Document reference number: SDS046AAntigen

Issue number: 1/07/2020

ACCORDING TO EC-REGULATIONS 1907/2006 (REACH),

1272/2008 (CLP) & 2015/830



1. SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Telephone

Product code(s) & Product Name 046511A VDRL Stabilised Reagent Kit antigen

CAS No. Mixture EINECS No. Mixture

Product Description A solution of Cardiolipin, Lecithin, and Cholesterol in phosphate buffer,

pH 7.0, to which is added a preservative.

1.2 Relevant identified uses of the substance or mixture

and uses advised against

Identified Use(s)

Detection of Syphilis in human plasma/serum/cerebral spinal fluid.

Uses Advised Against Anything other than the above.

1.3 Details of the supplier of the safety data sheet

Company Identification Lorne Laboratories Ltd

Unit 1 Cutbush Park Industrial Estate

Danehill Lower Earley Berkshire RG6 4UT United Kingdom +44(0) 0118 921 2264 +44(0) 0118 986 4518

Fax +44(0) 0118 986 451
E-Mail (competent person) Info@lornelabs.com

1.4 Emergency telephone number +44(0) 0118 921 2264

Available 0900 - 1700 (GMT)

Languages spoken English

2. SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

2.1.1 Regulation (EC) No. 1272/2008 (CLP) Not classified as hazardous for supply/use.

2.2 Label elements According to Regulation (EC) No. 1272/2008 (CLP)

Hazard Pictogram(s)

None assigned

Signal Word(s)

None assigned

Hazard Statement(s)

None assigned

Precautionary Statement(s)

None assigned

2.3 Other hazards None known.

3. SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures Substances in preparations / mixtures

EC Classification Regulation (EC) No. 1272/2008 (CLP)

Chemical identity of the	%W/W	CAS No.	EC No.	REACH Registration	Hazard Statement(s)
substance				No.	
Sodium Azide	0.095	26628-22-8	247-852-1	Not yet assigned in the	Acute Tox. 2; H300
				supply chain	Aquatic Acute 1; H400
					Aquatic Chronic 1; H410

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4. **SECTION 4: FIRST AID MEASURES**



4.1 Description of first aid measures

Inhalation Remove from exposure. Remove victim to fresh air and keep at rest in a position

comfortable for breathing. Keep warm and at rest. Get medical advice/attention if

Skin Contact Wash affected skin with soap and water. Remove contaminated clothing and

wash clothing before reuse. If irritation (redness, rash, blistering) develops, get

medical attention.

Eye Contact Flush eyes with water for at least 15 minutes while holding eyelids open.

Remove contact lenses, if present and easy to do. Continue rinsing. If eye

irritation persists, get medical advice/attention.

Ingestion Rinse mouth. Do NOT induce vomiting. Give plenty of water to drink. Do not give

anything by mouth to an unconscious person. Get medical advice/attention if

you feel unwell. None known.

4.2 Most important symptoms and effects, both acute

and delayed

4.3 Indication of any immediate medical attention and

special treatment needed

Treat symptomatically.

5. SECTION 5: FIRE-FIGHTING MEASURES

5.1 **Extinguishing media**

Suitable Extinguishing Media

Non-flammable. As appropriate for surrounding fire. Water spray, foam, dry

powder or CO2.

Unsuitable extinguishing Media

Special hazards arising from the substance or

mixture

5.2

Do not use water jet. Direct water jet may spread the fire. Combustion or thermal decomposition will evolve toxic vapours.

5.3 Advice for fire-fighters

Fight fire with normal precautions from a reasonable distance. Fire fighters should wear complete protective clothing including self-contained breathing apparatus. Avoid all contact. Do not allow run-off from fire fighting to enter drains or water courses.

SECTION 6: ACCIDENTAL RELEASE MEASURES 6.

6.1 Personal precautions, protective equipment and emergency procedures

6.2 **Environmental precautions**

6.3 Methods and material for containment and cleaning

Ensure adequate ventilation. Avoid all contact. Ensure suitable personal protection during removal of spillages. See Section: 8

Avoid release to the environment.

Absorb spillage in suitable inert material such as clay or diatomaceous earth. Transfer to a lidded container for disposal or recovery. Ventilate the area and wash spill site after material pick-up is complete. Avoid release to the

environment.

6.4 Reference to other sections See Section: 8, 13

7. SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling Avoid all contact. Use personal protective equipment as required. Ensure adequate ventilation. Keep good industrial hygiene. Wash hands thoroughly

7.2 Conditions for safe storage, including any

incompatibilities

Storage temperature

Storage life

after handling. Contaminated clothing should be thoroughly cleaned. Keep only in the original container/package in a cool well-ventilated place. Keep away from food, drinks and animal food.

Storage temperature should be controlled to between 2 and 8°C.

Keep only in the original container/package in a cool well-ventilated place.

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Incompatible materials None known. 7.3 Specific end use(s) See Section: 1.2

8. SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

8.1.1 **Occupational Exposure Limits**

	SUBSTANCE	CAS No.	LTEL (8 hr TWA ppm)	LTEL (8 hr TWA mg/m³)	STEL (ppm)	STEL (mg/m³)	Source
ĺ	Sodium azide (as NaN3)	26628-22-8	-	0.1	-	0.3	WEL

Source: WEL: Workplace Exposure Limit (UK HSE EH40)

8.1.2 **Biological limit value** Not established.

8.1.3 **PNECs and DNELs** Not established.

8.2 **Exposure controls**

8.2.1 Appropriate engineering controls Ensure adequate ventilation. Good hygiene practices and housekeeping

8.2.2 Individual protection measures, such as personal

protective equipment (PPE)

Use personal protective equipment as required. Avoid all contact. Keep good industrial hygiene. Wash hands before breaks and after work. Keep work clothes separately. Wash contaminated clothing before reuse. Do not eat, drink or

smoke at the work place.

Not normally required. Recommended: Wear eye protection with side protection Eye/face protection

(EN166).

Skin protection Prolonged, direct contact: Wear impervious gloves (EN374).

Respiratory protection



Not normally required. In case of insufficient ventilation, wear suitable respiratory equipment. Respiratory protective equipment should conform to the appropriate

EN standard.

Thermal hazards None anticipated.

8.2.3 **Environmental Exposure Controls** Avoid release to the environment.

9. **SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

9.1 Information on basic physical and chemical properties

Appearance Liquid, colourless. Odour Not established. Odour Threshold Not established.

Melting Point/Freezing Point Not established. Initial boiling point and boiling range Not established. Flash Point Not established. **Evaporation Rate** Not established. Flammability (solid, gas) Not established. Upper/lower flammability or explosive limits Not applicable. Vapour pressure Not established.

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Vapour density Not established. Not established. Relative density Solubility(ies) Miscible with water. Partition coefficient: n-octanol/water Not established. Auto-ignition temperature Not established. **Decomposition Temperature** Not established. Viscosity Not established. Explosive properties Not explosive Oxidising properties Not oxidising.

9.2 Other information None known.

SECTION 10: STABILITY AND REACTIVITY 10.

10.1 Reactivity Stable under normal conditions.

10.2 Chemical stability Stable for 30 months after the date of production when stored at between 2 and

8°C.

10.3 Possibility of hazardous reactions None known. Hazardous polymerisation will not occur.

10.4 Conditions to avoid Keep away from heat, sources of ignition and direct sunlight.

10.5 Incompatible materials Not known when used appropriately.

10.6 Hazardous decomposition product(s) No hazardous decomposition products known.

SECTION 11: TOXICOLOGICAL INFORMATION 11.

11.1 Information on toxicological effects (Substances in preparations / mixtures)

Acute toxicity

Ingestion Based on available data, the classification criteria are not met.

Acute Toxicity Estimate Mixture Calculation: LD50 >2000 mg/kg bw/day Inhalation

Based on available data, the classification criteria are not met. Acute Toxicity Estimate Mixture Calculation: LD50 >20 mg/l.

Skin Contact Based on available data, the classification criteria are not met.

Acute Toxicity Estimate Mixture Calculation: LD50 >2000 mg/kg bw/day

Skin corrosion/irritation Based on available data, the classification criteria are not met. Serious eye damage/irritation Based on available data, the classification criteria are not met. Respiratory or skin sensitization Based on available data, the classification criteria are not met. Germ cell mutagenicity Based on available data, the classification criteria are not met. Carcinogenicity Based on available data, the classification criteria are not met. Reproductive toxicity Based on available data, the classification criteria are not met. STOT - single exposure Based on available data, the classification criteria are not met. STOT - repeated exposure Based on available data, the classification criteria are not met. Aspiration hazard Based on available data, the classification criteria are not met.

11.2 Other information None known.

SECTION 12: ECOLOGICAL INFORMATION 12.

12.1 **Toxicity** Based on available data, the classification criteria are not met.

Estimated LC50 (96 hour) Fish > 100 mg/l

12.2 Persistence and degradability Not established. Some of the ingredients are expected to be resistant to

biodegradation.

12.3 Bioaccumulative potential Not established. Predicted to be be unlikely.

12.4 Mobility in soil The product has high mobility in soil. Miscible with water.

12.5 Results of PBT and VPVB assessment Not classified as PBT or vPvB. None of the substances in this product fulfil the

criteria for being regarded as a PBT or vPvB substance.

12.6 Other adverse effects None known.

SECTION 13: DISPOSAL CONSIDERATIONS 13.

13.1 Waste treatment methods Disposal should be in accordance with local, state or national legislation.

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13.2 Additional Information

Empty containers may contain hazardous residues. Containers shall be disposed of by incineration as soon as possible.

14. SECTION 14: TRANSPORT INFORMATION

Not classified according to the United Nations 'Recommendations on the Transport of Dangerous Goods'.

		ADR/RID	IMDG	IATA/ICAO
14.1	UN number	None assigned.	None assigned.	None assigned.
14.2	UN proper shipping name	None assigned.	None assigned.	None assigned.
14.3	Transport hazard class(es)	None assigned.	None assigned.	None assigned.
14.4	Packing group	None assigned.	None assigned.	None assigned.
14.5	Environmental hazards	Not classified.	Not classified.	Not classified.
14.6	Special precautions for user	See Section: 2		
14.7	Transport in bulk according to Annex II of	Not applicable.	Not applicable.	Not applicable.
	MARPOL73/78 and the IBC Code			
14.8	Additional Information	None.		

15. SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental

regulations/legislation specific for the substance or

mixture

15.1.1 EU regulations

Authorisations and/or Restrictions On Use None.

15.1.2 National regulations

Germany Water hazard class: 1

15.2 Chemical Safety Assessment None.

16. SECTION 16: OTHER INFORMATION

The following sections contain revisions or new statements: 1-16.

References: Existing Safety Data Sheet (SDS).

This Safety Data Sheet was prepared in accordance with EC Regulation (EC) 1907/2006 (REACH), 1272/2008 (CLP) & 2015/830.

LEGEND

LTEL Long Term Exposure Limit
STEL Short Term Exposure Limit
DNEL Derived No Effect Level

PNEC Predicted No Effect Concentration

PBT PBT: Persistent, Bioaccumulative and Toxic PvB PBT: very Persistent and very Toxic

OECD Organisation for Economic Cooperation and Development

Training advice: Consideration should be given to the work procedures involved and the potential extent of exposure as they may determine whether a higher level of protection is required.

Disclaimers

Customers are urged to ensure that the product is entirely suitable for their own purpose. It is the customers' responsibility to ensure that a suitable and sufficient assessment of the risks created by the use of the product is undertaken. The use of the reagent and the interpretation of results must be carried out by properly trained and qualified personnel in accordance with the requirements of the country where the reagent is in use.

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Annex to the extended Safety Data Sheet (eSDS)

Not applicable

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