

SAFETY DATA SHEET

SECTION 1: IDENTIFICATION OF PRODUCT (SUBSTANCE) AND SUPPLIER (1):

Product Name: MONOLISA™ Anti-HAV EIA

Product Number: 72496 (2 plates - 192 tests)
Catalog number(s) for replacement, optional and/or separately purchased components that can be obtained for use with this kit, and which are covered by this SDS include: **25260, 26181, 26182 and 72700** (refer to Section 2).

Intended Use: The MONOLISA™ Anti-HAV EIA is an in vitro enzyme immunoassay kit intended for use in the qualitative detection of total antibodies (IgG and IgM) to Hepatitis A Virus (anti-HAV) in human (adult and pediatric) serum or plasma (EDTA, Heparin, Citrate, ACD). This kit can be used as an aid in the diagnosis of acute or past Hepatitis A Virus (HAV) infection or as an aid in the identification of HAV-susceptible individuals for vaccination. However, any diagnosis should take into consideration the patient's clinical history and symptoms, as well as serological data. The MONOLISA™ Anti-HAV EIA is intended for manual use and with the Evolis™ Automated Microplate System in the detection of total antibodies to hepatitis A virus. Assay performance characteristics have not been established for immunocompromised or immunosuppressed patients, and cord blood or neonatal specimens.
WARNING : This assay is not intended for screening blood or solid or soft tissue donors.

Supplier's Name: 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

Manufactured by: *FRANCE: Bio-Rad Laboratories*
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92430 Marnes-la-Coquette
Phone: +33 (0) 1 47 95 60 00 / Fax: +33 (0) 1 47 41 91 33
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Emergency Phone Number: **This SDS is listed with CHEMTREC 1-800-424-9300 / 1-703-527-3887.** Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION, or ACCIDENT with this product. Refer to section 16 for non-US local Bio-Rad agent contact information.

SECTION 2: HAZARDS IDENTIFICATION -- HAZARDOUS COMPONENTS

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

Component *	Content
R1 Anti-HAV Microwell Strip, Plates (2)	- Microplate containing 12 strips with 8 wells each, coated with monoclonal anti-HAV antibodies. - Tabs are labeled "39"
R2 Wash Solution Concentrate (20X), 1 bottle (235 mL) Catalog No. 72700	- Sodium chloride (NaCl) [CAS# 7647-14-5, EC No 231-598-3] with < 2% Tween 20 (C ₅₈ H ₁₁₄ O ₂₆) [CAS#: 9005-64-5, EC No 585-580-06-X in a trizma buffered solution (pH 7.4). - Preserved with 0.004% ProClin 300 (< 0.001% active ingredient), EC Index No 613-167-00-5 with CAS# 55965-84-9 [dilution below GHS and EU (2008/1272/EC, 1999/45/EC and 2001/59/EC) regulated labeling levels].

Component *	Content
C0 Anti-HAV Negative Control, 1 vial (1.5 mL)  WARNING	- Normal human serum that is non-reactive for total anti-HAV antibodies, HBsAg and antibodies to HIV1/HIV-2 and HCV. - Preserved with ≤ 0.25% ProClin 300 (≤ 0.009% active ingredient), EC Index No 613-167-00-5 with CAS# 55965-84-9 [GHS / 2008/1272/EC Classification: WARNING; GHS07; H317; P280; P302 + P352, P333 + P313; P501.] [EU Classification per 2001/59/EC and 1999/45/EC: Irritant: Xi; R 43; S 24-35-37.] - Preserved with < 0.1% sodium azide [NaN₃], CAS# 26628-22-8 and EC No 247-852-1 [< 0.1% dilution is not subject to GHS and EU 2008/1272/EC or 1999/45/EC regulated labeling levels].
C1 Anti-HAV Positive Control, 1 vial (1.5 mL)  WARNING	- Human serum, positive for anti-HAV antibodies diluted in human serum pool negative for anti-HAV antibodies. - Non-reactive for HBsAg and antibodies to HIV1/HIV-2 and HCV. - Preserved with ≤ 0.25% ProClin 300 (≤ 0.009% active ingredient), EC Index No 613-167-00-5 with CAS# 55965-84-9 [GHS / 2008/1272/EC Classification: WARNING; GHS07; H317; P280; P302 + P352, P333 + P313; P501.] [EU Classification per 2001/59/EC and 1999/45/EC: Irritant: Xi; R 43; S 24-35-37.] - Preserved with < 0.1% sodium azide [NaN₃], CAS# 26628-22-8 and EC No 247-852-1 [< 0.1% dilution is not subject to GHS and EU 2008/1272/EC or 1999/45/EC regulated labeling levels].
C2 Anti-HAV Calibrator, 2 vials (1.5 mL)  WARNING	- Human serum, positive for anti-HAV antibodies diluted in human serum pool negative for anti-HAV antibodies. - Non-reactive for HBsAg and antibodies to HIV1/HIV-2 and HCV. - Preserved with ≤ 0.25% ProClin 300 (≤ 0.009% active ingredient), EC Index No 613-167-00-5 with CAS# 55965-84-9 [GHS / 2008/1272/EC Classification: WARNING; GHS07; H317; P280; P302 + P352, P333 + P313; P501.] [EU Classification per 2001/59/EC and 1999/45/EC: Irritant: Xi; R 43; S 24-35-37.] - Preserved with < 0.1% sodium azide [NaN₃], CAS# 26628-22-8 and EC No 247-852-1 [< 0.1% dilution is not subject to GHS and EU 2008/1272/EC or 1999/45/EC regulated labeling levels].
R6 Anti-HAV Viral Antigen, 2 bottles (14 mL)  WARNING	- Inactivated HAV in a trizma buffered solution with protein stabilizers and red sample indicator dye (Azorubin, Carmoisine, Food Red 3, CAS# 3567-69-9). [HAV viral antigen that has been treated with formalin to inactivate the virus.] - Preserved with 0.1% ProClin 300 (0.003% active ingredient), EC Index No 613-167-00-5 with CAS# 55965-84-9 [GHS / 2008/1272/EC Classification: WARNING; GHS07; H317; P280; P302 + P352, P333 + P313; P501.] [EU Classification per 2001/59/EC and 1999/45/EC: Irritant: Xi; R 43; S 24-35-37.]
R7 Anti-HAV Conjugate, 2 bottles (14 mL)  WARNING	- Peroxidase labeled mouse monoclonal antibody to HAV in Tris buffer containing proteins, detergent, glycerol [C₃H₈O₃, EC No 200-289-5, CAS# 56-81-5] and purple sample indicator dye (bromocresol purple). - Preserved with 0.1% ProClin 300 (0.003% active ingredient), EC Index No 613-167-00-5 with CAS# 55965-84-9 [GHS / 2008/1272/EC Classification: WARNING; GHS07; H317; P280; P302 + P352, P333 + P313; P501.] [EU Classification per 2001/59/EC and 1999/45/EC: Irritant: Xi; R 43; S 24-35-37.]
R8 Substrate Buffer, 1 bottle (120 mL) <i>Catalog No. 26181</i>	- Dilute citric acid/sodium acetate buffer (pH ~4.0, clear liquid). - < 5% dimethylsulfoxide [DMSO - C₂H₆OS], CAS# 67-68-5, EC No 200-644-3. - < 0.1% hydrogen peroxide [H₂O₂], CAS# 7722-84-1, EC No 231-765-0. [Dilution is not subject to GHS and EU 2008/1272/EC regulatory requirements.]
R9 Chromogen (11X), 1 bottle (12 mL) <i>Catalog No. 26182</i>	- ≤ 0.25% 3,3',5,5' tetramethylbenzidine dihydrochloride [TMB- C₁₆H₂₀N₂•2HCl], CAS# 207738-08-7, EC No 264-769-6. - ≤ 0.04 N hydrochloric acid [~ 0.3% HCl, CAS# 7647-01-0, EC No 231-595-7] solution (pH ~ 1.5, clear liquid). [Dilution is not subject to GHS and EU 2008/1272/EC regulatory requirements.]

Component *	Content
R10. Stopping Solution, 1 bottle (120 mL) <i>Catalog No. 25260</i>  DANGER	- 1N H ₂ SO ₄ (4.4% w/w sulfuric acid), CAS# 7664-93-9, EC No 231-639-5 [pH ≤ 2, clear liquid]; severely irritating to skin, corrosive to eyes [GHS / 2008/1272/EC Classification: DANGER! GHS05; H290, H314; P280; P301 + P330 + P331, P305 + P351 + P338; P501.] [EU Classification per 1999/45/EC and 2001/60/EC: Corrosive: C; R 34 (eyes)-36/38-41; S 24/25-26-36/37/39-45-60.]

- Replacement 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 (HCS) and European Community (EC) 2008/1272/EC guidelines:

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

[Component R10] 1N H₂SO₄ [4.4% w/w Sulfuric acid], CAS# 7664-93-9, EC No 231-639-5 (pH ≤ 2); severely irritating to skin, corrosive to eyes. *[This STOP solution has been evaluated with the CORROSITEX® test method to determine its corrosive potential and classification. The results of this testing classified this STOP solution as Class: 8, Packing group II (UN2796)]*

GHS - 2008/1272/EC Classification [* denotes precautionary statements included on the product label]: **Skin Corrosive Category 1B**



Label(s):

GHS05

Signal Word:

DANGER!

Label Hazard Statement:

H290: May be corrosive to metals.

H314: Causes severe skin burns and eye damage.

Supplemental Hazard – Statement:

None Specified

Precautionary Statement – Prevention:

P260: Do not breathe mist / vapours / spray.

P280: Wear protective gloves / protective clothing / eye protection / face protection. *

Precautionary Statement – Response:

P301 + P330 + P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. *

P303 + P361 + P353: IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.

P304 + P340: IF INHALED: Remove victim to fresh air and keep at rest in a position 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. *

P309 + P313: If exposed or if you feel unwell: Get medical advice/ attention.

Precautionary Statement – Storage:

P405: Store locked up.

Precautionary Statement – Disposal:

P501: This material and its container must be disposed of as hazardous waste. *

[Components C0, C1, C2, R6, R7] 0.1% and 0.25% ProClin 300 [$\leq 0.015\%$ active ingredients – reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one (C_4H_4ClNOS ; CAS# 26172-55-4, EC No 247-500-7) and 2-methyl-2H -isothiazol-3-one (C_4H_5NOS ; CAS# 2682-20-4, EC No 220-239-6) (3:1)], EC Index No 613-167-00-5 with CAS# 55965-84-9.

GHS - 2008/1272/EC Classification [* denotes precautionary statements included on the product label]: **Skin Sensitizer Category 1**



Label(s):

Signal Word:

Label Hazard Statement:

Supplemental Hazard Statement:

Precautionary Statement – Prevention:

Precautionary Statement – Response:

Precautionary Statement – Storage:

Precautionary Statement – Disposal:

GHS07

WARNING

H317: May cause an allergic skin reaction.

None Specified

P261: Avoid breathing 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.*

P302 + P352: IF ON SKIN: Wash with plenty of soap and water.*

P333 + P313: If skin irritation or rash occurs: Get medical advice/ attention.*

None Specified

P501: Dispose of contents and container in accordance to local, regional, national and international regulations.*

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

The following information is furnished for those product hazardous constituents that require regulatory control or disclosure at the concentration found in the product. Note that the information here is often based on data from the chemical raw material (LD50, exposure limits, etc.) and that 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 Section 16 for the Key / legend to abbreviations and acronyms.

Chemical Ingredient	Data / Information
1 N Sulfuric acid [4.4% w/w H_2SO_4 / water in R10]  DANGER!  <i>Continued on next page</i>	CAS#: 7664-93-9 (Conc. sulfuric acid 100%) + EC No: 231-639-5 (100%) + Chemical Formula: H_2SO_4 (100%) + LD ₅₀ (oral-rat): 2,140 mg/kg (100%) + TWA-PEL: 1 mg/m ³ (100%) + STEL: 3 mg/m ³ (100%) + IATA/DOT ID: UN2796, Class 8 (< 51% sulfuric acid solutions) ++ HMIS Codes: H=2, F=0, R=1 ++ RCRA Code: D002 (if not neutralized) ++ EU Classification per 1999/45/EC and 2001/60/EC: Corrosive: C; R 34 (eyes)-36/38-41; S 24/25-26-36/37/39-45-60 [Note: Per Directive 1999/45/EC, < 5% H_2SO_4 is rated an Irritant: Xi, but was upgraded to Corrosive: C with the conservative application of 2001/60/EC.] ++ GHS / 2008/1272/EC Classification: DANGER! GHS05; H290, H314; P280; P301 + P330 + P331, P305 + P351 + P338; P501 ++ <i>[This STOP solution has been evaluated with the CORROSITEX® test method to determine its corrosive potential and classification. The results of this testing classified this STOP solution as Class: 8, Packing group II (UN2796)]</i> 1N Sulfuric acid (H_2SO_4) solutions are irritating to skin and severely irritating or corrosive to eyes, depending on the amount and length of exposure; greater exposures can cause eye damage, including permanent impairment of vision or blindness. Causes severe skin burns and eye damage [H314]. Risk of serious eye damage. May be corrosive to metals [H290]. Wear protective gloves / protective clothing / eye protection / face protection [P280]. Do not breathe mist / vapours / spray. IF exposed or if you feel unwell: Get medical advice / attention. IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER or doctor/ physician [P301 + P330 + P331]. IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. [P305 + P351 + P338]. Keep away from strong bases and reducing agents. Store locked up. This material must be disposed of as hazardous acidic waste; it may be neutralized to pH 6-8 for disposal if trained and equipped to do so, however always dispose of acidic solutions as required by local, regional, national and international regulations [P501]. Handle appropriately with the requisite Good Laboratory Practices.

Chemical Ingredient	Data / Information
1 N Sulfuric acid [4.4% w/w H ₂ SO ₄ / water in R10]  DANGER! 	EU Labeling Classification for 100% chemical concentration per Table 3.2 of 2008/1272/EC - from Annex I to Directive 67/548/EEC: Corrosive: C R 35: Causes severe burns. 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 30: Never add water to this product. S 45: In case of accident or if you feel unwell, seek medical advice immediately.
ProClin 300 [0.25% (≤ 0.009% active ingredient) in C0, C1 and C2; 0.1% (0.003% active ingredient) in R6 and R7 (0.04% (< 0.0015% Active Ingredient) in R2)]  WARNING	Hazardous ingredient concentration in raw material - According to the supplier, Sigma-Aldrich, the concentrated preservative is a mixture with 3-3.6% Active Ingredients in 3:1 ratio: 5-chlor-2-methyl-4-isothiazolin-3-one (C ₄ H ₄ CINOS; CAS# 26172-55-4, EC# 247-500-7) and 2-methyl-4-isothiazolin-3-one (C ₄ H ₅ NOS; CAS# 2682-20-4, EC# 220-239-6), Index No. 613-167-00-5 and CAS# 55965-84-9. Also contains 91-94% glycol and .3.5-5% Modified Alkyl Carboxylate (no CAS# or formula given for last two). RTECS#: NE LD ₅₀ (oral-rat): 862 mg/kg (100%) + PEL/TLV: NE Flash Point: 244° F / 118° C (100%) + LD ₅₀ (skin-rabbit): 2,800 mg/kg (100%) + IATA/DOT ID: UN3265, Class 8 (undiluted, 100%) + / IATA/DOT ID: NE (dilution) ++ HMIS Codes: H=2, F=0, R=0 ++ RCRA Code: Non-RCRA ++ EU Classification per 1999/45/EC and 2001/59/EC: Irritant: Xi, R 43; S 24-35-37 (≤ 0.06% and > 0.0015 % Active-Ingredient) ++ GHS / 2008/1272/EC Classification: WARNING; GHS07; H317; P280; P302 + P352, P333 + P313; P501 ++ The chemical, physical and toxicological properties have not been thoroughly investigated. At this concentration, this biocidal preservative is irritating to eyes and skin, and may be detrimental if enough is ingested (quantities above those found in the kit). ProClin 300 is a skin sensitizer; prolonged or repeated exposure may cause allergic reaction in certain sensitive individuals [H317]. Wear protective gloves / protective clothing / eye protection / face protection [P280]. Contaminated work clothing should not be allowed out of the workplace. Avoid breathing mist / vapours / spray. IF ON SKIN: Wash with plenty of soap and water [P302 + P352]. If skin irritation or rash occurs: Get medical advice/ attention [P333 + P313]. The potential for adverse health effects is unknown for the highly diluted, small volume of ProClin 300 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 [P501]. EU Labeling Classification for 100% chemical concentration per Table 3.2 of 2008/1272/EC - from Annex I to Directive 67/548/EEC: Toxic: T, Environmental Danger: N R 23/24/25: Toxic by inhalation, in contact with skin and if swallowed. R 34: Causes burns. R 43: May cause sensitisation by skin contact. R 50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. S (2-): Keep 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 28: After contact with skin, wash immediately with plenty of soap and water. 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 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 sheets.

Chemical Ingredient	Data / Information
3,3',5,5'-Tetramethylbenzidine, Dihydrochloride [≤ 0.25_% w/v TMB in R9]	CAS#: 207738-08-7 (54827-17-7 Free base) (100%) + RTECS#: DV2300000 (100%) + EC No: 264-769-6 (100%) + Chemical Formula: C ₁₆ H ₂₀ N ₂ •2HCl (100%) + Flash Point: NE LD ₅₀ (ipr-mouse): 135 mg/kg (100%) + TLV and PEL: NE IATA/DOT ID: NE HMIS Codes: H=0, F=0, R=0 ++ RCRA Code: NE <i>GHS / 2008/1272/EC Classification:</i> Not subject to GHS and EU 2008/1272/EC regulatory requirements ++ The chemical, physical and toxicological properties have not been thoroughly investigated. 3,3',5,5'-Tetramethylbenzidine Dihydrochloride (TMB) is considered a non-carcinogenic and non-mutagenic analog of benzidine suitable as an EIA Chromogen for peroxidase. The raw material supplier indicates that it may cause slight irritation by all routes of entry; the potential for adverse health effects is unknown for the small volume of TMB in this product, but is unlikely if handled appropriately with the requisite Good Laboratory Practices. Dispose of this material in accordance with local, regional, national and international regulation. EU Labeling Classification for 100% chemical concentration per Table 3.2 of 2008/1272/EC - from Annex I to Directive 67/548/EEC: Not Listed
Sodium azide [< 0.1% NaN ₃ in C0, C1 and C2]	CAS#: 26628-22-8 (100%) + RTECS#: VY8050000 (100%) EC No: 247-852-1 (100%) + Chemical Formula: NaN ₃ (100%) + Flash Point: NE LD ₅₀ (oral-rat): 27 mg/kg (100%) + LC ₅₀ (inhalation-rat): 37 mg/m ³ (100%) + PEL/TLV: 0.3 mg/m ³ (ceiling) (100%) + IATA/DOT ID: UN1687, Class 6.1 (undiluted, 100%) + / IATA/DOT ID: NE (dilution) ++ HMIS Codes: H=1, F=0, R=1 ++ RCRA Code: P105 (undiluted, 100%) + EU Classification per 1999/45/EC: None (due to dilution, < 0.1%); S 35-36 ++ <i>GHS / 2008/1272/EC Classification:</i> None (due to dilution, < 0.1%) ++ Sodium azide is a biocidal preservative, which may be detrimental if enough is ingested (quantities above those found in the kit). 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 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. EU Labeling Classification for 100% chemical concentration per Table 3.2 of 2008/1272/EC - from Annex I to Directive 67/548/EEC: 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 soap and water. 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.
Azorubin dye [< 0.01% in R6]	CAS#: 3567-69-9 (100%) + RTECS#: QK1925000 (100%) + EC No: 222-657-4 (100%) + Synonyms: Carmoisin, CI Food Red 3, E122, Acid Red 14, Brilliant Crimson Red. Chemical Formula: C ₂₀ H ₁₂ N ₂ O ₇ S ₂ •2Na (100%) + Flash Point: NE LD ₅₀ (oral-rat): > 10 g/kg (100%) + LD ₅₀ (oral mouse): > 8 g/kg (100%) + TLV and PEL: NE IATA/DOT ID: NE HMIS Codes: H=1, F=0, R=0 ++ RCRA Code: NE <i>GHS / 2008/1272/EC Classification:</i> Not subject to EU 2008/1272/EC and GHS regulatory requirements ++ < 0.01% Azorubin dye may be detrimental if swallowed or in contact with skin. Most organic azo dyes are potential skin sensitizers. IARC rates Azorubin in Group 3: the agent is <i>not classifiable as to its carcinogenicity to humans</i> . The potential for adverse health effects is unknown for the highly diluted, small volume of Azorubin in this kit, but is unlikely if handled appropriately with the requisite Good Laboratory Practices and Universal Precautions. Dispose of this material in accordance with local, regional, national and international regulation. EU Labeling Classification for 100% chemical concentration per Table 3.2 of 2008/1272/EC - from Annex I to Directive 67/548/EEC: Not Listed

Biological Ingredient	Data / Information
Animal proteins [components R6, R7]	This material is of animal origin (bovine and murine) and may be a potential contact irritant. Hazard Unknown. Handle as potentially infectious. The chemical, physical and toxicological properties have not been thoroughly investigated. Handle appropriately with the requisite Good Laboratory Practices and <i>Standard and Universal Precautions</i> . Dispose of this material in accordance with local, regional, national and international regulation.
Human Serum [reactive and non-reactive in C0, C1 and C2]	The Human sera/plasma in the components of this product were tested and found non-reactive for hepatitis B surface antigen (HBsAg) and antibodies to hepatitis C virus (HCV) and human immunodeficiency virus (HIV-1 and HIV-2) by FDA or CE approved methods. No known test method can offer complete assurance that HIV, hepatitis B or C virus or other infectious agents are absent. Moreover, patient blood samples tested with this kit represent an unknown, heightened hazard. Employ <i>Standard and Universal Precautions</i> when handling these reagents and all human blood or specimens. Handle as if capable of transmitting infectious disease, in a Biosafety Level 2 lab, applying the guidelines from the current CDC/NIH <i>Biosafety in Microbiological and Biomedical Laboratories</i> or WHO <i>Laboratory Biosafety Manual</i> . Avoid splashing, spills and the generation of aerosols. Secure in secondary containment with proper biohazard labeling. Do not inhale mists or aerosols; avoid contact with skin, eyes, mucous membranes and clothing. In case of contact with eyes, immediately rinse with copious water and seek medical attention. Employ decontamination procedures with appropriate decon agent or disinfectant (typically a 1:10 dilution of household bleach, 70-80% ethanol or isopropanol, an iodophor like 0.5% Wescodyne Plus (EPA Reg. #4959-16), an o-phenylphenol/amyphenol such as 0.8% Vesphene (EPA Reg. #1043-87), or equiv.) before discarding any materials utilized or returning equipment used to general use. Dispose of this material in accordance with local, regional, national and international regulations. Handle appropriately with the requisite Good Laboratory Practices, <i>Standard and Universal Precautions</i> . Persons handling blood samples should have the option of receiving hepatitis B vaccination.
Inactivated HAV virus [component R6]	The HAV viral antigen reagent (R6) has been treated with formalin to inactivate the virus. Handle as if capable of transmitting infectious disease, in a Biosafety Level 2 lab, applying the guidelines from the current CDC/NIH <i>Biosafety in Microbiological and Biomedical Laboratories</i> , or WHO <i>Laboratory Biosafety Manual</i> . Employ decontamination procedures with appropriate decon agent or disinfectant before discarding any materials utilized or returning equipment used to general use. Dispose of this material in accordance with local, regional, national and international regulation. Handle appropriately with the requisite Good Laboratory Practices, <i>Standard and Universal Precautions</i> .

+ 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 concentrated form unless otherwise specified.
Abbreviations for component HMIS hazard ratings are as follows: H=Health, F=Flammability, R=Reactivity

Related product information:

- ◆ 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, US or GHS hazard labeling]:
 - ≤ 2% v/v **Tween 20** [C₅₈H₁₁₄O₂₆], EC No 585-580-06-X, CAS# 9005-64-5. (R2, R7)
 - Diluted (< 5%) **Tris** (TRIZMA HCl) buffer solution; Tris (hydroxymethyl)aminomethane: 2-amino-2-(hydroxy-methyl)-1, 3-propanediol [C₄H₁₁NO₃ • HCl], EC No 214-684-5, CAS# 1185-53-1 [< 20% dilution]. (R6)
 - Diluted (< 5%) **Tris** (TRIZMA BASE) buffer solution; 2-amino-2-(hydroxymethyl)-3,1-propanediol, [C₄H₁₁NO₃], EC No 201-064-4, CAS# 77-86-1, 25149-07-9; 108195-86-4 [< 20% dilution]. (R6, R7, R2)
 - Diluted **bromocresol purple**, sodium salt C₂₁H₁₅Br₂O₅SNa, CAS# 62625-30-3, EC No 263-655-3. (R7)
 - ≤ 25% **glycerol** [C₃H₈O₃], EC No 200-289-5, CAS# 56-81-5. (R7)
 - ≤ 5% v/v **dimethyl sulfoxide** [DMSO - C₂H₆OS], EC No 200-644-3, CAS# 67-68-5-4 [< 20% dilution]. (R8)
 - ≤ 0.1% v/v **hydrogen peroxide** [H₂O₂], EC No 231-765-0, CAS# 7722-84-1. (R8)
 - ≤ 0.04N **hydrochloric acid** (~0.3% v/v HCl, CAS# 7647-01-0, EC No 231-595-7) solution. (R9)
 - The miscellaneous salts, sugars, buffers, water, animal sera and other chemicals found in the HRP conjugate, buffers with protein stabilizers, dyes, and citric acid/sodium acetate solutions.
- ◆ According to the concept of *Universal Precautions* (29 CFR 1910.1030), all human blood and certain human body fluids must be treated as if known to be infectious for HIV, HBV and other bloodborne pathogens. No known test method can offer complete assurance that products derived from human blood will not transmit infection; thus, they should be handled as though they contain infectious agents. Furthermore, individual patient samples being tested represent a heightened, unknown hazard. Aerosolization/inhalation, contact and mucous membrane exposure should be avoided during sample and kit handling.

Consider equipment that potentially comes in contact with human source material as contaminated until appropriately decontaminated.

- ◆ Do not eat, drink or smoke when using this product.
- ◆ Wear protective gloves/protective clothing/eye protection/face protection. Take off contaminated clothing and wash before reuse.

SECTION 4: EMERGENCY FIRST AID MEASURES

Health Effects:	Symptoms of overexposure may include headache, dizziness, congestion and breathing difficulty. Skin contact may result in dermatitis and may cause allergic skin reaction upon repeated exposure. Causes severe skin burns and eye damage. Severely irritating or corrosive to eyes; greater exposures can cause eye damage, including permanent impairment of vision. May cause ingestion corrosive effects including burning throat, mouth and stomach.
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, wash 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 taking immunosuppressant drugs may be more susceptible to infectious pathogens. Persons handling human blood samples should be offered hepatitis B vaccination prior to working with human source material.

SECTION 5: FIREFIGHTING MEASURES

Extinguishing Media:	Use extinguishing media appropriate for the surrounding fire.
Hazardous Combustion Products:	May release toxic oxides of carbon, nitrogen and sulfur or toxic hydrogen chloride 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.
- ◆ Follow established laboratory policy and applicable CDC/NIH biosafety and/or OSHA/WISHA hazardous material spill and/or NFPA/Fire Code guidelines for appropriate hazardous chemical and/or biological material spill response and cleanup. Avoid release to the environment.
- ◆ Wear appropriate PPE. Immediately, and on-site if possible:
 - Decontaminate biohazard/human source material spills, which should always be treated as potentially infectious, including the area, spill materials and any contaminated surfaces or equipment. Utilize an appropriate chemical decon

agent or disinfectant that is effective for the known or potential pathogens relative to the samples involved (commonly a 1:10 dilution of bleach, 70-80% ethanol or isopropanol, an iodophor (such as Wescodyne Plus) or a phenolic, etc.).

- Neutralize corrosive acidic spills with the appropriate *Acid neutralization / adsorbent* product.
- ◆ Clean the spill area with water and wipe dry. Spills can also be absorbed with appropriate inert materials (e.g. spill pillows, absorbent pads, etc.), which are secured in an appropriate, labeled, sealed container. Material used to absorb the spill may require hazardous material waste disposal. Infectious, chemical and laboratory wastes must be handled and discarded in accordance with all local, regional and national regulations.
- ◆ Refer to Sections 8 and 11 for more specifics.

SECTION 7: HANDLING AND STORAGE INFORMATION

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

Chemical	CAS-No.	Value	Control parameter	Update	Basis
Sulfuric acid	7664-93-9	TWA – TLV	0.2 mg/m ³ (thoracic fraction)	2004-01-01	USA. ACGIH Threshold Limit Values (TLV)
		TWA – PEL	1 mg/m ³ *	1993-06-30	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
		REL IDLH	1 mg/m ³ 15 mg/m ³	2005-149 [SEP-2007]	USA. National Institute for Occupational Safety and Health (NIOSH)
	* The value in mg/m ³ is approximate Remarks: TLV CARCINOGENICITY DESIGNATION A2 – Suspected Human Carcinogen: Substance is carcinogenic in laboratory animals under conditions that are considered relevant to worker exposure. Available human studies are conflicting or insufficient to confirm an increased risk of cancer in exposed humans. Worker exposure to an A2 carcinogen should be controlled to levels as low as reasonably achievable below the TLV. The A2 Carcinogenicity Designation refers to sulfuric acid contained in strong inorganic acid mists .				
Hydrochloric acid	7647-01-0	TLV – C	2 ppm	2007-01-01	USA. ACGIH Threshold Limit Values (TLV)
		PEL – C	7 mg/m ³ * 5 ppm	2006-02-28	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
		REL – C IDLH	7 mg/m ³ 5 ppm 50 ppm	2005-149 [SEP-2007]	USA. National Institute for Occupational Safety and Health (NIOSH)
	* The value in mg/m ³ is approximate. Ceiling limit is to be determined from breathing-zone air samples.				

Chemical	CAS-No.	Value	Control parameter	Update	Basis
	Remarks: TLV CARCINOGENICITY DESIGNATION A4 – Not Classifiable as a Human Carcinogen: Inadequate data on which to classify the substance as a human and/or animal carcinogen.				
Hydrogen peroxide	7722-84-1	TWA – TLV	1 ppm	2007-01-01	USA. ACGIH Threshold Limit Values (TLV)
		TWA – PEL	1.4 mg/m ³ * 1 ppm	1997-08-04	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
		REL	1.4 mg/m ³ 1 ppm	2005-149 [SEP-2007]	USA. National Institute for Occupational Safety and Health (NIOSH)
		IDLH	75 ppm		
* The value in mg/m ³ is approximate					
Remarks: TLV CARCINOGENICITY DESIGNATION A3 – Animal Carcinogen: Substance is carcinogenic in laboratory animals under conditions that are not considered relevant to worker exposure. Available human studies and evidence suggest that the substance is not likely to cause cancer in humans except under unusual or unlikely routes or levels of exposure. Worker exposure to an A3 carcinogen should be controlled to levels as low as reasonably achievable below the TLV.					

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, (French)	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, (German))	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, (German))	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

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/patient samples in a biological safety cabinet (BSC), expressly if aerosols might be generated.
Eye/Face Protection:	Wear ANSI approved safety glasses, goggles or face shield with safety glasses or goggles. Contact lenses should not be worn when handling lab hazards.
Protective Gloves:	Suitable gloves must be worn at all times when handling kit reagents or patient samples to provide skin protection from splash and intermittent contact. Synthetic gloves such as nitrile, neoprene and vinyl are recommended because they are sturdy, effective and contain no natural latex ingredients associated with

	latex glove allergic reactions. Disposable (single use) gloves should be changed often and never be reused. Wash hands thoroughly after removing gloves.
Protective Clothing:	Wear a lab coat, clinic jacket, gown, apron and/or smock. Disposable clothing is strongly recommended when handling biohazardous material. If reusable clothing is used, procedures for handling potentially infectious laundry under the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030) are required.
Respiratory Protection:	Do not breathe mist / vapours / spray.
Other:	All personal protective equipment should be removed before leaving the work area and placed in an appropriately designated area or container for storage, processing, decontamination or disposal. 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:	Exposure limit values and health hazard data were given in Section 3. Environmental controls are included in following sections.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Variable, generally aqueous liquids. Exceptions are the solid microtiter plate and related materials.		
Odour:	No applicable information was found.	Odour threshold:	Not Established.
pH:	Most of the liquid chemical components are between pH 6 and 8, Exceptions are the following acidic solutions: Substrate Buffer at pH~4, Stopping Solution at pH ≤ 2, Chromogen at pH ~1.5.		
Boiling point:	Not Established.	Melting point:	Not Established.
Flash point:	Not Applicable. Flammable limits: LEL/LFL is <u>Not Applicable</u> ; UEL/UFL is <u>Not Applicable</u>		
Evaporation rate:	No applicable information was found.		
Fire hazard:	Although the components have not been tested for fire hazard and explosion data, being water-based, they are not expected to be fire hazards, but some of the kit packaging materials may burn under fire conditions.		
Vapor pressure:	No applicable information was found.		
Vapor density:	No applicable information was found.		
Relative density:	Variable, approximately 1-2.		
Solubility:	The liquid chemical components are soluble in water. The acidic solutions may release heat.		
Partition coefficient (n-octanol/water):	No applicable information was found.		
Auto igniting:	Product is not known to be self-igniting.		
Decomposition temperature:	No applicable information was found.		
Viscosity:	No applicable information was found.		
Danger of explosion:	Sodium azide may react with lead or copper plumbing to form highly explosive metal azides; build-up in metal plumbing has led to laboratory explosions, so flush with copious water when pouring dilute solutions down the drain to prevent such explosive build-up. Generally, the product is not known to present an explosion hazard; however, the small amount of glycerol in component R3 should be kept away from strong oxidizing agents, including sodium hypochlorite (bleach) and potassium permanganate, as these could potentially form explosive mixtures.		
No Other Standard Characteristics applicable to the identification or hazards of the product are known.			

SECTION 10: STABILITY AND REACTIVITY INFORMATION

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

Chemical Stability / Reactivity:	Components are stable with no known inherent significant reactivity, except the acidic solutions, which may have an exothermic reaction with certain chemicals, particularly strong bases and reducing agents.
Materials to Avoid:	Do not allow the acidic solutions to come in contact with strong bases, oxidizing agents and metals. Keep glycerol solutions away from strong oxidizing agents, including sodium hypochlorite (bleach) and potassium permanganate, as these could potentially form explosive mixtures.
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.
Hazardous Decomposition Products:	May release toxic oxides of carbon, nitrogen and sulfur or toxic hydrogen chloride 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

Toxicity:	May be detrimental in contact with skin, if swallowed, and to eyes upon contact; in case of contact with eyes, immediately rinse with copious water and seek medical attention.
Primary Irritant Effect:	Irritating to skin and severely irritating or corrosive to eyes, and with greater exposures can cause eye damage, including permanent impairment of vision or blindness.
Corrosivity:	Causes severe skin burns and eye damage. The Stopping Solution is Corrosive, able to cause severe burns of the mucous membranes, skin and eyes; can cause permanent eye damage or blindness. May cause ingestion corrosive effects, including burning throat, mouth and stomach.
Serious Eye Damage / Irritation:	The Stopping Solution is Corrosive, able to cause severe burns of the eyes; can cause permanent eye damage or blindness. The Stopping Solution poses a risk of serious damage to eyes. Harmful to eyes upon contact; in case of contact with eyes, immediately rinse with copious water and seek medical attention.
STOT-Single Exposure:	No applicable information was found.
STOT-Repeated Exposure:	No applicable information was found.
Aspiration Hazard:	No applicable information was found.
Other Acute Health Effects:	No significant other health effect is known.

Biohazard Potential

Inactivated HAV virus, though verified to be non-infectious, should be handled with *Standard* and *Universal Precautions*, as if capable of transmitting infectious disease. The **human sera** in the components of this product were tested and found non-reactive for hepatitis B surface antigen (HBsAg) and antibodies to hepatitis C virus (HCV) and human immunodeficiency virus (HIV-1 and HIV-2) on FDA or CE licensed tests. No known test method can offer complete assurance that HIV, hepatitis B or C virus or other infectious agents are absent. Moreover, patient blood samples tested with this kit represent an unknown, heightened hazard. Employ *Standard* and *Universal Precautions*; handle these reagents, all human blood and specimens as if capable of transmitting infectious disease, in a Biosafety Level 2 laboratory, applying the guidelines from the

current CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories*, WHO *Laboratory Biosafety Manual* or equivalent. Persons handling blood samples should have the option of receiving hepatitis B vaccination.

Chronic Toxicity

Sensitization:	Contains a small volume of a very dilute, sensitizing preservative (ProClin 300); though the potential for an allergic response is greatly reduced by the dilution, sensitization threshold is unknown, thus handle accordingly. R6 contains Azorubin dye (Carmoisine, Food Red 3, E122, CAS# 3567-69-9); Most organic azo dyes are potential skin sensitizers; prolonged or repeated exposure may cause allergic reaction in certain sensitive individuals.
Carcinogenicity:	Component R10 contains 1N Sulfuric Acid , CAS# 7664-93-9: IARC Group 1, The agent is Carcinogenic to Humans, NTP listed as Known to be a Human Carcinogen and ACGIH-TLV Group A2, Suspected Human Carcinogen. <i>Note: The IARC Group and ACGIH A2 1 classifications refers specifically to sulfuric acid contained in strong inorganic acid mists and does not apply to sulfuric acid or sulfuric acid solutions.</i>
Germ Cell Mutagenicity:	No applicable information was found.
Reproductive hazard:	No reproductive toxic effect known.

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

SECTION 12: ECOLOGICAL INFORMATION

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

Ecotoxicity:	100% Sodium Azide [CAS# 26628-22-8]*: Fish LC ₅₀ - Lepomis macrochirus - 0.68 mg/l - 96 h Daphnia EC ₅₀ - Daphnia pulex (Water flea) - 4.2 mg/l - 48 h Concentrated Sulfuric acid [CAS# 7664-93-9]*: Fish LC ₅₀ - Gambusia affinis (Mosquito fish) – 42 mg/l - 96 h Concentrated Hydrochloric acid [CAS# 7647-01-0]*: Fish LC ₅₀ - Bluegill/Sunfish – 282 mg/l - 48 h <i>* Source: Raw Material Vendor Safety Data Sheets</i>
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:	Components R8 (pH 4) , R9 (pH 1.5) and R10 (pH < 2) are hazardous for drinking water and toxic to aquatic organisms by pH modification if not neutralized. An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

Disposal of hazardous and/or laboratory wastes, product or packaging must be conducted in accordance with all applicable local, regional, national and international regulations. This section specifies the general and United States RCRA requirements. Processing, use or contamination of the kit components may change waste management requirements and options. Contact your Environmental Health & Safety Office for your specific disposal procedures.

Recommended Product Disposal:

- Sodium azide** may react with lead or copper plumbing to form highly explosive metal azides; buildup in metal plumbing has led to laboratory explosions, so flush with copious water when pouring dilute solutions down the drain to prevent such explosive buildup. Check your applicable ordinances accordingly.

- All **human source** and other potentially infectious material must be appropriately decontaminated or disposed of as infectious material; check your applicable ordinances accordingly.
- **Acidic** stopping solution (sulfuric acid, pH ≤ 2), chromogen (pH ~1.5), and substrate buffer (pH ~4.0) wastes should be neutralized to pH 6-8 for safe sewer disposal; check your applicable ordinances accordingly. In addition, if the final pH measures ≤ 2, it requires disposal as a corrosive material in an RCRA approved waste facility (or equivalent). The US RCRA Waste Disposal Code for this waste, if not neutralized, is D002; check your national and regional ordinances accordingly.

Do not allow undiluted product or large quantities of it to reach ground water or water course.

Recommended Unclean Packaging Disposal: Dispose of in accordance with all applicable local, regional, national and international regulations.

SECTION 14: TRANSPORT INFORMATION

Shipping 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: According to US DOT, IATA and UN "Model Regulations," the **stopping solution** in the kit must be transported as follows:

Acidic component **Stopping Solution** in this kit contains 1N **sulfuric acid**; thus, any un-neutralized discarded kit component or waste generated from its use resulting in a corrosive liquid (pH ≤ 2 or an pH ≥ 12.5 per Method 9040 [USEPA Publication SW-846] or Corrodes Steel [NACE Standard TM-01-69]) must be transported as follows:

Proper Shipping name: **Sulphuric acid [with not more than 51% acid]**

DOT Class: **8**

Packing group **II**

DOT ID Number: **UN 2796**

Recommended Used Product Hazardous Waste Disposal Transportation: Potential air and land transportation information for discarded kit components and waste from this product when used as intended is:

The acidic **Chromogen** is at pH ~1.5 and 1N sulfuric acid **Stopping Solution** is at pH ≤ 2; thus, any un-neutralized discarded kit component or waste generated from its use resulting in a corrosive liquid (pH ≤ 2 or an pH ≥ 12.5 per Method 9040 [USEPA Publication SW-846] or Corrodes Steel [NACE Standard TM-01-6]) must be transported as follows:

Proper Shipping name: **Waste Corrosive Liquid n.o.s.**

DOT Class: **8**

Packing group **III**

DOT ID Number: **UN 1760**

SECTION 15: REGULATORY INFORMATION

Composite HMIS Rating:

Health: 2

Flammability: 0

Reactivity: 1

California Proposition 65:

The product does not contain listed substances.

Carcinogenicity Categories:

Component R10 contains 1N **Sulfuric Acid**, CAS# 7664-93-9: IARC Group 1 The agent is Carcinogenic to Humans, NTP listed as Known to be a Human Carcinogen and ACGIH-TLV Group A2 Suspected Human Carcinogen

Note: The IARC Group and ACGIH A2 1classifications refers specifically to sulfuric acid contained in strong inorganic acid mists and does not apply to sulfuric acid or sulfuric acid solutions.

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.

Composite WHMIS Hazard Class: Class D2B - Materials causing other toxic effects (Toxic material)
Class E - Corrosive material

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

Australian Code: This SDS contains the required information for preparation according to the **Australian Code of Practice on Preparation of Safety Data Sheets for Hazardous Chemicals** under Section 274 of the **Work Health and Safety Act. Australian Inventory of Chemical Substances:** All pertinent ingredients are listed.

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* 1999/45/EC, 2001/59/EC 2001/60/EC and 2006/102/EC.

Hazard Designation of Composite Product: CORROSIVE: C ; IRRITANT: Xi 

Hazards Determining substance(s) of labeling:

1N sulfuric acid (4.4% w/w H₂SO₄), EC No 231-639-5; CAS# 7664-93-9, [Corrosive: C; R 34 (eyes)-36/38-41; S 24/25-26-36/37/39-45-60 (1999/45/EC and 2001/60/EC)].

0.25% and 0.1% ProClin 300, per 2001/59/EC: Index No: 613-167-00-5 with CAS# 55965-84-9 [Irritant: Xi; R 43; S 24-35-37 (≤ 0.06% and > 0.0015% active ingredient)].

< 0.1% **sodium azide**, EC No 247-852-1, CAS# 26628-22-8 [S 35-36].

SECTION 16: OTHER INFORMATION

Risk Phrases:

- | | |
|---------|--|
| R 34 | Causes burns. |
| R 36/38 | Irritating to eyes and skin. |
| R 41 | Risk of serious damage to eyes. |
| R 43 | May cause sensitization by skin contact. |
| Caution | Contains human source material and inactivated pathogen. Handle as if capable of transmitting potentially infectious agents (Universal Precautions). |

Safety Phrases:

- | | |
|------------|---|
| S 24 | Avoid contact with skin. |
| S 24/25 | Avoid contact with skin and eyes. |
| S 26 | In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. |
| S 35 | This material and its container must be disposed of in a safe way. |
| S 37 | Wear suitable gloves. |
| 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 60 | This material and its container must be disposed of as hazardous waste. |

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

For *in vitro* diagnostic use.

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

Raw Material Vendor Safety Data Sheets
United Nations (UN) Globally Harmonized System (GHS)
United States OSHA Hazard Communication Standard (HCS) 1910.1200
Canadian Workplace Hazardous Materials Information System (WHMIS)
European Community (EC) Regulations 2008/1272/EC, 2010/453/EC, 2006/1907/EC
Mexican Standard NMX-R-019-SCFI-2011
Australian Code of Practice on Preparation of Safety Data Sheets for Hazardous Chemicals (Section 274 of the *Work Health and Safety Act*)
 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)
 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) [7-27-2012]
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 Labelling of Chemicals (GHS) Fourth edition unless otherwise specified.

Key / legend to abbreviations and acronyms used in the safety data sheet:

ACGIH – American Conference of Governmental Industrial Hygienists
 ACIS – Australian Inventory of Chemical Substances
 ANSI – American National Standards Institute
 CAS – Chemical Abstracts Service
 CDC – Centers for Disease Control, USA
 CNS – Central Nervous System
 DOT – Department of Transportation
 EC₅₀ – half maximal effective concentration
 EU – European Union
 GHS – Globally Harmonized System
 HCS – Hazard Communication Standard, USA
 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
 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
 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
 WHMIS – Workplace Hazardous Materials Information System, Canada
 WHO – World Health Organization (United Nations)

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

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



MONOLISA™ Anti-HAV EIA

[Catalog # 72496]

Bio-Rad Laboratories:

Department issuing SDS: Environmental Health and Safety.

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