

## SAFETY DATA SHEET (SDS)

### SECTION 1: IDENTIFICATION OF PRODUCT (MIXTURE) AND SUPPLIER

<b>Product Name:</b>	<b>VZV IgG EIA</b>
<b>Product Number:</b>	<b>25180</b> (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: <b>25186, 25190, 25191, and 25192</b> (refer to Section 2).
<b>Intended Use:</b>	For the qualitative and semi-quantitative detection of human IgG antibodies to varicella zoster virus (VZV) in human serum by enzyme immunoassay. Individual serum specimens may be used for the determination of immune status. Paired (acute/convalescent) sera may be used to demonstrate seroconversion or significant rises in antibody level, as an aid in the diagnosis of primary infection, or reactivation of VZV. This assay has not been cleared/approved by the FDA for blood/plasma donor screening. <i>For In Vitro Diagnostic Use Only.</i>
<b>Supplier's Name:</b>	<b>Bio-Rad Laboratories, Inc.</b>
<b>Address:</b>	6565 185th Avenue NE Redmond, WA 98052-5039, USA
<b>Website:</b>	<a href="http://www.bio-rad.com">www.bio-rad.com</a>
<b>Phone Number:</b>	1-800-2-BIORAD (1-800-224-6723); or 1-425-881-8300 (daytime PT)
<b>SDS e-mail contact:</b>	<a href="mailto:ro-sds@bio-rad.com">ro-sds@bio-rad.com</a>
<b>Technical Information Contacts:</b>	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. <i>Refer to section 16 for non-US local Bio-Rad agent contact information.</i>
<b>Emergency Phone Number:</b>	<b>This SDS is listed with CHEMTREC 1-800-424-9300 (US) or 001-703-527-3887 (international – can be called collect).</b> Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION, or ACCIDENT with this product. <i>Refer above and to section 16 for non-US local Bio-Rad agent contact information.</i>

### 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
<b>Coated Wells,</b> 12 eight-well strips	- Coated with VZV antigen (Ellen strain). The antigen is a VZV glycoprotein enriched cell extract. [Color ID: Clear]
Well Support, 1 Frame	- No known hazardous ingredients.
<b>Diluent,</b> 25 mL bottle, (pink color) Catalog #25186	- Phosphate-buffered saline with a protein stabilizer. - Preserved with <b>0.1% sodium azide</b> [NaN <sub>3</sub> ], 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
<b>VZV IgG Calibrator 1</b> , 0.5 mL vial	<ul style="list-style-type: none"> <li>- Normal human serum, Strongly reactive for VZV IgG antibodies. Index or IU/mL values shown on vial label.</li> <li>- Preserved with <b>0.1% sodium azide</b> [NaN<sub>3</sub>], 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</li> </ul>
<b>VZV IgG Calibrator 2</b> , 0.5 mL vial	<ul style="list-style-type: none"> <li>- Normal human serum, Moderately reactive for VZV antibodies. Index or IU/mL values shown on vial label.</li> <li>- Preserved with <b>0.1% sodium azide</b> [NaN<sub>3</sub>], 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.</li> </ul>
<b>VZV IgG Positive Control</b> , 0.5 mL vial	<ul style="list-style-type: none"> <li>- Normal human serum, Reactive for VZV antibodies. Index or IU/mL values shown on vial label.</li> <li>- Preserved with <b>0.1% sodium azide</b> [NaN<sub>3</sub>], 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.</li> </ul>
<b>VZV IgG Negative Control</b> , 0.5 mL vial	<ul style="list-style-type: none"> <li>- Normal human serum, Non-reactive for VZV antibodies.</li> <li>- Preserved with <b>0.1% sodium azide</b> [NaN<sub>3</sub>], 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.</li> </ul>
<b>VZV IgG Conjugate</b> , Two (2) 12 mL bottles (green color)	<ul style="list-style-type: none"> <li>- Goat anti-human IgG labeled with alkaline phosphatase (calf).</li> <li>- Preserved with <b>0.1% sodium azide</b> [NaN<sub>3</sub>], 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.</li> </ul>
<b>Substrate</b> , 12 mL bottle Catalog #25192	<ul style="list-style-type: none"> <li>- Diluted <b>p-Nitrophenyl phosphate</b> [PNPP - C<sub>6</sub>H<sub>6</sub>NO<sub>6</sub>P•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.</li> </ul>
<b>Wash Concentrate</b> , 30 mL bottle Catalog #25190	<ul style="list-style-type: none"> <li>- <b>Tris-buffered saline</b> with <b>Tween 20</b>, pH 8.0. Not subject to GHS, US HCS, EC CLP, and analogous global GHS-based regulatory requirements in this product mixture and concentration.</li> <li>- Preserved with <b>0.1% sodium azide</b> [NaN<sub>3</sub>], 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.</li> </ul>
<b>Stop Reagent</b> , 12 mL bottle Catalog #25191	<ul style="list-style-type: none"> <li>- <b>0.5M Trisodium phosphate</b> [Na<sub>3</sub>PO<sub>4</sub>•12H<sub>2</sub>O], 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.</li> </ul>

\* 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<sub>50</sub>, 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%)	LD <sub>50</sub> (oral-rat): 27 mg/kg (100%)
EC No: 247-852-1 (100%)	LC <sub>50</sub> (inhalation-rat): 37 mg/m <sup>3</sup> (100%)
Index No: 011-004-00-7 (100%)	LD <sub>50</sub> (skin-rat): 50 mg/kg (100%)
RTECS#: VY8050000 (100%)	Fish LC <sub>50</sub> – <i>Lepomis macrochirus</i> (Bluegill) – 0.68 mg/l – 96 h (100%)
Chemical Formula: NaN <sub>3</sub> (100%)	
Molecular weight: 65.01g/mol (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%)	LD <sub>50</sub> (oral-rat): 7400 mg/kg (100%)
EC No: 231-509-8 (100%)	LC <sub>50</sub> (inhalation-rat): No data available (100%)
RTECS#: TC9575000 (100%)	LD <sub>50</sub> (skin-rabbit): No data available mg/kg (100%)
Index No: NE (100%)	LC <sub>50</sub> (96 hr-fish): 2,400 mg/L (100%) – 48H (Leuciscus idus (Golden orfe))
Chemical Formula: Na <sub>3</sub> PO <sub>4</sub> ·12H <sub>2</sub> O (100%)	Flash Point: NS°F / NS°C (100%)
Molecular weight: 380.12 g/mol (100%)	pH value: ~11.9 (1%)
Synonyms/Trade Names: TSP, Phosphoric acid, trisodium salt dodecahydrate	

**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 + P533, P304 + P340, P305 + P351 + P338, P310, P363, P405, P501

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

Biological Ingredient	Data / Information
<p><b>Microwell Coated Plate</b></p>	<p>The microwells in this test kit have been coated with VZV antigen, glycoprotein enriched cell extract (Ellen strain), 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.</p>
<p><b>Human Serum</b> [reactive and non-reactive in the High and Low Positive Control and Negative Control Reagents]</p> 	<p>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.</p> <p>Employ <i>Standard</i> and <i>Universal Precautions</i> 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 <i>Biosafety in Microbiological and Biomedical Laboratories</i> or WHO <i>Laboratory Biosafety Manual</i>. 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, <i>Standard</i> and <i>Universal Precautions</i>. Persons handling blood samples should have the option of receiving hepatitis B vaccination.</p>

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 <b>Stop Reagent</b> 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. <b>OBTAIN MEDICAL ATTENTION.</b>
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 <b>OBTAIN MEDICAL ATTENTION.</b> 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:	<p>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.</p> <p>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.</p> <p>Keep containers tightly closed; avoid splashing, spills, and the generation of aerosols.</p> <p>Handle all human source materials, specimens, and equipment used to perform the operations as though they were capable of transmitting infectious disease, as per <i>Standard and Universal Precautions</i>.</p> <p>All personal protective equipment should be removed before leaving the work area. Refer to Section 8 for more specifics.</p> <p>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.</p> <p>Consult with your Environmental Health &amp; Safety Office for assistance.</p>
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 <i>in vitro</i> diagnostic use.	

**SECTION 8: EXPOSURE CONTROL / PERSONAL PROTECTION MEASURES**

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

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

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

<b>100% Sodium Phosphate, Tribasic, Dodecahydrate (TSP) [CAS# 10101-89-0] - OEL:</b>			
UNITED STATES:	STEL REL-Ceiling	5 mg/m <sup>3</sup>	USA, Workplace Environmental Exposure Levels (WEEL)
<i>[Source: Raw Material Vendor Safety Data Sheet]</i>			

*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**

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

<b>Flash Point:</b>	Not Applicable. Flammable limits: LEL/LFL is <u>Not Applicable</u> ; UEL/UFL is <u>Not Applicable</u>
<b>Evaporation rate:</b>	No applicable information was found.
<b>Fire Hazard:</b>	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.
<b>Vapor Pressure:</b>	No applicable information was found.
<b>Vapor Density:</b>	No applicable information was found.
<b>Relative Density:</b>	Approximately 1.
<b>Solubility:</b>	The liquid chemical components are soluble in water.
<b>Partition coefficient (n-octanol/water):</b>	No applicable information was found.
<b>Auto Igniting:</b>	Product is not known to be self-igniting.
<b>Decomposition temperature:</b>	No applicable information was found.
<b>Viscosity:</b>	No applicable information was found.
<b>Danger of Explosion:</b>	<i>Sodium azide</i> 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.
<b>Molecular mass:</b>	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 <b>basic Stop Reagent</b> to come in contact with strong acids, oxidizing agents, and metals.
Conditions and/or materials to avoid:	Avoid contact with metals. <i>Sodium azide</i> 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:	<b>Stop Reagent</b> – 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 <b>Stop Reagent</b> can severely irritate skin and eyes; prolonged contact may cause eye injury (alkaline Stop reagent).
Serious Eye Damage / Irritation:	<b>Stop Reagent</b> 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:	<p><b>100% Sodium Azide</b> [CAS# 26628-22-8]*:                      Fish LC<sub>50</sub> – <i>Lepomis macrochirus</i> (Bluegill) – 0.68 mg/l – 96 h                      Daphnia EC<sub>50</sub> – <i>Daphnia pulex</i> (Water flea) – 4.2 mg/l – 48 h</p> <p><b>100% Sodium Phosphate, Tribasic, Dodecahydrate (TSP)</b> [CAS# 10101-89-0]:                      TLC<sub>50</sub> (96 hr-fish): 2,400 mg/L (100%) – 48H (<i>Leuciscus idus</i> (Golden orfe))                      * Source: Raw Material Vendor Safety Data Sheet, RTECS and/or CCOHS Cheminfo</p>
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  $\geq 12.5$ , 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<sup>®</sup> 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.

**Transport 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  
DGSM Act – Dangerous Goods Safety Management Act  
DOT – Department of Transportation, USA  
EC<sub>50</sub> – 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<sub>50</sub> – median lethal concentration, 50%  
LD<sub>50</sub> – 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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**Bio-Rad Laboratories:**

**Department issuing SDS:** Environmental Health and Safety.

**Contact for general SDS information:** Seattle Operations, Environmental Health & Safety, 6565 185th Ave. NE, Redmond, WA 98052, USA, Phone: 425-881-8300 (8 am to 5 pm PT), [ro-sds@bio-rad.com](mailto:ro-sds@bio-rad.com)

**Customer support contact:** Clinical Diagnostics Group, 4000 Alfred Nobel Drive, Hercules, CA 94547, USA  
Phone: 1-800-224-6723, [www.bio-rad.com/diagnostics](http://www.bio-rad.com/diagnostics)

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

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