# 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	830100A RF Latex Kit Positive Control	
	CAS No.	Mixture	
	EINECS No.	Mixture	
	Product Description	Rheumatoid Factors positive human serum containing a buffer, Bovine Serum Albumin and Proclin 950, pH 8.2.	
1.2	Relevant identified uses of the substance or mixture		
	and uses advised against		
	Identified Use(s)	Positive Control in RF Latex Kit for detection of Rheumatoid Factors in human 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		
	Fax	+44(0) 0118 921 2264 +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 classed 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 human 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): None

Storage temperature

Storage life

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### 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 Not expected to present a significant hazard under anticipated conditions of and delayed normal use. 4.3 Indication of any immediate medical attention and Treat symptomatically. special treatment needed 5. SECTION 5: FIRE-FIGHTING MEASURES 5.1 Extinguishing media Non-flammable. As appropriate for surrounding fire. Water spray, foam, dry Suitable Extinguishing Media 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 Combustion or thermal decomposition will evolve toxic vapours. mixture 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. SECTION 6: ACCIDENTAL RELEASE MEASURES 6. 6.1 Personal precautions, protective equipment and Ensure adequate ventilation. Avoid all contact. Ensure suitable personal emergency procedures 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 earth. Transfer to a lidded container for disposal or recovery. Ventilate the area and up 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 away from food, drinks and animal food. incompatibilities

Storage temperature should be controlled to between 2 and 8°C. Keep only in the original container/package in a cool well-ventilated place.

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7.3	Incompatible materials Specific end use(s)	Strong acids and strong bases. See Section: 1.2
8.	SECTION 8: EXPOSURE CONTROLS/PERS	ONAL PROTECTION
8.1 8.1.1	Control parameters Occupational Exposure Limits	Not established.
8.1.2	Biological limit value	Not established.
8.1.3	PNECs and DNELs	Not established.
8.2 8.2.1	Exposure controls 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.
8.2.3	Thermal hazards Environmental Exposure Controls	None anticipated. Avoid release to the environment.
9.	SECTION 9: PHYSICAL AND CHEMICAL PR	ROPERTIES
9.1	Information on basic physical and chemical propertie	S

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Appearance	Liquid, colourless.
Odour	Not established.
Odour Threshold	Not established.
рН	8.1-8.3
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.

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	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 REACTIV	/ITY
10.1	Reactivity	Stable under normal conditions.
10.2	Chemical stability	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 INFORM	MATION
11.1	Information on toxicological effects (Substance	es in preparations / mixtures)
	Acute toxicity	
	Ingestion	Based on available data, the classification criteria are not met.
	Inhalation	Based on available data, the classification criteria are not met.
	Skin Contact	Based on available data, the classification criteria are not met.
	Skin corrosion/irritation	Based on available data, the classification criteria are not met.

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Serious eye damage/irritation Respiratory or skin sensitization Germ cell mutagenicity Carcinogenicity Reproductive toxicity STOT - single exposure STOT - repeated exposure Aspiration hazard Other information

Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. None known.

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

### 12. **SECTION 12: ECOLOGICAL INFORMATION**

12.1 Toxicity

11.2

- 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. **Results of PBT and VPVB assessment** 12.5 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

**Additional Information** 13.2

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'.

14.1 **UN** number

ADR/RID None assigned. IMDG None assigned. IATA/ICAO None assigned.

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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	Not applicable.	Not applicable.	Not applicable.	
	MARPOL73/78 and the IBC Code				
14.8	Additional Information	None.			
15.1	Safety, health and environmental regulations/legislation specific for the substance mixture	e or			
15.1.1	EU regulations				
	Authorisations and/or Restrictions On Use	None.			
15.1.2	National regulations	None.			
15.2					
13.2	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.

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## Annex to the extended Safety Data Sheet (eSDS)

Not applicable

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