

Document	QL801-094
Revision	C
Prepared by	Jenifer Ohta
Approved by	Xiaoyan Hu
Issue date	11/30/2023

1268 N. Lakeview Ave. Anaheim, CA 92807 Phone: (714)463-1111 Fax: (714)463-1169 www.tecodiagnostics.com

Section 1 – Identification

Product Name	Antistreptolysin (ASO) Reagent Set	Emergency Telephone Number
Catalog Number(s)	ASO-50, ASO-100	CHEMTREC (800) 424-9300
Product Type	Serology	International CHEMTREC (703) 527-3887
Company Name	Teco Diagnostics	Company Contact Numbers
Street Address	1268 N. Lakeview Avenue	Tel: (800) 222-9880 or (714) 463-1111
City, State, Zip Code, Country	Anaheim, CA 92807 USA	Monday - Friday 8:00-4:30 Pacific Time
-		Fax: (714) 463-1169
<b>Recommended use:</b> For in vita	ro diagnostic use only. For professional use only.	
<b>Restrictions on use:</b> Not for in	vivo use.	

#### Section 2 – Hazards identification

Section 2 – Hazarus identi	incation
Classification	Not classified / not hazardous according to Regulation (EC) No. 1272/2008 [CLP].
	Not classified / not hazardous according to 29 CFR 1910 (OSHA HCS).
Label elements	According to Regulation (EC) No. 1272/2008 [CLP], the product does not require hazard labeling.
	According to 29 CFR 1910 (OSHA HCS), the product does not require hazard labeling.
Routes of exposure	Potential health effects
Skin Contact	May cause irritation.
Eye Contact	May cause irritation.
Inhalation	May cause irritation.
Ingestion	May cause irritation.
Hazards not otherwise	The positive control contains human-sourced material which has been tested at the donor site and
classified (HNOC)	found non-reactive for HBsAg and HIV antibodies. Because no known test method can completely
	assure that products derived from human origin will not transmit infectious agents, this product
	should be handled cautiously as potentially infectious.

Section 3 – Composition/information on ingredients

Chemical/ Mixture Name	Concentration or %	CAS#
ASO latex contains inert latex particles coated with streptolysin O	Sodium azide <0.1%	26628-22-8
and has sodium azide as a preservative.	Boric acid ≤0.1%	10043-35-3
ASO positive control contains human serum with an ASO concentration >200 IU/mL and has ProClin 950 as a preservative.	ProClin 950 <0.1%	2682-20-1
ASO negative control contains glycine-saline solution with an ASO concentration <200 IU/mL and has ProClin 300 as a preservative.	ProClin 300 <0.1%	55965-84-9
Glycine-saline buffer is a diluent (20X concentrate) of 0.1 M glycine and 0.15 M NaCl and has sodium azide as a preservative.	Sodium azide <0.1%	26628-22-8
Other components are either non-hazardous or at concentrations less than hazard r	reporting levels.	

# Section 4 – First aid measures

General advice	Never give anything by mouth to an unconscious person. If person feels unwell, seek medical assistance.		
Skin contact	Wash exposed skin with soap and water. If irritation develops, call for medical assistance.		
Eye contact	Immediately rinse the eye with plenty of water. Obtain medical attention if pain, blinking or redness persists.		
Ingestion	Rinse mouth with water provided person is conscious. Do NOT induce vomiting. Call for medical assistance.		
Inhalation	Move person to fresh air. Allow victim to rest. If breathing becomes difficult, call for medical assistance.		

Section 5 - Fire-fighting measures

Suitable extinguishing media	Foam. Dry powder. Carbon dioxide. Water spray. Sand.
Special hazards arising from the substance or mixture	No information available
Special protective equipment for fire-fighters	Wear proper protective equipment, including respiratory protection.



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### Section 6 – Accidental release measures

Personal precautions	Non-emergency personnel should evacuate the area.	
	Emergency responders should wear proper equipment. Refer to section 8.	
<b>Environmental precautions</b>	There are no known risks to the environment; however, prevent liquid entry into sewers or public waters.	
Methods and material for	Soak up spills with inert solids. Collect spillage. Place material and contaminated disposables into a	
containment and clean up	suitable waste container. Refer to section 13 for disposal considerations.	

## Section 7 – Handling and storage

Precautions for safe handling	Ensure adequate ventilation in the work area. After handling, wash hands thoroughly with soap and water. Do not eat, drink, smoke, or apply cosmetics in the work area.
Conditions for safe storage	Keep only in the original container and keep closed when not in use. Store at 2-8°C.
Incompatible materials	Strong bases, strong acids
Incompatible conditions	Protect from heat, direct sunlight and sources of ignition.

## Section 8 – Exposure controls/ personal protection

### **Control parameters**

Components with workplace control parameters

Component	CAS#	Value	Control parameters	Basis	
Sodium azide	26628-22-8	Ceiling	0.29 mg/m3	USA.ACGIH Threshold Limit Values (TLV)	
			0.11 ppm		
		Remarks: Not	t classifiable as a human	carcinogen	
		Ceiling	0.1 ppm	USA. NIOSH Recommended Exposure Limits	
		_	0.3 mg/m3		
		Remarks: Pot	Remarks: Potential for dermal absorption		
		Ceiling	0.1 ppm	California permissible exposure limits for	
			0.3 mg/m3	chemical contaminants (Title 8, Article 107)	
		Remarks: Ski	n		
EU					
Component	CAS#	Value	Control parameters	Basis	
Sodium azide	26628-22-8	Ceiling	0.1 mg/m3	IOELV TWA	
		Ceiling	0.3 mg/m3	IOELV STEL	
		Remarks: Ski	n		

<b>United States</b>				
Component	CAS#	Value	Control parameters	Basis
Boric acid	10043-35-3	TWA	2 mg/m3	USA.ACGIH Threshold Limit Values (TLV)
		Remarks: Not classifiable as a human carcinogen		
		STEL	6 mg/m3	USA.ACGIH Threshold Limit Values (TLV)
		Remarks: Not	classifiable as a human c	arcinogen

### **Exposure controls**

Personal protective equipment

Hand protection	Wear protective gloves.	
Eye protection	Chemical safety glasses are recommended, but not required.	
Skin and body protection	Wear laboratory coat.	
Respiratory protection	A mask is recommended, but not required unless indicated by local procedures.	
Other information	Avoid all unnecessary exposure. An eye wash station should be near the work area.  Do not pipette by mouth. Do not eat, drink, smoke, or apply cosmetics in the work area.	



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Section 9 – Physical and chemical properties

Appearance	ASO Latex: yellow liquid
	Positive control: colorless or yellow or pink liquid
	Negative control: clear liquid
	Glycine-saline buffer: clear liquid
Odor	Odorless
Odor threshold	No data available
рН	ASO Latex: $8.2 \pm 0.1$
	Positive control: No data available
	Negative control: No data available
	Glycine-saline buffer: $8.2 \pm 0.1$
Melting point	No data available
Freezing point	No data available
Boiling point	No data available
Flash point	No data available
Evaporation rate	No data available
Flammability	Non flammable
Upper/lower flammability or explosive limits	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Solubility	Soluble in water.
Partition coefficient: n-octanol/water	No data available
Auto ignition temperature	No data available
Decomposition temperature	No data available
Viscosity	No data available
Explosive properties	No data available
Oxidizing properties	No data available

### Section 10 – Stability and reactivity

Reactivity	No data available.	
Chemical stability	The product is stable when used as indicated in the package insert.	
-	The product is stable under recommended storage conditions indicated in section 7.	
Possibility of hazardous reactions	No hazardous reactions are known.	
Conditions to avoid	Protect from direct sunlight. Avoid temperatures outside the range of 2-8°C.	
Incompatible materials	Strong bases. Strong acids	
Hazardous decomposition products	No hazardous decomposition products are known.	

Section 11 – Toxicological information

Section II Tomeorogica		
Routes of exposure	Potential health effects	
Skin Contact	May cause irritation.	
Eye Contact	May cause irritation.	
Inhalation	May cause irritation.	
Ingestion	May cause irritation	

Information on toxicological effects		
Acute toxicity (dermal)	Not classified.	
Acute toxicity (inhalation)	Not classified.	
Acute toxicity (oral)	Not classified.	
Skin corrosion/irritation	Not classified / does not meet classification criteria.	
Serious eye damage/irritation	Not classified / does not meet classification criteria.	
Respiratory or skin sensitization	Not classified / does not meet classification criteria.	
Germ cell mutagenicity	Not classified / does not meet classification criteria.	



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Informat	ion on toxicological effects (continued)		
Carcinoge	<u> </u>		
IARC		ter than or equal to 0.1% is identified as probable, possible or confirmed	
NTP	NTP No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.		
OSHA	OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.		
Reproduc	tive toxicity	No data available	
Specific target organ toxicity (STOT) -single exposure  No data available		No data available	
Specific target organ toxicity (STOT) -repeated exposure  No data available		No data available	
Aspiration hazard No data available		No data available	
Potential a	adverse human health effects and symptoms	No data available	

Section 12 - Ecological information

Acute aquatic toxicity	Not classified	
Chronic aquatic toxicity	Not classified	
Persistence and degradability	No data available	
Bio-accumulative potential	No data available	
Mobility in soil	No data available	
Other adverse effects	No data available	

Section 13 – Disposal considerations

Section 15 Disposar considerations	
Product disposal and spilled material disposal.	Contact a licensed professional waste disposal service to dispose of product/ material in
	accordance with local and national regulations.
Packaging disposal	Packaging may retain product residues; therefore, contact a licensed professional waste
	disposal service for disposal of used packaging.
Ecology -waste materials	There are no known environmental risks; however, avoid release of product/materials to the
	environment, sewers, or public waters.
	Contact a licensed professional waste disposal service to dispose of waste material in
	accordance with local and national regulations.

Section 14 - Transport information

	ADR	IMDG	IATA	ADN	RID
UN Number	Not applicable				
Proper shipping name	Not applicable				
Transport hazard class	Not applicable				
Packing group	Not applicable				

Environmental hazards	Dangerous for the environment: No
	Marine pollutant: No
	Other information: No supplementary information available.
Special precautions	Overland transport: No data available
	Maritime transport: No data available
	Air transport: No data available
	Inland waterway transport: No data available
	Rail transport: No data available
Bulk transport according to	Annex II of Marpol and the IBC code: Not applicable
United States (DOT): Nor	n-hazardous



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Section 15 - Regulatory information

EU Regulations	Contains no REACH substances with Annex XVII restrictions.				
	Contains a substance on the REACH candidate list in a concentration ≥0.1% or with a lower specific limit:				
	Boric acid (CAS 10043-35-3, EC 233-139-2).				
	Contains no REACH Annex XIV substances.				
United States	HCS Classification: Does not apply.				
United States	Federal: 21 CFR 866.3720: The product is 510k exempt.				
United States	State:				
	Regulation	Component	CAS No.	<b>Revision Date</b>	
	Massachusetts Right to Know	Sodium azide	26628-22-8	07/01/2007	
	Pennsylvania Right to Know	Sodium azide	26628-22-8	07/01/2007	
	New Jersey Right to Know	Sodium azide	26628-22-8	07/01/2007	
					State of California to

### **Section 16 – Other information**

United States: This product is labeled in accordance with 21 CFR (Food and Drugs), Section 809.10.

The information contained herein has been compiled from data presented in various technical sources believed to be accurate.

Teco Diagnostics makes no warranties and assumes no liability in connection with the use of this information.

It is the user's responsibility to determine the suitability of this information and to assure the adoption of necessary safety precautions.

Date of SDS Preparation: 11/30/2023