

1. IDENTIFICATION OF THE PRODUCT AND OF THE COMPANY

1.1 Identification of the product

Product Name: **HEMOSIL® SPECIAL TEST CONTROL LEVEL 1**

Product Number: **0020011000**

1.2 Use of the product:

Kit for in vitro diagnostic use.

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 Roma, 103
 20040 Cavenago Brianza (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)

2. COMPOSITION/INFORMATION ON PRODUCT

P/N	Mixture name	Mixture classification According to 67/548/EEC and 1999/45/EEC Directives	Mixture classification According to 1272/2008/EC Regulation	Kit configuration
0020011100	SPECIAL TEST CONTROL LEVEL 1	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 MSDS are in accordance with Annex II of Regulation no.1907/2006 (REACH) and in accordance with ANSI "Standard for Hazardous Industrial Chemicals - Material Safety Data Sheets - Preparation" (ANSI Z400.1-2004) as recommended by US OSHA.

Prepared by: Chemsafe Srl

1. IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY

1.1 Identification of the mixture

Product Name: **SPECIAL TEST CONTROL LEVEL 1**

Product Number: **0020011100**

1.2 Use of the mixture: For in vitro diagnostic use.

1.3 Company identification:

MANUFACTURER:

Instrumentation Laboratory Co.
180 Hartwell Road,
Bedford, MA 01730-2443 (USA)
Tel. +1 800 678 0710
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2. HAZARDS IDENTIFICATION

2.1 Mixture classification

Classified: not dangerous

(see also ch. 15)
according to 67/548/EEC and 1999/45/EEC Directives

Classified: not hazardous

according to 1272/2008/EC Regulation

2.2 Potential health and environmental effects

Ingestion: May be harmful if swallowed.

Inhalation exposure: May cause irritation.

Contact with skin: May cause irritation.

Contact with eyes: May cause irritation.

Sensitization: Might cause sensitization by inhalation or skin contact.

Environmental exposure: Might cause adverse effects for the environment.

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.

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Composition: powder containing organic and inorganic components, human and animal source material.

3.1 Hazardous components: not known hazardous ingredients.

4. FIRST AID MEASURES

Ingestion: If swallowed rinse mouth with plenty of water provided person is conscious. Get medical advice if adverse symptoms appear.

Inhalation exposure: If inhaled, move person to fresh air. Get medical advice if adverse symptoms appear.

Contact with skin: Remove contaminated clothes and shoes. Wash affected area with soap or mild detergent and plenty of water. Get medical advice if adverse symptoms appear.

Contact with eyes: Wash immediately with plenty of water or normal saline. Keep eyelid open with the finger. Get medical advice if adverse symptoms appear.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing means:	Water spray or regular foam, CO ₂ , dry powder.
Mean of extinguishing NOT to be used:	Not known.
Known hazards caused by combustion:	Thermal decomposition or combustion may generate toxic and hazardous fumes of CO _x , NO _x , SO _x .
Equipment for self-protection: (fire fighters):	Self-contained breathing apparatus, flame and chemical resistant clothing, boots and gloves.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions:	Suitable protective clothing, rubber or polythene gloves, rubber shoes, safety glasses.
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.
Cleaning procedure to recover spilled material:	Soak up with inert absorbent material, and clean with plenty of water. Send to the storage waiting for disposal procedures.

7. HANDLING AND STORAGE

7.1 Handling

Handling procedures:	Wear suitable protective clothing, gloves, eye protection. When use do not eat, drink or smoke. Provide sufficient ventilation in all work areas.
Work/Hygienic practices:	Wash hands with soap and water after use.

7.2 Storage

Room ventilation:	Well ventilated workplace.
Special precautions: (see also Section 8)	Avoid environmental release.
Recommended temperature:	Store at 2°C – 8°C.
Humidity, light and other environmental factors:	Avoid light exposure and keep away from heat sources and non compatible materials.
Containers:	Keep containers tightly closed and labelled with the name of the product.
Other storage precautions:	Keep away from food and drinks.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Exposure limit values

TLV/TWA: not available	LV EU: not available
TLV /STEL: not available	

8.2 Exposure Controls

Respiratory protection:	Respiratory protection is not required. Where risk assessment shows air-purifying respirators are appropriate, use masks with approved filter.
Skin protection:	Protective clothing, rubber or polythene gloves.
Eye protection:	Safety glasses.
Hand protection:	Rubber or polythene gloves.
Other protective systems:	Personal protective equipment (PPE) useful for reducing individual exposure.
Environmental protection:	Avoid any release into the environment.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 General information

Appearance: Powder, cake
 Odor: Odorless
 Color: Off white

9.2 Important health, safety and environmental information

	Value	Related to
pH:	not available	
Flammability:	not available	
Explosive properties:	not available	
Oxidizing properties:	not available	
Density:	not available	
Solubility:	not available	
Water Solubility:	miscible	Mixture

9.3 Other information

Melting point/range: not available

10. STABILITY AND REACTIVITY

Stability: The product is stable until the expiration date shown on the box and on the labels when stored at 2 - 8°C.

- 10.1** Conditions to avoid: Keep out from hot temperature, humidity and light.
- 10.2** Materials to avoid: Oxidizing agents.
- 10.3** Hazardous decomposition products: Thermal decomposition or combustion may include toxic and hazardous fumes of COx, NOx, SOx.

11. TOXICOLOGICAL INFORMATION

11.1 Toxicokinetic effects (ADME)

Absorption: not available
 Distribution: not available
 Metabolism: not available
 Excretion: not available

11.2 Acute toxicity

	Value	m.u.	Effects	Related to
<u>Oral:</u>	LD50 (rat) = not available	mg/Kg		
<u>Dermal:</u>	LD50 (rat) = not available	mg/Kg		
<u>Inhalation:</u>	not available	mg/m ³		
<u>Other data:</u>	not available			

11.3 Irritation

Skin: not available
 Eye: not available
 Inhalation: not available

11.4 Sensitization:

Skin sensitization: not available
 Sensitization by inhalation: not available

11.5 Prolonged exposure toxicity: not available

11.6 CMR effects

			Related to
Mutagenicity:	Ames test:	not available	

Mouse lymphoma:	not available
Chromosomal aberration:	not available
Micronucleus test:	not available
Teratogenesis:	not available
Carcinogenesis:	not available

12. ECOLOGICAL INFORMATION

12.1 Ecotoxicology	Value	m.u.	Related to
Acute toxicity with fish:	LC50 = not available	mg/l/96 hours	
Acute toxicity with Daphnia Magna:	EC50 = not available	mg/l/48 hours	
Acute toxicity with algae:	ErC50 = not available	mg/l/72 hours	
12.2 Mobility:	not available		
12.3 Persistency and degradability:	not available		
12.4 Bioaccumulation potential:	not available		
12.5 Evaluation PBT result:	not available		
12.6 Other toxic effects:	not available		

13. DISPOSAL CONSIDERATION

National laws on disposal must be considered, local and UE requirements for wastes recycling must be respected. Used waste product, surplus product or spillage products shall be disposed of in accordance with national, state and local laws.

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

Regulatory information on labeling according to 67/548/EEC, to 1999/45/EEC Directive and to 1272/2008 Regulation (EC)(European reinforcement of GHS), and according to their following amendments/atp.

	According to 67/548/EEC and 1999/45/EEC Directives	According to 1272/2008/EC Regulation
Classification:	Not classified as dangerous	Not classified as hazardous
Labeling symbols: (signal word)	none	none
Labeling risk phrases: (hazard statements)	none	none
Labeling safety phrases: (precautionary statements)	none	none

Other labeling details: ≈ 31.11 % percent of this mixture consist of ingredient(s) of unknown toxicity for human health and aquatic environment.

Safety precautions: Wear suitable protective clothing, gloves and eye/face protection.

Authorization: no

Restriction: no

16. OTHER INFORMATION

Phrases R: none

Hazard Statements: none

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Bibliographic references: none