SAFETY DATA SHEET (SDS)

SECTION 1: IDENTIFICATION OF PRODUCT (MIXTURE) AND SUPPLIER

Product Name:	**BioPlex® 2200 System 25-OH Vitamin D Reagent Pack**
Product Number:	**665-3750** (200 tests)
Intended Use:	The BioPlex® 2200 25-OH Vitamin D assay is a multiplex flow competitive immunoassay intended for the quantitative determination of 25-hydroxyvitamin D in human serum. The BioPlex 2200 25-OH Vitamin D assay is to be used as an aid in the assessment of vitamin D sufficiency. The BioPlex 2200 25-OH Vitamin D kit is intended for use with the Bio-Rad BioPlex 2200 System
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* 3 boulevard Raymond Poincaré 92430 Marnes-la-Coquette Phone: +33 (0) 1 47 95 60 00 / Fax: +33 (0) 1 47 41 91 33 [fds-msds.fr@bio-rad.com]
Emergency Phone Number:	**This SDS is listed with CHEMTREC 1-800-424-9300 / 1-703-527-3887.** 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. Refer to Section 16 for the full text of any *Risk (R)* and *Safety (S)* statement provided below.

Component	Content
Bead Set **BioPlex 2200** **25-OH Vitamin D** 1 x 10 mL vial (Faint brown liquid)	- Dyed beads coated with anti-25-OH Vitamin D, an Internal Standard bead (ISB), a Serum Verification bead (SVB) in phosphate buffer with protein stabilizers (bovine, CAS# 9007-83-4) (pH 7.4). - **50-100% water** [H_20] CAS# 7732-18-5, EC No 231-791-2. [Not subject to GHS, US HCS and EU 2008/1272/EC regulatory requirements.] - **< 1% Sodium chloride** [NaCl], CAS# 7647-14-5, EC No 231-598-3. [Not subject to GHS, US HCS and EU 2008/1272/EC regulatory requirements.] - Preserved with **< 1% ProClin 950** containing < 0.1% active ingredient: 9.5-9.9% 2-methyl-4-isothiazolin-3-one (C_4H_5NOS); CAS# 2682-20-4, EC No 220-239-6. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration. - Preserved with **< 0.1% sodium azide** [NaN_3], CAS# 26628-22-8 and EC No 247-852-1. [< 0.1% dilution is not subject to GHS, US HCS and EU 2008/1272/EC or 1999/45/EC regulated labeling levels.]

Component	Content
Release Buffer **BioPlex 2200** **25-OH Vitamin D** 1 x 10 mL vial (Clear liquid)	- 25-OH Vitamin D releasing reagents in citrate and trisodium citrate acid buffer at pH 4.1. - **50-100% water** [H_20] CAS# 7732-18-5, EC No 231-791-2. [Not subject to GHS, US HCS and EU 2008/1272/EC regulatory requirements.] - **< 3% Citric acid,** Anhydrous [$C_6H_8O_7$], CAS# 77-92-9, EC No 201-063-1. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration. - **< 3% Trisodium Citric acid,** Dihydrate [$Na_3C_6H_5O_7 \bullet 2H_2O$], CAS# 6132-04-3, EC No 200-675-3. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration. - **< 1% Sodium chloride** [NaCl], CAS# 7647-14-5, EC No 231-598-3. [Not subject to GHS, US HCS and EU 2008/1272/EC regulatory requirements.] - Preserved with **< 1% ProClin 950** containing < 0.1% active ingredient: 9.5-9.9% 2-methyl-4-isothiazolin-3-one (C_4H_5NOS); CAS# 2682-20-4, EC No 220-239-6. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration.
Conjugate 1 **BioPlex 2200** **25-OH Vitamin D** 1 x 5 mL vial (Clear liquid)	- Biotinylated 25-OH Vitamin D conjugate and biotinylated anti-human FXIII antibody conjugate (murine) in phosphate buffer with protein stabilizers (bovine CAS# 9007-83-4) and chemical blockers (pH 7.4). - **50-100% water** [H_20] CAS# 7732-18-5, EC No 231-791-2. [Not subject to GHS, US HCS and EU 2008/1272/EC regulatory requirements.] - **< 1% Sodium chloride** [NaCl], CAS# 7647-14-5, EC No 231-598-3. [Not subject to GHS, US HCS and EU 2008/1272/EC regulatory requirements.] - Preserved with **< 1% ProClin 950** containing < 0.1% active ingredient: 9.5-9.9% 2-methyl-4-isothiazolin-3-one (C_4H_5NOS); CAS# 2682-20-4, EC No 220-239-6. 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% Bronidox (m-Dioxane, 5-Bromo-5-nitro-1,3-) [**$C_4H_6BrNO_4$], CAS#: 30007-47-7, EC No: 250-001-7. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory labeling and related requirements.
Conjugate 2 **BioPlex 2200** **25-OH Vitamin D** 1 x 5 mL vial (Pink aqueous liquid)	- Phycoerythrin conjugated streptavidin (SA-PE) in a buffer comprising protein stabilizer (bovine CAS# 9007-83-4), chemical blockers and detergent (Tween 20) (pH 6.1). - **50-100% water** [H_20] CAS# 7732-18-5, EC No 231-791-2. [Not subject to GHS, US HCS and EU 2008/1272/EC regulatory requirements.] - **< 1% MES** buffer (2[N-Morpholino] ethane-sulfonic acid – $C_6H_{13}NO_4S \bullet H_2O$], CAS# 4432-31-9, EC No 224-632-3. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory labeling and related requirements. - **< 1% Sodium chloride** [NaCl], CAS# 7647-14-5, EC No 231-598-3. [Not subject to GHS, US HCS and EU 2008/1272/EC regulatory requirements.] - Preserved with **< 1% ProClin 950** containing < 0.1% active ingredient: 9.5-9.9% 2-methyl-4-isothiazolin-3-one (C_4H_5NOS); CAS# 2682-20-4, EC No 220-239-6. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration. - Preserved with **< 0.1% sodium azide** [NaN_3], CAS# 26628-22-8 and EC No 247-852-1. [< 0.1% dilution is not subject to GHS, US HCS and EU 2008/1272/EC or 1999/45/EC regulated labeling levels.]

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 guidelines:

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.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS -- HAZARDOUS COMPONENTS

The following information is furnished for those product hazardous constituents that require regulatory control or disclosure at the concentration found in the product. Note that the information here is often based on data from the chemical raw material (LD50, exposure limits, etc.) and that product contains a significantly diluted concentration in an aqueous solution, thus this assessment has taken hazard reduction processing into consideration when possible. The GHS, US HCS and EC CLP classifications were made according to the latest editions and expanded upon from company and literature data. Refer to Section 16 for the Key / legend to abbreviations and acronyms.

Chemical Ingredient Data / Information

Chemical Ingredient: Citric acid

Chemical concentrations found in this product: **< 3% (Release Buffer)**

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

CAS#: 77-92-9 (100%)
EC No: 201-069-1 (100%)
RTECS#: GE7350000 (100%)
Synonyms/Trade Names: Aciletten; Anhydrous citric acid; Citretten; Citro; 2-Hydroxy-1,2,3-propanetricarboxylic acid; beta-Hydroxytricarballylic acid; Kyselina citronova
Chemical Formula: $C_6H_8O_7$ (100%)
Molecular weight: 192.12 g/mol (100%)

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pH value: 1.8 at ca.50 g/l at 25 °C (77 °F) (100%)
LD_{50} (oral-rat): 5400 mg/kg (100%)
LC_{50} (inhalation-rat): NE
LD_{50} (skin-rabbit): >2000 mg/kg (100%)
Skin corrosion/irritation: Skin - rabbit - Mild skin irritation - OECD Test Guideline 404
Serious eye damage/eye irritation: Eyes - rabbit - Irritating to eyes. - OECD Test Guideline 405
Respiratory or skin sensitization: Prolonged or repeated exposure may cause allergic reactions in certain sensitive individuals.
IATA/DOT/IMDG ID: Not Dangerous Goods (100%)
US RCRA Code: Non-RCRA (100%)

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

GHS Signal word: **WARNING**

GHS Hazard Class and Category (100%):

Acute toxicity, Dermal (Category 5)
Skin irritation (Category 3)
Eye irritation (Category 2A)

GHS Hazard Statements (100%):

H313	May be harmful in contact with skin.
H316	Causes mild skin irritation.
H319	Causes serious eye irritation.

GHS Precautionary Statements (100%):

P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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

GHS / US HCS / EC CLP Rating for Product dilution: Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration (< 10%).

Chemical Ingredient Data / Information

Chemical Ingredient: ProClin 950

Chemical concentrations found in this product: **< 1.0% (Beads, Release Buffer, Conjugate 1, Conjugate 2)**

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

Hazardous ingredient concentration in raw material: the concentrated preservative contains:
5-10% of 2-methyl-4-isothiazolin-3-one (active ingredient).
CAS#: 2682-20-4 (active ingredient)
EC No: 220-239-6 (active ingredient)
RTECS#: NE
Chemical Formula: C_4H_5NOS (active ingredient)
Classification: Acute Tox. 4; Acute Tox. 3; Skin Corr. 1B; Skin Sens. 1; STOT SE 3, Aquatic Acute 1; H302, H314, H317, H331, H335, H400

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pH value: 3.0-6.0 (concentrated solution)
LD_{50} (oral-rat): No data available (concentrated solution)
LC_{50} (inhalation-rat): No data available (concentrated solution)
LD_{50} (skin-rabbit): No data available (concentrated solution)
IATA/DOT/IMDG ID: UN3265, Class 8, packing group III (undiluted, 100%)
IATA/DOT/IMDG ID: Not Dangerous Goods (product dilution)
US RCRA Code: Non-RCRA (product dilution)

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

GHS Signal word: **DANGER**!

GHS Hazard Class and Category (100%):

Acute toxicity, Inhalation (Category 3)
Skin corrosion (Category 1B)
Serious eye damage (Category 1)
Skin sensitisation (Category 1)
Acute aquatic toxicity (Category 1)

GHS Hazard Statements (100%):

H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H331	Toxic if inhaled.
H400	Very toxic to aquatic life.

GHS Precautionary Statements (100%):

P261	Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P273	Avoid release to the environment.
P280	Wear protective gloves/ protective clothing/ eye protection/ face protection.
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.

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

GHS / US HCS / EC CLP Rating for Product dilution: Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration (< 1%).

Chemical Ingredient Data / Information

Chemical Ingredient: Bronidox (m-Dioxane, 5-Bromo-5-nitro-1,3-)
Chemical concentrations found in this product: **≤ 0.1% (Conjugate 1)**

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

CAS#: 30007-47-7 (100%)
EC No: 250-001-7 (100%)
RTECS#: JG9650000 (100%)
Synonyms/Trade Names: BND, Brom-5-nitro-1,3-dioxan; 5-Bromo-5-nitro-m-dioxane; 5-Bromo-5-nitro-1,3-dioxane; Bronidox; 1,3-Dioxane, 5-bromo-5-nitro-
Chemical Formula: $C_4H_6BrNO_4$ (100%)
Molecular weight: 212.02 g/mol (100%)

LD_{50} (oral-rat): 455 mg/kg (100%)
IATA/DOT/IMDG ID: Not Dangerous Goods (100%)
US RCRA Code: Non-RCRA (100%)

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

GHS Signalword: **WARNING**

GHS Hazard Class and Category (100%):
Acute toxicity, Oral (Category 4)
Skin irritation (Category 2)

GHS Hazard Statements (100%):

H302	Harmful if swallowed.
H315	Causes skin irritation.

GHS Precautionary Statements (100%):

P301 + P312	IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

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

GHS / US HCS / EC CLP Rating for Product dilution: Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration (< 1%).

Chemical Ingredient Data / Information

Chemical Ingredient: Sodium azide

Chemical concentrations found in this product: **< 0.1% (Beads, Conjugate 2)**

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

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

LD_{50} (oral-rat): 27 mg/kg (100%)
LC_{50} (inhalation-rat): 37 mg/m^3 (100%)
LD_{50} (skin-rat): 50 mg/kg (100%)
IATA/DOT/IMDG ID: UN1687, Class 6.1' Packing Group II (undiluted, 100%)
IMDG EMS-No: F-A, S-A
IATA/DOT/IMDG ID: Not Dangerous Goods (product dilution)
US RCRA Code: P105 (undiluted, 100%)

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

GHS Signal word: **DANGER**!

GHS Hazard Class and Category (100%):
Acute toxicity, Oral (Category 2)
Acute toxicity, Dermal (Category 1)
Acute aquatic toxicity (Category 1)
Chronic aquatic toxicity (Category 1)

GHS Hazard Statements (100%):

H300 + H310	Fatal if swallowed or in contact with skin.
H410	Very toxic to aquatic life with long lasting effects.

GHS Precautionary Statements (100%):

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.
P310	Immediately call a POISON CENTER or doctor/ physician.
P501	Dispose of contents/ container to an approved waste disposal plant.

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

Biological Ingredient	Data / Information
Animal proteins (Beads, Conjugate 1, Conjugate 2)	This material is of animal origin (bovine, murine and sheep) 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 Universal Precautions. Dispose of this material in accordance with local, regional, national and international regulation.

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

Related product information:

- Refer to section 2 for the full text of any GHS \ US HCS \ 2008/1272/EC statement coded above.
  Refer to section 16 for the full text of any *Risk (R)* and *Safety (S)* statement for the above kit component concentration.
- No significant adverse health effects are expected by any route for the sodium chloride, miscellaneous salts, MES buffer, buffers, protein-stabilizers, antibodies, conjugates, water or other non-reactive ingredients, in the kit volumes and/or concentrations present. [Chemical or dilution is not subject to GHS, EC CLP or US HCS 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, congestion and breathing difficulty. 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:	Sodium oxides, 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.
- 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. 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.
- Refer to Sections 8 and 13 for more specifics.

SECTION 7: HANDLING AND STORAGE INFORMATION

Handling:	This test kit should be handled only by qualified personnel trained in laboratory procedures and familiar with their potential hazards. Follow proper Good Laboratory Practices and safety guidelines for handling chemical, biological and laboratory hazards. Do not smoke, eat, or drink in areas where patient samples and kit reagents are handled. Wash your hands after use. Wear appropriate personal protective equipment (PPE) including gloves, lab coat or equivalent and eye/face protection. Keep containers tightly closed; avoid splashing, spills and the generation of aerosols. Handle all human source specimens, materials and equipment used to perform the operations as though they were capable of transmitting infectious disease, as per *Standard* and *Universal Precautions.* All personal protective equipment should be removed before leaving the work area. Refer to Section 8 for more specifics. Avoid release to the environment. Do not allow undiluted product hazardous chemical ingredient or large quantities of it to reach ground water or water course. Consult with your Environmental Health & Safety Office for assistance.
Storage:	Store 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 *Instructions For Use / Package Insert* for additional product information. Read and follow *BioPlex® 2200 System Instrument Manual* instructions.	
For *in vitro* diagnostic use.	

SECTION 8: EXPOSURE CONTROL / PERSONAL PROTECTION MEASURES

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

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

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

Concentrated 5-BROMO-5-NITRO-1,3-DIOXANE (BRONIDOX) [CAS# 30007-47-7] - OEL:			
RUSSIA:	STEL	10 mg/m^3	JUL2003
UNITED STATES:	WEEL	10 mg/m^3	Workplace Environmental Exposure Level
		[Source: 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 / 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:	Plastic cartridge containing various bottles with aqueous solutions		
Odour:	No applicable information was found.	**Odour threshold:**	Not established.
pH:	The liquid chemical components are between pH 4 and 8.		
Boiling point:	Undetermined.	**Melting point:**	Undetermined.
Flash point:	Not Applicable. Flammable limits: LEL/LFL is Not applicable; UEL/UFL is Not applicable.		
Evaporation rate:	No applicable information was found.		
Fire hazard:	Although the components have not been tested for fire hazard and explosion data, being water-based, they are not expected to be fire hazards, but some of the kit packaging materials may burn under fire conditions.		
Vapor pressure:	No applicable information was found.		
Vapor density:	No applicable information was found.		
Relative density:	Undetermined.		
Solubility:	The liquid chemical components are soluble in water. The bead set is not miscible or is difficult to mix.		
Partition coefficient (n-octanol/water):	No applicable information was found.		
Auto igniting:	Product is not known to be self-igniting.		
Decomposition temperature:	No applicable information was found.		
Viscosity:	No applicable information was found.		
Danger of explosion:	**Sodium azide** may react with lead or copper plumbing to form highly explosive metal azides; build-up in metal plumbing has led to laboratory explosions, so flush with copious water when pouring dilute solutions down the drain to prevent such explosive build-up.		
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:	**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. ***ProClin*** - Oxidizing agents, Amines, Reducing agents, Mercaptans.
Hazardous Decomposition Products:	Sodium oxides, Oxides of carbon or nitrogen may form when heated to decomposition.
Hazardous Polymerization:	Has not been reported to occur.

SECTION 11: TOXICOLOGICAL INFORMATION -- GENERAL COMPOSITE

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

Acute Health Effects

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

Biohazard Potential:

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*, WHO *Laboratory Biosafety Manual* or equivalent. Persons handling blood samples should have the option of receiving hepatitis B vaccination.

Chronic Toxicity

Sensitization:	May cause an allergic skin reaction. Contains a small volume of a very dilute, sensitizing preservative (**ProClin 950**); 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.

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:	**Concentrated *Citric acid*** [CAS#: 77-92-9]*: Toxicity to fish mortality LC_{50} - Leuciscus idus melanotus - 440 mg/l - 48 h Method: OECD Test Guideline 203 Toxicity to daphnia and other aquatic invertebrates: static test - Daphnia magna (Water flea) - 1,535 mg/l - 24 h **Concentrated *2-methyl-4-isothiazolin*** [CAS# 2682-20-4]**: Fish LC_{50} – Lepomis macrochirus (Bluegill) – 300 µg/l [min. 240 µg/l max. 320 µg/l] – 96 h Fish LC_{50} – Oncorhynchus mykiss (rainbow trout) – 190 µg/l [min. 130 µg/l max. 310 µg/l] – 96 h Fish LC_{50} – Oncorhynchus mykiss (rainbow trout) – 70 µg/l [min. 60 µg/l max. 90 µg/l] – 96 h **100% Sodium Azide [26628-22-8]***: Fish LC_{50} - Lepomis macrochirus - 0.68 mg/l - 96 h Daphnia EC_{50} - Daphnia pulex (Water flea) - 4.2 mg/l - 48 h * *Source: Raw Material Vendor Safety Data Sheet, RTECS and/or CCOHS Cheminfo* ** *Source: PAN Pesticides Database – Chemical Studies on Aquatic Organisims [obtained 3/7/2012]*
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 affects:	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.

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: 1 Flammability: 0 Reactivity: 1

Carcinogenicity Categories: No component, mixture or constituent has been classified as a carcinogen by NTP (National Toxicity Program), IARC (International Agency for Research on Cancer), TLV-CAR (Threshold Limit Value established by ACGIH) or OSHA (Occupational Health and Safety Administration, U.S. Department of Labor).]

National Regulations – Other Domestic / Foreign Laws:

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

1. **United States** – Occupational Safety Health Administration *Hazard Communication Standard* **29 CFR 1910.1200 (US HCS)**
2. **People's Republic of China** – National Standard **GB/T 17519-2013, GB 30000-2013**
3. **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)
4. **Mexico: Mexican Standard (NMX-R-019-SCFI-2011)** *SISTEMA ARMONIZADO DE CLASIFICACIÓN Y COMUNICACIÓN DE PELIGROS DE LOS PRODUCTOS QUÍMICOS GLOBALLY HARMONIZED SYSTEM (GHS)*.
5. **Korea: Korean Public Notice 2008-26** for the hazard classification criteria for this product.
6. **European Community** (EC) – applicable ***CLP*** related regulations **(2010/453/EC, 2008/1272/EC, 2006/1907/EC** etc.)
7. **Canada - *WHMIS Classification:* Workplace Hazardous Materials Information System (WHMIS) Canadian Standard** for the hazard classification criteria for this product.

8. **Australia:** *Australian Code of Practice on Preparation of Safety Data Sheets for Hazardous Chemicals* under Section 274 of the **Work Health and Safety Act**.
9. Analogous GHS-based global regulations

Australian Inventory of Chemical Substances: All pertinent ingredients are listed.

United States SARA: SARA 302 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

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.

Markings according to *European Community* 1999/45/EC, 2001/59/EC, 2001/60/EC, 2006/102/EC guidelines:
The dilution of chemicals in this product is not subject to EU labeling classification or identification according to EU Directives 1999/45/EC, 2001/59/EC, 2001/60/EC and other sources of literature known to us.

SECTION 16: OTHER INFORMATION

Risk Phrases: None

Safety Phrases: None

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.

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)
European Community Regulations (EC) 2008/1272/EC, 2010/453/EC, 2006/1907/EC
Mexican Standard *(NMX-R-019-SCFI-2011)*
Australian Code of Practice on 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]
Korean Public Notice 2008-26 [regulatory translation if available and summaries]
EU Directives 1999/45/EC, 2001/59/EC, 2001/60/EC, 2006/102/EC
Registry of Toxic Effects of Chemical Substances (RTECS)
Canadian Centre for Occupational Health and Safety (CCOHS) *CHEMINFO databases, etc.*
International Agency for Research on Cancer (IARC)
American Conference of Governmental Industrial Hygienists (ACGIH)
Occupational Safety and Health Administration, U.S. Department of Labor (OSHA)
National Toxicity Program (NTP)
National Institute for Occupational Safety and Health (NIOSH)
World Health Organization. *Laboratory Biosafety Manual*
CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories*
PAN Pesticides Database – *Chemical Studies on Aquatic Organisims*
Australian Inventory of Chemical Substances (ACIS) [7-27-2012]
California Proposition 65

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

Key / legend to abbreviations and acronyms used in the safety data sheet:
ACGIH – American Conference of Governmental Industrial Hygienists
ACIS – Australian Inventory of Chemical Substances
ANSI – American National Standards Institute
CAS – Chemical Abstracts Service
CDC – Centers for Disease Control, USA

CNS – Central Nervous System
DOT – Department of Transportation, USA
EC_{50} – half maximal effective concentration
EC CLP – European Commission regulation for the Classification, Labeling and Packaging of chemical substances and mixtures
EU – European Union
GHS – Globally Harmonized System
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
LC_{50} – median lethal concentration, 50%
LD_{50} – 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
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: New Safety Data Sheet (SDS).

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