SAFETY DATA SHEET
COATEST™ APC™ RESISTANCE
Control Plasma Level 2

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IDENTIFICATION OF THE PRODUCT AND OF THE COMPANY

Identification of the product

Product Name: **COATEST™ APC™ Resistance Control Plasma Level 2**

Product Number: **000822668 63**

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:
DiaPharma Group, Inc.
8948 Beckett Rd.
West Chester, OH 45069 (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
000H01444	**Control Plasma Level 2**	**Not classified**	**Not classified**	**5 x 1 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: **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,
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1.4 Emergency phone: +44 (0) 3700 492 795
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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:	**≈ 98.7% of the mixture consists of component of unknown acute toxicity (oral, dermal, inhalation) for the human health and unknown hazard to the aquatic environment.**

Safety precautions: Use the product in accordance with the Good Laboratory Practice.
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 1, H410 (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 1, H410 (M = 1)

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

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

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

7.3 Specific end use *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/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:	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 feces (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 oedema 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 oedema 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 bio concentration 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 02/28/2011.
- Revision n. 01, dated 11/23/2015. Main changes are in sections 2 to 16, 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, Bio accumulative 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 Bio accumulative

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

(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