



SAFETY DATA SHEET

IDENTIFICATION OF PRODUCT (SUBSTANCE) AND SUPPLIER (1):

Product Name: ImmunoFA Toxoplasma Slide, Glycerol
Product Number: 1201
Intended Use: Component of ImmunoFA™ Kit
Supplier's Name: GenBio
Address: 15222 Avenue of Science
Suite A
San Diego, CA 92128
Phone Number: (858) 592-9300

COMPOSITION / INFORMATION ON INGREDIENTS – HAZARDOUS COMPONENTS (2):

The *Toxoplasma gondii* slides 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.

Component	Content
R1 Toxoplasma Slides 1 Assembly (10 slides)	Ten 10-well microscope slides with dried, formalin-fixed <i>T. gondii</i> , strain RH. The slides are contained in a plastic insert containing 0.01M Phosphate buffer solution with sodium chloride [CAS# 7647-14-5, EINECS/ELINCS No. 231-598-3] (pH 7.0-7.4) and 30% Glycerol [CAS# 56-81-5, EC No. 200-289-5] as a preservative. Note: <i>Toxoplasma gondii</i> cells were rendered non-infectious by formalin fixing the cells.

HAZARDS IDENTIFICATION – HAZARDOUS COMPONENTS (3):

The following information is furnished for those kit 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 assessment below has taken hazard reduction processing into consideration when possible. The EU classification was made according to the latest editions of the EU lists and expanded upon from company and literature data.

Chemical Ingredient	Chemical Data / Information
Toxoplasma gondii cells [Component in R1]	This material consists of <i>Toxoplasma gondii</i> cells rendered non-infectious by treatment with formalin prior to drying down onto glass slides. Handle appropriately with the requisite Good Laboratory Practices and Universal Precautions. Dispose of this material in accordance with local, regional and national regulations.



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Chemical Ingredient	Chemical Data / Information
Glycerol [30% C ₃ H ₈ O ₃ in R1]	CAS#: 56-81-5 (100%) + EINECS/ELINCS No: 200-289-5 (100%) + RTECS#: MA8050000 (100%) + Flash Point: 320°F / 160°C (100%) + LD50 (oral-rat): 12,600 mg/kg (100%) + LC50 (inhalation-rat): >570 mg/m ³ (100%) + PEL/TLV: 10 mg/m ³ total mist (100%) + IATA/DOT ID: NE HMIS Codes: H=1, F=0, R=1 ++ RCRA Code: NE EU Classification: None; S36 ++ Keep glycerol solutions away from strong oxidizing agents, including sodium hypochlorite (bleach) and potassium permanganate, as these could potentially form explosive mixtures. The potential for adverse effects is unknown for the small volume of glycerol in this kit, but unlikely if handled appropriately with the requisite Good Laboratory Practices and Universal Precautions. Dispose of this material in accordance with local, regional and national regulations.
+ The Kit Concentration was not tested; the values refer to the solution concentration as tested, designated by percentage within parentheses. ++ The Kit Concentration was tested or the values given were estimated for the general diagnostic laboratory usage of the kit reagent dilution. NE: Not Established or Unknown (unable to locate data); typically for concentrated form unless otherwise specified. Abbreviations for component HMIS hazard ratings are as follows: H=Health, F=Flammability, R=Reactivity	

General Kit Composite Health Hazards:

- No significant adverse health effects are expected by any route for the following chemical constituents in the kit volumes and concentrations present (dilution not subject to EU Directive labeling):
 - Diluted (<5%) **Disodium orthophosphate heptahydrate** [HNa₂O₄P·7H₂O], CAS# 7782-85-6, EINECS/ELINCS No. unlisted. (R1)
 - Diluted (<1%) **Sodium dihydrogen phosphate monohydrate** [NaH₂PO₄·H₂O], EINECS/ELINCS No. 231-449-2, CAS# 10049-21-5. (R1)
 - Diluted (<1%) **Sodium Chloride** [HCl], CAS# 7647-14-5, EINECS/ELINCS No. 231-598-3. (R1)

EMERGENCY FIRST AID MEASURES (4):

Health Effects:	Skin contact may result in dermatitis and may cause allergic skin reaction upon repeated exposure.
Eye Contact:	Not applicable.
Skin Contact:	May result in dermatitis and may cause allergic skin reaction upon repeated exposure.
Inhalation:	Not applicable.
If Swallowed:	Not applicable.



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Notes to Physician: Not applicable.

FIREFIGHTING MEASURES (5):	
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Extinguishing Media	Use extinguishing media appropriate for the surrounding fire.
Special Firefighting Procedures	Conventional firefighting full protective equipment (with NIOSH-approved self-contained breathing apparatus) and procedures appropriate for the surrounding fire should be sufficient.

ACCIDENTAL RELEASE MEASURES (6):

- Avoid direct contact with skin, eyes, mucous membranes and clothing by wearing appropriate lab personal protective equipment (PPE) including gloves, lab coat and eye/face protection.
 - Follow established laboratory policy and applicable CDC/NIH biosafety and/or OSHA/WISHA hazardous material spill and/or NFPA/Fire Code guidelines for appropriate hazardous chemical and/or biological material spill response and cleanup.
 - Wear appropriate PPE. Immediately perform the following on-site if possible:
 - Decontaminate biohazard source material spills, which should always be treated as potentially infectious, including the area, spill materials and any contaminated surfaces or equipment. Utilize an appropriate chemical decon agent or disinfectant that is effective for the known or potential pathogens relative to the samples involved (commonly a 1:10 dilution of bleach, 70-80% ethanol or isopropanol, an iodophor (such as Wescodyne Plus) or a phenolic, etc.).
 - Infectious, chemical and laboratory wastes must be handled and discarded in accordance with all local, regional and national regulations.
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HANDLING AND STORAGE INFORMATION (7):

Handling: This test kit should be handled only by qualified personnel trained in laboratory procedures and familiar with their potential hazards. Follow proper Good Laboratory Practices and safety guidelines for handling chemical, biological and laboratory hazards. Wear appropriate personal protective equipment (PPE) including gloves, lab coat or equivalent and eye/face protection. Keep containers tightly closed; avoid splashing, spills and the generation of aerosols. Handle all specimens, materials and equipment used to perform the operations as though they were capable of transmitting infectious disease, as per Universal Precautions. Refer to Section 8 for more specifics. Consult with your Environmental Health & Safety Office for assistance.

Storage: Store according to product label instructions (generally between 2-8°C).
Read and follow all the precautions and warnings in the kit product instructions.



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EXPOSURE CONTROL / PERSONAL PROTECTION MEASURES (8):

The following personal protective equipment (PPE) is recommended to prevent potentially infectious or hazardous materials from reaching the user's work or street clothes, skin, mouth, mucous membranes and eyes, and to prevent hazard inhalation, 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 source material in a biological safety cabinet (BSC), expressly if aerosols might be generated.
- Eye Protection:** Wear ANSI approved safety glasses, goggles or face shield with safety glasses or goggles. Contact lenses should not be worn when handling lab hazards.
- Protective Gloves:** Suitable gloves must be worn at all times when handling kit reagents to provide skin protection from splash and intermittent contact. Synthetic gloves such as nitrile, neoprene and vinyl are recommended because they are sturdy, effective and contain no natural latex ingredients associated with latex glove allergic reactions. Disposable (single use) gloves should be changed often and never reused. Wash hands thoroughly after removing gloves.
- Protective Clothing:** Wear a lab coat, clinic jacket, gown, apron and/or smock. Disposable clothing is strongly recommended when handling biohazardous material. If reusable clothing is used, procedures for handling potentially infectious laundry under the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030) are required.
- Other:** All personal protective equipment should be removed before leaving the work area and placed in an appropriately designated area or container for storage, processing, decontamination or disposal. Protective coverings such as plastic wrap, aluminum foil or imperviously-backed absorbent pads used to cover equipment and/or surfaces must be removed and replaced if they become overtly contaminated.
- Note:** Exposure limit values and health hazard data were given in Section 3. Environmental controls are included in the following sections.

PHYSICAL AND CHEMICAL PROPERTIES (9):

- Appearance:** Solid glass slides consisting of 10 wells with dried, formalin-fixed *Toxoplasma gondii* cells, strain RH. The slides are contained in a plastic insert and packaged in buffered glycerol (30%) preservative.
- Fire Hazard:** The components have not been tested for fire hazard and explosion data; however, they are not expected to be fire hazards, but some of the kit packaging materials may burn under fire conditions.
- Flash Point:** Not applicable.
- Auto Igniting:** Product is not known to be self-igniting.



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Danger of Explosion:	Not applicable.
Boiling Point:	Not applicable.
Melting Point:	Not applicable.
Solubility:	Not applicable.
pH:	Not applicable.
Specific Gravity:	Not applicable.

No other standard characteristics applicable to the identification or hazards of the kit are known.

STABILITY AND REACTIVITY INFORMATION (10):
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Stability:	Components are stable with no known inherent significant reactivity.
Materials to Avoid:	None identified.
Conditions to Avoid:	None identified.
Hazardous Decomposition Products:	None identified.
Hazardous Polymerization:	Has not been reported to occur.

TOXICOLOGICAL INFORMATION – GENERAL COMPOSITE (11):

Refer to Section 3 for the kit component concentrations. The composite toxicological information for this product is:

Acute Health Effects

Toxicity: May be detrimental in contact with skin.

Primary Irritant Effect: A possible skin irritant.

Biohazard Potential

The glass slide applied with inactivated *T. gondii cells* (RH strain) should be handled following general biosafety guidelines and Universal Precautions.

Chronic Toxicity

Sensitization: No sensitizing effect known. Though, the potential for an allergic response is small, handle accordingly.

Carcinogenicity: No carcinogenic effect known. No component, mixture or constituent has been classified as a carcinogen by NTP, IARC or OSHA.

Reproductive Hazard: No reproductive hazard known.



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Additional Toxicological Information

To the best of our knowledge, the chemical, physical and toxicological properties have NOT been thoroughly investigated for some of the component chemicals and/or mixtures.

ECOLOGICAL INFORMATION (12):

Toxicity:

no data available

Persistence and degradability:

no data available

Bioaccumulative potential:

no data available

Mobility in soil:

no data available

PBT and vPvB assessment:

no data available

Other adverse effects:

no data available

DISPOSAL CONSIDERATIONS (13):

Disposal of hazardous and/or laboratory wastes, product or packaging must be conducted in accordance with all applicable local, regional and national regulations. This section specifies the general and United States RCRA requirements. Processing, use or contamination of the kit components may change waste management requirements and options. Contact your Environmental Health & Safety Office for your specific disposal procedures.

Recommended Product Disposal:

- **All potentially infectious material** must be appropriately decontaminated or disposed of as infectious material; check your national, regional and local ordinances accordingly. It is recommended that the *Toxoplasma gondii* glass slides are disposed in appropriate Sharps containers.

Recommended cleansing agent: Water, if necessary with appropriate cleanser. Contact your Environmental Health & Safety Office for your specific cleansing materials and procedures.

Recommended Unclean Packaging Disposal: Dispose of in accordance with all applicable local, regional and national regulations.



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TRANSPORTATION INFORMATION (14):

Shipping and disposal of product, packaging and waste must be conducted in accordance with all applicable local, regional and national regulations. Processing, use or contamination of the kit components may change shipping requirements and options. Contact your Environmental Health & Safety Office for your specific shipping procedures.

Recommended Unused Product Transportation:

No known transport restrictions. Hazardous substance, non-dangerous goods.

Recommended Used Product Hazardous Waste Disposal Transportation:

No known transport restrictions. Hazardous substance, non-dangerous goods.

REGULATORY INFORMATION (15):

Composite HMIS Rating	Health: 1	Flammability: 0	Reactivity: 1
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California Proposition 65:	The product does not contain listed substances.
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Carcinogenicity Categories:	No component, mixture or constituent has been classified as a carcinogen by NTP (National Toxicity Program), IARC (International Agency for Research on Cancer), TLV-CAR (Threshold Limit Value established by ACGIH) or OSHA.
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WHMIS Classification:	This MSDS contains the required information in accordance with the WHMIS hazard classification criteria for this product.
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Markings according to European guidelines:

This product has been classified and labeled in accordance with applicable European Community (EC) Directives (refer to 1999/45/EC, 2001/59/EC and 2001/60/EC).

Hazard Designation of Composite Product:

Hazard Determining Substance(s) of Labeling (rated under 1999/45/EC unless otherwise specified):

None identified.

Risk Phrases:

Caution Contains *Toxoplasma gondii* fixed cells source material. Handle as if capable of transmitting potentially infectious agents (Universal Precautions).

R21: Harmful in contact with skin.

Safety Phrases:

S53: Avoid exposure – obtain special instructions before use.

S35: This material and its container must be disposed of in a safe way.

S36: Wear suitable protective clothing.



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OTHER INFORMATION (16):

Health Hazard Phrases:

H312: Harmful in contact with skin.

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Contact for general information: GenBio
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Phone: (858) 592-9300
www.genbio.com

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