



# Teco Diagnostics

Document	QL801-097
Revision	B
Prepared by	Jenifer Ohta
Approved by	Xiaoyan Hu
Issue date	12/14/2023

[SDS]

## Rheumatoid Factor (RF) Reagent Set

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

### Section 1 – Identification

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

### Section 2 – Hazards identification

<b>Classification</b>	Not classified / not hazardous according to Regulation (EC) No. 1272/2008 [CLP]. Not classified / not hazardous according to 29 CFR 1910 (OSHA HCS).	
<b>Label elements</b>	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.	
<b>Routes of exposure</b> <b>Skin Contact</b> <b>Eye Contact</b> <b>Inhalation</b> <b>Ingestion</b>	Potential health effects May cause irritation. May cause irritation. May cause irritation. May cause irritation.	
<b>Hazards not otherwise classified (HNOC)</b>	The positive control contains human-sourced material which has been tested at the donor site and 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#
RF latex contains inert latex particles coated with human IgG in buffer solution with sodium azide as a preservative.	Sodium azide <0.1%	26628-22-8
RF positive control contains human serum with a RF concentration >8 IU/mL and has ProClin 950 as a preservative.	ProClin 950 <0.1%	2682-20-1
RF negative control contains glycine-saline solution with a RF concentration <8 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 reporting levels.		

### Section 4 – First aid measures

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

### Section 5 – Fire-fighting measures

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



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### Section 6 – Accidental release measures

<b>Personal precautions</b>	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.
<b>Methods and material for containment and clean up</b>	Soak up spills with inert solids. Collect spillage. Place material and contaminated disposables into a suitable waste container. Refer to section 13 for disposal considerations.

### Section 7 – Handling and storage

<b>Precautions for safe handling</b>	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.
<b>Conditions for safe storage</b>	Keep only in the original container and keep closed when not in use. Store at 2-8°C.
<b>Incompatible materials</b>	Strong bases, strong acids
<b>Incompatible conditions</b>	Protect from heat, direct sunlight and sources of ignition.

### Section 8 – Exposure controls/ personal protection

#### Control parameters

##### Components with workplace control parameters

United States					
Component	CAS#	Value	Control parameters	Basis	
Sodium azide	26628-22-8	Ceiling	0.29 mg/m <sup>3</sup> 0.11 ppm	USA.ACGIH Threshold Limit Values (TLV)	
		Remarks: Not classifiable as a human carcinogen			
		Ceiling	0.1 ppm 0.3 mg/m <sup>3</sup>	USA. NIOSH Recommended Exposure Limits	
		Remarks: Potential for dermal absorption			
		Ceiling	0.1 ppm 0.3 mg/m <sup>3</sup>	California permissible exposure limits for chemical contaminants (Title 8, Article 107)	
Remarks: Skin					
EU					
Component	CAS#	Value	Control parameters	Basis	
Sodium azide	26628-22-8	Ceiling	0.1 mg/m <sup>3</sup>	IOELV TWA	
		Ceiling	0.3 mg/m <sup>3</sup>	IOELV STEL	
		Remarks: Skin			

#### 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	RF Latex Reagent – milky white liquid RF Positive Control – clear colorless or yellow liquid RF Negative Control – clear liquid Glycine-saline buffer: clear liquid
Odor	Odorless
Odor threshold	No data available
pH	RF Latex: 8.2 ± 0.2 RF Positive control: No data available RF Negative control: No data available Glycine-saline buffer: 8.2 ± 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

Routes of exposure	Potential health effects
<b>Skin Contact</b>	May cause irritation.
<b>Eye Contact</b>	May cause irritation.
<b>Inhalation</b>	May cause irritation.
<b>Ingestion</b>	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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<b>Information on toxicological effects (continued)</b>	
Carcinogenicity	
IARC	No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC
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	No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.
Reproductive toxicity	No data available
Specific target organ toxicity (STOT) -single exposure	No data available
Specific target organ toxicity (STOT) -repeated exposure	No data available
Aspiration hazard	No data available
Potential 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

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	Not applicable	Not applicable	Not applicable	Not applicable
Proper shipping name	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Transport hazard class	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Packing group	Not applicable	Not applicable	Not applicable	Not applicable	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):	Non-hazardous				



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### Section 15 – Regulatory information

EU Regulations	Contains no REACH substances with Annex XVII restrictions. Contains no REACH Annex XIV substances.																
United States	<b>HCS Classification:</b> Does not apply.																
United States	<b>Federal:</b> 21 CFR 866.5775 The product 510(k) is K962015. It is class II and CLIA complexity is moderate..																
United States	<b>State:</b>																
	<table border="1"> <thead> <tr><th>Regulation</th><th>Component</th><th>CAS No.</th><th>Revision Date</th></tr> </thead> <tbody> <tr><td>Massachusetts Right to Know</td><td>Sodium azide</td><td>26628-22-8</td><td>07/01/2007</td></tr> <tr><td>Pennsylvania Right to Know</td><td>Sodium azide</td><td>26628-22-8</td><td>07/01/2007</td></tr> <tr><td>New Jersey Right to Know</td><td>Sodium azide</td><td>26628-22-8</td><td>07/01/2007</td></tr> </tbody> </table>	Regulation	Component	CAS No.	Revision Date	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
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	<b>State:</b> California Prop. 65 Components: This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.																

### 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: 12/14/2023