



**GTi<sup>®</sup>DIAGNOSTICS**

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# MATERIAL SAFETY DATA SHEET

(Based on Directives 91/155, 93/112/EEC and 2001/58/EC. Compiled following article 14 of 1999/45/EC)

Product Name: ADAMTS-13 Activity Assay (ATS-13<sup>®</sup>)

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

1.1	Product name	ADAMTS-13 Activity Assay	
	Catalog #	ATS	
	Kit components	Black Microwell Strips	Calibrator A
		Substrate	Calibrator B
		Specimen Diluent	Calibrator C
		Substrate Buffer	Calibrator D
		Positive Control: High	Calibrator E
		Positive Control: Low	
1.2	Intended purpose	For Research Use Only	
1.3	Company	GTI DIAGNOSTICS 20925 Crossroads Circle, Suite 200 Waukesha, WI 53186-4054, USA (262) 754-1000 OR 1-800-233-1843	
1.4	In emergencies	After normal business hours, weekends, and holidays: Call your local emergency center. For Chemical Emergency Spill Leak Fire Exposure or Accident call CHEMTREC Domestic North America: 800-424-9300 International: 703-527-3887 (collect calls accepted)	

## 2. COMPONENTS AND HAZARDOUS INGREDIENTS

Kit Components	Hazardous Ingredients	Classification Substance	EINECS NR.
<b>Positive Control: High</b>	46% Stabilizer Contains material from human origin	Xn; R22	203-473-3
<b>Positive Control: Low</b>	50% Stabilizer Contains material from human origin	Xn; R22	203-473-3
<b>Calibrator Material A</b>	50% Stabilizer	Xn; R22	203-473-3
<b>Calibrator Material B</b>	50% Stabilizer Contains material from human origin	Xn; R22	203-473-3
<b>Calibrator Material C</b>	49% Stabilizer Contains material from human origin	Xn; R22	203-473-3



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<b>Calibrator Material D</b>	47% Stabilizer Contains material from human origin	Xn; R22	203-473-3
<b>Calibrator Material E</b>	44% Stabilizer Contains material from human origin	Xn; R22	203-473-3
<b>Specimen Diluent</b>	50% Stabilizer	Xn; R22	203-473-3

### 3. HAZARDS IDENTIFICATION

**Positive Control: High, Positive Control: Low, Calibrator B, Calibrator C, Calibrator D, Calibrator E**

Harmful if swallowed.

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.

**Calibrator A, Specimen Diluent**

Harmful if swallowed.

### 4. FIRST AID MEASURES

#### All Kit Components

- Eye contact:* - Rinse immediately with copious amounts of water for 15 minutes
  - Do not apply neutralizing agents
  - Consult a doctor/medical service if irritation persists
- Skin contact:* - Immediately wash skin with soap and copious amounts of water
  - Consult a doctor/medical service if irritation persists
- After inhalation:* - Remove the victim into fresh air
  - If not breathing give artificial respiration.
  - If breathing is difficult, give oxygen.
  - Consult a doctor/medical service if breathing problems develop
- After ingestion:* - Wash out mouth with water provided person is conscious
  - Call a physician

### 5. FIRE FIGHTING MEASURES

**Positive Control: High, Positive Control: Low, Calibrator A, Calibrator B, Calibrator C, Calibrator D, Calibrator E, Specimen Diluent**

- Suitable extinguishing media:* - Carbon dioxide, dry chemical powder, or appropriate foam.
- Unsuitable extinguishing media:* - No data available
- Special exposure hazards:* - Emits toxic fumes under fire conditions
- Special protective equipment for firefighters:* - Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.
- Specific methods for fire fighting:* - Do not direct a solid stream of water at burning materials as spattering may result.



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## Other 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

## 6. ACCIDENTAL RELEASE MEASURES

**Positive Control: High, Positive Control: Low, Calibrator A, Calibrator B, Calibrator C, Calibrator D, Calibrator E, Specimen Diluent**

*Personal Protection :*

- wear respirator, chemical safety goggles and heavy rubber gloves.

*Clean-up :*

- Absorb on sand or vermiculite and place in closed containers for disposal
- When spilled, the floor may be slippery. Wipe up the floor completely

## Other 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

**Positive Control: High, Positive Control: Low, Calibrator A, Calibrator B, Calibrator C, Calibrator D, Calibrator E, Specimen Diluent**

*Handling:*

- Do not breathe vapor
- Avoid contact with eyes, skin and clothing
- Avoid prolonged or repeated exposure

*Storage:*

- Keep container tightly closed

*Special requirements :*

- Hygroscopic



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Product Name: ADAMTS-13 Activity Assay (ATS-13®)

## All Kit Components

### Handling:

- Observe normal hygiene standards
- 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

### Control of Exposure

Not available

### Personal Protection

**Positive Control: High, Positive Control: Low, Calibrator A, Calibrator B, Calibrator C, Calibrator D, Calibrator E, Specimen Diluent**

*Eye protection:* - Chemical safety glasses

*Hand protection:* - Compatible chemical-resistant gloves

*Respiratory protection:* - Government approved respirator

### Other Kit Components

*Eye protection:* - Safety glasses

- Face shield

*Hand protection:* - Gloves

*Suitable materials:* - Butyl rubber, natural rubber, neoprene, nitrile rubber, polyethylene

*Skin protection:* - Protective clothing

*Respiratory protection:* - NA

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### All Kit Components

Liquid (except Black Fluorescent Microwell Strips and Substrate)

### Substrate

Yellow amorphous powder, solid

### Specimen Diluent, Substrate Buffer

Clear liquid



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Clear to faintly yellow liquid

## 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.

## 11. TOXICOLOGICAL INFORMATION

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

### Acute toxicity:

*Stabilizer:*

Oral – Human - Lethal Dose: 100 ML OR 3 OZ

### Chronic toxicity:

*Stabilizer:*

Mutagen Human lymphocyte DNA inhibition 320 MMOL/L

### Routes of exposure

*General:*

Ingestion, inhalation, eyes and skin

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

*Stabilizer:*

Skin Contact: May cause skin irritation.

Skin Absorption: May be harmful if absorbed through the skin.

Eye Contact: Causes eye irritation.

Inhalation: Material may be irritating to mucous membranes and upper respiratory tract. May be harmful if inhaled.

Ingestion: Harmful if swallowed.

### Acute effects/symptoms

*Stabilizer:*

Exposure to and/or consumption of alcohol may increase toxic effects. When ingested early symptoms mimic alcohol inebriation and are followed by nausea, vomiting, abdominal pain, weakness, muscle tenderness, respiratory failure, convulsions, cardiovascular collapse, pulmonary edema, hypocalcemic tetany, and severe metabolic acidosis. Without treatment, death may occur in 8 to 24 hours. Victims who survive the initial toxicity period usually develop renal failure along with brain and liver damage.



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## Chronic effects

See also Chronic Toxicity.

### Stabilizer:

Overexposure may cause reproductive disorder(s) based on tests with laboratory animals.

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

## 12. ECOLOGICAL INFORMATION

### Aquatic toxicity

- N/A

### 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, Positive control: High, Positive Control: Low, Calibrator B, Calibrator C, Calibrator D, Calibrator E 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.

## 14. TRANSPORT INFORMATION

No restrictions.



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## 15. REGULATORY INFORMATION

**Positive Control: High, Positive Control: Low, Calibrator A, Calibrator B, Calibrator C, Calibrator D, Calibrator E, Specimen Diluent**



Harmful

R22: Harmful if swallowed

## 16. OTHER INFORMATION

This product is designed for use by professionals.

R and S phrases used in sections 2 and 15 :

R22: Harmful if swallowed

Reagents made with human source material have been made with materials that have been tested by FDA approved methods and found negative for HBsAg, anti-HCV and anti-HIV-1/2. 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.

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.

Sources of information: European Directives 67/548/EC (and amendments) and 99/45/EC, MSDS from individual substances.

**MSDS established** : 2006-04-20

**Revision number** : 3