Document reference number: SDS031 ASO Pos Ctrl

Issue number: REV 2 / 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 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

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

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 +44(0) 0118 986 4518

 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]

Skin sensitization, Category 1 H317

Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2 Label elements According to Regulation (EC) No. 1272/2008 (CLP)

Hazard pictograms (CLP)



GHS07

Signal word (CLP) Warning

Contains 2-Methyl-2H-isothiazol-3-one (Proclin 950)

Hazard Statements (CLP) H317 - May cause an allergic skin reaction

Precautionary Statements (CLP) P261 - Avoid breathing vapours

P272 - Contaminated work clothing should not be allowed out of the workplace P501 - Dispose of contents/container to hazardous or special waste collection

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point, in accordance with local, regional, national and/or international regulation

2.3 Other hazards

Other hazards which do not result in classification

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

Contains no PBT/vPvB substances ≥ 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 %

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]
2-methylisothiazol-3(2H)-one (PROCLIN 950)	CAS-No.: 2682-20-4 EC-No.: 220-239-6 EC Index-No.: 613-326-00-9	< 0.1	Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Dermal), H311 Acute Tox. 2 (Inhalation), H330 Skin Corr. 1B, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Specific concentration limits:			
Name	Product identifier	Specific concentration limits	
2-methylisothiazol-3(2H)-one (PROCLIN 950)	CAS-No.: 2682-20-4 EC-No.: 220-239-6 EC Index-No.: 613-326-00-9	(0.0015 ≤C ≤ 100) Skin Sens. 1A, H317	

Full text of H- and EUH-statements: see section 16

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)

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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

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

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 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

Incompatible products

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

Incompatible materials Sources of ignition. Direct sunlight

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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/m³	
IOEL STEL	0.3 mg/m³	
Remark	Skin	

Air contaminants formed No additional information available

DNEL and PNECNo additional information available

Control banding No additional information available

8.2 Exposure controls

Appropriate engineering controls:

No additional information available

Personal protective equipment: Avoid all unnecessary exposure

 $\label{protective} \textbf{Personal protective equipment symbol(s):}$

Eye/face protection Chemical goggles or safety glasses

Skin protection Wear protective gloves

Respiratory protection Wear appropriate mask

(FO)

Thermal hazards No additional information available

Environmental Exposure ControlsDo not eat, drink or smoke during use

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9. SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance Liquid, colourless to yellowish to faintly pink

Odour Odourless Not available Odour threshold Melting point Not available Freezing point Not available Not available Boiling point Non flammable Flammability Not available **Explosive limits** Lower explosion limit Not available Upper explosion limit Not available Not available Flash point Auto-ignition temperature Not available Decomposition temperature Not available 81 - 83pН Not available Viscosity, kinematic Solubility Not available Partition coefficient n-octanol/water (Log Kow) Not available Not available Vapour pressure 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

10. SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity No additional information available

10.2 Chemical stability
 10.3 Possibility of hazardous reactions
 Not established
 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)

Acute toxicity (dermal)

Acute toxicity (inhalation)

Not classified

Not classified

Skin corrosion/irritation Not classified pH: 8.1 – 8.3

Additional information Based on available data, the classification criteria are not met

Serious eye damage/irritation Not classified pH: 8.1 – 8.3

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

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

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

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

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

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

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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 No additional information available

Potential adverse human health effects and symptoms 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 Not classified

(acute)

Hazardous to the aquatic environment, long-term Not classified

(chronic)

12.2 Persistence and degradability

ASO Positive Control Not established

12.3 Bioaccumulative potential Not established

12.4Mobility in soilNo additional information available12.5Results of PBT and VPVB assessmentNo additional information available12.6Endocrine disrupting propertiesNo additional information available12.7Other adverse effectsAvoid 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

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)

UN-No. (IMDG)

UN-No. (IATA)

UN-No. (ADN)

UN-No. (ADN)

Not applicable

UN-No. (RID)

Not applicable

14.2 UN proper shipping name

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

14.3 Transport hazard class(es)

Transport hazard class(es) (ADR)

Transport hazard class(es) (IMDG)

Not applicable

Transport hazard class(es) (IATA)

Transport hazard class(es) (ADN)

Transport hazard class(es) (RID)

Not applicable

Not applicable

14.4 Packing group

Packing group (ADR) Not applicable
Packing group (IMDG) Not applicable

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Packing group (IATA)

Packing group (ADN)

Packing group (RID)

Not applicable

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
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

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

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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.

Full text of H- and EUH-statements:		
Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2	
Acute Tox. 3 (Dermal)	Acute toxicity (dermal), Category 3	
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3	
Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1	
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1	
Eye Dam. 1	Serious eye damage/eye irritation, Category 1	
H301	Toxic if swallowed.	
H311	Toxic in contact with skin.	
H314	Causes severe skin burns and eye damage.	
H317	May cause an allergic skin reaction.	
H318	Causes serious eye damage.	
H330	Fatal if inhaled.	
H400	Very toxic to aquatic life.	
H410	Very toxic to aquatic life with long lasting effects.	
Skin Corr. 1B	Skin corrosion/irritation, Category 1, Sub-Category 1B	
Skin Sens. 1A	Skin sensitisation, category 1A	

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:		
Skin Sens. 1	H317	Calculation method

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