SAFETY DATA SHEET (SDS)

SECTION 1: IDENTIFICATION OF PRODUCT (MIXTURE) AND SUPPLIER

Product Name:	**Pathfinder® Chlamydia Culture Confirmation System**
Product Number:	**30701** Catalog number(s) for replacement, optional and/or separately purchased components that can be obtained for use with this kit, and which are covered by this SDS include**: 30693** (refer to Section 2).
Intended Use:	The Pathfinder® Chlamydia Culture Confirmation Assay is a direct fluorescent procedure for the identification of chlamydia in cell culture.
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) / 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 Key / legend to abbreviations and acronyms.

Component *	Content
Chlamydia Culture Confirmation Monoclonal Antibody (4.2 mL)	- Fluorescein-conjugated murine monoclonal antibody to chlamydia (genus-specific) with a protein stabilizer (bovine), in a phosphate buffered saline solution (pH 7.3). - **< 0.1% Evans Blue stain** [$C_{34}H_{24}N_6O_{14}S_4$•4Na], CAS# 314-13-6, EC No 206-242-5.. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration. - Preserved with **0.1% sodium azide** [NaN_3], CAS# 26628-22-8 and EC No 247-852-1. Not subject to US HCS, EC CLP and analogous global GHS-based regulatory requirements without Cat 5 Acute Toxic designations in this product mixture and concentration. [Acute toxic Cat. 5 rating: Warning; H303, H313; P312]

Component *	Content
Additional Required Items, available from Bio-Rad **Pathfinder® Mounting Medium** (2.75 mL) *Cat. No. 30693*	- Tris-buffered **glycerol** (≤ 80%) solution with a photobleaching retardant. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration. - Contains **< 1% sodium metabisulfite** [$Na_2S_2O_5$], EC No 231-673-0, CAS# 7681-57-4. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration. - **≤ 0.2% EDTA, tetrasodium salt, dihydrate** [$C_{10}H_{12}N_2O_8Na_4 \bullet 2H_2O$], CAS# 10378-23-1. 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], EC No 247-852-1 and CAS# 26628-22-8. Dilution is not subject to US HCS, EC CLP and analogous global GHS-based regulatory requirements without Cat 5 Acute Toxic designations in this product mixture and concentration. [Acute toxic Cat. 5 rating: Warning; H303, H313; P312.]- The Pathfinder® Mounting Medium has been specifically formulated to complement Pathfinder® fluorescent antibody products.

- Replacement separately purchased component catalog numbers are provided in this column where available.

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

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

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

The following information is furnished for those product hazardous constituents that require regulatory control or disclosure regardless of the concentration found in the product. Note that the information here is often based on data from the chemical raw material safety data sheet and literature (LD_{50}, 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 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 list of sources utilized in the assessment and the Key / legend to abbreviations and acronyms.

Chemical Ingredient Data / Information

Chemical Ingredient: Sodium metabisulfite

Chemical concentrations found in this product: **< 1% w/v in the Pathfinder Mounting Media**

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

CAS#: 7681-57-4 (100%)
EC No: 231-673-0 (100%)
Index No: 016-063-00-2 (100%)
RTECS#: UX8225000 (100%)
Chemical Formula: $Na_2S_2O_5$ (100%)
Molecular weight: 190.11 g/mol (100%)

LD_{50} (oral-rat): 1131 mg/kg (100%)
LD_{50} (oral, rat): 1540 mg/kg (conducted according to OECD guidelines)
LC_{50} (inhalation-rat): NE (100%)
LD_{50} (skin-rabbit): NE (100%)
LC_{50} (96 hr-fish): Oncorhynchus mykiss (rainbow trout) – 150-200 mg/l (100%)
pH value: 4.5 at 5- g/L (100%)

Synonyms/Trade Names: Disodium disulfite; Disodium metabisulfite; Disodium pyrosulfite; Disulfurous acid, disodium salt; Sodium disulfite; Sodium metabisulfite; Sodium metabisulfite; Sodium metabisulphite; Sodium pyrosulfite

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

DANGER!
Acute Tox. – oral., Cat. 4, Acute Tox. – skn., Cat. 5, Eye Damage, Cat. 1, Aquatic Acute, Cat. 3
H302, H313, H318, H402
P280, P305 + P351 + P338

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

Chemical Ingredient: Sodium azide

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

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

CAS#: 26628-22-8 (100%)
EC No: 247-852-1 (100%)
Index No: 011-004-00-7 (100%)
RTECS#: VY8050000 (100%)
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%)
Fish LC_{50} – Lepomis macrochirus (Bluegill) – 0.68 mg/l – 96 h (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 Chronic Cat. 1
H300 + H310, H410
P264, P273, P280, P302 + P350, P310, P501

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

Chemical Ingredient Data / Information

Chemical Ingredient: **Evans Blue**
Chemical concentrations found in this product: **< 0,1% w/v in Culture Confirmation Monoclonal Antibody**

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

CAS#: 314-13-6 (100%)
EC No: 206-242-5 (100%)
RTECS#: QJ6440000 (100%)
Chemical Formula: $C_{34}H_{24}N_6Na_4O_{14}S_4$ (100%)
Molecular weight: 960.81 g/mol (100%)

LD_{50} (Intraperitonea-mus): 340 mg/kg (100%)
LC_{50} (inhalation-rat): NE (100%)
LD_{50} (skin-rabbit): NE (100%)
LC_{50} (96 hr-fish): NE (100%)

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

Synonyms/Trade Names: 1,3-Naphthalenedisulfonic acid, 6,6'-((3,3'-dimethyl-4,4'-biphenylylene)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(l,l-biphenyl)-4,4'-diyl]bis(azo)-bis-(4-amino-5-hydroxy)-1,3-naphthalenedisulfonic acid, tetrasodiun salt; Azovan Blue; Blekit evansa; Diazobleu; Direct Blue 53; Evablin; Geigy-blau 536; Modr Evansova; Modr Prima 53

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

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

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

Biological Ingredient	Data / Information
Animal Proteins	This material is of animal origin (bovine) and may be a potential contact irritant. Hazard unknown. Handle as though potentially infectious. The chemical, physical and toxicological properties have not been thoroughly investigated. Handle appropriately with the requisite Good Laboratory Practices, *Standard* and *Universal Precautions*. Dispose of this material in accordance with local, regional, national and international regulations.

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

Related product information:

- Refer to section 16 for the full text of any Comprehensive GHS-based Classification statements coded above. Refer to Section 16 for the list of sources utilized in the assessment and the Key / legend to abbreviations and acronyms.
- No significant adverse health effects are expected by any route for the following chemical constituents in the kit volumes and concentrations present [chemical or dilution is not subject to GHS, EC CLP or GHS-based hazard labeling]:
  - **≤ 80% Glycerol** [$C_3H_8O_3$], CAS# 56-81-5, EC No 200-289-5. [Pathfinder® Mounting Media]
  - **< 2% Tris (TRIZMA BASE) buffer** solution; 2-amino-2-(hydroxymethyl)-3,1-propanediol, [$C_4H_{11}NO_3$], EC No: 201-064-4, CAS# 77-86-1, 25149-07-9; 108195-86-4. [Pathfinder® Mounting Media]
  - **≤ 0.2% EDTA, tetrasodium salt, dihydrate** [$C_{10}H_{12}N_2O_8Na_4 \bullet 2H_2O$], CAS# 10378-23-1, EC No 200-573-9. [Pathfinder® Mounting Media]
  - The miscellaneous salts, buffers, protein-stabilizers, antibodies, conjugates, water or other non-reactive ingredients.
- According to the concept of Universal Precautions (29 CFR 1910.1030), all human blood and certain human body fluids must be treated as if known to be infectious for HIV, HBV and other bloodborne pathogens. No known test method can offer complete assurance that products derived from human blood will not transmit infection; thus, they should be handled as though they contain infectious agents. Furthermore, individual patient samples being tested represent a heightened, unknown hazard. Aerosolization/inhalation, contact and mucous membrane exposure should be avoided during sample and kit handling. Consider equipment that potentially comes in contact with human source material as contaminated until appropriately decontaminated.
- Do not eat, drink or smoke when using this product.

- Wear protective gloves/protective clothing/eye protection/face protection. Take off contaminated clothing and wash before reuse.

SECTION 4: EMERGENCY FIRST AID MEASURES

Health Effects:	Symptoms of overexposure may include headache, and congestion. May be harmful if swallowed. May be harmful in contact with skin.
Eye Contact:	Flush eyes with copious water for at least 15 minutes. Ensure adequate flushing by separating the eyelids with fingers while flushing with water. OBTAIN MEDICAL ATTENTION.
Skin Contact:	Remove contaminated clothing. Flush skin with copious water and wash affected area with soap and water. If blood-to-blood contact occurs or if more severe symptoms develop, consult a physician.
Inhalation:	Remove person from exposure area to fresh air. Treat symptomatically and supportively. If breathing becomes difficult, immediately call for emergency medical assistance. 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:	May release toxic oxides of carbon, nitrogen and sulfur.
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 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 according to product and label instructions (generally at 2-8°C).
Caution, consult accompanying documents. Read and follow all the Precautions and Warnings in the kit product instructions.	
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*: The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

100% Glycerol [CAS# 56-81-5] - OEL:			
BELGIUM:	TWA	10 mg/m^3	MAR2002
FINLAND:	TWA	20 mg/m^3	NOV2011
FRANCE:	VME	10 mg/m^3	FEB2006
GERMANY:	MAK	50 mg/m^3, inhal	2011
ITALY:	TWA	10 mg/m^3	
KOREA:	TWA	10 mg/m^3 (mist)	2006
MEXICO:	TWA	10 mg/m^3 (inhalable)	2004
THE NETHERLANDS:	MAC-TGG	10 mg/m^3	2003
NEW ZEALAND:	TWA	10 mg/m^3 (mist)	JAN2002
PERU:	TWA	10 mg/m^3	JUL2005
SWITZERLAND:	MAK-W KZG-W	50 mg/m^3 100 mg/m^3, inhal	 JAN2011
UNITED KINGDOM:	TWA	10 mg/m^3	OCT2007
ARGENTINA, BULGARIA, COLOMBIA, JORDAN		check ACGIH TLV	
SINGAPORE, VIETNAM		check ACGIH TLV	
UNITED STATES:	TLV-TWA PEL-T-TWA	10* ppm (*total mist) 15* 5** mg/m^3 (*total dust **respirable fraction) ***Remarks***: Upper Respiratory Tract irritation	ACGIH Threshold Limit Values (TLV) OSHA 29,1910.1000 Z-1, 1989
[Source: RTECS September 2013 Update and Raw Material Vendor Safety Data Sheet]			

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
ITALY	TWA	*Valore a breve termine: C 0,29 mg/m³, C 0,11* ppm* *A4; sodio azide; *come azido idrazonico, vapore*	
KOREA:	CL	0.1 ppm (0.3 mg/m^3)	2006
THE NETHERLANDS:	MAC-TGG	0.1 mg/m^3, skin	2003
NEW ZEALAND:	CL	0.11 ppm (0.29 mg/m^3)	JAN2002
PERU:	TWA 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]	

100% Sodium Metabisulfite [CAS# 7681-57-4] - OEL:			
AUSTRALIA:	TWA	5 mg/m^3`	JUL2008
BELGIUM:	TWA	5 mg/m^3	MAR2002
DENMARK:	TWA	5 mg/m^3	MAY2011
FRANCE:	VME	5 mg/m^3	FEB2006
ICELAND:	TWA	5 mg/m^3	NOV2011
KOREA:	TWA	5 mg/m^3	2006
NEW ZEALAND:	TWA	5 mg/m^3	JAN2002
THE NETHERLANDS:	MAC-TGG	5 mg/m^3	2003
NORWAY:	TWA	5 mg/m^3	JAN1999
PERU:	TWA	5 mg/m^3	JUL2005
SWITZERLAND:	MAK-W	5 mg/m^3, inhal	JAN2011

100% Sodium Metabisulfite [CAS# 7681-57-4] - OEL:		
UNITED KINGDOM: TWA	5 mg/m^3	OCT2007
ARGENTINA, BULGARIA, COLOMBIA, JORDAN	check ACGIH TLV	
SINGAPORE, VIETNAM	check ACGIH TLV	
UNITED STATES: TLV-TWA PEL-T-TWA	5 mg/m^3 5 mg/m^3	ACGIH, 1996, 2013 OSHA 29,1910.1000 Z-1, 1989
Remarks: TLV-TWA refers to Appendix A – Carcinogens. 1996 Adoption.		
[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, 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 or 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 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:	Chlamydia Culture Confirmation Monoclonal Antibody: Blue aqueous liquid. Pathfinder® Mounting Media: Clear aqueous liquid.		
Odor/odour:	No applicable information was found.	**Odor/odour threshold:**	Not Established.
pH:	Neutral, pH between 6 and 8.		
Boiling point:	Undetermined.	**Melting point:**	Undetermined.
Flash point:	Not applicable. Flammable limits: LEL/LFL is Not applicable; UEL/UFL is Not applicable.		
Evaporation rate:	Data is not available.		
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:	Chlamydia Culture Confirmation Monoclonal Antibody: Approximately 1. Other data is not available.
Solubility:	Miscible in water.
Partition coefficient (n-octanol/water):	No applicable information was found.
Auto igniting:	Product is not known to be self-igniting.
Decomposition temperature:	No applicable information was found.
Viscosity:	No applicable information was found.
Danger of explosion:	**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. Keep **Glycerol** solutions away from strong oxidizing agents, including sodium hypochlorite (bleach) and potassium permanganate, as could potentially form explosive mixtures.
Molecular mass:	Mixture**.**
No Other Standard Characteristics applicable to the identification or hazards of the product are known.	

SECTION 10: STABILITY AND REACTIVITY INFORMATION

NOTE: Chemical reactions that could result in a hazardous situation (e.g. generation of flammable or toxic chemicals, fire or detonation) are listed here. Although not intended to be complete, an overview of important reactions involving common chemicals is provided to assist in the development of safe work practices.

Chemical Stability / Reactivity:	Stable under ordinary conditions of use and storage.
Conditions and/or Materials to Avoid:	**Sodium azide** may react with lead or copper plumbing to form highly explosive metal azides; buildup in metal plumbing has led to laboratory explosions, so flush with copious water when pouring dilute solutions down the drain to prevent such explosive buildup.
Materials to Avoid:	Keep **glycerol** solutions away from strong oxidizing agents, including sodium hypochlorite (bleach) and potassium permanganate, as these could potentially form explosive mixtures.
Hazardous Decomposition Products:	May release toxic oxides of carbon, nitrogen and sulfur.
Hazardous Polymerization:	Has not been reported to occur.

SECTION 11: TOXICOLOGICAL INFORMATION -- GENERAL COMPOSITE

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

Acute Health Effects

Acute Toxicity:	May be harmful if swallowed. May be harmful in contact with skin.
Primary Irritant Effect:	May slightly irritate eyes or skin, depending on amount and contact time.
Serious Eye Damage / Irritation:	May slightly irritate eyes depending on amount and contact time.
STOT-Single Exposure:	No applicable information was found.
Aspiration Hazard:	No applicable information was found.
Other Acute Health Effects:	Possible risk of irreversible effects.

Chronic Toxicity

Respiratory or Skin Sensitization:	Prolonged or repeated exposure may cause allergic reaction in certain sensitive individuals.
Carcinogenicity:	IARC designates **Evans Blue** (CAS# 314-13-6) in the carcinogen Group 3, which specifies, "the Agent is NOT CLASSIFIABLE as Carcinogenic."
Germ Cell Mutagenicity:	No applicable information was found.
Reproductive Hazard:	No reproductive toxic effect known.
STOT-Repeated Exposure:	No applicable information was found.

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

SECTION 12: ECOLOGICAL INFORMATION

This product was not tested. The following assessment is based on information for the ingredients.	
Ecotoxicity:	**100% Sodium Azide [CAS# 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 **Concentrated *Sodium Metabisulfite* [CAS# 7681-57-4] *:** Fish LC_{50} - Oncorhynchus mykiss (rainbow trout) – 150-200 mg/l – 96 h Daphnia EC_{50} - Daphnia magna (Water flea) – 89 mg/l – 24 h Algae LC_{50} - Scenedesmus subspicatus – 48 mg/l – 72 h Bacteria - Pseudomonas putida – 56 mg/l – 17 h ** Source: Raw Material Vendor Safety Data Sheet, RTECS and/or CCOHS Cheminfo*
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; buildup in metal plumbing has led to laboratory explosions, so flush with copious water when pouring dilute solutions down the drain to prevent such explosive buildup. 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 of 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: 0

Carcinogenicity Categories:

IARC (International Agency for Research on Cancer): IARC Group 3, The Agent is NOT CLASSIFIABLE as Carcinogenic to Humans: **Evans Blue**, CAS# 314-13-6.

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

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

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

National Regulations – Other Domestic / Foreign Laws:

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

1. **United States** – Occupational Safety Health Administration *Hazard Communication Standard* 29 CFR 1910.1200 (US HCS)
2. **Taiwan** – Regulation Lao-An-3-Tzu-No. 0960145703 / Published National Standard CNS 15030
3. **People's Republic of China** – National Standard GB/T 17519-2013, GB 30000-2013
4. **New Zealand** – *Hazardous Substances and New Organisms* Act 1996 (HSNO), *Hazardous Substances (Classification)* Regulations 2001 and *Thresholds and Classifications* January 2012 (as published in 2008)
5. **Mexico** – Standard NMX-R-019-SCFI-2011
6. **Korea** – *Public Notice 2008-26* for the hazard classification criteria for this product
7. **Japan** – Industrial Safety and Health Law (ISHL) National Standard JIS Z7252, JIS Z7253
8. **European Community** (EC) – applicable *CLP* related regulations (2010/453/EC, 2008/1272/EC, 2006/1907/EC etc.)
9. **Canada** – Standard *Workplace Hazardous Materials Information System* (WHMIS-GHS) Canadian Standard for the hazard classification criteria for this product.
10. **Brazil** – Regulation NRB 14725:2009
11. **Australia** – Code of Practice *Preparation of Safety Data Sheets for Hazardous Chemicals* under Section 274 of the Work Health and Safety (WHS) Act.
    Australian Inventory of Chemical Substances (AICS): All pertinent ingredients are listed.
12. Analogous GHS-based global regulations

Inventory status

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

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

United States SARA:

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

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

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

Japan – Industrial Safety and Health Law (ISHL) National Standard **JIS Z7252, JIS Z7253**
Classification JIS – listed in Class 1: ***Sodium Azide***, CAS-No. 26628-22-8 [No. PRTR Law: 11], product concentration: **< 0.1%**.

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

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

SECTION 16: OTHER INFORMATION

Hazard statement abbreviation(s)

Acute Tox. – oral.	Acute toxicity – ingested (swallowed)
Acute Tox. – skn.	Acute toxicity – skin contact (dermal)
Skin Irrit.	Skin irritation
Eye Irrit.	Eye irritation
Eye Damage	Serious eye damage
Aquatic Acute	Acute aquatic toxicity
Aquatic Chronic	Chronic aquatic toxicity
Cat.	Category
H300 + H310	Fatal if swallowed or in contact with skin.
H302	Harmful if swallowed.
H303	Harmful if swallowed.
H313	May be harmful in contact with skin.
H318	Causes serious eye damage.
H402	Harmful to aquatic life.
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.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER or doctor/ physician.
P312	Call a POISON CENTER or doctor/physician if you feel unwell.
P501	Dispose of this material in a safe way, and in accordance with local, regional, national and international regulations.
Caution	Contains inactivated pathogen. Handle as if capable of transmitting potentially infectious agents (*Standard* and *Universal Precautions*)

This test kit should be handled only by qualified personnel trained in laboratory procedures and familiar with their potential hazards. Specific warnings are given in the instructions for use. The absence of a specific warning should not be interpreted as an indication of safety.

For *in vitro* diagnostic use.

Sources of key data used to compile the Safety Data Sheet:

Raw Material Vendor Safety Data Sheets
United Nations (UN) Globally Harmonized System (GHS)
United States OSHA Hazard Communication Standard (HCS)1910.1200
Canadian Workplace Hazardous Materials Information System (WHMIS)
Mexican Standard (NMX-R-019-SCFI-2011) [regulatory translation and summaries]
European Community (EC) Regulations 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]
Taiwan Regulation Lao-An-3-Tzu-No. 0960145703 / Published National Standard CNS 15030 [regulatory translation if available / summaries]
Korean Public Notice 2008-26 [regulatory translation if available and summaries]
Japanese Industrial Standard JIS Z7252, JIS Z7253 [regulatory translation if available and summaries]
Registry of Toxic Effects of Chemical Substances (RTECS)
Canadian Centre for Occupational Health and Safety (CCOHS) *CHEMINFO databases, etc.*
International Agency for Research on Cancer (IARC)
American Conference of Governmental Industrial Hygienists (ACGIH)
Occupational Safety and Health Administration, U.S. Department of Labor (OSHA)
National Toxicity Program (NTP)
National Institute for Occupational Safety and Health (NIOSH)
World Health Organization. *Laboratory Biosafety Manual*
CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories*
Australian Inventory of Chemical Substances (ACIS)
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
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
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
HNOC – Hazard Not Otherwise Classified
HSNO – Hazardous Substances and New Organisms Act 1996 (New Zealand)
IARC – International Agency for Research on Cancer
IATA – International Air Transport Association
ICAO - International Civil Aviation Organization
IDLH – Immediately Dangerous to Life or Health
IMDG – International Maritime Dangerous Goods
IPCS – International Programme on Chemical Safety
ISHA – Industrial Safety and Health Act
LC_{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
STOT – Specific Target Organ Toxicity
TCCA – Toxic Chemical Control Act
TLV/TWA – Threshold Limit Value / Time-Weighted Average
UN – United Nations
US EPA – United States Environmental Protection Agency
US HCS – Hazard Communication Standard, USA
US OSHA – Occupational Safety and Health Administration, U.S. Department of Labor
WHMIS –Workplace Hazardous Materials Information System, Canada
WHO – World Health Organization (United Nations

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

This revision: Update, reformatted and added new GHS information.

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