

SAFETY DATA SHEET (SDS)

SECTION 1: IDENTIFICATION OF PRODUCT (MIXTURE) AND SUPPLIER

Product Name: BioPlex 2200 Syphilis Total & RPR Control Set

Product Number: 12000653

Intended Use: The BioPlex 2200 Syphilis Total & RPR Control Set is intended for use as an assayed quality control to monitor the overall performance of the BioPlex 2200 Instrument and BioPlex 2200 Syphilis Total & RPR Reagent Pack in the clinical laboratory. The performance of the BioPlex 2200 Syphilis Total & RPR Control Set has not been established with any other Syphilis assays.

Manufactured by: 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.*


Authorized Representative in the European Community: **FRANCE: Bio-Rad**
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Emergency Phone Number: **This SDS is listed with CHEMTREC 1-800-424-9300 (US) / 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 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. Refer to Section 16 for the full text of any solely abbreviated or coded hazard statements provided below and for the Key / legend to abbreviations and acronyms.

Component	Content
<p>BioPlex 2200 Syphilis Total & RPR Negative Controls - 2 x 1.5 mL</p> <div style="text-align: center;">  WARNING </div>	<ul style="list-style-type: none"> - The negative controls are provided in a human serum matrix made from defibrinated plasma. The negative controls are provided in a human serum matrix made from defibrinated plasma. Normal human serum/plasma that is non-reactive for HBsAg and antibodies to HIV and HCV. - Preserved with $\leq 0.3\%$ ProClin 300 ($\leq 0.009\%$ active ingredient), EC Index No 613-167-00-5 with CAS# 55965-84-9 [GHS \ US HCS \ EC CLP Classification: WARNING; GHS07; H317; P280; P302 + P352, P333 + P313; P501.] - Preserved with $\leq 0.1\%$ sodium benzoate [C₇H₅O₂•Na], CAS# 532-32-1, EC No 208-534-8. Not subject to UN GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration. - Preserved with $< 0.1\%$ sodium azide [NaN₃], CAS# 26628-22-8 and EC No 247-852-1. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration.

Component	Content
BioPlex 2200 Syphilis Total & RPR Positive Controls - 4 x 1.5 mL  WARNING	<ul style="list-style-type: none"> - The positive controls are provided in a human serum matrix made from defibrinated plasma, two vials with known analyte concentrations of <i>Treponema pallidum</i> antibody and two vials with known analyte concentrations of human reagin antibody, derived from human disease state plasma. Analytes: Antibodies to <i>Treponema pallidum</i> and reagin. - Each human donor unit used to manufacture this product was tested by FDA accepted methods and found non-reactive for Hepatitis B Surface Antigen (HBsAg), antibody to hepatitis C (HCV) and antibody to HIV-1/HIV-2. - Preserved with ≤ 0.3% ProClin 300 (≤ 0.009% active ingredient), EC Index No 613-167-00-5 with CAS# 55965-84-9 [GHS \ US HCS \ EC CLP Classification: WARNING; GHS07; H317; P280; P302 + P352, P333 + P313; P501.] - Preserved with ≤ 0.1% sodium benzoate [C₇H₅O₂•Na], CAS# 532-32-1, EC No 208-534-8. Not subject to UN GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration. - Preserved with < 0.1% sodium azide [NaN₃], CAS# 26628-22-8 and EC No 247-852-1. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration.

Markings according to the United Nations (UN) Globally Harmonized System (GHS), United States Hazard Communication Standard (US HCS) and European Community (EU) 2008/1272/EC (EC CLP) guidelines and analogous GHS-based global regulation: This product has been conservatively classified and labeled in accordance with applicable United Nations (UN) GHS, United States Hazard Communication Standard (US HCS) and related European Community (EC) 2008/1272/EC (EC CLP) guidelines and applicable analogous GHS-based global regulation. The following regulated hazardous chemical concentrations are found in product component(s):

≤ 0.3% ProClin 300 [≤ 0.009% active ingredients – reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one (C₄H₄CINOS; CAS# 26172-55-4, EC No 247-500-7) and 2-methyl-2H -isothiazol-3-one (C₄H₅NOS; CAS# 2682-20-4, EC No 220-239-6) (3:1)], EC Index No 613-167-00-5 with CAS# 55965-84-9.

Comprehensive GHS Based Classification: Skin Sensitizer Category 1



Label(s): GHS07
Signal Word: WARNING
Label Hazard Statement: H317: May cause an allergic skin reaction.

Precautionary Statements (statements for product intended use and as codified on the product label):

P280 Wear protective gloves / protective clothing / eye protection / face protection.
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P501 Dispose of contents and container in accordance to local, regional, national, and international regulations.

Supplemental Precautionary Statements (additional precautions to consider relative to specific customer use):

P261 Avoid breathing mist / vapours / spray.
P272 Contaminated work clothing should not be allowed out of the workplace.

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

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].

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 existing editions and expanded upon from company and literature data. Refer to section 16 for the full text of any *Comprehensive GHS-based Classification* statements coded below, for the list of sources utilized in the assessment and for the Key / legend to abbreviations and acronyms.

Chemical Ingredient Data / Information

Chemical Ingredient: ProClin 300

Chemical concentrations found in this product: **≤ 0.3% (≤ 0.009% active ingredient)**

Hazardous ingredient concentration in raw material:

60-100% Glycols;

1-5% Mixture (3:1) of 5-Chloro-2-methyl-4-isothiazolin-3-one (C₄H₅NOS; CAS# 2682-20-4, EC# 220-239-6)
 and **2-Methyl-2H -isothiazol-3-one** (C₄H₄ClNOS; CAS# 26172-55-4, EC# 247-500-7)
 CAS#: 55965-84-9
 Index No: 613-167-00-5

Data for chemical used in the product (concentration tested):

RTECS#: NE

Synonyms/Trade Names: **Synonyms/Trade Names:** 5-Chloro-2-methyl-4-isothiazolin-3-one solution; Kathon 300; Isothiazolinone chloride solution

pH value: 4.1 at 100 g/L (concentrated solution)

Flash Point: 244° F / 118° C (concentrated solution)

LD₅₀ (oral-rat): 862 mg/kg (concentrated solution)

LD₅₀ (skin-rabbit): 2,800 mg/kg (concentrated solution)

LC₅₀ (inhalation-rat): NE

LD₅₀ (skin-rabbit): NE

Skin corrosion/irritation - rabbit – Corrosive (concentrated solution)

Serious eye damage/eye irritation - rabbit - Corrosive to eyes (concentrated solution)

Respiratory or skin sensitization - May cause allergic skin reaction (concentrated solution)

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

DANGER!

Acute Tox. – inh. Cat. 4, Skin Corr. Cat. 1B, Eye Damage Cat. 1,

Skin Sens. Cat. 1, Aquatic Acute Cat. 1, Aquatic Chronic Cat. 1

H302, H314, H317, H410

P261, P264, P270, P272, P273, P280, P301 + P312 + P330, P301 + P330 + P331,

P303 + P361 + P353, P305 + P351 + P338 + P310, P333 + P313, P363, P391, P405, P501



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

Chemical Ingredient Data / Information

Chemical Ingredient: Sodium azide

Chemical concentrations found in this product: **< 0.1% in aqueuous solution**

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

CAS#: 26628-22-8 (100%)	LD ₅₀ (oral-rat): 27 mg/kg (100%)
EC No: 247-852-1 (100%)	LC ₅₀ (inhalation-rat): 37 mg/m ³ (100%)
Index No: 011-004-00-7 (100%)	LD ₅₀ (skin-rat): 50 mg/kg (100%)
RTECS#: VY8050000 (100%)	Fish LC ₅₀ – Lepomis macrochirus (Bluegill) – 0.68 mg/l – 96 h (100%)
Chemical Formula: NaN ₃ (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]

Biological Ingredient	Data / Information
<p>Human Serum [reactive and-non-reactive]</p> <div style="text-align: center;"> </div>	<p>The human source material used to make the Positive Controls has been tested and certified non-reactive for HBsAg, and antibodies to HCV and HIV-1/HIV-2, but has not been verified to be free of <i>Treponema pallidum</i> antigens. The Human sera in the components of this product were tested and found non-reactive for hepatitis B surface antigen (HBsAg) and antibodies to hepatitis C virus (HCV) and human immunodeficiency virus (HIV-1 and HIV-2) by FDA approved methods. 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 <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 or equivalent</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 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.
- ◆ 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 overexposure may include headache, dizziness, and congestion. May cause allergic skin reaction upon repeated exposure, generally at concentrations and volumes that greatly exceed that of this kit.
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:	Carbon oxides, nitrogen oxides (NO _x), Sulphur oxides, Hydrogen chloride gas, Magnesium oxide.
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.
- ◆ Prevent material from entering sewers, waterways or confined spaces.
- ◆ 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), 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 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>. 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 & Safety Office for assistance.</p>
Storage:	Store the kit components as specified on the product label and/or in the product instructions provided with the test kit.
Caution, read accompanying documents. Refer to the <i>Instructions For Use / Package Insert</i> for additional product information. Read and follow <i>BioPlex 2200 System Instrument Manual</i> instructions.	
This product is intended for use with the Bio-Rad BioPlex 2200 System.	

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.

Concentrated Active Ingredient ratio in ProClin 300 [CAS# 55965-84-9] - OEL:			
GERMANY:	MAK	0.2 mg/m ³ , inhal	2011
THE NETHERLANDS:	MAC-TGG	0.2 mg/m ³	2003
SWITZERLAND:	MAK-W KZG-W	0.2 mg/m ³ 0.4 mg/m ³ , inhal, sen	JAN2011
<i>[Source: RTECS September 2013 Update and Raw Material Vendor Safety Data Sheet]</i>			

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/m ³ , 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

100% Sodium Azide [CAS# 26628-22-8] - OEL:			
ITALY	TWA	<i>Valore a breve termine: C 0,29 mg/m³, C 0,11* ppm A4; sodio azide; *come azido idrazonico, vapore</i>	
KOREA:	CL	0.1 ppm (0.3 mg/m ³)	2006
THE NETHERLANDS:	MAC-TGG	0.1 mg/m ³ , skin	2003
NEW ZEALAND:	CL	0.11 ppm (0.29 mg/m ³)	JAN2002
PERU:	TWA	0.1 mg/m ³	JUL2005
	STEL	0.29 mg/m ³	
SWEDEN:	TWA	0.1 mg/m ³	JUN2005
	STEL	0.3 mg/m ³ , Skin	
SWITZERLAND:	MAK-W	0.2 mg/m ³	JAN2011
	KZG-W	0.4 mg/m ³ , inhal	
UNITED KINGDOM:	TWA	0.1 mg/m ³	OCT2007
	STEL	0.3 mg/m ³ , skin	
ARGENTINA, BULGARIA, COLOMBIA, JORDAN, SINGAPORE, VIETNAM		check ACGIH TLV	
UNITED STATES:	TLV-TWA-Ceiling	0.11* ppm / 0.29** mg/m ³	ACGIH, 1996, 2013 NIOSH Recommended Exposure Limits *as HN ₃ vapor; **as NaN ₃ ; Skin
	REL-Ceiling	0.1* ppm / 0.3** mg/m ³	
<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 hazardous 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.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Amber/yellow liquid.		
Odor/odour:	No applicable information was found.	Odor/odour threshold:	Not established.
pH:	The liquid chemical components are between pH 6 and 8.		
Boiling point:	Undetermined.	Melting point:	Undetermined.

Flash point:	Not Applicable. Flammable limits: LEL/LFL is <u>Not applicable</u> ; UEL/UFL is <u>Not applicable</u> .
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/vapour pressure:	No applicable information was found.
Vapor/vapour density:	No applicable information was found.
Relative density:	Undetermined.
Solubility:	Miscible 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:	<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.
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.
Conditions and/or Materials to Avoid:	<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..
Hazardous Decomposition Products:	Hazardous decomposition products formed under fire conditions: Carbon oxides, nitrogen oxides (NOx), Sulphur oxides, Hydrogen chloride gas, Magnesium oxide.
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 detrimental if enough is ingested (typically in quantities above those found in the kit).
Primary Irritant Effect:	May slightly irritate respiratory system, 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.
Other Acute Health Effects:	No significant other acute health effect known.

Biohazard Potential:

The human source material used to make the **Positive Controls** has been tested and certified / found non-reactive for HBsAg, and antibodies to HCV and HIV-1/HIV-2, but has not been verified to be free of *Treponema pallidum* antigens. This product may also contain other human agents capable of transmitting infectious disease. In accordance with good laboratory practice, all human source material should be considered potentially infectious and handled with the same precautions used with patient specimens. Each human donor unit used to manufacture this product was tested by FDA accepted methods and found non-reactive for Hepatitis B Surface Antigen (HBsAg), antibody to hepatitis C (HCV) and antibody to HIV-1/HIV-2. 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 *Laboratory Biosafety Manual* or equivalent. Persons handling blood samples should have the option of receiving hepatitis B vaccination.

Chronic Toxicity

Respiratory and Skin Sensitization:	May cause an allergic skin reaction. Contains a small volume of a very dilute, sensitizing preservative (ProClin 300); though the potential for an allergic response is greatly reduced by the dilution, sensitization threshold is unknown, thus handle accordingly.
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.
STOT-Repeated Exposure:	No applicable information was found.

Additional Toxicological Information: The chemical, physical and toxicological properties have not been thoroughly investigated.

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 - <i>Lepomis macrochirus</i> - 0.68 mg/l - 96 h Daphnia EC ₅₀ - <i>Daphnia pulex</i> (Water flea) - 4.2 mg/l - 48 h <i>* Source: Raw Material Vendor Safety Data Shee, 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.

- 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.

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 Unused 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: 2 Flammability: 0 Reactivity: 0

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).
2008/1272/EC (EC CLP): Not listed

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:

- United States** – Occupational Safety Health Administration *Hazard Communication Standard 29 CFR 1910.1200 (US HCS)*
- Taiwan** – Regulation *Lao-An-3-Tzu-No. 0960145703* / Published National Standard **CNS 15030**
- People’s Republic of China** – National Standard **GB/T 17519-2013, GB 30000-2013**
- 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)
Composite HSNO Hazard Class: Subclass 6.5 Category B (contact sensitizers)
- Mexico** – **Standard NOM-018-STPS-2015, NMX-R-019-SCFI-2011**
- Korea** – **Public Notice 2016-19, 2013-37 Standard for Classification and Labeling of Chemical Substances and Material Safety Data Sheets**
- Japan** – Industrial Safety and Health Law (ISHL) National Standard **JIS Z7252, JIS Z7253**
- European Community (EC)** – applicable **CLP** related regulations (**2010/453/EC, 2008/1272/EC, 2006/1907/EC** etc.)
- Canada** – Hazardous Products Regulations (HPR) / Standard *Workplace Hazardous Materials Information System (WHMIS-GHS) Canadian Standard* for the hazard classification criteria for this product.
Composite WHMIS Hazards: Skin Sensitization
- Brazil** – Regulation **NRB 14725**
- Australia** – Code of Practice *Preparation of Safety Data Sheets for Hazardous Chemicals* under Section 274 of the **Work Health and Safety (WHS) Act**.
- Analogous GHS-based global regulations

Inventory status

Country(s) or region Inventory name	In Compliance (yes/no)*
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
Taiwan inventory (CSNN):	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)

Regulation (EC) No. 1907/2006 (REACH):

Chemicals included in the Candidate List of Substances of Very High Concern (SVHC): **None**

REACH No.: A registration number is not available for this substance as the substance or its uses are exempted from registration, the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline.

United States SARA:

SARA 302 (extremely hazardous substance) components: The following components are subject to reporting levels established by SARA Title III, Section 302: **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.

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

Classification JIS – listed in Class 1 - Listed substances: **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.

SECTION 16: OTHER INFORMATION

Hazard statement abbreviation(s):

Acute Tox. – oral.	Acute toxicity – ingested (swallowed)
Acute Tox. – skn.	Acute toxicity – skin contact (dermal)
Acute Tox. – inhl.	Acute toxicity – inhaled
Skin Corr.	Skin corrosion
Eye Damage.	Serious eye damage
Skin Sens.	Skin sensitisation
Aquatic Acute	Acute aquatic toxicity
Aquatic Chronic	Chronic aquatic toxicity
Cat.	Category
H300 + H310	Fatal if swallowed or in contact with skin.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H410	Very toxic to aquatic life with long lasting effects.
P261	Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P264	Wash hands thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P272	Contaminated work clothing should not be allowed out of the workplace.
P273	Avoid release to the environment.
P280	Wear protective gloves/ protective clothing/ eye protection/ face protection.
P301 + P312 + P330	IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell. Rinse mouth
P301 + P330 + P331	IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
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.
P303 + P361 + P353	IF ON SKIN (or hair): Remove/ Take off immediately all contaminated clothing. Rinse skin with water/ shower.
P305 + P351 + P338 + P310	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/ physician.
P310	Immediately call a POISON CENTER or doctor/ physician.

P333 + P313	If skin irritation or rash occurs: Get medical advice/ attention.
P363	Wash contaminated clothing before reuse.
P391	Collect spillage.
P405	Store locked up.
P501	Dispose of contents and container in accordance to local, regional, national and international regulations.
P501	This material and its container must be disposed of as hazardous waste.

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.

This product is intended for use with the Bio-Rad BioPlex 2200 System.

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.

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]
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*
 PAN Pesticides Database – *Chemical Studies on Aquatic Organisms*
 CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories*
Australian Inventory of Chemical Substances (ACIS) Listing
 California Proposition 65

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 – Dangerous Goods Safety Management Act
 DOT – Department of Transportation, USA
 EC₅₀ – 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
 HNO – 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
 LC₅₀ – median lethal concentration, 50%
 LD₅₀ – 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, 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)

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

This Revision: New Safety Data Sheet (SDS).

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