EC CERTIFICATE

Lorne Laboratories Ltd

Unit 1 Cutbush Park Industrial Estate,
Danehill, Lower Earley, Berkshire RG6 4UT, UK

EC Certificate - Full Quality Assurance System Approval Certificate

Annex IV, (excluding sections 4 and 6) of Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices

Scope of Certificate:
The design and manufacture of in vitro diagnostic reagents for identification of blood groups

Device Classification:
Annex II, List A and B

Device Descriptions:
Please refer to Attachment 1

Model:
Please refer to Attachment 1

Digitally signed by Ceaicovschi Tudor
Date: 2021.12.29 16:39:21 EET
Reason: MoldSign Signature
Location: Moldova

File Number	A12241	Cycle Start Date	23 May 2017
Certificate No.	354.170425	Effective Date	23 May 2017
		Expiry Date	22 May 2022

Authorised by

B. Rodgers
Certification Manager
For and on Behalf of UL International (UK) Ltd

We hereby declare that an examination of the full quality assurance system has been carried out per report 11640248 , following the requirements of the national legislation to which the undersigned is subject, transposing Annex IV (with the exemption of sections 4 and 6) of Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive and is subject to periodic surveillance as required by 98/79/EC, Annex IV, Section 5. For Annex II, List A devices where they are covered by this certificate, an EC Design Examination certificate according to 98/79/EC, Annex IV, Section 4 is required. This certificate is issued with 1 attachment listing model numbers.

Notified Body

0843

UL International (UK) Limited
Wonersh House, The Guildway, Old Portsmouth Road,
Guildford, Surrey, GU3 1LR, United Kingdom

EC CERTIFICATE

Lorne Laboratories Ltd

Unit 1 Cutbush Park Industrial Estate,
Danehill, Lower Earley, Berkshire RG6 4UT, UK

Attachment 1 of 1

The products detailed below are covered under the scope of this certificate

Device Description	Model	Classification
Anti-A Monoclonal	600005/600010/600000	Annex II List A
Anti-B Monoclonal	610005/610010/610000	Annex II List A
Anti-A,B Monoclonal	620005/620010/620000	Annex II List A
Anti-C Monoclonal	690005	Annex II List A
Anti-E Monoclonal	691005	Annex II List A
Anti-c Monoclonal	692005	Annex II List A
Anti-e Monoclonal	693005	Annex II List A
Anti-K Monoclonal	760005/760010	Annex II List A
Anti-D Clone 2 Monoclonal	710010/710000	Annex II List A
Anti-D Clone 1 Monoclonal	730010/730000	Annex II List A
Anti-D Duoclone Monoclonal	740010/740000	Annex II List A
Anti-Jka Polyclonal	323002/323000	Annex II List B
Anti-Jkb Polyclonal	324002/324000	Annex II List B
Anti-Fyb Polyclonal	317002/317000	Annex II List B
AHG Elite Clear	415010/415100/415000	Annex II List B
AHG Elite Green	435010/435100/435000	Annex II List B
Anti-Fya Monoclonal	774000/774002	Annex II List B
Anti-C+D+E Monoclonal	700005/700010/700000	Annex II List A
Anti-Human IgG Clear	401010/401000	Annex II List B
Anti-Human IgG Green	402010/402000	Annex II List B
Monoclonal Rh Control	640010	Annex II List A
Monoclonal D Negative Control	650010	Annex II List A

File Number A12241
Certificate No. 354.170425

Cycle Start Date 23 May 2017
Effective Date 23 May 2017
Expiry Date 22 May 2022

Authorised by

B. Rodgers
Certification Manager
For and on Behalf of UL International (UK) Ltd

Notified Body

0843

UL International (UK) Limited
Wonersh House, The Guildway, Old Portsmouth Road,
Guildford, Surrey, GU3 1LR, United Kingdom

CERTIFICATE OF REGISTRATION

Lorne Laboratories Ltd

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

UL LLC®(UL) 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 manufacture of in vitro diagnostic blood grouping reagents. The purchase for resale of in vitro diagnostic serology test kit.

4426

Authorized by

Michael J. Windler, P.E.
Manager of Global Regulatory Service
Distinguished Member of the Technical Staff
Life and Health Sciences, UL LLC

Check Certificate Status: here

File Number	A12241	Cycle Start	May 23, 2020
Certificate Number	1458.200523	Effective Date	May 23, 2020
Initial Issue Date	June 26, 2018	Expiry Date	May 22, 2023

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 LLC
333 Pfingsten Road
Northbrook, IL 60062-2096 USA

CERTIFICATE

EC No 1434-IVDD-132/2019
Full Quality Assurance System

Directive 98/79/EC on 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 devices
List B

Products list in attachments: 1

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

Validity of Certificate: from 10.04.2019 to 22.03.2022

The date of issue of the Certificate: 10.04.2019

The date of the first issue of the Certificate: 10.04.2019

CE 1434

Application No: 648/2019
Module: H7

mgr Anna Wyroba
Vice-President

Polish Centre for Testing and Certification 23A Kłobucka Street, 02-699 Warsaw Poland, phone +48 22 46 45 200, e-mail:pcbc@pcbc.gov.pl

Certificate No **1434-IVDD-132/2019**
Issued under the Contract No MD-59/2019
Bears the PCBC hologram.
Warsaw, 10.04.2019

ANNEX 1 TO CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-IVDD-132/2019

The products detailed below are covered under the scope of this certificate:

Name:	GMDN code:
Anti-Jka Polyclonal 323002	52586
Anti-Jkb Polyclonal 324002	52587
Anti-Fyb Polyclonal 317002	52570
AHG Elite Clear 415010	52731
AHG Elite Green 435010	52731
Anti-Fya Monoclonal 774002	52569
Anti-Human IgG Clear 401010	45811
Anti-Human IgG Green 402010	45811
Anti-Jka Monoclonal 775002	52586
Anti-Jkb Monoclonal 776002	52587

CE 1434

mgr Anna Wyroba
Vice-President

Annex 1 to certificate No. **1434-IVDD-132/2019**
Issued under the Contract No. MD-59/2019
Bears the PCBC hologram.
Warsaw, 10.04.2019

LORNE LABORATORIES LTD

RELEASE PROTOCOL

CE 1434

PRODUCT:	Anti-D Duoclone Monoclonal Blood Grouping Reagent
LOT NUMBER:	740177-C1 and all sub-lots (i.e. 740177-C2, 740177-C3, 740177-C4, etc)
MANUFACTURE DATE:	2020-12-10
EXPIRY DATE:	2023-06-10
PRESERVATIVE:	<0.1% Sodium Azide w/v
DYE:	None
STERILITY:	Product filtered through a sterile 0.2 μm filter
STORAGE:	Refrigerate at 2 – 8°C
MICRO TESTING:	Source materials used to produce this lot were tested at source and found to be non-reactive for anti-HIV 1+2, anti-HCV and HBsAg.

POTENCY:

	Tube Test	BioVue Card	DiaMed Card	Microplate
O R_1r Cells	1 in 128	1 in 256	1 in 512	1 in 64

AVIDITY: (1st sign of agglutination) **O R_1r Cells** 6 seconds **R_2r Cells** 5 seconds

SPECIFICITY:

Positive Phenotypes		Negative Phenotypes	
O R_1r Cells	Grade 5	**r'r Cells**	Negative
R_2r Cells	Grade 5	**r"r Cells**	Negative
Weak D (D^u) Cells	Grade 4	**rr Cells**	Negative
Variant D^{VI} Cells	Grade 5		

QUALITY CONTROL: This lot of Anti-D Duoclone conforms to the specifications stated in the current issue of "The Guidelines for the Blood Transfusion Services in the UK" and the Common Technical Specifications (CTS)

RELEASED BY: **DATE:** 18 January 2021

(Laboratory Manager or Nominee)

CERTIFICATE

Certificate No. 1434-V-024/2021

Product Verification

Directive 98/79/EC concerning
***in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies
that the device manufactured by:

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

i.e. *in vitro* diagnostic medical device List A

Anti-D Duoclone Monoclonal 740010

LOT number: 740177-C1 inc. all sub-lots produced according to Lorne procedure GENSOP0102
Lot size: 10000 x 10mL
Date of expiry: 10-06-2023
Name of the laboratory: N/A
Number of the report/opinion/declaration: N/A
Date of the report: 14-01-2021

Complies with requirements
of Annex IV (Section 6) to Directive 98/79/EC (as amended)
implemented into Polish law

The date of issue of the Certificate: 15-01-2021

CE 1434

Contract No: MD-59/2019

Elektronicznie podpisany przez Monika Elżbieta Mroczkiewicz
Data: 2021.01.15 08:19:11 +01'00'

Deputy Director
Medical Devices Certification Department

POLISH CENTER FOR TESTING AND CERTIFICATION 02-844 Warsaw, 469 Puławska Street, tel. +48 22 46 45 200, email: pcbc@pcbc.gov.pl

LORNE LABORATORIES LTD

Unit 1 Cutbush Park Industrial Estate
Danehill, Lower Earley, Berkshire, RG6 4UT
United Kingdom

Phone: +44 (0) 118 921 2264
Fax: +44 (0) 118 986 4518
Email: info@lornelabs.com

CERTIFICATE OF ANALYSIS

DESCRIPTION	LOT NO.	EXPIRY	PRODUCT CODE
LE Latex Kit	**315040**	**2022-06**	**840050**

STORAGE: Refrigerated at 2 – 8ºC. Protect from light. Do not freeze.

SHIPPING: This product has data supporting stability tolerance during fluctuations in ambient shipping temperature.

This product is in compliance with **MEDICAL DEVICES REGULATIONS 2002** for Annex 3 and Self-Certification. This product was manufactured, packaged and tested in accordance with **LORNE QUALITY SYSTEMS** and meets all product specifications.

We certify that this product has been released as meeting all our acceptance criteria

If applicable:

- Components from human origin have been tested and found negative for the presence of antibody to HIV as well as HBsAg and HCV. However handle cautiously as potentially infectious.
- This product was tested by methods described in the manufacturers package insert.
- This product is intended for ***In Vitro*** Diagnostic use only.
- This product contains <0.1% sodium azide.

APPROVED BY: **DATE: 19 January 2021**

Eddy Velthuis
Technical Director

SAFETY DATA SHEET

Document reference number: MSDS460/470
Issue number: 3/08/2015

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	460 LISS Concentrate 470 LISS Ready for Use
CAS No.	Mixture
EINECS No.	Mixture
Product Description	A clear, colourless solution containing 0.1% sodium azide (LISS Concentrate) or 0.01% sodium azide (LISS Ready for Use), Glycine and Sodium salts.

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

Identified Use(s)	Potentiating agent in blood group serology.
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 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 substance	%W/W	CAS No.	EC No.	REACH Registration No.	Hazard Statement(s)
Sodium Azide	0.1 - 0.01	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. 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.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 — Keep only in the original container/package in a well-ventilated place. Keep away from food, drinks and animal food.

Storage temperature	Storage temperature is at ambient room temperature.
Storage life	Keep only in the original container/package in a well-ventilated place.
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**	None assigned.
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, colourless
Odour	Not established.
Odour Threshold	Not established.
pH	6.7
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.
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 12 months after the date of production when stored at ambient room temperature.
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**	Strong acids, strong oxidizing agents.
10.6	**Hazardous decomposition product(s)**	Combustion or thermal decomposition will evolve toxic vapours.

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 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.

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

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 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 August 2001

SAFETY DATA SHEET

Document reference number: MSDSAHGGreen
Issue number: 4/08/2015

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	435 AHG Elite (Green)
CAS No.	Mixture
EINECS No.	Mixture
Product Description	A solution of clone BRIC-8 (specific Anti-C3d antibody derived from culture supernatants of antibody producing human hybridoma cell lines) and rabbit anti-human IgG diluted in a solution containing various salts, bovine serum albumin, sodium azide, Tartrazine yellow and Patent Blue V.

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

Identified Use(s)	Identification of blood groups on human red cells.
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 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 substance	%W/W	CAS No.	EC No.	REACH Registration No.	Hazard Statement(s)
Sodium Azide	0.09	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
Rabbit plasma	3 - 7	Not applicable	Not applicable	Not yet assigned in the supply chain	Not hazardous

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. 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. 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. Human source materials from which these products are derived have been tested and found negative for HBsAg and antibodies to HIV1, HIV2 and HCV. No known

		test method can guarantee that products derived from human or animal sources will not transmit infectious agents.
7.2	**Conditions for safe storage, including any incompatibilities**	Keep only in the original container/package in a cool well-ventilated place. Keep away from food, drinks and animal food.
	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.
	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
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 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, green coloured.
Odour	Not established.
Odour Threshold	Not established.
pH	7
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.
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 24 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**	None known.
10.6	**Hazardous decomposition product(s)**	Combustion or thermal decomposition will evolve toxic vapours.

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 >5000 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 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.

13. SECTION 13: DISPOSAL CONSIDERATIONS

13.1	**Waste treatment methods**	Dispose of contents 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: Not hazardous
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). Existing ECHA registration for Sodium Azide (CAS No. 26628-22-8).

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.

Annex to the extended Safety Data Sheet (eSDS)
Not applicable

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