

SAFETY DATA SHEET (SDS)

SECTION 1: IDENTIFICATION OF PRODUCT (MIXTURE) AND SUPPLIER

Product Name: Kallestad® *Crithidia luciliae* Substrate

Product Number: **30404** (4 Wells/Slide, 24 Tests/Kit)
31069 (8 Wells/Slide, 48 Tests/Kit)
 Catalog number(s) for replacement, optional and separately purchased components that can be obtained for use with this kit, and which are covered by this SDS include: **26107, 26108, 26109, 26110, 30403, 30431, 30446, 30480, 31098** and **31996** (refer to Section 2).

Intended Use: An indirect fluorescent antibody procedure for the detection and semi-quantitation of human native nDNA autoantibodies. The detection and semi-quantitation of autoantibodies aid in the diagnosis of autoimmune diseases. With the choice of the appropriate substrate, the Kallestad *Crithidia luciliae* (nDNA) Test detects autoantibodies to native DNA (nDNA) antigens.

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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 92430 Marnes-la-Coquette
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[\[fds-msds.fr@bio-rad.com\]](mailto:fds-msds.fr@bio-rad.com)

Emergency Phone Number: **This SDS is listed with CHEMTREC 1-800-424-9300 (US) or 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
R1 Kallestad® <i>Crithidia luciliae</i> Substrate Slides 4 Well/Slide, <i>Cat. No. 26107, 26108</i> 8 Well/Slide, <i>Cat. No. 26109, 26110</i>	- <i>Crithidia luciliae</i> substrate fixed onto glass slides. - Handle slides by the edges. Do not apply pressure to surface of foil bag. Note: The slide pigment contains a bound Cadmium compound (Pigment Red #108, Cadmium sulfoselenide red, CAS# 58339-34-7), which is unlikely to leach under normal conditions of use. Do not grind, abrade, etch or sandblast the pigment from the slide.

Component *	Content
R2 Kallestad[®] FITC Conjugate , 2.5 mL, <i>Catalog # 30446</i> <i>Optional Materials Available:</i> Kallestad[®] FITC Conjugate , 100 mL, <i>Catalog # 30480</i>	<ul style="list-style-type: none"> - Fluorescein conjugated antiserum to human immunoglobulins with 1% bovine serum albumin in a phosphate buffered saline solution (pH ~ 7). - Preserved with 0.1% sodium azide [NaN₃], CAS# 26628-22-8 and EC No 247-852-1. Dilution is not subject to UN GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements without Cat 5 Acute Toxic designations in this product mixture and concentration. [Acute toxic Cat. 5 rating: Warning; H303, H313; P312.]
R3 Kallestad[®] Mounting Media , 2.5 mL, <i>Catalog # 30403</i>	<ul style="list-style-type: none"> - A semi-permanent buffered mounting media in a Trizma buffered solution, pH 7 - 8, containing antiquencher, and: - ≤ 7.5% Polyvinyl alcohol [PVA – C₂H₄O]_n], CAS# 9002-89-5, EC No 209-183-3. Not subject to UN GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration. - ≤ 20% 1,2-Propanediol [propylene glycol – C₃H₈O₂], CAS# 57-55-6, EC No 200-338-0. Not subject to UN GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration.
R4 Phosphate Buffered Saline , pH 7.3, 11.34 g <i>Catalog # 31098</i>	<ul style="list-style-type: none"> - Phosphate buffered saline (PBS) prepared with dibasic sodium phosphate, monobasic sodium phosphate, and sodium chloride (dissolved pH 7.3). Not subject to UN GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration.
R5 Kallestad[®] Evans Blue Counterstain , 2.5 mL, <i>Catalog #30431</i>	<ul style="list-style-type: none"> - 50-100% water [H₂O] CAS# 7732-18-5, EC No 231-791-2. Not subject to UN GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration. - ≤ 2% Evans blue stain [C₃₄H₂₄N₆O₁₄S₄•4Na], CAS# 314-13-6, EC No 206-242-5. 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. Dilution is not subject to UN GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements without Cat 5 Acute Toxic designations in this product mixture and concentration. [Acute toxic Cat. 5 rating: Warning; H303, H313; P312.]
C0 Kallestad[®] Negative Control , 0.5 mL	<ul style="list-style-type: none"> - Pooled normal human serum, 1% bovine serum albumin. - Preserved with 0.1% sodium azide [NaN₃], CAS# 26628-22-8 and EC No 247-852-1. Dilution is not subject to UN GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements without Cat 5 Acute Toxic designations in this product mixture and concentration. [Acute toxic Cat. 5 rating: Warning; H303, H313; P312.]
C1 Kallestad[®] Positive Control , 0.5 mL	<ul style="list-style-type: none"> - Pooled human serum with a specific autoantibody activity, 1% bovine serum albumin. - Preserved with 0.1% sodium azide [NaN₃], CAS# 26628-22-8 and EC No 247-852-1. Dilution is not subject to UN GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements without Cat 5 Acute Toxic designations in this product mixture and concentration. [Acute toxic Cat. 5 rating: Warning; H303, H313; P312.]
<i>Optional Materials Available:</i> Kallestad[®] Patient Sample Diluent , 100 mL, <i>Catalog # 31996</i>	<ul style="list-style-type: none"> - Buffer with protein stabilizers (1% bovine serum albumin) in a phosphate buffered saline solution (pH ~ 7). - Preserved with 0.1% sodium azide [NaN₃], CAS# 26628-22-8 and EC No 247-852-1. Dilution is not subject to UN GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements without Cat 5 Acute Toxic designations in this product mixture and concentration. [Acute toxic Cat. 5 rating: Warning; H303, H313; P312.]

* Replacement, optional and separately purchased component Catalog numbers are provided in this column where available.

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

Note: **0.1% Sodium Azide** concentration falls under the UN GHS Cat 5 Acute Toxic which is not recognized in much of the world. [Acute toxic Cat. 5 rating would be: Warning; H303, H313; P312].

Note: IARC (International Agency for Research on Cancer) Group 3, The Agent is NOT CLASSIFIABLE as Carcinogenic to Humans: **Evans blue**, CAS# 314-13-6, EC No 206-242-5. This chemical is not listed in 2008/1272/EC. *Note:* IARC Group 3 classed materials are not considered carcinogenic in most regulations. GHS, US HCS and EU CLP regulations do not classify this IARC Group 3 classed material as a carcinogen.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

The following information is furnished for those product hazardous constituents that require regulatory control or disclosure regardless of the concentration found in the product. Note that the information here is often based on data from the chemical raw material safety data sheet and literature (LD₅₀, exposure limits, etc.). Chemical constituents that do not require regulatory disclosure are not generally included here. This product contains a significantly diluted concentration in an aqueous solution, thus the assessment below has not considered the dilution reduction effect on the hazard. That hazard communication information is provided in Section 2 above. Some components were tested at the concentration found in the kit. In that case, the assessment is provided for the chemical dilution tested and the tested concentration will be provided at the beginning of the *Chemical Ingredient Data/Information* box. The UN GHS, US HCS, EC CLP and analogous GHS-based global regulation classifications were made according to the 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 the Key / legend to abbreviations and acronyms.

Chemical Ingredient Data / Information

Chemical Ingredient: Sodium azide

Chemical concentrations found in this product: **0.1% w/v in component C0, C1, R2, R5, FITC Conjugate and Patient Sample Diluent (aqueous 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
EC No: 247-852-1 (100%)	LC ₅₀ (inhalation-rat): 37 mg/m ³
Index No: 011-004-00-7 (100%)	LD ₅₀ (skin-rat): 50 mg/kg
RTECS#: VY8050000 (100%)	Fish LC ₅₀ – Lepomis macrochirus (Bluegill) – 0.68 mg/l – 96 h
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, 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]

Chemical Ingredient Data / Information

Chemical Ingredient: Propylene glycol

Chemical concentrations found in this product: **≤ 20% v/v in component R3**

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

CAS#: 57-55-6 (100%)	LD ₅₀ (oral-rat): 20,000 mg/kg
EC No: 200-338-0 (100%)	LC ₅₀ (inhalation-rat): NE
RTECS#: TY2000000 (100%)	LD ₅₀ (skin-rabbit): 20,800 mg/kg
Index No: NE	LC ₅₀ (96 hr-fish): NE (100%)
Chemical Formula: C ₃ H ₈ O ₂ (100%)	Molecular weight: 76.09 g/mol (100%)
Flash Point: 217°F / 103°C (100%)	
Flammable limits: LEL/LFL is <u>2.6%</u> ; UEL/UFL is <u>12.5%</u> vv in air.	
Synonyms/Trade Names: 1,2,-Propanediol	

Raw Material GHS / US HCS / EC CLP Classification (100%): Not a dangerous substance according to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements.

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

Chemical Ingredient: Polyvinyl alcohol

Chemical concentrations found in this product: **≤ 7.5% w/v PVA in component R3**

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

CAS#: 9002-89-5 (100%)	LD ₅₀ (oral-rat): >20,000 mg/kg
EC No: 209-183-3 (100%)	LC ₅₀ (inhalation-rat): NE
RTECS#: TY2000000 (100%)	LD ₅₀ (skin-rabbit): NE
Chemical Formula: (C ₂ H ₄ O) _n (100%)	LC ₅₀ (96 hr-fish): NE
Synonyms/Trade Names: PVA	Flash Point: 174°F / 79°C (100%)
IARC: Group 3 (100%) - "the Agent is NOT CLASSIFIABLE as Carcinogenic to Humans"	

Raw Material GHS / US HCS / EC CLP Classification (100%): Not a dangerous substance according to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements.

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

Chemical Ingredient Data / Information

Chemical Ingredient: Evans Blue

Chemical concentrations found in this product: **≤ 2% w/v in component R5 (aqueous solution)**

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

CAS#: 314-13-6 (100%)	LD ₅₀ (Intraperitonea-mus): 340 mg/kg
EC No: 206-242-5 (100%)	LC ₅₀ (inhalation-rat): NE
RTECS#: QJ6440000 (100%)	LD ₅₀ (skin-rabbit): NE
Chemical Formula: C ₃₄ H ₂₄ N ₆ Na ₄ O ₁₄ S ₄ (100%)	LC ₅₀ (96 hr-fish): NE
Molecular weight: 960.81 g/mol (100%)	Index Number: 611-030-00-4


IUPAC name: tetrasodium (6E,6'E)-6,6-[(3,3'-dimethylbiphenyl-4,4'-diyl)di(1E)hydrazin-2-yl-1-ylidene]bis(4-amino-5-oxo-5,6-dihydronaphthalene-1,3-disulfonate)

Synonyms/Trade Names: 1,3-Naphthalenedisulfonic acid, 6,6'-((3,3'-dimethyl-4,4'-biphenyl)ylene)bis(azo))bis(4-amino-5-hydroxy-, tetrasodium salt; 4,4'-Bis(1-amino-8-hydroxy-2,4-disulfo-7-naphthylazo)-3,3'-bitolyl, tetrasodium salt; 4,4'-Bis(7-(1-amino-8-hydroxy-2,4-disulfo)naphthylazo)-3,3'-bitolyl, tetrasodium salt; 6,6'-[3,3'-Dimethyl(1,1-biphenyl)-4,4'-diyl]bis(azo)-bis-(4-amino-5-hydroxy)-1,3-naphthalenedisulfonic acid, tetrasodium salt; Azovan Blue; Blekit evansa; Diazobleu; Direct Blue 53; Evablin; Geigy-blau 536; Modr Evansova; Modr Prima 53

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

Raw Material GHS / US HCS / EC CLP Classification (100%): Not a dangerous substance according to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements. This chemical is not listed in 2008/1272/EC.

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

Biological Ingredient	Data / Information
Human Serum [reactive and non-reactive in C0, C1] 	The Human sera in the components of this product was tested and certified to be non-reactive for HBsAg and antibodies to HCV and HIV 1 / HIV 2 by FDA licensed or CE Marked tests. No known test method can offer complete assurance that HIV, hepatitis B or C virus or other infectious agents are absent. Moreover, patient blood samples tested with this kit represent an unknown, heightened hazard. 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. Handle appropriately with the requisite Good Laboratory Practices, <i>Standard</i> and <i>Universal Precautions</i> . Persons handling blood samples should have the option of receiving hepatitis B vaccination.
Crithidia luciliae Slide Component	Crithidia luciliae substrate slides have been solvent fixed and are not considered infectious. 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. These Slides consist of 96-100% inert glass with a ~0-4% inert polymer coating, which have been biologically and chemically processed. However, because these slides are made of glass, they could potentially pose a slight physical cutting hazard, especially if broken or chipped, so handle carefully, wear suitable gloves and/or other appropriate personal protective equipment and follow Good Laboratory Practices. Do not handle broken slides with unprotected hands.
Animal sera [Component C0, C1, FITC Conjugate and Patient Sample Diluent]	This material is of animal origin (bovine) 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.

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 following chemical constituents in the kit volumes and concentrations present [chemical or dilution is not subject to GHS, EC CLP or other GHS-based hazard labeling]:
 - Fluorescein conjugated antiserum to human immunoglobulins with 1% bovine serum albumin [in component R2].

- < 1% Tris (TRIZMA HCl) Buffer solution; Tris(hydroxymethyl)aminomethane: 2-amino-2-(hydroxy-methyl)-1, 3-propanediol [C₄H₁₁NO₃•HCl], CAS# 1185-53-1, EC No 214-684-5 [in component R3].
 - < 1% Tris (TRIZMA BASE) Buffer solution; 2-Amino-2-(hydroxymethyl)-3,1-propanediol, [C₄H₁₁NO₃], CAS# 77-86-1, 25149-07-9; 108195-86-4, EC No 201-064-4 [in component R3].
 - **Phosphate buffered saline (PBS)** prepared with dibasic sodium phosphate, monobasic sodium phosphate, and sodium chloride (dissolved pH 7.3) [in component R4].
 - The miscellaneous salts, buffers, protein-stabilizers, antibodies, conjugates, water, catalytic or other non-reactive ingredients.
- ◆ **Cadmium compound** - Pigment Red #108, Cadmium sulfoselenide red, CAS# 58339-34-7. The slide pigment contains a bound Cadmium compound (Pigment Red #108), which is unlikely to leach under normal conditions of use. Do not grind, abrade, etch or sandblast the pigment from the slide.
 - ◆ 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:	May be harmful if swallowed, generally at concentrations and volumes that greatly exceed that of this kit. Do not grind, abrade, etch or sandblast the pigment from the slide.
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 Decomposition 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.).
 - **Broken slides** contaminated with blood or other human source or potentially infectious material must be handled as **Sharps** per 29 CFR 1910.1030, OSHA Bloodborne Pathogen and other regulations; however, dispose of this material in accordance with local, regional, national and international regulation.
Slides processed with material that is not of human origin and is not pathogenic to humans, if broken, can typically be handled as normal uncontaminated broken glass labware however, dispose of this material in accordance with local, regional, national and international regulations. Do not grind, abrade, etch or sandblast the pigment from the slide.
- ◆ 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:	<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.</p> <p>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 <i>in vitro</i> diagnostic use.	

SECTION 8: EXPOSURE CONTROL / PERSONAL PROTECTION MEASURES

Control Parameters – Component chemicals with limit values that require monitoring at the workplace: The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

100% Sodium Azide [CAS# 26628-22-8] - OEL:			
AUSTRALIA:	CL	0.11 ppm (0.3 mg/m ³)	2008
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	2002
DENMARK:	TWA	0.1 mg/m ³ , skin	2011
EC (European Union):	TWA STEL	0.1 mg/m ³ 0.3 mg/m ³ , skin	2000
FINLAND:	TWA STEL	0.1 mg/m ³ 0.3 mg/m ³ , skin	2011
FRANCE:	VME VLE	0.1 mg/m ³ 0.3 mg/m ³ , Skin	2006
GERMANY:	MAK	0.2 mg/m ³ , inhal	2011
HUNGARY:	TWA STEL	0.1 mg/m ³ 0.3 mg/m ³	2000
ICELAND:	TWA STEL	0.1 mg/m ³ 0.3 mg/m ³ , skin	2011
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)	2002
PERU:	TWA STEL	0.1 mg/m ³ 0.29 mg/m ³	2005
SWEDEN:	TWA STEL	0.1 mg/m ³ 0.3 mg/m ³ , Skin	2005
SWITZERLAND:	MAK-W KZG-W	0.2 mg/m ³ 0.4 mg/m ³ , inhal	2011
UNITED KINGDOM:	TWA STEL	0.1 mg/m ³ 0.3 mg/m ³ , skin	2007
ARGENTINA, BULGARIA, COLOMBIA, JORDAN, SINGAPORE, VIETNAM		check ACGIH TLV	
UNITED STATES:	TLV-TWA-Ceiling REL-Ceiling	0.11* ppm / 0.29** mg/m ³ 0.1* ppm / 0.3** mg/m ³	ACGIH, 1996, 2013 NIOSH Recommended Exposure Limits *as HN ₃ vapor; **as NaN ₃ ; Skin

[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.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Variable, generally aqueous liquids. Exceptions are the solid slides and related materials. <i>Crithidia luciliae Substrate Slides</i> -- Solid Glass Slides. <i>FITC Conjugate</i> -- Clear aqueous liquid. <i>Mounting Media</i> -- Clear aqueous liquid. <i>Phosphate Buffered Saline (PBS)</i> -- White to off-white solid. <i>Evans Blue Counterstain</i> -- Blue aqueous liquid. <i>Kallestad® Negative Control</i> -- Amber / yellow liquid. <i>Kallestad® Anti-nDNA Positive Control</i> -- Amber / yellow liquid. <i>Kallestad® Patient Sample Diluent</i> -- Clear aqueous liquid.		
Odor/odour:	Data is not available.	Odor/odour threshold:	Not established.
pH:	The liquid chemical components are between pH pH 6 and 9.		
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:	Variable; Approximately 1.		
Solubility:	The liquid chemical components are soluble 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:	Mixtures.		
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:	Avoid contact with metals. 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.
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 harmful if enough is ingested (generally 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:	Because these slides are made of glass, they could potentially pose a slight physical cutting hazard, especially if broken or chipped, so handle carefully, wear suitable gloves and/or other appropriate personal protective equipment and follow Good Laboratory Practices. Do not handle broken slides with unprotected hands.

Biohazard Potential

Crithidia luciliae cells have been solvent fixed and are not considered infectious or carcinogenic. 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) on FDA licensed tests. No known test method can offer complete assurance that HIV, hepatitis B or C virus or other infectious agents are absent. Moreover, patient blood samples tested with this kit represent an unknown, heightened hazard. Employ *Standard* and *Universal Precautions*; handle these reagents, all human blood and specimens as if capable of transmitting infectious disease, in a Biosafety Level 2 laboratory, applying the guidelines from the current CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories*, the WHO *Laboratory Biosafety Manual* or equivalent. Persons handling blood samples should have the option of receiving hepatitis B vaccination.

Chronic Toxicity

Respiratory or Skin Sensitization:	No sensitization effect known..
Carcinogenicity:	IARC Group 3, The Agent is NOT CLASSIFIABLE as Carcinogenic to Humans: Polyvinyl alcohol , CAS# 9002-89-5, EC No 209-183-3. Evans blue , CAS# 314-13-6, EC No 206-242-5. The slide pigment contains a bound Cadmium compound (Pigment Red #108, Cadmium sulfoselenide red, CAS# 58339-34-7), which is unlikely to leach under normal conditions of use. Do not grind, abrade, etch or sandblast the pigment from the slide. IARC Group 1, The agent is Carcinogenic to Humans

	<p>NTP listed as <i>Known to be a Human Carcinogen</i> ACGIH-TLV Group A2, <i>Suspected Human Carcinogen</i> OSHA Subpart Z CA Prop 65 WARNING: <i>THIS PRODUCT CONTAINS A CHEMICAL KNOWN TO THE STATE OF CALIFORNIA TO CAUSE CANCER</i> (Cadmium and Cadmium Compounds - Listed 1987-10-01).</p>
Germ Cell Mutagenicity:	No applicable information was found.
Reproductive hazard:	No reproductive toxic effect known.
STOT-Repeated Exposure:	No applicable information was found.

Additional Toxicological Information: To the best of our knowledge, the chemical, physical and toxicological properties have NOT been thoroughly investigated for some of the component chemicals and/or mixtures.

SECTION 12: ECOLOGICAL INFORMATION

This product was not tested. The following assessment is based on information for the ingredients.	
Ecotoxicity:	<p>100% Sodium Azide [CAS# 26628-22-8] *: Fish LC₅₀ - <i>Lepomis macrochirus</i> - 0.68 mg/l - 96 h Daphnia EC₅₀ - <i>Daphnia pulex</i> (Water flea) - 4.2 mg/l - 48 h</p> <p>Concentrated Propane-1,2-diol [CAS# 57-55-6]*: Toxicity to fish mortality NOEC – <i>Pimephales promelas</i> (fathead minnow) – 52930 mg/l – 96 h Daphnia EC₅₀ – <i>Daphnia magna</i> (Water flea) – < 10000 mg/l – 48 h – mortality NOEC - <i>Daphnia</i> – 13020 mg/l - 48 h</p> <p><i>*Source: Raw Material vendor SDS, RTECS, CCOHS databases and/or regulatory research</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.

- **Broken slides** contaminated with blood or other human source or potentially infectious material must be handled as **Sharps** per 29 CFR 1910.1030, OSHA Bloodborne Pathogen and other regulations however, dispose of this material in accordance with local, regional, national and international regulations. Slides processed with material that is not of human origin and is not pathogenic to humans, if broken, can typically be handled as normal uncontaminated broken glass labware however, dispose of this material in accordance with local, regional, national and international regulation.
- Do not grind, abrade, etch or sandblast the pigment from the slide.

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: 01

Carcinogenicity Categories:

IARC (International Agency for Research on Cancer):

IARC Group 1, The agent is Carcinogenic to Humans:

Cadmium and cadmium compounds, (2012). The red pigment in the slide masking contains cadmium sulfoselenide red, CAS# 58339-34-7

IARC Group 3, The Agent is NOT CLASSIFIABLE as Carcinogenic to Humans:

Polyvinyl alcohol, CAS# 9002-89-5, EC No 209-183-3.

Evans blue, CAS# 314-13-6, EC No 206-242-5.

NTP (National Toxicity Program):

NTP listed as Known to be a Human Carcinogen:

Cadmium and cadmium compounds - The red pigment in the slide masking contains cadmium sulfoselenide red, CAS# 58339-34-7

ACGIH TLV-CAR (Threshold Limit Value established by American Conference of Governmental Industrial Hygienists):

ACGIH-TLV Group A2, Suspected Human Carcinogen:

Cadmium and cadmium compounds - The red pigment in the slide masking contains cadmium sulfoselenide red, CAS# 58339-34-7

OSHA Subpart Z (Occupational Safety and Health Administration, U.S. Department of Labor):

OSHA Regulated Carcinogen:

Cadmium and cadmium compounds - The red pigment in the slide masking contains cadmium sulfoselenide red, CAS# 58339-34-7

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

Note: The slide pigment contains a **bound Cadmium compound** (Pigment Red #108, Cadmium sulfoselenide red, CAS# 58339-34-7), which is unlikely to leach under normal conditions of use. Do not grind, abrade, etch or sandblast the pigment from the slide.

National Regulations – Other Domestic / Foreign Laws:

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

1. **United States** – Occupational Safety Health Administration *Hazard Communication Standard 29 CFR 1910.1200 (US HCS)*
2. **Taiwan** – Regulation **Lao-An-3-Tzu-No. 0960145703** / Published National Standard **CNS 15030**
3. **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
4. **People's Republic of China** – National Standard **GB/T 17519-2013, GB 30000-2013**
5. **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: Based on available data, the classification criteria are not met.
6. **Mexico** – Standard **NOM-018-STPS-2015, NMX-R-019-SCFI-2011**
7. **Korea** – Public Notice **2016-19, 2013-37 Standard for Classification and Labeling of Chemical Substances and Material Safety Data Sheets**
8. **Japan** – Industrial Safety and Health Law (ISHL) National Standard JIS Z7252, JIS Z7253
9. **European Community (EC)** – applicable CLP related regulations (2010/453/EC, 2008/1272/EC, 2006/1907/EC etc.)
10. **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: Based on available data, the classification criteria are not met.
11. **Brazil** – Regulation NRB 14725:2009
12. **Australia** – Code of Practice *Preparation of Safety Data Sheets for Hazardous Chemicals* under Section 274 of the Work Health and Safety (WHS) Act.
13. Analogous GHS-based global regulations

Inventory status

<u>Country(s) or region</u>	<u>Inventory name</u>	<u>In Compliance (yes/no)*</u>
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 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 in greater quantities than found in this product: **Sodium Azide**, CAS-No. 26628-22-8; Revision Date: 2007-07-01

SARA 313 components: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

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

California Proposition 65: WARNING: THIS PRODUCT CONTAINS A CHEMICAL(S) KNOWN TO THE STATE OF CALIFORNIA TO CAUSE CANCER.

Chemical(s) Known to cause Cancer: **Cadmium compound** - Cadmium sulfoselenide red, CAS# 58339-34-7. [The slide pigment contains a bound Cadmium compound (Pigment Red #108), which is unlikely to leach under normal conditions of use. Do not grind, abrade, etch or sandblast the pigment from the slide. (Cadmium and Cadmium compound listed 1987-10-01)]

SECTION 16: OTHER INFORMATION

Hazard statement abbreviation(s)

Acute Tox. – oral.	Acute toxicity – ingested (swallowed)
Acute Tox. – skn.	Acute toxicity – skin contact (dermal)
Aquatic Acute	Acute aquatic toxicity
Aquatic Chronic	Chronic aquatic toxicity
Cat.	Category
H300 + H310	Fatal if swallowed or in contact with skin.
H303	May be harmful if swallowed.
H313	May be harmful in contact with skin.
H410	Very toxic to aquatic life with long lasting effects.
P264	Wash hands thoroughly after handling.
P273	Avoid release to the environment.
P280	Wear protective gloves/ protective clothing.
P302 + P350	IF ON SKIN: Gently wash with plenty of soap and water.
P310	Immediately call a POISON CENTER or doctor/ physician.
P312	Call a POISON CENTER or doctor/physician if you feel unwell.
P501	This material and its container must be disposed of as hazardous waste.
P501	Dispose of this material in a safe way, and in accordance with local, regional, national and international regulations.
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.

For in vitro diagnostic use.

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 Labelling 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 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 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*
 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
DGSMA – 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
HNOX – 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: Reformatted and updated existing information.

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

Contact 24/7/365: 1-800-424-9300

Contact Local Bio-Rad Agents for general information:

Australia, Bio-Rad Laboratories Pty. Ltd., Level 5, 446 Victoria Road, Gladesville NSW 2111 • Phone 61-2-9914-2800 • Telefax 61-2-9914-2888 •
24h/365d: 61-2-9914-2800 • Poison Information Centre: 13 11 26 (24 hours a day, anywhere in Australia); +61 13 11 26

Austria, Bio-Rad Laboratories Ges.m.b.H., Hummelgasse 88/3-6, A-1130 Vienna • Phone 43-1-877-8901 • Telefax 43-1-876-5629 • **24h/365d:** 43-1-877-8901 •
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Belgium, Bio-Rad S.A.-N.V. Winninglaan 3, BE-9140 Temse • Phone +32 (3)710-53-00 • Telefax +32 (3)710-53-01 • **24h/365d:** 09-385-5511 • Poison Information Centre
/ Belgisch Antigifcentrum: Brussels: +32 70 245 245; Luxembourg: 070 245 245 / 8002 5500 (every day, 24 to 24 hours)

Brazil, Bio-Rad Laboratórios Brasil Ltda, Rua Alfredo Albano da Costa, 100, Lagoa Santa - MG, CEP: 33400-000 • Phone +55 (31)3689-6600 •
Telefax +55 (31)3689-6611 • **24h/365d:** (11) 99118 7957 • Centro de Informações Toxicológicas: 0800 643 5252

- Canada**, Bio-Rad Laboratories, Ltd., 2403 Guénette Street, Montréal, Québec H4R 2E9 • Phone 1-514-334-4372 • Telefax 1-514-334-4415 • **24h/365d**: 1-514-334-4372 • Poison Information Centre: Alberta: 1 800 332 1414; British Columbia: 1 800 567 8911; Manitoba: 1 855 776 4766; New Brunswick: 911; Newfoundland: 709 722 110; Northwest Territories: 1 800 332 1414; Nunavut: 867 979 7350 (Iqaluit), 867 983 2531 (Cambridge Bay), 867 645 2816 (Rankin Inlet); Ontario: 1 800 268 9017; Prince Edward Island: 1 800 565 8161; Québec: 1 800 463 5060; Saskatchewan: 1 866 454 1212; Yukon: 867 393 8700
- China**, Bio-Rad Laboratories Shanghai Ltd. 3rd Floor, #18 Dong Fang Road, Bldg E, Poly Plaza, Pudong, Shanghai, PRC 200120 • Phone 86-21-61698500 • Telefax 86-21-61698599 • **24h/365d**: 86-21-63052255 • Emergency Poison Center: +86 10 831 323 45
- Czech Republic**, Bio-Rad spol. s r.o., Nad ostrovem 1119/7, 147 00 Prague 4 • Phone 420-241-430-532 • Telefax 420-241-431-642 • **24h/365d**: 420 224 919 293 • Toxicological Information Centre: Phone: +420 224 919 293, +420 224 915 402
- Denmark**, Bio-Rad Laboratories, Symbion Science Park, Fruebjergvej 3, DK-2100 Copenhagen East • Phone +45-4452-1000 • Telefax +45-4452-1001 • **24h/365d**: +45 4452 1000 • Poison Information Center / Giftlinjen Ring: +45 82 12 12 12
- Finland**, Bio-Rad Laboratories, Linnanherrankuja 16, FIN-00950 Helsinki • Phone 358-9-804-22-00 • Telefax 358-9-7597-5010 • **24h/365d**: +358 9 804 2200 • Poison Information Centre: Myrkytystietokeskus: Avoimna 24 t / vrk +358 9 471977
- France**, Bio-Rad, 3 boulevard Raymond Poincaré, 92430 Marnes-la-Coquette • Phone 33-1-47-95-60-00 • Telefax 33-1-47-41-91-33 • **24h/365d**: +33 (0)1 47 95 60 00 • Centres Antipoison et de Toxicovigilance : Angers : 02 41 48 21 21; Bordeaux : 05 56 96 40 80; Lille : 0800 59 59 59; Lyon : 04 72 11 69 11; Marseille : 04 91 75 25 25; Nancy : 03 83 22 50 50; Paris : 01 40 05 48 48; Strasbourg : 03 88 37 37 37; Toulouse : 05 61 77 74 4 (24 heures sur 24 - 7 jours sur 7)
- Germany**, Bio-Rad Laboratories GmbH, Heidemannstrasse 164, D-80939 Munich • Phone +49-(0)89-318-840 • Telefax +49-(0)89-318-84100 • **24h/365d**: +49-(0)89-318-840 • Poison Information Centre: Berlin: +49 30 192 40; Bonn: +49 228 192 40; Erfurt: +49 361 730 730; Freiburg: +49 761 192 40; Göttingen: +49 551 192 40; Homburg: +49 6841 192 40; Mainz: +49 6131 192 40; München : +49 89 192 40
- Greece**, Bio-Rad Laboratories M.E.P.E., 2-4 Mesogeion Street, Fourth Floor 115 27 Athens • Phone 30-210-7774396 • Telefax 30-210-7774376 • Poison Information Centre: +30 21 07 79 37 77 (24 h/365d)
- Hong Kong**, Bio-Rad Pacific Ltd., Unit 1101, 11/F DCH Commercial Centre, 25 Westlands Road, Quarry Bay • Phone 852-2789-3300 • Telefax 852-2789-1290 • **24h/365d**: 852-2789-3300 • Poison Information Centre: +852 2772 2211
- Hungary**, Bio-Rad Hungary Ltd., H-1082 Budapest, Futo Street 47-53, Hungary • Phone +36-1-459-6100 • Telefax +36-1-459-6101 • **24h/365d**: +36-1-459-6100 • Poison Information Centre: Információsztaláltás akut mérgezés esetén +36 80 20 11 99 (0-24 h, díjmentesen hívható)
- India**, Bio-Rad Laboratories (India) Pvt. Ltd., Bio-Rad House, 86-87, Udyog Vihar, Phase IV, Gurgaon, Haryana 122 015 • Phone 1-800-180-1224 • Telefax 91-124-2398115 • **24h/365d**: 91-124-2398112/113/114 • National Poison Information Centre: Toll Free No. – 1 800 116 117 (24h/365d)
- Israel**, Bio-Rad Laboratories Ltd., 14 Homa Street, New Industrial Area, Rishon Le Zion 75655 • Phone 972-3-9636050 • Telefax 972-3-9514129 • **24h/365d**: 972-3-951-4127 • Poison Control Center: +972 4 854 19 00
- Italy**, Bio-Rad Laboratories S.r.l., Via Cellini 18/A, 20090 Segrate, Milan • Phone +39-02-216091 • Telefax +39-02-21609553 • **24h/365d**: +39-02-216091 • Poison Information Centre / Centro Antiveneni: Bergamo: +39 800 883 300; Firenze: +39 55 794 7819; Foggia: +39 881 732 326; Milan: +39 02 6610 1029; Pavia: +39 38 224 444; Rome: +39 06 305 43 43; Turin: +39 011 663 7637
- Japan**, Bio-Rad Laboratories K.K., Tennoz Central Tower 20F, 2-2-24 Higashi-Shinagawa, Shinagawa-ku, Tokyo 140 0002 • Phone 81-3-6361-7070 • Telefax 81-3-5463-8481 • Poison Information Centre: Tsukuba-City: +81 72 727 2499 / +81 29 852 9999; Minoh City: +81 (0)72 727 2499
- Korea**, Bio-Rad Korea Ltd., 10th Floor, Hyunjuk Building, 832-41, Gangnam-gu, Seoul 135-080 • Phone 82-2-3473-4460 • Telefax 82-2-3472-7003 • **24h/365d**: 852-2789-330 • Poison Control Information: Yongsan Army Base: 7917-5545/6001; Seoul Poison Center: 129
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- The Netherlands**, Bio-Rad Laboratories B.V., Postbus 222, 3900 AE Veenendaal • Phone +31-318-540666 • Telefax +31-318-542216 • **24h/365d**: +31-318-540666 • Poison Information Centre: NVIC (+31 30 274 88 88), Only for the purpose of informing medical personnel in cases of acute intoxications. Uitsluitend bestemd om professionele hulpverleners te informeren bij acute vergiftigingen.
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- Norway**, Bio-Rad Laboratories, Nydalsveien 33, 0484 Oslo • Phone +47-23-38-41-30 • Telefax +46(0)8-5551-2780 / +47-23-38-41-39 • **24h/365d**: +47 23 38 41 30 • Giftinformasjonen er det nasjonale rådgivnings- og kompetanseorganet vedrørende akutte forgiftninger og forgiftningsfare: +47 22 59 13 00 (24h/365d)
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- Thailand**, Bio-Rad Laboratories Ltd., 1st & 2nd Floor, Lumpini I Bldg., 239/2 Rajdamri Rd., Lumpini, Pathumwan, Bangkok 10330 • Phone 662-651-8311 • Telefax 662-651-8312 • Poisons Control Center: 1367, Line ID poisrequest (national callers); +66 2 419 7007
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