

IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

Product identifier

Product name : **HEMOSIL® CALIBRATION PLASMA**
 Product code : **0020003700**

Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture : For in vitro diagnostic use.

Uses advised against

No additional information available

Details of the supplier of the safety data sheet

Manufacturer

Instrumentation Laboratory Co.
 180 Hartwell Road
 Bedford MA 01730-2443 - USA
 T +1 800 678 0710 - F +1 781 863 9928

E-mail address of competent person responsible for the SDS :
infosds@werfen.com

Distributor EU

Instrumentation Laboratory Co.
 Via Leonardo da Vinci 36
 20877 Roncello (MB), Italy

Distributor US/CANADA

Instrumentation Laboratory Co.
 18B Independence Dr.
 Devens, MA 01434-5294 (USA)

Australian Distributor

Werfen Australia Pty Limited
 59-61 Dickson Avenue
 Artarmon NSW 2064 Australia
 Tel: 1300 369 132 (24/7)

Emergency telephone number

Emergency number : +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
0020003710	CALIBRATION PLASMA	Not classified	Not classified	10 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 substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Mixture
 Product name : CALIBRATION PLASMA
 Product code : 0020003710

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Use of the substance/mixture : For in vitro diagnostic use.

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Manufacturer

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1.4. Emergency telephone number

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

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Classification according to Regulation OSHA 29 CFR 1910.1200 and Hazardous Product Regulation HPR (WHMIS 2015)

Not classified

Adverse physicochemical, human health and environmental effects

Under normal conditions of use, the mixture does not cause adverse effects to humans and to the environment. Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

2.2. Label elements

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

No labelling applicable

Other labelling details : Up to 100% of the mixture consists of ingredients of unknown acute toxicity (oral, dermal, inhalation) for human health and unknown hazard to the aquatic environment.

2.3. Other hazards

Other hazards which do not result in classification : 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.

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Comments :Composition: powder containing organic components, human plasma.

Comments :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

This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of REACH Annex II

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation :If inhaled, move person to fresh air. If breathing is difficult, oxygen should be administered. Get medical advice if adverse symptoms appear.

First-aid measures after skin contact :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.

First-aid measures after eye contact :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.

First-aid measures after ingestion :If swallowed rinse mouth with plenty of water provided person is conscious. Do not induce vomiting. Get medical advice if adverse symptoms appear.

4.2. Most important symptoms and effects, both acute and delayed

Chronic symptoms :Delayed symptoms and effects are not known.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media :CO2. Dry powder. Foam. Water spray.

5.2. Special hazards arising from the substance or mixture

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

5.3. Advice for firefighters

Protection during firefighting :Water jets can be used successfully to cool containers exposed to the fire and disperse fumes.

Other information :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

6.1.1. For non-emergency personnel

Protective equipment :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.

Emergency procedures :No flames, no sparks. Eliminate all sources of ignition. Ventilate spillage area. Evacuate area. Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment :Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment. 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

Methods for 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.

Other information :Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 8: "Exposure controls/personal protection". For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

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).

Hygiene measures :Contaminated work clothing should not be allowed out of the workplace. Do not eat, drink or smoke when using this product. Always wash hands after handling the product. Remove contaminated clothing and personal protective equipments (PPE) before entering eating areas.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions :Keep containers tightly closed and labelled with the name of the product. Avoid environmental release. Keep away from food and drinks.

Incompatible materials :Heat sources. Direct sunlight.

Storage temperature :2 – 8 °C

Storage area :Store in a well-ventilated place.

7.3. Specific end use(s)

CALIBRATION PLASMA is intended for in vitro diagnostic use. This product contains human source material. This product should be treated as potentially infectious; it 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

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

Monitoring methods	
Monitoring methods	The measurement of substances at the workplace must be carried out with standardized methods or, failing that, with appropriate methods.

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

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. Personal protection equipment

Personal protective equipment:

Wear recommended personal protective equipment.

8.2.2.1. Eye and face protection

Eye protection:

Safety glasses

8.2.2.2. Skin protection

Skin and body protection:

Protective clothing, rubber gloves.

Hand protection:

Protective gloves

8.2.2.3. Respiratory protection

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).

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	:Solid
Colour	:Off white.
Appearance	:Powder, cake.
Odour	:odourless.
Odour threshold	:Not available
Melting point	:Not available
Freezing point	:Not available
Boiling point	:Not available
Flammability	:Not available
Explosive limits	:Not applicable
Lower explosion limit	:Not applicable
Upper explosion limit	:Not applicable
Flash point	:Not applicable
Auto-ignition temperature	:Not applicable
Decomposition temperature	:Not available
pH	:Not available
pH solution	:Not available
Viscosity, kinematic	:Not applicable
Solubility	:Water: Soluble
Partition coefficient n-octanol/water (Log Kow)	:Not available
Vapour pressure	:Not applicable
Vapour pressure at 50°C	:Not applicable
Density	:Not available
Relative density	:Not available
Relative vapour density at 20°C	:Not applicable
Particle size	:Not available
Particle size distribution	:Not available
Particle shape	:Not available
Particle aspect ratio	:Not available
Particle aggregation state	:Not available
Particle agglomeration state	:Not available
Particle specific surface area	:Not available
Particle dustiness	:Not available

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

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

Oxidizing agent.

10.6. Hazardous decomposition products

Thermal decomposition or combustion may generate toxic and hazardous fumes of COx, HCl, SOx, NOx.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	:Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal)	:Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation)	:Not classified (Based on available data, the classification criteria are not met)
Skin corrosion/irritation	:Not classified (Based on available data, the classification criteria are not met)
Serious eye damage/irritation	:Not classified (Based on available data, the classification criteria are not met)
Respiratory or skin sensitisation	:Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity	:Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	:Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity	:Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure	:Not classified (Based on available data, the classification criteria are not met)
STOT-repeated exposure	:Not classified (Based on available data, the classification criteria are not met)
Aspiration hazard	:Not classified (Based on available data, the classification criteria are not met)

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties

:The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605

11.2.2. Other information

Experience with humans

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

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute)	:Not classified (Based on available data, the classification criteria are not met)
Hazardous to the aquatic environment, long-term (chronic)	:Not classified (Based on available data, the classification criteria are not met)
Additional information	:The environmental effects of the product have not been thoroughly investigated. Data on toxicological effects of the hazardous ingredients are provided below.

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

CALIBRATION PLASMA	
This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII	
This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII	

12.6. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties

:The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional legislation (waste)	:Disposal must be done according to official regulations.
Waste treatment methods	:Used waste product, surplus product or spillage products shall be disposed of in accordance with national, state and local laws.
Ecology - waste materials	:Avoid release to the environment. Do not empty into drains.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / RID

ADR	IMDG	IATA	RID
14.1. UN number or ID number			
Not applicable	Not applicable	Not applicable	Not applicable
14.2. UN proper shipping name			
Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)			
Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group			
Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards			
Not applicable	Not applicable	Not applicable	Not applicable
No supplementary information available			

14.6. Special precautions for user

Overland transport

Not applicable

Transport by sea

Not applicable

Air transport

Not applicable

Rail transport

Not applicable

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

Contains no substance(s) listed on the REACH Candidate List

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Other information, restriction and prohibition 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.

Commission Directive 2000/39/EC of 8 June 2000 establishing a first list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

REGULATION (EU) 2016/425 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC.

15.1.2. US Regulations

US State regulations:

State	Components listed	Note
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California Proposition 65:

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:

Name	CAS No./SARA/313 Category Code ^I	SARA Section 302 Threshold Planning Quantity (TPQ) ^{II}	RQ (Reportable quantity, section 304 of EPA's List of Lists) ^{III}	CERCLA RQ ^{IV}	SARA Section 313 ^V	RCRA ^{VI}	CAA 112 (R)TQ ^{VII}
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^ISARA/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)

^VSARA/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® RMP TQ: Risk Management Plan Threshold Quantity (Clean Air Act Section 112®)

TSCA : All components of this product are present and listed as Active on the United States Environmental Protection Agency Toxic Substances Control Act (TSCA) inventory

Canada DSL : No component listed

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Revision :	
Edition n. 01, dated 2010-07-28.	
Version n. 01, dated 2012-06-29.	
Version n. 02, dated 2015-09-09.	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) and Regulation (EU) No 2015/830 of 28 May 2015.
Version n. 03, dated 2015-09-29	Main changes are in sections 15.1 and 16, updating information per the most recent version of REACH.
Version n. 04, dated 2023-04-18.	Main changes are in sections 2 to 16, adapting the SDS format and contents to Regulation (EU) 2020/878

Abbreviations and acronyms:	
ACGIH	American Conference of Governmental Industrial Hygienists
AIHA	American Industrial Hygiene Association
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
BCF	Bioconcentration factor
BEI	Biological Exposure Indices
CAS	Chemical Abstract Service (division of the American Chemical Society)
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DNEL	Derived-No Effect Level
EC50	Median effective concentration
EINECS	European Inventory of Existing Commercial Substances
EPA	US Environmental Protection Agency
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
MADL	Maximum Allowable Daily (or Dose) Level
NOEC	No-Observed Effect Concentration
NOAEL	No-Observed Adverse Effect Level
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 Toxic
PNEC	Predicted No-Effect Concentration
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
TLV/TWA	Threshold Limit Value/Threshold Weighted Average
vPvB	Very Persistent and Very Bioaccumulative
WEEL	Workplace Environmental Exposure Level (air concentration of agents in a healthy worker's breathing zone)

Training advice

: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) :

<i>Classification according to Regulation (EC) 1272/2008:</i>	<i>Classification procedure</i>
Not classified	-
<i>Classification according to Hazard Communication Standard, 29 CFR 1910.1200 (HCS) and HPR (WHMIS 2015)</i>	<i>Classification procedure</i>
Not classified	-

Bibliographic references

SDS EU (REACH Annex II)

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).