



**GTi DIAGNOSTICS®**  
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# MATERIAL SAFETY DATA SHEET

(Based on Directive 91/155/EEC et seq.)

Art. Code: F8S

Product Name: Factor VIII Antibody Screen

## 1. INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

- |     |                |   |
|-----|----------------|---|
| 1.1 | Product name   | Factor VIII Antibody Screen   |
|     | Catalog #      | F8S   |
|     | Kit components | Microwell Strips with holder<br>Concentrated Wash<br>Specimen Diluent<br>Conjugate: Anti-Human IgG<br>PNPP Reagent<br>Substrate Buffer<br>Stopping Solution<br>Positive Control<br>Kit Control<br>Negative Control<br>Plate Sealers                                       |
| 1.2 | Company        | GTI DIAGNOSTICS<br>20925 Crossroads Circle, Suite 200<br>Waukesha, WI 53186-4054, USA<br>(262) 754-1000 OR 1-800-233-1843   |
| 1.3 | In emergencies | After normal business hours, weekends, and holidays:<br>Call your local emergency center.<br>For Chemical Emergency Spill Leak Fire Exposure<br>or Accident call CHEMTREC<br>Domestic North America: 800-424-9300<br>International: 703-527-3887 (collect calls accepted) |

## 2. HAZARDS IDENTIFICATION

### Concentrated Wash

Toxic if swallowed

Irritating to eyes, respiratory system and skin

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment

### Stopping Solution

Causes severe burns

### Specimen Diluent

Harmful if swallowed.

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment. Animal proteins are potentially infectious.



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## Negative Control

Harmful if swallowed

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment

Contains material of human origin. Although these materials have been tested for HBsAg, anti-HCV and anti-HIV-1/2 and have been found not reactive, they should be considered as potentially infectious.

## Positive Control/Kit Control

Harmful if swallowed

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment

Contains animal proteins and material of human origin. The latter was negative for HBsAg and anti-HIV-1/2, but was positive for anti-HCV. Therefore human material was inactivated by heat treatment. This component should be considered as potentially infectious.

## Substrate Buffer

Irritating to eyes

## Conjugate: Anti-Human IgG

Harmful if swallowed

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment

Animal proteins are potentially infectious

### 3. COMPONENTS AND HAZARDOUS INGREDIENTS

Kit Components	Hazardous Ingredients	Classification Substance	EINECS NR.
<b>Concentrated Wash</b>	1 % Sodium azide (NaN <sub>3</sub> )	T+, N, R28-32-50/53	247-852-1
	2 % Tween 20		
	8.5 % NaCl		231-598-3
	6.9 % Trizma HCl		214-684-5
<b>Specimen Diluent</b>	0.05 % Sodium azide (NaN <sub>3</sub> )	T+, N, R28-32-50/53	247-852-1
	0.85 % NaCl		231-598-3
	Contains bovine proteins		
<b>Negative Control</b>	0.1 % Sodium azide (NaN <sub>3</sub> )	T+, N, R28-32-50/53	247-852-1
	Contains material from human origin		
<b>Positive Control/ Kit Control</b>	0.1 % Sodium azide (NaN <sub>3</sub> )	T+, N, R28-32-50/53	247-852-1
	May contain bovine proteins		
	Contains material from human origin		
<b>Stopping Solution</b>	12 % Sodium hydroxide (NaOH)	C, R35	215-185-5
	<b>Substrate Buffer</b>		
<b>Conjugate: Anti-Human IgG</b>	0.02 % Sodium azide (NaN <sub>3</sub> )	T+, N, R28-32-50/53	247-852-1
	9.7 % Diethanolamine	Xn, R22-38-41-48/22	203-868-0
	0.1 % Sodium azide (NaN <sub>3</sub> )	T+, N, R28-32-50/53	247-852-1
	Contains bovine and goat proteins		
	0.8 % NaCl		231-598-3



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## 4. FIRST AID MEASURES

### **Concentrated Wash, Negative Control, Positive Control, Kit Control, Conjugate: Anti-Human IgG, Substrate Buffer, Specimen Diluent**

- Eye contact:*
- Rinse immediately with water for 15 minutes
  - Do not apply neutralizing agents
  - Consult a doctor/medical service if irritation persists
- Skin contact:*
- Rinse with plenty of water
  - Remove clothing before washing
  - Consult a doctor/medical service if irritation persists
- After inhalation:*
- Remove the victim into fresh air
  - Unconscious: maintain adequate airway and respiration
  - Consult a doctor/medical service if breathing problems develop
- After ingestion:*
- Never give water to an unconscious person
  - Give nothing (little) to drink
  - Consult a doctor/medical service if you feel unwell

### **Stopping Solution**

- Eye contact:*
- Rinse immediately with plenty of water for 15 minutes
  - Do not apply neutralizing agents
  - Consult a doctor/medical service if irritation persists
- Skin contact:*
- Consult a doctor/medical service
  - Wash immediately with lots of water and soap for 15 minutes
  - Remove clothing while washing
  - Consult a doctor/medical service if irritation persists
- After inhalation:*
- Remove the victim into fresh air
  - Unconscious: maintain adequate airway and respiration
  - Consult a doctor/medical service if breathing problems develop
- After ingestion:*
- Immediately give lots of water to drink
  - Never give water to an unconscious person
  - Do not induce vomiting
  - Consult a doctor/medical service if you feel unwell

## 5. FIRE FIGHTING MEASURES

### **All Kit Components**

- Suitable extinguishing media:*
- All non combustible extinguishing media allowed
- Unsuitable extinguishing media:*
- No data available
- Special exposure hazards:*
- On heating, burning: formation of small quantities of nitrous vapors, carbon monoxide, carbon dioxide
- Instructions:*
- Take account of toxic fire fighting water
  - Use fire fighting water moderately and contain it
- Special protective equipment for firefighters:*
- Heat/fire exposure: compressed air/oxygen apparatus
  - Heat/fire exposure: gas-tight suit



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## 6. ACCIDENTAL RELEASE MEASURES

### All Kit Components

*Personal protection:* see 8

*Environmental precautions:*

- Prevent soil and water pollution
- Discharge according to local regulations

*Clean-up:*

- Take up liquid spill into absorbent material
- Discharge of absorbed material according to local regulations
- Clean contaminated surfaces with an excess of water
- Wash clothing and equipment after handling

## 7. HANDLING AND STORAGE

### All Kit Components

*Handling:*

- Observe normal hygiene standards, except concentrated wash (strict hygiene) and stopping solution (very strict hygiene)
- Discharge according to local regulations
- Remove and clean contaminated clothing
- Handle and open the container with care

*Storage:*

- Keep container tightly closed
- Meet the legal requirements
- Keep away from: heat sources, combustible materials, acids, metals
- Storage temperature: see component label

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Exposure Limits

Chemical/Component	TLV/NIOSH REL	OSHA PEL
Sodium azide (as NaN <sub>3</sub> )	0.3 mg/m <sup>3</sup> ACGIH TLV-CL	Not listed
Sodium azide (as HN <sub>3</sub> )	0.1 ppm	Not listed
Sodium hydroxide	2 mg/m <sup>3</sup>	TWA 2mg/m <sup>3</sup>
Diethanolamine	3 ppm (15 mg/m <sup>3</sup> )	None

Information in above table from NIOSH Pocket Guide to Chemical Hazards, 2003.



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## 8.2 Control of Exposure

### All Kit Components

- Eye protection:* - Safety glasses (Substrate Buffer)  
- Face shield (Other components)
- Hand protection:* - Gloves
- Suitable materials:* - Butyl rubber, natural rubber, neoprene, nitrile rubber, polyethylene, PVC (Stopping Solution)  
- No data available (Other components)
- Skin protection:* - Corrosion proof clothing (Stopping Solution)  
- Protective clothing (Other components)
- Respiratory protection:* - Insufficient ventilation: wear respiratory protection (Concentrated Wash)

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### All Kit Components

Liquid (except PNPP powder and Microwell strips)

### Conjugate: Anti-Human IgG, Specimen Diluent

Light blue

### Positive Control, Kit Control, Negative Control

Clear and slightly yellow to amber

### Substrate Buffer

Clear to faintly yellow

## 10. STABILITY AND REACTIVITY

### All Kit Components

*Stability:* All components are stable until expiry date if stored in specified conditions (see label)

*Reactivity/Hazardous decomposition products:* No hazardous decomposition products are formed in high quantities

*Conditions/Materials to avoid:* Keep away from metals and acids (Stopping Solution, Azide containing components)

## 11. TOXICOLOGICAL INFORMATION

See "2. Composition/Information on ingredients" to identify the kit components that contain the substances mentioned in this section

### Acute toxicity:

<i>Sodium azide:</i>	LD50 oral rat	: 27 mg/kg
	LD50 dermal rabbit	: 20 mg/kg
<i>Sodium hydroxide:</i>	LD50 dermal rabbit	: 1350 mg/kg
<i>Diethanolamine:</i>	LD50 oral rat	: 710/3450 mg/kg
<i>Tween 20:</i>	LD50 oral rat	: 36,700 µL/kg



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*NaCl*: LD50 oral rat : 3,000 mg/kg  
LD 50 dermal rat : > 10,000 mg/kg

## Chronic toxicity:

*Sodium azide*: Carcinogenicity (TLV) : A4  
Target Organ(s): nervers, heart, brain, laboratory experiments have shown mutagenic effects

*Diethanolamine*: Carcinogenicity (MAK) : 3A  
Target Organ(s): liver, kidneys, blood

*Sodium Hydroxide*: Teratogen, Mutagen, Carcinogen

*Tween 20*: Teratogen, Reproductive Hazard

*NaCl*: Teratogen, Mutagen, Reproductive Hazard

## Routes of exposure

Ingestion, inhalation, eyes and skin

Caution! Most components contain (a) substance(s) that are absorbed through the skin

## Acute effects/symptoms

*Concentrated Wash*:

- Toxic if swallowed
- May cause skin irritation, eye irritation, vomiting, and diarrhea upon ingestion.
- May irritate mucous membranes and upper respiratory tract.

*Negative Control, Positive Control, Kit Control, Conjugate: Anti-Human IgG, Specimen Diluent*:

- Harmful if swallowed

*Substrate Buffer*:

- After skin contact: red skin
- After eye contact: irritation and redness of the eye tissue

*Stopping Solution*:

- Highly corrosive to skin and eyes
- After ingestion: vomiting, diarrhea, burns to the gastric/intestinal mucosa, possible esophageal perforation, bleeding of the gastrointestinal tract, shock.
- After skin contact: caustic burns/corrosion of the skin and slow-healing wounds
- After eye contact: corrosion

*Sodium azide containing components*:

- May cause nausea, headache, vomiting. Experiments have shown animals to produce hypotensive effects, demyelination of myelinated nerve fibers in the CNS, testicular damage, blindness, attacks of rigidity, hepatic and cerebral effects.

## Chronic effects

See also Chronic Toxicity. Other components do not contain substances with a known chronic effect (e.g. carcinogenicity, mutagenicity, toxicity to reproduction)



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## 12. ECOLOGICAL INFORMATION

### Aquatic toxicity

- Sodium azide:*
- LC50 (96 h) : 0.8 mg/l (SALMO GAIRDNERI/ONCORHYNCHUS MYKISS)
  - LC50 (96 h) : 0.7 mg/l (LEPOMIS MACROCHIRUS)
  - LC50 (48 h) : 9 mg/l (GAMMARUS SP.)
- Diethanolamine:*
- LC50 (96 h) : 1664 mg/g (PIMEPHALES PROMELAS)
  - EC50 (48 h) : 55 mg/l (DAPHNIA MAGNA)
  - EC50 (72 h) : 75 mg/l (SCENEDESMUS SUBSPICATUS)
- Caustic soda:*
- LC50 (96 h) : 45.4 mg/l (SALMO GAIRDNERI/ONCORHYNCHUS MYKISS)
  - LC50 (48 h) : 100 mg/l (DAPHNIA MAGNA)

### Other information

- WGK: 1 (Classification based on the components as per Verwaltungsvorschrift wassergefährdender Stoffe (VwVwS) of 17 May 1999)
- Effect on the ozone layer: Not dangerous for the ozone layer (1999/45/EC)
- Greenhouse effect: No data available
- Effect on waste water purification: No data available

## 13. WASTE DISPOSAL CONSIDERATIONS

*Provisions relating to waste:* Hazardous waste (91/689/EEC)

### *Packaging/container:*

- Waste material code packaging (91/689/EEC, Council Decision 2001/118/EC, O.J. L47 of 16/2/2001): 15 01 10 (packaging containing residues of or contaminated by dangerous substances)

### *Disposal methods:*

- Patient samples, Negative Control, Positive Control, Kit Control, and Conjugate: Anti-Human IgG are potentially infectious. They should be disposed of following established safety procedures and local regulations.
- All the kit components must be considered as hazardous waste. They should be disposed of following local regulations.
- Sodium azide reacts with lead and copper plumbing forming highly explosive metal azides.

## 14. TRANSPORT INFORMATION

No restrictions.



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## 15. REGULATORY INFORMATION

Classification according to directives 67/548/EEC and 1999/45/EC

### Concentrated Wash

Contains: Sodium azide

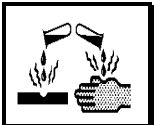


Toxic

- R25 : Toxic if swallowed  
R36/37/38 : Irritating to eyes, respiratory system and skin  
R52/53 : Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment  
S23 : Do not breathe vapour  
S45/46 : If swallowed, in case of accident, or if you feel unwell, seek medical advice immediately and show this container or label  
S61 : Avoid release to the environment. Refer to special instructions/safety data sheets.

### Stopping Solution

Contains: Sodium hydroxide (Caustic soda)



Corrosive

- R35 : Causes severe burns  
S26 : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice  
S37/39 : Wear suitable gloves and eye/face protection  
S45 : In case of accident or if you feel unwell, seek medical advice (show the label where possible)

### Negative Control, Conjugate: Anti-Human IgG, Specimen Diluent

Contains: Sodium azide



Harmful

- R22 : Harmful if swallowed  
R52/53 : Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment  
S23 : Do not breathe vapour



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- S45/46 : If swallowed, in case of accident, or if you feel unwell, seek medical advice immediately and show this container or label  
S61 : Avoid release to the environment. Refer to special instructions/safety data sheets.

## Positive Control, Kit Control

Contains: Sodium azide



Harmful



Biohazard  
HCV inactivated

- R22 : Harmful if swallowed  
R52/53 : Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment  
S23 : Do not breathe vapour  
S45/46 : If swallowed, in case of accident, or if you feel unwell, seek medical advice immediately and show this container or label  
S61 : Avoid release to the environment. Refer to special instructions/safety data sheets.

## Substrate Buffer



Irritant

- R36 : Irritating to eyes  
S26 : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice  
S36/37/39 : Wear eye/face protection, suitable protective clothing and gloves.  
S45/46 : If swallowed, in case of accident, or if you feel unwell, seek medical advice immediately and show this container or label

## 16. OTHER INFORMATION

This product is designed for use by professionals.

### R & S Phrases used in Sections 2 and 15:

- R22: Harmful if swallowed  
R28: Very toxic if swallowed  
R32: Contact with acids liberates very toxic gas  
R35: Causes severe burns  
R38: Irritating to skin



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R41: Risk of serious damage to eyes

R48/22: Harmful: danger of serious damage to health by prolonged exposure if swallowed.

R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

The human blood components included in this kit have been tested by FDA approved methods and found negative for HBsAg, anti-HCV and anti-HIV-1/2, with the exception of the Positive Serum Controls (anti-HCV positive). The human material in the Positive Serum Controls has been heat inactivated. No known method can offer complete assurance that human blood derivatives will not transmit hepatitis, AIDS or other infections. Therefore, handling of reagents, serum or plasma specimens should be in accordance with local safety procedures.

All animal products and derivatives have been collected from healthy animals. Bovine components originate from countries where BSE has not been reported.

The information provided on this MSDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

It remains the user's own responsibility to make sure that the information is appropriate and complete for his specific use of this product. The user is also responsible for observing any laws and applicable guidelines.

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