SAFETY DATA SHEET

1. IDENTIFICATION OF PRODUCT (SUBSTANCE) AND SUPPLIER

Product Name:	FastPack & FastPack IP Immunoassay PSA Controls
Product Number:	25000003
Intended Use:	In-Vitro Quantitative Testing
CAS No.	Mixture
Einecs No.	Mixture
Supplier's Name	**Qualigen, Inc**
Address:	2042 Corte del Nogal, Carlsbad, CA 92011
Phone Number:	(760) 918-9165
Emergency Phone Numbers:	(877) 709-2169

2. HAZARD IDENTIFICATION – HAZARDOUS COMPONENTS

The following information is furnished for the kits' hazardous constituents that require regulatory control or disclosure at the concentration found in the kit. Note that the information here is often based on data from the chemical raw material (LD50, exposure limits, etc.) The kit contains a significant diluted concentration in an aqueous solution yet the assessment below was made based on the hazards of its component parts at full concentration. This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29CFR 1910.1200)

HMIS: Health-1, Flammability-0 Reactivity-0

Code letter and hazard designation of product:

Xi Irritant

Hazard-determining components of labeling: Tris HCL

Hazard phrases:
H315: Causes skin irritation.
H319: Causes serious eye irritation.
H335: May cause respiratory irritation.

Precautionary phrases:
P264: Wash (hands and exposed skin) thoroughly after handling.
P280: Wear protective gloves/protective clothing
P501: Dispose of contents/container to: approved disposal facility.

3. COMPOSITION/INFORMATION ON INGREDIENTS – HAZARDOUS COMPONENTS

This vial should be handled only by qualified personnel trained in laboratory procedures and familiar with their potential hazards. Specific warnings are given in the instructions for use. The absence of a specific warning should not be interpreted as an indicator of safety.

Chemical Ingredient	CAS No.	Quantity in Controls
Tris HCL	**1185-53-1**	**≤ 1.25%**

4. EMERGENCY FIRST AID MEASURES

General Information:	Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident is recommended
Eye Contact:	Immediately flush eyes with plenty of tepid water for 15 minutes while separating eye lids with fingers. Remove contact lenses if worn. Obtain medical attention if needed or if symptoms, such as redness or irritation persist.
Skin Contact:	In case of contact, flush skin with copious amounts of cool water and remove contaminated clothing. Obtain medical attention if needed or if irritation or other symptoms develop.
Inhalation:	If inhaled, move from exposure area to fresh air. Seek medical attention if breathing becomes difficult or if cough or other symptoms develop.
Ingestion:	In case of ingestion, contact a poison control center or physician for instructions.
Notes to Physician:	According to OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030), Universal Precautions apply. Persons handling human blood source samples should be offered hepatitis B vaccination prior to working with human source material.

5. FIRE FIGHTING MEASURES

Flammable Properties:	Dilute aqueous solution not considered a fire hazard.
Suitable Extinguishing Media:	Use extinguishing media appropriate for the surrounding fire.
Unsuitable Extinguishing Media:	Unknown
Special Fire Fighting Procedures:	Conventional fire fighting full protective equipment (with NIOSH-approved self-contained breathing apparatus) and procedures appropriate for the surrounding fire should be sufficient.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions:	Wear Personal Protective Equipment (PPE) as indicated in Section 8. Avoid physical contact with material. Wash hands thoroughly after handling.
Environmental Precautions:	This preparation contains a small amount of sodium azide which can react with copper, lead, brass or solder in plumbing systems and form potentially explosives metal azides. Follow proper disposal procedures.
Methods and Materials for Containment and Clean-Up:	Absorb spills with inert material/sorbent. Decontaminate the spill site following standard procedures. Dispose of materials in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.

7. HANDLING AND STORAGE

Handling: Follow universal/standard precautions when handling this material. See Section 8. Minimize contact and contamination of personal clothing and skin. Wash hands thoroughly after handling.

Storage: Store the kit components as specified in the product instructions/package insert provided with the test kit or the instrument operation manual.

8. EXPOSURE CONTROL/PERSONAL PROTECTION MEASURES

The following personal protective equipment (PPE) is recommended to prevent blood or other potentially infectious or hazardous materials from reaching the user's work or street cloths, skin, mouth, mucous membranes and eyes, under normal conditions of use and for the time during which the protective equipment is utilized:

Ventilation: Adequate lab ventilation is required. It is recommended that users handle potentially infectious human source material/patient samples in a dedicated location.

Eye Protection: Wear appropriate protective chemical safety glasses.

Protective Gloves: Wear chemical resistant protective gloves

Protective Clothing: Wear a labcoat, clinic jacket, gown, apron and/or smock.

Other: All personal protective equipment should be removed before leaving the work area and placed in an appropriate designated area or container for storage, processing, decontamination or disposal.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Clear to yellowish liquid.

Fire Hazard: None

Flash Point: None

Auto Igniting: None

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions

Incompatible Materials: Strong Acids

Hazardous Decomposition Products: Variable Oxides under fire conditions only.

Possibility of Hazardous Reactions: Can react if in contact with – Strong acids (releases toxic gas)

11. TOXICOLOGICAL INFORMATION

Acute Health Effects:	Harmful in contact with skin and if swallowed. May cause headache, nausea and vomiting.
Biohazard Potential:	Consists of ≥1% human and/or animal protein. Human source material used was tested and found negative for HIV 1/2, HBsAg, HCV, HIV-1(NAT), HCV(NAT) and RPR by FDA approved methods.
Carcinogenicity:	No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen.
Reproductive Effects:	No information available

12. ECOLOGICAL INFORMATION

Toxicity	No information available
Bioaccumulative Potential	No information available
Persistence and Degradability	No information available
Other Adverse Effects	None known

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods	Disposal should be in accordance with local, state or national legislation. Do NOT dispose of via domestic waste. Ensure that all packaging is disposed of safely.

14. TRANSPORT INFORMATION

Basic Shipping Description:	Not classified as dangerous for transport via land, sea, or air.

15. REGULATORY INFORMATION

US Federal Regulations:	This preparation is a component of an FDA-regulated in vitro diagnostic device.
US State Regulations:	This product does not contain components whose ingredients are listed under California Proposition 65.

16.	OTHER INFORMATION

This test kit should be handled only by qualified personnel trained in laboratory procedures and familiar with their potential hazards.
Specific warnings are given in the instructions for use. The absence of a specific warning should not be interpreted as an indication of safety.

Contact for general information:

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USA
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(877) 709-2169
Qualigeninc.com

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