Document reference number: SDS ABO IVD

Issue number: REV 7 / SEP 2025

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 600010 Anti-A Monoclonal

610010 Anti-B Monoclonal 620010 Anti-A,B Monoclonal

CAS No. Mixture EINECS No. Mixture

Product Description A solution of a specific antibody (ies) derived from culture supernatants

of antibody producing murine hybridoma cell lines, diluted in a solution containing bovine serum albumin, buffer salts, sodium azide and Patent Blue V as dye for Anti-A, Tartrazine yellow as dye for Anti-B. Anti-A,B

has no dye added.

1.2 Relevant identified uses of the substance or mixture

and uses advised against

Identified Use(s)IVD. Blood grouping reagentUses Advised AgainstAnything 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

 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

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

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3.2 Mixtures -EC Classification Regulation (EC) No. 1272/2008 (CLP)

Chemical identity of the	%W/W	CAS No.	EC No.	REACH Registration	Hazard Statement(s)	Concentration
substance				No.		Limit (%)
DiSodium EDTA dihydrate	0.2	6381-92-6	205-358-3	Not yet assigned in the	Acute Tox. 4; H302	≥1
				supply chain	Skin Irrit. 2; H315	≥ 1
					Eye Irrit. 2; H319	≥ 1
					Acute Tox. 4; H332	≥ 1
					STOT RE 2; H373	≥ 1
					STOT SE 3; H335	≥ 1
					Aquatic Chronic 3; H412	≥ 1
Sodium Azide	0.09	26628-22-8	247-852-1	Not yet assigned in the	Acute Tox. 2; H300	≥ 0,1
				supply chain	Aquatic Acute 1; H400	≥ 0,1
					Aquatic Chronic 1; H410	≥ 0,1

SECTION 4: FIRST AID MEASURES 4.



Description of first aid measures 4.1

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

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

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

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

medical attention.

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

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

irritation persists, get medical advice/attention.

Ingestion Rinse mouth. 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.

SECTION 5: FIRE-FIGHTING MEASURES 5.

5.1 **Extinguishing media**

mixture

5.2

5.3

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

Unsuitable extinguishing Media

Special hazards arising from the substance or

Advice for fire-fighters

powder or CO₂. Do not use water jet. Direct water jet may spread the fire.

Combustion or thermal decomposition will evolve toxic vapours.

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 Ensure adequate ventilation. Avoid all contact. Ensure suitable personal emergency procedures

6.2 **Environmental precautions**

6.3 Methods and material for containment and cleaning protection during removal of spillages. See Section: 8

Avoid release to the environment.

Absorb spillage in suitable inert material. Transfer to a lidded container for

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up

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.

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

7.2 Conditions for safe storage, including any

incompatibilities
Storage temperature

Storage life Incompatible materials Specific end use(s) 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.

None known. See Section: 1.2

8. SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

7.3

8.1.1 National occupational exposure and biological limit values

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	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

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.

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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:

Anti-A Liquid, Blue Anti-B Liquid, Yellow

Anti-A,B Liquid, Colourless to Straw

Odour Not established

pН

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 Not established Vapour pressure Not established Vapour density Not established Relative vapour density Solubility(ies) Miscible with water Partition coefficient n-octanol/water Not applicable Not applicable Auto-ignition temperature **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 36 months after the date of production when stored at between 2 and 8°C.

Possibility of hazardous reactions 10.3 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.

Hazardous decomposition product(s) 10.6 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.

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

Skin Contact

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.

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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.

SECTION 12: ECOLOGICAL INFORMATION 12.

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

SECTION 13: DISPOSAL CONSIDERATIONS 13.

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'.

	ADIVIND	IIIIDO	IAIAIOAO
UN number	None assigned.	None assigned.	None assigned.
UN proper shipping name	None assigned.	None assigned.	None assigned.
Transport hazard class(es)	None assigned.	None assigned.	None assigned.
Packing group	None assigned.	None assigned.	None assigned.
Environmental hazards	Not classified.	Not classified.	Not classified.
Special precautions for user	See Section: 2		
Transport in bulk according to Annex II of Marpol	Not applicable.	Not applicable.	Not applicable.
and the IBC Code			
	UN proper shipping name Transport hazard class(es) Packing group Environmental hazards Special precautions for user Transport in bulk according to Annex II of Marpol	UN proper shipping name Transport hazard class(es) Packing group Environmental hazards Special precautions for user Transport in bulk according to Annex II of Marpol None assigned. Not classified. See Section: 2 Transport in bulk according to Annex II of Marpol	UN number UN proper shipping name None assigned. UN proper shipping name None assigned. Special precautions for user Transport in bulk according to Annex II of Marpol 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 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**

Water hazard class: 1 Germany

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15.2 Chemical Safety Assessment

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.

None.

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 PvB PBT: very Persistent and very Toxic

OECD Organisation for Economic Cooperation and Development

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

Disclaimers

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

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Annex to the extended Safety Data Sheet (eSDS)

Not applicable

Revision History

Revision	Date	Description
6	FEB 2025	Issue 6
7	SEP 2025	Issue 7