

SAFETY DATA SHEET (SDS)


SECTION 1: IDENTIFICATION OF PRODUCT (MIXTURE) AND SUPPLIER

Product Name:	MONOFLUO™ <i>Pneumocystis jirovecii</i> (carinii) IFA Test Kit
Product Number:	32515, 24 Tests 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: 32524 (refer to Section 2).
Intended Use:	Immunofluorescent Antibody Test Kit for the Detection and Identification of <i>Pneumocystis jirovecii</i> (<i>P. carinii</i>) in Respiratory Tract Specimens. The MONOFLUO™ <i>Pneumocystis</i> Immunofluorescent Antibody Test Kit is to be used for the detection of <i>Pneumocystis jirovecii</i> (<i>P. carinii</i>) cysts and trophozoites in specimens collected from the respiratory tract.
Manufactured by:	Bio-Rad Laboratories, Inc.
Address:	6565 185th Avenue NE Redmond, WA 98052-5039, USA
Website:	www.bio-rad.com
Phone Number:	1-800-2-BIORAD (1-800-224-6723); or 1-425-881-8300 (daytime PT)
SDS e-mail contact:	ro-sds@bio-rad.com
Technical Information Contacts:	Bio-Rad provides a toll free line for technical assistance, available 24 hours a day, 7 days a week. In the United States of America and Puerto Rico, call toll free 1-800-2-BIORAD (1-800-224-6723). Outside the U.S.A., please contact your regional Bio-Rad office for assistance. <i>Refer to section 16 for non-US local Bio-Rad agent contact information.</i>
EU CE 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 (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. <i>Refer to section 16 for non-US local Bio-Rad agent contact information.</i>

SECTION 2: HAZARDS IDENTIFICATION -- HAZARDOUS COMPONENTS

This test kit should be handled only by qualified personnel trained in laboratory procedures and familiar with their potential hazards. Specific warnings are given in the instructions for use. The absence of a specific warning should not be interpreted as an indication of safety. The following information is furnished for those product hazardous constituents that require regulatory control or disclosure at the concentration found in the product. 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 <i>Pneumocystis jirovecii</i> Staining Reagent, 1 Dropper bottle (2.2 mL)	<ul style="list-style-type: none"> - FITC-labeled monoclonal antibodies (murine); protein-stabilized buffer, pH 8. - < 0.5% Triton X-100 [C₁₄H₂₂O(C₂H₄O)_n (n=9-10)], CAS# 9002-93-1, EC No: not found. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration. - Preserved with ~ 0.1% sodium azide [NaN₃], CAS# 26628-22-8 and EC No 247-852-1. Not subject to UN GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration - < 0.1% Evans blue stain [C₃₄H₂₄N₆O₁₄S₄ • 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. <p>Volume sufficient for staining 24 individual test wells.</p>

Component*	Content
R2 Mounting Medium, 1 Dropper bottle (3.5 mL)  WARNING	- Buffered glycerol [$\leq 50\%$ C ₃ H ₈ O ₃], CAS# 56-81-5, EC No 200-289-5 with an anti-quencher, pH 8.3. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration. - Contains $\leq 2\%$ formalin buffered solution. [$< 0.8\%$ Formaldehyde (HCHO), CAS# 50-00-0, EC No 200-001-8 with $\leq 0.1\%$ Methanol (CH ₃ OH), CAS# 67-56-1, EC No. 200-659-6]. GHS \ US HCS \ EC CLP Classification: WARNING; GHS07; H317; P280; P302 + P352, P333 + P313.
R3 Fluorescence Microscopy Slides, (24 x 2 wells each) <i>Catalog # 32524</i>	- Fluorescence microscopy slides (2 wells each). - These Collection Slides consist of ~ 98% inert glass with a ~2% inert polymer coating, which have not been chemically or biologically processed since manufacture into new glass slides and thus, should not intrinsically pose a chemical or biological hazard as regulated under CFR 29 §1910.1200 (WA WAC 296-800-170). - Do not handle broken slides with unprotected hands.

* 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 regulation:

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

Component R2 - $< 0.8\%$ **Formaldehyde** (HCHO, CAS# 50-00-0, EC No 200-001-8) [with $\leq 0.1\%$ **Methanol** (CH₃OH, CAS# 67-56-1, EC No. 200-659-6)] buffered solution ($\leq 2\%$ Formalin).

Comprehensive GHS Based Classification: Skin Sensitizer Category 1



Label(s):

Signal Word:

WARNING

Label Hazard Statements:

H317

May cause an allergic skin reaction.

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

P280

Wear protective gloves / protective clothing / eye protection / face protection.

P302 + P352

IF ON SKIN: Wash with plenty of soap and water.

P333 + P313

If skin irritation or rash occurs: Get medical advice/ attention.

P501

This material and its container must be disposed of in a safe way and in accordance with local, regional, national and international regulations.

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

P261

Avoid breathing mist / vapors/vapours / spray.

P272

Contaminated work clothing should not be allowed out of the workplace.

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

Note: 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 latest 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: Glycerol

 Chemical concentrations found in this product: **50% v/v in component R2 (aqueous solution)**
Data for Concentrated / 100% chemical used in the product mixture (concentration tested):

CAS#: 56-81-5 (100%)	LD ₅₀ (oral-rat): 12,600 mg/kg
EC No: 200-289-5 (100%)	LC ₅₀ (inhalation-rat): > 570 mg/m ³ /1H
RTECS#: MA8050000 (100%)	LD ₅₀ (skin-rabbit): > 10000 mg/kg
Index No: NA (100%)	LC ₅₀ (96 hr-fish): NE
Chemical Formula: C ₃ H ₈ O ₃ (100%)	Flash Point: 320 F / 160° C (100%)
Molecular weight: 92.09 g/mol (100%)	Flammable limits: LEL/LFL is <u>0.9%</u> vv in air.
Synonyms/Trade Names: 1,2,3-Propanetriol; 1,2,3-Trihydroxypropane; 90 Technical glycerine; Citifluor AF 2; lyzerin, wasserfrei, Glycerin; Glycerin mist; Glycerin mist; Glycerin, anhydrous; Glycerin, synthetic; Glycerine; Glyceritol; Glycyl alcohol; Grocolene; MOON; Osmoglyn; Star; Synthetic glycerin; Trihydroxypropane	

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 concentration found in this product: **≤ 0.8% (v/v) non-gaseous formaldehyde in an < 0.1% (v/v) buffered methanol / water solution [≤ 2% Formalin Solution] in component R2 (aqueous solution)**

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

Hazardous ingredient concentration in raw material: Formaldehyde, (≤ 0.8% v/v; Methanol: ≤ 0.1% v/v (100%) +

CAS#: 50-00-0 (formaldehyde), 67-56-1 (methanol)

EC No: 200-001-8 (formaldehyde), 200-659-6 (methanol)

Index No: 605-001-00-5 (formaldehyde); 603-001-00-X (methanol)

Registration No: 01-2119433307-44-XXXX (methanol)

RTECS#: LP8925000 (formaldehyde), PC1400000 (methanol)

Chemical Formula: HCHO (formaldehyde), CH₃OH (methanol)

Flash Point: 185°F / 85°C (10% Formalin solution), 52° F / 11° C (100% methanol)

LD₅₀ (oral-rat): > 100 mg/kg (100% formaldehyde), 5628 mg/kg (100% methanol)

LC₅₀ (inhalation-rat): 1000 mg/m³ (30 min.) (100% formaldehyde), 64000ppm/4H (100% methanol)

LD50 (skin-rabbit): NE

Synonyms/Trade Names: Aldehyde formique; Aldehyd mravenci; Aldeide formica; Fannoform; Formaldehyd; BFV; Formalin 40; Formalina; Formalin-loesungen; Formalith; Formic aldehyde; FYDE; Lysoform; Methaldehyde; Methanal; Methyl aldehyde; Methylene oxide; Formaldehyde; Formaldehyde, gas; Formalin; Formaline; Formol; Morbicid; Oplossingen; Oxomethane; Oxymethylene; Paraform; Superlysoform; NCI-C02799

Listed Carcinogen: TLV A2, NTP 2, IARC 2A (concentrated formaldehyde)

CA Proposition 65: Chemical known to the State of California to cause cancer; this designation is for formaldehyde gas, not formaldehyde containing solutions (concentrated formaldehyde)

Raw Material GHS / US HCS / EC CLP Classification (10%):
DANGER!

Flam. Liq. Cat. 4, Acute Tox. – oral Cat. 4, Skin Irrit. Cat. 2, Eye Damage Cat. 1, Skin Sens., Cat. 1, Carc. Cat. 2, STOT-SE Cat. 1

H226, H302, H315, H317, H318, H351, H370, H402

P260, P280, P303+P361+P353, P304+P340, P305 + P351 + P338, P308 + P310, P333+P313, P501

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


Chemical Ingredient: Triton X100

Chemical concentrations found in this product: **≤ 0.5% v/v in Component R1 (aqueous solution)**

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

CAS#: 9002-93-1 (100%)

LD₅₀ (oral-rat): 1800 mg/kg

EC No: not found (100%)

LD₅₀ (skin-rabbit): 8000 mg/kg

RTECS#: MD0907700 (100%)

Flash Point: 484°F / 251°C

Chemical Formula: (C₂H₄O)_nC₁₄H₂₂O (100%)

pH value: ~ 9.7

LC₅₀ (96 hr-fish): Pimephales promelas (fathead minnow) - 8.9 mg/l

Synonyms/Trade Names: t-Octylphenoxypolyethoxyethanol; 4-(1,1,3,3-Tetramethylbutyl)phenyl-polyethylene glycol; Polyethylene glycol tert-octylphenyl ether

Serious eye damage/eye irritation, Eyes – rabbit Result: Moderate eye irritation - 24 h

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

Acute Tox. – Oral Cat. 4, Eye Damage Cat. 1, Skin Irr. Cat 2, Aquatic Acute Cat. 2. Aquatic Chron. Cat. 1

H302, H315, H318, H401, H410

P264, P270, P273, P280, P301 + P312 + P330, P302 + P352, P305 + P351 + P338, P332 + P313, P362, P391, P501

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



Chemical Ingredient Data / Information
Chemical Ingredient: Sodium azide

 Chemical concentrations found in this product: **~0.1% w/v in component R1 (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 (100%)
RTECS#: VY8050000 (100%)	Fish LC ₅₀ – Lepomis macrochirus (Bluegill) – 0.68 mg/l – 96 h
Chemical Formula: NaN ₃ (100%)	Molecular weight: 65.01 g/mol (100%)
Synonyms/Trade Names: Azide, sodium; Azoture de sodium; Azydek sodu; NSC 3072; Kazoe; Natriumazid; Natriummazide; NCI-C06462; Nemazyd; Sodium azide; Sodium, azoture de; Sodium, azoturo di, Smitte; U-3886;	

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

Acute Tox. – oral. Cat. 2, Acute Tox. – skn. Cat. 1, Aquatic Acute Cat. 1, Aquatic 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: Evans Blue

 Chemical concentrations found in this product: **≤ 0.1% w/v in component R1 (aqueous solution)**
Data for Concentrated / 100% chemical used in the product mixture (concentration tested):

CAS#: 314-13-6 (100%)	LD ₅₀ (Intraperitoneal-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 No: 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'-biphenylene)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%): 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. This chemical is not listed in 2008/1272/EC.

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

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 GHS-based hazard labeling]:
 - **EDTA, tetrasodium salt, dihydrate** [C₁₀H₁₂N₂O₈Na₄•2H₂O], CAS# 10378-23-1 [≤ 0.5% in component **R1**].
 - The miscellaneous salts, buffers, protein-stabilizers, antibodies, conjugates, water, anti-quencher, 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 congestion and breathing difficulty. May cause allergic skin reaction upon repeated exposure. May be harmful if enough is ingested (generally quantities above those found in the kit).
Eye Contact:	Flush eyes with copious water for at least 15 minutes. Ensure adequate flushing by separating the eyelids with fingers while flushing with water. OBTAIN MEDICAL ATTENTION.
Skin Contact:	Remove contaminated clothing. Flush skin with copious water and wash affected area with soap and water. If blood-to-blood contact occurs or if more severe symptoms develop, consult a physician.
Inhalation:	Remove person from exposure area to fresh air. If breathing becomes difficult, immediately call for emergency medical assistance. Treat symptomatically and supportively. Generally, this aqueous product is not a significant inhalation hazard in the kit volumes and concentrations present.
If Swallowed:	If ingested, rinse out mouth thoroughly with water, provided the person is conscious, and OBTAIN MEDICAL ATTENTION. Call a physician or the local poison control center. Treat symptomatically and supportively. If vomiting occurs, keep head lower than hips to prevent aspiration.
Notes to Physician:	According to the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030), Universal Precautions apply. Persons handling human blood source samples should be offered Hepatitis B vaccination prior to working with human source material.

SECTION 5: FIREFIGHTING MEASURES

Extinguishing Media:	Use extinguishing media appropriate for the surrounding fire.
Hazardous Combustion Products:	May release toxic oxides of carbon, nitrogen or sodium, and toxic ammonia or formaldehyde gas.
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 and/or equivalent hazardous material 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 an appropriate inert material (e.g. spill pillows, acid absorbent pads), which are secured in an appropriate, labeled, sealed container. Material used to absorb the spill may require hazardous material waste disposal. Infectious, chemical and laboratory wastes must be handled and discarded in accordance with all local, regional, national and international regulations.
- ◆ Broken slides contaminated with blood or other humans 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.
- ◆ Refer to Sections 8 and 13 for more specifics.

SECTION 7: HANDLING AND STORAGE INFORMATION

Handling:	<p>This test kit should be handled only by qualified personnel trained in laboratory procedures and familiar with their potential hazards. Follow proper good laboratory practices and safety guidelines for handling chemical, biological and laboratory hazards.</p> <p>Do not smoke, eat, or drink in areas where patient samples and kit reagents are handled. Wash your hands after use. Wear appropriate personal protective equipment (PPE) including gloves, lab coat or equivalent and eye/face protection.</p> <p>Keep containers tightly closed; avoid splashing, spills and the generation of aerosols.</p> <p>Handle all specimens, materials and equipment used to perform the operations as though they were capable of transmitting infectious disease, as per <i>Standard</i> and <i>Universal Precautions</i>.</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. 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.

Concentrated Formaldehyde [CAS# 50-00-0]: - OEL:			
ARAB Republic of Egypt:	TWA	2 ppm (3 mg/m ³)	1993
AUSTRALIA:	TWA	1 ppm (1.2 mg/m ³)	2008
	STEL	2 ppm (2.5 mg/m ³), Carcinogen	
AUSTRIA:	MAK-TMW	0.5 ppm (0.6 mg/m ³)	2007
	KZW	0.5 ppm (0.6 mg/m ³), skin, sen	
BELGIUM:	STEL	0.3 ppm (0.38 mg/m ³)	2002
DENMARK:	CL	0.3 ppm (0.4 mg/m ³), carc	2011
EC (European Union):	TWA	10 ppm / 25 mg/m ³	
FINLAND:	TWA	0.3 ppm (0.37 mg/m ³)	2011
	CL	1 ppm (1.2 mg/m ³)	
FRANCE:	VME	0.5 ppm,	2006
	VLE	1 ppm, C3 Carcinogen	

Concentrated Formaldehyde [CAS# 50-00-0]: - OEL:			
GERMANY:	MAK	0.3 ppm (0.37 mg/m ³)	2011
HUNGARY:	TWA STEL	0.6 mg/m ³ 0.6 mg/m ³ , skin	2000
ICELAND:	TWA STEL	0.3 ppm (0.4 mg/m ³) 1 ppm (1.2 mg/m ³), sen	2011
JAPAN:	OEL CL	0.1 ppm (0.12 mg/m ³), 2A carc, a2 sen, s1 sen 0.2 ppm (0.24 mg/m ³)	2012
KOREA:	TWA STEL	1 ppm (1.5 mg/m ³) 2 ppm (3 mg/m ³)	2006
MEXICO:	peak	2 ppm (3 mg/m ³)	2004
THE NETHERLANDS:	MAC-TGG	1.5 mg/m ³	2003
NEW ZEALAND:	CL	1 ppm (1.2 mg/m ³), sen	2002
NORWAY:	TWA	0.5 ppm (0.6 mg/m ³)	1999
PERU:	TWA	0.3 ppm (0.37 mg/m ³)	2005
THE PHILIPPINES:	TWA	5 ppm (6 mg/m ³)	1993
POLAND:	MAC(TWA) MAC(STEL)	0.5 mg/m ³ 1 mg/m ³	1999
RUSSIA:	STEL	0.5 mg/m ³ , skin	2003
SWEDEN:	TWA CL	0.5 ppm (0.6 mg/m ³) 1 ppm (1.2 mg/m ³), Carcinogen, Sen	2005
SWITZERLAND:	MAK-W KZG-W	0.3 ppm (0.37 mg/m ³) 0.6 ppm (0.74 mg/m ³), carc 3, sen	2011
THAILAND:	TWA	3 ppm 5 ppm	1993
TURKEY:	TWA	5 ppm (6 mg/m ³)	
UNITED KINGDOM:	TWA STEL	2 ppm (2.5 mg/m ³) 2 ppm (2.5 mg/m ³)	2007
ARGENTINA, BULGARIA, COLOMBIA, JORDAN, SINGAPORE, VIETNAM		check ACGIH TLV	
UNITED STATES*:	TLV-TWA PEL-T-TWA TLV-STEL TWA-REL Ceiling-REL	0.3 ppm / 0.37 mg/m ³ 0.75 ppm 2 ppm 0.016 ppm 0.1 ppm	ACGIH - TLV] *gas / airborne OSHA 1910.1048 OSHA 1910.1048 NIOSH Recommended Exposure Limits NIOSH Recommended Exposure Limits
<p>* Remarks: Eye & Upper Respiratory Tract irritation Suspected human carcinogen Sensitizer. Substance listed; for more information see OSHA document 1910.1048.</p> <p>Potential Occupational Carcinogen Formalin is an aqueous solution that is 37% formaldehyde by weight; inhibited solutions usually contain 6-12% methyl alcohol. Also see specific listings for Sigma - HT501128 Page 4 of 8 Formaldehyde and Methyl alcohol. See Appendix A.</p> <p>Potential Occupational Carcinogen Formalin is an aqueous solution that is 37% formaldehyde by weight; inhibited solutions usually contain 6-12% methyl alcohol. Also see specific listings for Formaldehyde and Methyl alcohol. See Appendix A</p>			
[Source: CCOHS CHEMINFO 2013, 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)	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

100% Sodium Azide [CAS# 26628-22-8] - OEL:

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	C 0.29 mg/m ³ , C 0.11* ppm	*sodium azide, vapor
KOREA:	CL	0.1 ppm (0.3 mg/m ³)	2006
THE NETHERLANDS:	MAC-TGG	0.1 mg/m ³ , skin	2003
NEW ZEALAND:	CL	0.11 ppm (0.29 mg/m ³)	2002
PERU:	TWA 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]

Concentrated Methanol [CAS# 67-56-1] - OEL:

ARAB Republic of Egypt:	TWA	200 ppm (260 mg/m ³), skin	1993
AUSTRALIA:	TWA STEL	200 ppm (262 mg/m ³) 250 ppm (328 mg/m ³)	2008
AUSTRIA:	MAK-TMW KZW	200 ppm (260 mg/m ³) 800 ppm (1040 mg/m ³), skin	2007
BELGIUM:	TWA STEL	200 ppm (266 mg/m ³) 250 ppm (333 mg/m ³), skin	2002 2002
DENMARK:	TWA	200 ppm (260 mg/m ³), skin	2011
EC (European Union):	TWA	260 mg/m ³ (200 ppm), skin	2006
FINLAND:	TWA STEL	200 ppm (270 mg/m ³) 250 ppm (330 mg/m ³), skin	2011
FRANCE:	VME VLE	200 ppm (260 mg/m ³) 1000 ppm (1300 mg/m ³)	2006
GERMANY:	MAK	200 ppm (270 mg/m ³)	2011
HUNGARY:	TWA STEL	260 mg/m ³ 1040 mg/m ³ , skin	2000
ICELAND:	TWA	200 ppm (260 mg/m ³), skin	2011
JAPAN:	OEL	200 ppm (260 mg/m ³), skin	2012
KOREA:	TWA STEL	200 ppm (260 mg/m ³) 250 ppm (310 mg/m ³), skin	2006
MEXICO:	TWA STEL	200 ppm (260 mg/m ³) 310 mg/m ³ (250 ppm)	2004

Concentrated Methanol [CAS# 67-56-1] - OEL:

THE NETHERLANDS:	MAC-TGG	260 mg/m ³ , Skin	2003
NEW ZEALAND:	TWA STEL	200 ppm (262 mg/m ³) 250 ppm (328 mg/m ³), skin	2002
NORWAY:	TWA	100 ppm (130 mg/m ³)	1999
PERU:	TWA STEL	200 ppm (262 mg/m ³) 250 ppm (328 mg/m ³)	2005
THE PHILIPPINES:	TWA	200 ppm (260 mg/m ³)	1993
POLAND:	MAC(TWA) MAC(STEL)	100 mg/m ³ 300 mg/m ³	1999
RUSSIA:	TWA STEL	5 mg/m ³ 15 mg/m ³ , skin	2003
SWEDEN:	TWA STEL	200 ppm (250 mg/m ³) 250 ppm (350 mg/m ³), skin	2005
SWITZERLAND:	MAK-W KZG-W	200 ppm (260 mg/m ³) 800 ppm (1040 mg/m ³), skin	2011
THAILAND:	TWA	200 ppm (260 mg/m ³)	1993
TURKEY:	TWA	200 ppm (260 mg/m ³)	1993
UNITED KINGDOM:	TWA STEL	200 ppm (266 mg/m ³) 250 ppm (333 mg/m ³), skin	2007
ARGENTINA, BULGARIA, COLOMBIA, JORDAN, SINGAPORE, VIETNAM		check ACGIH TLV	
UNITED STATES:	TLV-TWA TLV-STEL PEL-T-TWA PEL-T-STEL REL-TWA REL-STEL	200 ppm (260 mg/m ³), skin 250 ppm (325 mg/m ³), skin 200 ppm (260 mg/m ³), skin 250 ppm (325 mg/m ³), skin 200 ppm (260 mg/m ³), skin 250 ppm (325 mg/m ³), skin	ACGIH, 1996, 2013 OSHA 29,1910.1000 Z-1, 1994 NIOSH Recommended Exposure Limits
Remark: Headache / Eye damage Substances for which there is a Biological Exposure Index or Indices (see BEI® section) Danger of cutaneous absorption. The value in mg/m ³ is approximate.			
[Source: CCOHS CHEMINFO 2013, RTECS September 2013 Update and Raw Material Vendor Safety Data Sheet]			

100% Glycerol [CAS# 56-81-5] - OEL:

BELGIUM:	TWA	10 mg/m ³	2002
FINLAND:	TWA	20 mg/m ³	2011
FRANCE:	VME	10 mg/m ³	2006
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)	2002
PERU:	TWA	10 mg/m ³	2005
SWITZERLAND:	MAK-W KZG-W	50 mg/m ³ 100 mg/m ³ , inhal	2011
UNITED KINGDOM:	TWA	10 mg/m ³	2007
ARGENTINA, BULGARIA, COLOMBIA, JORDAN, 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)	ACGIH Threshold Limit Values (TLV) OSHA 29,1910.1000 Z-1, 1989
Remarks: Upper Respiratory Tract irritation			
[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, and to prevent hazard 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 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:	<i>Pneumocystis jirovecii Staining Reagent:</i> <i>Mounting Media:</i> <i>Fluorescence Microscopy Slides:</i>	Blue aqueous liquid. Clear aqueous liquid. Solid Glass Slides.	
Odor/odour:	No applicable information was found.	Odor/odour threshold:	Not Established.
pH:	The liquid chemical components are between 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, 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:	Not Established.		
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. Keep <i>Glycerol</i> solutions away from strong oxidizing agents, including sodium hypochlorite (bleach) and potassium permanganate, as could potentially form explosive mixtures.
Molecular mass:	Mixtures.
No Other Standard Characteristics applicable to the identification or hazards of the product are known.	
Source: Raw Material Vendor SDS, RTECS, CCOHS databases and/or regulatory research	

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.

Stability:	Components are stable with no known inherent significant reactivity.
Conditions to Avoid:	Avoid contact with metals. <i>Sodium azide</i> 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 <i>glycerol</i> 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 or sodium, and toxic ammonia or formaldehyde gas.
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 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.

Chronic Toxicity

Respiratory or Skin Sensitization:	Contains a small volume of a very dilute, sensitizing chemical (<i>Formaldehyde</i>); though the potential for an allergic response is greatly reduced by the dilution, sensitization threshold is unknown, thus handle accordingly.
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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.
- **Broken slides** contaminated with blood or other humans 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 and national regulations.

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 and disposal 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 Product Multi-Modal Transportation: According to US DOT, IATA and UN "Model Regulations", the product must be transported as follows: No known transport restrictions.

Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code: Not applicable

SECTION 15: REGULATORY INFORMATION

Composite HMIS Rating:

Health: 2

Flammability: 0

Reactivity: 0

Carcinogenicity Categories:

IARC (International Agency for Research on Cancer):

- **IARC Group 2A**, The agent is PROBABLY Carcinogenic to Humans: **Formalin solution** (non-gaseous formaldehyde (< 0.8%) in a methanol/water solution) CAS# 50-00-0, EC No 200-659-6 (formaldehyde) (2012).
- **IARC Group 3**, The agent is NOT CLASSIFIABLE as Carcinogenic to Humans: **Evans Blue**, CAS# 314-13-6, EC No 206-242-5 (1987).

NTP (National Toxicity Program): NTP listed as *Reasonably Anticipated to be a Human Carcinogen*: **Formalin solution** (non-gaseous formaldehyde (< 0.8%) in a methanol/water solution), CAS# 50-00-0, EC No 200-659-6 (formaldehyde).

ACGIH TLV-CAR (Threshold Limit Value established by American Conference of Governmental Industrial Hygienists): **ACGIH-TLV Group A2**, *Suspected Human Carcinogen*: **Formalin solution** (non-gaseous **formaldehyde** (< 0.8%) in a methanol/water solution) CAS# 50-00-0, EC No 200-659-6 (formaldehyde).

OSHA Subpart Z (Occupational Health and Safety Administration, U.S. Department of Labor): *OSHA Regulated Carcinogen*: **Formaldehyde** (see 1910.1048) CAS# 50-00-0.

2008/1272/EC (EC CLP): Listed Carcinogen 2

Formalin solution (non-gaseous formaldehyde (< 0.8%) in a methanol / water solution), CAS# 50-00-0, EC No 200-659-6 (formaldehyde).

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: Subclass 6.5 Category B (contact sensitizers)
6. **Mexico** – Standard NOM-018-STPS-2015, NMX-R-019-SCFI-2011
7. **Korea** – Public Notice 2013-37, MoEL 2016-19 Standard for classification and labeling of chemical substances and MSDS
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: Skin Sensitization
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

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 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): Included in the Candidate List of Substances of Very High Concern (SVHC):
None known

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

United States SARA (Superfund Amendments and Reauthorization Act):

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
- **Formaldehyde**, CAS-No. 50-00-0

SARA 313 components: The following components are subject to reporting levels established by SARA Title III, Section 313 in greater quantities than found in this product:

- **Methanol**, CAS-No. 67-56-1
- **Formaldehyde**, CAS-No. 50-00-0

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: $\leq 0.1\%$.
- **Formaldehyde**, CAS-No. 50-00-0 [No. PRTR Law: 411], product concentration: $\leq 0.8\%$.

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 OR REPRODUCTIVE TOXICITY.

Chemical(s) Known to cause Cancer: Formalin Solution (non-gaseous < 0.8% formaldehyde in a methanol / water solution) CAS# 50-00-0; classified under Formaldehyde gas (CAS# 50-00-0). Formaldehyde gas was listed 1988-01-01.

Chemicals known to cause reproductive Toxicity: **Methanol**, CAS# 65-56-1. (Listed 2012-03-16)

SECTION 16: OTHER INFORMATION

Hazard statement abbreviation(s):

Acute Tox. – oral.	Acute toxicity – ingested (swallowed)
Acute Tox. – skn.	Acute toxicity – skin contact (dermal)
Eye Damage	Serious eye damage
Skin Irrit.	Skin irritation
Skin Sens.	Skin sensitisation
Carc.	Carcinogenicity
STOT-SE	Specific target organ toxicity - single exposure
Aquatic Acute	Acute aquatic toxicity
Aquatic Chron	Chronic aquatic toxicity
Flam. Liq.	Flammable liquid Aquatic Acute Acute aquatic toxicity
Cat.	Category
H226	Flammable liquid and vapour.
H300 + H310	Fatal if swallowed or in contact with skin.
H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H351	Suspected of causing cancer.
H370	Causes damage to organs.
H402	Harmful to aquatic life.
H401	Toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P261	Avoid breathing mist / vapors/vapours / spray.
P264	Wash hands thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P272	Contaminated work clothing should not be allowed out of the workplace.
P273	Avoid release to the environment.
P280	Wear protective gloves/ protective clothing.
P301 + P312 + P330	IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell. Rinse mouth.
P302 + P350	IF ON SKIN: Gently wash with plenty of soap and water.
P302 + P352	IF ON SKIN: Wash with plenty of soap and water.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P310	If exposed concerned: Immediately call a POISON CENTER or doctor/ physician.
P310	Immediately call a POISON CENTER or doctor/ physician.
P332 + P313	If skin irritation occurs: Get medical advice/ attention.
P333 + P313	If skin irritation or rash occurs: Get medical advice/attention.
P362	Take off contaminated clothing and wash before reuse.
P391	Collect spillage.
P501	Dispose of contents/ container to an approved waste disposal plant.
P501	This material and its container must be disposed of in a safe way and in accordance with local, regional, national and international regulations.

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 Labeling of Chemicals (GHS) Fifth edition unless otherwise specified.

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

Raw Material Vendor Safety Data Sheets
United Nations (UN) Globally Harmonized System (GHS)
United States OSHA Hazard Communication Standard (US HCS) 1910.1200
Canadian Workplace Hazardous Materials Information System (WHMIS)
Mexican Standard (NOM-018-STPS-2015, NMX-R-019-SCFI-2011) [regulatory translation and summaries]
European Commission (EC) Regulations 2008/1272/EC, 2010/453/EC, 2006/1907/EC (EC CLP)
Australian Code of Practice – Preparation of Safety Data Sheets for Hazardous Chemicals (Section 274 of the *Work Health and Safety Act*)
New Zealand – Hazardous Substances and New Organisms Act 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
 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
 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.

Note: The *Pneumocystis* organisms found in humans were originally referred to as *P. carinii* f. sp. *hominis*, the subspecies name used to distinguish the *Pneumocystis* organisms found in humans from *Pneumocystis* organisms found in other mammals. Recently the *Pneumocystis* organism found in humans was recognized as a distinct species and renamed *Pneumocystis jirovecii*.

This revision: Expanded Triton X100 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:

<p>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</p>
<p>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 • Poison Information Centre: +43 1 406 43 43</p>
<p>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)</p>
<p>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</p>
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