

SAFETY DATA SHEET

Document reference number: SDS041A IM Pos Ctrl

Issue number: REV 2 / 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	041050A IM Positive Control
CAS No.	Mixture
EINECS No.	Mixture
Product Description	Artificial serum containing Glycine, Bovine Serum Albumin and Sodium azide, pH 8.2
1.2 Relevant identified uses of the substance or mixture and uses advised against	
Identified Use(s)	Positive Control in IM kit for detection of heterophile antibody associated with Infectious Mononucleosis in plasma/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	Classification according to Regulation (EC) No. 1272/2008 [CLP] Not classified Adverse physicochemical, human health and environmental effects No additional information available
2.2 Label elements	Labelling according to Regulation (EC) No. 1272/2008 [CLP]
Hazard Pictogram (CLP)	Not applicable
Signal Word (CLP)	Not applicable
Hazard Statement (CLP)	Not applicable
Precautionary Statement (CLP)	Not applicable
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 be handled as potential biohazard

Contains no PBT/vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII

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 %

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3. SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances Not Applicable

3.2 Mixtures

Name	Product identifier	Conc. (%)	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Sodium Azide	CAS-No: 26628-22-8 EC No: 247-852-1	0.095	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

First-aid measures general:

Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible)

Inhalation:

Allow affected person to breathe fresh air. Allow the victim to rest

Skin Contact:

Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse

Eye Contact:

Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persists

Ingestion:

Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention

4.2 Most important symptoms and effects, both acute and delayed

Not expected to present a significant hazard under anticipated conditions of normal use

4.3 Indication of any immediate medical attention and special treatment needed

No additional information available

5. SECTION 5: FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing Media

Foam. Dry powder. Carbon dioxide. Water spray. Sand

Unsuitable extinguishing Media

Do not use a heavy water stream

5.2 Special hazards arising from the substance or mixture

No additional information available

5.3 Advice for fire-fighters

Firefighting instructions

Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent firefighting water from entering the environment

Protection during firefighting

Do not enter fire area without proper protective equipment, including respiratory protection

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6. SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Evacuate unnecessary personnel

For emergency responders

Protective equipment

Equip cleanup crew with proper protection

Emergency procedures

Ventilate area

6.2 Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters

6.3 Methods and material for containment and cleaning up

Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage. Store away from other materials

6.4 Reference to other sections

See Section: 8, 13

7. SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions

Keep only in the original container in a cool, well-ventilated place away from :
Heat sources. Keep container closed when not in use
Strong bases. Strong acids
Sources of ignition. Direct sunlight

Incompatible products

Incompatible materials

7.3 Specific end use(s)

See Section: 1.2

8. SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

National occupational exposure and biological limit values

Sodium azide (26628-22-8)	
EU - Indicative Occupational Exposure Limit (IOEL)	
Local name	Sodium azide
IOEL TWA	0.1 mg/m ³
IOEL STEL	0.3 mg/m ³
Remark	Skin

Recommended monitoring procedures

No additional information available

Air contaminants formed

No additional information available

DNEL and PNEC

No additional information available

Control banding

No additional information available

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8.2 Exposure controls

Appropriate engineering controls: No additional information available

Personal protective equipment: Avoid all unnecessary exposure

Personal protective equipment symbol(s):

Eye/face protection



Chemical goggles or safety glasses

Skin protection



Wear protective gloves

Respiratory protection



Wear appropriate mask

Thermal hazards

No additional information available

Environmental Exposure Controls

Do not eat, drink or smoke during use

9. SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	Liquid, colourless
Odour	Odourless
Odour threshold	Not available
Melting point	Not available
Freezing point	Not available
Boiling point	Not available
Flammability	Non flammable
Explosive limits	Not available
Lower explosion limit	Not available
Upper explosion limit	Not available
Flash point	Not available
Auto-ignition temperature	Not available
Decomposition temperature	Not available
pH	8.2
Viscosity, kinematic	Not available
Solubility	Not available
Partition coefficient n-octanol/water (Log Kow)	Not available
Vapour pressure	Not available
Vapour pressure at 50°C	Not available
Density	Not available
Relative density	Not available
Relative vapour density at 20°C	Not available
Particle characteristics	Not applicable

9.2 Other information

No additional information available

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10. SECTION 10: STABILITY AND REACTIVITY

10.1	Reactivity	No additional information available
10.2	Chemical stability	Not established
10.3	Possibility of hazardous reactions	Not established
10.4	Conditions to avoid	Direct sunlight. Extremely high or low temperatures
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

Acute toxicity (oral)	Not classified
Acute toxicity (dermal)	Not classified
Acute toxicity (inhalation)	Not classified
Skin corrosion/irritation	Not classified
Additional information	Based on available data, the classification criteria are not met

Serious eye damage/irritation	Not classified
Additional information	Based on available data, the classification criteria are not met

Respiratory or skin sensitization	Not classified. Based on available data, the classification criteria are not met
Germ cell mutagenicity	Not classified. Based on available data, the classification criteria are not met
Carcinogenicity	Not classified. Based on available data, the classification criteria are not met
Reproductive toxicity	Not classified. Based on available data, the classification criteria are not met
STOT - single exposure	Not classified. Based on available data, the classification criteria are not met
STOT - repeated exposure	Not classified. Based on available data, the classification criteria are not met
Aspiration hazard	Not classified. Based on available data, the classification criteria are not met

11.2 Other information

Endocrine disrupting properties	None known.
Potential adverse human health effects and symptoms	No additional information available Based on available data, the classification criteria are not met

12. SECTION 12: ECOLOGICAL INFORMATION

12.1	Toxicity	
	Hazardous to the aquatic environment, short-term (acute)	Not classified
	Hazardous to the aquatic environment, long-term (chronic)	Not classified
12.2	Persistence and degradability	
	IM Latex Positive Control	Not established
12.3	Bioaccumulative potential	Not established
12.4	Mobility in soil	No additional information available
12.5	Results of PBT and VPVB assessment	No additional information available
12.6	Endocrine disrupting properties	No additional information available
12.7	Other adverse effects	Avoid release to the environment

13. SECTION 13: DISPOSAL CONSIDERATIONS

13.1	Waste treatment methods	
	Product/Packaging disposal recommendations	Dispose in a safe manner in accordance with local/national regulations
	Ecological waste information	Avoid release to the environment

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14. SECTION 14: TRANSPORT INFORMATION

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

In accordance with ADR / IMDG / IATA / ADN / RID

14.1 UN number

UN-No. (ADR)	Not applicable
UN-No. (IMDG)	Not applicable
UN-No. (IATA)	Not applicable
UN-No. (ADN)	Not applicable
UN-No. (RID)	Not applicable

14.2 UN proper shipping name

Proper Shipping Name (ADR)	Not applicable
Proper Shipping Name (IMDG)	Not applicable
Proper Shipping Name (IATA)	Not applicable
Proper Shipping Name (ADN)	Not applicable
Proper Shipping Name (RID)	Not applicable

14.3 Transport hazard class(es)

Transport hazard class(es) (ADR)	Not applicable
Transport hazard class(es) (IMDG)	Not applicable
Transport hazard class(es) (IATA)	Not applicable
Transport hazard class(es) (ADN)	Not applicable
Transport hazard class(es) (RID)	Not applicable

14.4 Packing group

Packing group (ADR)	Not applicable
Packing group (IMDG)	Not applicable
Packing group (IATA)	Not applicable
Packing group (ADN)	Not applicable
Packing group (RID)	Not applicable

14.5 Environmental hazards

Dangerous for the environment	No
Marine pollutant	No
Other information	No supplementary information available

14.6 Special precautions for user

Overland transport	Not applicable
Transport by sea	Not applicable
Air transport	Not applicable
Inland waterway transport	Not applicable
Rail transport	Not applicable

14.7 Maritime transport in bulk according to IMO instruments

Not applicable

15. SECTION 15: REGULATORY INFORMATION

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

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EU-Regulations

REACH Annex XVII (Restriction List)

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

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation 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)

National regulations

No additional information available

15.2 Chemical Safety Assessment

No chemical safety assessment has been carried out

16. SECTION 16: OTHER INFORMATION

Indication of changes: Sections 1 - 16

Regulatory information

Data sources

REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

The classification complies with : ATP 12

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Revision History

Revision	Date	Description
1	JUL 2020	Issue 1
2	SEP 2025	Issue 2