

1. IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY

1.1 Identification of the mixture

Product Name: **HemosIL® D-Dimer**

Product Number: **0020008500**

1.2 Use of the mixture: 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:
Beckman Coulter Inc.
250 S. Kraemer Blvd.
Brea, CA 92821, U.S.A

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
0020008520	Latex Reagent	Not Classified	Not Classified	4 vials x 3 mL
0020008521	Reaction Buffer	Not Classified	Not Classified	4 vials x 9 mL
0020008522	D-Dimer Calibrator	Not Classified	Not Classified	2 vials 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: **Latex Reagent**

Product Number: **0020008520**

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)
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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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Composition: aqueous solution containing organic and inorganic compounds, bovine serum albumin and mouse source material.

3.1 Hazardous components:

Name	EINECS/ ELINCS n°	CAS n°	Conc. % w/w	Classification 67/548/EEC	Classification 1272/2008/EC
Borax decahydrate(**)	215-540-4	1303-96-4	< 0.5 %	Repr. Cat. 2, R60-61 <u>Specific Conc. Limits:</u> Repr. Cat. 2, R60-61: c ≥ 8,5 %	Repr. 1B, H360FD <u>Specific Conc. Limits:</u> Repr. 1B, H360FD: c ≥ 8,5 %
Sodium Azide (*)	247-852-1	26628-22-8	< 0.1 %	T ⁺ , R28 R32 N, R50-53	Acute Tox. 2, H300 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Name	EINECS/ ELINCS n°	CAS n°	Conc. % w/w	Classification 67/548/EEC	Classification 1272/2008/EC
Hydrochloric acid (aqueous solution) (*)	231-595-7	7647-01-0 (Hydrogen chloride anhydrous)	< 0.05 %	C; R34 Xi; R37 <u>Specific Conc. Limits:</u> C; R34-37: c ≥ 25 % Xi; R36/37/38: 10 % ≤ c < 25 %	Skin Corr. 1B, H314 STOT SE 3, H335 <u>Specific Conc. Limits:</u> Skin Corr. 1B; H314: c ≥ 25 % Skin Irrit. 2, H315: 10 % ≤ c < 25 % Eye Irrit. 2, H319: 10 % ≤ c < 25 % STOT SE 3, H335: c ≥ 10 %
<i>For exposure limits see ch. 8, for phrases R and hazard statements text see ch. 16</i>					

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 (CO _x , NO _x , Na ₂ O, HCl).
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 – 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. Keep away from contamination with heavy metals. Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussion.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Exposure limit values

TLV (ACGIH): TWA = 2 mg/m³; STEL = 6 mg/m³(inhalable), 2007, for Borax decahydrate ⁽¹⁾ EU OEL: 0.1 mg/m³ as TWA, 0.3 mg/m³ as STEL (skin) for Sodium azide ⁽²⁾

TLV (ACGIH, 2000) (HCl anhydrous): 2 ppm, 3 mg/m³ Ceiling ⁽³⁾ US OSHA PEL FINAL-CL: 0.3 mg/m³ (as NaN₃) (skin) for Sodium azide

TLV/TWA: 0.1 mg/m³ for Sodium azide ⁽²⁾

OEL-STEL (HCl anhydrous) : 15 mg/m³ (2000/39/EC Directive)

TLV /STEL: 0.3 mg/m³ for Sodium azide ⁽²⁾

OEL Belgium: time-weighted average 2 mg/m³, short term exposure limit 6 mg/m³, Mar 2002, for Borax decahydrate ⁽¹⁾

TLV-CEILING (ACGIH): 0.29 mg/m³ for Sodium azide ⁽²⁾

NIOSH REL: 10 hour time-weighted average 5 mg/m³, for Borax decahydrate ⁽¹⁾

OEL UK: time-weighted average 5 mg/m³, 2005, for Borax decahydrate ⁽¹⁾

NIOSH Recommended Exposure Limit (REL) (HCl anhydrous): 5 ppm, 7 mg/m³ Ceiling ⁽³⁾ OEL France: VME 5 mg/m³, Feb 2006, for Borax decahydrate ⁽¹⁾

NIOSH Immediately Dangerous To Life or Health Concentration (IDLH) (HCl anhydrous): 50 ppm ⁽³⁾

MAK: 0.2 mg/m³, inhalable fraction for Sodium azide ⁽⁴⁾

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: Liquid

Odor: Odorless

Color: Colorless

9.2 Important health, safety and environmental information

	Value	Related to
pH:	8.4 – 8.6	Mixture
Boiling point/range:	not available	
Flash point:	not available	
Vapor pressure:	not available	
Density:	not available	
Solubility:	not available	
Water Solubility:	miscible	Mixture
Viscosity:	not available	
Vapor density:	not available	
Evaporation rate:	not available	

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 heat, water, humidity and light.

10.2 Materials to avoid: Strong oxidising agents. Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussions. Sodium azide reacts vigorously with heated water.

10.3 Hazardous decomposition products: Thermal decomposition or combustion may include toxic and hazardous fumes of CO_x, NO_x, Na₂O, HCl.

11. TOXICOLOGICAL INFORMATION

11.1 Toxicokinetic effects (ADME)

Absorption:	Absorption of borates via the oral route is nearly 100%. Dermal absorption through intact skin is very low. ⁽⁵⁾
	Sodium azide is rapidly absorbed from the gastrointestinal tract and from injection sites. ⁽⁶⁾
Distribution:	Borates are distributed rapidly and evenly through the body, with concentrations in bone 2 - 3 higher than in other tissues. ⁽⁵⁾
Metabolism:	not available
Excretion:	Boron is excreted rapidly, with elimination half-lives of 1h in the mouse, 3h in the rat and < 27.8 h in humans, and has low potential for accumulation. Boric acid is mainly excreted in the urine. ⁽⁵⁾

11.2 Acute toxicity

	Value	m.u.	Effects	Related to
<u>Oral:</u>	LD50 (rat) = 2,660	mg/Kg		⁽⁷⁾ Borax decahydrate
	LD50 (rat) = 27	mg/Kg		⁽⁸⁾ Sodium azide
	LD50 (rat) = not available	mg/Kg	Single administration of 1 ml caused stomach damage	⁽⁹⁾ HCl 2% solution
	LD50 (rabbit) = 900	mg/Kg		⁽⁹⁾ HCl
<u>Dermal:</u>	LD50 (rat) > 2,000	mg/Kg		⁽⁵⁾ Borax decahydrate
	LD50 (rat) = 50	mg/Kg		⁽⁸⁾ Sodium azide
<u>Inhalation:</u>	LC50 (rat) > 2.03	mg/l	In an inhalation study in which rats were exposed to boric acid at concentrations of 2.12 mg (0.37 mg B)/L (highest attainable concentration) for 4 hours, no deaths were observed.	⁽⁵⁾ Borax decahydrate
	LC50 (rat) = 37	mg/m ³	Structural or functional change in trachea or bronchi, effects on eye, convulsions or effect on seizure threshold	⁽⁸⁾ Sodium azide
	LC50 (rat) = 3,124	ppm		⁽⁹⁾ HCl anhydrous
<u>Other data:</u>	not available			

11.3 Irritation

Skin:	In animal studies, 10 ml of 5% Borax (Disodium Tetraborate Decahydrate) in water caused a very mild irritation on rabbit skin; in Guinea pigs, neither boric acid nor borax was irritating when applied on abraded skin. ⁽⁵⁾
	Hydrochloric acid 1% aqueous solution proved to be not irritating on rabbits after 5 applications of 0.5 ml within 5 days. Hydrochloric acid 17% and 37% aqueous solutions produced severe damage to the skin of rabbits. ⁽⁹⁾
Eye:	Two animal studies with Disodium Tetraborate Decahydrate have been carried out, both indicating eye irritancy. In normal handling and use the large glassy crystals would not be able to enter the eye easily and in addition over 50 years of occupational exposure to all borate has indicated no adverse effects on the human eye. ⁽⁵⁾
	Hydrochloric acid 0.33% and 3.3% aqueous solutions proved to be not irritating and slightly irritating respectively, after an application of 0.1 ml into the conjunctival sac (observation period: 48 hours). Rabbits treated with 0.1 ml of HCl 10% solution showed severe irritation to eyes. ⁽⁹⁾
Inhalation:	There is no data from animal studies on boric acid, disodium tetraborate anhydrous, disodium tetraborate pentahydrate and disodium tetraborate decahydrate that indicated respiratory irritation. ⁽⁵⁾
	Rabbits exposed by inhalation to 0.15 mg/l of HCl for 6 hours/day for 5 days showed irritation of the nasal mucosa and eyes. ⁽⁹⁾

11.4 Sensitization:

Skin sensitization:	No signs of skin sensitisation were observed in a Buehler method skin sensitisation test with Disodium tetraborate decahydrate. There is no evidence of skin sensitisation in humans exposed occupationally to borates. ⁽⁵⁾
Sensitization by inhalation:	Disodium tetraborate decahydrate is not a respiratory sensitizer. ⁽⁵⁾

11.5 Prolonged exposure toxicity:

A number of studies in which rats were fed boric acid or disodium tetraborate decahydrate in their diet or drinking water for periods of 70 days to two years in rats, mice and dogs indicated that the main target organ for toxicity is the testis. Other effects observed at high doses include rapid respiration, hunched position, bloody nasal discharge; urine stains on the abdomen, inflamed bleeding eyes, desquamation and swollen paws and tail, reduced food consumption and body weight gain. Based on the clinical effects and the testicular atrophy the lowest NOAEL for the effects of boron is 17.5 mg B/kg bw/day (equivalent to 100mg boric acid or 155 mg disodium tetraborate decahydrate/kg bw/day).⁽⁵⁾

Rabbits, exposed by inhalation at the dose of 0.05 mg/l of HCl for 4 weeks, showed irritation of the eyes and the mucous membranes.⁽⁹⁾

11.6 CMR effects

Mutagenicity:

		Related to
Ames test:	Sodium azide was mutagenic in <i>Salmonella typhimurium</i> strains TA100 and TA1535 with or without exogenous metabolic activation (S9); it was not mutagenic in strain TA1537 or TA98.	Sodium azide ⁽¹⁰⁾
	negative	⁽⁹⁾ HCl (purity 95%)
Mouse lymphoma:	negative	⁽⁹⁾ HCl (purity 95%)
Chromosomal aberration:	not available	
Cytogenetic tests with Chinese hamster ovary cells:	Sodium azide induced sister chromatid exchanges, but not chromosomal aberrations.	Sodium azide ⁽¹⁰⁾
Micronucleus test:	negative	⁽⁹⁾ HCl (purity 95%)

Teratogenesis:

Developmental effects have been observed in three species, rats, mice and rabbits, the most sensitive species being the rat. This is based on a reduction in mean foetal body weight/litter, increase in wavy ribs and an increased incidence in short rib XIII at 76 mg/kg bw/day (13.3 mg B/kg bw/day). At maternally toxic doses, visceral malformations observed included enlarge lateral ventricles and cardiovascular effects. The NOAEL (rat) for this endpoint is 9.6 mg B/kg corresponding to: 55 mg boric acid/kg/day, or 85 mg disodium tetraborate decahydrate/kg/day.⁽¹¹⁾

Repeated dose studies in several animal species have consistently demonstrated that the testis is a primary target organ for boron. Based on the data from the 2 years feeding study with boric acid in rats, the overall NOAEL for fertility is therefore 100 mg/kg bw/day, equal to 17.5 mg B/kgbw/day. This conclusion is supported by the study with disodium tetraborate decahydrate.⁽¹²⁾

In a teratogenic study employing albino rats treated orally with technical Sodium azide at dose levels of 0.5, 1.5, or 5.0 mg/kg daily during gestation days 6 through 15, no teratogenic effects due to Sodium azide were found. Sterility has been produced in male mice given sodium azide.⁽⁶⁾

Carcinogenesis:

In carcinogenicity studies in mice and rats no evidence of a carcinogenic effects of boric acid or sodium tetraborate decahydrate was observed.⁽¹²⁾

Carcinogenicity studies were conducted by administering sodium azide (greater than 99% pure) in distilled water by gavage to groups of male and female rats once daily, 5 days per week for 14 days, 13 weeks, or 2 years. Under the conditions of these 2-year gavage studies, there was no evidence of carcinogenic activity of sodium azide in male or female rats administered 5 or 10 mg/kg. Sodium azide induced necrosis in the cerebrum and the thalamus of the brain in both male and female rats.⁽¹⁰⁾

HCl is not listed in NTP, IARC and OSHA lists.⁽⁹⁾

12. ECOLOGICAL INFORMATION

12.1 Ecotoxicology

	Value	m.u.	Related to
Acute toxicity with fish:	LC50 <i>Carassius auratus</i> = 178	mg/l/72 h	⁽¹³⁾ Borax decahydrate
	LC50 bluegill fish = 0.7	mg/l/96 hours	⁽⁶⁾ Sodium azide
	LC50 (<i>Leuciscus idus</i>) = 862	mg/l/48 hours	⁽⁹⁾ HCl solution 3%
Acute toxicity with <i>Daphnia Magna</i> :	EC50 <i>Daphnia magna</i> = 1,085 – 1,402	mg/l/48 hours	⁽¹³⁾ Borax decahydrate
	EC50 <i>daphnia pulex</i> = 4.2	mg/l/96 hours	⁽⁶⁾ Sodium azide
Acute toxicity with algae:	IC50 - <i>Desmodesmus subspicatus</i> = 158	mg/l/96 hours	⁽¹³⁾ Borax decahydrate

12.2 Mobility:

The dissipation of azides in soil is not by microbial action but is strictly a chemical process accelerated by increasing acidity and elevated temperatures.⁽⁶⁾

The high water solubility of HCl indicates high mobility in soil.⁽³⁾

- 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:** ≈ 8.3 % of this mixture consist of ingredient(s) of unknown toxicity for health and for aquatic environment.
- Safety precautions:** Wear suitable protective clothing, gloves and eye/face protection.
- Authorization:** The mixture contains a substance included in the Candidate List of Substances of Very High Concern (Borax decahydrate).
- Restriction:** No

16. OTHER INFORMATION

- Phrases R:**
 - R28: Very toxic if swallowed.
 - R32: Contact with acids liberates very toxic gas.
 - R34: Causes burns.
 - R36/37/38: Irritating to eyes, respiratory system and skin.
 - R37: Irritating to the respiratory system.
 - R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
 - R60: May impair fertility.
 - R61: May cause harm to the unborn child.
- Hazard Statements:**
 - H300: Fatal if swallowed.
 - H314: Causes severe skin burns and eye damage.
 - H315: Causes skin irritation.
 - H319: Causes serious eye irritation.
 - H335: May cause respiratory irritation
 - H360FD: May damage fertility. May damage the unborn child.
 - H400: Very toxic to aquatic life.
 - H410: Very toxic to aquatic life with long lasting effects.

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.

Bibliographic references:

- (1) RTECS:VZ2275000, The Registry of Toxic Effects of Chemical Substances, Sodium borate, decahydrate
- (2) International Chemical Safety Cards, Sodium azide
- (3) www.OSHA.gov, Chemical Sampling Information, Hydrogen Chloride
- (4) Haz-Map Occupational exposure to hazardous Agents, Sodium azide
- (5) European Union Risk Assessment Report: Disodium tetraborate, Anhydrous boric acid, Boric acid crude natural, Risk assesment
- (6) HSDB Hazardous Substances Databank, Sodium azide
- (7) ChemIDplus Lite, Borax, full record
- (8) ChemIDplus Lite, Sodium azide, full record
- (9) IUCLID file, Hydrogen Chloride
- (10) National Toxicology Program database Search Application, Toxicology and Carcinogenesis Studies of Sodium azide (CAS: 26628-22-8) in F344 Rats (Gavage Studies)
- (11) J Am Coll Toxicol 1990;9(2):279-88
- (12) Directive 98/8/EC concerning the placing biocidal products on the market, Assessment Report, 20 February 2009
- (13) Sigma Aldrich, Material Safety Data Sheet for Sodium tetraborate decahydrate, Revision date 12.03.2010
- (*) Classification in Annex I of Dir 67/548/EEC and in Annex VI of the 1272/2008/EC Regulation
- (**) Commission Regulation (EC) No 790/2009 of 10 August 2009 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures

1. IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY

1.1 Identification of the mixture

Product Name: **Reaction Buffer**

Product Number: **0020008521**

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
Fax +1 781 863 9928

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

1.4 Emergency phone: +44 (0)3700 492 795
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2. HAZARDS IDENTIFICATION

2.1 Mixture classification

(see also ch. 15)

Classified: not dangerous

according to 67/548/EEC and 1999/45/EEC Directives

Classified: not hazardous

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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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Composition: liquid containing organic, inorganic components and bovine material.

3.1 Hazardous components:

Name	EINECS/ ELINCS n°	CAS n°	Conc. % w/w	Classification 67/548/EEC	Classification 1272/2008/EC
Sodium Azide (*)	247-852-1	26628-22-8	< 0.1 %	T ⁺ , R28 R32 N, R50-53	Acute Tox. 2, H300 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

For exposure limits see ch. 8, for phrases R and hazard statements text see ch. 16

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 (CO _x , NO _x , Na ₂ O, HCl).
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- 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. Keep away from contamination with heavy metals. Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussion.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Exposure limit values

TLV/TWA: 0.1 mg/m ³ for Sodium azide ⁽¹⁾	EU OEL: 0.1 mg/m ³ as TWA, 0.3 mg/m ³ as STEL (skin) for Sodium azide ⁽¹⁾
TLV /STEL: 0.3 mg/m ³ for Sodium azide ⁽¹⁾	US OSHA PEL FINAL-CL: 0.3 mg/m ³ (as NaN ₃) (skin) for Sodium azide
TLV-CEILING (ACGIH): 0.29 mg/m ³ for Sodium azide ⁽¹⁾	MAK: 0.2 mg/m ³ , inhalable fraction for Sodium azide ⁽²⁾

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:	Liquid
Odor:	Odorless
Color:	Colourless

9.2 Important health, safety and environmental information

	Value	Related to
pH:	7.1 – 7.3	Mixture
Boiling point/range:	not available	
Flash point:	not available	
Vapor pressure:	not available	
Density:	1.009 – 1.035 g/ml	Mixture
Solubility:	not available	
Water Solubility:	miscible	Mixture
Viscosity:	not available	
Vapor density:	not available	
Evaporation rate:	not available	

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 heat and light.
- 10.2** Materials to avoid: Strong oxidising agents, acids, alkalis, heavy metals and their salts. Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussions. Sodium azide reacts vigorously with heated water.
- 10.3** Hazardous decomposition products: Thermal decomposition or combustion may include toxic and hazardous fumes of CO_x, NO_x, Na₂O, HCl.

11. TOXICOLOGICAL INFORMATION

11.1 Toxicokinetic effects (ADME)

Absorption: Sodium azide is rapidly absorbed from the gastrointestinal tract and from injection sites. ⁽³⁾

Distribution: not available

Metabolism: not available

Excretion: not available

11.2 Acute toxicity

	Value	m.u.	Effects	Related to
<u>Oral:</u>	LD50 (rat) = 27	mg/Kg		⁽⁴⁾ Sodium azide
<u>Dermal:</u>	LD50 (rat) = 50	mg/Kg		⁽⁴⁾ Sodium azide
<u>Inhalation:</u>	LC50 (rat) = 37	mg/m ³	Structural or functional change in trachea or bronchi, effects on eye, convulsions or effect on seizure threshold	⁽⁴⁾ Sodium azide
<u>Other data:</u>	LD ₅₀ oral rabbit = not available	mg/Kg		

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

<p>Mutagenicity:</p> <p>Ames test:</p> <p>Mouse lymphoma:</p> <p>Chromosomal aberration:</p> <p>Cytogenetic tests with Chinese hamster ovary cells:</p> <p>Micronucleus test:</p> <p>Teratogenesis:</p> <p>Carcinogenesis:</p>	<p>Sodium azide was mutagenic in <i>Salmonella typhimurium</i> strains TA100 and TA1535 with or without exogenous metabolic activation (S9); it was not mutagenic in strain TA1537 or TA98.</p> <p>not available</p> <p>Negative</p> <p>Sodium azide induced sister chromatid exchanges, but not chromosomal aberrations.</p> <p>not available</p> <p>In a teratogenic study employing albino rats treated orally with technical Sodium azide at dose levels of 0.5, 1.5, or 5.0 mg/kg daily during gestation days 6 through 15, no teratogenic effects due to Sodium azide were found. Sterility has been produced in male mice given sodium azide.⁽³⁾</p> <p>Carcinogenicity studies were conducted by administering sodium azide (greater than 99% pure) in distilled water by gavage to groups of male and female rats once daily, 5 days per week for 14 days, 13 weeks, or 2 years. Under the conditions of these 2-year gavage studies, there was no evidence of carcinogenic activity of sodium azide in male or female rats administered 5 or 10 mg/kg. Sodium azide induced necrosis in the cerebrum and the thalamus of the brain in both male and female rats.⁽⁵⁾</p>	<p>Related to</p> <p>(5) Sodium azide</p> <p>(5) Sodium azide</p> <p>(5) Sodium azide</p>
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12. ECOLOGICAL INFORMATION

<p>12.1 Ecotoxicology</p> <p>Acute toxicity with fish:</p> <p>Acute toxicity with Daphnia Magna:</p> <p>Acute toxicity with algae:</p> <p>12.2 Mobility:</p> <p>12.3 Persistency and degradability:</p> <p>12.4 Bioaccumulation potential:</p> <p>12.5 Evaluation PBT result:</p> <p>12.6 Other toxic effects:</p>	<p>Value</p> <p>LC50 bluegill fish = 0.7</p> <p>EC50 daphnia pulex = 4.2</p> <p>ErC50 = not available</p> <p>not available</p> <p>not available</p> <p>not available</p> <p>not available</p>	<p>m.u.</p> <p>mg/l/96 hours</p> <p>mg/l/96 hours</p> <p>mg/l/72 hours</p> <p>not available</p> <p>not available</p> <p>not available</p> <p>not available</p>	<p>Related to</p> <p>(3) Sodium azide</p> <p>(3) Sodium azide</p> <p>(3) Sodium azide</p> <p>(3) Sodium azide</p>
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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:	≈ 1.8 % of this mixture consist of ingredient(s) of unknown toxicity for health and aquatic environment.
Safety precautions:	Wear suitable protective clothing, gloves and eye/face protection.
Authorization:	no
Restriction:	no

16. OTHER INFORMATION

Phrases R:	R28: Very toxic if swallowed. R32: Contact with acids liberates very toxic gas. R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Hazard Statements:	H300: Fatal if swallowed. H400: Very toxic to aquatic life. H410: Very toxic to aquatic life with long lasting effects.

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.

Bibliographic references:

- (1) International Chemical Safety Cards, Sodium azide
 - (2) Haz-Map Occupational exposure to hazardous Agents, Sodium azide
 - (3) HSDB Hazardous Substances Databank, Sodium azide
 - (4) ChemIDplus Lite, Sodium azide, full record
 - (5) National Toxicology Program database Search Application, Toxicology and Carcinogenesis Studies of Sodium azide (CAS: 26628-22-8) in F344 Rats (Gavage Studies)
- (*) Classification in Annex I of Dir 67/548/EEC and in Annex VI of the 1272/2008/EC Regulation

1. IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY

1.1 Identification of the mixture

Product Name: **D-Dimer Calibrator**
Product Number: **0020008522**

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

1.3 Company identification:

<p><u>MANUFACTURER:</u> Instrumentation Laboratory Co. 180 Hartwell Road, Bedford, MA 01730-2443 (USA) Tel. +1 800 678 0710 Fax +1 781 863 9928</p>	<p><u>DISTRIBUTOR EU:</u> Via Roma, 103 20040 Cavenago Brianza (Italy)</p> <p><u>DISTRIBUTOR US/CANADA:</u> Beckman Coulter Inc. 250 S. Kraemer Blvd. Brea, CA 92821, U.S.A</p>
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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. HAZARDS IDENTIFICATION

2.1 Mixture classification *(see also ch. 15)*
Classified: not dangerous 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: lyophilized containing organic, inorganic components, bovine material and human source material.

3.1 Hazardous components:

Name	EINECS/ ELINCS n°	CAS n°	Conc. % w/w	Classification 67/548/EEC	Classification 1272/2008/EC
Sodium Azide (*)	247-852-1	26628-22-8	< 0.1 %	T+, R28 R32 N, R50-53	Acute Tox. 2, H300 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

For exposure limits see ch. 8, for phrases R and hazard statements text see ch. 16

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 (CO _x , NO _x , Na ₂ O, HCl, 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- 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. Keep away from contamination with heavy metals. Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussion.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Exposure limit values

TLV/TWA: 0.1 mg/m ³ for Sodium azide ⁽¹⁾	EU OEL: 0.1 mg/m ³ as TWA, 0.3 mg/m ³ as STEL (skin) for Sodium azide ⁽¹⁾
TLV /STEL: 0.3 mg/m ³ for Sodium azide ⁽¹⁾	US OSHA PEL FINAL-CL: 0.3 mg/m ³ (as NaN ₃) (skin) for Sodium azide
TLV-CEILING (ACGIH): 0.29 mg/m ³ for Sodium azide ⁽¹⁾	MAK: 0.2 mg/m ³ , inhalable fraction for Sodium azide ⁽²⁾

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: Lyophilized
 Odor: Odorless
 Color: Colorless

9.2 Important health, safety and environmental information

	Value	Related to
pH:	7.4 – 7.6	
Flammability:	not available	
Explosive properties:	not available	
Oxidizing properties:	not available	
Density:	not available	
Solubility:	soluble	Mixture
Water Solubility:	not available	

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 heat and light.
10.2 Materials to avoid: Strong oxidising agents, acids, alkalis, heavy metals and their salts. Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussions. Sodium azide reacts vigorously with heated water.
10.3 Hazardous decomposition products: Thermal decomposition or combustion may include toxic and hazardous fumes of CO_x, NO_x, Na₂O, HCl, SO_x.

11. TOXICOLOGICAL INFORMATION

11.1 Toxicokinetic effects (ADME)

Absorption: Sodium azide is rapidly absorbed from the gastrointestinal tract and from injection sites. ⁽³⁾
 Distribution: not available
 Metabolism: not available
 Excretion: not available

11.2 Acute toxicity

	Value	m.u.	Effects	Related to
<u>Oral:</u>	LD50 (rat) = 27	mg/Kg		⁽⁴⁾ Sodium azide
<u>Dermal:</u>	LD50 (rat) = 50	mg/Kg		⁽⁴⁾ Sodium azide
<u>Inhalation:</u>	LC50 (rat) = 37	mg/m ³	Structural or functional change in trachea or bronchi, effects on eye, convulsions or effect on seizure threshold	⁽⁴⁾ Sodium azide
<u>Other data:</u>	LD _{Lo} oral rabbit = not available	mg/Kg		

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

Mutagenicity: Ames test: Sodium azide was mutagenic in *Salmonella typhimurium* strains TA100 and TA1535 with or without exogenous metabolic activation (S9); it was not mutagenic in strain TA1537 or TA98. ⁽⁵⁾ Sodium azide

Mouse lymphoma: not available

Chromosomal aberration: Negative ⁽⁵⁾ Sodium azide

Cytogenetic tests with Chinese hamster ovary cells: Sodium azide induced sister chromatid exchanges, but not chromosomal aberrations. ⁽⁵⁾ Sodium azide

Micronucleus test: not available

Teratogenesis: In a teratogenic study employing albino rats treated orally with technical Sodium azide at dose levels of 0.5, 1.5, or 5.0 mg/kg daily during gestation days 6 through 15, no teratogenic effects due to Sodium azide were found. Sterility has been produced in male mice given sodium azide.⁽³⁾

Carcinogenesis: Carcinogenicity studies were conducted by administering sodium azide (greater than 99% pure) in distilled water by gavage to groups of male and female rats once daily, 5 days per week for 14 days, 13 weeks, or 2 years. Under the conditions of these 2-year gavage studies, there was no evidence of carcinogenic activity of sodium azide in male or female rats administered 5 or 10 mg/kg. Sodium azide induced necrosis in the cerebrum and the thalamus of the brain in both male and female rats. ⁽⁵⁾

12. ECOLOGICAL INFORMATION

12.1 Ecotoxicology

Value	m.u.	Related to
Acute toxicity with fish: LC50 bluegill fish = 0.7	mg/l/96 hours	⁽³⁾ Sodium azide
Acute toxicity with Daphnia Magna: EC50 daphnia pulex = 4.2	mg/l/96 hours	⁽³⁾ Sodium azide
Acute toxicity with algae: ErC50 = not available	mg/l/72 hours	

12.2 Mobility: The dissipation of azides in soil is not by microbial action but is strictly a chemical process accelerated by increasing acidity and elevated temperatures. ⁽³⁾

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: ≈ 5.8% of this mixture consist of ingredient(s) of unknown toxicity for health and aquatic environment.

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

Authorization: no

Restriction: no

16. OTHER INFORMATION

Phrases R: R28: Very toxic if swallowed.
R32: Contact with acids liberates very toxic gas.
R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Hazard Statements: H300: Fatal if swallowed.
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.

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.

Bibliographic references:

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- (3) HSDB Hazardous Substances Databank, Sodium azide
- (4) ChemIDplus Lite, Sodium azide, full record
- (5) National Toxicology Program database Search Application, Toxicology and Carcinogenesis Studies of Sodium azide (CAS: 26628-22-8) in F344 Rats (Gavage Studies)
- (*) Classification in Annex I of Dir 67/548/EEC and in Annex VI of the 1272/2008/EC Regulation