SAFETY DATA SHEET (SDS)

SECTION 1: IDENTIFICATION OF PRODUCT (MIXTURE) AND SUPPLIER

Product Name: **HSV IgG EIA**

Product Number: **25179** (96 tests)
Catalog number(s) for replacement, optional, and/or separately purchased components that can be obtained for use with this kit, and which are covered by this SDS include**: 25186, 25190, 25191,** and **25192** (refer to Section 2).

Intended Use: For the qualitative and semi-quantitative detection of human IgG antibodies to type 1 and type 2 herpes simplex virus (HSV) in human serum by enzyme immunoassay. To aid in the evaluation of the patient's immunological history with HSV, including women of childbearing age. These reagents have not received FDA clearance for use in testing blood or plasma donors. *For In Vitro Diagnostic Use Only.*

Supplier's Name: **Bio-Rad Laboratories, Inc.**

Address: 6565 185th Avenue NE
Redmond, WA 98052-5039, USA

Website: www.bio-rad.com

Phone Number: 1-800-2-BIORAD (1-800-224-6723); or 1-425-881-8300 (daytime PT)

SDS e-mail contact: ro-sds@bio-rad.com

Technical Information Contacts: Bio-Rad provides a toll free line for technical assistance, available 24 hours a day, 7 days a week. In the United States of America and Puerto Rico, call toll free 1-800-2-BIORAD (1-800-224-6723). Outside the U.S.A., please contact your regional Bio-Rad office for assistance. *Refer to section 16 for non-US local Bio-Rad agent contact information.*

Emergency Phone Number: **This SDS is listed with CHEMTREC 1-800-424-9300** (US) or **001-703-527-3887** (international – can be called collect)**.** Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION, or ACCIDENT with this product.
Refer above and to section 16 for non-US local Bio-Rad agent contact information.

SECTION 2: HAZARDS IDENTIFICATION -- HAZARDOUS COMPONENTS

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. The following information is furnished for those product hazardous constituents that require regulatory control or disclosure at the concentration found in the product. The GHS, US HCS, EC CLP, and related classifications were made according to the latest editions and expanded upon from company and literature data. Refer to Section 16 for the full text of any solely abbreviated or coded hazard statements provided below. Refer to Section 16 for the Key / legend to abbreviations and acronyms.

Component*	Content
Coated Wells, 12 eight-well strips	- Coated with equal portions of sonicated Type 1 HSV (MacIntyre strain) and Type 2 HSV (MS strain) antigen. [Color ID: Brown]
Well Support, 1 Frame	- No known hazardous ingredients.
Diluent, 25 mL bottle, (pink color) Catalog #25186	- Phosphate-buffered saline with a protein stabilizer. - Preserved with **0.1% sodium azide** [NaN_3], CAS# 26628-22-8 and EC No 247-852-1. Not subject to US HCS, EC CLP, and analogous global GHS-based regulatory requirements without Cat 5 Acute Toxic designations in this product mixture and concentration.

Component*	Content
HSV IgG Calibrator 1, 0.5 mL vial	- Normal human serum, Strongly reactive for HSV IgG antibodies. Index or IU/mL values shown on vial label. - Preserved with **0.1% sodium azide** [NaN_3], CAS# 26628-22-8 and EC No 247-852-1. Not subject to US HCS, EC CLP, and analogous global GHS-based regulatory requirements without Cat 5 Acute Toxic designations in this product mixture and concentration
HSV IgG Calibrator 2, 0.5 mL vial	- Normal human serum, Moderately reactive for HSV antibodies. Index or IU/mL values shown on vial label. - Preserved with **0.1% sodium azide** [NaN_3], CAS# 26628-22-8 and EC No 247-852-1. Not subject to US HCS, EC CLP, and analogous global GHS-based regulatory requirements without Cat 5 Acute Toxic designations in this product mixture and concentration.
HSV IgG Positive Control, 0.5 mL vial	- Normal human serum, Reactive for HSV antibodies. Index or IU/mL values shown on vial label. - Preserved with **0.1% sodium azide** [NaN_3], CAS# 26628-22-8 and EC No 247-852-1. Not subject to US HCS, EC CLP, and analogous global GHS-based regulatory requirements without Cat 5 Acute Toxic designations in this product mixture and concentration.
HSV IgG Negative Control, 0.5 mL vial	- Normal human serum, Non-reactive for HSV antibodies. - Preserved with **0.1% sodium azide** [NaN_3], CAS# 26628-22-8 and EC No 247-852-1. Not subject to US HCS, EC CLP, and analogous global GHS-based regulatory requirements without Cat 5 Acute Toxic designations in this product mixture and concentration.
HSV IgG Conjugate, Two (2) 12 mL bottles (green color)	- Goat anti-human IgG labeled with alkaline phosphatase (calf). - Preserved with **0.1% sodium azide** [NaN_3], CAS# 26628-22-8 and EC No 247-852-1. Not subject to US HCS, EC CLP, and analogous global GHS-based regulatory requirements without Cat 5 Acute Toxic designations in this product mixture and concentration.
Substrate, 12 mL bottle Catalog #25192	- Diluted **p-Nitrophenyl phosphate** [PNPP - $C_6H_6NO_6P•2Na$], CAS# 4264-83-9, EC No 224-246-5. Not subject to GHS, US HCS, EC CLP, and analogous global GHS-based regulatory requirements in this product mixture and concentration.
Wash Concentrate, 30 mL bottle Catalog #25190	- **Tris-buffered saline** with **Tween 20**, pH 8.0. Not subject to GHS, US HCS, EC CLP, and analogous global GHS-based regulatory requirements in this product mixture and concentration. - Preserved with **0.1% sodium azide** [NaN_3], CAS# 26628-22-8 and EC No 247-852-1. Not subject to US HCS, EC CLP, and analogous global GHS-based regulatory requirements without Cat 5 Acute Toxic designations in this product mixture and concentration.
Stop Reagent, 12 mL bottle Catalog #25191	- **0.5M Trisodium phosphate** [$Na_3PO_4•12H_2O$], CAS# 10101-89-0 (Dodecahydrate). Not subject to GHS, US HCS, EC CLP, and analogous global GHS-based regulatory requirements in this product mixture and concentration.

* Replacement, optional, and separately purchased component Catalog numbers are provided in this column where available.

Markings according to the *United Nations* (UN) Globally Harmonized System (GHS), *United States* Hazard Communication Standard (US HCS), *European Community* (EC) 2008/1272/EC (EC CLP**) guidelines, and analogous GHS-based global regulations:**

No Known Regulated Hazards: This product contains no hazardous constituents, or the concentrations of all chemical constituents are below the regulatory threshold limits requiring hazard communication and labeling. The information included here is in compliance with chemical hazard classification, hazard communication, and Safety Data Sheets (SDS) requirements as per the **United States** – Occupational Safety Health Administration *Hazard Communication Standard* **29 CFR 1910.1200 (US HCS).**
Note: 0.1% Sodium Azide concentration falls under the UN GHS Cat 5 Acute Toxic which is not recognized in the US.

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

The following information is furnished for those product hazardous constituents that require regulatory control or disclosure regardless of the concentration found in the product. Note that the information here is often based on data from the chemical raw material safety data sheet and literature (LD_{50}, exposure limits, etc.). Chemical constituents that do not require regulatory disclosure are not generally included here. This product contains a significantly diluted concentration in an aqueous solution, thus the assessment below has not considered the dilution reduction effect on the hazard. That hazard communication information is provided in Section 2 above.

Some components were tested at the concentration found in the kit. In that case, the assessment is provided for the chemical dilution tested and the tested concentration will be provided at the beginning of the *Chemical Ingredient Data/Information* box. The GHS, US HCS, EC CLP, and analogous GHS-based global regulation classifications were made according to the existing editions and expanded upon from company and literature data.

Refer to Section 16 for the list of sources utilized in the assessment and the Key / legend to abbreviations and acronyms.

Chemical Ingredient Data / Information

Chemical Ingredient: Sodium azide
Chemical concentrations found in this product: **0.1%**

Data for Concentrated / 100% chemical used in the product mixture (concentration tested)**:**

CAS#: 26628-22-8 (100%)
EC No: 247-852-1 (100%)
Index No: 011-004-00-7 (100%)
RTECS#: VY8050000 (100%)
Chemical Formula: NaN_3 (100%)
Molecular weight: 65.01g/mol (100%)

LD_{50} (oral-rat): 27 mg/kg (100%)
LC_{50} (inhalation-rat): 37 mg/m^3 (100%)
LD_{50} (skin-rat): 50 mg/kg (100%)
Fish LC_{50} – Lepomis macrochirus (Bluegill) – 0.68 mg/l – 96 h (100%)

Synonyms/Trade Names: Azide, sodium; Azoture de sodium; Azydek sodu; NSC 3072; Kazoe; Natriumazid; Natriummazide; NCI-C06462; Nemazyd; Sodium azide; Sodium, azoture de; Sodium, azoturo di, Smite; U-3886;

Raw Material GHS / US HCS / EC CLP Classification (100%):

DANGER!
Acute Tox. – ing. Cat. 2, Acute Tox. – skn. Cat. 1, Aquatic Acute Cat. 1, Aquatic Chronic Cat. 1
H300 + H310, H410
P264, P273, P280, P302 + P350, P310, P501

[Source: Raw Material vendor SDS, CCOHS databases and regulatory research]

Chemical Ingredient Data / Information

Chemical Ingredient: **Sodium Phosphate, Tribasic, Dodecahydrate (TSP)**
Chemical concentrations found in this product: **0.5M in the Stop reagent (< 1%)**

Data for Concentrated / 100% chemical used in the product mixture (concentration tested)**:**

CAS#: 10101-89-0 (Dodecahydrate) (100%)
EC No: 231-509-8 (100%)
RTECS#: TC9575000 (100%)
Index No: NE (100%)
Chemical Formula: $Na_3PO_4.12H_2O$ (100%)
Molecular weight: 380.12 g/mol (100%)
Synonyms/Trade Names: TSP, Phosphoric acid, trisodium salt dodecahydrate

LD_{50} (oral-rat): 7400 mg/kg (100%)
LC_{50} (inhalation-rat): No data available (100%)
LD_{50} (skin-rabbit): No data available mg/kg (100%)
LC_{50} (96 hr-fish): 2,400 mg/L (100%) – 48H (Leuciscus idus (Golden orfe)
Flash Point: NS°F / NS°C (100%)
pH value: ~11.9 (1%)

Raw Material GHS / US HCS / EC CLP Classification (100%):

DANGER!
Skin Corr. Cat. 1B, Eye Damage Cat. 1
H314
P260, P264, P280, P301 + P330 + P331, P303 + P361 + P353, P304 + P340, P305 + P351 + P338, P310, P363, P405, P501
[Source: Raw Material vendor SDS, CCOHS databases and regulatory research]

Biological Ingredient	Data / Information
Microwell Coated Plate	The microwells in this test kit have been coated with equal portions of sonicated Type 1 HSV (MacIntyre strain), and Type 2 HSV (MS strain) antigen, which has been certified by the supplier to be inactivated; however, according to Universal Precautions, it should be handled as though capable of transmitting infection.
Human Serum [reactive and non-reactive in the High and Low Positive Control and Negative Control Reagents] 	The Human sera in the components of this product were tested and certified to be non-reactive for HBsAg and antibodies to HCV and HIV 1 / HIV 2 by FDA licensed or CE Marked tests. No known test method can offer complete assurance that HIV, hepatitis B or C virus, or other infectious agents are absent. Moreover, patient blood samples tested with this kit represent an unknown, heightened hazard. Employ *Standard* and *Universal Precautions* when handling these reagents and all human blood or specimens. Handle as if capable of transmitting infectious disease, in a Biosafety Level 2 lab, applying the guidelines from the current CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories* or WHO *Laboratory Biosafety Manual*. Avoid splashing, spills, and the generation of aerosols. Secure in secondary containment with proper biohazard labeling. Do not inhale mists or aerosols; avoid contact with skin, eyes, mucous membranes, and clothing. In case of contact with eyes, immediately rinse with copious water and seek medical attention. Employ decontamination procedures with appropriate decon agent or disinfectant (typically a 1:10 dilution of household bleach, 70-80% ethanol or isopropanol, an iodophor like 0.5% Wescodyne Plus (EPA Reg. #4959-16), an o-phenylphenol/amyphenol such as 0.8% Vesphene (EPA Reg. #1043-87), or equiv.) before discarding any materials utilized or returning equipment used to general use. Dispose of this material in accordance with local, regional, national, and international regulations. Handle appropriately with the requisite Good Laboratory Practices, *Standard* and *Universal Precautions*. Persons handling blood samples should have the option of receiving hepatitis B vaccination.

NA: Not Applicable.
NE: Not Established or Unknown (unable to locate data); typically for concentrate form unless otherwise specified.

Related product information:

- Refer to section 2 for the full text of any *Comprehensive GHS-based Classification* statements coded above.
  Refer to Section 16 for the list of sources utilized in the assessment and the Key / legend to abbreviations and acronyms.
- No significant adverse health effects are expected by any route for the miscellaneous salts, water, tris and phosphate saline buffers, protein stabilizers, Tween 20 [CAS# 9005-64-5], p-nitrophenyl phosphate [CAS# 4264-83-9], dyes, and other chemicals found in the kit reagents, in the kit volumes and concentrations present. [Chemical or dilution is not subject to EC CLP, US HCS, or GHS hazard labeling.]

- According to the concept of Universal Precautions (29 CFR 1910.1030), all human blood and certain human body fluids must be treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens. No known test method can offer complete assurance that products derived from human blood will not transmit infection; thus, they should be handled as though they contain infectious agents. Furthermore, individual patient samples being tested represent a heightened, unknown hazard. Aerosolization/inhalation, contact, and mucous membrane exposure should be avoided during sample and kit handling. Consider equipment that potentially comes in contact with human source material as contaminated until appropriately decontaminated.
- Do not eat, drink, or smoke when using this product.
- Wear protective gloves/protective clothing/eye protection/face protection. Take off contaminated clothing and wash before reuse.

SECTION 4: EMERGENCY FIRST AID MEASURES

Health Effects:	Skin contact may result in irritation or dermatitis. Symptoms of overexposure may include headache and dizziness, generally at concentrations and volumes that greatly exceed that of this kit. The ***Stop Reagent*** may cause serious eye irritation with possible corneal damage with extended exposure.
Eye Contact:	Flush eyes with copious water for at least 15 minutes. Ensure adequate flushing by separating the eyelids with fingers while flushing with water. OBTAIN MEDICAL ATTENTION.
Skin Contact:	Remove contaminated clothing. Flush skin with copious water and wash affected area with soap and water. If blood-to-blood contact occurs, or if more severe symptoms develop, consult a physician.
Inhalation:	Remove person from exposure area to fresh air. If breathing becomes difficult, immediately call for emergency medical assistance. Treat symptomatically and supportively. Generally, this aqueous product is not a significant inhalation hazard in the kit volumes and concentrations present.
If Swallowed:	If ingested, rinse out mouth thoroughly with water, provided the person is conscious, and OBTAIN MEDICAL ATTENTION. Call a physician or the local poison control center. Treat symptomatically and supportively. If vomiting occurs, keep head lower than hips to prevent aspiration.
Notes to Physician:	According to the 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**.**

SECTION 5: FIREFIGHTING MEASURES

Extinguishing Media:	Use extinguishing media appropriate for the surrounding fire.
Hazardous Combustion Products:	Oxides of carbon or nitrogen may form when heated to decomposition.
Protection of Fire Fighters:	Conventional firefighting full protective equipment (with NIOSH-approved self-contained breathing apparatus) and procedures appropriate for the surrounding fire should be sufficient.

SECTION 6: ACCIDENTAL RELEASE MEASURES

- 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.
- In the event of a hazardous material spill, contain the spill if it is safe to do so and immediately move to a safe area, free from potential aerosols, to decontaminate and/or safely remove any contaminated clothing, as necessary. IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. Isolate the hazard area and ventilate if appropriate. Ensure that appropriate spill cleanup materials and PPE are available and used.
- Prevent material from entering sewers, waterways, or confined spaces.
- Follow established laboratory policy and applicable CDC/NIH biosafety and/or OSHA/WISHA and/or NFPA/Fire Code hazardous material spill guidelines for appropriate hazardous chemical and/or biological material spill response and cleanup. Avoid release to the environment.

- Wear appropriate PPE. Immediately, and on-site if possible: Clean the spill area with water and wipe dry. Spills can also be absorbed with appropriate inert materials (e.g., spill pillows, absorbent pads), which are secured in an appropriate, labeled, sealed container. Material used to absorb the spill may require hazardous material waste disposal. Infectious, chemical, and laboratory wastes must be handled and discarded in accordance with all local, regional, national, and international regulations.
- Refer to Sections 8 and 13 for more specifics.

SECTION 7: HANDLING AND STORAGE INFORMATION

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. Do not smoke, eat, or drink in areas where patient samples and kit reagents are handled. Wash your hands after use. 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 human source materials, specimens, and equipment used to perform the operations as though they were capable of transmitting infectious disease, as per *Standard* and *Universal Precautions.* All personal protective equipment should be removed before leaving the work area. Refer to Section 8 for more specifics. Avoid release to the environment. Do not allow undiluted product hazardous chemical ingredient or large quantities of it to reach ground water or water course. Consult with your Environmental Health & Safety Office for assistance.
Storage:	Store according to product and label instructions (generally at 2-8°C).
Caution, consult accompanying documents. Read and follow all the precautions and warnings in the kit product instructions for use.	
For *in vitro* diagnostic use.	

SECTION 8: EXPOSURE CONTROL / PERSONAL PROTECTION MEASURES

Control Parameters – *Component chemicals with limit values that require monitoring at the workplace*:

100% Sodium Azide [CAS# 26628-22-8] - OEL:			
AUSTRALIA:	CL	0.11 ppm (0.3 mg/m^3)	JUL2008
AUSTRIA:	MAK-TMW KZW	0.1 mg/m^3 0.3 mg/m^3, skin	 2007
BELGIUM:	TWA STEL	0.1 mg/m^3, 0.3 mg/m^3, skin	 MAR2002
DENMARK:	TWA	0.1 mg/m3, skin	MAY2011
EC (European Union):	TWA STEL	0.1 mg/m^3 0.3 mg/m^3, skin	 JUN2000
FINLAND:	TWA STEL	0.1 mg/m^3 0.3 mg/m^3, skin	 NOV2011
FRANCE:	VME VLE	0.1 mg/m^3 0.3 mg/m^3, Skin	 FEB2006
GERMANY:	MAK	0.2 mg/m^3, inhal	2011
HUNGARY:	TWA STEL	0.1 mg/m^3 0.3 mg/m^3	 SEP2000
ICELAND:	TWA STEL	0.1 mg/m^3 0.3 mg/m^3, skin	 NOV2011
KOREA:	CL	0.1 ppm (0.3 mg/m^3)	2006
THE NETHERLANDS:	MAC-TGG	0.1 mg/m^3, skin	2003

100% Sodium Azide [CAS# 26628-22-8] - OEL:			
NEW ZEALAND:	CL	0.11 ppm (0.29 mg/m^3)	JAN2002
PERU:	TWA STEL	0.1 mg/m^3 0.29 mg/m^3	JUL2005
SWEDEN:	TWA STEL	0.1 mg/m^3 0.3 mg/m^3, Skin	JUN2005
SWITZERLAND:	MAK-W KZG-W	0.2 mg/m^3 0.4 mg/m^3, inhal	JAN2011
UNITED KINGDOM:	TWA STEL	0.1 mg/m^3 0.3 mg/m^3, skin	OCT2007
UNITED STATES:	TLV-TWA-Ceiling REL-Ceiling	0.11* ppm / 0.29** mg/m³ 0.1* ppm / 0.3** mg/m³	ACGIH, 1996, 2013 NIOSH Recommended Exposure Limits *as HN_3 vapor; **as NaN_3; Skin
[Source: RTECS September 2013 Update and/or Raw Material Vendor Safety Data Sheet]			

100% Sodium Phosphate, Tribasic, Dodecahydrate (TSP) [CAS# 10101-89-0] - OEL:			
UNITED STATES:	STEL REL-Ceiling	5 mg/m³	USA, Workplace Environmental Exposure Levels (WEEL)
[Source: Raw Material Vendor Safety Data Sheet]			

Additional information: The lists that were valid during the creation were used as basis.

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 clothes, skin, mouth, mucous membranes and eyes, or hazardous inhalation, under normal conditions of use and for the time during which the protective equipment is utilized:

Ventilation:	Adequate lab ventilation is required.
Eye / Face 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 or patient samples 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 be 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.
Respiratory Protection:	Not 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.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Variable, generally aqueous liquids.		
Odour / Odor:	No applicable information was found.	**Odour/Odor Threshold:**	Not established.
pH:	Most of the liquid chemical reagents are between pH 5 and 9, with the exception of the alkaline Stop solution at pH ≥ 10.		
Boiling Point:	Undetermined.	**Melting Point:**	Undetermined.

Flash Point:	Not Applicable. Flammable limits: LEL/LFL is Not Applicable; UEL/UFL is Not Applicable
Evaporation rate:	No applicable information was found.
Fire Hazard:	Although the components have not been tested for fire hazard and explosion data, being water-based, they are not expected to be fire hazards, but some of the kit packaging materials may burn under fire conditions.
Vapor Pressure:	No applicable information was found.
Vapor Density:	No applicable information was found.
Relative Density:	Approximately 1.
Solubility:	The liquid chemical components are soluble in water.
Partition coefficient (n-octanol/water):	No applicable information was found.
Auto Igniting:	Product is not known to be self-igniting.
Decomposition temperature:	No applicable information was found.
Viscosity:	No applicable information was found.
Danger of Explosion:	***Sodium azide*** may react with lead or copper plumbing to form highly explosive metal azides; build-up in metal plumbing has led to laboratory explosions, so flush with copious water when pouring dilute solutions down the drain to prevent such explosive build-up.
Molecular mass:	Mixture.
No other standard characteristics applicable to the identification or hazards of the product are known.	

SECTION 10: STABILITY AND REACTIVITY INFORMATION

NOTE: Chemical reactions that could result in a hazardous situation (e.g., generation of flammable or toxic chemicals, fire, or detonation) are listed here. Although not intended to be complete, an overview of important reactions involving common chemicals is provided to assist in the development of safe work practices.

Chemical stability / Reactivity:	Components are stable with no known inherent significant reactivity.
Possible hazardous reactions:	Do not allow the ***basic Stop Reagent*** to come in contact with strong acids, oxidizing agents, and metals.
Conditions and/or materials to avoid:	Avoid contact with metals. ***Sodium azide*** may react with lead or copper plumbing to form highly explosive metal azides; build-up in metal plumbing has led to laboratory explosions, so flush with copious water when pouring dilute solutions down the drain to prevent such explosive build-up.
Incompatible Materials:	***Stop Reagent*** – Strong oxidizing agents, Strong acids, Organic materials.
Hazardous decomposition products:	Oxides of carbon or nitrogen may form when heated to decomposition
Hazardous polymerization:	Has not been reported to occur.

SECTION 11: TOXICOLOGICAL INFORMATION -- GENERAL COMPOSITE

Refer to Sections 2 and 3 for the kit component concentrations. The composite toxicological information for this product is:

Acute Health Effects

Toxicity:	Harmful if enough is ingested (generally quantities above those found in the kit).
Primary Irritant Effect:	Contact with the ***Stop Reagent*** can severely irritate skin and eyes; prolonged contact may cause eye injury (alkaline Stop reagent).
Serious Eye Damage / Irritation:	***Stop Reagent*** can irritate eyes depending on concentration, amount, and contact time.
STOT-Single Exposure:	No applicable information was found.

STOT-Repeated Exposure:	No applicable information was found.
Aspiration Hazard:	No applicable information was found.
Other Acute Health Effects:	No significant other acute health effect known.

Biohazard Potential:

The ***Human sera (plasma)*** in the components were tested and found non-reactive for HBsAg, HBsAb, anti-HBc, HIV-1 Ag, HCVAb, HIV-1 and HIV-2 Ab. ***Patient blood samples*** tested with this kit represent an unknown, heightened hazard. Employ *Standard* and *Universal Precautions*; handle these reagents, all human blood, and specimens as if capable of transmitting infectious disease, in a Biosafety Level 2 laboratory, applying the guidelines from the current CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories* or WHO the *Laboratory Biosafety Manual* or equivalent. Persons handling blood samples should have the option of receiving hepatitis B vaccination.

Chronic Toxicity

Sensitization:	No sensitization effect known.
Carcinogenicity:	No carcinogenic effect known. No component, mixture, or constituent has been classified as a carcinogen by NTP, IARC, or OSHA.
Germ Cell Mutagenicity:	No applicable information was found.
Reproductive hazard:	No reproductive toxic effect known.

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.

SECTION 12: ECOLOGICAL INFORMATION

This product was not tested. The following assessment is based on information for the ingredients.

Ecotoxicity:	**100% *Sodium Azide*** [CAS# 26628-22-8]*: Fish LC_{50} – Lepomis macrochirus (Bluegill) – 0.68 mg/l – 96 h Daphnia EC_{50} – Daphnia pulex (Water flea) – 4.2 mg/l – 48 h **100% *Sodium Phosphate, Tribasic, Dodecahydrate* (TSP)** [CAS# 10101-89-0]: TLC_{50} (96 hr-fish): 2,400 mg/L (100%) – 48H (Leuciscus idus (Golden orfe) ** Source: Raw Material Vendor Safety Data Sheet, RTECS and/or CCOHS Cheminfo*
Persistence and degradability:	No information found.
Bioaccumulation potential:	No information found.
Mobility in soil:	No information found.
PBT and vPvB assessment:	No information found.
Other adverse effects:	An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

Disposal of hazardous and/or laboratory wastes, product, or packaging must be conducted in accordance with all applicable local, regional, national, and international 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:

- ***Sodium azide*** may react with lead or copper plumbing to form highly explosive metal azides; build-up in metal plumbing has led to laboratory explosions, so flush with copious water when pouring dilute solutions down the drain to prevent such explosive build-up; check your applicable ordinances accordingly.

- All ***human source*** and other potentially infectious material must be appropriately decontaminated or disposed of as infectious material; check your international, national, regional, and local ordinances accordingly.
- Basic / Alkaline Waste ***Stop Reagent*** (0.5M trisodium phosphate, pH > 10) should be neutralized to pH 6-8 for safe sewer disposal; check your local, regional, national, and international ordinances accordingly.
  In addition, if the final pH measures ≥ 12.5, it requires disposal as a corrosive material in a RCRA approved dangerous waste facility (or equivalent); the US RCRA Waste disposal Code for this waste, if not neutralized, is D002, check your international, national, regional, and local ordinances accordingly.

Do not allow undiluted product or large quantities of it to reach ground water or water course.

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

SECTION 14: TRANSPORT INFORMATION

Shipping of product, packaging, and waste must be conducted in accordance with all applicable local, regional, national, and international 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 Product Multi-Modal Transportation: According to US DOT, IMDG, IATA, and UN "Model Regulations", the product must be transported as follows: No known transport restrictions.

Note: The Waste **STOP Reagent** in this product is potentially corrosive. This STOP solution has been evaluated with the CORROSITEX® test method to determine its corrosive potential and any packing group classification. The results of this testing classified this STOP solution as non-corrosive for shipping purposes.

T**ransport in bulk according to Annex II of MARPOL73/78 and the IBC Code:** Not applicable.

SECTION 15: REGULATORY INFORMATION

Composite HMIS Rating: **Health**: 2 **Flammability**: 0 **Reactivity**: 1

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 (Occupational Health and Safety Administration, U.S. Department of Labor).

National Regulations – Other Domestic / Foreign Laws:

Hazard communication compliance – This SDS contains the required information for preparation in accordance with the following GHS-based global regulations:

1. **United States** – Occupational Safety Health Administration *Hazard Communication Standard* **29 CFR 1910.1200 (*US HCS*)**
2. **Mexico** – **Standard NMX-R-019-SCFI-2011**
3. **European Community** (EC) – applicable ***CLP*** related regulations **(2010/453/EC, 2008/1272/EC, 2006/1907/EC,** etc.)
4. **Canada** – Standard *Workplace Hazardous Materials Information System* (WHMIS-GHS) **Canadian Standard** for the hazard classification criteria for this product.
5. Analogous GHS-based global regulations

United States SARA:

SARA 302 Components: SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components: SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

California Proposition 65: The Product does not contain listed substances.

SECTION 16: OTHER INFORMATION

Hazard statement abbreviation(s):

Acute Tox.	Acute toxicity
Acute Tox. – skn.	Acute toxicity – skin contact
Acute Tox. – ing.	Acute toxicity – ingested (swallowed)
Skin Corr.	Skin corrosion
Eye Damage.	Serious eye damage
Aquatic Acute	Acute aquatic toxicity
Aquatic Chronic	Chronic aquatic toxicity

H300 + H310	Fatal if swallowed or in contact with skin.
H314	Causes severe skin burns and eye damage
H410	Very toxic to aquatic life with long lasting effects
P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P264	Wash thoroughly after handling.
P273	Avoid release to the environment.
P280	Wear protective gloves / protective clothing / eye protection / face protection.*
P301 + P330 + P331	IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P302 + P350	IF ON SKIN: Gently wash with plenty of soap and water.
P303 + P361 + P353	IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
P304 + P340	IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
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	Immediately call a POISON CENTER or doctor/physician.
P363	Wash contaminated clothing before reuse.
P405	Store locked up.
P501	Dispose of contents/container to an approved waste disposal plant.
P501	Dispose of this material and its container to hazardous or special waste collection point.

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.

For *in vitro* diagnostic use.

Sources of key data used to compile the Safety Data Sheet:

Raw Material Vendor Safety Data Sheets
United Nations (UN) Globally Harmonized System (GHS)
United States OSHA Hazard Communication Standard (US HCS) 1910.1200
Canadian Workplace Hazardous Materials Information System (WHMIS)
Mexican Standard (NMX-R-019-SCFI-2011) [regulatory translation and summaries]
European Commission (EC) Regulations 2008/1272/EC, 2010/453/EC, 2006/1907/EC (EC CLP)
Australian Code of Practice – Preparation of Safety Data Sheets for Hazardous Chemicals (Section 274 of the *Work Health and Safety Act*)
New Zealand – Hazardous Substances and New Organisms Act 1996 (HSNO)
The *People's Republic of China* National Standard GB/T 17519-2013, GB 30000-2013 [regulatory translation if available and summaries]
Taiwan Regulation Lao-An-3-Tzu-No. 0960145703 / Published National Standard CNS 15030 [regulatory translation if available / summaries]
Korean Public Notice 2008-26 [regulatory translation if available and summaries]
Japanese Industrial Standard JIS Z7252, JIS Z7253 [regulatory translation if available and summaries]
EU Directives 1999/45/EC, 2001/59/EC, 2001/60/EC, 2006/102/EC
Registry of Toxic Effects of Chemical Substances (RTECS)
Canadian Centre for Occupational Health and Safety (CCOHS) *CHEMINFO databases, etc.*
International Agency for Research on Cancer (IARC)
American Conference of Governmental Industrial Hygienists (ACGIH)
Occupational Safety and Health Administration, U.S. Department of Labor (OSHA)
National Toxicity Program (NTP)
National Institute for Occupational Safety and Health (NIOSH)
World Health Organization. *Laboratory Biosafety Manual*
CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories*

Australian Inventory of Chemical Substances (ACIS) Listing
California *Proposition 65*

Chemical safety assessment: Mixtures covered in this SDS were classified using the US HCS, EC CLP, and/or UN Globally Harmonized System of Classification and Labeling of Chemicals (GHS) Fourth edition unless otherwise specified.

Key / legend to abbreviations and acronyms used in the safety data sheet:
ACGIH – American Conference of Governmental Industrial Hygienists
ACIS – Australian Inventory of Chemical Substances
ANSI – American National Standards Institute
CAS – Chemical Abstracts Service
CCOHS – Canadian Centre for Occupational Health and Safety
CDC – Centers for Disease Control, USA
CNS – Central Nervous System
DGSMA – Dangerous Goods Safety Management Act
DOT – Department of Transportation, USA
EC_{50} – half maximal effective concentration
EC CLP – European Commission regulation for the Classification, Labeling and Packaging of chemical substances and mixtures
EU – European Union
GHS – Globally Harmonized System
HNOC – Hazard Not Otherwise Classified
HSNO – Hazardous Substances and New Organisms Act 1996 (New Zealand)
IARC – International Agency for Research on Cancer
IATA – International Air Transport Association
ICAO - International Civil Aviation Organization
IDLH – Immediately Dangerous to Life or Health
IMDG – International Maritime Dangerous Goods
IPCS – International Programme on Chemical Safety
ISHA – Industrial Safety and Health Act
LC_{50} – median lethal concentration, 50%
LD_{50} – median lethal dose, 50%
MSDS – Material Safety Data Sheet
NIOSH – National Institute for Occupational Safety and Health
NTP – National Toxicity Program
OEL – Occupational Exposure Limit
PEL – Permissible Exposure Limit
ppm – parts per million
RTECS – Registry of Toxic Effects of Chemical Substances
SDS – Safety Data Sheet
STEL – Short Term Exposure Limit
STOT – Specific Target Organ Toxicity
TCCA – Toxic Chemical Control Act
TLV/TWA – Threshold Limit Value / Time-Weighted Average
UN – United Nations
US EPA – United States Environmental Protection Agency, USA
US HCS – Hazard Communication Standard, USA
US OSHA – Occupational Safety and Health Administration, U.S. Department of Labor
WHMIS –Workplace Hazardous Materials Information System, Canada
WHO – World Health Organization (United Nations)

This Revision: Updated, reformatted, and added new GHS information.

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Contact 24h/365d emergency contact: 1-800-424-9300

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