IMMUCOR

PRODUCT TYPE: For In Vitro Diagnostic Use

# 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:** **PakPlus®, Pak12®**
**Catalog Number** **REF** **:** PAKPLUS, PAK12

| Kit Components | Size |
|---|---|
| Microwell Strips | 6 - 2 x 8 Microwell Strips |
| Concentrated Wash (10X) | 1 x 50 mL |
| Specimen Diluent | 1 x 14 mL |
| Anti-Human IgG/A/M Conjugate | 1 x 80 µL |
| PNPP Substrate | 3 x 50 mg |
| Substrate Buffer | 1 x 14 mL |
| Stopping Solution | 1 x 14 mL |
| Positive Serum Control | 1 x 0.3 mL |
| Negative Serum Control | 1 x 0.7 mL |
| Plate Sealers | 6 Plate Sealers |

**SPECIFIC USE: For In Vitro Diagnostic Use** **IVD** CE

**Product Name:** **Pak12®G**
**Catalog Number** **REF** **:** PAK12G

| Kit Components | Size |
|---|---|
| Microwell Strips | 6 - 2 x 8 Microwell Strips |
| Concentrated Wash (10X) | 1 x 50 mL |
| Specimen Diluent | 1 x 14 mL |
| Anti-Human IgG Conjugate | 1 x 80 µL |
| PNPP Substrate | 3 x 50 mg |
| Substrate Buffer | 1 x 14 mL |
| Stopping Solution | 1 x 14 mL |
| Positive Serum Control | 1 x 0.3 mL |
| Negative Serum Control | 1 x 0.7 mL |
| Plate Sealers | 6 Plate Sealers |

**SPECIFIC USE: For In Vitro Diagnostic Use** **IVD** CE

**Product Name:** **Pak2-LE**
**Catalog Number** **REF** **:** PAK2-LE

| Kit Components | Size |
|---|---|
| Microwell Strips | 12 - 1 x 8 Microwell Strips |
| Concentrated Wash (10X) | 1 x 50 mL |
| Specimen Diluent | 1 x 14 mL |
| Anti-Human IgG Conjugate | 1 x 80 µL |
| PNPP Substrate | 3 x 50 mg |
| Substrate Buffer | 1 x 14 mL |
| Stopping Solution | 1 x 14 mL |
| Positive Serum Control | 1 x 0.7 mL |
| Negative Serum Control | 1 x 0.7 mL |
| Plate Sealers | 6 Plate Sealers |

**SPECIFIC USE: For In Vitro Diagnostic Use** **IVD** CE

**Product Name:** **PakPlus® (100)**
**Catalog Number** **REF** **:** PAKPLUS100

| **BOX 1 of 2** | |
|---|---|
| **Kit Components** | **Size** |
| Microwell Strips | 60 x 6 - 2 x 8 Microwell Strips |
| Concentrated Wash (10X) | 3 x 1L |
| Specimen Diluent | 4 x 250 mL |
| Anti-Human IgG/A/M Conjugate | 100 x 80 µL |
| Positive Serum Control | 78 x 0.3 mL |
| Negative Serum Control | 78 x 0.7 mL |
| Substrate Buffer | 4 x 500 mL |
| **BOX 2 of 2** | |
| **Kit Components** | **Size** |
| Microwell Strips | 40 x 6 – 2 x 8 Microwell Strips |
| Specimen Diluent | 3 x 250 mL |
| Stopping Solution | 4 x 500 mL |
| Concentrated Wash (10x) | 4 x 1L |
| PNPP Substrate | 102 x 50 mg |
| Plate Sealers | 200 Plate Sealers |

**SPECIFIC USE: For In Vitro Diagnostic Use** **IVD** CE

## 2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture:

**Concentrated Wash (10x)**
Acute Toxicity – Oral CAT 4
Chronic Aquatic Toxicity - CAT 3

**Substrate Buffer**
Eye Damage - CAT 1

## 2.2 Label elements:

**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 |
|---|---|---|---|---|
| Concentrated Wash (10X) | 1 % Sodium azide ($NaN_3$) | 26628-22-8 | 247-852-1 | Acute Tox. Oral – CAT 2; H300<br>Acute Aquatic Tox ; CAT 1; H400<br>Chronic Aquatic Tox ; CAT 1; H410 |
| Substrate Buffer | 0.02% Sodium azide (NaN3) | 26628-22-8 | 247-852-1 | Acute Tox. Oral – CAT 2; H300<br>Acute Aquatic Tox ; CAT 1; H400<br>Chronic Aquatic Tox ; CAT 1; H410 |
| | 9.7% Diethanolamine | 111-42-2 | 203-868-0 | Acute Tox. Oral CAT 4; H302<br>Skin Irrit. CAT 2; H315<br>Eye Damage CAT 1; H318<br>STOT RE CAT 2; H373 |

## 4. FIRST AID MEASURES

| **Concentrated Wash (10X), Negative Serum Control, Positive Serum Control, Anti-Human IgG/A/M Conjugate, Anti-Human IgG Conjugate, Substrate Buffer, Specimen Diluent, Stopping Solution** | |
|---|---|
| Eye contact | Rinse immediately with plenty of water for 15 minutes<br>Do not apply neutralizing agents<br>Consult a doctor/medical service if irritation persists |

| | |
|---|---|
| Skin contact | Rinse with water<br>Remove clothing before washing<br>Consult a doctor/medical service if irritation persists |
| After inhalation | Remove the victim into fresh air<br>Unconscious: maintain adequate airway and respiration<br>Consult a doctor/medical service if breathing problems develop |
| After ingestion | Never give water to an unconscious person<br>Victim is fully conscious: immediately induce vomiting (only applies to Concentrated Wash)<br>Give nothing (little) to drink<br>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<br>Use fire fighting water moderately and contain it |
| Special protective equipment for firefighters: | Heat/fire exposure: compressed air/oxygen apparatus<br>Heat/fire exposure: gas-tight suit |
| Hazardous Decomposition Products: | Not determined |

## 6. ACCIDENTAL RELEASE MEASURES

| | |
|---|---|
| Personal Protection: | See Section 8 |
| Environment precautions: | - Prevent soil and water pollution<br>- Discharge according to local regulations |
| Clean up: | - Take up liquid spill into absorbent material<br>- Discharge of absorbed material according to local regulations<br>- Clean contaminated surfaces with an excess of water<br>- Wash clothing and equipment after handling |

## 7. HANDLING AND STORAGE

| | |
|---|---|
| Handling: | - Observe normal hygiene standards, except Concentrated Wash (strict hygiene)<br>- Discharge according to local regulations<br>- Remove and clean contaminated clothing<br>- Handle and open the container with care |
| Storage: | - Keep container tightly closed<br>- Meet the legal requirements<br>- Keep away from: heat sources, combustible materials, acids, metals<br>- 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 |

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

**Control of Exposure**

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

## 9. PHYSICAL AND CHEMICAL PROPERTIES

| | |
|---|---|
| (a) Appearance (physical state, color, etc.); | **All Kit Components**<br>Liquid (except PNPP powder and Microwell strips)<br><br>**Anti-Human IgG/A/M Conjugate, Anti-Human IgG Conjugate, Specimen Diluent**<br>Light blue<br><br>**Positive Serum Control, Negative Serum Control**<br>Clear and slightly yellow to amber<br><br>**Substrate Buffer**<br>Clear to faintly yellow |
| (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 |

## 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:<br>LD50 dermal rabbit: | 27 mg/kg<br>20 mg/kg |
| Diethanolamine: | LD50 oral rat: | 710/3450 mg/kg |
| **Chronic toxicity:** | | |
| Sodium azide: | - Carcinogenicity (TLV): A4<br>- Target Organ(s): nerves, heart, brain, laboratory experiments have shown mutagenic effects | |
| Diethanolamine: | - Carcinogenicity (MAK): 3A<br>- Target Organ(s): liver, kidneys, blood | |
| **Routes of exposure** | - Ingestion, inhalation, eyes and skin<br>- Caution! Most components contain (a) substance(s) that are absorbed through the skin | |
| **Acute effects/symptoms** | | |
| *Concentrated Wash (10X):* | - Toxic if swallowed<br>- May cause skin irritation, eye irritation, vomiting, and diarrhea upon ingestion.<br>- 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<br>- After eye contact: irritation and redness of the eye tissue | |
| *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**

| | | |
|---|---|---|
| *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) |

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

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 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.

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Based on Regulation 1907/2006 (REACH)

## REVISION DATE: 2017-03-16