

SAFETY DATA SHEET

1. IDENTIFICATION

This Safety Data Sheet is for the following products:

MANUFACTURER:

Immucor GTI Diagnostics, Inc.

20925 Crossroads Circle

Waukesha WI 53186 USA

Manufacturer's Phone: 855-IMMUCOR
(855-466-8267)

AUTHORIZED REPRESENTATIVE:

Immucor Medizinische Diagnostik GmbH

Robert-Bosch-Strasse 32

63303 Dreieich

Germany

After normal business hours, weekends, and holidays:
Call your local emergency center.

Chemical Emergency Spill Leak Fire Exposure

or Accident call **CHEMTREC**

Domestic North America: 800-424-9300

International: 703-527-3887 (collect calls accepted)

Product Name: PF4 Enhanced[®] Assay, PF4 IgG Assay

Catalog Number REF : X-HAT13, X-HAT45, HAT13G, HAT45G

Kit Components	Size
Microwell Strips	4 - 1 x 8 Microwell Strips (X-HAT13, HAT13G) 12 - 1 x 8 Microwell Strips (X-HAT45, HAT45G)
PF4 Concentrated Wash (10X)	1 x 50 mL
Specimen Diluent	1 x 30 mL
Conjugate: Anti-Human IgG/A/M Reagent (PF4 Enhanced)	1 x 80 µL
Conjugate: Anti-Human IgG Reagent (PF4 IgG)	
PNPP Substrate	4 x 50 mg (X-HAT13, HAT13G) 6 x 50 mg (X-HAT45, HAT45G)
Substrate Buffer	1 x 14 mL
Stopping Solution	1 x 14 mL
Positive Serum Control	1 x 100 µL
Negative Serum Control	1 x 100 µL
Plate Sealers	8 - sealers (X-HAT13, HAT13G) 12 - sealers (X-HAT45, HAT45G)

SPECIFIC USE: For In Vitro Diagnostic Use



2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture:

PF4 Concentrated Wash (10x)

Acute Toxicity – Oral CAT 4

Chronic Aquatic Toxicity - CAT 3

Substrate Buffer

Eye Damage - CAT 1

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2.2 Label elements:

PF4 Concentrated Wash (10X)



Hazard pictogram: GHS07
 Signal Word: **Warning**
 H302 Harmful if swallowed
 H412 Harmful to aquatic life with long lasting effects
 EUH032: Contact with acids liberates very toxic gas
 P301 + P312 IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
 P330 Rinse mouth.
 P264 Wash hands thoroughly after handling
 P270 Do not eat, drink or smoke when using this product
 P273 Avoid release to the environment

Substrate Buffer



Hazard pictogram: GHS05
 Signal Word: **Danger**
 H318 Causes serious eye damage.
 EUH032: Contact with acids liberates very toxic gas
 P280 Wear protective gloves/ eye protection/ face protection.
 P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P310 If Swallowed: Immediately call a POISON CENTER or doctor/physician.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Kit Components	Hazardous Ingredients Concentration	CAS NUMBER	EINECS NR.	Classification
PF4 Concentrated Wash (10X)	1 % Sodium azide (NaN ₃)	26628-22-8	247-852-1	Acute Tox. Oral – CAT 2; H300 Acute Aquatic Tox ; CAT 1; H400 Chronic Aquatic Tox ; CAT 1; H410
Substrate Buffer	0.02% Sodium azide (NaN ₃)	26628-22-8	247-852-1	Acute Tox. Oral – CAT 2; H300 Acute Aquatic Tox ; CAT 1; H400 Chronic Aquatic Tox ; CAT 1; H410
	9.7% Diethanolamine	111-42-2	203-868-0	Acute Tox. Oral CAT 4; H302 Skin Irrit. CAT 2; H315 Eye Damage CAT 1; H318 STOT RE CAT 2; H373

4. FIRST AID MEASURES

PF4 Concentrated Wash (10X), Negative Serum Control, Positive Serum Control, Substrate Buffer, Conjugate: Anti-Human IgG/A/M reagent, Conjugate: Anti-Human IgG reagent, Specimen Diluent, Stopping Solution

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 water Remove clothing before washing Consult a doctor/medical service if irritation persists

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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 Victim is fully conscious: immediately induce vomiting (only applies to Wash Solution) Give nothing (little) to drink Consult a doctor/medical service if you feel unwell

5. FIRE-FIGHTING MEASURES

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
Hazardous Decomposition Products:	Not determined

6. ACCIDENTAL RELEASE MEASURES

Personal Protection:	See Section 8
Environment precautions:	<ul style="list-style-type: none"> - Prevent soil and water pollution - Discharge according to local regulations
Clean up:	<ul style="list-style-type: none"> - 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

Handling:	<ul style="list-style-type: none"> - Observe normal hygiene standards, except PF4 Concentrated Wash (strict hygiene) - Discharge according to local regulations - Remove and clean contaminated clothing - Handle and open the container with care
Storage:	<ul style="list-style-type: none"> - 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

Exposure Limits

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

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Information in above table from NIOSH Pocket Guide to Chemical Hazards, 2010.

Control of Exposure

Eye protection:	Safety glasses (Substrate Buffer) Face shield (Other components)
Hand protection:	Gloves
Suitable materials:	No data available
Skin protection:	Protective clothing
Respiratory protection:	Insufficient ventilation: wear respiratory protection (PF4 Concentrated Wash)

9. PHYSICAL AND CHEMICAL PROPERTIES

(a) Appearance (physical state, color, etc.);	<p>All Kit Components Liquid (except PNPP powder and Microwell strips)</p> <p>Conjugate (Anti-Human IgG/A/M Reagent, Anti-Human IgG Reagent), Specimen Diluent Light blue</p> <p>Positive Serum Control, Negative Serum Control Clear and slightly yellow to amber</p> <p>Substrate Buffer Clear to faintly yellow</p>
(b) Odor;	None
(c) Odor threshold;	None
(d) pH;	various
(e) Melting point/freezing point;	No data available
(f) Initial boiling point and boiling range;	No data available
(g) Flash point;	No data available
(h) Evaporation rate;	No data available
(i) Flammability (solid, gas);	No data available
(j) Upper/lower flammability or explosive limits;	No data available
(k) Vapor pressure;	No data available
(l) Vapor density;	No data available
(m) Relative density;	No data available
(n) Solubility(ies);	No data available
(o) Partition coefficient: n-octanol/water;	No data available
(p) Auto-ignition temperature;	No data available
(q) Decomposition temperature;	No data available
(r) Viscosity.	No data available

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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 (Azide containing components)

11. TOXICOLOGICAL INFORMATION

See "3. Composition/Information on ingredients" to identify the kit components that contain the substances mentioned in this section

Acute toxicity:	
Sodium azide:	LD50 oral rat: 27 mg/kg LD50 dermal rabbit: 20 mg/kg
Diethanolamine:	LD50 oral rat: 710/3450 mg/kg
Chronic toxicity:	
Sodium azide:	- Carcinogenicity (TLV): A4 - Target Organ(s): nerves, heart, brain, laboratory experiments have shown mutagenic effects
Diethanolamine:	- Carcinogenicity (MAK): 3A - Target Organ(s): liver, kidneys, blood
Routes of exposure	- Ingestion, inhalation, eyes and skin - Caution! Most components contain (a) substance(s) that are absorbed through the skin
Acute effects/symptoms	
<i>PF4 Concentrated Wash (10X):</i>	- Toxic if swallowed - May cause skin irritation, eye irritation, vomiting, and diarrhea upon ingestion. - May irritate mucous membranes and upper respiratory tract.
<i>Negative Serum Control, Positive Serum Control, Conjugate (Anti-Human IgG/A/M, Anti-Human IgG Reagent), Specimen Diluent:</i>	- Harmful if swallowed
<i>Substrate Buffer:</i>	- After skin contact: red skin - After eye contact: irritation and redness of the eye tissue
<i>Sodium azide containing components:</i>	- 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)	

12. ECOLOGICAL INFORMATION

Aquatic toxicity

<i>Sodium azide:</i>	- 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.)
<i>Diethanolamine:</i>	- LC50 (96 h): 1664 mg/g (PIMEPHALES PROMELAS)
	- EC50 (48 h): 55 mg/l (DAPHNIA MAGNA)
	- EC50 (72 h): 75 mg/l (SCENEDESMUS SUBSPICATUS)

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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. DISPOSAL CONSIDERATIONS

Dispose in accordance with applicable federal, state, and local government regulations. Waste generators must determine whether a discarded material is classified as a hazardous waste. USEPA guidelines for the classification determination are listed in 40 CFR parts 261.3. Additionally, waste generators must consult state and local hazardous waste regulations to ensure complete and accurate classification.

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 Serum Control, Positive Serum Control, Specimen Diluent, and Conjugate (Anti-Human IgG/A/M Reagent and Anti-Human IgG Reagent) 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

15. REGULATORY INFORMATION

TSCA: All components of this product are listed on the TSCA inventory.

CERCLA Reportable Quantity: None

Clean Air Amendments-Hazardous Air Pollutant (HAPS): None

SARA Title III	Section 302: None Section 311/312 Section 313	None Diethanolamine: Acute Health Hazard, Chronic Health Hazard Diethanolamine: subject to reporting levels established by SARA Title III, Section 313 CAS-No. 111-42-2
California State Proposition 65:	This product contains Diethanolamine which is classified as Group 2B, the agent is possibly carcinogenic to humans	
Massachusetts Right To Know Components	This product contains Diethanolamine	CAS-No. 111-42-2
Pennsylvania Right To Know Components	This product contains Diethanolamine	CAS-No. 111-42-2
New Jersey Right To Know	This product contains Diethanolamine	CAS-No. 111-42-2

16. OTHER INFORMATION

This product is designed for use by professionals.

The human sera included in this kit has 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.

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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.

List of relevant hazard statements mentioned in section 3.

H300 Fatal if swallowed

H302 Harmful if swallowed

H315 Causes skin irritation

H318 Causes serious eye damage

H373 May cause damage to organs through prolonged or repeated exposure.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as 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.

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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.

Based on Regulation 1907/2006 (REACH)

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