



MATERIAL SAFETY DATA SHEET

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

Art. Code : PAK1, PAKPLUS, PAK12, PAK12G, PAK2-LE, PAK2-MP

Product Name: PAK®1, PAKPLUS®, PAK®12, PAK®12G, PAK®2-LE, PAK®2-MP

1. INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

- | | | |
|-----|----------------|---|
| 1.1 | Product name | PAK®1, PAKPLUS®, PAK®12, PAK®12G, PAK®2-LE, PAK®2-MP |
| | Catalog # | PAK1, PAKPLUS, PAK12, PAK12G, PAK2-LE, PAK2-MP |
| | Kit components | Microwell Strips with holder
Concentrated Wash
Specimen Diluent
Conjugate: Anti-Human IgG/A/M Reagent
PNPP Substrate
Substrate Buffer
Stopping Solution
Positive Serum Control
Negative Serum Control
Plate Sealers |
| 1.2 | Company | GTI DIAGNOSTICS
20925 Crossroads Circle, Suite 200
Waukesha, WI 53186-4054, USA
(262) 754-1000 OR 1-800-233-1843 |
| 1.3 | 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. 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

Negative Serum Control

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.

Positive Serum Control

Harmful if swallowed



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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.
Animal proteins are potentially infectious.

Substrate Buffer

Irritating to eyes

Conjugate (Anti-Human IgG/A/M Reagent or Anti-Human IgG Reagent), Specimen Diluent

Harmful if swallowed

Animal proteins are potentially infectious.

3. COMPONENTS AND HAZARDOUS INGREDIENTS

Kit Components NR.	Hazardous Ingredients	Classification Substance	EINECS
Concentrated Wash	1 % Sodium azide (NaN ₃) 2 % Tween 20 8.5 % NaCl 6.9 % Trizma HCl	T+, N, R28-32-50/53	247-852-1 231-598-3 214-684-5
Specimen Diluent	0.1% Sodium azide (NaN ₃) Contains bovine and murine proteins 0.2 % Tween 20	T+, N, R28-32-50/53	247-852-1
Negative Serum Control	0.1 % Sodium azide (NaN ₃) Contains material from human origin	T+, N, R28-32-50/53	247-852-1
Positive Serum Control	0.1 % Sodium azide (NaN ₃) May contain bovine proteins Contains material from human origin	T+, N, R28-32-50/53	247-852-1
Microwell Strips	Contains bovine and murine proteins Contains material from human origin		
Stopping Solution	12 % Sodium hydroxide (NaOH)	C, R35	215-185-5
Substrate Buffer	0.02 % Sodium azide (NaN ₃) 9.7 % Diethanolamine	T+, N, R28-32-50/53 Xn, R22-38-41-48/22	247-852-1 203-868-0
Conjugate: Anti-Human IgG/A/M and Anti-Human IgG Reagent	0.1 % Sodium azide (NaN ₃) Contains bovine and goat proteins	T+, N, R28-32-50/53	247-852-1

4. FIRST AID MEASURES

Concentrated Wash, Negative Serum Control, Positive Serum Control, Substrate Buffer, Conjugate (Anti-Human IgG/A/M Reagent, Anti-Human IgG Reagent), 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 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 Concentrated Wash)
- 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

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



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- 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 ₃)	0.3 mg/m ³ ACGIH TLV-CL	Not listed
Sodium azide (as HN ₃)	0.1 ppm	Not listed
Sodium hydroxide	2 mg/m ³	TWA 2mg/m ³
Diethanolamine	3 ppm (15 mg/m ³)	None

Information in above table from NIOSH Pocket Guide to Chemical Hazards, 2005.

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)



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Conjugate (Anti-Human IgG/A/M Reagent, Anti-Human IgG Reagent), Specimen Diluent

Light blue

Positive Serum Control, Negative Serum 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
<i>NaCl:</i>	LD50 oral rat	: 3,000 mg/kg
	LD 50 dermal rat	: > 10,000 mg/kg

Chronic toxicity:

<i>Sodium azide:</i>	Carcinogenicity (TLV) : A4
	Target Organ(s): nerves, heart, brain, laboratory experiments have shown mutagenic effects
<i>Diethanolamine:</i>	Carcinogenicity (MAK) : 3A
	Target Organ(s): liver, kidneys, blood
<i>Sodium Hydroxide:</i>	Teratogen, Mutagen, Carcinogen
<i>Tween 20:</i>	Teratogen, Reproductive Hazard
<i>NaCl:</i>	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



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

Negative Serum Control, Positive Serum Control, Conjugate (Anti-Human IgG/A/M Reagent, Anti-Human IgG Reagent), 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)

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)
<i>Caustic soda:</i>	- 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)



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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

Stopping Solution (12% Sodium Hydroxide)

UN1824

Packing Group II

Hazard Class 8

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



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- 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 Serum Control, Positive Serum Control, Conjugate (Anti-Human IgG/A/M Reagent, Anti-Human IgG Reagent), 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
 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 Section 2 (not described in Section 15):

- R28: Very toxic if swallowed
 R32: Contact with acids liberates very toxic gas
 R38: Irritating to skin
 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.



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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. 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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