

**SAFETY DATA SHEET (SDS)****SECTION 1: IDENTIFICATION OF PRODUCT (MIXTURE) AND SUPPLIER**





|  |  |
|--|--|
| <b>Product Name:</b>                   | <b>Multispot HIV-1/HIV-2 Rapid Test</b>  |
| <b>Product Number:</b>                 | <b>25228</b> (50 tests).   |
| <b>Intended Use:</b>                   | The Multispot HIV-1/HIV-2 rapid test is a single use qualitative immunoassay to detect and differentiate circulating antibodies to Human Immunodeficiency Virus Types 1 and 2 (HIV-1, HIV-2) in fresh or frozen human serum and plasma. This rapid HIV-1/HIV-2 test kit is intended as an aid in the diagnosis of infection with HIV-1 and/or HIV-2 in fresh or frozen human serum or plasma. This test is suitable for use in multi-test algorithms designed for statistical validation of an HIV test screening result or as a part of an HIV-1/HIV-2 diagnostic test algorithm that includes differentiation of HIV-1 and HIV-2 antibodies. |
| <b>Manufactured by:</b>                | <b>Bio-Rad Laboratories, Inc.</b>  |
| <b>Address:</b>                        | 6565 185th Avenue NE<br>Redmond, WA 98052-5039, USA  |
| <b>Website:</b>                        | <a href="http://www.bio-rad.com">www.bio-rad.com</a>   |
| <b>Phone Number:</b>                   | 1-800-2-BIORAD (1-800-224-6723); or 1-425-881-8300 (daytime PT)  |
| <b>SDS e-mail contact:</b>             | <a href="mailto:ro-sds@bio-rad.com">ro-sds@bio-rad.com</a>   |
| <b>Technical Information Contacts:</b> | 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>   |
| <b>Emergency Phone Number:</b>         | This SDS is listed with <b>CHEMTREC 1-800-424-9300</b> (US) / <b>001-703-527-3887</b> (international – can be called collect). Use only in the event of a <b>CHEMICAL EMERGENCY</b> involving a <b>SPILL, LEAK, FIRE, EXPLOSION</b> or <b>ACCIDENT</b> with this product.  |

**SECTION 2: HAZARDS IDENTIFICATION -- HAZARDOUS COMPONENTS**

This test kit should be handled only by qualified personnel trained in laboratory procedures and familiar with their potential hazards. Specific warnings are given in the instructions for use. The absence of a specific warning should not be interpreted as an indication of safety. The following information is furnished for those product hazardous constituents that require regulatory control or disclosure at the concentration found in the product. Refer to Section 16 for the full text of any solely abbreviated or coded hazard statements provided below and for the Key / legend to abbreviations and acronyms.

| <b>Component</b>   | <b>Contents</b>  |
|--|--|
| <b>1. Multispot HIV-1/HIV-2 Cartridge (50)</b>               | - Foil-sealed base container with specimen prefilter; Membrane with 1 Procedural Control Spot (anti-human IgG (goat)) and 3 Test Spots (HIV-1 recombinant ( rDNA), HIV-1 peptide and HIV-2 peptide).   |
| <b>2. Positive Control Serum,</b><br>1 dropper bottle (1 mL) | - Heat-inactivated human serum/plasma containing anti-HIV-1 and anti-HIV-2 immunoglobulin; non-reactive for detectable HBsAg and antibody to HCV.<br>- Preserved with <b>0.5% ProClin 300</b> (0.015% active ingredient), EC Index No 613-167-00-5 with CAS# 55965-84-9 [GHS \ US HCS \ EC CLP Classification: WARNING; GHS07; H317; P280; P302 + P352, P333 + P313; P501.]<br>- Preserved with <b>0.1% sodium azide</b> [NaN <sub>3</sub> ], CAS# 26628-22-8 and EC No 247-852-1. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements without Cat 5 Acute Toxic designations in this product mixture and concentration. |



|  |  |
|--|--|
| <p><b>3. Negative Control Serum,</b><br/>1 dropper bottle (1 mL)</p>  <p><b>WARNING</b></p> <p><i>Catalog No. 26166</i></p> | <ul style="list-style-type: none"> <li>- Normal human serum; nonreactive for detectable HBsAg and antibodies to HIV-1 and HIV-2 and HCV.</li> <li>- Preserved with <b>0.5% ProClin 300</b> (0.015% active ingredient), EC Index No 613-167-00-5 with CAS# 55965-84-9 [GHS \ US HCS \ EC CLP Classification: WARNING; GHS07; H317; P280; P302 + P352, P333 + P313; P501.]</li> <li>- Preserved with <b>0.1% sodium azide</b> [NaN<sub>3</sub>], CAS# 26628-22-8 and EC No 247-852-1. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements without Cat 5 Acute Toxic designations in this product mixture and concentration.</li> </ul>   |
| <p><b>4. Specimen Diluent,</b><br/>1 dropper bottle (25 mL)</p>  <p><b>WARNING</b></p>                                      | <ul style="list-style-type: none"> <li>- Diluent for specimens and controls, containing protein [goat] stabilized buffer solution with <b>≤ 1% Tween 20</b> [C<sub>58</sub>H<sub>114</sub>O<sub>26</sub>], CAS# 9005-64-5, EC No 585-580-06-X. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration.</li> <li>- Preserved with <b>0.1% ProClin 150</b> and <b>0.125% ProClin 300</b> (≤ 0.005% active ingredient), EC Index No 613-167-00-5 with CAS# 55965-84-9. GHS \ US HCS \ EC CLP Classification: WARNING; GHS07; H317; P280; P302 + P352, P333 + P313; P501.]</li> </ul>   |
| <p><b>5. Conjugate,</b><br/>1 dropper bottle (9.5 mL)</p>  <p><b>WARNING</b></p>  | <ul style="list-style-type: none"> <li>- Anti-human IgG (H+L) (goat) alkaline phosphatase conjugated solution in a protein [goat] stabilized buffer solution.</li> <li>- <b>≤ 50% Glycerol</b> [C<sub>3</sub>H<sub>8</sub>O<sub>3</sub>], CAS# 56-81-5, EC No 200-289-5. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration.</li> <li>- Preserved with <b>≤ 0.125% ProClin 150</b> (≤ 0.0015% active ingredient), EC Index No 613-167-00-5 with CAS# 55965-84-9. GHS \ US HCS \ EC CLP Classification: WARNING; GHS07; H317; P280; P302 + P352, P333 + P313; P501.]</li> </ul>  |
| <p><b>6. Wash Solution,</b><br/>2 dropper bottles (85 mL each)</p>  <p><b>WARNING</b></p>                                 | <ul style="list-style-type: none"> <li>- <b>Tris buffered saline</b> solution with diluted <b>≤ 10% Urea</b> [CH<sub>4</sub>N<sub>2</sub>O], CAS# 57-13-6, EC No 200-315-5. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration.</li> <li>- Contains <b>26% 1,2,-propanediol</b> [propylene glycol – C<sub>3</sub>H<sub>8</sub>O<sub>2</sub>]; CAS# 57-55-6, EC No 200-338-0. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration.</li> <li>- Preserved with <b>≤ 0.1% ProClin 150</b> (≤ 0.0015% active ingredient), per 2001/59/ EC Index No 613-167-00-5 with CAS# 55965-84-9. GHS \ US HCS \ EC CLP Classification: WARNING; GHS07; H317; P280; P302 + P352, P333 + P313; P501.]</li> <li>- Contains <b>&lt; 0.001% nitro blue tetrazolium</b> [NBT- C<sub>40</sub>H<sub>30</sub>N<sub>10</sub>O<sub>6</sub>Cl<sub>2</sub>], CAS# 298-83-9, EC No 206-067-4. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration.</li> </ul> |
| <p><b>7. Development Reagent,</b><br/>1 dropper bottle (8.5 mL)</p>  | <ul style="list-style-type: none"> <li>- <b>≤ 0.5% 3-Indoxyl phosphate</b> in a <b>&lt; 10% AMP Buffer</b> [CAS# 124-68-5, EC No 204-709-8] solution with a pH ~ 10. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration.</li> </ul>   |
| <p><b>8. Stop Solution,</b><br/>1 dropper bottle (55 mL)</p>   | <ul style="list-style-type: none"> <li>- <b>0.1N Sulfuric Acid</b> (≤ 0.48% H<sub>2</sub>SO<sub>4</sub>), CAS# 7664-93-9, EC No 231-639-5 (pH ≤ 2, Clear Liquid). Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration.</li> </ul>  |
| <p><b>9. Disposable Transfer Pipets (60)</b></p>   | <ul style="list-style-type: none"> <li>- Polyethylene transfer pipets.</li> <li>- No known hazardous chemical ingredients.</li> </ul>  |
| <p><b>10. Eyedropper (1)</b></p>   | <ul style="list-style-type: none"> <li>- Polyethylene eyedropper and cap with rubber bulb.</li> <li><i>Note: The dropper bulb used in this bottle (supplied separately in the kit, but then placed in the Specimen Diluent bottle for kit use) contains Dry Natural Rubber, a potential sensitizer.</i></li> </ul>   |

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

**Component 2, 3, 4, 5, 6 - 0.1% ProClin 150 or ≤ 0.5% ProClin 300** [0.0015% or 0.0075% active ingredients – reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one (C<sub>4</sub>H<sub>4</sub>ClNOS; CAS# 26172-55-4, EC No 247-500-7) and 2-methyl-2H - isothiazol-3-one (C<sub>4</sub>H<sub>5</sub>NOS; CAS# 2682-20-4, EC No 220-239-6) (3:1)], EC Index No 613-167-00-5 with CAS# 55965-84-9.

**Comprehensive GHS Based Classification:** Skin Sensitizer Category 1



Label(s):

Signal Word:

**WARNING**

Label Hazard Statements:

**H317** May cause an allergic skin reaction.

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

P280 Wear protective gloves / protective clothing / eye protection / face protection.  
 P302 + P352 IF ON SKIN: Wash with plenty of soap and water.  
 P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.  
 P501 Dispose of contents and container in accordance to local, regional, national and international regulations.

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

P261 Avoid breathing mist / vapors/vapours / spray.  
 P272 Contaminated work clothing should not be allowed out of the workplace.

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

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

**SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS**

The following information is furnished for those hazardous constituents in the product that require regulatory control or disclosure at the concentration found in the product. Note that the information here is often based on data for the chemical raw material (LD<sub>50</sub>, exposure limits, etc.) Chemical constituents that do not require regulatory disclosure are not generally included here. This product contains a significantly diluted concentration in an aqueous solution, thus the assessment below has not considered the dilution reduction effect on the hazard. That hazard communication information is provided in Section 2 above. Some components were tested at the concentration found in the kit. In that case, the assessment is provided for the chemical dilution tested and the tested concentration will be provided at the beginning of the *Chemical Ingredient Data/Information* box. The UN GHS, US HCS, EC CLP and analogous GHS-based global regulation classifications were made according to the existing editions and expanded upon from company and literature data. Refer to section 16 for the full text of any *Comprehensive GHS-based Classification* statements coded below, for the list of sources utilized in the assessment and for the Key / legend to abbreviations and acronyms.

**Chemical Ingredient Data / Information**

**Chemical Ingredient: Glycerol**

Chemical concentrations found in this product: **≤ 50% in component 5 (aqueous solution)**

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

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

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

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

**Chemical Ingredient: Propylene glycol**

Chemical concentrations found in this product: **26% w/v in component 6**

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

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

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

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

**Chemical Ingredient: AMP Buffer [2-amino-2-methyl-propanol]**

Chemical concentrations found in this product: **≤ 10% in component 7**

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

|   |  |
|---|--|
| CAS#: 124-68-5 (100%)   | LD <sub>50</sub> (oral-rat): 2900 mg/kg (100%)     |
| EC No: 204-709-8 (100%)   | LC <sub>50</sub> (inhalation-rat): NE              |
| RTECS#: UA5950000 (100%)  | LD <sub>50</sub> (skin-rabbit): >2000 mg/kg (100%) |
| Index No: 603-070-00-6 (100%)   | LC <sub>50</sub> (96 hr-fish): >100 mg/L (100%)    |
| Chemical Formula: C <sub>4</sub> H <sub>11</sub> NO (100%)  | Flash Point: 154.4°F / 68°C (100%)                 |
| Molecular weight: 89.14 g/mol (100%)  | pH value ~ 11-12 (8.9g/L) at 25 °C (77 °F) (100%)  |
| Synonyms/Trade Names: 2-amino-2-methyl-propanol   |  |
| Skin corrosion/irritation: Skin - rabbit - Draize Test - Irritating to skin (100%)                                      |  |
| Serious eye damage/eye irritation: Eyes - rabbit - Corrosive to eyes - Draize Test (100%)                               |  |
| Respiratory or skin sensitization: Buehler Test - guinea pig - Did not cause sensitisation on laboratory animals (100%) |  |

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

**DANGER**

Acute Tox. – oral. Cat. 5, Acute Tox. – skn. Cat. 5, Skin Irrit. Cat. 2, Eye damage Cat. 1, Aquatic Acute Cat. 3  
 Aquatic Chronic Cat. 3,

H303 + H313, H315, H318, H412  
 P273, P280, P305 + P351 + P338, P501



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

**Chemical Ingredient Data / Information**

**Chemical Ingredient: Urea**

Chemical concentrations found in this product: **≤ 10% w/v in Component 6**

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

|   |  |
|---|--|
| CAS#: 57-13-6 (100%)  | LD <sub>50</sub> (oral-rat): 8471 mg/kg (100%)                                 |
| EC No: 200-315-5 (100%)                                     | LC <sub>50</sub> (inhalation-rat): No data available (100%)                    |
| RTECS#: YR6250000 (100%)                                    | LD <sub>50</sub> (skin-rabbit): No data available mg/kg (100%)                 |
| Index No: NA (100%)   | LC <sub>50</sub> (96 hr-fish): Poecilia reticulata (guppy) - 17500 mg/l (100%) |
| Chemical Formula: CH <sub>4</sub> N <sub>2</sub> O (100%) + | Flash Point: NE +  |
| Molecular weight: 60.06 g/mol (100%)                        |  |
| Synonyms/Trade Names: Carbamide, Carbonyldiamide            |  |

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

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

**Chemical Ingredient: ProClin 300**

Chemical concentrations found in this product: **0.5% v/v (0.015% active ingredient) in Components 2 and 3**  
**≤ 0.125% in Component 4**

Hazardous ingredient concentration in raw material:

**60-100% Glycols;**

**1-5% Mixture (3:1) of 5-Chloro-2-methyl-4-isothiazolin-3-one** (C<sub>4</sub>H<sub>5</sub>NOS; CAS# 2682-20-4, EC# 220-239-6)  
and **2-Methyl-2H -isothiazol-3-one** (C<sub>4</sub>H<sub>4</sub>CINOS; CAS# 26172-55-4, EC# 247-500-7)  
CAS#: 55965-84-9  
Index No: 613-167-00-5

**Data for chemical used in the product (concentration tested):**

RTECS#: NE  
Synonyms/Trade Names: **Synonyms/Trade Names:** 5-Chloro-2-methyl-4-isothiazolin-3-one solution; Kathon 300; Isothiazolinone chloride solution  
pH value: 4.1 at 100 g/L (concentrated solution)  
Flash Point: 244° F / 118° C (concentrated solution)  
LD<sub>50</sub> (oral-rat): 862 mg/kg (concentrated solution)  
LD<sub>50</sub> (skin-rabbit): 2,800 mg/kg (concentrated solution)  
LC<sub>50</sub> (inhalation-rat): NE  
LD<sub>50</sub> (skin-rabbit): NE  
Skin corrosion/irritation - rabbit – Corrosive (concentrated solution)  
Serious eye damage/eye irritation - rabbit - Corrosive to eyes (concentrated solution)  
Respiratory or skin sensitization - May cause allergic skin reaction (concentrated solution)

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

**DANGER!**

Acute Tox. – oral Cat. 4, Skin Corr. Cat. 1B, Eye Damage.1, Skin. Sens. Cat.1, Aquatic Acute Cat. 1, Aquatic Chronic Cat. 1  
H302,, H314, H317, H410  
P261, P264, P270, P272, P273, P280, P301 + P312 + P330, P301 + P330 + P331,  
P303 + P361 + P353, P305 + P351 + P338 + P310, P333 + P313, P363, P391, P405, P501



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

**Chemical Ingredient Data / Information**

**Chemical Ingredient: Sulfuric acid**

Chemical concentrations found in this product: **0.1 N (< 0.5% (w/w) H<sub>2</sub>SO<sub>4</sub> in water) in Component 8**

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

CAS#: 7664-93-9 (Conc. sulfuric acid 100%) LD<sub>50</sub> (oral-rat): 2,140 mg/kg (100%)  
 EC No: 231-639-5 (100%) LC<sub>50</sub> (inhalation-rat): 510 mg/m<sup>3</sup>/2H (100%)  
 Index No: 016-020-00-8 (100%) LD<sub>50</sub> (skin-rabbit): NE (100%)  
 Registration No: 01-2119458838-20-XXXX LC<sub>50</sub> (96 hr-fish): Gambusia affinis (Mosquito fish) – 42 mg/l (100%)  
 RTECS#: WS5600000 (100%) pH value: 1.2 at 5 g/L  
 Skin corrosion/irritation: Skin - rabbit - Extremely corrosive and destructive to tissue.  
 Serious eye damage/eye irritation: Eyes - rabbit - Severe eye irritation  
 Chemical Formula: H<sub>2</sub>SO<sub>4</sub> (100%)  
 Molecular weight: 98.08 g/mol (100%)  
 Synonyms/Trade Names: Acide sulfurique ;Acido solforico; BOV; Battery acid; Dihydrogen sulfate; Dipping acid; Electrolyte acid; Mattling acid; Oil of vitriol; Schwefelsaeureloesungen; Strong inorganic acid mists containing sulfuric acid; Sulfuric acid; Sulfuric acid, aerosol; Sulphuric acid; Vitriol Brown Oil; Zwavelzuuroplossingen

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

**DANGER!**

Skin Corr. Cat. 1A, Eye Damage Cat. 1, Aquatic Acute Cat. 3, Aquatic Chronic Cat. 3  
 H314, H412



P264, P273, P280, P301 + P330 + P331, P303 + P361 + P353, P304 + P340, P305 + P351 + P338, P310, P363, P405, P501

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

**Chemical Ingredient: ProClin 150**

Chemical concentrations found in this product: **0.1% v/v (0.0015% active ingredient) in Components 4, 5 and 6**

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

Hazardous ingredient concentration in raw material (in water):

**10-30% Magnesium nitrate** MgCl<sub>2</sub>; CAS# 7786-30-3, EC No: 232-094-6

Classification: Ox. Sol. 3; Skin Irrit. 2; Eye Irrit. 2; STOT SE 3; H272, H315, H319, H335

**1-5% Mixture (3:1) of 5-Chloro-2-methyl-4-isothiazolin-3-one** (C<sub>4</sub>H<sub>5</sub>NOS; CAS# 2682-20-4, EC# 220-239-6)

and **2-Methyl-2H -isothiazol-3-one** (C<sub>4</sub>H<sub>4</sub>CINOS; CAS# 26172-55-4, EC# 247-500-7), CAS#: 55965-84-9, Index No: 613-167-00-5

Classification: Acute Tox. 3; Skin Corr. 1B; Skin Sens. 1; Aquatic Acute 1; Aquatic Chronic 1; H301 + H311 + H331, H314, H317, H410

RTECS#: NE

Synonyms/Trade Names: 5-Chloro-2-methyl-4-isothiazolin-3-one solution; Kathon 150; Isothiazolinone chloride solution

Flash Point: NE

LD<sub>50</sub> (oral-rat-female): 2630 mg/kg (concentrated solution)

LD<sub>50</sub> (oral-rat-male): 3350 mg/kg (concentrated solution)

LC<sub>50</sub> (inhalation-rat): NE

LD<sub>50</sub> (skin-rabbit): NE

Skin corrosion/irritation - rabbit – Corrosive (concentrated solution)

Serious eye damage/eye irritation - rabbit - Corrosive to eyes (concentrated solution)

Respiratory or skin sensitization - guinea pig - May cause sensitisation by skin contact (concentrated solution)

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

**DANGER!**

Acute Tox. – oral Cat. 4, Skin Corr. Cat. 1B,

Eye Damage Cat. 1, Skin. Sens. Cat. 1, Aquatic Acute Cat. 2, Aquatic Chronic Cat. 1

H302, H314, H317, H410

P220, P261, P264, P270, P272, P273, P280, P301 + P312 + P330, P301 + P330 + P331,

P303 + P361 + P353, P305 + P351 + P338, P310, P333 + P313, P363, P391, P405, P501

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



**Chemical Ingredient Data / Information**

**Chemical Ingredient: Sodium azide**

Chemical concentrations found in this product: **0.1 % w/v in Components 2 and 3**

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

|   |  |
|---|--|
| CAS#: 26628-22-8 (100%)   | LD <sub>50</sub> (oral-rat): 27 mg/kg (100%)                                     |
| EC No: 247-852-1 (100%)   | LC <sub>50</sub> (inhalation-rat): 37 mg/m <sup>3</sup> (100%)                   |
| Index No: 011-004-00-7 (100%)   | LD <sub>50</sub> (skin-rat): 50 mg/kg (100%)                                     |
| RTECS#: VY8050000 (100%)  | Fish LC <sub>50</sub> – Lepomis macrochirus (Bluegill) – 0.68 mg/l – 96 h (100%) |
| Chemical Formula: NaN <sub>3</sub> (100%)   |  |
| Molecular weight: 65.01g/mol (100%)   |  |
| Synonyms/Trade Names: Azide, sodium; Azoture de sodium; Azydek sodu; NSC 3072; Kazoe; Natriumazid; Natriumazide; NCI-C06462; Nemazyd; Sodium azide; Sodium, azoture de; Sodium, azoturo di, Smitte; U-3886; |  |

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

**DANGER!**



Acute Tox. – oral. Cat. 2, Acute Tox. – skn. Cat. 1, Aquatic Acute Cat. 1, Aquatic Chronic Cat. 1

H300 + H310, H410

P264, P273, P280, P302 + P350, P310, P501



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

| Biological Ingredient  | Data / Information   |
|--|--|
| <b>Procedural Control</b>  | Spot 1: Anti-human IgG (goat).   |
| <b>3 (three) Test Spots</b><br>   | Spot 2: HIV-2 peptide representing the immunodominant epitope of the HIV-2 virus gp36 envelope glycoprotein.<br>Spot 3: HIV-1 recombinant gp41 (HIV-1 envelope glycoprotein) expressed in E. coli.<br>Spot 4: HIV-1 peptide representing the immunodominant epitope of the HIV-1 virus gp41 envelope glycoprotein.   |
| <b>Animal proteins,</b><br>[Components 4 and 5]  | This material is of animal origin (goat and bovine) and may be a potential contact irritant. Hazard unknown. Handle as potentially infectious. The chemical, physical and toxicological properties have not been thoroughly investigated. Handle appropriately with the requisite Good Laboratory Practices, <i>Standard and Universal Precautions</i> . Dispose of this material in accordance with local, regional, national and international regulations.  |
| <b>Human Serum</b><br>[Reactive and Non-reactive in the Positive (2) and Negative Control (3) Components]<br><br> | The positive control (2) was heat-treated to inactivate the HIV. Human sera in reagents were tested and found non-reactive for hepatitis B surface antigen and antibodies to HCV (the negative control (3) is also non-reactive for antibodies to HIV-1/HIV-2). No known test method can offer complete assurance that HIV, hepatitis B or C virus or other infectious agents are absent. Employ <i>Standard and Universal Precautions</i> when handling these reagents and all human blood, specimens or patient samples, which represent an unknown, heightened hazard. 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% dil 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. |

NA: Not applicable.

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

**Related product information:**

- ◆ Refer to Section 16 for the full text of any *Comprehensive GHS-based Classification* statements coded above.
- ◆ Refer to Section 16 for the list of sources utilized in the assessment and the Key / legend to abbreviations and acronyms.
- ◆ No significant adverse health effects are expected by any route for the following chemical constituents in the kit volumes and concentrations present [chemical or dilution is not subject to GHS, US HCS, EC CLP or other GHS-based hazard labeling]:
  - **Tween® 20** [C<sub>38</sub>H<sub>114</sub>O<sub>26</sub>], CAS# 9005-64-5, EC No 585-580-06-X, ≤ 1% w/v in component 4.

- Nitro blue tetrazolium (NBT –  $C_{40}H_{30}N_{10}O_6Cl_2$ ), CAS# 298-83-9, EC No 206-067-4,  $\leq 0.001\%$  w/v in component 6.
- 3-Indoxyl phosphate [ $C_8H_8NO_4P \cdot 2(C_4H_{11}NO_2)$ ], CAS# 107475-12-7  $\leq 0.5\%$  v/v in component 7.
- The miscellaneous salts, buffers, protein-stabilizers, antibodies, conjugates, water and other nonreactive ingredients

- ◆ **The dropper bulb used in this bottle (supplied separately in the kit, but then placed in the Specimen Diluent bottle for kit use) contains Dry Natural Rubber, a potential sensitizer.**
- ◆ 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 the products derived from human blood will not transmit infection; thus, they should be handled as though they contain infectious agents. Furthermore, individual patient samples being tested represent a heightened, unknown hazard. Aerosolization/inhalation, contact and mucous membrane exposure should be avoided during sample and kit handling. Consider equipment that potentially comes in contact with human source material as contaminated until appropriately decontaminated.
- ◆ Do not eat, drink or smoke when using this product.
- ◆ Wear protective gloves/protective clothing/eye protection/face protection. Take off contaminated clothing and wash before reuse.

### SECTION 4: EMERGENCY FIRST AID MEASURES

|                    |   |
|--------------------|---|
| Health Effects:    | Symptoms of overexposure may include headache and congestion. May cause an allergic skin reaction upon repeated exposure, 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.   |

### SECTION 5: FIREFIGHTING MEASURES

|                                  |  |
|----------------------------------|--|
| Extinguishing Media:             | Use extinguishing media appropriate for the surrounding fire.  |
| Hazardous Combustion Products:   | May release toxic oxides of carbon, nitrogen and sulfur.   |
| Special Firefighting Procedures: | Conventional firefighting full protective equipment (with NIOSH-approved self-contained breathing apparatus) and procedures appropriate for the surrounding fire should be sufficient. |

### SECTION 6: ACCIDENTAL RELEASE MEASURES

- ◆ Avoid direct contact with skin, eyes, mucous membranes and clothing by wearing appropriate lab personal protective equipment (PPE) including gloves, lab coat and eye/face protection.
- ◆ In the event of a hazardous material spill, contain the spill if it is safe to do so; immediately move to a safe area free from potential aerosols, to decontaminate and/or safely remove any contaminated clothing, as necessary. IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. Isolate the hazard area and ventilate if appropriate. Ensure that appropriate spill cleanup materials and PPE are available and used.
- ◆ Prevent material from entering sewers, waterways or confined spaces.



- ◆ Follow established laboratory policy, OSHA/WISHA hazardous material spill and/or CDC/NIH biosafety 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.
  - Neutralize corrosive **alkaline** spills with the appropriate *base neutralization / adsorbent* product.
- ◆ Clean the spill area with water and wipe dry. Spills can also be absorbed with an appropriate inert material (e.g. spill pillows, absorbent pads, etc.), which are secured in an appropriate, labeled, sealed container. Material used to absorb the spill may require hazardous material waste disposal. Infectious, chemical and laboratory wastes must be handled and discarded in accordance with all local, regional, national and international regulations.
- ◆ Refer to Sections 8 and 13 for more specifics.

**SECTION 7: HANDLING AND STORAGE INFORMATION**

|  |   |
|--|---|
| Handling:  | <p>This test kit should be handled only by qualified personnel trained in laboratory procedures and familiar with their potential hazards. Follow proper Good Laboratory Practices and safety guidelines for handling chemical, biological and laboratory hazards.</p> <p>Do not smoke, eat, or drink in areas where patient samples and kit reagents are handled. Wash your hands after use. Wear appropriate personal protective equipment (PPE) including gloves, lab coat and eye/face protection.</p> <p>Keep containers tightly closed; avoid splashing, spills and the generation of aerosols.</p> <p>Handle all human source specimens, materials and equipment used to perform the test as though they were capable of transmitting infectious disease, as per <i>Standard and Universal Precautions</i>.</p> <p>All personal protective equipment should be removed before leaving the work area. Refer to Section 8 for more specifics.</p> <p>Avoid release to the environment. Do not allow undiluted product hazardous chemical ingredient or large quantities of it to reach ground water or water course.</p> <p>Consult with your Environmental Health &amp; Safety Office for assistance.</p> |
| 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 <i>in vitro</i> diagnostic use.  |   |

**SECTION 8: EXPOSURE CONTROL / PERSONAL PROTECTION MEASURES**

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

| <b>100% Glycerol [CAS# 56-81-5] - OEL:</b> |         |                                  |         |
|--|---------|----------------------------------|---------|
| BELGIUM:                                   | TWA     | 10 mg/m <sup>3</sup>             | MAR2002 |
| FINLAND:                                   | TWA     | 20 mg/m <sup>3</sup>             | NOV2011 |
| FRANCE:                                    | VME     | 10 mg/m <sup>3</sup>             | FEB2006 |
| GERMANY:                                   | MAK     | 50 mg/m <sup>3</sup> , inhal     | 2011    |
| ITALY:                                     | TWA     | 10 mg/m <sup>3</sup>             |         |
| KOREA:                                     | TWA     | 10 mg/m <sup>3</sup> (mist)      | 2006    |
| MEXICO:                                    | TWA     | 10 mg/m <sup>3</sup> (inhalable) | 2004    |
| THE NETHERLANDS:                           | MAC-TGG | 10 mg/m <sup>3</sup>             | 2003    |
| NEW ZEALAND:                               | TWA     | 10 mg/m <sup>3</sup> (mist)      | JAN2002 |
| PERU:                                      | TWA     | 10 mg/m <sup>3</sup>             | JUL2005 |

| <b>100% Glycerol [CAS# 56-81-5] - OEL:</b>   |                      |  |   |
|--|----------------------|--|---|
| SWITZERLAND:   | MAK-W<br>KZG-W       | 50 mg/m <sup>3</sup><br>100 mg/m <sup>3</sup> , inhal  | JAN2011   |
| UNITED KINGDOM:  | TWA                  | 10 mg/m <sup>3</sup>   | OCT2007   |
| ARGENTINA, BULGARIA,<br>COLOMBIA, JORDAN,<br>SINGAPORE, VIETNAM                        |                      | check ACGIH TLV<br>[Professionally Translated 1-2016]  |   |
| UNITED STATES:   | TLV-TWA<br>PEL-T-TWA | 10* ppm (*total mist)<br>15* 5** mg/m <sup>3</sup> (*total dust **respirable fraction)<br><b>Remarks:</b> Upper Respiratory Tract irritation | ACGIH Threshold Limit Values (TLV)<br>OSHA 29,1910.1000 Z-1, 1989 |
| <i>[Source: RTECS September 2013 Update and Raw Material Vendor Safety Data Sheet]</i> |                      |  |   |

| <b>100% Sodium Azide [CAS# 26628-22-8] - OEL:</b>                                      |                                |   |   |
|--|--------------------------------|---|---|
| AUSTRALIA:   | CL                             | 0.11 ppm (0.3 mg/m <sup>3</sup> )   | JUL2008   |
| AUSTRIA:   | MAK-TMW<br>KZW                 | 0.1 mg/m <sup>3</sup><br>0.3 mg/m <sup>3</sup> , skin   | 2007  |
| BELGIUM:   | TWA<br>STEL                    | 0.1 mg/m <sup>3</sup> ,<br>0.3 mg/m <sup>3</sup> , skin   | MAR2002   |
| DENMARK:   | TWA                            | 0.1 mg/m <sup>3</sup> , skin  | MAY2011   |
| EC (European Union):   | TWA<br>STEL                    | 0.1 mg/m <sup>3</sup><br>0.3 mg/m <sup>3</sup> , skin   | JUN2000   |
| FINLAND:   | TWA<br>STEL                    | 0.1 mg/m <sup>3</sup><br>0.3 mg/m <sup>3</sup> , skin   | NOV2011   |
| FRANCE:  | VME<br>VLE                     | 0.1 mg/m <sup>3</sup><br>0.3 mg/m <sup>3</sup> , Skin   | FEB2006   |
| GERMANY:   | MAK                            | 0.2 mg/m <sup>3</sup> , inhal   | 2011  |
| HUNGARY:   | TWA<br>STEL                    | 0.1 mg/m <sup>3</sup><br>0.3 mg/m <sup>3</sup>  | SEP2000   |
| ICELAND:   | TWA<br>STEL                    | 0.1 mg/m <sup>3</sup><br>0.3 mg/m <sup>3</sup> , skin   | NOV2011   |
| ITALY  | TWA                            | <i>Valore a breve termine: C 0,29 mg/m<sup>3</sup>, C 0,11* ppm<br/>A4; sodio azide; *come azido idrazonico, vapore</i> |   |
| KOREA:   | CL                             | 0.1 ppm (0.3 mg/m <sup>3</sup> )  | 2006  |
| THE NETHERLANDS:   | MAC-TGG                        | 0.1 mg/m <sup>3</sup> , skin  | 2003  |
| NEW ZEALAND:   | CL                             | 0.11 ppm (0.29 mg/m <sup>3</sup> )  | JAN2002   |
| PERU:  | TWA<br>STEL                    | 0.1 mg/m <sup>3</sup><br>0.29 mg/m <sup>3</sup>   | JUL2005   |
| SWEDEN:  | TWA<br>STEL                    | 0.1 mg/m <sup>3</sup><br>0.3 mg/m <sup>3</sup> , Skin   | JUN2005   |
| SWITZERLAND:   | MAK-W<br>KZG-W                 | 0.2 mg/m <sup>3</sup><br>0.4 mg/m <sup>3</sup> , inhal  | JAN2011   |
| UNITED KINGDOM:  | TWA<br>STEL                    | 0.1 mg/m <sup>3</sup><br>0.3 mg/m <sup>3</sup> , skin   | OCT2007   |
| ARGENTINA, BULGARIA, COLOMBIA,<br>JORDAN, SINGAPORE, VIETNAM                           |                                | check ACGIH TLV   |   |
| UNITED STATES:   | TLV-TWA-Ceiling<br>REL-Ceiling | 0.11* ppm / 0.29** mg/m <sup>3</sup><br>0.1* ppm / 0.3** mg/m <sup>3</sup>  | ACGIH, 1996, 2013<br>NIOSH Recommended Exposure Limits<br>*as HN <sub>3</sub> vapor; **as NaN <sub>3</sub> ; Skin |
| <i>[Source: RTECS September 2013 Update and Raw Material Vendor Safety Data Sheet]</i> |                                |   |   |

| <b>Concentrated Active Ingredient ratio in ProClin 150 and ProClin 300 [CAS# 55965-84-9] - OEL:</b> |         |                               |      |
|---|---------|-------------------------------|------|
| GERMANY:  | MAK     | 0.2 mg/m <sup>3</sup> , inhal | 2011 |
| THE NETHERLANDS:  | MAC-TGG | 0.2 mg/m <sup>3</sup>         | 2003 |

| <b>Concentrated Active Ingredient ratio in ProClin 150 and ProClin 300 [CAS# 55965-84-9] - OEL:</b>   |   |  |  |
|---|---|--|--|
| SWITZERLAND:  | MAK-W<br>KZG-W                                    | 0.2 mg/m <sup>3</sup><br>[Professionally Translated 1-2016]<br>0.4 mg/m <sup>3</sup> , inhal, sen                                      | JAN2011  |
| <i>[Source: RTECS September 2013 Update and Raw Material Vendor Safety Data Sheet]</i>  |   |  |  |
| <b>Concentrated Sulfuric acid [CAS# 7664-93-9] - OEL:</b>   |   |  |  |
| ARAB Republic of Egypt:   | TWA   | 1 mg/m <sup>3</sup>  | JAN1993  |
| AUSTRALIA:  | TWA<br>STEL                                       | 1 mg/m <sup>3</sup><br>3 mg/m <sup>3</sup>   | JUL2008  |
| AUSTRIA:  | MAK-TMW<br>KZW                                    | 1 mg/m <sup>3</sup><br>2 mg/m <sup>3</sup> , inhal   | 2007   |
| BELGIUM:  | TWA<br>STEL                                       | 1 mg/m <sup>3</sup><br>3 mg/m <sup>3</sup>   | MAR2002  |
| DENMARK:  | TWA   | 1 mg/m <sup>3</sup>  | MAY2011  |
| FINLAND:  | TWA   | 0.05 mg/m <sup>3</sup><br>0.1 mg/m <sup>3</sup>  | NOV2011  |
| FRANCE:   | VME<br>VLE  | 1 mg/m <sup>3</sup><br>3 mg/m <sup>3</sup>   | FEB2006  |
| GERMANY:  | MAK   | 0.1 mg/m <sup>3</sup> , inhal  | 2011   |
| HUNGARY:  | TWA<br>STEL                                       | 1 mg/m <sup>3</sup><br>1 mg/m <sup>3</sup>   | SEP2000  |
| ICELAND:  | TWA   | 1 mg/m <sup>3</sup>  | NOV2011  |
| JAPAN:  | CL  | 1 mg/m <sup>3</sup>  | MAY2012  |
| KOREA:  | TWA   | 1 mg/m <sup>3</sup>  | 2006   |
| MEXICO:   | TWA   | 1 mg/m <sup>3</sup>  | 2004   |
| THE NETHERLANDS:  | MAC-TGG   | 1 mg/m <sup>3</sup>  | 2003   |
| NEW ZEALAND:  | TWA   | 1 mg/m <sup>3</sup>  | JAN2002  |
| NORWAY:   | TWA   | 1 mg/m <sup>3</sup>  | JAN1999  |
| PERU:   | TWA<br>STEL                                       | 1 mg/m <sup>3</sup><br>3 mg/m <sup>3</sup>   | JUL2005  |
| POLAND:   | MAC(TWA)<br>MAC(STEL)                             | 1 mg/m <sup>3</sup><br>3 mg/m <sup>3</sup>   | JAN1999  |
| RUSSIA:   | STEL  | 1 mg/m <sup>3</sup> , skin   | JUN2003  |
| SWEDEN:   | TWA<br>STEL                                       | 1 mg/m <sup>3</sup><br>3 mg/m <sup>3</sup>   | JUN2005  |
| SWITZERLAND:  | CL  | 0.1 mg/m <sup>3</sup> , inhal  | JAN2011  |
| TURKEY:   | TWA   | 1 mg/m <sup>3</sup>  | JAN1993  |
| THAILAND:   | TWA   | 1 mg/m <sup>3</sup>  | JAN1993  |
| ARGENTINA, BULGARIA, COLOMBIA,<br>JORDAN, SINGAPORE, VIETNAM  |   | check ACGIH TLV  |  |
| UNITED STATES:  | TLV-TWA<br>PEL-T-TWA<br>STEL-T-TWA<br>REL<br>IDLH | 0.2 mg/m <sup>3</sup> (thoracic fraction)<br>1 mg/m <sup>3</sup><br>3 mg/m <sup>3</sup><br>1 mg/m <sup>3</sup><br>15 mg/m <sup>3</sup> | [ACGIH, 2004]<br>[OSHA 29,1910.1000 Z-1, 1993]<br>[NIOSH 2007] |
| <p><b>Remarks:</b> 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.<br/>The A2 Carcinogenicity Designation refers to sulfuric acid contained in <b>strong inorganic acid mists</b>.</p> |   |  |  |
| <i>[Source: RTECS September 2013 Update and Raw Material Vendor Safety Data Sheet]</i>  |   |  |  |

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

The following personal protective equipment (PPE) is recommended to prevent blood or other potentially infectious or hazardous materials from reaching the user's work or street clothes, skin, mouth, mucous membranes, and eyes, or hazardous inhalation under normal conditions of use and for the time during which the protective equipment is utilized.

|                         |   |
|-------------------------|---|
| Ventilation:            | Adequate lab ventilation is required. It is recommended that users handle potentially infectious human source material/patient samples in a biological safety cabinet (BSC), expressly if aerosols might be generated.  |
| Eye / Face Protection:  | Wear ANSI approved safety glasses, goggles or face shield with safety glasses or goggles. Contact lenses should not be worn when handling lab hazards.  |
| Protective Gloves:      | Suitable gloves must be worn at all times when handling kit reagents or patient samples to provide skin protection from splash and intermittent contact. Synthetic gloves such as nitrile, neoprene and vinyl are recommended because they are sturdy, effective and contain no natural latex ingredients associated with latex glove allergic reactions. Disposable (single use) gloves should be changed often and never reused. Wash hands thoroughly after removing gloves. |
| Protective Clothing:    | Wear a lab coat, clinic jacket, gown, apron and/or smock. Disposable clothing is strongly recommended when handling biohazardous material. If reusable clothing is used, procedures for handling potentially infectious laundry under the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030) are required.   |
| Respiratory Protection: | Do not breathe mist / vapors/vapours / spray.   |
| Other:                  | All personal protective equipment should be removed before leaving the work area and placed in an appropriately designated area or container for storage, processing, decontamination or disposal. 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.   |

### SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

|   |   |                              |                  |
|---|---|------------------------------|------------------|
| <b>Appearance:</b>                              | Variable, generally aqueous liquids. Exceptions are the solid cartridges and transfer pipets.   |                              |                  |
| <b>Odor/odour:</b>                              | No applicable information was found.  | <b>Odor/odour threshold:</b> | Not established. |
| <b>pH:</b>                                      | Most of the liquid chemical reagents are between pH 6 and 8; exceptions are the following solutions:<br><i>Development Reagent</i> at pH ~10, and the acidic <i>Stop solution</i> at pH ≤ 2.            |                              |                  |
| <b>Boiling point</b>                            | Undetermined  | <b>Melting Point:</b>        | Undetermined     |
| <b>Flash point:</b>                             | Not applicable.<br>Flammable limits: LEL/LFL is <u>Not applicable</u> ; UEL/UFL is <u>Not applicable</u> .  |                              |                  |
| <b>Evaporation rate:</b>                        | No applicable information was found.  |                              |                  |
| <b>Fire hazard:</b>                             | Although the components have not been tested for fire hazard data, being water-based, they are not expected to be fire hazards, but some of the kit packaging materials may burn under fire conditions. |                              |                  |
| <b>Vapor/vapour pressure:</b>                   | No applicable information was found.  |                              |                  |
| <b>Vapor/vapour density:</b>                    | No applicable information was found.  |                              |                  |
| <b>Relative density:</b>                        | Variable.   |                              |                  |
| <b>Solubility:</b>                              | All chemical reagents are soluble in water; the acidic and corrosive solutions may release heat. (The solid cartridges and transfer pipets are not soluble).  |                              |                  |
| <b>Auto igniting:</b>                           | Product is not known to be self-igniting.   |                              |                  |
| <b>Partition coefficient (n-octanol/water):</b> | No applicable information was found.  |                              |                  |
| <b>Decomposition temperature:</b>               | No applicable information was found.  |                              |                  |
| <b>Viscosity:</b>                               | No applicable information was found.  |                              |                  |

|   |   |
|---|---|
| <b>Danger of explosion:</b>   | <i>Sodium azide</i> may react with lead or copper plumbing to form highly explosive metal azides; buildup in metal plumbing has led to laboratory explosions, so flush with copious water when pouring dilute solutions down the drain to prevent such explosive buildup. |
| No other standard characteristics are known to be applicable to the identification or hazards of the product are known. |   |

**SECTION 10: STABILITY AND REACTIVITY INFORMATION**

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

|                                   |  |
|-----------------------------------|--|
| Chemical stability / Reactivity:  | Stable under ordinary conditions of use and storage.   |
| Conditions to Avoid:              | <i>Sodium azide</i> may react with lead or copper plumbing to form highly explosive metal azides; buildup in metal plumbing has led to laboratory explosions, so flush with copious water when pouring dilute solutions down the drain to prevent such explosive buildup.  |
| Materials to Avoid:               | Do not allow the acidic <b>Stop Solution</b> to come in contact with strong bases or reducing agents (may lead to a violent exothermic reaction).<br>Keep <b>Glycerol</b> solutions away from strong oxidizing agents, including sodium hypochlorite (bleach) and potassium permanganate, as could potentially form explosive mixtures.<br>Keep <b>urea</b> away from oxidizers and bleach (can form explosive nitrogen trichloride when mixed with sodium hypochlorite).<br><b>Sulfuric Acid</b> - Bases, Halides, Organic materials, Carbides, fulminates, Nitrates, picrates, Cyanides, Chlorates, alkali halides, Zinc salts, permanganates, e.g. potassium permanganate, Hydrogen peroxide, Azides, Perchlorates., Nitromethane, phosphorous, Reacts violently with: cyclopentadiene, cyclopentanone oxime, nitroaryl amines, hexalithium disilicide, phosphorous(III) oxide, Powdered metals   |
| Incompatible materials:           | <b>Sulfuric acid:</b><br>Although concentrated <b>sulfuric acid</b> is referred to as an oxidizing agent in some sources, it is not a very strong oxidizing agent. The 98% acid has some oxidizing ability when hot.<br><b>Sulfuric acid</b> does not polymerize and does not form peroxides.<br><b>Sulfuric acid</b> is a very reactive substance. The concentrated acid dehydrates, or sulfonates most organic compounds. <b>Sulfuric acid</b> reacts vigorously, violently or explosively with many organic and inorganic chemicals including water, acrylonitrile, alkali solutions, carbides, chlorates, fulminates, nitrates, perchlorates, permanganates, picrates, powdered metals, metal acetylides or carbides, epichlorohydrin, aniline, ethylenediamine, alcohols with strong hydrogen peroxide, chlorosulfonic acid, cyclopentadiene, hydrofluoric acid, nitromethane, 4-nitrotoluene, phosphorus (III) oxide, potassium, sodium, ethylene glycol, isoprene, styrene. Hazardous gases, such as hydrogen, hydrogen cyanide, hydrogen sulfide and acetylene, are evolved on contact with chemicals such as metals, cyanides, sulfides and mercaptans and carbides respectively. |
| Hazardous decomposition products: | May release toxic oxides of carbon, nitrogen and sulfur.   |
| Hazardous polymerization:         | Has not been reported to occur.  |

**SECTION 11: TOXICOLOGICAL INFORMATION -- GENERAL COMPOSITE**

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

Acute Health Effects

|                                  |   |
|----------------------------------|---|
| Acute Toxicity:                  | May be harmful if swallowed. May be harmful in contact with skin.         |
| Primary Irritant Effect:         | May slightly irritate eyes or skin, depending on amount and contact time. |
| Serious Eye Damage / Irritation: | Can irritate eyes depending on concentration, amount and contact time.    |

|                             |   |
|-----------------------------|---|
| STOT-Single Exposure:       | No applicable information was found.            |
| Aspiration Hazard:          | No applicable information was found.            |
| Other Acute Health Effects: | No significant other acute health effect known. |

Biohazard Potential:

The **Positive Control (2)** was heat-treated to inactivate the HIV. Human sera in reagents were tested and found nonreactive for hepatitis B surface antigen and antibodies to HCV (the **Negative Control (3)**) is also nonreactive for antibodies to HIV. 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 lab, applying the guidelines from the current CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories*, the WHO *Laboratory Biosafety Manual*. Persons handling blood samples should have the option of receiving hepatitis B vaccination.

Chronic Toxicity

|                                    |   |
|------------------------------------|---|
| Respiratory or Skin Sensitization: | The <b>dropper bulb</b> used in this bottle (supplied separately in the kit, but then placed in the Specimen Diluent bottle for kit use) contains Dry Natural Rubber, a potential sensitizer. May cause an allergic skin reaction. Contains a small volume of a very dilute, sensitizing preservative ( <b>ProClin 300 or ProClin 150</b> ); though the potential for an allergic response is greatly reduced by the dilution, sensitization threshold is unknown, thus handle accordingly. |
| Carcinogenicity:                   | Component <b>8</b> contains <b>0.1N Sulfuric Acid</b> , 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 Iclassifications refers specifically to sulfuric acid contained in strong inorganic acid mists are 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.   |
| STOT-Repeated Exposure:            | No applicable information was found.  |

Additional Toxicological information:

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

**SECTION 12: ECOLOGICAL INFORMATION**

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

|                                |  |
|--------------------------------|--|
| Ecotoxicity:                   | <p><b>100% Sodium Azide [CAS# 26628-22-8] *:</b><br/>           Fish LC<sub>50</sub> - Lepomis macrochirus - 0.68 mg/l - 96 h<br/>           Daphnia EC<sub>50</sub> - Daphnia pulex (Water flea) - 4.2 mg/l - 48 h</p> <p><b>Concentrated Sulfuric acid [CAS# 7664-93-9] *:</b><br/>           Fish LC<sub>50</sub> - Gambusia affinis (Mosquito fish) – 42 mg/l - 96</p> <p><b>Concentrated Urea [CAS#: 57-13-6]*:</b><br/>           Toxicity to fish LC<sub>50</sub> – Poecilia reticulata (guppy) - 17500 mg/l - 96 h<br/>           Daphnia EC<sub>50</sub> – Daphnia magna (Water flea) – 3910 mg/l - 48 h</p> <p><b>Concentrated Propane-1,2-diol [CAS# 57-55-6]*:</b><br/>           Toxicity to fish mortality NOEC – Pimephales promelas (fathead minnow) – 52930 mg/l – 96 h<br/>           Daphnia EC<sub>50</sub> – Daphnia magna (Water flea) – &lt; 10000 mg/l – 48 h<br/>           – mortality NOEC - Daphnia - 13020 mg/l - 48 h</p> <p><i>* Source: Raw Material Vendor Safety Data Sheet, RTECS and/or CCOHS Cheminfo</i></p> |
| Persistence and degradability: | No information found.  |
| Bioaccumulation potential:     | No information found.  |

|                          |  |
|--------------------------|--|
| Mobility in soil:        | No information found.  |
| PBT and vPvB assessment: | No information found.  |
| Other adverse effects:   | <p><b>Concentrated AMP Buffer</b> [CAS# 124-68-5]*:<br/>           Biochemical Oxygen Demand (BOD): &lt; 10 mg/l Concentration: 1 g/l<br/>           Chemical Oxygen Demand (COD): 2,050 mg/g<br/> <i>* Source: Raw Material Vendor Safety Data Sheet</i></p> <p><b>AMP Buffer</b> may be harmful to aquatic organisms and/or the aquatic environment.<br/>           The <b>Stop Solution</b> (dilute sulfuric acid) is hazardous for drinking water and toxic to aquatic organisms by pH modification if not neutralized.<br/>           An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.</p> |

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 and Safety Office for your specific disposal procedures.

**Recommended Product Disposal:**

All **human source** and other **potentially infectious** material must be appropriately decontaminated or disposed of as infectious material; check your applicable ordinances accordingly.

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

Acidic Waste **Stop Solution** (sulfuric acid, **pH ≤ 2**) must be neutralized to pH 6-8 for safe sewer disposal; check your local and regional 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 applicable ordinances accordingly.

Dilute Basic Waste; the **Development Reagent pH ≥ 10** may need to be neutralized to pH 6-8 for safe sewer disposal in many areas. Check your applicable ordinances accordingly. [Note: if the final pH measures ≥ 12.5, it requires disposal as a corrosive material in an RCRA approved waste facility (or equivalent), the RCRA Waste Code for this waste, if not neutralized is D002.]

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

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

**SECTION 14: TRANSPORT INFORMATION**

Shipping of product, packaging and waste must be conducted in accordance with all applicable local, regional, national and international regulations. Processing, use or contamination of the kit components may change shipping requirements and options. Contact your Environmental Health and Safety Office for your specific shipping procedures.

**Recommended Product Multi-Modal Transport:** According to US DOT, IATA and UN “Model Regulations”, the product must be transported as follows: No known transport restrictions.

The Waste **Stop Solution** is the only component in this test kit that is potentially corrosive for shipping purposes. This Stop Solution has been evaluated with the CORROSITEX® test method to determine its corrosive potential and any packing group classification. The results of this testing classified this Stop solution as non-corrosive for shipping purposes.

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

## SECTION 15: REGULATORY INFORMATION

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

**Carcinogenicity Categories:** Component 8 contains **0.1N 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 are and does not apply to sulfuric acid or sulfuric acid solutions.*

### National Regulations – Other Domestic / Foreign Laws:

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

1. **United States** – Occupational Safety Health Administration *Hazard Communication Standard 29 CFR 1910.1200 (US HCS)*
2. **Taiwan** – Regulation **Lao-An-3-Tzu-No. 0960145703** / Published National Standard **CNS 15030**
3. **People’s Republic of China** – National Standard **GB/T 17519-2013, GB 30000-2013**
4. **New Zealand** – *Hazardous Substances and New Organisms Act 1996 (HSNO), Hazardous Substances (Classification) Regulations 2001 and Thresholds and Classifications January 2012* (as published in 2008) *Composite HSNO Hazard Class: Subclass 6.5 Category B (contact sensitizers)*
5. **Mexico** – **Standard NMX-R-019-SCFI-2011**
6. **Korea** – **Public Notice 2013-37 Standard for Classification and Labeling of Chemical Substances and Material Safety Data Sheets**
7. **Japan** – Industrial Safety and Health Law (ISHL) National Standard **JIS Z7252, JIS Z7253**
8. **European Community (EC)** – applicable **CLP** related regulations (**2010/453/EC, 2008/1272/EC, 2006/1907/EC** etc.)
9. **Canada** – Standard *Workplace Hazardous Materials Information System (WHMIS-GHS) Canadian Standard* for the hazard classification criteria for this product.  
*Composite WHMIS Hazards: Skin Sensitization*
10. **Brazil** – Regulation **NRB 14725**
11. **Australia** – Code of Practice *Preparation of Safety Data Sheets for Hazardous Chemicals* under Section 274 of the **Work Health and Safety (WHS) Act**.
12. Analogous GHS-based global regulations

### Inventory status

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

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

### Regulation (EC) No. 1907/2006 (REACH):

*Chemicals included in the Candidate List of Substances of Very High Concern (SVHC):* None

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

### United States SARA:

**SARA 302 (extremely hazardous substance) components:** The following components are subject to reporting levels established by SARA Title III, Section 302: **Sulfuric Acid**, CAS# 7664-93-9; Revision Date: 2007-07-01

**SARA 313 components:** The following components are subject to reporting levels established by SARA Title III, Section 313: **Sulfuric Acid**, CAS# 7664-93-9; Revision Date: 2007-07-01



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

## SECTION 16: OTHER INFORMATION

### Hazard statement abbreviation(s):

|                           |   |
|---------------------------|---|
| Acute Tox. – oral.        | Acute toxicity – ingested (swallowed)   |
| Acute Tox. – skn.         | Acute toxicity – skin contact (dermal)  |
| Skin Corr.                | Skin corrosion  |
| Skin Irrit.               | Skin irritant   |
| Eye Damage.               | Serious Eye damage  |
| Skin Sens.                | Skin sensitisation  |
| Aquatic Acute             | Acute aquatic toxicity  |
| Aquatic Chronic           | Chronic aquatic toxicity  |
| Met. Corr.                | Corrosive to Metals   |
| Cat.                      | Category  |
|                           |   |
| H300 + H310               | Fatal if swallowed or in contact with skin.   |
| H302                      | Harmful if swallowed  |
| H303 + H313               | May be harmful if swallowed or in contact with skin.  |
| H314                      | Causes severe skin burns and eye damage.  |
| H315                      | Causes skin irritation.   |
| H317                      | May cause an allergic skin reaction.  |
| H318                      | Causes serious eye damage.  |
| H410                      | Very toxic to aquatic life with long lasting effects.   |
| H412                      | Harmful to aquatic life with long lasting effects.  |
|                           |   |
| P220                      | Keep/Store away from clothing/ combustible materials.   |
| P261                      | Avoid breathing mist / vapors/vapours / spray.  |
| P264                      | Wash skin thoroughly after handling.  |
| P270                      | Do not eat, drink or smoke when using this product.   |
| P272                      | Contaminated work clothing should not be allowed out of the workplace.  |
| P273                      | Avoid release to the environment.   |
| P280                      | Wear protective gloves/ protective clothing/ eye protection/ face protection.   |
| P301 + P312 + P330        | IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell. Rinse mouth.  |
| P301 + P330 + P331        | IF SWALLOWED: rinse mouth. Do NOT induce vomiting.  |
| P302 + P350               | IF ON SKIN: Gently wash with plenty of soap and water.  |
| 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.  |
| P305 + P351 + P338 + P310 | IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/ physician. |
| P310                      | Immediately call a POISON CENTER or doctor/ physician   |
| P312                      | Call a POISON CENTER or doctor/physician if you feel unwell.  |
| P333 + P313               | If skin irritation or rash occurs: Get medical advice/ attention.   |
| P363                      | Wash contaminated clothing before reuse.  |
| P391                      | Collect spillage.   |
| P405                      | Store locked up.  |
| P501                      | Dispose of this material in a safe way, and in accordance with local, regional, national and international regulations.   |
| P501                      | This material and its container must be disposed of as hazardous waste.   |
| Caution                   | Contains human source material. Handle as if capable of transmitting potentially infectious agents (Universal Precautions).   |

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

*For in vitro diagnostic use.*

**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.

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

- Raw Material Vendor Safety Data Sheets
- United Nations (UN) Globally Harmonized System (GHS)
- United States OSHA Hazard Communication Standard (HCS) 1910.1200
- Canadian Workplace Hazardous Materials Information System (WHMIS)

*Mexican Standard* (NMX-R-019-SCFI-2011) [regulatory translation and summaries]  
*European Community* (EC) Regulations 2008/1272/EC, 2010/453/EC, 2006/1907/EC  
*Australian Code of Practice on Preparation of Safety Data Sheets for Hazardous Chemicals* (Section 274 of the Work Health and Safety Act)  
*New Zealand – Hazardous Substances and New Organisms Act 1996* (HSNO)  
*The People's Republic of China National Standard GB/T 17519-2013, GB 30000-2013* [regulatory translation if available and summaries]  
*Taiwan Regulation Lao-An-3-Tzu-No. 0960145703 / Published National Standard CNS 15030* [regulatory translation if available / summaries]  
*Korean Public Notice 2008-26* [regulatory translation if available and summaries]  
*Japanese Industrial Standard JIS Z7252, JIS Z7253* [regulatory translation if available and summaries]  
*Registry of Toxic Effects of Chemical Substances* (RTECS)  
Canadian Centre for Occupational Health and Safety (CCOHS) *CHEMINFO databases, etc.*  
International Agency for Research on Cancer (IARC)  
American Conference of Governmental Industrial Hygienists (ACGIH)  
Occupational Safety and Health Administration, U.S. Department of Labor (OSHA)  
National Toxicity Program (NTP)  
National Institute for Occupational Safety and Health (NIOSH)  
World Health Organization. *Laboratory Biosafety Manual*  
CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories*  
*Australian Inventory of Chemical Substances* (ACIS)  
California Proposition 65

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  
CCOHS – Canadian Centre for Occupational Health and Safety  
CDC – Centers for Disease Control, USA  
CNS – Central Nervous System  
DGSMA – Dangerous Goods Safety Management Act  
DOT – Department of Transportation  
EC<sub>50</sub> – half maximal effective concentration  
EC CLP – European Commission regulation for the Classification, Labeling and Packaging of chemical substances and mixtures  
EU – European Union  
GHS – Globally Harmonized System  
HNOC – Hazard Not Otherwise Classified  
HSNO – Hazardous Substances and New Organisms Act 1996 (New Zealand)  
IARC – International Agency for Research on Cancer  
IATA – International Air Transport Association  
ICAO – International Civil Aviation Organization  
IDLH – Immediately Dangerous to Life or Health  
IMDG – International Maritime Dangerous Goods  
IPCS – International Programme on Chemical Safety  
ISHA – Industrial Safety and Health Act  
LC<sub>50</sub> – median lethal concentration, 50%  
LD<sub>50</sub> – median lethal dose, 50%  
NIOSH – National Institute for Occupational Safety and Health  
NTP – National Toxicity Program  
OEL – Occupational Exposure Limit  
PEL – Permissible Exposure Limit  
ppm – parts per million  
RTECS – Registry of Toxic Effects of Chemical Substances  
SDS – Safety Data Sheet  
STEL – Short Term Exposure Limit  
STOT – Specific Target Organ Toxicity  
TCCA – Toxic Chemical Control Act  
TLV/TWA – Threshold Limit Value / Time-Weighted Average  
UN – United Nations  
US EPA – United States Environmental Protection Agency  
US HCS – Hazard Communication Standard, USA  
US OSHA – Occupational Safety and Health Administration, U.S. Department of Labor  
WHMIS – Workplace Hazardous Materials Information System (Canadian)  
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.

---

### Bio-Rad Laboratories

**Department issuing SDS:** Environmental Health and Safety.

**Contact for general SDS information:** Seattle Operations, Environmental Health & Safety, 6565 185th Ave. NE, Redmond, WA 98052, USA, Phone: 425-881-8300 (8 am to 5 pm PT), [ro-sds@bio-rad.com](mailto:ro-sds@bio-rad.com)

**Customer support contact:** Clinical Diagnostics Group, 4000 Alfred Nobel Drive, Hercules, CA 94547, USA  
Phone: 1-800-224-6723, [www.bio-rad.com/diagnostics](http://www.bio-rad.com/diagnostics)

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

**Contact Local Bio-Rad Agents for general information:**

- Australia**, Bio-Rad Laboratories Pty. Ltd., Level 5, 446 Victoria Road, Gladesville NSW 2111 • Phone 61-2-9914-2800 • Telefax 61-2-9914-2888 •  
*24h/365d:* 61-2-9914-2800
- Austria**, Bio-Rad Laboratories Ges.m.b.H., Hummelgasse 88/3-6, A-1130 Vienna • Phone 43-1-877-8901 • Telefax 43-1-876-5629 • *24h/365d:* 43-1-877-89 01
- Belgium**, Bio-Rad S.A.-N.V. Begoniastraat 5, B-9810 Nazareth Eke • Phone 32-9-385-5511 • Telefax 32-9-385-6554 • *24h/365d:* 09-385-5511
- Brazil**, Bio-Rad Laboratórios Brasil Ltda, Rua Alfredo Albano da Costa, 100, sl 1, 2 e 3, Lagoa Santa, CEP: 33.400-000 • Phone +55 (31)3689-6600 •  
Telefax +55 (31)3689-6611 • *24h/365d:* (11) 99118 7957
- Canada**, Bio-Rad Laboratories, Ltd., 2403 Guénette Street, Montréal, Québec H4R 2E9 • Phone 1-514-334-4372 • Telefax 1-514-334-4415 •  
*24h/365d:* 514-334-4372
- China**, Bio-Rad Laboratories Shanghai Ltd. 3rd Floor, #18 Dong Fang Road, Bldg E, Poly Plaza, Pudong, Shanghai, PRC 200120 • Phone 86-21-61698500 •  
Telefax 86-21-61698599 • *24h/365d:* 86-21-63052255
- Czech Republic**, Bio-Rad spol. s r.o., Nad ostrovem 1119/7, 147 00 Prague 4 • Phone 420-241-430-532 • Telefax 420-241-431-642 • *24h/365d:* 224 919 293
- Denmark**, Bio-Rad Laboratories, Symbion Science Park, Fruebjergvej 3, DK-2100 Copenhagen East • Phone +45-4452-1000 • Telefax +45-4452-1001 •  
*24h/365d:* +45 4452 1000
- Finland**, Bio-Rad Laboratories, Linnanherrankuja 16, FIN-00950 Helsinki • Phone 358-9-804-22-00 • Telefax 358-9-7597-5010 • *24h/365d:* +358 9 804 2200
- France**, Bio-Rad, 3 boulevard Raymond Poincaré, 92430 Marnes-la-Coquette • Phone 33-1-47-95-60-00 • Telefax 33-1-47-41-91-33 •  
*24h/365d:* +33 (0)1 47 95 60 00
- Germany**, Bio-Rad Laboratories GmbH, Heidemannstrasse 164, D-80939 Munich • Phone +49-(0)89-318-840 • Telefax +49-(0)89-318-84100 •  
*24h/365d:* 0049-89-31884-0
- Greece**, Bio-Rad Laboratories M.E.P.E, 2-4 Mesogeion Street, Fourth Floor 115 27 Athens • Phone 30-210-7774396 • Telefax 30-210-7774376
- Hong Kong**, Bio-Rad Pacific Ltd., Unit 1101, 11/F DCH Commercial Centre, 25 Westlands Road, Quarry Bay • Phone 852-2789-3300 •  
Telefax 852-2789-1290 • *24h/365d:* 852-2789-3300
- Hungary**, Bio-Rad Hungary Ltd., H-1082 Budapest, Futo Street 47-53, Hungary • Phone +36-1-459-6100 • Telefax +36-1-459-6101 • *24h/365d:* 36 1 459 6100
- India**, Bio-Rad Laboratories (India) Pvt. Ltd., Bio-Rad House, 86-87, Udyog Vihar, Phase IV, Gurgaon, Haryana 122 015 • Phone 1-800-180-1224 •  
Telefax 91-124-2398115 • *24h/365d:* 91-124-2398112/113/114
- Israel**, Bio-Rad Laboratories Ltd., 14 Homa Street, New Industrial Area, Rishon Le Zion 75655 • Phone 972-3-9636050 • Telefax 972-3-9514129 •  
*24h/365d:* 972-3-951-4127
- Italy**, Bio-Rad Laboratories S.r.l., Via Cellini 18/A, 20090 Segrate, Milan • Phone +39-02-216091 • Telefax +39-02-21609553 • *24h/365d:* 02-216091
- Japan**, Bio-Rad Laboratories K.K., Tennoz Central Tower 20F, 2-2-24 Higashi-Shinagawa, Shinagawa-ku, Tokyo 140-0002 • Phone 81-3-6361-7070
- Korea**, Bio-Rad Korea Ltd., 10th Floor, Hyunjuk Building, 832-41, Gangnam-gu, Seoul 135-080 • Phone 82-2-3473-4460 • Telefax 82-2-3472-7003 •  
*24h/365d:* 852-2789-330
- Mexico**, Bio-Rad, S.A., Avenida Eugenia 197, Piso 10-A, Col. Narvarte, C.P. 03020 Mexico, D.F. • Phone +52 (55) 54 88 76 70 • Telefax +52 (55) 1107-7246 •  
*24h/365d:* + 52 1 (55) 20 46 47 77
- The Netherlands**, Bio-Rad Laboratories B.V., Fokkerstraat 2-8, 3905 KV Veenendaal • Phone +31-318-540666 • Telefax +31-318-542216 •  
*24h/365d:* 31-318-540666
- New Zealand**, Bio-Rad New Zealand, 189 Bush Road Unit B, Albany, Auckland • Phone 64-9-415-2280 • Telefax 64-9-415-2284 • *24h/365d:* 64-9-415-2280
- Norway**, Bio-Rad Laboratories, Nydalsveien 33, 0484 Oslo • Phone +47-23-38-41-30 • Telefax +46(0)8-5551-2780 • *24h/365d:* 47 23 38 41 30
- Poland**, Bio-Rad Polska Sp. z o.o., Nakielska Str. 3, 01-106 Warsaw • Phone 48-22-3319999 • Telefax 48-22-3319988 • *24h/365d:* 48 (22) 331 99 85
- Portugal**, Bio-Rad Laboratories, Lda., Edificio Prime, Ave. Quinta Grande, 53 – Fracção 3B Alfragide 26114-521 Amadora • Phone 351-21-472-7700 •  
Telefax 351-21-472-7777 • *24h/365d:* 351-21-472-7700
- Russia**, Bio-Rad Laboratorii, Russian Federation, Moscow, Varshavskoe sh., 9, Bldg., 1B • Phone: +7-495-721-1404 • Telefax +7-495-721-1412
- Singapore**, Bio-Rad Laboratories (Singapore) Pte. Ltd., 27 International Business Park, #01-02 iQuest @IBP, Singapore 609924 • Phone 65-6415-3170 •  
Telefax 65-6415-3189 • *24/7/365:* 65-6415-3188 • *24h/365d:* 65-6415-3188
- South Africa**, Bio-Rad Laboratories (Pty) Ltd., 34 Bolton Road, Parkwood, Johannesburg 2193 • Phone 27-11-442-85-08 • Telefax 27-11-442-85-25
- Spain**, Bio-Rad Laboratories, S.A., C/ Caléndula, 95, Edificio M. Miniparc II, El Soto de la Moraleja, 28109 Madrid • Phone 34-91-590-5200 •  
Telefax 34-91-590-5211 • *24h/365d:* 34-91-590-5200
- Sweden**, Bio-Rad Laboratories A.B., Box 1097, Solna Strandväg 3, SE-171 54, Solna • Phone +46-8-555-127-00 • Telefax +46-8-555-127-80 •  
*24h/365d:* 46-8-55 51 27 00
- Switzerland**, Bio-Rad Laboratories AG, Pra Rond 23 CH-1785 Cressier • Phone +41 (0)26-674-55-05/06 • Telefax +41 (0)26-674-52-19 •  
Email: [swiss@bio-rad.com](mailto:swiss@bio-rad.com) • *24h/365d:* 41-61-7179555
- Taiwan**, Bio-Rad Laboratories Taiwan Ltd., 14F-B, No. 126 Nan-King East Road, Sec. 4, Taipei, Taiwan 10546 R.O.C. • Phone 886-2-2578-7189 •  
Telefax 886-2-2578-6890
- Thailand**, Bio-Rad Laboratories Ltd., 1st & 2nd Floor, Lumpini I Bldg., 239/2 Rajdamri Rd., Lumpini, Pathumwan, Bangkok 10330 • Phone 662-651-8311 •  
Telefax 662-651-8312
- United Kingdom**, Bio-Rad Laboratories Ltd., Bio-Rad House, Maxted Road, Hemel Hempstead, Herts HP2 7DX • Phone +44 (0)20-8328-2000 •  
Telefax +44 (0)20-8328-2550 • *24h/365d:* 020-8328-2000



## Multispot HIV-1/HIV-2 Rapid Test

[Catalog 25228]

---

This document was developed from information obtained from reputable sources, but does not purport to be all-inclusive. The data contained herein, which is based on our present knowledge and is intended for information purposes only, shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship. Regulatory requirements are subject to change and vary from one location to another; thus it is the buyer's responsibility to ensure that its activities comply with international, national, regional and local laws and regulations. Bio-Rad Laboratories makes no warranty, expressed or implied, regarding the accuracy or completeness of these data or the results to be obtained from the use thereof. Since the use of this information and the conditions of use of the product are not within the control of Bio-Rad Laboratories, it is the user's obligation to determine the suitability of the information for the intended application and use appropriate safety procedures.

---