

SAFETY DATA SHEET

Document reference number: SDS RHESUS/K IVD

Issue number: REV 3 / SEP 2025



A CALIBRE SCIENTIFIC COMPANY

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

640010 Monoclonal Rh Control
650010 Monoclonal D Negative Control
690005 Anti-C Monoclonal
691005 Anti-E Monoclonal
692005 Anti-c Monoclonal
693005 Anti-e Monoclonal
700010 Anti-C+D+E Monoclonal
710010 Anti-D Clone 2 Monoclonal
730010 Anti-D Clone 1 Monoclonal
740010 Anti-D Duoclone Monoclonal
760010 Anti-K Monoclonal

CAS No.

Mixture

EINECS No.

Mixture

Product Description

Antibody-containing solutions:

Solutions containing specific clones (antibodies derived from culture supernatants of antibody producing human B lymphocyte cell lines), diluted in a solution containing bovine serum albumin, buffer salts, and potentiators.

Negative control solutions (640010 and 650010): A solution of sodium chloride, buffer salts, potentiators and bovine serum albumin.

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

Identified Use(s)

IVD.

The Antibody-containing solutions are Blood grouping reagents.

640010 is a control reagent used with the Lorne's Rhesus blood grouping reagents.

650010 is a negative control for Lorne's Monoclonal Anti-D reagents.

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
Info@lornelabs.com

Telephone

Fax

E-Mail (competent person)

1.4 Emergency telephone number

+44(0) 0118 921 2264
Available 0900 – 1700 (GMT)
English

Languages spoken

2. SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

SAFETY DATA SHEET

Document reference number: SDS RHESUS/K IVD

Issue number: REV 3 / SEP 2025



A CALIBRE SCIENTIFIC COMPANY

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

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

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %.

3. SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1	Substances -	Not applicable
3.2	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)	Concentration Limit (%)
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	≥ 0,1 ≥ 0,1 ≥ 0,1

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 CO ₂ .
Unsuitable extinguishing Media	Do not use water jet. Direct water jet may spread the fire.

SAFETY DATA SHEET

Document reference number: SDS RHESUS/K IVD

Issue number: REV 3 / SEP 2025



LORNE
LABORATORIES

A CALIBRE SCIENTIFIC COMPANY

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

- 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 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.
- 7.3 Specific end use(s)** None known.
See Section: 1.2

8. SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

- 8.1 Control parameters**
- 8.1.1 National occupational exposure and biological limit values**

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 Recommended monitoring procedures** Not established.
- 8.1.3 Air contaminants formed** Not established.
- 8.1.4 DNEL and PNEC** Not established.
- 8.1.5 Control banding** 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).

SAFETY DATA SHEET

Document reference number: SDS RHESUS/K IVD

Issue number: REV 3 / SEP 2025



A CALIBRE SCIENTIFIC COMPANY

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

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 to Straw
Odour	Not established
pH	7
Melting Point/Freezing Point	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 vapour density	Not established
Solubility(ies)	Miscible with water
Partition coefficient n-octanol/water	Not applicable
Auto-ignition temperature	Not applicable
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

For Anti-C, Anti-c, Anti-E, Anti-e, Anti-C+D+E and Monoclonal Rh Control: Stable for 24 months after the date of production when stored at between 2 and 8°C.

For Anti-Ds and D Negative control FFMU: 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

Strong acids.

10.6 Hazardous decomposition product(s)

Combustion or thermal decomposition will evolve toxic vapours.

11. SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

Ingestion

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

SAFETY DATA SHEET

Document reference number: SDS RHESUS/K IVD

Issue number: REV 3 / SEP 2025



A CALIBRE SCIENTIFIC COMPANY

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

Inhalation	Acute Toxicity Estimate Mixture Calculation: LD50 >5000 mg/kg bw/day Based on available data, the classification criteria are not met.
Skin Contact	Acute Toxicity Estimate Mixture Calculation: LD50 >20 mg/l. Based on available data, the classification criteria are not met.
Skin corrosion/irritation	Acute Toxicity Estimate Mixture Calculation: LD50 >2000 mg/kg bw/day 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.
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	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. 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 Marpol and the IBC Code	Not applicable.	Not applicable.

15. SECTION 15: REGULATORY INFORMATION

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

REACH Annex XVII (Restriction List): Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

REACH Annex XIV (Authorization List): Contains no substance(s) listed on REACH Annex XIV (Authorization List)

REACH Candidate List (SVHC): Contains no substance(s) listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent): Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

POP Regulation (Persistent Organic Pollutants): Contains no substance(s) listed on the POP list (Regulation EU 2019/1021)

SAFETY DATA SHEET

Document reference number: SDS RHESUS/K IVD

Issue number: REV 3 / SEP 2025



A CALIBRE SCIENTIFIC COMPANY

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

on persistent organic pollutants)

Ozone Regulation (1005/2009): Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

Explosives Precursors Regulation (2019/1148): Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004): Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances).

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). Existing ECHA registration for Sodium Azide (CAS No. 26628-22-8), the Classification and Labelling Inventory for DiSodium EDTA dehydrate.

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

Legend to abbreviations and acronyms

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

Revision History

Revision	Date	Description
2	AUG 2015	Issue 2
3	SEP 2025	Issue 3