



SAFETY DATA SHEET (SDS)

IDENTIFICATION OF PRODUCT (PREPARATION) AND SUPPLIER (1):

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 Laboratories 3 boulevard Raymond Poincaré 92430 Marnes-la-Coquette Phone: +33 (0) 1 47 95 60 00 / Fax: +33 (0) 1 47 41 91 33 [fds-msds.fr@bio-rad.com]
Emergency Phone Number:	This SDS is listed with CHEMTREC 1-800-424-9300 / 1-703-527-3887. Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION or ACCIDENT with this product. <i>Refer to section 16 for non-US local Bio-Rad agent contact information.</i>

HAZARDS IDENTIFICATION -- HAZARDOUS COMPONENTS (2):

This test kit should be handled only by qualified personnel trained in laboratory procedures and familiar with their potential hazards. Specific warnings are given in the instructions for use. The absence of a specific warning should not be interpreted as an indication of safety. Refer to Section 16 for the full text of any *Risk (R)* and *Safety (S)* statement provided below.



Component*	Content
R1 <i>Pneumocystis jirovecii</i> Staining Reagent 1 Dropper bottle (2.2 mL) WARNING	- FITC-labeled monoclonal antibodies (murine); protein-stabilized buffer, pH 8. - ≤ 1% Evans blue counterstain [C ₃₄ H ₂₄ N ₆ O ₁₄ S ₄ • 4Na], CAS# 314-13-6, EC No 206-242-5, [dilution is not subject to GHS and EU 2008/1272/EC Regulation or 1999/45/EC Directive labeling requirements]. - Preserved with 0.1% sodium azide [NaN ₃], CAS# 26628-22-8 and EC No 247-852-1 [GHS / 2008/1272/EC Classification: WARNING; H303, H313; P312] [EU Classification per 1999/45/EC: Harmful: Xn; R 22; S 24-35-37 (dilution < 1%, but ≥ 0.1%).] Volume sufficient for staining 24 individual test wells.
R2 Mounting Medium 1 Dropper bottle (3.5 mL)   WARNING	- Buffered glycerol [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 and EU 2008/1272/EC regulatory requirements]. - Contains 2% formalin [≤ 0.8% formaldehyde CAS# 50-00-0, EC No 200-001-8 0 with ≤ 0.1% methanol, CAS# 67-56-1, EC No. 200-659-6] [GHS / 2008/1272/EC Classification: WARNING; GHS07, GHS08; H317, H351; P202, P280; P302 + P352, P308 + P313; P501] [EU Classification per 1999/45/EC: R 43-68; S 24/25-28-35-36/37/39] buffered solution.

Component*	Content
R3 Fluorescence Microscopy Slides 24 <i>Catalog # 32524</i>	<ul style="list-style-type: none"> - 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)* and *European Community (EC) 2008/1272/EC guidelines*:

This product has been conservatively classified and labeled in accordance with applicable *United Nations (UN) GHS (GHS)* and related *European Community (EC) 2008/1272/EC guidelines*. The following regulated hazardous chemical concentrations are found in product component(s):

[Component R1] 0.1% sodium azide [NaN₃], CAS# 26628-22-8 and EC No 247-852-1 (dilution < 1%, but ≥ 0.1%). GHS \ 2008/1272/EC Classification [* denotes precautionary statements included on the product label]:	
<u>Label(s):</u>	No Pictogram
<u>Signal Word:</u>	WARNING
<u>Label Hazard Statement:</u>	H303: May be harmful if swallowed. H313: May be harmful in contact with skin.
<u>Supplemental Hazard Statement:</u>	None Specified.
<u>Precautionary Statement – Prevention:</u>	P264: Wash thoroughly after handling.
<u>Precautionary Statement – Response:</u>	P312: Call a POISON CENTER or doctor/physician if you feel unwell. *
<u>Precautionary Statement – Storage:</u>	None Specified
<u>Precautionary Statement – Disposal:</u>	P501: Dispose of contents and container in accordance to local, regional, national and international regulations. *
[Component R2] ≤ 2% Formalin (≤ 0.8% Formaldehyde, CAS# 50-00-0, EC No 200-001-8 with ≤ 0.1% Methanol, CAS# 67-56-1, EC No. 200-659-6) buffered solution (dilution < 1%). GHS \ 2008/1272/EC Classification [* denotes precautionary statements included on the product label]:	
<u>Label(s):</u>	GHS07  GHS08 
<u>Signal Word:</u>	WARNING!
<u>Label Hazard Statement:</u>	H317: May cause an allergic skin reaction. H351: Suspected of causing cancer.
<u>Supplemental Hazard Statement:</u>	None Specified
<u>Precautionary Statement – Prevention:</u>	P201: Obtain special instructions before use. P202: Do not handle until all safety precautions have been read and understood. * P261: Avoid breathing dust/fume/ gas/mist/vapours/spray. P272: Contaminated work clothing should not be allowed out of the workplace. P280: Wear protective gloves/protective clothing/eye protection/face protection. *
<u>Precautionary Statement – Response:</u>	P302 + P352: IF ON SKIN: Wash with plenty of soap and water. * P308 + P313: IF exposed or concerned: Get medical advice/attention. * P333 + P313: If skin irritation or rash occurs: Get medical advice/ attention.
<u>Precautionary Statement – Storage:</u>	P405: Store locked up.
<u>Precautionary Statement – Disposal:</u>	P501: Dispose of contents and container in accordance to local, regional, national and international regulations. *


COMPOSITION/INFORMATION ON INGREDIENTS -- HAZARDOUS COMPONENTS (3):

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

Chemical Ingredient	Data / Information
Glycerol [50% v/v in R2]	CAS#: 56-81-5 (100%) + RTECS#: MA8050000 (100%) + EC No: 200-289-5 (100%) + Chemical Formula: C ₃ H ₈ O ₃ (100%) + Flash Point: 320 F / 160° C (100%) + LD ₅₀ (oral-rat): 12,600 mg/kg (100%) + LC ₅₀ (inhalation-rat): > 570 mg/m ³ /1H (100%) + TLV and PEL: 10 mg/m ³ total mist (100%) + IATA/DOT ID: NE HMIS Codes: H=1, F=0, R=1 ++ RCRA Code: NE <i>GHS / 2008/1272/EC Classification:</i> Not subject to EU 2008/1272/EC and GHS regulatory requirements. ++ Keep glycerol solutions away from strong oxidizing agents, including sodium hypochlorite (bleach) and potassium permanganate, as could potentially form explosive mixtures. Handle appropriately with the requisite Good Laboratory Practices and Universal Precautions. Dispose of this material in accordance with local, regional, national and international regulation. EU Labelling Classification for 100% chemical concentration per Table 3.2 of 2008/1272/EC - <i>from Annex I to Directive 67/548/EEC</i> : Not Listed
Formalin solution [non-gaseous formaldehyde < 0.8%, in a buffered methanol/water solution, in R2]	Hazardous ingredient concentration in raw material: Formaldehyde, (≤ 0.8% v/v; Methanol: ≤ 0.1% v/v (100%) + CAS#: 50-00-0 (100% formaldehyde), 67-56-1 (100% methanol) + EC No: 200-001-8 (100% formaldehyde), 200-659-6 (100% methanol) + RTECS#: LP8925000 (100% formaldehyde), PC1400000 (100% methanol) + Chemical Formula: HCHO (100% formaldehyde), CH ₃ OH (100% methanol) + Flash Point: 185°F / 85°C (10% Formalin solution), 52° F / 11° C (100% methanol) + LD ₅₀ (oral-rat): > 100 mg/kg (100% formaldehyde), 5,628 mg/kg (100% methanol) + LC ₅₀ (inhalation-rat): 1000 mg/m ³ (30 min.) (100% formaldehyde), 64,000ppm/4H (100% methanol) + PEL/TLV: 0.75 ppm (100% formaldehyde), 200 ppm (100% methanol) + Listed Carcinogen: TLV A2, NTP 2, IARC 2A (100% formaldehyde) + CA Proposition 65: Chemical known to the State of California to cause cancer; this designation is for formaldehyde gas, not formaldehyde containing solutions (100% formaldehyde) + IATA/DOT ID: UN3082 (10% Formalin solution) UN1230 (100% methanol) + RCRA Code: U122 (100% formaldehyde), U154, D001 (100% methanol) + HMIS Codes: H=2, F=0, R=1 ++ EU Classification per 1999/45/EC: None (due to dilution, < 1%); R 43-68; S 24/25-28-35-36/37/39 ++ <i>GHS / 2008/1272/EC Classification:</i> WARNING; GHS07; H317, P280; P302 + P352, P333 + P313 ++ Formalin solutions (diluted non-gaseous formaldehyde) are significant sensitizers, prolonged or repeated exposure may cause allergic skin reaction in certain sensitive individuals [H317]. Formalin solutions may reasonably be anticipated to be carcinogenic and reproductive toxins. Suspected of causing cancer. May be detrimental if in contact with skin or ingested (generally quantities above those found in the kit). Avoid breathing mist/vapours/spray. Wear protective gloves/protective clothing/eye protection/face protection [P280]. Contaminated work clothing should not be allowed out of the workplace. IF ON SKIN: Wash with plenty of soap and water [P302 + P352]. If skin irritation or rash occurs: Get medical advice/ attention [P333 + P313]. If skin irritation or rash occurs: Get medical advice/ attention [P308 + P313]. Store locked up. The potential for adverse health effects is unknown for the highly diluted, small volume of formalin in this kit, but is unlikely if handled appropriately with the requisite Good Laboratory Practices and Universal Precautions. This material and its container must be disposed of in a safe way and in accordance with local, regional, national and international regulations].


WARNING

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THE NEXT PAGE

Chemical Ingredient	Data / Information
Formalin solution [non-gaseous formaldehyde < 0.8%, in a buffered methanol/water solution, in R2]  WARNING <i>CONTINUED</i>	EU Labelling Classification for 100% chemical concentration per Table 3.2 of 2008/1272/EC - <i>from Annex I to Directive 67/548/EEC</i> : Formaldehyde - EC No: 200-001-8, CAS#: 50-00-0 Toxic :T R 23/24/25: Toxic by inhalation, in contact with skin and if swallowed. R 34: Causes burns. R 40: Limited evidence of a carcinogenic effect. R 43: May cause sensitisation by skin contact. S (1/2-): Keep locked up and out of the reach of children. S 26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. S 36/37/39: Wear suitable protective clothing, gloves and eye/face protection. S 45: In case of accident or if you feel unwell, seek medical advice immediately. S 51: Use only in well-ventilated areas. Methanol - EC No: 200-659-6, CAS#: 67-56-1 Flammable: F, Toxic: T R 11: Highly Flammable. R 23/24/25: Toxic by inhalation, in contact with skin and if swallowed. R39/23/24/25: Toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed. S (1/2-): Keep locked up and out of the reach of children. S 7: Keep container tightly closed. S 16: Keep away from sources of ignition – No smoking. S 36/37: Wear suitable protective clothing and gloves. S 45: In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
Sodium azide [0.1% w/v in R1] WARNING	CAS#: 26628-22-8 (100%) + EC No: 247-852-1 (100%) + Chemical Formula: NaN_3 (100%) + LD ₅₀ (oral-rat): 27 mg/kg (100%) + PEL/TLV: 0.3 mg/m ³ (ceiling) (100%) + HMIS codes: H=2, F=0, R=1 ++ EU Classification per 1999/45/EC: Harmful: Xn; R 22; S 24-35-37 (< 1% and ≥ 0.1%) ++ GHS / 2008/1272/EC Classification: WARNING; H303, H213; P312 ++ RTECS#: VY8050000 (100%) + Flash Point: NE LC ₅₀ (inhalation-rat): 37 mg/m ³ (100%) + IATA/DOT ID: UN1687 (undiluted, 100%) + RCRA Code: P105 (undiluted, 100%) + <p>Sodium azide, a biocidal preservative, may be harmful if swallowed [H303]; it has been evident to kill at low concentrations, if enough is ingested (more than supplied in kit). May be harmful in contact with skin. [H313]. May cause eye, skin or tissue irritation. May cause long lasting harmful effects to aquatic life. Avoid contact. Wash thoroughly after handling. Call a POISON CENTER or doctor/physician if you feel unwell [P312]. Avoid release to the environment. Avoid contact with metals; sodium azide may react with lead or copper plumbing to form highly explosive metal azides; build-up in metal plumbing has led to laboratory explosions, so flush with copious water when pouring dilute solutions down the drain to prevent such explosive build-up. The potential for these adverse health effects is unknown for the highly diluted, small volume of sodium azide in this kit, but is unlikely if handled appropriately with the requisite Good Laboratory Practices and Universal Precautions. This material and its container must be disposed of in a safe way and in accordance with local, regional, national and international regulations.</p> EU Labelling Classification for 100% chemical concentration per Table 3.2 of 2008/1272/EC - <i>from Annex I to Directive 67/548/EEC</i> : Toxic: T, Environmental Danger: N R 28: Very toxic if swallowed. R 32: Contact with acids liberates very toxic gas. R 50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. S (1/2-): Keep locked up and out of the reach of children. S 28: After contact with skin, wash immediately with plenty of <i>soap and water</i> . S 45: In case of accident or if you feel unwell, seek medical advice immediately. S 60: This material and its container must be disposed of as hazardous waste. S 61: Avoid release to the environment. Refer to special instructions/safety data sheet.

Key:

- + The Kit Concentration was not tested; the values refer to the solution concentration as tested, designated by Percentage within parentheses.
- ++ The Kit Concentration was tested or the values given were estimated for the general diagnostic laboratory usage of the kit reagent dilution.
- NE: Not Established or Unknown (unable to locate data); typically for concentrate form unless otherwise specified.
- Abbreviations for component HMIS hazard ratings are as follows: H=Health, F=Flammability, R=Reactivity
- GHS = Globally Harmonized System
- RTECS # - Registry of Toxic Effects of Chemical Substances number
- PEL - Permissible Exposure Limit / Occupational Exposure Limit (OEL)
- TLV/TWA – Threshold Limit Value / Time-Weighted Average
- STEL - Short Term Exposure Limit
- IDLH - Immediately Dangerous to Life or Health

Related product information:

- ◆ Refer to section 2 for the full text of any GHS /2008/1272/EC statement coded above.
Refer to section 16 for the full text of any Risk (R) and Safety (S) statement provided above.
- ◆ No significant adverse health effects are expected by any route for the following chemical constituents in the kit volumes and concentrations present [dilution not subject to EU or GHS hazard labeling]:
 - **< 0.1% Evans blue stain** [C₃₄H₂₄N₆O₁₄S₄ • 4Na], EC No 206-242-5, CAS# 314-13-6. [NOTE: this chemical has been designated by IARC with a carcinogen Classification 3, which indicates that "the Agent is NOT CLASSIFIABLE as Carcinogenic"]. The chemical, physical and toxicological properties have not been thoroughly investigated [R1].
 - **≤ 0.5% EDTA, tetrasodium salt, dihydrate** [C₁₀H₁₂N₂O₈Na₄•2H₂O], CAS# 10378-23-1 [R1].
 - **≤ 0.5% Triton X-100** [C₁₄H₂₂O(C₂H₄O)_n (n=9-10)], CAS# 9002-93-1 [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.

EMERGENCY FIRST AID MEASURES (4)

Health Effects:	Symptoms of overexposure may include headache, dizziness, congestion and breathing difficulty. May be harmful if swallowed. May be harmful in contact with skin. May cause allergic skin reaction upon repeated exposure. Suspected of causing cancer. May be toxic to developing fetus, generally at concentrations and volumes that greatly exceed that of this kit.
Eye Contact:	Flush eyes with copious water for at least 15 minutes. Ensure adequate flushing by separating the eyelids with fingers while flushing with water. OBTAIN MEDICAL ATTENTION.
Skin Contact:	Remove contaminated clothing. Flush skin with copious water and wash affected area with soap and water. If blood-to-blood contact occurs or if more severe symptoms develop, consult a physician.
Inhalation:	Remove person from exposure area to fresh air. If breathing becomes difficult, immediately call for emergency medical assistance. Treat symptomatically and supportively. Generally, this aqueous product is not a significant inhalation hazard in the kit volumes and concentrations present.
If Swallowed:	If ingested, rinse out mouth thoroughly with water, provided the person is conscious, and OBTAIN MEDICAL ATTENTION. Call a physician or the local poison control center. Treat symptomatically and supportively. If vomiting occurs, keep head lower than hips to prevent aspiration.

Notes to Physician: According to the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030), Universal Precautions apply. Persons handling human blood source samples should be offered Hepatitis B vaccination prior to working with human source material.

FIREFIGHTING MEASURES (5):

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.

ACCIDENTAL RELEASE MEASURES (6):

- ◆ 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 and/or NFPA/Fire Code 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 an appropriate inert material (e.g. spill pillows, acid 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.
- ◆ 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. Slides processed with material that is not of human origin and is not pathogenic to humans, if broken, can typically be handled as normal uncontaminated broken glass labware; however, dispose of this material in accordance with local, regional, national and international regulations.

HANDLING AND STORAGE INFORMATION (7):

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 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.

EXPOSURE CONTROL / PERSONAL PROTECTION MEASURES (8):
Control Parameters – Component chemicals with limit values that require monitoring at the workplace:

Sodium Azide [CAS# 26628-22-8]:		
REL (United States)	Short-term value: C 0.3** mg/m ³ , C 0.1* ppm	*as HN ₃ vapor; **as NaN ₃ ; Skin
TLV (United States)	Short-term value: C 0.29** mg/m ³ , C 0.11* ppm	*as HN ₃ vapor **as NaN ₃
EL (Canada (LSG) English)	Short-term value: C 0,29* mg/m ³ , C 0,11** ppm	*sodium azide; **hydrazoic acid vapour
IOELV (European Union)	Short-term value: 0,3 mg/m ³ Long-term value: 0,1 mg/m ³	Skin Skin
WEL (United Kingdom)	Short-term value: 0,3 mg/m ³ Long-term value: 0,1 mg/m ³	(as NaN ₃) Sk (as NaN ₃) Sk
NES (AUS)	0.3* mg/m ³ , 0.11 ppm	*Peak limitation
VME (France)	Short-term value: 0,3 mg/m ³ , 0,1 ppm	risque de pénétration percutanée
VL (Belgium, (France)	Short-term value: 0,3 mg/m ³ Long-term value: 0,1 mg/m ³	D, M D, M
AGW (Germany)	0,2 mg/m ³	2(I);DFG
MAK (Austria, (Germany))	Short-term value: 0,3 mg/m ³ Long-term value: 0,1 mg/m ³	
TWA (Italy)	Short-term value: C 0,29 mg/m ³ , C 0,11* ppm A4; sodio azide; *come azido idrazonico, vapore	
MAK (Switzerland, (Germany))	Short-term value: 0,4 e mg/m ³ Long-term value: 0,2 e mg/m ³	
GV (Denmark)	0,1 mg/m ³	EH
MAK (Netherland)	Short-term value: 0,3 mg/m ³ Long-term value: 0,1 mg/m ³	
OEL (Sweden)	Short-term value: 0,3 mg/m ³ Long-term value: 0,1 mg/m ³	H H

Formaldehyde [CAS# 50-00-0]:		
TLV (United States)	0.3* ppm / 0.37 mg/m ³ [ACGIH]	*gas / airborne
PEL-TWA (United States)	0.75 ppm [OSHA]	
STEL (United States)	2 ppm	
OEL (Canada)	0.3 ppm	
STEL (Canada)	1 ppm	
TWA (United Kingdom)	2 ppm / 2.5 mg/m ³	
TWA (United Kingdom)	2 ppm / 2.5 mg/m ³	
MAK (Switzerland)	Week 0.5 ppm / 0.6 mg/m ³	
KZG (Switzerland)	Week 1 ppm / 1.2 mg/m ³	
NGV (Sweden)	0.5 ppm / 0.6 mg/m ³	
TGV (Sweden)	1 ppm / 1.26 mg/m ³	
MAK (Germany)	0.5 ppm / 0.6 mg/m ³	
VME (France)	0.5 ppm	
VLE (France)	1 ppm	
EUOED - TWA (European Union)	10 ppm / 25 mg/m ³	
TWA (Denmark)	0.3 ppm / 0.4 mg/m ³	
TWA (Belgium)	1 ppm / 1,2 mg/m ³	
STEL (Belgium)	2 ppm	

Glycerol [CAS# 56-81-5]:		
PEL (United States)	15* 5** mg/m ³	*total dust **respirable fraction
TLV (United States)	10* ppm	*Mist
EL (Canada (LSG) English)	10* 3** mg/m ³	*mist; **mist, respirable
WEL (United Kingdom)	10 mg/m ³	
NES (AUS)	10 mg/m ³	
VME (France)	10 mg/m ³	
VL (Belgium, (French)	10 mg/m ³	
MAK (Germany)	50E mg/m ³	
TWA (Italy)	10 mg/m ³	
MAK (Switzerland, (Germany))	Short-term value: 100 e mg/m ³ Long-term value: 50 e mg/m ³	
WEL ()	Long-term value: 10 mg/m ³	

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/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. Protective coverings such as plastic wrap, aluminum foil or imperviously backed absorbent pads used to cover equipment and/or surfaces must be removed and replaced if they become overtly contaminated.
Note:	Occupational exposure limit values and health hazard data were given in Section 3. Environmental Controls are included in the following sections.

PHYSICAL AND CHEMICAL PROPERTIES (9):

Appearance:	Variable, generally aqueous liquids. Exceptions are the solid slides and related materials.		
pH:	The liquid chemical components are between pH 6 and 9.		
Boiling Point:	Not Established	Melting Point:	Not Established
Flash Point:	Not Applicable		

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.
Auto Igniting:	Product is not known to be self-igniting.
Danger of Explosion:	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. Keep glycerol solutions away from strong oxidizing agents including sodium hypochlorite (bleach) and potassium permanganate, as these could potentially form explosive mixtures.
Relative Density:	Not established.
Solubility:	The liquid chemical components are soluble in water.
Partition coefficient (n-octanol/water):	Data is not available.
Decomposition temperature:	Data is not available.
Viscosity:	Data is not available.
No other standard characteristics applicable to the identification or hazards of the kit are known.	

STABILITY AND REACTIVITY INFORMATION (10):

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:	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. 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 or sodium, and toxic ammonia or formaldehyde gas.
Hazardous Polymerization:	Has not been reported to occur.

TOXICOLOGICAL INFORMATION -- GENERAL COMPOSITE (11):

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

Acute Health Effects

Toxicity: May be 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: Data is not available.

STOT-Repeated Exposure: Data is not available.

Aspiration Hazard: Data is not available.

Other Acute Health Effects:

Because these slides are made of glass, they could potentially pose a slight physical cutting hazard, especially if broken or chipped, so handle carefully; wear suitable gloves and/or other appropriate personal protective equipment and follow Good Laboratory Practices. Do not handle broken slides with unprotected hands.

Chronic Toxicity

Sensitization: Sensitization possible through skin contact; prolonged or repeated exposure may cause allergic reaction in certain sensitive individuals.

Carcinogenicity:

IARC designates **Formalin** solution (non-gaseous formaldehyde ~ 0.8% in a methanol/water solution) CAS#: 50-00-0 in the carcinogen Group 2A, which specifies, “*The agent is PROBABLY Carcinogenic to Humans.*” Known to the State of California to cause cancer.

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: Data is not available.

Reproductive hazard: Suspected reproductive toxin based on limited animal evidence.

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.

ECOLOGICAL INFORMATION (12):

This product was not tested. The following assessment is based on information for the ingredients.

<p>Toxicity:</p>	<p>100% Sodium Azide [CAS# 26628-22-8] *: Fish LC₅₀ - Lepomis macrochirus - 0.68 mg/l - 96 h Daphnia EC₅₀ - Daphnia pulex (Water flea) - 4.2 mg/l - 48 h 100% Methanol [CAS# 67-56-1] *: Fish LC₅₀ - Oncorhynchus mykiss (rainbow trout) – 19,000 mg/l - 96 h - Cyprinus carpio (Carp) – 36,000 mg/l - 48 h Daphnia EC₅₀ - Daphnia pulex (Water flea) – 24,500 mg/l - 48 h Concentrated Formaldehyde [CAS# 50-00-0] *: Fish LC₅₀ - Bluegill/Sunfish – 3.6 mg/l - 48 h * Source: Raw Material Vendor Safety Data Sheet</p>
Persistence and degradability:	No information found.
Bioaccumulation potential:	No information found.
Mobility in soil:	No information found.
PBT and vPvB assessment:	No information found.
Other adverse affects:	An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

Avoid release to the environment.

General notes: Water hazard class 1 (Self-assessment): slightly hazardous for water.

DISPOSAL CONSIDERATIONS (13):

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.

- **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. Slides processed with material that is not of human origin and is not pathogenic to humans, if broken, can typically be handled as normal uncontaminated broken glass labware; however, dispose of this material in accordance with local, regional, national and international regulations.

Do not 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.

TRANSPORT INFORMATION (14):

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 Unused Product Multi-Modal Transportation: No known transport restrictions.

REGULATORY INFORMATION (15):

Composite HMIS Rating: Health: 2 Flammability: 0 Reactivity: 1

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).

Chemicals known to cause reproductive toxicity: Methanol, CAS# 65-56-1.

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.

IARC Group 3, The agent is NOT CLASSIFIABLE as Carcinogenic to Humans: **Evans Blue**, CAS# 314-13-6.

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.

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.

National Regulations:

WHMIS Classification: This SDS contains the required information in accordance with the **Workplace Hazardous Materials Information System (WHMIS) Canadian Standard** for the hazard classification criteria for this product.

Mexican Standard: This SDS contains the required information for preparation in accordance with the **Mexican Standard Mexican Standard (NMX-R-019-SCFI-2011) SISTEMA ARMONIZADO DE CLASIFICACIÓN Y COMUNICACIÓN DE PELIGROS DE LOS PRODUCTOS QUÍMICOS GLOBALLY HARMONIZED SYSTEM (GHS)**.

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

Markings according to European Community 1999/45/EC, 2001/59/EC, 2001/60/EC, 2006/102/EC guidelines:

This product has been classified and labeled in accordance with applicable European Community (EC) Directives (refer to 1999/45/EC, 2001/59/EC, 2001/60/EC and 2001/102/EC).

Hazard Designation of Composite Product:

HARMFUL: Xn



Hazard Determining Substance(s) of Labeling (rated under 1999/45/EC unless otherwise specified):

0.1% Sodium azide [NaN₃], CAS# 26628-22-8, EC No 247-852-1 [Harmful: Xn; R 22; S 24-35-37 (< 1% and ≥ 0.1%).]

≤ 2% Formalin buffered solution - ≤ 0.8% Formaldehyde, EC No 200-001-8, CAS# 50-00-0 with ≤ 0.2% methanol, EC No 200-659-6, CAS# 67-56-1 [R 43-68; S 24/25-28-35-36/37/39].

OTHER INFORMATION (16):**Risk Phrases:**

- | | |
|------|--|
| R 22 | Harmful if swallowed. |
| R 43 | May cause sensitisation by skin contact. |
| R 68 | Possible risk of irreversible effects. |

Safety Phrases:

- | | |
|------------|--|
| S 24 | Avoid contact with skin. |
| S 24/25 | Avoid contact with skin and eyes. |
| S 28 | After contact with skin, wash immediately with plenty of soap and water. |
| S 35 | This material and its container must be disposed of in a safe way. |
| S 36/37/39 | Wear suitable protective clothing, gloves and eye/face protection. |
| S 37 | Wear suitable gloves. |

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)
European Community (EC) 2008/1272/EC, 2010/453/EC, 2006/1907/EC Regulations
EU Directives 1999/45/EC, 2001/59/EC, 2001/60/EC, 2006/102/EC
Registry of Toxic Effects of Chemical Substances (RTECS)
International Agency for Research on Cancer (IARC)
American Conference of Governmental Industrial Hygienists (ACGIH)
National Toxicity Program (NTP)
Occupational Safety and Health Administration, U.S. Department of Labor (OSHA)
National Institute for Occupational Safety and Health (NIOSH)
World Health Organization. *Laboratory Biosafety Manual*
CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories*
Mexican Standard (NMX-R-019-SCFI-2011)
California Proposition 65

Chemical safety assessment: Mixtures covered in this SDS were classified using the EU Regulation 1272/2008/EC 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
ANSI – American National Standards Institute
CAS – Chemical Abstracts Service
CDC – Centers for Disease Control, USA
CNS – Central Nervous System
DOT – Department of Transportation
EC₅₀ – half maximal effective concentration
EU – European Union
GHS – Globally Harmonized System
IATA – International Air Transport Association
IARC – International Agency for Research on Cancer
ICAO – International Civil Aviation Organization
IDLH – Immediately Dangerous to Life or Health
IMDG – International Maritime Dangerous Goods
IPCS – International Programme on Chemical Safety
LC₅₀ – median lethal concentration, 50%
LD₅₀ – 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 number
SDS – Safety Data Sheet
STEL – Short Term Exposure Limit
TLV/TWA – Threshold Limit Value / Time-Weighted Average
UN – United Nations
US EPA – United States Environmental Protection Agency
US OSHA – Occupational Safety and Health Administration, U.S. Department of Labor
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: Reviewed existing information and made minor updates.

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