

**SAFETY DATA SHEET (SDS)****SECTION 1: IDENTIFICATION OF PRODUCT (MIXTURE) AND SUPPLIER**

<b>Product Name:</b>	<b>MONOFLUO™ Legionella pneumophila IFA Test Kit</b>
<b>Product Number:</b>	<b>32514</b> (24 Tests) Catalog number(s) for replacement, optional and separately purchased components that can be obtained for use with this kit, and which are covered by this SDS include: <b>32524</b> (refer to Section 2).
<b>Intended Use:</b>	MONOFLUO™ Legionella Immunofluorescent Antibody Test Kit is intended for the detection and identification of <i>Legionella pneumophila</i> in clinical specimens and culture.
<b>Manufactured by:</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>Authorized Representative in the European Community:</b>	<b>FRANCE : Bio-Rad Laboratories</b> 3 boulevard Raymond Poincaré 92430 Marnes-la-Coquette Phone: +33 (0) 1 47 95 60 00 / Fax: +33 (0) 1 47 41 91 33 <a href="mailto:fds-msds.fr@bio-rad.com">[fds-msds.fr@bio-rad.com]</a>
<b>Emergency Phone Number:</b>	<b>This SDS is listed with CHEMTREC 1-800-424-9300 / 001-703-527-3887</b> (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. <i>Refer 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. Refer to Section 16 for the Key / legend to abbreviations and acronyms.

<b>Component *</b>	<b>Content</b>
<b>R1 Anti-Legionella pneumophila Staining Reagent,</b> 1 dropper bottle (1.3 mL)	- FITC- labeled monoclonal antibody in a protein-stabilized (bovine) buffer, pH 9. - ≤ 0.1% Evans blue stain [C <sub>34</sub> H <sub>24</sub> N <sub>6</sub> O <sub>14</sub> S <sub>4</sub> •4Na], CAS# 314-13-6, EC No 206-242-5. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration. - Preserved with 0.01% sodium azide [NaN <sub>3</sub> ], CAS# 26628-22-8 and EC No 247-852-1. Dilution is 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. [Acute toxic Cat. 5 rating: Warning; H303, H313; P312.]

Component *	Content
<b>C1 Positive Control Antigen Suspension,</b> 1 dropper bottle (2.0 mL)  <p style="text-align: center;"><b>WARNING</b></p>	- Killed <i>L. pneumophila</i> in a phosphate buffered saline solution (pH 7 ). - Preserved with <b>0.1% sodium azide</b> [NaN <sub>3</sub> ], CAS# 26628-22-8 and EC No 247-852-1. Dilution is 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. [Acute toxic Cat. 5 rating: Warning; H303, H313; P312.] - Potential trace amount of <b>Formalin</b> (≤ 0.4% formaldehyde, CAS# 50-00-0, EC No 200-001-8 with ≤ 0.1% methanol, CAS# 67-56-1, EC No. 200-659-6) used for <i>L. pneumophila</i> inactivation. NOTE: The <i>Legionella pneumophila</i> positive control was Formalin inactivated, then subsequently thoroughly washed to remove the formalin solution, and though an insignificant trace amount could theoretically remain, it is unlikely to pose a significant adverse health effect (formaldehyde within the formalin solution is listed as TLV A2, NTP 2, and IARC 2A).
<b>R2 Mounting Medium,</b> 1 dropper bottle (4.0 mL)	- Buffered <b>glycerol</b> [50% C <sub>3</sub> H <sub>8</sub> O <sub>3</sub> , EC No 200-289-5, CAS# 56-81-5] with an anti-quencher, pH 9. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration.
<b>R3 Fluorescence Microscopy Slides,</b> 24 (2 wells each) <i>Catalog # 32524</i>	- Fluorescence microscopy slides. - These Collection Slides consist of ~ 98% inert glass with a ~2% inert polymer coating, which have not been chemically or biologically processed since manufacture into new glass slides and thus, should not intrinsically pose a chemical or biological hazard as regulated under CFR 29 §1910.1200 (WA WAC 296-800-170). - Do not handle broken slides with unprotected hands.

\* 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) and European Community (EC) 2008/1272/EC (EC CLP) guidelines and analogous GHS-based global regulation:***

The chemical dilutions in this product are not subject to classification or labeling according *United Nations (UN) GHS, United States Hazard Communication Standard (US HCS), related European Community (EC) 2008/1272/EC (EC CLP) guidelines and applicable analogous GHS-based global regulations.*

- Note: **0.1% Sodium Azide** concentration falls under the UN GHS Cat 5 Acute Toxic which is not recognized in much of the world. [Acute toxic Cat. 5 rating would be: Warning; H303, H313; P312].
- IARC (International Agency for Research on Cancer) Group 3, The Agent is NOT CLASSIFIABLE as Carcinogenic to Humans: **Evans blue**, CAS# 314-13-6, EC No 206-242-5. NOTE: IARC Group 3 classed materials are not considered carcinogenic under GHS. US HCS and EU CLP regulations do not classify this IARC Group 3 classed material as a carcinogen.

**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 (LD50, 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 UN GHS, US HCS, EC CLP and analogous GHS-based global regulation classifications were made according to the latest 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.

**Ingrediente chimico / Dati /informazioni**

**Chemical Ingredient: Sodium azide**

Chemical concentrations found in this product: **0.1% w/v in component R1**

**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> – Lepomis macrochirus (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, Smitte; U-3886;	

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

**DANGER!**

Acute Tox. – oral. 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: Evans Blue**

Chemical concentrations found in this product: **≤0.1% w/v in component R1**

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

CAS#: 314-13-6 (100%)	LD <sub>50</sub> (Intraperitonea-mus): 340 mg/kg (100%)
EC No: 206-242-5 (100%)	LC <sub>50</sub> (inhalation-rat): NE (100%)
RTECS#: QJ6440000 (100%)	LD <sub>50</sub> (skin-rabbit): NE (100%)
Chemical Formula: C <sub>34</sub> H <sub>24</sub> N <sub>6</sub> Na <sub>4</sub> O <sub>14</sub> S <sub>4</sub> (100%)	LC <sub>50</sub> (96 hr-fish): NE (100%)
Molecular weight: 960.81 g/mol (100%)	
IUPAC name: tetrasodium (6E,6'E)-6,6-[(3,3'-dimethylbiphenyl-4,4'-diyl)di(1E)hydrazin-2-yl-1-ylidene]bis(4-amino-5-oxo-5,6-dihydronaphthalene-1,3-disulfonate	
Synonyms/Trade Names: 1,3-Naphthalenedisulfonic acid, 6,6'-((3,3'-dimethyl-4,4'-biphenylene)bis(azo))bis(4-amino-5-hydroxy-, tetrasodium salt; 4,4'-Bis(1-amino-8-hydroxy-2,4-disulfo-7-naphthylazo)-3,3'-bitolyl, tetrasodium salt; 4,4'-Bis(7-(1-amino-8-hydroxy-2,4-disulfo)naphthylazo)-3,3'-bitolyl, tetrasodium salt; 6,6'-[3,3'-Dimethyl(1,1-biphenyl)-4,4'-diyl]bis(azo)-bis-(4-amino-5-hydroxy)-1,3-naphthalenedisulfonic acid, tetrasodium salt; Azovan Blue; Blekit evansa; Diazobleu; Direct Blue 53; Evablin; Geigy-blau 536; Modr Evansova; Modr Prima 53	

**IARC: Group 3 (100%) - "the Agent is NOT CLASSIFIABLE as Carcinogenic"**

**Raw Material GHS / US HCS / EC CLP Classification (100%):** IARC Group 3 classed materials are not considered carcinogenic under GHS. **US HCS** does not classify this IARC Group 3 classed material as a carcinogen.

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

Biological Ingredient	Data / Information
<b>Animal Proteins</b> [≤ 10% v/v in 1]	This material is of animal origin (bovine, marine) and may be a potential contact irritant. Hazard Unknown. Handle as potentially infectious. The chemical, physical and toxicological properties have not been thoroughly investigated. Handle appropriately with the requisite Good Laboratory Practices and <i>Standard and Universal Precautions</i> . Dispose of this material in accordance with local, regional, national and international regulation.
<b>Legionella pneumophila positive control antigen suspension</b>	<p><i>Legionella pneumophila</i> Positive Control Antigen Suspension has been formalin inactivated and is not considered infectious. Handle as if capable of transmitting infectious disease, with <i>Standard and Universal Precautions</i> in a Biosafety Level 2 lab, applying the guidelines from the current CDC/NIH <i>Biosafety in Microbiological and Biomedical Laboratories</i> and WHO <i>Laboratory Biosafety Manual</i>. Employ aseptic technique for personal protection and to avoid product contamination; use of a Biosafety Cabinet (BSC) may be warranted or desired in certain situations. 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 and <i>Standard and Universal Precautions</i>.</p> <p>Potential trace amount of <b>Formalin</b> [≤ 0.4% formaldehyde, EC No 200-001-8, CAS# 50-00-0 with ≤ 0.1% methanol, EC No 200-659-6, CAS# 67-56-1] used for the <i>L. pneumophila</i> inactivation.</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 16 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 following chemical constituents in the kit volumes and concentrations present [chemical or dilution is not subject to GHS, EC CLP or GHS-based hazard labeling]:
  - **50% Glycerol** [C<sub>3</sub>H<sub>8</sub>O<sub>3</sub>], CAS# 56-81-5, EC No 200-289-5. [Component **R2**].
  - **≤ 0.5% EDTA, tetrasodium salt, dihydrate** [C<sub>10</sub>H<sub>12</sub>N<sub>2</sub>O<sub>8</sub>Na<sub>4</sub>•2H<sub>2</sub>O], CAS# 10378-23-1 [Component **R1**].
  - **≤ 0.5% Triton X-100** [C<sub>14</sub>H<sub>22</sub>O(C<sub>2</sub>H<sub>4</sub>O)<sub>n</sub> (n=9-10)], CAS# 9002-93-1 [Component **R1**].
  - The miscellaneous salts, buffers, protein-stabilizers, antibodies, conjugates, water, anti-quencher, or other non-reactive ingredients.
- ◆ 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:	Symptoms of over exposure may include headache, dizziness, congestion and breathing difficulty. May be harmful if swallowed. May be harmful in contact with skin.
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), <i>Universal Precautions</i> 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:	May emit toxic oxides of carbon and nitrogen under fire conditions.
Special Firefighting Procedures:	Conventional firefighting full protective equipment (with NIOSH-approved self-contained breathing apparatus) and procedures appropriate for the surrounding fire should be sufficient.

### 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.
- ◆ Follow established laboratory policy and applicable CDC/NIH biosafety and/or OSHA/WISHA hazardous material spill and/or NFPA/Fire Code guidelines for appropriate hazardous chemical and/or biological material spill response and cleanup. Avoid release to the environment.
- ◆ Wear appropriate PPE. Immediately, and on-site if possible: Decontaminate Biohazard / Human Source Material spills, which should always be treated as potentially infectious, including the area, spill materials and any contaminated surfaces or equipment. Utilize an appropriate chemical decon agent or disinfectant that is effective for the known or potential pathogens relative to the samples involved (commonly a 1:10 dilution of bleach, 70-80% Ethanol or Isopropanol, an iodophor (such as Wescodyne Plus), or a phenolic, etc.).
- ◆ Clean the spill area with water and wipe dry. Spills can also be absorbed with appropriate inert materials (e.g. spill pillows, absorbent pads, etc.), 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.
- ◆ Broken slides contaminated with blood or other human source or potentially infectious material must be handled as **Sharps** per 29 CFR 1910.1030, OSHA Bloodborne Pathogen and other regulations; however, dispose of this material in accordance with local, regional, national and international regulations.  
Slides processed with material that is not of human origin and is not pathogenic to humans, if broken, can typically be handled as normal uncontaminated broken glass labware; however, dispose of this material in accordance with 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.</p> <p>Do not smoke, eat, or drink in areas where patient samples and kit reagents are handled. Wash your hands after use. Follow proper Good Laboratory Practices and safety guidelines for handling chemical, biological and laboratory hazards.</p> <p>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.</p> <p>Handle all human source specimens, materials and equipment used to perform the operations as though they were capable of transmitting infectious disease, as per <i>Standard</i> and <i>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 (e.g. <i>PREPARATION AND STORAGE OF REAGENTS, WARNINGS FOR USERS, PRECAUTIONS FOR USERS</i> ).	
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:** The product does not contain any relevant quantities of materials with critical values that have to be monitored 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
ITALY	TWA	<i>Valore a breve termine: C 0,29 mg/m<sup>3</sup>, C 0,11* ppm A4; sodio azide; *come azido idrazonico, vapore</i>	
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
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

<b>100% Sodium Azide [CAS# 26628-22-8] - OEL:</b>			
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
ARGENTINA, BULGARIA, COLOMBIA, JORDAN, SINGAPORE, VIETNAM		check ACGIH TLV	
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 Raw Material Vendor Safety Data Sheet]</i>			

<b>100% Glycerol [CAS# 56-81-5] - OEL:</b>			
BELGIUM:	TWA	10 mg/m <sup>3</sup>	MAR2002
FINLAND:	TWA	20 mg/m <sup>3</sup>	NOV2011
FRANCE:	VME	10 mg/m <sup>3</sup>	FEB2006
GERMANY:	MAK	50 mg/m <sup>3</sup> , inhal	2011
ITALY:	TWA	10 mg/m <sup>3</sup>	
KOREA:	TWA	10 mg/m <sup>3</sup> (mist)	2006
MEXICO:	TWA	10 mg/m <sup>3</sup> (inhalable)	2004
THE NETHERLANDS:	MAC-TGG	10 mg/m <sup>3</sup>	2003
NEW ZEALAND:	TWA	10 mg/m <sup>3</sup> (mist)	JAN2002
PERU:	TWA	10 mg/m <sup>3</sup>	JUL2005
SWITZERLAND:	MAK-W KZG-W	50 mg/m <sup>3</sup> 100 mg/m <sup>3</sup> , inhal	JAN2011
UNITED KINGDOM:	TWA	10 mg/m <sup>3</sup>	OCT2007
ARGENTINA, BULGARIA, COLOMBIA, JORDAN		check ACGIH TLV	
SINGAPORE, VIETNAM		check ACGIH TLV	
UNITED STATES:	TLV-TWA PEL-T-TWA	10* ppm (*total mist) 15* 5** mg/m <sup>3</sup> (*total dust **respirable fraction)	ACGIH Threshold Limit Values (TLV) OSHA 29,1910.1000 Z-1, 1989
<b>Remarks:</b> Upper Respiratory Tract irritation			
<i>[Source: RTECS September 2013 Update and 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 hazard inhalation, under normal conditions of use and for the time during which the protective equipment is utilized:

Ventilation:	Adequate lab ventilation is required. It is recommended that users handle potentially infectious human source material / patient samples in a biological safety cabinet (BSC), expressly if aerosols might be generated.
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:	Do not breathe mist / vapors/vapours / spray.
Other:	All personal protective equipment should be removed before leaving the work area and placed in an appropriately designated area or container for storage, processing, decontamination or disposal. Protective coverings such as plastic wrap, aluminum foil, or imperviously-backed absorbent pads used to cover equipment and/or surfaces must be removed and replaced if they become overtly contaminated.

**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

<b>Appearance:</b>	Variable, generally aqueous liquids. Exceptions are the solid Slides and related materials. <i>Anti-Legionella pneumophila Staining Reagent:</i> Blue aqueous liquid. <i>Positive Control Antigen Suspension:</i> Clear aqueous liquid. <i>Mounting Media:</i> Clear aqueous liquid. <i>Fluorescence Microscopy Slides:</i> Solid Glass Slides.		
<b>Odor/odour:</b>	No applicable information was found.	<b>Odor/odour Threshold:</b>	Not Established.
<b>pH:</b>	Neutral, pH between 6 and 9		
<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, 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>	Not Established.		
<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>Danger of explosion:</b>	<p><b>Sodium azide</b> 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.</p> <p>Keep <b>Glycerol</b> solutions away from strong oxidizing agents, including sodium hypochlorite (bleach) and potassium permanganate, as could potentially form explosive mixtures.</p>		
<b>Molecular mass:</b>	Mixture		
<b>Viscosity:</b>	Data is not available.		
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.

Stability:	Stable under ordinary conditions of use and storage.
Conditions and/or Materials to Avoid:	<b>Sodium azide</b> 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.
Materials to Avoid:	Keep <b>Glycerol</b> solutions away from strong oxidizing agents, including sodium hypochlorite (bleach) and potassium permanganate, as could potentially form explosive mixtures.
Hazardous Decomposition Products:	May emit toxic oxides of carbon and nitrogen under fire conditions
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

Acute Toxicity:	May be harmful if swallowed. May be harmful in contact with skin.
Primary Irritant Effect:	May slightly irritate eyes or skin, depending on amount and contact time.
Serious Eye Damage / Irritation:	May slightly irritate eyes, depending on amount and contact time.
STOT-Single Exposure:	No applicable information was found.
Aspiration Hazard:	No applicable information was found. Data is not available.
Other Acute Health Effects:	Because these slides are made of glass, they could potentially pose a slight physical cutting hazard, especially if broken or chipped, so handle carefully, wear suitable gloves and/or other appropriate personal protective equipment and follow Good Laboratory Practices. Do not handle broken slides with unprotected hands.

Biohazard Potential:

**Legionella pneumophila** Positive Control Antigen Suspension has been formalin inactivated and is not considered infectious. 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*, the WHO *Laboratory Biosafety Manual* or equivalent. Persons handling blood samples should have the option of receiving hepatitis B vaccination.

Chronic Toxicity

Respiratory or Skin Sensitization:	No sensitization effect known..
Carcinogenicity:	IARC designates <b>Evans Blue</b> (CAS# 314-13-6) in the carcinogen Group 3, which specifies "the Agent is NOT CLASSIFIABLE as Carcinogenic."
Germ Cell Mutagenicity:	No applicable information was found.
Reproductive hazard:	No reproductive toxic effect known.
STOT-Repeated Exposure:	No applicable information was found.

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:	<b>100% Sodium Azide [CAS# 26628-22-8] *:</b> Fish LC <sub>50</sub> - Lepomis macrochirus - 0.68 mg/l - 96 h Daphnia EC <sub>50</sub> - Daphnia pulex (Water flea) - 4.2 mg/l - 48 h <i>* Source: Raw Material Vendor Safety Data Sheet, RTECS and/or CCOHS Cheminfo</i>
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.

*General notes:* Water hazard class 1 (Self-assessment): slightly hazardous for water.

**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 international, national, regional and local ordinances accordingly.
- **Broken slides** contaminated with blood or other human source or potentially infectious material must be handled as **Sharps** per 29 CFR 1910.1030, OSHA Bloodborne Pathogen and other regulations; however, dispose of this material in accordance with local, regional, national and international regulations.

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, IATA and UN “Model Regulations”, the product must be transported as follows: No known transport restrictions.

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

**SECTION 15: REGULATORY INFORMATION**

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

**Carcinogenicity Categories:**

IARC (International Agency for Research on Cancer):

- IARC Group 3, The Agent is NOT CLASSIFIABLE as Carcinogenic to Humans: **Evans Blue**, CAS# 314-13-6.
- IARC Group 3, The Agent is NOT CLASSIFIABLE as Carcinogenic to Humans: **Polyvinyl alcohol**, CAS# 9002-89-5.

NTP (National Toxicity Program): The Product does not contain listed ingredients.

ACGIH TLV-CAR (Threshold Limit Value established by American Conference of Governmental Industrial Hygienists):  
The Product does not contain listed ingredients.

OSHA Subpart Z (Occupational Safety and Health Administration, U.S. Department of Labor): The Product does not contain listed ingredients.

**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. **Taiwan** – Regulation **Lao-An-3-Tzu-No. 0960145703** / Published National Standard **CNS 15030**
3. **People’s Republic of China** – National Standard **GB/T 17519-2013, GB 30000-2013**
4. **New Zealand** – *Hazardous Substances and New Organisms Act 1996 (HSNO), Hazardous Substances (Classification) Regulations 2001 and Thresholds and Classifications January 2012* (as published in 2008)
5. **Mexico** – Standard **NMX-R-019-SCFI-2011**
6. **Korea** – **Public Notice 2008-26** for the hazard classification criteria for this product
7. **Japan** – Industrial Safety and Health Law (ISHL) National Standard **JIS Z7252, JIS Z7253**
8. **European Community (EC)** – applicable **CLP** related regulations (**2010/453/EC, 2008/1272/EC, 2006/1907/EC** etc.)
9. **Canada** – Standard *Workplace Hazardous Materials Information System (WHMIS-GHS) Canadian Standard* for the hazard classification criteria for this product.
10. **Brazil** – Regulation **NRB 14725:2009**
11. **Australia** – Code of Practice *Preparation of Safety Data Sheets for Hazardous Chemicals* under Section 274 of the **Work Health and Safety (WHS) Act**.  
*Australian Inventory of Chemical Substances (AICS):* All pertinent ingredients are listed.
12. Analogous GHS-based global regulations

**Inventory status**

<b>Country(s) or region</b>	<b>Inventory name</b>	<b>In Compliance (yes/no)*</b>
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	Yes
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS) or Europe European List of Notified Chemical Substances (ELINCS)	Yes
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

\* A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

**United States SARA:**

SARA 302 Components: The following components are subject to reporting levels established by SARA Title III, Section 302 in greater quantities than found in this product: **Sodium Azide**, CAS-No. 26628-22-8; Revision Date: 2007-07-01

SARA 313 Components: 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.

**Regulation (EC) No. 1907/2006 (REACH):** Included in the Candidate List of Substances of Very High Concern (SVHC): **None**

**Japan – Industrial Safety and Health Law (ISHL) National Standard JIS Z7252, JIS Z7253**

**Classification JIS – listed in Class 1: Sodium Azide**, CAS-No. 26628-22-8 [No. PRTR Law: 11], product concentration: **≤ 0.1%**.

**Water hazard class:** Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.

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

<b>SECTION 16: OTHER INFORMATION</b>
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**Hazard statement abbreviation(s):**

Acute Tox. – oral.	Acute toxicity – ingested (swallowed)
Acute Tox. – skn.	Acute toxicity – skin contact (dermal)
Skin Irrit.	Skin irritation
Eye Irrit.	Eye irritation
Aquatic Acute	Acute aquatic toxicity
Aquatic Chronic	Chronic aquatic toxicity
Cat.	Category
H300 + H310	Fatal if swallowed or in contact with skin.
H303	May be harmful if swallowed.
H313	May be harmful in contact with skin.
H316	Causes mild skin irritation.
H320	Causes eye irritation.
H410	Very toxic to aquatic life with long lasting effects.
P264	Wash hands thoroughly after handling.
P273	Avoid release to the environment.
P280	Wear protective gloves/ protective clothing.
P302 + P350	IF ON SKIN: Gently wash with plenty of soap and water.
P302 + P352	IF ON SKIN: Wash with plenty of soap and water.
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.
P312	Call a POISON CENTER or doctor/physician if you feel unwell.
P501	Dispose of contents/ container to an approved waste disposal plant.
Caution	Contains inactivated pathogen. Handle as if capable of transmitting potentially infectious agents ( <i>Standard and Universal Precautions</i> ).

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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)  
 European Community (EC) 2008/1272/EC, 2010/453/EC, 2006/1907/EC Regulations  
 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]  
 Canadian Centre for Occupational Health and Safety (CCOHS) CHEMINFO databases, etc.  
 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)  
 National Toxicity Program (NTP)  
 Occupational Safety and Health Administration, U.S. Department of Labor (OSHA)  
 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  
 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 – Dangerous Goods Safety Management Act  
 DOT – Department of Transportation  
 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%  
 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  
US HCS – Hazard Communication Standard, USA  
US OSHA – Occupational Safety and Health Administration, U.S. Department of Labor  
WHMIS – Workplace Hazardous Materials Information System, Canadian  
WHO – World Health Organization (United Nations)

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

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

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