SAFETY DATA SHEET
COATEST™ APC™ RESISTANCE
Control Plasma Level 1

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Revision: 01
CO: 461097
Edited on: 11/30/2015

IDENTIFICATION OF THE PRODUCT AND OF THE COMPANY

Identification of the product

Product Name: **COATEST™ APC™ Resistance Control Plasma Level 1**

Product Number: **00082265063**

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
000C00423	Control Plasma Level 1	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 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.
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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, Hazardous Product Regulations OSHA 29 CFR 1910.1200 and 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 Regulations (EC) No 1272/2008, Hazard Communication Standard, 29 CFR 1910.1200 (HCS), and Hazardous Product Regulation HPR (WHMIS 2015):

Hazard class	*Hazard category*	*Hazard statement*
Not classified		
		For exposure limits see 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 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:	**≈ 100% 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: no 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 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 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 CO_x, NO_x, Na_2O, SOx.

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 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. Avoid inhalation of vapor/spray. 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 established.

DNEL values (components): Not established.

PNEC values (components): Not established.

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:	Solid	
Odor:	not available	
Color:	Beige	
pH:	not available	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:	not available	

9.2 Other information

Miscibility	Not applicable

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 CO_x, NO_x, Na_2O, SOx.

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.

		species, media, units, test duration and test conditions.	Related to
12.1	**Toxicity**		
	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 expected to adsorb on soil.	
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 302EHS TPQ* [II]	*SARA/ EPCRA 304 EHS RQ* [III]	*CERCLA RQ* [IV]	*SARA/EPCRA 313 TRI* [V]	*RCRA Code* [VI]	*CAA 112(r) RMP TQ* [VII]
No component listed							

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

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

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

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

SECTION 16. OTHER INFORMATION

Revisions:
▪ Edition n. 01, dated 02/28/2011.
▪ Revision n. 01 dated 11/30/2015. 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: 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