

1.	SECTION 1: IDENTIFICATION OF THE SUBS	TANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING
1.1	Product identifier	
	Product code(s) & Product Name	041050A IM Latex reagent
	CAS No.	Mixture
	EINECS No.	Mixture
	Product Description	A solution of latex particles coated with bovine erythrocyte antigen
		extract, pH 7.2, 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 the heterophile antibody associated with Infectious Mononucleosis in
		human 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	
2.1		
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)



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	Acute Tox. 2; H300
				supply chain	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	Absorb spillage in suitable inert material such as clay or diatomaceous
	ир	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	Keep only in the original container/package in a cool well-ventilated place. Keep
	incompatibilities	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

SUBSTANCE	CAS No.	LTEL (8 hr TWA ppm)	LTEL (8 hr TWA mg/m <sup>3</sup> )	STEL (ppm)	STEL (mg/m³)	Source
Sodium azide (as NaN3)	26628-22-8	-	0.1	_	0.3	WEL

Sourc <b>8.1.2</b>	ce: WEL: Workplace Exposure Limit (UK HSE EH40) Biological limit value	Not established.
8.1.3	PNECs and DNELs	Not established.
8.2 8.2.1 8.2.2	Exposure controls Appropriate engineering controls Individual protection measures, such as personal protective equipment (PPE)	Ensure adequate ventilation. Good hygiene practices and housekeeping measures. 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 Odour Odour Threshold	Liquid, white. Not established. Not established.



	рН	7.2
	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.
	Explosive properties	Not explosive
	Oxidising properties	Not oxidising.
,	Other information	Nono known

#### 9.2 Other information

None known.

#### 10. SECTION 10: STABILITY AND REACTIVITY

10.1 10.2	Reactivity Chemical stability	Stable under normal conditions. 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

	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
------	----------

- 12.2 Persistence and degradability
- 12.3 Bioaccumulative potential

Based on available data, the classification criteria are not met. Estimated LC50 (96 hour) Fish > 100 mg/l Not established. Some of the ingredients are expected to be resistant to biodegradation. Not established. Predicted to be be unlikely.



- 12.4 Mobility in soil
- 12.5 Results of PBT and VPVB assessment

Not established. Miscible with water.

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. None known.

12.6 Other adverse effects

#### 13. SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

13.2 Additional Information

Disposal should be 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
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	Not applicable.	Not applicable.	Not applicable.
MARPOL73/78 and the IBC Code			
Additional Information	None.		
	UN proper shipping name Transport hazard class(es) Packing group Environmental hazards Special precautions for user Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	UN numberNone assigned.UN proper shipping nameNone assigned.Transport hazard class(es)None assigned.Packing groupNone assigned.Environmental hazardsNot classified.Special precautions for userSee Section: 2Transport in bulk according to Annex II ofNot applicable.MARPOL73/78 and the IBC CodeVot applicable.	UN numberNone assigned.None assigned.UN proper shipping nameNone assigned.None assigned.Transport hazard class(es)None assigned.None assigned.Packing groupNone assigned.None assigned.Environmental hazardsNot classified.Not classified.Special precautions for userSee Section: 2Transport in bulk according to Annex II ofNot applicable.Not applicable.MARPOL73/78 and the IBC CodeUnit and the image.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	
15.1.2	Authorisations and/or Restrictions On Use National regulations	None.
	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

### SAFETY DATA SHEET Document reference number: SDS041ALatex Issue number: 1/07/2020

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



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 July 2020