



CERTIFICATE

EC Certificate No. 1434-IVDD-075/2022
Full Quality Assurance System
Directive 98/79/EC concerning
***in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

Lorne Laboratories Ltd
Unit 1 Cutbush Park Industrial Estate
Danehill
Lower Earley
Berkshire RG6 4UT, UNITED KINGDOM

for the design, manufacture and final inspection of *in vitro* diagnostic medical device
List A

*The list of medical devices covered by this certificate is provided
in the Annex 1 to EC Design-examination Certificate No. 1434-IVDD-074/2022*

complies with requirements
of Annex IV (excluding Section 4, 6) to Directive 98/79/EC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 28.04.2022 to 27.05.2025

The date of issue of the Certificate: 28.04.2022

The date of the first issue of the Certificate: 10.04.2019



Issued under the Contract No. MD-004/2022
Application No: 505/2022
Certificate bears the qualified signature.
Warsaw, 28/04/2022
Module H7

President



CERTIFICATE

EC Certificate No. 1434-IVDD-027/2022

**Full Quality Assurance System
Directive 98/79/EC concerning
in vitro diagnostic medical devices**

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

Lorne Laboratories Ltd

**Unit 1 Cutbush Park Industrial Estate, Danehill,
Lower Earley, Berkshire RG6 4UT, UNITED KINGDOM**

for the design, manufacture and final inspection of *in vitro* diagnostic medical device
List B

The list of medical devices covered by this certificate is provided in the Annex 1

complies with requirements
of Annex IV (excluding Section 4, 6) to Directive 98/79/EC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 23.03.2022 to 27.05.2025

The date of issue of the Certificate: 03.03.2022

The date of the first issue of the Certificate: 10.04.2019



Issued under the Contract No. MD-173/2021
Application No: 577/2022
Certificate bears the qualified signature.
Warsaw, 03/03/2022
Module H7

President

CERTIFICATE OF REGISTRATION

Lorne Laboratories Ltd

Unit 1 Cutbush Park Industrial Estate
Danehill
Lower Earley
Berkshire RG6 4UT UNITED KINGDOM

UL LLC® (UL Solutions) issues this certificate to the Firm named above, after assessing the Firm's quality system and finding it in compliance with:

ISO 13485:2016
EN ISO 13485:2016

The design and manufacture of in vitro diagnostic blood grouping reagents. The purchase for resale of in vitro diagnostic serology test kits.



Authorized by



Paul Hilgeman
Senior Business Manager - Medical
CMIT – Medical Regulatory



Check Certificate Status:
[here](#)

File Number	A12241	Cycle Start	May 23, 2023
Certificate Number	1458.230523	Effective Date	May 23, 2023
Initial Issue Date	June 26, 2018	Expiry Date	May 22, 2026

This quality system registration is included in UL's Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of UL LLC® (UL Solutions).



UL Solutions
333 Pfingsten Road
Northbrook, IL 60062-2096 USA

SAFETY DATA SHEET

Document reference number: SDS031ALatex

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**
Product code(s) & Product Name 031100A ASO Latex Kit
CAS No. Mixture
EINECS No. Mixture
Product Description A solution of latex particles coated with streptolysin O, pH 8.2, 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 Streptolysin O antibodies associated with rheumatic fever, streptococcal infections and glomerulonephritis in human serum.
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
Telephone +44(0) 0118 921 2264
Fax +44(0) 0118 986 4518
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.

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

SAFETY DATA SHEET

Document reference number: SDS031ALatex

Issue number: 1/07/2020



ACCORDING TO EC-REGULATIONS 1907/2006 (REACH),
1272/2008 (CLP) & 2015/830

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 you feel unwell.

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.

4.2 Most important symptoms and effects, both acute and delayed

None known.

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

Do not use water jet. Direct water jet may spread the fire.

5.2 Special hazards arising from the substance or mixture

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.

6. SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

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

6.2 Environmental precautions

Avoid release to the environment.

6.3 Methods and material for containment and cleaning up

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 after handling. Contaminated clothing should be thoroughly cleaned.

7.2 Conditions for safe storage, including any incompatibilities

Storage temperature

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

Storage life

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

SAFETY DATA SHEET

Document reference number: SDS031ALatex

Issue number: 1/07/2020



ACCORDING TO EC-REGULATIONS 1907/2006 (REACH),
1272/2008 (CLP) & 2015/830

7.3 Incompatible materials
Specific end use(s)

None known.
See Section: 1.2

8. SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

SUBSTANCE	CAS No.	LTEL (8 hr TWA ppm)	LTEL (8 hr TWA mg/m ³)	STEL (ppm)	STEL (mg/m ³)	Source
Sodium azide (as NaN ₃)	26628-22-8	-	0.1	-	0.3	WEL
Formaldehyde	50-00-0	2.0	2.5	2	2.5	WEL
Methanol	67-56-1	200	266	250	333	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 measures.

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.

Eye/face protection



Not normally required. Recommended: Wear eye protection with side 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

8.2.3 Environmental Exposure Controls

None anticipated.
Avoid release to the environment.

9. SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	Liquid, white to slightly yellowish.
Odour	Not established.
Odour Threshold	Not established.
pH	8.2
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.

SAFETY DATA SHEET

Document reference number: SDS031ALatex

Issue number: 1/07/2020



ACCORDING TO EC-REGULATIONS 1907/2006 (REACH),
1272/2008 (CLP) & 2015/830

Upper/lower flammability or explosive limits	Not applicable.
Vapour pressure	Not established.
Vapour density	Not established.
Relative density	Not established.
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.

10. SECTION 10: STABILITY AND REACTIVITY

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.

11. SECTION 11: TOXICOLOGICAL INFORMATION

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.

12. SECTION 12: ECOLOGICAL INFORMATION

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 unlikely.
12.4 Mobility in soil	Not established. 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.

SAFETY DATA SHEET

Document reference number: SDS031ALatex

Issue number: 1/07/2020



ACCORDING TO EC-REGULATIONS 1907/2006 (REACH),
1272/2008 (CLP) & 2015/830

13. SECTION 13: DISPOSAL CONSIDERATIONS

- | | | |
|------|--------------------------------|---|
| 13.1 | Waste treatment methods | Disposal should be in accordance with local, state or national legislation. |
| 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.
14.2	UN proper shipping name	None assigned.	None assigned.
14.3	Transport hazard class(es)	None assigned.	None assigned.
14.4	Packing group	None assigned.	None assigned.
14.5	Environmental hazards	Not classified.	Not classified.
14.6	Special precautions for user	See Section: 2	
14.7	Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.	Not applicable.
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
vPvB	vPvT: 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.

Information contained in this publication or as otherwise supplied to Users is believed to be accurate and is given in good faith, but it is for the Users to satisfy themselves of the suitability of the product for their own particular purpose. Lorne Laboratories Ltd gives no warranty as to the fitness of the

SAFETY DATA SHEET

Document reference number: SDS031ALatex

Issue number: 1/07/2020



**ACCORDING TO EC-REGULATIONS 1907/2006 (REACH),
1272/2008 (CLP) & 2015/830**

product for any particular purpose and any implied warranty or condition (statutory or otherwise) is excluded except to the extent that exclusion is prevented by law. Lorne Laboratories Ltd accepts no liability for loss or damage (other than that arising from death or personal injury caused by defective product, if proved), resulting from reliance on this information. Freedom under Patents, Copyright and Designs cannot be assumed.

Annex to the extended Safety Data Sheet (eSDS)

Not applicable

Date of First Issue

28 July 2020

SAFETY DATA SHEET

Document reference number: SDS830ALatex

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	
Product code(s) & Product Name	830100A RF Latex Kit – Latex Reagent
CAS No.	Mixture
EINECS No.	Mixture
Product Description	A solution of latex particles coated with human IgG antibodies, pH 8.2, 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 Rheumatoid Factors, which is the causative agent of rheumatoid arthritis, in human serum.
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
Telephone	+44(0) 0118 921 2264
Fax	+44(0) 0118 986 4518
E-Mail (competent person)	Info@lornelabs.com
1.4 Emergency telephone number	+44(0) 0118 921 2264
Languages spoken	Available 0900 – 1700 (GMT) 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	Contains material from human origin. No known test method can guarantee that products derived from human or animal sources will not transmit infectious agents. It is recommended that this product and assay material are handled as a potential biohazard.

3. SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures Substances in preparations / mixtures
EC Classification Regulation (EC) No. 1272/2008 (CLP): None

SAFETY DATA SHEET

Document reference number: SDS830ALatex

Issue number: 1/07/2020



ACCORDING TO EC-REGULATIONS 1907/2006 (REACH),
1272/2008 (CLP) & 2015/830

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 you feel unwell.

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.

4.2 Most important symptoms and effects, both acute and delayed

None known.

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

Do not use water jet. Direct water jet may spread the fire.

5.2 Special hazards arising from the substance or mixture

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.

6. SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

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

6.2 Environmental precautions

Avoid release to the environment.

6.3 Methods and material for containment and cleaning up

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 especially during pregnancy or whilst nursing. Use personal protective equipment as required. Ensure adequate ventilation. Keep good industrial hygiene. Wash hands thoroughly after handling. Contaminated clothing should be thoroughly cleaned.

7.2 Conditions for safe storage, including any incompatibilities

Storage temperature

Keep only in the original container/package in a cool well-ventilated place. Keep away from food, drinks and animal food.

Storage life

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

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

SAFETY DATA SHEET

Document reference number: SDS830ALatex




Issue number: 1/07/2020



ACCORDING TO EC-REGULATIONS 1907/2006 (REACH),
1272/2008 (CLP) & 2015/830

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

8. SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1	Control parameters	Not established.
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 measures.
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.
	Eye/face protection	Not normally required. Recommended: Wear eye protection with side 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.
		
8.2.3	Thermal hazards Environmental Exposure Controls	None anticipated. Avoid release to the environment.

9. SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1	Information on basic physical and chemical properties	
	Appearance	Liquid, white.
	Odour	Not established.
	Odour Threshold	Not established.
	pH	8.2
	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.
	Vapour density	Not established.
	Relative density	Not established.
	Solubility(ies)	Miscible with water.
	Partition coefficient: n-octanol/water	Not established.
	Auto-ignition temperature	Not established.
	Decomposition Temperature	Not established.
	Viscosity	Not established.

SAFETY DATA SHEET

Document reference number: SDS830ALatex

Issue number: 1/07/2020



ACCORDING TO EC-REGULATIONS 1907/2006 (REACH),
1272/2008 (CLP) & 2015/830

Explosive properties Not explosive
Oxidising properties Not oxidising.

9.2 Other information None known.

10. SECTION 10: STABILITY AND REACTIVITY

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 Oxidising agents and reducing agents, Halogenated hydrocarbons, Alkali metals, Halogens, Halides, Nitrates, Triethylaluminium.
10.6 Hazardous decomposition product(s) No hazardous decomposition products known.

11. SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects (Substances in preparations / mixtures)
Acute toxicity
Ingestion Based on available data, the classification criteria are not met.
Inhalation Based on available data, the classification criteria are not met.
Skin Contact Based on available data, the classification criteria are not met.
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.

12. SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity Based on available data, the classification criteria are not met.
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 unlikely.
12.4 Mobility in soil Not established. 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.

13. SECTION 13: DISPOSAL CONSIDERATIONS

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

SAFETY DATA SHEET

Document reference number: SDS830ALatex

Issue number: 1/07/2020



ACCORDING TO EC-REGULATIONS 1907/2006 (REACH),
1272/2008 (CLP) & 2015/830

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 MARPOL73/78 and the IBC Code	Not applicable.	Not applicable.	Not applicable.
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	
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
vPvB	vPvT: 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.

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Information contained in this publication or as otherwise supplied to Users is believed to be accurate and is given in good faith, but it is for the Users to satisfy themselves of the suitability of the product for their own particular purpose. Lorne Laboratories Ltd gives no warranty as to the fitness of the product for any particular purpose and any implied warranty or condition (statutory or otherwise) is excluded except to the extent that exclusion is prevented by law. Lorne Laboratories Ltd accepts no liability for loss or damage (other than that arising from death or personal injury caused by defective product, if proved), resulting from reliance on this information. Freedom under Patents, Copyright and Designs cannot be assumed.

Annex to the extended Safety Data Sheet (eSDS)

Not applicable

Date of First Issue

28 July 2020

SAFETY DATA SHEET

Document reference number: SDS850ALatex

Issue number: 1/08/2020



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	
Product code(s) & Product Name	850100A CRP Latex Kit
CAS No.	Mixture
EINECS No.	Mixture
Product Description	A solution of latex particles coated with goat IgG Anti-Human CRP, pH 8.2, 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 CRP antibodies in human serum/plasma.
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
Telephone	+44(0) 0118 921 2264
Fax	+44(0) 0118 986 4518
E-Mail (competent person)	Info@lornelabs.com
1.4 Emergency telephone number	+44(0) 0118 921 2264
Languages spoken	Available 0900 – 1700 (GMT) 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	Contains material from animal origin. No known test method can guarantee that products derived from human or animal sources will not transmit infectious agents. It is recommended that this product and assay material are handled as a potential biohazard

3. SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures Substances in preparations / mixtures
EC Classification Regulation (EC) No. 1272/2008 (CLP)

SAFETY DATA SHEET

Document reference number: SDS850ALatex

Issue number: 1/08/2020



ACCORDING TO EC-REGULATIONS 1907/2006 (REACH),
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Chemical identity of the substance	%W/W	CAS No.	EC No.	REACH Registration No.	Hazard Statement(s)
Sodium Azide	0.095	26628-22-8	247-852-1	Not yet assigned in the supply chain	Acute Tox. 2; H300 Aquatic Acute 1; H400 Aquatic Chronic 1; H410

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 you feel unwell.

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.

4.2 Most important symptoms and effects, both acute and delayed

None known.

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

Do not use water jet. Direct water jet may spread the fire.

5.2 Special hazards arising from the substance or mixture

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.

6. SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

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

6.2 Environmental precautions

Avoid release to the environment.

6.3 Methods and material for containment and cleaning up

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

SAFETY DATA SHEET

Document reference number: SDS850ALatex

Issue number: 1/08/2020



ACCORDING TO EC-REGULATIONS 1907/2006 (REACH),
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7.2 Conditions for safe storage, including any incompatibilities

Storage temperature
Storage life
Incompatible materials

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.
Strog bases, strong acids.
See Section: 1.2

7.3 Specific end use(s)

8. SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

SUBSTANCE	CAS No.	LTEL (8 hr TWA ppm)	LTEL (8 hr TWA mg/m ³)	STEL (ppm)	STEL (mg/m ³)	Source
Sodium azide (as NaN ₃)	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 measures.

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.

Eye/face protection



Not normally required. Recommended: Wear eye protection with side 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, white.
Odour	Not established.
Odour Threshold	Not established.
pH	8.2
Melting Point/Freezing Point	Not established.
Initial boiling point and boiling range	Not established.
Flash Point	Not established.

SAFETY DATA SHEET

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Evaporation Rate	Not established.
Flammability (solid, gas)	Not established.
Upper/lower flammability or explosive limits	Not applicable.
Vapour pressure	Not established.
Vapour density	Not established.
Relative density	Not established.
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.

10. SECTION 10: STABILITY AND REACTIVITY

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.

11. SECTION 11: TOXICOLOGICAL INFORMATION

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.

12. SECTION 12: ECOLOGICAL INFORMATION

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 unlikely.
12.4 Mobility in soil	Not established. 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.

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13. SECTION 13: DISPOSAL CONSIDERATIONS

- | | |
|-------------------------------------|---|
| 13.1 Waste treatment methods | Disposal should be in accordance with local, state or national legislation. |
| 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 MARPOL73/78 and the IBC Code	Not applicable.	Not applicable.	Not applicable.
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
vPvB	vPvT: very Persistent and very Toxic
OECD	Organisation for Economic Cooperation and Development

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Not applicable

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02 August 2020