Document reference number: SDS031APosCtrl

Issue number: 1/07/2020

# 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 031100A ASO Latex Kit Positive Control

CAS No. Mixture EINECS No. Mixture

Product Description ASO positive human serum containing Glycine, 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 ASO kit for detection of antibodies associated with rheumatic

fever, streptococcal infections and glomerulonephritis 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 +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 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

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#### 4. **SECTION 4: FIRST AID MEASURES**



4.3

5.2

6.2

6.4

7.2

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

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

Indication of any immediate medical attention and

special treatment needed

Not expected to present a significant hazard under anticipated conditions of

normal use.

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

Special hazards arising from the substance or

mixture

Do not use water jet. Direct water jet may spread the fire.

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.

#### SECTION 6: ACCIDENTAL RELEASE MEASURES 6.

6.1 Personal precautions, protective equipment and emergency procedures

**Environmental precautions** 

6.3 Methods and material for containment and cleaning

Ensure adequate ventilation. Avoid all contact. Ensure suitable personal

protection during removal of spillages. See Section: 8

Avoid release to the environment.

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

wash spill site after material pick-up is complete. Avoid release to the

environment.

See Section: 8, 13

#### 7. SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Reference to other sections

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

Conditions for safe storage, including any

incompatibilities

Storage temperature

Storage life

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.

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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

8.1.1 **Occupational Exposure Limits** Not established.

8.1.2 Not established. **Biological limit value** 

8.1.3 **PNECs and DNELs** 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).

Skin protection

Prolonged, direct contact: Wear impervious gloves (EN374).

Not normally required. In case of insufficient ventilation, wear suitable respiratory Respiratory protection 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.

#### **SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES** 9.

#### Information on basic physical and chemical properties 9.1

Liquid, colourless to yellowish to faintly pink. Appearance

Odour Not established. Odour Threshold Not established. 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. Not established. Relative density Solubility(ies) Miscible with water. Partition coefficient: n-octanol/water Not established.

Auto-ignition temperature Not established.

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Decomposition TemperatureNot established.ViscosityNot established.Explosive propertiesNot explosiveOxidising propertiesNot 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 30 months after the date of production when stored at between 2 and

8°C.

10.3 Possibility of hazardous reactions
 10.4 Conditions to avoid
 None known. Hazardous polymerisation will not occur.
 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** 

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

**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.

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
 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

14.1 UN number None assigned. None assigned. 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 or

SECTION 15: REGULATORY INFORMATION

mixture

15.1.1 EU regulations

15.

Authorisations and/or Restrictions On Use

None.

15.1.2 National regulations

None.

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 PPVB PPT: 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

#### **Date of First Issue**

28 July 2020