



SAFETY DATA SHEET (SDS) ELISA Kit

This Safety Data Sheet applies to ELISA kits manufactured by Krishgen Biosystems Private Limited. It covers plates, standards, controls, enzyme conjugates, substrates (except TMB Substrate), and buffers (Wash, Assay Diluent) that do NOT contain hazardous preservatives. Hazardous reagents are supplied with SDS documents as Annexure in this SDS.

Note: In summary the ELISA kit is not hazardous as supplied, but individual components are hazardous and supplied with separate SDS annexures

SECTION 1: Identification

Product Name: ELISA Kit (Enzyme Linked Immunosorbent Assay Kit)
Product Type: For Research / Laboratory Reagent Kit.
Recommended Use: Detection and quantification of analytes using ELISA methodology.
Restrictions on use: For Research Use Only (RUO) or In Vitro Diagnostic (IVD) use. Not for therapeutic use.
Manufacturer: Krishgen Biosystems Private Limited
Address: Unit No#318, Shah & Nahar, Off Dr E Moses Road, Worli, Mumbai 400018.
Telephone: +91-22-49198700 Email: kbiinfo@krishgen.com
Emergency: +91-22-49198700

SECTION 2: Hazard(s) Identification

GHS Classification: Not classified as hazardous according to GHS criteria when used as intended.

Label Elements:

Signal Word: None

Hazard Pictograms: None required

Hazard Statements: None required

Other Hazards:

- Product contains biological materials (proteins/antibodies/enzymes).
- Not for ingestion or injection.
- Avoid contact with skin, eyes, and mucous membranes.

SECTION 3: Composition/Information on Ingredients

Mixture Description: The ELISA kit consists is a multi-component kit including plates, protein standards, enzyme conjugates, buffers. Hazardous preservatives are addressed in separate SDS annexures.

Components included in the kit with non-hazardous materials:

- Microtiter plates coated with proteins (antigen/antibodies/peptides)
- Standards and controls (protein-based)
- Enzyme-labeled antibodies (HRP based)
- Sample Diluents (non-hazardous)

Hazardous components are provided with separate SDS documents as Annexure in this SDS.

Components included in the kit with hazardous materials:

- Wash Buffer
- Assay/Sample Diluent(s) (if included, please refer to the specific IFU; instructions for use accompanying the kit)
- TMB Substrate

SECTION 4: First-Aid Measures

General Advice: Remove from exposure. Seek medical advice if symptoms persist. Show this SDS to medical personnel if required.

Inhalation: Move to fresh air. Unlikely to be hazardous under normal laboratory use.

Skin Contact: Wash with soap and water. Remove contaminated clothing.



Eye Contact: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do.
Ingestion: Rinse mouth with water. Do NOT induce vomiting. Seek medical advice if discomfort occurs.
Important Symptoms/Effects: Mild irritation may occur upon prolonged or repeated contact.

SECTION 5: Fire-Fighting Measures

Suitable Extinguishing Media: Water spray, dry chemical, foam, or CO₂ as appropriate for surrounding fire.
Specific Hazards: Product is aqueous and not flammable.
Hazardous Combustion Products: May produce irritating fumes if involved in a fire.
Protective Equipment for Firefighters: Standard protective equipment and self-contained breathing apparatus if necessary.

SECTION 6: Accidental Release Measures

Personal Precautions: Wear laboratory gloves, lab coat, and eye protection.
Environmental Precautions: Avoid large-scale release into the environment.
Methods for Cleanup: Absorb liquid with inert material (paper towels, absorbent pads). Clean area with water and laboratory disinfectant.

SECTION 7: Handling and Storage

Handling: Follow good laboratory practices. Do not eat, drink, or smoke while handling. Do not pipette by mouth.
Storage: Store at 2–8°C unless otherwise specified on kit labels or IFU.
Incompatible Materials: Strong acids, strong bases, or oxidizing agents may affect reagent performance.

SECTION 8: Exposure Controls/Personal Protection

Control Parameters: No occupational exposure limits established for this mixture.
Engineering Controls: Standard laboratory ventilation.

Personal Protective Equipment:

- Eye protection: Safety glasses
- Skin protection: Protective gloves and lab coat
- Respiratory protection: Not normally required under standard laboratory conditions

Hygiene Measures: Wash hands thoroughly after handling.

SECTION 9: Physical and Chemical Properties

Appearance: Clear to slightly colored liquids; coated solid microtiter plate.
Odor: Odorless or mild.
pH: Near neutral (varies by reagent).
Melting/Freezing Point: Not determined.
Boiling Point: ~100°C (aqueous components).
Flash Point: Not applicable.
Flammability: Not flammable.
Solubility: Water-soluble.

SECTION 10: Stability and Reactivity

Reactivity: No hazardous reactions expected under normal conditions.
Chemical Stability: Stable when stored as recommended.
Possibility of Hazardous Reactions: None known.
Conditions to Avoid: Extreme temperatures, contamination.
Incompatible Materials: Strong oxidizing agents.
Hazardous Decomposition Products: None expected under normal conditions.



SECTION 11: Toxicological Information

Likely routes of exposure: Skin contact, eye contact, ingestion.
Acute toxicity: Not classified as toxic at supplied concentrations.
Skin corrosion/irritation: May cause mild irritation.
Serious eye damage/irritation: May cause irritation.
Sensitization: No data available; proteins may cause reactions in sensitive individuals.
Carcinogenicity, mutagenicity, reproductive toxicity: No components classified at supplied concentrations.

SECTION 12: Ecological Information

Ecotoxicity: Not expected to be hazardous to the environment in small laboratory quantities.
Persistence and Degradability: Not determined.
Bioaccumulative Potential: Not determined.
Mobility in Soil: Not determined.
Other Adverse Effects: None known.

SECTION 13: Disposal Considerations

Dispose of unused reagents and contaminated materials according to local laboratory and biomedical waste regulations.
Do not dispose of large quantities into drains.

SECTION 14: Transport Information

UN Number: Not regulated.
UN Proper Shipping Name: Not applicable.
Transport Hazard Class(es): Not applicable.
Packing Group: Not applicable.
Environmental Hazards: Not applicable.
Special Precautions: Ensure containers are tightly closed and protected from breakage during transport.

SECTION 15: Regulatory Information

This SDS is prepared in accordance with EU CLP, REACH, OSHA HazCom, JIS Z 7253, K-OSHA compliant.
Product is intended for laboratory and diagnostic use only.
Users must ensure compliance with local, regional, and national regulations.

SECTION 16: Other Information

Revision: 1.0
Revision date: 01st Feb 2026
Prepared by: Quality Assurance – Krishgen Biosystems Private Limited

Disclaimer: The information provided in this SDS is based on current knowledge and is intended as guidance for safe handling, storage, and disposal. Krishgen Biosystems makes no warranty, expressed or implied, and assumes no liability for misuse of the product.

Abbreviations and Acronyms

- CAS: Chemical Abstracts Service.
- K-OSHA GHS: Korea Occupational Safety and Health Agency.
- K-REACH: Act on the Registration and Evaluation of Chemicals (Korea).
- MoEL: Ministry of Employment and Labor (Korea).
- GHS: Globally Harmonized System.
- PDSCA: Poisonous and Deleterious Substances Control Act.
- ISHL: Industrial Safety and Health Law.
- RUO: Research Use Only.
- IVD: In vitro Use Only.



References

1. EU REACH Annex II (Regulation (EU) 2020/878), EU CLP (EC No. 1272/2008), US OSHA HazCom 2012, Japan JIS Z 7253:2019.
2. Korean K-OSHA GHS.
3. Occupational Safety and Health Act (OSHA), Republic of Korea.
4. K-REACH (Act on the Registration and Evaluation of Chemicals).
5. MoEL Notice on Classification and Labelling of Chemicals.



SAFETY DATA SHEET (SDS)
Thiomersal (Thimerosal) - Containing Buffers
Component to ELISA Kit (ELISA Wash Buffer / Assay Diluent)

This Safety Data Sheet applies to ELISA Wash Buffer and Assay/Sample Diluent(s) containing Thiomersal supplied as part of ELISA kits manufactured by Krishgen Biosystems Private Limited

SECTION 1: Identification

Product Name: Thiomersal-Containing Buffer (Wash Buffer / Assay Diluent)
Product Type: Aqueous buffered solution (mixture)
Recommended Use: Laboratory reagent for ELISA procedures (RUO / IVD). Not for therapeutic use.
Supplier/Manufacturer: Krishgen Biosystems Private Limited
Address: Unit No#318, Shah & Nahar, Off Dr E Moses Road, Worli, Mumbai 400018.
Telephone: +91-2249198700 Email: kbiinfo@krishgen.com
Emergency: +91-22-49198700

SECTION 2: Hazard(s) Identification

GHS Classification (mixture):

- Acute Toxicity (Oral): Category 4
- Hazardous to the Aquatic Environment – Chronic: Category 1

Label Elements:

Signal Word: Warning

Hazard Statements:

- H302: Harmful if swallowed.
- H410: Very toxic to aquatic life with long lasting effects.

Precautionary statements (recommended):

- P264 Wash hands thoroughly after handling.
- P270 Do not eat, drink or smoke when using this product.
- P273 Avoid release to the environment.
- P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
- P391 Collect spillage.
- P501 Dispose of contents/container in accordance with local regulations.

Other hazards: Contains an organic mercury compound preservative; may cause allergic reactions in sensitive individuals.

SECTION 3: Composition/Information on Ingredients

Mixture Components:

- Phosphate Buffered Saline (PBS) / similar buffer salts: Proprietary, non-hazardous at supplied concentrations.
- Thiomersal (Thimerosal) (CAS: 54-64-8): 0.01% w/v (100 ppm).

Note: Exact buffer composition may vary slightly between kits; hazard profile is driven primarily by thiomersal content.

SECTION 4: First-Aid Measures

General Advice: Remove from exposure. Show this SDS to medical personnel if seeking treatment.
Inhalation: Move to fresh air. If symptoms occur, seek medical advice.
Skin Contact: Wash with soap and water. Remove contaminated clothing. Seek medical advice if irritation or rash occurs.
Eye Contact: Rinse cautiously with water for at least 15 minutes. Remove contact lenses if present and easy to do. Seek medical attention if irritation persists.
Ingestion: Rinse mouth. Do NOT induce vomiting. Seek medical advice/attention.
Most important symptoms/effects: Irritation; gastrointestinal discomfort if swallowed; possible hypersensitivity in susceptible persons.



SECTION 5: Fire-Fighting Measures

Suitable Extinguishing Media: Use media appropriate for surrounding fire (water spray, foam, dry chemical, CO₂).

Specific Hazards arising from the Mixture: Aqueous product; not expected to be flammable. Combustion may produce irritating fumes.

Special Protective Equipment for Firefighters: Standard protective equipment and self-contained breathing apparatus when required.

SECTION 6: Accidental Release Measures

Personal Precautions: Wear gloves, lab coat, and eye protection. Avoid contact with skin/eyes and avoid ingestion.

Environmental Precautions: Prevent entry into drains, waterways, and soil. Very toxic to aquatic life with long lasting effects.

Methods for Containment/Cleanup: Absorb with inert material (e.g., paper towels/absorbent pads). Place in suitable labeled waste container. Clean area with water and detergent. Collect spillage.

SECTION 7: Handling and Storage

Handling: Use good laboratory hygiene. Avoid eating/drinking/smoking while handling. Avoid contact with skin/eyes. Do not pipette by mouth.

Storage: Store at 2 - 8°C unless otherwise specified on the label. Keep container tightly closed. Protect from excessive heat.

Incompatible Storage: Keep away from strong oxidizers. Store away from food and beverages.

SECTION 8: Exposure Controls/Personal Protection

Control Parameters: No occupational exposure limits established for this mixture. Follow institutional chemical hygiene plan.

Engineering Controls: Standard laboratory ventilation.

Personal Protective Equipment:

- Eye/Face Protection: Safety glasses or chemical splash goggles.
- Skin Protection: Protective gloves (nitrile recommended) and lab coat.
- Respiratory Protection: Not normally required under standard lab use; use appropriate protection if aerosols/mists are generated.

Hygiene Measures: Wash hands after handling. Remove contaminated clothing and wash before reuse.

SECTION 9: Physical and Chemical Properties

Appearance: Clear, colorless to slightly colored liquid.

Odor: Odorless or mild.

pH: Typically near neutral (varies by formulation).

Melting/Freezing Point: Not determined.

Boiling Point/Range: ~100°C (water-based).

Flash Point: Not applicable (aqueous).

Flammability: Not flammable.

Vapor Pressure: Similar to water.

Relative Density: ~1.0 (water-based).

Solubility: Miscible with water.

Partition Coefficient (n-octanol/water): Not determined for mixture.

Auto-Ignition Temperature: Not applicable.

Decomposition Temperature: Not determined.

Viscosity: Low (water-like).



SECTION 10: Stability and Reactivity

Reactivity: No dangerous reactivity expected under normal use.
Chemical Stability: Stable under recommended storage conditions.
Possibility of Hazardous Reactions: Not expected.
Conditions to avoid: Extreme temperatures; contamination.
Incompatible Materials: Strong oxidizing agents; strong acids/bases may affect buffer performance.
Hazardous Decomposition Products: Not expected under normal conditions; combustion may yield irritating vapors.

SECTION 11: Toxicological Information

Likely Routes of Exposure: Skin contact, eye contact, ingestion; inhalation of mists is unlikely but possible.
Acute Toxicity: Harmful if swallowed (mixture classification Cat. 4).
Skin Corrosion/Irritation: May cause mild irritation with prolonged contact.
Serious Eye Damage/Irritation: May cause irritation.
Respiratory or Skin Sensitization: May cause allergic reactions in sensitive individuals.
Germ Cell Mutagenicity: No data for mixture.
Carcinogenicity: No data for mixture at supplied concentration.
Reproductive Toxicity: No data for mixture.
STOT (single/repeated exposure): No data for mixture; avoid unnecessary exposure.
Aspiration Hazard: Not expected (aqueous).
Reproductive toxicity: No data for mixture.
Additional Information: Thiomersal is an organic mercury compound; handle with care and avoid ingestion.

SECTION 12: Ecological Information

Ecotoxicity: Very toxic to aquatic life with long lasting effects (mixture classification Chronic 1).
Persistence and Degradability: Not determined for mixture.
Bioaccumulative Potential: Mercury-containing compounds may bioaccumulate; avoid environmental release.
Mobility in Soil: Not determined.
Other Adverse Effects: Avoid discharge to drains and waterways.

SECTION 13: Disposal Considerations

Waste Treatment Methods: Dispose as hazardous chemical waste in accordance with local/regional/national regulations.
Do not Dispose into Sinks, Drains, or the Environment.
Contaminated Packaging: Empty containers may retain residue; dispose as chemical waste or as per local regulations.

SECTION 14: Transport Information

UN Number: Not regulated for transport in diluted laboratory quantities (typical kit volumes).
UN Proper Shipping Name: Not applicable.
Transport Hazard Class(es): Not applicable.
Packing Group: Not applicable.
Environmental Hazards: Contains aquatic chronic hazard; prevent release.
Special Precautions for User: Secure containers to prevent leakage; carry with secondary containment.
Transport in Bulk (MARPOL/IBC): Not applicable.



SECTION 15: Regulatory Information

This Safety Data Sheet has been prepared in accordance with EU REACH Annex II (Regulation (EU) 2020/878), EU CLP (EC No. 1272/2008), US OSHA HazCom 2012, Japan JIS Z 7253:2019, and Korean K-OSHA GHS requirements.

Safety, health and environmental regulations specific for the product:

- Contains Thiomersal (Thimerosal), CAS 54-64-8 (organic mercury compound).
- Intended for laboratory use only (RUO/IVD).

Note: Users are responsible for ensuring compliance with local regulations applicable to their use and disposal.

(Declaration for Japan & South Korea)

Japan – METI (GHS / ISHL / PRTR)

Regulatory Status (Japan):

This product has been classified and labeled in accordance with:

- **Industrial Safety and Health Law (ISHL), Japan**
- **Poisonous and Deleterious Substances Control Act (PDSCA), Japan**
- **PRTR Law (Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment)**
- **JIS Z 7253:2019** — *Globally Harmonized System (GHS) of Classification and Labelling of Chemicals*

GHS Classification (Japan):

Classification is based on the **GHS criteria adopted in JIS Z 7253:2019**.

Hazard communication is provided by this SDS in a 16-section format consistent with Japanese requirements.

PRTR Status:

- Components are **not listed** as Class I or Class II designated substances under the Japanese PRTR Law **at the supplied concentrations, or**
- If listed, present **below reportable thresholds**.

Notes for Importers:

This SDS is intended to support import, distribution, and occupational safety compliance in Japan. Local workplace labelling and handling must follow employer-specific ISHL obligations.

South Korea – MoEL / K-OSHA (K-REACH / GHS)

Regulatory Status (South Korea):

This product has been classified and communicated in accordance with:

- **Occupational Safety and Health Act (OSHA), Republic of Korea**
- **K-OSHA GHS standards**
- **K-REACH (Act on the Registration and Evaluation of Chemicals)**
- **MoEL Notice on Classification and Labelling of Chemicals**

GHS Classification (Korea):

Classification follows **Korean GHS criteria** aligned with the UN GHS system.

This SDS is prepared in a format acceptable for **MoEL workplace hazard communication**.

K-REACH Status:

- This product is supplied as a **mixture for laboratory/diagnostic use**.
- Components are present **below registration or notification thresholds, or** qualify for **exemptions applicable to R&D / laboratory reagents**.

Notes for Importers:

Importers are responsible for confirming substance registration status under K-REACH where applicable. This SDS supports workplace safety compliance and downstream user communication.



Component-specific Notes Table:

Component	Particulars	Clarification
TMB	Is it PRTR/K-REACH listed?	Present below reportable thresholds
Thiomersal	Mercury compound concern	Low concentration, lab reagent exemption
Sodium Azide	K-REACH scrutiny	≤0.1%, lab reagent, SDS provided
Phosphoric Acid	Transport / corrosive	Properly classified; UN1805 SDS attached

SECTION 16: Other Information

Revision: 1.0

Revision date: 1st Feb, 2026

Prepared by: Quality Assurance – Krishgen Biosystems Private Limited



SAFETY DATA SHEET (SDS)
Component to ELISA Kit (ELISA Stop Solution)
(Phosphoric Acid 0.73 M)

This Safety Data Sheet applies to ELISA Stop Solution containing phosphoric acid supplied as part of ELISA kits manufactured by Krishgen Biosystems Private Limited

SECTION 1: Identification

Product name: ELISA Stop Solution
Chemical name: Phosphoric Acid Solution
Concentration: 0.73 M (~7% w/v)
Recommended use: ELISA stop reagent for laboratory use
Restrictions on use: For Research Use Only (RUO) / In Vitro Diagnostic (IVD) use only
Manufacturer: Krishgen Biosystems Private Limited
Address: Unit No#318, Shah & Nahar, Off Dr E Moses Road, Worli, Mumbai 400018.
Telephone: +91-22-49198700 Email: kbiinfo@krishgen.com
Emergency: +91-22-49198700

SECTION 2: Hazard(s) Identification

GHS classification:

- Skin Corrosion/Irritation – Category 1B
- Serious Eye Damage – Category 1

Signal word: Danger

Hazard pictogram: Corrosion

Hazard statements:

- H314: Causes severe skin burns and eye damage.

Precautionary statements:

- P260 Do not breathe mist or vapors.
- P264 Wash hands thoroughly after handling.
- P280 Wear protective gloves/eye protection.
- P301+P330+P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
- P303+P361+P353 IF ON SKIN: Rinse skin with water/shower.
- P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes.
- P310 Immediately call a POISON CENTER/doctor.

SECTION 3: Composition/Information on Ingredients

Mixture:

- Phosphoric acid (CAS No. 7664-38-2): ~7% w/v (0.73 M)
- Water: Balance

SECTION 4: First-Aid Measures

General advice: Seek immediate medical attention in case of exposure.
Inhalation: Move to fresh air. Seek medical advice if symptoms occur.
Skin contact: Immediately flush skin with plenty of water for at least 15 minutes. Remove contaminated clothing.
Eye contact: Rinse immediately with plenty of water for at least 15 minutes. Seek immediate medical attention.
Ingestion: Rinse mouth. Do NOT induce vomiting. Seek immediate medical attention.

SECTION 5: Fire-Fighting Measures

Suitable Extinguishing Media: Use extinguishing measures appropriate to surrounding fire.
Specific Hazards: Non-flammable, but corrosive. Heating may release irritating fumes.
Protective Equipment: Self-contained breathing apparatus and full protective gear.



SECTION 6: Accidental Release Measures

Personal Precautions: Wear protective gloves, lab coat, and eye/face protection.
Environmental Precautions: Prevent release into drains and waterways.
Cleanup Methods: Absorb with inert material. Neutralize cautiously with suitable neutralizing agent.
Dispose as hazardous waste.

SECTION 7: Handling and Storage

Handling: Handle with care. Avoid contact with skin and eyes. Do not pipette by mouth.
Storage: Store at 2–8°C or as specified on label. Keep container tightly closed.
Incompatible Materials: Strong bases, metals, oxidizing agents.

SECTION 8: Exposure Controls/Personal Protection

Exposure Limits: No occupational exposure limit established for this solution.
Engineering Controls: Adequate laboratory ventilation.
Personal Protective Equipment:
• Eye/Face Protection: Safety goggles or face shield
• Skin Protection: Acid-resistant gloves and lab coat
• Respiratory Protection: Not normally required under laboratory use

SECTION 9: Physical and Chemical Properties

Appearance: Clear, colorless liquid
Odor: Odorless
pH: <2
Boiling Point: ~100°C
Flash Point: Not applicable
Solubility: Completely soluble in water

SECTION 10: Stability and Reactivity

Reactivity: Corrosive to metals.
Chemical Stability: Stable under recommended storage conditions.
Hazardous Reactions: Reacts with bases to form heat.
Conditions to Avoid: Excessive heat.
Hazardous Decomposition Products: Phosphorus oxides.

SECTION 11: Toxicological Information

Routes of exposure: Skin contact, eye contact, ingestion.
Acute toxicity: Corrosive; causes severe burns.
Skin Corrosion/Irritation: Causes severe burns.
Serious Eye Damage: Causes irreversible eye damage.
Chronic Effects: No data available for diluted solution.
Reproductive toxicity: No data mixture.

SECTION 12: Ecological Information

Ecotoxicity: May cause local pH changes harmful to aquatic life.
Persistence and Degradability: Inorganic acid; dissociates in water.
Bioaccumulative Potential: Not bioaccumulative.

SECTION 13: Disposal Considerations

Dispose as hazardous chemical waste in accordance with local regulations.
Neutralization may be required prior to disposal.

SECTION 14: Transport Information

UN Number: UN1805 (Phosphoric acid solution)



Transport Hazard Class: Class 8 (Corrosive)
Packing Group: III
Special Precautions: Ensure leak-proof secondary containment.

SECTION 15: Regulatory Information

This Safety Data Sheet has been prepared in accordance with EU REACH Annex II (Regulation (EU) 2020/878), EU CLP (EC No. 1272/2008), US OSHA HazCom 2012, Japan JIS Z 7253:2019, and Korean K-OSHA GHS requirements.

Safety, health and environmental regulations specific for the product:

- Contains Thiomersal (Thimerosal), CAS 54-64-8 (organic mercury compound).
- Intended for laboratory use only (RUO/IVD).

Note: Users are responsible for ensuring compliance with local regulations applicable to their use and disposal.

(Declaration for Japan & South Korea)

Japan – METI (GHS / ISHL / PRTR)

Regulatory Status (Japan):

This product has been classified and labeled in accordance with:

- **Industrial Safety and Health Law (ISHL), Japan**
- **Poisonous and Deleterious Substances Control Act (PDSCA), Japan**
- **PRTR Law (Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment)**
- **JIS Z 7253:2019** — *Globally Harmonized System (GHS) of Classification and Labelling of Chemicals*

GHS Classification (Japan):

Classification is based on the **GHS criteria adopted in JIS Z 7253:2019**.

Hazard communication is provided by this SDS in a 16-section format consistent with Japanese requirements.

PRTR Status:

- Components are **not listed** as Class I or Class II designated substances under the Japanese PRTR Law **at the supplied concentrations, or**
- If listed, present **below reportable thresholds**.

Notes for Importers:

This SDS is intended to support import, distribution, and occupational safety compliance in Japan. Local workplace labelling and handling must follow employer-specific ISHL obligations.

South Korea – MoEL / K-OSHA (K-REACH / GHS)

Regulatory Status (South Korea):

This product has been classified and communicated in accordance with:

- **Occupational Safety and Health Act (OSHA), Republic of Korea**
- **K-OSHA GHS standards**
- **K-REACH (Act on the Registration and Evaluation of Chemicals)**
- **MoEL Notice on Classification and Labelling of Chemicals**

GHS Classification (Korea):

Classification follows **Korean GHS criteria** aligned with the UN GHS system.

This SDS is prepared in a format acceptable for **MoEL workplace hazard communication**.

K-REACH Status:

- This product is supplied as a **mixture for laboratory/diagnostic use**.
- Components are present **below registration or notification thresholds, or** qualify for **exemptions applicable to R&D / laboratory reagents**.



Notes for Importers:

Importers are responsible for confirming substance registration status under K-REACH where applicable. This SDS supports workplace safety compliance and downstream user communication.

Component-specific Notes Table:

Component	Particulars	Clarification
TMB	Is it PRTR/K-REACH listed?	Present below reportable thresholds
Thiomersal	Mercury compound concern	Low concentration, lab reagent exemption
Sodium Azide	K-REACH scrutiny	≤0.1%, lab reagent, SDS provided
Phosphoric Acid	Transport / corrosive	Properly classified; UN1805 SDS attached

SECTION 16: Other Information

Revision: 1.0

Revision Date: 1st Feb, 2026

Prepared by: Quality Assurance – Krishgen Biosystems Private Limited



SAFETY DATA SHEET (SDS)

Component to ELISA Kit (TMB SUBSTRATE SOLUTION)

This Safety Data Sheet applies to ELISA TMB Solution supplied as part of ELISA kits manufactured by Krishgen Biosystems Private Limited

SECTION 1: Identification of the substance/mixture and of the company/undertaking

Product Name: TMB Substrate Solution (ELISA)
Chemical Name: 3,3',5,5'-Tetramethylbenzidine (TMB) in stabilized buffer
Recommended Use: Chromogenic substrate for ELISA assays
Uses Advised Against: Not for therapeutic or in vivo use

Manufacturer: Krishgen Biosystems Private Limited
Address: Unit No#318, Shah & Nahar Industrial Estate, Off Dr. E Moses Road, Worli, Mumbai 400018, India
Telephone: +91-22-49198700 Email: kbiinfo@krishgen.com
Emergency Contact: +91-22-49198700

SECTION 2: Hazards Identification

Classification according to Regulation (EC) No. 1272/2008 (CLP):

- Acute Toxicity (Oral): Category 4
- Skin Sensitization: Category 1

Signal Word: Warning

Hazard Pictograms: GHS07 (Exclamation Mark)

Hazard Statements:

- H302: Harmful if swallowed.
- H317: May cause an allergic skin reaction.

Precautionary Statements:

- P264 Wash hands thoroughly after handling.
- P270 Do not eat, drink or smoke when using this product.
- P280 Wear protective gloves/eye protection.
- P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
- P333+P313 If skin irritation or rash occurs: Get medical advice.
- P501 Dispose of contents/container in accordance with local regulations.

Other Hazards: Light-sensitive reagent. No PBT/vPvB components $\geq 0.1\%$.

SECTION 3: Composition/Information on Ingredients

Mixture:

- 3,3',5,5'-Tetramethylbenzidine (CAS No. 54827-17-7): $<0.1\%$
- Organic solvent / buffer system: Proprietary

Classification of TMB according to CLP:

Acute Tox. 4 (H302), Skin Sens. 1 (H317)

SECTION 4: First-Aid Measures

General Advice: Remove from exposure. Show this SDS to medical personnel if required.
Inhalation: Move to fresh air. Seek medical advice if symptoms persist.
Skin Contact: Wash with soap and plenty of water. Remove contaminated clothing.
Eye Contact: Rinse cautiously with water for at least 15 minutes. Seek medical advice if irritation persists.
Ingestion: Rinse mouth. Do NOT induce vomiting. Seek medical advice.



SECTION 5: Fire-Fighting Measures

Suitable Extinguishing Media: Water spray, foam, dry chemical, or CO₂.
Special Hazards: Combustion may release carbon oxides and nitrogen oxides.
Protective Equipment for Firefighters: Self-contained breathing apparatus and full protective clothing.

SECTION 6: Accidental Release Measures

Personal Precautions: Wear gloves, lab coat, and eye protection.
Environmental Precautions: Prevent entry into drains and waterways.
Methods for Cleaning Up: Absorb with inert material, collect in suitable container, and dispose as chemical waste.

SECTION 7: Handling and Storage

Handling: Avoid contact with skin and eyes. Do not ingest. Protect from light.
Storage: Store at 2–8°C. Keep container tightly closed. Protect from light.
Incompatible Materials: Strong oxidizing agents.

SECTION 8: Exposure Controls/Personal Protection

Control Parameters: No occupational exposure limits established for this mixture.
Engineering Controls: Standard laboratory ventilation.
Personal Protective Equipment:

- Eye Protection: Safety glasses or goggles
- Skin Protection: Nitrile gloves, lab coat
- Respiratory Protection: Not normally required under laboratory conditions

SECTION 9: Physical and Chemical Properties

Appearance: Clear, colorless to pale yellow liquid
Odor: Odorless or mild
pH: ~3.0 – 4.0
Melting/Freezing Point: Not determined
Boiling Point: ~100°C
Flash Point: Not applicable
Solubility: Miscible with water
Relative Density: ~1.0

SECTION 10: Stability and Reactivity

Reactivity: No hazardous reactions expected under normal use.
Chemical Stability: Stable under recommended storage conditions.
Conditions to Avoid: Light exposure, excessive heat.
Incompatible Materials: Strong oxidizers.
Hazardous Decomposition Products: Carbon oxides, nitrogen oxides.

SECTION 11: Toxicological Information

Routes of Exposure: Ingestion, skin contact, eye contact.
Acute Toxicity: Harmful if swallowed.
Skin Sensitization: May cause allergic skin reaction.
Serious Eye Damage/Irritation: May cause irritation.
Carcinogenicity: No component classified as carcinogenic at supplied concentration.
Reproductive toxicity: Not available.

SECTION 12: Ecological Information

Ecotoxicity: Not expected to be hazardous at supplied concentration.
Persistence and Degradability: Not determined.
Bioaccumulative Potential: Not expected.
Mobility in Soil: Not determined.



SECTION 13: Disposal Considerations

Dispose of contents/container as hazardous chemical waste according to local regulations.
Do not dispose into drains.

SECTION 14: Transport Information

UN Number: Not regulated.
Transport Hazard Class: Not applicable.
Environmental Hazards: None.

SECTION 15: Regulatory Information

This Safety Data Sheet has been prepared in accordance with EU REACH Annex II (Regulation (EU) 2020/878), EU CLP (EC No. 1272/2008), US OSHA HazCom 2012, Japan JIS Z 7253:2019, and Korean K-OSHA GHS requirements.

Safety, health and environmental regulations specific for the product:

- Contains Thiomersal (Thimerosal), CAS 54-64-8 (organic mercury compound).
- Intended for laboratory use only (RUO/IVD).

Note: Users are responsible for ensuring compliance with local regulations applicable to their use and disposal.

(Declaration for Japan & South Korea)

Japan – METI (GHS / ISHL / PRTR)

Regulatory Status (Japan):

This product has been classified and labeled in accordance with:

- **Industrial Safety and Health Law (ISHL), Japan**
- **Poisonous and Deleterious Substances Control Act (PDSCA), Japan**
- **PRTR Law (Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment)**
- **JIS Z 7253:2019 — Globally Harmonized System (GHS) of Classification and Labelling of Chemicals**

GHS Classification (Japan):

Classification is based on the **GHS criteria adopted in JIS Z 7253:2019**.

Hazard communication is provided by this SDS in a 16-section format consistent with Japanese requirements.

PRTR Status:

- Components are **not listed** as Class I or Class II designated substances under the Japanese PRTR Law **at the supplied concentrations, or**
- If listed, present **below reportable thresholds**.

Notes for Importers:

This SDS is intended to support import, distribution, and occupational safety compliance in Japan.
Local workplace labelling and handling must follow employer-specific ISHL obligations.

South Korea – MoEL / K-OSHA (K-REACH / GHS)

Regulatory Status (South Korea):

This product has been classified and communicated in accordance with:

- **Occupational Safety and Health Act (OSHA), Republic of Korea**
- **K-OSHA GHS standards**
- **K-REACH (Act on the Registration and Evaluation of Chemicals)**
- **MoEL Notice on Classification and Labelling of Chemicals**

GHS Classification (Korea):

Classification follows **Korean GHS criteria** aligned with the UN GHS system.

This SDS is prepared in a format acceptable for **MoEL workplace hazard communication**.



K-REACH Status:

- This product is supplied as a **mixture for laboratory/diagnostic use**.
- Components are present **below registration or notification thresholds**, or qualify for **exemptions applicable to R&D / laboratory reagents**.

Notes for Importers:

Importers are responsible for confirming substance registration status under K-REACH where applicable. This SDS supports workplace safety compliance and downstream user communication.

Component-specific Notes Table:

Component	Particulars	Clarification
TMB	Is it PRTR/K-REACH listed?	Present below reportable thresholds
Thiomersal	Mercury compound concern	Low concentration, lab reagent exemption
Sodium Azide	K-REACH scrutiny	≤0.1%, lab reagent, SDS provided
Phosphoric Acid	Transport / corrosive	Properly classified; UN1805 SDS attached

SECTION 16: Other Information

Revision: 1.0

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Prepared by: Quality Assurance – Krishgen Biosystems Private Limited