



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

Product Name:	BioPlex 2200 HIV Ag-Ab Calibrator Set (RxOnly)
Product Number:	663-3405 (3 x 0.8 mL)
Intended Use:	The BioPlex 2200 HIV Ag-Ab Calibrator Set is intended for the calibration of the BioPlex 2200 HIV Ag-Ab assay.
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. <i>Refer to section 16 for non-US local Bio-Rad agent contact information.</i>
Canadian Importer:	<i>Canada:</i> Bio-Rad Laboratories, Ltd. 2403 Gu�nette Street, Montr�al Qu�bec H4R 2E9 Phone 1-514-334-4372 Emergency number (24h/365d): 1-514-334-4372 CHEMTREC: 1-800-424-9300 or 1-703-527-3887
Emergency Phone Number:	This SDS is listed with CHEMTREC 1-800-424-9300 or 1-703-527-3887 (US/CA) / +1-703-741-5970 (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. 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
<p>HIV-1/HIV-2 Antibody Calibrator BioPlex 2200 Three (3) 0.8 mL vials</p>  <p>WARNING</p>	<ul style="list-style-type: none"> - Heat-treated Human serum/plasma containing HIV-1 and HIV-2 immunoglobulin, non-reactive for HBsAg and antibody to HCV. human antibodies to HIV-1 Group M and HIV-2, and purified rabbit antibody to HIV-1 Group O in Tris buffer [CAS# 77-86-1], protein stabilizer (bovine, CAS# 9048-46-8). Human plasma used in preparing this control has been inactivated. - < 1% Sodium chloride [NaCl], CAS# 7647-14-5, EC No 231-598-3. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration. - 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, H412; P273, 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 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.
<p>HIV Antigen Calibrator BioPlex 2200 Three (3) 0.8 mL vials</p>  <p>WARNING</p>	<ul style="list-style-type: none"> - Purified HIV-1 p24 antigen (from viral lysate inactivated with a chaotropic agent) in a Tris buffer [CAS# 77-86-1] with protein stabilizer (bovine CAS# 9048-46-8). - < 1% Sodium chloride [NaCl, CAS# 7647-14-5, EC No 231-598-3]. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration. - 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, H412; P273, 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 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 Commission (EC) 2008/1272/EC (EC CLP) guidelines and analogous GHS-based global regulations:

This product has been conservatively classified and labeled in accordance with applicable *United Nations (UN)* GHS, *United States Hazard Communication Standard (US HCS)*, related *European Commission (EC) 2008/1272/EC (EC CLP)* guidelines and applicable analogous GHS-based global regulations. 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):

Signal Word:

WARNING

Label Hazard Statement:

H317 May cause an allergic skin reaction.

H412 Harmful to aquatic life with long lasting effects.

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

P273 Avoid release to the environment.
 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]_

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)**

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

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

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

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

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

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

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)

OECD TG 429 (LLNA (2000a)): SI ≥ 3 for all concentrations; EC3 value of ≤ 2 (0.003%) – Positive, Skin Sens. Cat. 1A

OECD TG 429 (LLNA (2000b)): SI ≥ 3 from 70ppm; EC3 value of ≤ 2 (0.007%) – inconclusive

GPMT (2000a): OECD TG 416, GLP – Negative

GPMT (2000b): OECD TG 416, GLP – Positive

Buehler (1982): GLP 9/15 animals responded to an induction concentration of 0.01% - Positive, Skin Sens. Cat. 1A

Open Epicutaneous Test (2001) - Positive, Skin Sens. Cat. 1

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

DANGER!

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

Aquatic Acute Cat. 1, Aquatic Chron. 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: Sodium azide

Chemical concentrations found in this product: **≤ 0.1% w/v in an aqueous solution**

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

CAS#: 26628-22-8 (100%)

LD₅₀ (oral-rat): 27 mg/kg (100%)

EC No: 247-852-1 (100%)

LC₅₀ (inhalation-rat): 37 mg/m³ (100%)

Index No: 011-004-00-7 (100%)

LD₅₀ (skin-rat): 50 mg/kg (100%)

RTECS#: VY8050000 (100%)

Fish LC₅₀ – Lepomis macrochirus (Bluegill) – 0.68 mg/l – 96 h

Chemical Formula: NaN₃ (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. – oral. Cat. 2, Acute Tox. – skn. Cat. 1, Aquatic Acute Cat. 1, Aquatic Chron. 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
Animal proteins	This material is of animal origin (bovine and rabbit) 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, <i>Standard</i> and <i>Universal Precautions</i> . Dispose of this material in accordance with local, regional, national and international regulation.
Inactivated HIV-1 virus and Human Serum [reactive] 	Antigen Calibrator contains Inactivated Human Immunodeficiency Virus, type 1 (HIV-1) though verified to be non-infectious. Antibody Calibrator was heat-treated to inactivate the HIV. Human sera in reagents were tested and found non-reactive for Hepatitis B surface antigen and antibodies to HCV. 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</i> or equivalent. Persons handling blood samples should have the option of receiving hepatitis B vaccination.

NA: Not Applicable.

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

Related product information:

- ◆ Refer to section 16 for the full text of any *Comprehensive GHS-based Classification* statements, for the list of sources utilized in the assessment and for the key / legend to abbreviations and acronyms.
- ◆ No significant adverse health effects are expected by any route for the miscellaneous salts, Tris buffer, buffers, protein-stabilizers, water, sodium benzoate, catalytic or other non-reactive ingredients, in the kit volumes and/or concentrations present [chemical or dilution is not subject to EC CLP, US HCS or other GHS-based 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:	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:	Oxides of carbon or nitrogen may form when heated to decomposition.
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 WHO/CDC/NIH biosafety and/or WHO/OSHA hazardous material and/or equivalent 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 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 & 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, consult accompanying documents. Read and follow all the precautions and warnings in the kit product instructions for use. Read and follow *BioPlex® 2200 System Instrument Manual* 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	0.2 mg/m ³	
	KZG-W	0.4 mg/m ³ , inhal, sen	2011
<i>[Source: CCOHS CHEMINFO 2013, 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)	2008
AUSTRIA:	MAK-TMW	0.1 mg/m ³	
	KZW	0.3 mg/m ³ , skin	2007
BELGIUM:	TWA	0.1 mg/m ³ ,	
	STEL	0.3 mg/m ³ , skin	2002
DENMARK:	TWA	0.1 mg/m ³ , skin	2011
EC (European Union):	TWA	0.1 mg/m ³	
	STEL	0.3 mg/m ³ , skin	2000
FINLAND:	TWA	0.1 mg/m ³	
	STEL	0.3 mg/m ³ , skin	2011
FRANCE:	VME	0.1 mg/m ³	
	VLE	0.3 mg/m ³ , Skin	2006
GERMANY:	MAK	0.2 mg/m ³ , inhal	2011
HUNGARY:	TWA	0.1 mg/m ³	
	STEL	0.3 mg/m ³	2000
ICELAND:	TWA	0.1 mg/m ³	
	STEL	0.3 mg/m ³ , skin	2011
ITALY	TWA	C 0.29 mg/m ³ , C 0.11* ppm	*sodium azide, vapor
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)	2002
PERU:	TWA	0.1 mg/m ³	
	STEL	0.29 mg/m ³	2005
SWEDEN:	TWA	0.1 mg/m ³	
	STEL	0.3 mg/m ³ , Skin	2005
SWITZERLAND:	MAK-W	0.2 mg/m ³	
	KZG-W	0.4 mg/m ³ , inhal	2011
UNITED KINGDOM:	TWA	0.1 mg/m ³	
	STEL	0.3 mg/m ³ , skin	2007
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
	REL-Ceiling	0.1* ppm / 0.3** mg/m ³	NIOSH Recommended Exposure Limits *as HN ₃ vapor; **as NaN ₃ ; Skin

100% Sodium Azide [CAS# 26628-22-8] - OEL:
[Source: CCOHS CHEMINFO 2013, RTECS September 2013 Update and Raw Material Vendor Safety Data Sheet]

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

The following personal protective equipment (PPE) is recommended to prevent blood or other potentially infectious or hazardous materials from reaching the user's work or street clothes, skin, mouth, mucous membranes and eyes, or hazardous inhalation, under normal conditions of use and for the time during which the protective equipment is utilized:

Ventilation:	Adequate lab ventilation is required. 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.
Note:	Occupational Exposure limit values and health hazard data were given in section 3. Environmental Controls are included in following sections.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Amber/yellow liquid.		
Odor/odour:	No applicable information was found.	Odor/odour threshold:	Not established.
pH:	Neutral, pH between 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, 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:	Approximately 1.		
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.			
<i>Source: Raw Material vendor SDS, CCOHS databases and/or regulatory research</i>			

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:	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.
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

Acute Toxicity:	May be detrimental if enough is ingested (typically in quantities above those found in the kit).
Primary Irritant Effect:	Not generally considered an irritant. May slightly irritate eyes or skin, depending on amount and contact time.
Serious Eye Damage / Irritation:	Not generally considered an irritant. 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:

Antigen Calibrator - Inactivated HIV virus, though verified to be non-infectious, should be handled with Standard and Universal Precautions, as if capable of transmitting infectious disease. **Antibody Calibrator** - The human sera in the components was tested and found non-reactive for HBsAg and antibodies to HCV. 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. 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 or Skin Sensitization:	Skin Sensitizer Category 1. Contains a small volume of a very dilute, sensitizing preservative (<i>ProClin 300</i>); sensitization possible through skin contact. Prolonged or repeated exposure may cause allergic reaction in certain sensitive individuals.
Carcinogenicity:	No carcinogenic effect known. No component, mixture or constituent has been classified as a carcinogen by NTP, IARC, 2008/1272/EC (EC CLP) 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:	<p>100% Sodium Azide [26628-22-8]*: Fish LC₅₀ - Lepomis macrochirus - 0.68 mg/l - 96 h Daphnia EC₅₀ - Daphnia pulex (Water flea) - 4.2 mg/l - 48 h</p> <p>Concentrated ProClin 300 / 150 (reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one (CAS# 26172-55-4, EC No 247-500-7) and 2-methyl-2H -isothiazol-3-one (CAS# 2682-20-4, EC No 220-239-6) (3:1), EC Index No 613-167-00-5 with CAS# 55965-84-9)**: Fish LC₅₀ – Lepomis macrochirus (US EPA FIFRA 72-1, flow-through mm) – 0.28 mg a.s. /L – 96 h Fish LC₅₀ – Oncorhynchus mykiss (OECD TG 203, static) – 0.22 mg a.s. /L – 96 h Fish LC₅₀ – Oncorhynchus mykiss (OECD TG 204, flow-through mm) – 0.09 mg a.s. /L – 14 d h Fish 36-d NOEC – Pimephales promelas (US EPA FIFRA 72-4, flow-through mm) – 0.02-0.12 a.s. /L Fish 28-d NOEC – Oncorhynchus mykiss (OECD TG 215, semi-static nom) – 0.098 a.s. /L Daphnia EC₅₀ – Daphnia magna (US EPA 72-2, flow-through mm) – 0.16 mg a.s. /L – 48 h Daphnia EC₅₀ – Daphnia magna (US EPA 72-4, semi-static mm) – 0.10 mg a.s. /L – 21 d</p> <p><i>* Source: Raw Material Vendor Safety Data Sheet, RTECS, CCOHS databases and/or regulatory research</i> <i>** Source: ECHA RAC report for CAS#55965-84-9 [10 March 2016]</i></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.

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 procedure.

Recommended Unused Product Multi-Modal Transportation: According to IATA, ADG, ADN, ADR, DOT, IMDG, TDG 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), OSHA (Occupational Health and Safety Administration, U.S. Department of Labor) or 2008/1272/EC (EC CLP).

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** – OSHA Published National Standard **CNS 15030** Classification and Labelling of Chemicals
- Singapore** – SS 586 - 2 : 2014
- Russia** – GOST 31340-2013, GOST 32419-2013, GOST 32423-2013, GOST 32424-2013, GOST 32425-2013, R 50.1.102-2014, R 50.1.101-2014
- People’s Republic of China** – National Standard **GB/T 17519-2013, GB 30000-2013**
- New Zealand** – *Hazardous Substances and New Organisms Act (HSNO)*
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 2013-37, MoEL 2016-19, Standard for classification and labeling of chemical substances and MSDS*
- Japan** – Industrial Safety and Health Law (ISHL) National Standard **JIS Z7252, JIS Z7253**
- European Commission (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 **ABNT 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
European Union	European Inventory of Existing Commercial Chemical Substances (EINECS) or 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 (Superfund Amendments and Reauthorization Act of 1986):

SARA 302 (extremely hazardous substance) 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# 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# 26628-22-8 [No. PRTR Law: 11], product concentration: **≤ 0.1%**.

Classification JIS – listed in Class 2 - Listed substances: None

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

California Proposition 65 (California Safe Drinking Water and Toxic Enforcement Act of 1986):

The Product does not contain listed substances.

SECTION 16: OTHER INFORMATION

Hazard statement abbreviation(s):

Acute Tox. – oral.	Acute toxicity – ingested (swallowed)
Acute Tox. – inhl.	Acute toxicity – inhaled
Acute Tox. – skn.	Acute toxicity – skin contact (dermal)
Skin Corr.	Skin corrosion
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 + H332	Harmful if swallowed or if inhaled
H313	May be harmful in contact with skin.
H317	May cause an allergic skin reaction.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful 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	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.
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	Dispose of contents/ container to an approved waste disposal plant.
Caution	Contains human source material. Handle as if capable of transmitting potentially infectious agents (<i>Standard and Universal Precautions</i>).

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) Fifth 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 (NOM-018-STPS-2015, 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 (HSNO)
The People's Republic of China National Standard GB/T 17519-2013, GB 30000-2013 [regulatory translation if available and summaries]
Taiwan OSHA Published National Standard CNS 15030 [regulatory translation if available / summaries]
Korean MoEL-Public Notice 2016-19, 2013-37 [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*
 CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories*
 PAN Pesticides Database – *Chemical Studies on Aquatic Organisms*
Australian Inventory of Chemical Substances (AICS) Listing
 California Proposition 65

Key / legend to abbreviations and acronyms used in the safety data sheet:

ACGIH – American Conference of Governmental Industrial Hygienists
 AICS – 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%
 MSDS – Material Safety Data Sheet

NIH – National Institute of Health
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: Added H412 and P273 to ProClin 300 data (sections 1 & 2)..

Preparation date: Refer to date in the footer.

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

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

Emergency Contact (24h/365d) – Chemtrec:: 1-800-424-9300 or 1-703-527-3887 (USA/CAN) / +1-703-741-5970 (international – can be called collect).

American Association of Poison Control Centers call (800) 222-1222 (24h/365d)

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