reactions in laboratory workers after dealing with BSA powder. It is reported a case of occupational asthma and rhinitis in a laboratory worker caused by the inhalation of 100% BSA powder. The patient had a high serum-spercific IgE level to BSA, and experienced severe systemic reactions, including eye itching, conjunctivitis, rhinorrhea, nasal obstruction, sneezing, shortness of breath, bronchospasm and decreased blood pressure. It was suggested an IgE-mediated response as the pathogenic mechanism.(19) Based on the available data, the criteria for classification are not satisfied.

CMR effects

Germ cell mutagenicity;

Tris Amino: The supporting chemical, AMP, was not mutagenic to bacteria and mammalian cells in vitro, and did not induce micronuclei in mice in vivo.

Tris Hydrochloride: Ames test negative.(9)

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

Manganese dichloride : The current literature indicates that Mn may be weakly mutagenic in vitro and possibly clastogenic in vivo, with unknown genotoxic effects in humans. It seems probable that the positive results reported in several short term tests are not due to intrinsic, direct genotoxicity of manganese, but to indirect mechanisms. The genotoxicity of manganese compounds seems to be mediated by the bivalent ion Mn^{2+} at relatively high and cytotoxic concentrations. Based on the presently available data no overall conclusion can be made on the possible genotoxic hazard to humans.(17)(18)

Reproductive toxicity:

Tris Amino: In an oral gavage combined reproductive/developmental toxicity screening test in rats no effects on reproductive or developmental parameters were observed at the doses tested; the NOAEL for reproductive and developmental toxicity is 1000 mg/kg-day, the highest dose tested. (5)

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

Manganese dichloride : Evidence obtained in laboratory mammals indicates that exposure to high levels of manganese may adversely affect sperm quality, produce decreased testicular weights, and impair development of the male reproductive tract. Impotence and loss of libido are common symptoms in male workers afflicted with clinically identifiable signs of manganism. No direct effect of manganese toxicity has been observed on fertility in women. No information is available on developmental effects of manganese in humans. Decreased activity levels and a decrease in average pup weight have been noted in the offspring of mice exposed to manganese by inhalation.(13)

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			

Tris Amino: based on the available data, the substance is not carcinogenic. (7)

Manganese dichloride : Oral human and animal studies on manganese are inadequate. Several animal studies reported an increased incidence of thyroid gland follicular cell adenomas and hyperplasia, or increased incidence of pancreatic tumors. There is insufficient evidence to indicate that inorganic Mn exposure produces cancer in animals or humans. EPA has classified manganese as a Group D, not classifiable as to carcinogenicity in humans. (13)

STOT –single exposure

Not available.

STOT – repeated exposure

Tris Amino: There are no documented long-term effects of Tris Amino treatment, and no serious side-effects on record that are directly attributed to treatment with the compound. (6)

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

Manganese dichloride : The lungs, nervous system and reproductive system are the main organs affected following inhalation exposures to manganese, although other effects have also been observed.(12) Workers chronically exposed to concentrations of manganese dust averaging 20 mg/m3 showed signs of manganism.(15) Chronic exposure to concentrations averaging 210 mg/m3 Mn have been associated with pneumonia.

Aspiration hazards Not available.

Other information: Not available.

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

SECTION 12. ECOLOGICAL INFORMATION

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

12.1 Toxicity	**species, media, units, test duration and test conditions.**		**Related to**
Acute toxicity with fish:	LC50 *Leuciscus idus* > 10,000 mg/L/ 96-h	(5)	Tris Amino
	LC50 *Pimephales promelas*= 4,630 mg/l/96 hours	(1)	Calcium chloride
	LC50 *Oncorhynchus mykiss* = 4.8 mg/l/96 hours	(16)	Manganese
Chronic toxicity with fish:	28-day LC50 (embryo-larval test) = 2.9 mg/l	(16)	MnCl2
Acute toxicity with crustaceans:	Water fleas (Daphnia magna) were exposed to AMP at unspecified concentrations for 48 hours. LC50 = 193 mg/L/48 h.	(4)	Tris Amino
	EC50 daphnia > 100 mg/l/48h	(9)	Tris HCl
	EC50 *Daphnia magna* = 1062 mg/L/48 hr	(1)	Calcium chloride
	EC50 *Daphnia magna* = 4.7–56.1 mg/L/48 hr	(16)	MnCl2
Chronic toxicity with crustaceans:	The chronic toxicity study with Daphnia magna shows that a 16% impairment of reproduction (EC16) is caused at the concentration of 320 mg/L.	(1)	Calcium chloride
	21-day EC50 = 5.7 mg/L	(16)	MnCl2
	NOEC = 0.01 mg/l/60 days	(11)	Manganese chloride tetrahydrate
Acute toxicity with algae:	EC50 *Selenastrum capricornutum* >100 mg/L/ 96 h	(5)	Tris Amino
	EC50 *Selenastrum capricornutum* = 2900 mg/L/72 hours (biomass)	(1)	Calcium chloride
	EC50 (growth inhibition) = 8.3 mg/L/72h	(16)	Manganese
Chronic toxicity with algae:	EC50 *Pseudokirchneriella subcapitata* = 3.1 mg/L /14 day (total cell volume reduction)	(16)	MnCl2
Toxicity data on soil micro- and macroorganisms	Not available.		
Toxicity data on birds, bees and plants:	Not available.		

12.2 Persistency and degradability:

Tris Amino is not readily biodegradable is expected to have moderate persistence. (4)

Tris Hydrochloride: readily biodegradable. (9)

Once emitted into the environment, calcium chloride which hasa 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:

Tris-Hydroxymethyl aminomethane is expected to have low bioaccumulation potential. (4)

Manganese in water can be significantly bioconcentrated at lower trophic levels. Bioconcentration factors (BCFs) of 10000-20000 for marine and freshwater plants, 2500-6300 for phytoplankton, 300-5500 for marine algae, and 35-930 for fish have been estimated. The high reported BCFs probably reflect the essentiality of manganese for a wide variety of organisms. (12)

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

12.4 Mobility in soil: *Tris Amino* is expected to have high mobility in soil. (5)

Manganese is ubiquitous in the environment; it is often transported in rivers adsorbed to suspended sediments. (12)

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.

SECTION 13. DISPOSAL CONSIDERATION

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

13.1 Waste treatment methods

Used waste product, surplus product or spillage products shall be disposed of in accordance with national, state and local laws.

SECTION 14. TRANSPORT INFORMATION

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

SECTION 15. REGULATORY INFORMATION

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

EU Regulations

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

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

US Federal Regulations:

State	*Components listed*	*Note*
Massachusetts	No component listed	
New York	No component listed	
New Jersey	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 304EHS RQ* [III]	*CERCLA RQ* [IV]	*SARA/EPCRA 313 TRI* [V]	*RCRA Code* [VI]	*CAA 112(r) RMP TQ* [VII]
No component listed							

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

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

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

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 02/02/2012.
- Revision n. 01, dated 10/20/2015. Main changes are in sections 2 to16, adapting the SDS format and contents to Hazard Communication Standard (HCS), 29 CFR 1910.1200 (HazCom 2012), Hazardous Product Regulation HPR (WHMIS 2015), and Regulation (EU) 2015/830 of 28 May 2015.

Acronyms:

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

Information related to the Regulation EC/1272/2008:

Hazard statement(s): H315: Causes skin irritation.
H319: Causes serious eye irritation.
H302: Harmful if swallowed.
H335: May cause respiratory irritation.
H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H318: Causes serious eye damage.
H373: May cause damage to organs
H411: Toxic to aquatic life with long lasting effects**.**

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

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

Classification according to Regulation (EC) 1272/2008:	*Classification procedure*
Not classified	**-**
Classification according to 29 CFR 1910.1200 (HCS), and to HPR (WHMIS 2015)	
May cause allergy or asthma symptoms or breathing difficulties if inhaled.	**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) Calcium Chloride, SIDS Initial Assessment Report For SIAM 15 Boston, USA 22-25th October 2002

(2) ChemIDplus Lite, full records for CAS 302-95-4.

(3) 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

(4) HSDB Hazardous Substances Databank, Tromethamine

(5) Screening-Level Hazard Characterization, Sponsored chemical 2-Amino-2-hydroxymethyl-1,3-propanediol (TRIS AMINO) CASRN 77-86-1, U.S. Environmental Protection Agency, Hazard Characterization Document, September, 2014

(6) ECHA, Registration Dossier, Tromethamine, http://apps.echa.europa.eu/registered/data/dossiers/DISS-d7f60455-0965-1602-e044-00144f67d031/AGGR-932e53a4-4218-4161-b380-2c99a562941f_DISS-d7f60455-0965-1602-e044-00144f67d031.html#AGGR-932e53a4-4218-4161-b380-2c99a562941f

(7) TEST PLAN For Tris(hydroxymethy1)aminomethane (77-86-1) Submitted to the U.S. Environmental Protection Agency Under the High Production Volume (HPV) Chemicals Challenge Program The Dow Chemical Company Midland, Michigan, 48674

(8) Haz-Map, Tromethamine hydrochloride, available at http://hazmap.nlm.nih.gov/category-details?table=copytblagents&id=18456

(9) Sigma Aldrich, SDS for Tromethamine Hydrochloride, Version 5.0, revision date 17.10.2013

(10) Chem IDplus Lite, Manganese chloride CAS 13446-34-9, full record.

(11) Manganese chloride, Registration dossier on ECHA, http://apps.echa.europa.eu/registered/data/dossiers/DISS-d0199b46-1b60-45f1-e044-00144f67d249/AGGR-2bff20de-de08-4c42-98b1-1ea417f81bab_DISS-d0199b46-1b60-45f1-e044-00144f67d249.html#AGGR-2bff20de-de08-4c42-98b1-1ea417f81bab

(12) IPCS Inchem, Concise International Chemical Assesment Document, Manganese and its compounds.

(13) United States Environmental Protection Agency, Manganese Compounds, Hazard Summary-Created in April 1992; Revised in February 16,2010.

(14) Recommendation from the Scientific Committee on Occupational Exposure Limits for manganese and inorganic manganese compounds, SCOEL/SUM/127, June 2011

(15) Haz-Map: Occupational Exposure to Hazardous Agents, Manganese.

(16) Concise International Chemical Assessment Document 63, MANGANESE AND ITS COMPOUNDS:ENVIRONMENTAL ASPECTS

(17) The mutagenicity and carcinogenicity of inorganic manganese compounds: a synthesis of the evidence, J Toxicol Environ Health B Crit Rev. 2011;14(8):537-70. doi: 10.1080/10937404.2011.615111.

(18) SCF/CS/NUT/UPPLEV/21 Final Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of manganese (expressed on 19 October 2000)

(19) http://e-aair.org - Allergy, Asthma and Immunology Research (AAIR) 2009, October, Occupational asthma caused by inhalation of bovine serum albumin powder, Case report

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

SECTION 1. IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY

1.1 Identification of the mixture

Product Name: **Control Plasma Level 1**

Product Number: **000C00423**

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 (USA)

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 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, 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*
Not classified		
		For exposure limits see section 8.

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

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

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):	none
Precautionary statement(s):	none
Other labeling details:	**≈ 100% of the mixture consists of component of unknown acute toxicity (oral, dermal, inhalation) for the human health and for the aquatic environment.**

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.

Warning:
This product contains human source material that tested non-reactive for HIV antibody, Hepatitis B Surface Antigen and Anti-HCV at the donor stage. This product, as with all human based specimens, should be handled with proper laboratory safety procedures to minimize the risk of transmission of infectious disease.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Composition: powder containing organic and inorganic components, human plasma.

3.1 Hazardous components: not known hazardous ingredients.

The mixture does not contain substances listed in the Hazardous Substance Lists and/or evaluated for carcinogenicity by IARC, NTP, OSHA. 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 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 to respiratory ways. Skin : May be irritant for skin. Eyes: May cause irritation. Ingestion: may cause irritation to the gastrointestinal mucous membranes.
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, Na2O.

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 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 2 - 8°C. Avoid light exposure and keep away from heat sources. Room ventilation: well ventilated workplace. Keep containers tightly closed and labelled with the name of the product. Avoid environmental release.
Keep away from food and drinks.

7.3 Specific end use *Control Plasma Level 1* is intended for in vitro diagnostic use. This product contains human source material that tested non-reactive for HIV antibody, Hepatitis B Surface Antigen and Anti-HCV at the donor stage. This product, as with all human based specimens, should be handled with proper laboratory safety procedures to minimize the risk of transmission of infectious disease. 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: not available

Community/National biological exposure limit values: not available

DNEL values (components): not available

PNEC values (components): not available.

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:	Lyophilized, solid	
Odor:	not available	

	Color:	beige	
	pH:	not available	
	Flammability:	not available	
	Explosive properties:	not available	
	Oxidizing properties:	not available	
	Density:	not available	
	Solubility:	not available	
	Water Solubility:	soluble	Mixture
	Melting point/range:	not available	

9.2 Other information

Miscibility: miscible

SECTION 10. STABILITY AND REACTIVITY

10.1	**Reactivity**	This mixture is considered not reactive under the normal conditions of the usage.
10.2	**Chemical stability**	The product is stable until the expiration date shown on the box and on the labels when stored at 2 - 8°C.
10.3	**Possibility of hazardous reactions**	Not foreseen.
10.4	**Conditions to avoid:**	Keep out from hot temperature, humidity and light.
10.5	**Incompatible materials**	Oxidizing agent, 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, SOx, Na2O.

SECTION 11. TOXICOLOGICAL INFORMATION

The health effects of the product have not been thoroughly investigated.

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:	May cause eye irritation.

Toxicokinetic effects (Absorption, Distribution, Metabolism, Excretion): not available

Acute toxicity	**Value**	**m.u.**	**Effects**	**Related to**
Oral:	not available			
Dermal:	not available			
Inhalation:	not available			
Other data:	not available			

Corrosion/Irritation

Skin Corrosion/Irritation	not available
Serious eye damage/ irritation	not available

Sensitization:

Skin sensitization:	not available
Respiratory sensitization:	not available

CMR effects

Germ cell mutagenicity;	not available
Reproductive toxicity:	not available

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.			

STOT –single exposure Not available.

STOT – repeated exposure not available

Aspiration hazards Not available.

Other information: Not available.

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

SECTION 12. ECOLOGICAL INFORMATION

The environmental effects of the product have not been thoroughly investigated.

12.1 Toxicity	**species, media, units, test duration and test conditions.**	**Related to**
Acute toxicity with fish:	not available	
Chronic toxicity with fish:	not available	
Acute toxicity with crustaceans:	not available	
Chronic toxicity with crustaceans:	not available	
Acute toxicity with algae:	not available	
Chronic toxicity with algae:	Not available.	
Toxicity data on soil micro- and macroorganisms	Not available.	
Toxicity data on birds, bees and plants:	Not available.	

12.2 Persistency and degradability: not available

12.3 Bioaccumulation potential: not available

12.4 Mobility in soil: not available

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

12.6 Other toxic effects: not available

SECTION 13. DISPOSAL CONSIDERATION

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

13.1 Waste treatment methods

Used waste product, surplus product or spillage products shall be disposed of in accordance with national, state and local laws.

SECTION 14. TRANSPORT INFORMATION

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

SECTION 15. REGULATORY INFORMATION

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

EU Regulations

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

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

US Federal Regulations:

State	*Components listed*	*Note*
Massachusetts	No component listed	
New York	No component listed	
New Jersey	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] **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 02/02/2012.
- Revision n. 01, dated 10/20/2015. Main changes are in sections 2 to16, adapting the SDS format and contents to Hazard Communication Standard (HCS), 29 CFR 1910.1200 (HazCom 2012), Hazardous Product Regulation HPR (WHMIS 2015), and Regulation (EU) 2015/830 of 28 May 2015.

Acronyms: ACGIH: American Conference of Governmental Industrial Hygienists

AIHA: American Industrial Hygiene Association

ADR: Agreement concerning the carriage of dangerous goods by Road

BCF: Bioaccumulative factor

BEI : Biological Esposure Indices

CAS: Chemical Abstract Service (division of the American Chemical Society

CLP: Classification, Labeling and Packaging

DNEL: Derived No-Effect Levels

EC50: the effect concentration associated with 50% response.

EINECS: European Inventory of Existing Commercial Substances

EPA: US Environmental Protection Agency

IARC: International Agency for Research on Cancer

IATA: International Air Transport Association Code

IMDG: International Maritime Dangerous Goods Code

LC50: Lethal Concentration to 50 % of a test population

LD50: Lethal Dose to 50% of a test population (Median Lethal Dose)

LOEL: Lowest Observed Effect Level

MADL: Maximum Allowable Daily (or Dose) Level

NOAEL: No Observed Adverse Effect Level)

NOEC: no observed effect concentration, means the test concentration immediately below the lowest tested concentration with statistically significant adverse effect.

NSRL: National Science Research Laboratory

NTP: National Toxicology Program

OEL: Occupational Exposure Limit

OSHA: Occupational Safety and Health Administration

PPE : Personal protective Equipment

PBT: Persistent, Bioaccumulative and Toxic substances

PNEC: Predicted No Effect Concentration

RID: Regulation concerning the International carriage of Dangerous goods by rail

TLV/TWA: Threshold Limit Value/Threshold Weighted Average

vPvB: very Persistent, very Bioaccumulative

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

Information related to the Regulation EC/1272/2008: none

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*
Not classified	-

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

Bibliographic references: none

SECTION 1. IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY

1.1 Identification of the mixture

Product Name: **Control Plasma Level 2**

Product Number: **000H01444**

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 (USA)

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 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, 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*
Not classified		
		For exposure limits see section 8.

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

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

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):	none
Precautionary statement(s):	none
Other labeling details:	**≈ 98.75% of the mixture consists of component of unknown acute toxicity (oral, dermal, inhalation) for the human health and for the aquatic environment.**

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.

Warning:
This product contains human source material that tested non-reactive for HIV antibody, Hepatitis B Surface Antigen and Anti-HCV at the donor stage. This product, as with all human based specimens, should be handled with proper laboratory safety procedures to minimize the risk of transmission of infectious disease.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Composition: solid containing organic and inorganic components, human plasma.

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.)	< 0.01%	Eye damage/irritation, cat. 2	Eye Irrit.2, H319
Zinc chloride *Index N. (Annex VI of CLP Reg.): 030-003-00-2*	231-592-0	7646-85-7	< 0.001%	Acute Tox. – Oral, cat. 4 Skin Corrosion/Irritation, cat.1B Aquatic Acute, cat 1 ** Aquatic Chronic, cat. 1**	Acute Tox. 4, H302 Skin Corr. 1B, H314 Aquatic Acute 1, H400 (M = 10) Aquatic Chronic 1H410 (M = 1) *Specific Conc. Limits:* STOT SE 3; H335: C ≥ 5 %
Cupric chloride dihydrate	600-176-4 231-210-2 (Cupric chloride anhydrous	10125-13-0 (7447-39-4 as Cupric chloride anhydrous)	< 0.001%	Acute Tox. – Oral, cat. 4 Acute Tox. – Dermal, cat. 4 Skin Corrosion/Irritation, 2 Eye damage/irritation, cat. 1 Aquatic Acute, cat. 1** Aquatic Chronic, cat. 1**	Acute Tox 4, H302 Acute Tox. 4, H312 Skin Irit. 2, H315 Eye Dam.1, H318 Aquatic Acute 1, H400 (M = 10) Aquatic Chronic 1H410 (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 substances listed in the Hazardous Substance Lists and/or evaluated for carcinogenicity by IARC, NTP, OSHA: Zinc chloride, Cupric chloride dihydrate. 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 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 to respiratory ways.
Skin : May be irritant for skin.
Eyes: May cause irritation.
Ingestion: May cause irritation to the gastrointestinal mucous membranes.

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, 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 2-8°C.Avoid light exposure and keep away from heat sources. Room ventilation: well ventilated workplace. Keep containers tightly closed and labelled with the name of the product. Avoid environmental release.
Keep away from food and drinks.

7.3 Specific end use *Control Plasma Level 2* is intended for in vitro diagnostic use. This product contains human source material that tested non-reactive for HIV antibody, Hepatitis B Surface Antigen and Anti-HCV at the donor stage. This product, as with all human based specimens, should be handled with proper laboratory safety procedures to minimize the risk of transmission of infectious disease. 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 [(1)]
Canada – Ontario: Occupational exposure limit (OEL) for calcium chloride of 5 mg/m³ has been established by the Ministry of Labour

Zinc Chloride, fume or respirable dust [(3)(4)]	***Limit value – 8 hours***	***Limit value – short term***
Belgium	1 mg/m³	2 mg/m³
Denmark	0,5 mg/m³	1 mg/m³
Finland	1 mg/m³ as zinc chloride	

	France	1 mg/m³	
	Ireland	1 mg/m³	2 mg/m³- *15 minutes reference period*
	New Zealand	1 mg/m³	2 mg/m³
	Spain	1 mg/m³	2 mg/m³
	Sweden	1 mg/m³	
	Switzerland	1 mg/m³ - respirable aerosol	
	United Kingdom	[1] mg/m³	2 mg/m³
	The UK Advisory Committee on Toxic Substances has expressed concern that, for the OELs shown in parentheses [ ], health may not be adequately protected because of doubts that the limit was not soundly-based. These OELs were included in the published UK 2002 list and its 2003 supplement, but are omitted from the published 2005 list.		
	Canada – Québec	1 mg/m³	
	Canada – Ontario	1 mg/m³	2 mg/m³
	USA – NIOSH	1 mg/m³	2 mg/m³ *15 minutes average value*
	USA – OSHA	1 mg/m³	
	ACGIH (1992): Zinc chloride fume TWA = 1 mg/m³, STEL = 2 mg/m³		
Copper(II) chloride dehydrate[3]	Finland	1 mg/m³ calculated as Cu	
Copper and inorganic copper compounds (inhalable) [3]	Germany (DFG)	0.01 mg/m³ - Respirable fraction	0.02 mg/m³ - Respirable fraction, 15 minutes reference period
	Latvia	0.5 mg/m³	1mg/m³ -15 minutes average value
	Poland	0.2 mg/m³	
	The Netherlands	0.1 mg/m³	
Copper, dusts and mists (as Cu) [3][4(	Austria	1 mg/m³ - inhalable aerosol	
	Belgium	1 mg/m³	
	Denmark	1 mg/m³	2 mg/m³
	France	1 mg/m³	2 mg/m³
	Germany (DFG)	0.01 mg/m³ - Respirable fraction	0.02 mg/m³ - Respirable fraction, 15 minutes reference period
	Hungary	1 mg/m³	4 mg/m³
	Ireland	1 mg/m³	
	Poland	1 mg/m³	2 mg/m³
	Spain	1 mg/m³	
	Sweden	1 mg/m³	
	Switzerland	0.1 mg/m³ - inhalable aerosol	0.2 mg/m³ - inhalable aerosol
	The Netherlands	0.1 mg/m³- inhalable aerosol	
	United Kingdom	1 mg/m³	2 mg/m³
	Canada – Québec	1 mg/m³	
	Canada – Ontario	1 mg/m³	
	USA – OSHA	1 mg/m³	
	ACGIH(1990)	1 mg/m³	
Copper, fume, respirable dust[3][4]	Austria	0.1 mg/m³	0.4 mg/m³
	Belgium	0.2 mg/m³	
	Denmark	0.1 mg/m³	0.2 mg/m³
	Finland	0.1 mg/m³ - Respirable fraction, calculated as Cu	
	France	0.2 mg/m³	

Germany (DFG)	0.01 mg/m³ - Respirable fraction	0.02 mg/m³ - Respirable fraction, 15 minutes reference period
Hungary	0.1 mg/m³	0.4 mg/m³
Ireland	0.2 mg/m³	
Poland	0.1 mg/m³	0.3 mg/m³
Spain	0.2 mg/m³	
Sweden	0.2 mg/m³	
United Kingdom	0.2 mg/m³	
Canada – Québec	0.2 mg/m³	
Canada – Ontario	0.2 mg/m³	
USA – OSHA	0.1 mg/m³	
ACGIH(1990)	0.2 mg/m³	

Copper and its inorganic compounds[9] 8-hour TWA: 0.01 mg/m3 (respirable fraction)

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. [2]	*Oral (mg/(mg/kg bw/day*								
	Dermal (mg/kg bw/day)								
	Inhalation (mg/m³)	*10*		*5*		*5*		2.5	

PNEC values (components): *Zinc chloride* as well as other emitted zinc species will contribute to the effect of the total amount of zinc in the environment. In the RAR Zinc metal, PNEC add values have been derived for zinc, on the basis of tests with soluble zinc salts (especially zinc sulphate or zinc chloride), using the "added risk approach"[11]:
PNEC add aquatic freshwater = 7.8 µg/l for dissolved zinc
PNEC add, freshwater sediment = 49 mg/kg dwt
PNEC add STP = 52 µg/l dissolved zinc
PNEC add soil = 26 mg/kg dwt

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:	Lyophilized, Solid	
Odor:	not available	
Color:	beige	
pH:	not available	
Flammability:	not available	
Explosive properties:	not available	
Oxidizing properties:	not available	
Density:	not available	
Solubility:	not available	
Water Solubility:	Soluble	Mixture
Melting point/range:	not available	

9.2 Other information not available

SECTION 10. STABILITY AND REACTIVITY

10.1 Reactivity This mixture is considered not reactive under the normal conditions of the usage.

10.2 Chemical stability The product is stable until the expiration date shown on the box and on the labels when stored at 2 – 8°C.

10.3 Possibility of hazardous reactions Not foreseen.

10.4 Conditions to avoid: Keep out from heat, water, humidity 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 COx, 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:	Prolonged or repeated skin contact 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:	May cause irritation.

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

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

Copper is mainly absorbed through the gastrointestinal tract. From 20 to 60% of the dietary copper is absorbed, with the rest being excreted through the feces. The liver is the critical organ for copper homeostasis. The primary route of Copper excretion is through the bile. (5)

Zinc chloride: Absorption of zinc from oral exposure has been observed to vary between 8–80 %. The amount absorbed is dependent on the bioavailability from food. Zinc absorption may also be influenced by the endogenous secretion of zinc into the intestinal lumen via the gastrointestinal epithelium, as well as that contained in bile and pancreatic secretions. Animal studies have shown that inhalational absorption of zinc may occur in any region of the respiratory system. Dermal absorption of zinc is thought to be minimal. Zinc is distributed throughout all tissues in humans and is a cofactor in over 300 enzyme systems. The highest concentrations of zinc in human tissues are found in bone and muscle (60 % and 30 %, respectively), followed by the prostate, liver and kidney. Zinc does not undergo metabolism and is typically found in the body as a divalent cation complexed with albumin or other serum proteins. In humans, approximately 70–80 % of total ingested zinc is excreted via the faeces (5–10 mg/day depending on the concentration of dietary zinc). Zinc is also excreted via the urine (10 %), sweat, saliva, breast milk and may also be excreted via hair. (10)

Acute toxicity	**Value**	**m.u.**	**Effects**		**Related to**
Oral:	LD50 (rat) =3,798 - 4,179 LD50 (rabbit)=500 – 1,000	mg/Kg	The acute oral toxicity is attributed to the severe irritating property of the original substance or its high-concentration solutions to the gastrointestinal tract.	(1)	Calcium chloride
	LD50 (rat) = 584	mg/Kg	Somnolence (general depressed activity), convulsions or effect on seizure threshold	(6)	Copper dichloride anhydrous
	LD50 (rat) = 1,100	mg/Kg		(10)	Zinc chloride
Dermal:	LD50 (rabbit) > 5,000	mg/Kg		(1)	Calcium chloride
	LD50 (female rat) = 1,224 mg/Kg. LD50 (male rat) > 2,000 mg/Kg. Read across from copper monochloride				Copper dichloride
	LD50 (rat) was >2,000 mg/kg bw. Read across from zinc sulfate heptahydrate (CAS No. 7446-20-0)			(10)	Zinc chloride
Inhalation:	LC50 (rat) > 40	mg/m^3/4h		(1)	Calcium chloride
	LC50 (rat) (10 min) ≤ 1,975	mg/m^3		(11)	Zinc chloride
Other data:	not available				

Corrosion/Irritation

Skin Corrosion/Irritation

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

Cupric chloride anhydrous is irritating to skin. (5)

0.5 ml *$ZnCl_2$* (1% solution in deionized water) was applied on the dorsal skin for 5 consecutive days in open patch tests with mice, rabbits and guinea pigs and in an occlusive test with rabbits. In the open patch test 4/4 rabbits and 6/6 mice had severe irritancy and 3/8 guinea pigs had moderate irritancy. In the occlusive patch test 4/4 rabbits had severe irritancy. Zinc chloride has been classified as corrosive to the skin. (11)

Serious eye damage/ irritation

Calcium chloride is irritating for the eyes. (1)

Copper dichloride causes serious eye damage (read across from copper monochloride, in vivo test on rabbit. (7)

Zinc chloride was unintentionally splashed into the eyes of two patients. Corneal edema developed and some permanent corneal scarring resulted. The substance can be considered as corrosive to the eyes. (4)

Sensitization:

Skin sensitization:

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

Copper dichloride : copper monochloride was not sensitizing in a guinea pig maximization test. (7) Copper or copper salts may induce allergic contact dermatitis in susceptible individuals. (8) However, the number of reported cases with a clear copper-induced sensitization is very low and has been observed only at high concentrations of 5 % of copper salts. With regard to the extensive use of copper and its compounds and the small number of case reports, there is little concern about the sensitizing properties of copper. (9)

Zinc chloride: No data are available regarding the sensitizing effects of zinc chloride in humans as well as in animals. Based on the fact that zinc sulphate is not a skin sensitizer, it is consequently concluded that zinc chloride is not likely to have skin sensitizing potential. (10)

Respiratory sensitization:

Copper dichloride : A Local Lymph Node Assay (LLNA) with copper chloride (1–5 % in DMSO) exhibited a strong lymphocytic proliferation, but this was attributed to the local necrotic action of the compound.(9)

CMR effects

Germ cell mutagenicity;

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

Copper(II) has been reported to be genotoxic in vitro and also in some in vivo bone marrow micronucleus assays in mice after intraperitoneal injection. Therefore, Copper is known to have a genotoxic potential when present at high local concentrations. A genotoxic concern for the human population is not foreseen, except under conditions of overload. (8)

Zinc chloride: Based on the available data, there is insufficient evidence to classify zinc chloride as genotoxic (ATSDR, 2005). It is noteworthy that further testing may be required to assess the potential of zinc chloride to induce genetic mutations in vivo (EU RAR, 2004).[10]

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

Copper dichloride : There are no reprotoxicity data for copper chloride. Studies in rodents demonstrated that oral exposure to copper during gestation induced embryo/fetotoxic and developmental effects. Copper(II) sulphate induced embryo lethality in mink and mice when administered at the very high dose levels of 12 and 80 mg Cu/kg body weight and day, respectively. [5][8] The available data are not sufficient for the classification.

Zinc chloride: There are no indications that Zn^{2+} is of concern for developmental effects based on the results of developmental toxicity studies in different species (mice, rats, hamsters and rabbits) and several studies in which pregnant women were exposed to soluble zinc compounds. [11]

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

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

Copper dichloride : A clastogenic action of copper compounds cannot be excluded, but the data are inconsistent. There are no adequate studies on the carcinogenicity of copper compounds in laboratory animals with oral or inhalation exposure. The carcinogenic potential of copper cannot be evaluated on the basis of existing studies.[8][9]

Zinc chloride: There is no clear experimental or epidemiological evidence for a direct carcinogenic action of zinc or its compounds. According to the U.S. Environmental Protection Authority (EPA) Guidelines for Carcinogen Risk Assessment (U.S. EPA, 2005), there is 'inadequate information to assess carcinogenic potential of zinc' due to insufficient or inconclusive studies from occupational exposure to zinc and carcinogenic animal studies. [10][11]

STOT –single exposure In single exposure studies with *Zinc Chloride* in rats signs of respiratory distress and edema were reported. [11]

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

Copper dichloride : Long-term exposure with Cupric chloride anhydrous in rats and mice showed no overt signs of toxicity other than a dose-related reduction in growth after ingestion. [5]

Zinc chloride: Considering that the no observed effect levels (NOEL) available from 90-day mouse and rat studies were >100 mg/kg bw/d zinc sulfate heptahydrate (CAS No. 7446-20-0), and based on the treatment-related effects reported in various repeated dose toxicity studies, zinc chloride is not considered to cause serious damage to health from repeated oral exposure. The effects observed in a non-guideline repeated dose inhalation study using zinc sulfate (CAS No. 7733-02-0) did not meet the criteria for hazard classification. No data are available on repeated dose toxicity from dermal exposure for zinc chloride or similar compounds.[10]

Aspiration hazards Not available.

Other information:

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

SECTION 12. ECOLOGICAL INFORMATION

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

12.1 Toxicity	**species, media, units, test duration and test conditions.**		**Related to**
Acute toxicity with fish:	LC50 *Pimephales promelas*= 4,630 mg/l/96 hours	(1)	Calcium chloride
	LC50 Oncorhynchus mykiss = 17 µg/ l/96 hours (or 0.017 mg/l/96h)	(7)	Cupric chloride dihydrate
	LC50 Oncorhynchus mykiss = 0.14 mg Zn^{2+}/l	(13)	Zinc chloride
Chronic toxicity with fish:	EC10 *Salmo gairdneri* = 16.5 ug/l/28 days (0.0165 mg l/28 days)	(5)	Copper chloride
	LC50 fish /14 days = 0,67 mg/l.	(12)	Zinc chloride

Acute toxicity with crustaceans:	EC50 *Daphnia magna* = 1062 mg/L/48 hr	(1)	Calcium chloride
	LC50 = 26 - 69 µg/L/ 48h	(7)	Cupric chloride dihydrate
	EC50 *Daphnia magna* = 0.07 mg Zn/l	(13)	Zinc 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.	(1)	Calcium chloride
	NOEC = 6 µg Cu/L/ 30 d	(7)	Cupric chloride
Acute toxicity with algae:	EC_{50} *Selenastrum capricornutum* = 2,900 mg/L/72 hours (biomass)	(1)	Calcium chloride
	EC50 = 0.136 mg Zn^{2+}/l	(13)	Zinc chloride
Chronic toxicity with algae:	NOEC = 5.7 µg/L/72 h	(7)	Cupric chloride dihydrate
Toxicity data on soil micro- and macroorganisms	NOEC =0.32 - 0.64 mg/L Cu /24 h	(7)	Copper chloride
Toxicity data on birds, bees and plants:	Not available.		

12.2 Persistency and degradability: The methods for determining the biological degradability are not applicable to inorganic substances. Once emitted into the environment, zinc chloride, calcium chloride and copper chloride, which have a high water solubility, will dissociate into the zinc, calcium and copper cations and the chloride anion. The further speciation of zinc, which includes complexation, precipitation and sorption, depends on the environmental conditions. The calcium ion may bind to soil particulate or may form stable inorganic salts with sulphate and carbonate ions. Elemental copper does not break down in the environment.

12.3 Bioaccumulation potential: Zinc chloride presents low or no bioconcentration potential. (12)

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

12.4 Mobility in soil: 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 available.

12.6 Other toxic effects: Not available.

SECTION 13. DISPOSAL CONSIDERATION

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

13.1 Waste treatment methods

Used waste product, surplus product or spillage products shall be disposed of in accordance with national, state and local laws.

SECTION 14. TRANSPORT INFORMATION

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

SECTION 15. REGULATORY INFORMATION

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

EU Regulations

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

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

US Federal Regulations:

State	*Components listed*	*Note*
Massachusetts	Cupric chloride	-
	Zinc chloride	-
New York	Cupric chloride	-
	Zinc chloride	-
New Jersey	Copper chloride (CAS 1344-67-8)	Corrosive
	Zinc chloride	Corrosive
Pennsylvania	Copper chloride (CuCl2)	ENVIRONMENTAL HAZARD
	Zinc chloride	ENVIRONMENTAL HAZARD

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 304EHS RQ* [III]	*CERCLA RQ* [IV]	*SARA/EPCRA 313 TRI* [V]	*RCRA Code* [VI]	*CAA 112(r) RMP TQ* [VII]
Cupric chloride	7447-39-4	-	-	10	313c	-	-
Zinc chloride	7646-85-7	-	-	1,000	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 02/02/2012.
- Revision n. 01, dated 10/20/2015. Main changes are in sections 2 to16, adapting the SDS format and contents to Hazard Communication Standard (HCS), 29 CFR 1910.1200 (HazCom 2012), Hazardous Product Regulation HPR (WHMIS 2015), and Regulation (EU) 2015/830 of 28 May 2015.

Acronyms:

ACGIH: American Conference of Governmental Industrial Hygienists
AIHA: American Industrial Hygiene Association
ADR: Agreement concerning the carriage of dangerous goods by Road
BCF: Bioaccumulative factor
BEI : Biological Esposure Indices
CAS: Chemical Abstract Service (division of the American Chemical Society
CLP: Classification, Labeling and Packaging
DNEL: Derived No-Effect Levels
EC50: the effect concentration associated with 50% response.
EINECS: European Inventory of Existing Commercial Substances
EPA: US Environmental Protection Agency
IARC: International Agency for Research on Cancer
IATA: International Air Transport Association Code

IMDG: International Maritime Dangerous Goods Code

LC50: Lethal Concentration to 50 % of a test population

LD50: Lethal Dose to 50% of a test population (Median Lethal Dose)

LOEL: Lowest Observed Effect Level

MADL: Maximum Allowable Daily (or Dose) Level

NOAEL: No Observed Adverse Effect Level)

NOEC: no observed effect concentration, means the test concentration immediately below the lowest tested concentration with statistically significant adverse effect.

NSRL: National Science Research Laboratory

NTP: National Toxicology Program

OEL: Occupational Exposure Limit

OSHA: Occupational Safety and Health Administration

PPE : Personal protective Equipment

PBT: Persistent, Bioaccumulative and Toxic substances

PNEC: Predicted No Effect Concentration

RID: Regulation concerning the International carriage of Dangerous goods by rail

TLV/TWA: Threshold Limit Value/Threshold Weighted Average

vPvB: very Persistent, very Bioaccumulative

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

Information related to the Regulation EC/1272/2008:

Hazard statement(s):

H319: Causes serious eye irritation.

H302: Harmful if swallowed.

H314: Causes severe skin burns and eye damage.

H400: Very toxic to aquatic life.

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

H335: May cause respiratory irritation.

H315: Causes skin irritation.

H318: Causes serious eye damage.

H312: Harmful in contact with skin.

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*
Not classified	-

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

Bibliographic references:

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

(2) 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

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

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

(5) Hazardous Substances Data Bank (HSDB), Records containing Copper (II) chloride, HSN: 259

(6) ChemIDplus Lite, Cupric chloride anhydrous, Full record

(7) Copper dichloride, Registration Dossier on ECHA, http://apps.echa.europa.eu/registered/data/dossiers/DISS-dcedb361-d3a4-32a9-e044-00144f67d031/AGGR-0d0a38f1-9908-4f35-9b05-4bdb53e242c6_DISS-dcedb361-d3a4-32a9-e044-00144f67d031.html#AGGR-0d0a38f1-9908-4f35-9b05-4bdb53e242c6

(8) EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2015. Scientific Opinion on the safety and efficacy of copper compounds (E4) as feed additives for all animal species (cupric acetate, monohydrate; basic cupric carbonate, monohydrate; cupric chloride, dehydrate; cupric oxide; cupric sulphate, pentahydrate; cupric chelate of amino acids, hydrate; cupric chelate of glycine, hydrate), based on a dossier submitted by FEFANA asbl. EFSA Journal 2015;13(4):4057, 51 pp. doi:10.2903/j.efsa.2015.4057

(9) Recommendation from the Scientific Committee on Occupational Exposure Limits for Copper and its inorganic compounds, SCOEL/SUM/171 March 2014

(10) INVENTORY MULTI-TIERED ASSESSMENT AND PRIORITISATION (IMAP), HUMAN HEALTH TIER II ASSESSMENT FOR Zinc chloride (ZnCl2), CAS Number: 7646-85-7

(11) EU RISK ASSESSMENT REPORT – Zinc Chloride, Final report, May 2008

(12) Istituto Superiore di Sanità, Centro Nazionale Sostanze Chimiche Scheda di Dati di Sicurezza secondo l'Allegato II del Regolamento 1907/2006 (REACh), Cloruro di zinco, Data di emissione: 29/10/2014

(13) The Zincs Category, SIAM 21, 18-20 October 2005 SIDS INITIAL ASSESSMENT PROFILE

SECTION 1. IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY

1.1 Identification of the mixture

Product Name: **V-DEF Plasma**

Product Number: **000H01450**

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 (USA)

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 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, 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*
Not classified		
		For exposure limits see section 8.

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

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

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):	none
Precautionary statement(s):	none
Other labeling details:	**≈ 98.26% of the mixture consists of component of unknown acute toxicity (oral, dermal, inhalation) for the human health and for the aquatic environment.**

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.

Warning:
This product contains human source material that tested non-reactive for HIV antibody, Hepatitis B Surface Antigen and Anti-HCV at the donor stage. This product, as with all human based specimens, should be handled with proper laboratory safety procedures to minimize the risk of transmission of infectious disease.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Composition: solid containing organic and inorganic components, human plasma.

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 dehydrate *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.)	< 0.01%	Eye damage/irritation, cat. 2	Eye Irrit.2, H319
Zinc chloride *Index N. (Annex VI of CLP Reg.): 030-003-00-2*	231-592-0	7646-85-7	< 0.001%	Acute Tox. – Oral, cat. 4 Skin Corrosion/Irritation, 1B Aquatic Acute, cat 1 ** Aquatic Chronic, cat. 1**	Acute Tox. 4, H302 Skin Corr. 1B, H314 Aquatic Acute 1, H400 (M = 10) Aquatic Chronic 1H410 (M = 1) *Specific Conc. Limits:* STOT SE 3; H335: C ≥ 5 %
Cupric chloride dehydrate	600-176-4 231-210-2 (Cupric chloride anhydrous	10125-13-0 (7447-39-4 as Cupric chloride anhydrous)	< 0.001%	Acute Tox. – Oral, cat. 4 Acute Tox. – Dermal, cat. 4 Skin Corrosion/Irritation, cat.2 Eye damage/irritation, cat. 1 Aquatic Acute, cat. 1** Aquatic Chronic, cat. 1**	Acute Tox 4, H302 Acute Tox. 4, H312 Skin Irit. 2, H315 Eye Dam.1, H318 Aquatic Acute 1, H400 (M = 10) Aquatic Chronic 1H410 (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 substances listed in the Hazardous Substance Lists and/or evaluated for carcinogenicity by IARC, NTP, OSHA: Zinc chloride, Cupric chloride dehydrate. 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 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 to respiratory ways.
Skin : May be irritant for skin.
Eyes: May cause irritation.
Ingestion: May cause irritation to the gastrointestinal mucous membranes.

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, 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 2-8°C.Avoid light exposure and keep away from heat sources. Room ventilation: well ventilated workplace. Keep containers tightly closed and labelled with the name of the product. Avoid environmental release.
Keep away from food and drinks.

7.3 Specific end use *V-DEF Plasma* is intended for in vitro diagnostic use. This product contains human source material that tested non-reactive for HIV antibody, Hepatitis B Surface Antigen and Anti-HCV at the donor stage. This product, as with all human based specimens, should be handled with proper laboratory safety procedures to minimize the risk of transmission of infectious disease. 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 [(1)]

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

Zinc Chloride, fume or respirable dust [(3)(4)]	***Limit value – 8 hours***	***Limit value – short term***
Belgium	1 mg/m³	2 mg/m³
Denmark	0,5 mg/m³	1 mg/m³
Finland	1 mg/m³ as zinc chloride	

	France	1 mg/m³	
	Ireland	1 mg/m³	2 mg/m³- *15 minutes reference period*
	New Zealand	1 mg/m³	2 mg/m³
	Spain	1 mg/m³	2 mg/m³
	Sweden	1 mg/m³	
	Switzerland	1 mg/m³ - respirable aerosol	
	United Kingdom	[1] mg/m³	2 mg/m³
	The UK Advisory Committee on Toxic Substances has expressed concern that, for the OELs shown in parentheses [ ], health may not be adequately protected because of doubts that the limit was not soundly-based. These OELs were included in the published UK 2002 list and its 2003 supplement, but are omitted from the published 2005 list.		
	Canada – Québec	1 mg/m³	
	Canada – Ontario	1 mg/m³	2 mg/m³
	USA – NIOSH	1 mg/m³	2 mg/m³ *15 minutes average value*
	USA – OSHA	1 mg/m³	
	ACGIH (1992): Zinc chloride fume TWA = 1 mg/m³, STEL = 2 mg/m³		
Copper(II) chloride dehydrate[3]	Finland	1 mg/m³ calculated as Cu	
Copper and inorganic copper compounds (inhalable) [3]	Germany (DFG)	0.01 mg/m³ - Respirable fraction	0.02 mg/m³ - Respirable fraction, 15 minutes reference period
	Latvia	0.5 mg/m³	1mg/m³ -15 minutes average value
	Poland	0.2 mg/m³	
	The Netherlands	0.1 mg/m³	
Copper, dusts and mists (as Cu) [3][4(	Austria	1 mg/m³ - inhalable aerosol	
	Belgium	1 mg/m³	
	Denmark	1 mg/m³	2 mg/m³
	France	1 mg/m³	2 mg/m³
	Germany (DFG)	0.01 mg/m³ - Respirable fraction	0.02 mg/m³ - Respirable fraction, 15 minutes reference period
	Hungary	1 mg/m³	4 mg/m³
	Ireland	1 mg/m³	
	Poland	1 mg/m³	2 mg/m³
	Spain	1 mg/m³	
	Sweden	1 mg/m³	
	Switzerland	0.1 mg/m³ - inhalable aerosol	0.2 mg/m³ - inhalable aerosol
	The Netherlands	0.1 mg/m³- inhalable aerosol	
	United Kingdom	1 mg/m³	2 mg/m³
	Canada – Québec	1 mg/m³	
	Canada – Ontario	1 mg/m³	
	USA – OSHA	1 mg/m³	
	ACGIH(1990)	1 mg/m³	
Copper, fume, respirable dust[3][4]	Austria	0.1 mg/m³	0.4 mg/m³
	Belgium	0.2 mg/m³	
	Denmark	0.1 mg/m³	0.2 mg/m³
	Finland	0.1 mg/m³ - Respirable fraction, calculated as Cu	
	France	0.2 mg/m³	

Germany (DFG)	0.01 mg/m³ - Respirable fraction	0.02 mg/m³ - Respirable fraction, 15 minutes reference period
Hungary	0.1 mg/m³	0.4 mg/m³
Ireland	0.2 mg/m³	
Poland	0.1 mg/m³	0.3 mg/m³
Spain	0.2 mg/m³	
Sweden	0.2 mg/m³	
United Kingdom	0.2 mg/m³	
Canada – Québec	0.2 mg/m³	
Canada – Ontario	0.2 mg/m³	
USA – OSHA	0.1 mg/m³	
ACGIH(1990)	0.2 mg/m³	

Copper and its inorganic compounds[9] 8-hour TWA: 0.01 mg/m3 (respirable fraction)

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. [2]	*Oral (mg/(mg/kg bw/day*								
	Dermal (mg/kg bw/day)								
	Inhalation (mg/m³)	*10*		*5*		*5*		2.5	

PNEC values (components): *Zinc chloride* as well as other emitted zinc species will contribute to the effect of the total amount of zinc in the environment. In the RAR Zinc metal, PNEC add values have been derived for zinc, on the basis of tests with soluble zinc salts (especially zinc sulphate or zinc chloride), using the "added risk approach"[11]:
PNEC add aquatic freshwater = 7.8 µg/l for dissolved zinc
PNEC add, freshwater sediment = 49 mg/kg dwt
PNEC add STP = 52 µg/l dissolved zinc
PNEC add soil = 26 mg/kg dwt

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:	Lyophilized, Solid	
Odor:	not available	
Color:	White to yellow	
pH:	not available	
Flammability:	not available	
Explosive properties:	not available	
Oxidizing properties:	not available	
Density:	not available	
Solubility:	not available	
Water Solubility:	Soluble	Mixture
Melting point/range:	not available	

9.2 Other information not available

SECTION 10. STABILITY AND REACTIVITY

10.1 Reactivity This mixture is considered not reactive under the normal conditions of the usage.

10.2 Chemical stability The product is stable until the expiration date shown on the box and on the labels when stored at 2 – 8°C.

10.3 Possibility of hazardous reactions Not foreseen.

10.4 Conditions to avoid: Keep out from heat, water, humidity 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 COx, 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:	Prolonged or repeated skin contact 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:	May cause irritation.

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

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

Copper is mainly absorbed through the gastrointestinal tract. From 20 to 60% of the dietary copper is absorbed, with the rest being excreted through the feces. The liver is the critical organ for copper homeostasis. The primary route of Copper excretion is through the bile. (5)

Zinc chloride: Absorption of zinc from oral exposure has been observed to vary between 8–80 %. The amount absorbed is dependent on the bioavailability from food. Zinc absorption may also be influenced by the endogenous secretion of zinc into the intestinal lumen via the gastrointestinal epithelium, as well as that contained in bile and pancreatic secretions. Animal studies have shown that inhalational absorption of zinc may occur in any region of the respiratory system. Dermal absorption of zinc is thought to be minimal. Zinc is distributed throughout all tissues in humans and is a cofactor in over 300 enzyme systems. The highest concentrations of zinc in human tissues are found in bone and muscle (60 % and 30 %, respectively), followed by the prostate, liver and kidney. Zinc does not undergo metabolism and is typically found in the body as a divalent cation complexed with albumin or other serum proteins. In humans, approximately 70–80 % of total ingested zinc is excreted via the faeces (5–10 mg/day depending on the concentration of dietary zinc). Zinc is also excreted via the urine (10 %), sweat, saliva, breast milk and may also be excreted via hair. (10)

Acute toxicity	**Value**	**m.u.**	**Effects**		**Related to**
Oral:	LD50 (rat) =3,798 - 4,179 LD50 (rabbit)=500 – 1,000	mg/Kg	The acute oral toxicity is attributed to the severe irritating property of the original substance or its high-concentration solutions to the gastrointestinal tract.	(1)	Calcium chloride
	LD50 (rat) = 584	mg/Kg	Somnolence (general depressed activity), convulsions or effect on seizure threshold	(6)	Copper dichloride anhydrous
	LD50 (rat) = 1,100	mg/Kg		(10)	Zinc chloride
Dermal:	LD50 (rabbit) > 5,000	mg/Kg		(1)	Calcium chloride
	LD50 (female rat) = 1,224 mg/Kg. LD50 (male rat) > 2,000 mg/Kg. Read across from copper monochloride				Copper dichloride
	LD50 (rat) was >2,000 mg/kg bw. Read across from zinc sulfate heptahydrate (CAS No. 7446-20-0)			(10)	Zinc chloride
Inhalation:	LC50 (rat) > 40	mg/m^3/4h		(1)	Calcium chloride
	LC50 (rat) (10 min) ≤ 1,975	mg/m^3		(11)	Zinc chloride
Other data:	not available				

Corrosion/Irritation

Skin Corrosion/Irritation

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

Cupric chloride anhydrous is irritating to skin. (5)

0.5 ml $ZnCl_2$ (1% solution in deionized water) was applied on the dorsal skin for 5 consecutive days in open patch tests with mice, rabbits and guinea pigs and in an occlusive test with rabbits. In the open patch test 4/4 rabbits and 6/6 mice had severe irritancy and 3/8 guinea pigs had moderate irritancy. In the occlusive patch test 4/4 rabbits had severe irritancy. Zinc chloride has been classified as corrosive to the skin. (11)

Serious eye damage/ irritation

Calcium chloride is irritating for the eyes. (1)

Copper dichloride causes serious eye damage (read across from copper monochloride, in vivo test on rabbit. (7)

Zinc chloride was unintentionally splashed into the eyes of two patients. Corneal edema developed and some permanent corneal scarring resulted. The substance can be considered as corrosive to the eyes. (4)

Sensitization:

Skin sensitization:

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

Copper dichloride : copper monochloride was not sensitizing in a guinea pig maximization test. (7) Copper or copper salts may induce allergic contact dermatitis in susceptible individuals. (8) However, the number of reported cases with a clear copper-induced sensitization is very low and has been observed only at high concentrations of 5 % of copper salts. With regard to the extensive use of copper and its compounds and the small number of case reports, there is little concern about the sensitizing properties of copper. (9)

Zinc chloride: No data are available regarding the sensitizing effects of zinc chloride in humans as well as in animals. Based on the fact that zinc sulphate is not a skin sensitizer, it is consequently concluded that zinc chloride is not likely to have skin sensitizing potential. (10)

Respiratory sensitization:

Copper dichloride : A Local Lymph Node Assay (LLNA) with copper chloride (1–5 % in DMSO) exhibited a strong lymphocytic proliferation, but this was attributed to the local necrotic action of the compound.(9)

CMR effects

Germ cell mutagenicity:

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

Copper(II) has been reported to be genotoxic in vitro and also in some in vivo bone marrow micronucleus assays in mice after intraperitoneal injection. Therefore, Copper is known to have a genotoxic potential when present at high local concentrations. A genotoxic concern for the human population is not foreseen, except under conditions of overload. (8)

Zinc chloride: Based on the available data, there is insufficient evidence to classify zinc chloride as genotoxic (ATSDR, 2005). It is noteworthy that further testing may be required to assess the potential of zinc chloride to induce genetic mutations in vivo (EU RAR, 2004).[10]

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

Copper dichloride : There are no reprotoxicity data for copper chloride. Studies in rodents demonstrated that oral exposure to copper during gestation induced embryo/fetotoxic and developmental effects. Copper(II) sulphate induced embryo lethality in mink and mice when administered at the very high dose levels of 12 and 80 mg Cu/kg body weight and day, respectively. [5][8] The available data are not sufficient for the classification.

Zinc chloride: There are no indications that Zn^{2+} is of concern for developmental effects based on the results of developmental toxicity studies in different species (mice, rats, hamsters and rabbits) and several studies in which pregnant women were exposed to soluble zinc compounds. [11]

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

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

Copper dichloride : A clastogenic action of copper compounds cannot be excluded, but the data are inconsistent. There are no adequate studies on the carcinogenicity of copper compounds in laboratory animals with oral or inhalation exposure. The carcinogenic potential of copper cannot be evaluated on the basis of existing studies.[8][9]

Zinc chloride: There is no clear experimental or epidemiological evidence for a direct carcinogenic action of zinc or its compounds. According to the U.S. Environmental Protection Authority (EPA) Guidelines for Carcinogen Risk Assessment (U.S. EPA, 2005), there is 'inadequate information to assess carcinogenic potential of zinc' due to insufficient or inconclusive studies from occupational exposure to zinc and carcinogenic animal studies. [10][11]

STOT –single exposure In single exposure studies with *Zinc Chloride* in rats signs of respiratory distress and edema were reported. [11]

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

Copper dichloride : Long-term exposure with Cupric chloride anhydrous in rats and mice showed no overt signs of toxicity other than a dose-related reduction in growth after ingestion. [5]

Zinc chloride: Considering that the no observed effect levels (NOEL) available from 90-day mouse and rat studies were >100 mg/kg bw/d zinc sulfate heptahydrate (CAS No. 7446-20-0), and based on the treatment-related effects reported in various repeated dose toxicity studies, zinc chloride is not considered to cause serious damage to health from repeated oral exposure. The effects observed in a non-guideline repeated dose inhalation study using zinc sulfate (CAS No. 7733-02-0) did not meet the criteria for hazard classification. No data are available on repeated dose toxicity from dermal exposure for zinc chloride or similar compounds.[10]

Aspiration hazards Not available.

Other information:

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

SECTION 12. ECOLOGICAL INFORMATION

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

12.1 Toxicity	**species, media, units, test duration and test conditions.**		**Related to**
Acute toxicity with fish:	LC50 *Pimephales promelas*= 4,630 mg/l/96 hours	(1)	Calcium chloride
	LC50 Oncorhynchus mykiss = 17 µg/ l/96 hours (or 0.017 mg/l/96h)	(7)	Cupric chloride dihydrate
	LC50 Oncorhynchus mykiss = 0.14 mg Zn^{2+}/l	(13)	Zinc chloride
Chronic toxicity with fish:	EC10 *Salmo gairdneri* = 16.5 ug/l/28 days (0.0165 mg l/28 days)	(5)	Copper chloride
	LC50 fish /14 days = 0,67 mg/l.	(12)	Zinc chloride

Acute toxicity with crustaceans:	EC50 *Daphnia magna* = 1062 mg/L/48 hr	(1)	Calcium chloride
	LC50 = 26 - 69 µg/L/ 48h	(7)	Cupric chloride dihydrate
	EC50 *Daphnia magna* = 0.07 mg Zn/l	(13)	Zinc 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.	(1)	Calcium chloride
	NOEC = 6 µg Cu/L/ 30 d	(7)	Cupric chloride
Acute toxicity with algae:	EC_{50} *Selenastrum capricornutum* = 2,900 mg/L/72 hours (biomass)	(1)	Calcium chloride
	EC50 = 0.136 mg Zn^{2+}/l	(13)	Zinc chloride
Chronic toxicity with algae:	NOEC = 5.7 µg/L/72 h	(7)	Cupric chloride dihydrate
Toxicity data on soil micro- and macroorganisms	NOEC =0.32 - 0.64 mg/L Cu /24 h	(7)	Copper chloride
Toxicity data on birds, bees and plants:	Not available.		

12.2 Persistency and degradability: The methods for determining the biological degradability are not applicable to inorganic substances. Once emitted into the environment, zinc chloride, calcium chloride and copper chloride, which have a high water solubility, will dissociate into the zinc, calcium and copper cations and the chloride anion. The further speciation of zinc, which includes complexation, precipitation and sorption, depends on the environmental conditions. The calcium ion may bind to soil particulate or may form stable inorganic salts with sulphate and carbonate ions. Elemental copper does not break down in the environment.

12.3 Bioaccumulation potential: Zinc chloride presents low or no bioconcentration potential. (12)

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

12.4 Mobility in soil: 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 available.

12.6 Other toxic effects: Not available.

SECTION 13. DISPOSAL CONSIDERATION

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

13.1 Waste treatment methods

Used waste product, surplus product or spillage products shall be disposed of in accordance with national, state and local laws.

SECTION 14. TRANSPORT INFORMATION

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

SECTION 15. REGULATORY INFORMATION

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

EU Regulations

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

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

US Federal Regulations:

State	*Components listed*	*Note*
Massachusetts	Cupric chloride	-
	Zinc chloride	-
New York	Cupric chloride	-
	Zinc chloride	-
New Jersey	Copper chloride (CAS 1344-67-8)	Corrosive
	Zinc chloride	Corrosive
Pennsylvania	Copper chloride (CuCl2)	ENVIRONMENTAL HAZARD
	Zinc chloride	ENVIRONMENTAL HAZARD

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 304EHS RQ* [III]	*CERCLA RQ* [IV]	*SARA/EPCRA 313 TRI* [V]	*RCRA Code* [VI]	*CAA 112(r) RMP TQ* [VII]
Cupric chloride	7447-39-4	-	-	10	313c	-	-
Zinc chloride	7646-85-7	-	-	1,000	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 02/02/2012.
- Revision n. 01, dated 10/20/2015. Main changes are in sections 2 to16, adapting the SDS format and contents to Hazard Communication Standard (HCS), 29 CFR 1910.1200 (HazCom 2012), Hazardous Product Regulation HPR (WHMIS 2015), and Regulation (EU) 2015/830 of 28 May 2015.

Acronyms:

ACGIH: American Conference of Governmental Industrial Hygienists
AIHA: American Industrial Hygiene Association
ADR: Agreement concerning the carriage of dangerous goods by Road
BCF: Bioaccumulative factor
BEI : Biological Esposure Indices
CAS: Chemical Abstract Service (division of the American Chemical Society
CLP: Classification, Labeling and Packaging
DNEL: Derived No-Effect Levels
EC50: the effect concentration associated with 50% response.
EINECS: European Inventory of Existing Commercial Substances
EPA: US Environmental Protection Agency
IARC: International Agency for Research on Cancer
IATA: International Air Transport Association Code

IMDG: International Maritime Dangerous Goods Code

LC50: Lethal Concentration to 50 % of a test population

LD50: Lethal Dose to 50% of a test population (Median Lethal Dose)

LOEL: Lowest Observed Effect Level

MADL: Maximum Allowable Daily (or Dose) Level

NOAEL: No Observed Adverse Effect Level)

NOEC: no observed effect concentration, means the test concentration immediately below the lowest tested concentration with statistically significant adverse effect.

NSRL: National Science Research Laboratory

NTP: National Toxicology Program

OEL: Occupational Exposure Limit

OSHA: Occupational Safety and Health Administration

PPE : Personal protective Equipment

PBT: Persistent, Bioaccumulative and Toxic substances

PNEC: Predicted No Effect Concentration

RID: Regulation concerning the International carriage of Dangerous goods by rail

TLV/TWA: Threshold Limit Value/Threshold Weighted Average

vPvB: very Persistent, very Bioaccumulative

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

Information related to the Regulation EC/1272/2008:

Hazard statement(s):

H319: Causes serious eye irritation.

H302: Harmful if swallowed.

H314: Causes severe skin burns and eye damage.

H400: Very toxic to aquatic life.

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

H335: May cause respiratory irritation.

H315: Causes skin irritation.

H318: Causes serious eye damage.

H312: Harmful in contact with skin.

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*
Not classified	-

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

Bibliographic references:

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

(2) 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

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

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

(5) Hazardous Substances Data Bank (HSDB), Records containing Copper (II) chloride, HSN: 259

(6) ChemIDplus Lite, Cupric chloride anhydrous, Full record

(7) Copper dichloride, Registration Dossier on ECHA, http://apps.echa.europa.eu/registered/data/dossiers/DISS-dcedb361-d3a4-32a9-e044-00144f67d031/AGGR-0d0a38f1-9908-4f35-9b05-4bdb53e242c6_DISS-dcedb361-d3a4-32a9-e044-00144f67d031.html#AGGR-0d0a38f1-9908-4f35-9b05-4bdb53e242c6

(8) EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2015. Scientific Opinion on the safety and efficacy of copper compounds (E4) as feed additives for all animal species (cupric acetate, monohydrate; basic cupric carbonate, monohydrate; cupric chloride, dihydrate; cupric oxide; cupric sulphate, pentahydrate; cupric chelate of amino acids, hydrate; cupric chelate of glycine, hydrate), based on a dossier submitted by FEFANA asbl. EFSA Journal 2015;13(4):4057, 51 pp. doi:10.2903/j.efsa.2015.4057

(9) Recommendation from the Scientific Committee on Occupational Exposure Limits for Copper and its inorganic compounds, SCOEL/SUM/171 March 2014

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(13) The Zincs Category, SIAM 21, 18-20 October 2005 SIDS INITIAL ASSESSMENT PROFILE