

1. PRODUCT AND COMPANY INFORMATION

1.1.	Product	Identifier	

Product Code + Name:	870050 and 870100 Staph Test Kit
Product Description:	A qualitative latex test for the identification of Staphylococcus species processing clumping factor and / or protein A
Components:	Staphylococcus Latex Test Reagent Staphylococcus Latex Control Reagent Staphylococcus Positive controls

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

This product is intended for IN VITRO diagnostic use only. NOT FOR USE IN HUMANS. Only blood from donors proven to have no antibodies against HIV I, HIV II, HCV and HBsAg, with the FDA-licensed tests, is used in the manufacture of this product. Since, nevertheless, the risk of infection cannot be fully precluded, the product must be handled with the same care as a patient sample

1.3. Supplier Details

Supplier / Manufacturer:	Lorne Laboratories Ltd
Address:	Unit 1 Cutbush Park Industrial Estate
	Danehill
	Lower Earley
	Berkshire RG6 4UT
	United Kingdom
Phone Number:	+44 (0) 0118 921 2264
Fax Number:	+44 (0) 0118 986 4518
E mail Address:	info@lornelabs.com
Web-site Address:	www.lornelabs.com

2. HAZARD IDENTIFICATION

2.1. Classification of the substance or mixture

Classification under CLP: This product has no classification under CLP

2.2. Label Elements

The preparation is exempt from the above labelling requirements in accordance to Article 12.2 of Directive 99/45/EC as the form in which it is placed on the market does not present any significant risk to man or the environment when used according to the instructions for use.

Precautionary statements:	P102: Keep out of reach of children
	P234: Keep only in original container



2.3. Other Hazards

This product is not identified as a PBT/vPvB substance

3. COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Substance Composition:

Staph Test and Control Latex: Contain <0.1% Sodium Azide Suspension of coated polystyrene latex particles

Ingredient	CAS No.	Conc. (w/v)	Symbol	Hazard Statements
Sodium azide	026628-22-8	0.09%		H300, H310, H410

For reference only and not applicable to the concentrations supplied. Valid for the 100% chemical only

Sodium Azide T+; Very toxic R28: Very toxic if swallowed N; Dangerous for the environment R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment R32: Contact with acids liberates very toxic gas

4. FIRST AID MEASURES

4.1 First Aid Measures

Skin Contact: Remove contaminated clothing, avoid contamination of unaffected areas. Wash immediately with plenty of soap and water

Eye Contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do so. Continue rinsing. Seek medical advice/attention

Ingestion: Do not induce vomiting. Wash mouth with water and give plenty of water to drink. Seek medical attention immediately

Inhalation: Irritation is unlikely to occur but in the event of discomfort, provide plenty of fresh air and if necessary, seek medical assistance

Skin Contact:	There may be mild irritation at the site of contact. Sodium azide may enter body through skin
Eye Contact:	There may be irritation and redness
Ingestion:	May cause gastric distress. Symptoms may include nausea, vomiting and



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diarrhoea

Inhalation: May irritate the nose, throat and lungs

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

Immediate / Special Treatment: Not applicable

5. FIRE FIGHTING METHODS

5.1. Extinguishing media

Not combustible. Suitable extinguishing media for the surrounding fire should be used

5.2. Special hazards arising from the substance or mixture

Exposure hazards: None in small quantities

5.3. Advice for fire-fighters

Wear full protective suit and self- contained breathing apparatus (SCBA) when extinguishing fires

6. ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Wear appropriate protective clothing. Refer to section 8 of MSDS for personal protection details

6.2. Environmental precautions

Properly disinfect any spills. Do not discharge into drains or rivers. Contain large spillages using bunding

6.3. Methods and material for containment and cleaning up

Absorb in dry earth or sand. Transfer to a closable, labelled salvage container for disposal by an appropriate method

6.4. Reference to other sections

Refer to section 8 and 13 of SDS

7. HANDLING AND STORAGE

7.1. Precautions for safe handling

For in vitro diagnostic use only. Read the instructions for use. Avoid the formation of aerosols. Avoid direct contact with the substance

7.2. Conditions for safe storage, including any incompatibilities



Store in cool (2º to 8ºC), well-ventilated area. Keep original container tightly closed

7.3. Specific end use(s)

Use as per instructions for use

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1. Control Parameters

Workplace exposure limits: The product does not contain any relevant quantities of material with critical values that have to be monitored at the workplace

DNEL / PNEC No data available

8.2. Exposure controls

Adhere to Good Laboratory Practices (GLP), General protective and hygienic measures

Engineering measures:	Not relevant for this material
Respiratory protection:	Not Required
Hand protection:	Protective gloves, Wash hands before and after work
Eye protection: Skin protection:	Safety glasses with eyewash facility close by Laboratory coat

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties:

Physical State:	Liquid
Colour: Latex:	White
Odour:	Odourless
Threshold:	Not applicable
pH (Value):	7-7.3
Melting Point (°C) /	> 35°C
Freezing Point (°C):	Not determined
Boiling Point / Boiling Range (°C):	Not determined
Flash Point (°C):	>93 °C
Evaporation rate (BA = 1):	Not applicable
Flammability (solid, gas):	Not combustible
Explosive limit ranges:	Not applicable
Vapour Pressure (mm Hg):	Not applicable
Vapour Density (Air=1): 2.2 Density (g/mL):	Not determined
Solubility (Water):	Water soluble
Solubility (Other):	Not applicable
Partition Coefficient (n-Octanol/water):	Not determined
Auto Ignition Temperature (°C):	Not applicable
Decomposition Temperature (°C):	Not determined
Viscosity (mPa.s):	Not determined
Explosive properties:	Not determined
Oxidising properties:	Not determined



10. STABILITY AND REACTIVITY

10.1. Reactivity

Stable under recommended transport or storage conditions

10.2. Chemical Stability

Stable under normal storage and handling conditions Do not use after expiry date

10.3. Possibility of hazardous reactions

Avoid contact with lead and copper metals. Sodium azide can react with these metals in plumbing

10.4. Conditions to avoid:

Avoid acidification of solution

10.5. Incompatible materials

Avoid contact of the products with lead and copper (plumbing metals), mercury, acids, and oxidising agents

10.6. Hazardous decomposition products

Toxic fumes may be generated on thermal decomposition. Thermal decomposition may produce carbon monoxide and carbon dioxide

11. TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Reagents

Hazardous ingredients:

SODIUM AZIDE:	
ORAL MOUSE	LD50 27 mg/kg
ORAL RAT	LD50 27 mg/kg
SKIN RAT	LD50 50 mg/kg
SKIN MOUSE	LD50 50 mg/kg
SKIN RABBIT	LD50 20 mg/kg

11.2 Symptoms / Routes of exposure:

Eyes: Redness CNS: Nausea/vomiting Cardiovascular systems: Fall in blood pressure, change in heart rate Digestive: (nausea/vomiting/diarrhoea) Refer to section 4 of SDS for routes of exposure and corresponding symptoms.



12. ECOLOGICAL INFORMATION

12.1. Toxicity

Ecotoxicity values: Sodium azide may adversely affect the aquatic environment. Do not allow release into water supplies, wastewater, or soil

12.2. Persistence and degradability

No data available

12.3. Bio accumulative potential

No data available

12.4. Mobility in soil

Readily absorbed into soil

12.5. Results of PBT and vPvB assessment

PBT identification: This product is not identified as a PBT/vPvB substance

12.6. Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

Waste Code Number: 18 01 07 Non-Hazardous, Human Healthcare, laboratory waste

- **Product:** Used devices should be disposed of as potentially biohazardous material in compliance with anti -pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information
- **Packaging:** Disposal should be in accordance with local, state or national legislation. Contaminated packaging must be disposed of in the same manner as the product. Noncontaminated packaging materials may be recycled. Contact your local service providers for further information
- **NB:** The user's attention is drawn to the possible existence of regional or national regulations regarding disposal

14. TRANSPORT INFORMATION

14.1. UN number

Not applicable

14.2. UN proper shipping name

This product is not covered by international regulation on the transport of dangerous goods



(IMDG, IATA, ADR/RID)

14.3. Transport hazard class(es)

Not classified as dangerous for transport

14.4. Packing group

Not applicable

14.5. Environmental hazards

Environmental: No

Marine Pollutant: No

14.6. Special precautions for user

No special precautions

15. REGULATORY INFORMATION

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

Not applicable in concentrations present <0.1% Azide

15.2. Chemical Safety Assessment

Not applicable - product not subject to registration under REACH

For reference only and not applicable to the concentrations supplied. Valid for the 100% chemical only

SODIUM AZIDE:	
Hazard symbols:	Harmful
Risk phrases:	R22: Harmful if swallowed
	R32: Contact with acids liberates very toxic gas
EC classification:	Xn: Harmful
Safety phrases:	S29/35 Do not empty into drains; dispose of this material and its container in a safe way
	S36/37/39: Wear suitable protective clothing, gloves and eye / face protection
	S46: If swallowed, seek medical advice immediately and show this container or label

Note: The regulatory information given above only indicates the principal regulations specifically applicable to the product described in the safety data sheet. The user's attention is drawn to the possible existence of additional provisions that complete these regulations

Refer to all applicable national, international, and local regulations or provisions

16. OTHER INFORMATION

Warning: Because no test method can offer complete assurance that HIV, HCV, HbsAg or other infectious agents are absent, the components of this kit should be handled accordingly

Legal disclaimer: The above information is believed to be correct but does not purport to be all



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inclusive and shall be used only as a guide. This company (Lorne Laboratories Ltd) shall not be held liable for any damage resulting from handling or from contact with the above product

Sources of information used in this data sheet:

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, and amending Directive 67/548/EEC and Regulation (EC) No 1907/2006 (in short CLP)

COMMISSION REGULATION (EU) 2015/830 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Dangerous Preparations Directive 1999/45/EC