# SAFETY DATA SHEET (SDS)

## SECTION 1: IDENTIFICATION OF PRODUCT (MIXTURE) AND SUPPLIER

| | |
|---|---|
| **Product Name**: | **GS HBsAg EIA 3.0** |
| **Product Number**: | **25258** (4800 tests)<br>Catalog number(s) for replacement, optional and separately purchased components that can be obtained for use with this kit, and which are covered by this SDS include**: 25103, 25104, 25108, 25109, 25110, 26181** and **26182** (refer to Section 2). |
| **Intended Use**: | The GS HBsAg EIA 3.0 is a qualitative enzyme immunoassay (EIA) for the detection of Hepatitis B Surface Antigen (HBsAg) in human serum and plasma. It is indicated as a screening test for specimens from individual human donors, including donors of whole blood, blood components, and source plasma, and from other living donors. It is also intended for use in testing plasma and serum specimens to screen organ donors when specimens are obtained while the donor's heart is still beating, and in testing blood specimens from cadaveric (non-heart-beating) donors. The assay is not intended for use on cord blood specimens. The GS HBsAg EIA 3.0 is also intended for manual use or use with the ORTHO®Summit™ System (OSS) in the screening of blood donors. |
| **Maufactured by:** | **Bio-Rad Laboratories, Inc.** |
| **Address:** | 6565 185th Avenue NE<br>Redmond, WA 98052-5039, USA |
| **Website:** | www.bio-rad.com |
| **Phone Number:** | 1-800-2-BIORAD (1-800-224-6723); or 1-425-881-8300 (daytime PT) |
| **SDS e-mail contact:** | ro-sds@bio-rad.com |
| **Technical Information Contacts:** | Bio-Rad provides a toll free line for technical assistance, available 24 hours a day, 7 days a week. In the United States of America and Puerto Rico, call toll free 1-800-2-BIORAD (1-800-224-6723). Outside the U.S.A., please contact your regional Bio-Rad office for assistance. *Refer to section 16 for non-US local Bio-Rad agent contact information.* |
| **Authorized Representative in the European Community:** | ***FRANCE:*** *Bio-Rad*<br>3 boulevard Raymond Poincaré<br>92430 Marnes-la-Coquette<br>Phone: +33 (0) 1 47 95 60 00 / Fax: +33 (0) 1 47 41 91 33<br>[fds-msds.fr@bio-rad.com] |
| **Emergency Phone Number:** | **This SDS is listed with CHEMTREC 1-800-424-9300 (US) / 001-703-527-3887** (international – can be called collect)**.** Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION or ACCIDENT with this product. |

## SECTION 2: HAZARDS IDENTIFICATION -- HAZARDOUS COMPONENTS

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

| Component * | Content |
|---|---|
| **R3. HBsAg Conjugate Concentrate,** 5 vials (1.2 mL) *Catalog No. 25103*  **WARNING** | - Anti-HBsAg (mouse monoclonal): horseradish peroxidase conjugate in a buffer (pH neutral) with protein stabilizers (murine and/or bovine), **≤ 25% glycerol** [$C_3H_8O_3$, CAS#: 56-81-5, EC No 200-289-5], **< 3% Sodium chloride** [NaCl, CAS# 7647-14-5, EC No 231-598-3], **< 2% HEPES** [(4-[2-hydroxyethyl]-1-piperazineethanesulfonic acid), CAS# 7365-45-9; EC No 230-907-9] and green dye. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration.<br>- Preserved with **0.5% ProClin 300,** (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 **0.005% gentamicin sulfate,** CAS# 1405-41-0, EC No 215-778-9. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration. |
| **R1. Strip Plates Anti-HBsAg Microwell**, 50 plates | - Microwell strips in holder, coated with antibody to HBsAg (mouse monoclonal).<br>- Potential residue **of ProClin 150** and **sodium azide** used as production preservatives (aspirated prior to drying strips).<br>- Tabs are labeled "CC."<br>- Contains sealed pelletized desiccant packet(s): There are no health hazards associated with intact desiccant container; however, health hazards could result from dusts generated if the packet is cut, split or otherwise compromised and is crushed. |
| **C0. HBsAg Negative Control (Human),** 5 vials (12 mL) *Catalog No. 25108* | - Normal human serum that is nonreactive for HBsAg, anti-HBsAg, and antibodies to HIV and HCV.<br>- Preserved with **0.16% ProClin 950**, containing 0.016% active ingredient: 9.5-9.9% 2-methyl-4-isothiazolin-3-one ($C_4H_5NOS$); CAS # 2682-20-4, EC No 220-239-6. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration.<br>- Preserved with **0.005% gentamicin sulfate**, CAS# 1405-41-0, EC No 215-778-9. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration. |
| **C1. HBsAg Positive Control (Human),** 5 vials (8 mL) *Catalog No. 25109*  **WARNING** | - Purified HBsAg (human ad and ay subtypes) in synthetic diluent / Buffer with protein stabilizers (bovine), **≤ 20% Glycerol** [$C_3H_8O_3$, CAS# 56-81-5, EC No 200-289-5] and yellow dye. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration.<br>- Preserved with **0.5% ProClin 300** (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 **0.005% gentamicin sulfate**, CAS# 1405-41-0, EC No 215-778-9. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration. |
| **C2. HBsAg Low Positive Control (Human),** 5 vials (8 mL) *Catalog No. 25110*  **WARNING** | - Purified HBsAg (human ad and ay subtypes) in synthetic diluent / Buffer with protein stabilizers (bovine), **≤ 20% Glycerol** [$C_3H_8O_3$, CAS# 56-81-5, EC No 200-289-5] and yellow dye. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration.<br>- Preserved with **0.5% ProClin 300** (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 **0.005% gentamicin sulfate**, CAS# 1405-41-0, EC No 215-778-9. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration. |
| **R4. HBsAg Conjugate Diluent,** 5 bottles (120 mL) *Catalog No. 25104*  **WARNING** | - Buffer with protein stabilizers (murine and bovine), [pH neutral amber liquid] with **< 3% Sodium chloride** [NaCl, CAS# 7647-14-5, EC No 231-598-3) and **< 2% HEPES** [(4-[2-hydroxyethyl]-1-piperazineethanesulfonic acid), CAS# 7365-45-9; EC No 230-907-9]. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration.<br>- Preserved with **0.5% ProClin 300** (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 **0.005% Gentamicin sulfate**, CAS# 1405-41-0 , EC No 215-778-9. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration. |

| Component * | Content |
|---|---|
| **R8. Substrate Buffer,** 5 bottles (120 mL) *Catalog No. 26181* | - Dilute **citric acid (**$C_6H_8O_7$**,** CAS# 79-92-9, EC No 201-069-1) **/ sodium acetate buffer**, [pH ~ 4.0, clear liquid].<br>- **< 5% dimethylsulfoxide** [DMSO - $C_2H_6OS$], CAS# 67-68-5, EC No 200-644-3.<br>- **< 0.1% hydrogen peroxide** [$H_2O_2$], CAS# 7722-84-1, EC No 231-765-0.<br>Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration. |
| **R9. Chromogen,** 5 bottles (12 mL) *Catalog No. 26182* | - **≤ 0.25% 3,3',5,5' tetramethylbenzidine dihydrochloride** [TMB– $C_{16}H_{20}N_2$•2HCl], CAS# 207738-08-7, EC No 264-769-6.<br>- **≤ 0.04 N hydrochloric acid** [~ 0.3% HCl, CAS# 7647-01-0, EC No 231-595-7] solution [pH ~ 1.5, clear liquid].<br>Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration. |

* 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 (US HCS), *European Community* (EC) 2008/1272/EC (EC CLP) 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), 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 C1, C2, R3, and R4 - 0.5% ProClin 300** [≤ 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.

***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]*

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

The following information is furnished for those product hazardous constituents that require regulatory control or disclosure regardless of the concentration found in the product. Note that the information here is often based on data from the chemical raw material safety data sheet and literature ($LD_{50}$, exposure limits, etc.) Chemical constituents that do not require regulatory disclosure are not generally included here. This product contains a significantly diluted concentration in an aqueous solution, thus the assessment below has not considered the dilution reduction effect on the hazard. That hazard communication information is provided in Section 2 above. Some components were tested at the concentration found in the kit. In that case, the assessment is provided for the chemical dilution tested and the tested concentration will be provided at the beginning of the *Chemical Ingredient*

*Data/Information* box. 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: **≤ 25% in R3, C1 and C2**

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

CAS#: 56-81-5 (100%)
EC No: 200-289-5 (100%)
RTECS#: MA8050000 (100%)
Index No: NA (100%)
Chemical Formula: $C_3H_8O_3$ (100%)
Molecular weight: 92.09 g/mol (100%)

$LD_{50}$ (oral-rat): 12,600 mg/kg (100%)
$LC_{50}$ (inhalation-rat): > 570 mg/m$^3$/1H (100%)
$LD_{50}$ (skin-rabbit): > 10000 mg/kg (100%)
$LC_{50}$ (96 hr-fish): NE (100%)
Flash Point: 320 F / 160° C (100%)
Flammable limits: LEL/LFL is 0.9% vv in air.

Synonyms/Trade Names: 1,2,3-Propanetriol; 1,2,3-Trihydroxypropane; 90 Technical glycerine; Citifluor AF 2; lyzerin, wasserfrei, Glycerin; Glycerin mist; Glycerin mist; Glycerin, anhydrous; Glycerin, synthetic; Glycerine; Glyceritol; Glycyl alcohol; Grocolene; MOON; Osmoglyn; Star; Synthetic glycerin; Trihydroxypropane

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

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

**Chemical Ingredient: Dimethyl-sulfoxide** [DMSO]

Chemical concentrations found in this product: **≤ 5 % in R8, an aqueous solution**

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

CAS#: 67-68-5 (100%)
EC No: 200-644-3 (100%)
RTECS#: PV6210000 (100%)
Index No: NA (100%)
Chemical Formula: $C_2H_6OS$ (100%)
Molecular weight: 78.13 g/mol (100%)

$LD_{50}$ (oral-rat): 14500 mg/kg (100%)
$LC_{50}$ (inhalation-rat): 1600 mg/m$^3$ (4 hr) (100%)
$LD_{50}$ (skin-rabbit): >5000 mg/m$^3$ (100%)
$LC_{50}$ (96 hr-fish): NE mg/L (100%)
Flash point: 188-192°F / 86.7-88.9°C (100%)
Flammable limits: LEL/LFL is 3.5%; UEL/UFL is 42% vv in air (100%)

Synonyms/Trade Names: Dimethyl sulfoxide; Dimethyl sulphoxide; Dimexide; Dipirartril-tropico; DMS-70; DMS-90; DMSO; Dolicur; Domoso; Dromisol; Durasorb; A 10846; Deltan; Demeso; Demasorb; Demavet; Demsodrox; Dermasorb; Gamasol 90; Hyadur; Infiltrina; M 176, Methane, sulfinylbis-; Methylsulfinylmethane; Somipront; SQ 9453, Topsym; NSC-763; Rimso-50; Sulfinylbis(methane); Syntexan

***Raw Material GHS / US HCS / EC CLP Classification (100%):*** *No Pictogram required*

**WARNING**

Fla. Liq. Cat. 4
H227
P210, P280, P370 + P378, P403 + P235, P501

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

## Chemical Ingredient Data / Information

**Chemical Ingredient: Citric acid**

Chemical concentrations found in this product: **<.1.5% w/v in R8**

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

CAS#: 77-92-9 (100%)
EC No: 201-069-1 (100%)
RTECS#: GE7350000 (100%)
Index No: NA (100%)

$LD_{50}$ (oral-rat): 5400 mg/kg
$LC_{50}$ (inhalation-rat): NE
$LD_{50}$ (skin-rabbit): >2000 mg/kg

Toxicity to fish mortality $LC_{50}$ - Leuciscus idus melanotus - 440 mg/l - 48 h Method: OECD Test Guideline 203
Chemical Formula: $C_6H_8O_7$ (100%)
Molecular weight: 192.12 g/mol (100%)
pH value: 1.8 at ca.50 g/l at 25 °C (77 °F)
Synonyms/Trade Names: Aciletten; Anhydrous citric acid; Citretten; Citro; 2-Hydroxy-1,2,3-propanetricarboxylic acid; beta-Hydroxytricarballylic acid; Kyselina citronova

Skin corrosion/irritation: Skin - rabbit - Mild skin irritation - OECD Test Guideline 404
Serious eye damage/eye irritation: Eyes - rabbit - Irritating to eyes. - OECD Test Guideline 405
Respiratory or skin sensitization: Prolonged or repeated exposure may cause allergic reactions in certain sensitive individuals.

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

**WARNING**

Acute Tox. – skn Cat. 5, Skin Irrit. Cat. 1, Eye Irrit. Cat. 2A
H313, H316, H319
P264, P280, P305 + P351 + P338, P337 + P313

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

**Chemical Ingredient: ProClin 300**

Chemical concentrations found in this product: **0.5% (0.015% active ingredient) in C1, C2, R3 and R4**

Hazardous ingredient concentration in raw material:
**60-100% Glycols**;
**1-5% Mixture (3:1) of 5-Chloro-2-methyl-4-isothiazolin-3-one** ($C_4H_5NOS$; CAS# 2682-20-4, EC# 220-239-6)
and **2-Methyl-2H -isothiazol-3-one** ($C_4H_4ClNOS$; 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)
$LD_{50}$ (oral-rat): 862 mg/kg (concentrated solution)
$LD_{50}$ (skin-rabbit): 2,800 mg/kg (concentrated solution)
$LC_{50}$ (inhalation-rat): NE
$LD_{50}$ (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: Hydrochloric acid**

Chemical concentrations found in this product: **≤ 0.04N (< 0.4% v/v HCl)**

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

CAS#: 7647-01-0 (concentrate solution)
EC No: 231-595-7 (concentrate solution)
Index No: 017-002-01-X (concentrate solution)
RTECS#: MW4025000 (concentrate solution)
Chemical Formula: HCl (concentrate solution)
Molecular weight: 36.46 g/mol (concentrate solution)

$LD_{50}$ (oral, rat): 700 mg/kg (unconfirmed)
$LC_{50}$ (inhalation-rat): 3124 ppm/1H
$LD_{50}$ (skin-rabbit): Greater than 5010 mg/kg (unconfirmed)
Fish $LC_{50}$ – Bluegill/Sunfish – 282 mg/l – 48 h

pH value: highly acidic (30-50% concentrated solution)

Synonyms/Trade Names: Acide chlorhydrique; Acido cloridrico; Anhydrous hydrochloric acid; Chloorwaterstof; Chlorohydric acid; Chlorowodor; Chlorwasserstoff; Hydrochloride; Hydrogen chloride; Hydrogen chloride; Muriatic acid; Spirits of salt

$LC_{50}$ (male rat): 1405 ppm (4-hour exposure; head-only); cited as 2810 ppm (1-hour exposure; head-only) (30-50% solution)
$LC_{50}$ (male rat): 1562 ppm (4-hour exposure; whole-body); cited as 3124 ppm (1-hour exposure; whole-body) (30-50% solution)
Skin corrosion/irritation: Skin - rabbit - Causes burns. (30-50% solution)
Serious eye damage/eye irritation: Eyes - rabbit - Corrosive to eyes (30-50% solution)
IARC: Group 3: Not classifiable as to its carcinogenicity to humans (30-50% solution)

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

**DANGER**!

Skin Corr. Cat. 1B, Eye Damage Cat. 1, STOT SE Cat. 3, Met. Corr. Cat. 1
H290, H314, H335
P234, P261, P264, P271, P280, P301 + P330 + P331, P303 + P361 + P353, P304 + P340, P305 + P351 + P338, P310, P363, P390, P403 + P233, P405, P406, P501

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

**Chemical Ingredient: 3,3',5,5'-Tetramethylbenzidine, Dihydrochloride**

Chemical concentrations found in this product: **< 0.3% w/v in R9**

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

CAS#: 207738-08-7 (54827-17-7 Free base) (100%)
EC No: 264-769-6 (100%)
RTECS#: DV2300000 (100%)
Chemical Formula: $C_{16}H_{20}N_2 \bullet 2HCl$ (100%)
Molecular weight: 313.27 g/mol (100%)
Synonyms/Trade Names: TMB

$LD_{50}$ (ipr-mouse): 135 mg/kg (100%)
$LD_{50}$ (oral-rat): NE
$LC_{50}$ (inhalation-rat): NE
$LD_{50}$ (skin-rabbit): NE
$LC_{50}$ (96 hr-fish): NE (100%)

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

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

**Chemical Ingredient Data / Information**

**Chemical Ingredient: ProClin 950**

Chemical concentrations found in this product: **≤ 0.16% in C0**

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

Hazardous ingredient concentration in raw material: the concentrated preservative contains:
5-10% of 2-methyl-4-isothiazolin-3-one (active ingredient).

CAS#: 2682-20-4 (active ingredient)
EC No: 220-239-6 (active ingredient)
RTECS#: NE
Chemical Formula: $C_4H_5NOS$ (active ingredient)

$LD_{50}$ (oral-rat): No data available (concentrated solution)
$LC_{50}$ (inhalation-rat): No data available (concentrated solution)
$LD_{50}$ (skin-rabbit): No data available (concentrated solution)
pH value: 3.0-6.0 (concentrated solution)

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

**DANGER**!

Acute Tox. -- inhl. Cat. 3, Skin Corr. Cat. 1B, Eye Damage Cat. 1, Skin Sens. Cat. 1, Aquatic Acute Cat. 1, Aquatic Chronic Cat. 1

H314, H317, H331, H410

P261, P264, P271, P272, P273, P280, P301 + P330 + P331, P303 + P361 + P353, P305 + P351 + P338, P310, P403 + P233, P405, P501

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

**Chemical Ingredient: Gentamicin sulfate in**

Chemical concentrations found in this product: **< 0.01% from a 50 mg/ml Solution in C0, C1, C2, R3 and R4**

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

CAS#: 1405-41-0 (100%)
EC No: 215-778-9 (100%)
RTECS#: LY2625000 (100%)
Synonyms/Trade Names: Gentamicin sulfate salt; Garamycin; Gentiomycin C

$LD_{50}$ (oral-rat): > 5000 mg/kg (100%, 50 mg/ml)
$LC_{50}$ (inhalation-rat): NE
$LD_{50}$ (skin-rabbit): NE

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

**DANGER**!

Resp. Sens., Cat. 1, Skin Sens., Cat. 1

H317, H334

P261, P272, P280, P285, P302 + P352, P304 + P341, P333 + P313, P342 + P311, P363, P501

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

| Biological Ingredient | Data / Information |
|---|---|
| **Human Serum** [non-reactive in C0]  | Human source material used in the preparation of the Negative Control (C0) has been tested and found nonreactive for Hepatitis B surface antigen (HBsAg), anti-HBsAg, and antibodies to Hepatitis C virus (HCV) and human immunodeficiency virus (HIV-1 and HIV-2).<br>The human plasma derived viral antigen HBsAg subtypes ad and ay used in the preparation of the Positive Control (C1) and Low Positive Control (C2) are highly purified and heat treated.<br>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.<br>Employ *Standard* and *Universal Precautions* 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 *Biosafety in Microbiological and Biomedical Laboratories* and WHO *Laboratory Biosafety Manual*. 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, *Standard* and *Universal Precautions*. Persons handling blood samples should have the option of receiving hepatitis B vaccination. |
| **Animal proteins** [C1, C2, R1, R2, R4] | This material is of animal origin (bovine, caprine, murine, etc) 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, *Standard* and *Universal Precautions*. Dispose of this material in accordance with local, regional, national and international regulation. |

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 miscellaneous salts, **hydrogen peroxide** [$H_2O_2$, CAS# 7722-84-1,-≤ 0.1% v/v in R8], sugars, buffers, water, animal sera, and other chemicals found in the HRP conjugate, buffers with protein stabilizers, dyes, and sodium acetate solution, in the kit volumes and/or concentrations present [chemical or dilution is not subject to GHS, US HCS, EC CLP or other GHS-based hazard labeling].
- **Component R1** contains **< 0.1% of Cobalt (II) Chloride** [CAS# 7646-79-9, EC No. 231-589-4], which is classified as an IARC Group 2B (possible human carcinogen) and EU Category 2 carcinogen, and **silica quartz** [CAS# 14808-60-7, EC No. 238-87-4], which in dust form is classified as an ACGIH Class A2 (suspected human carcinogen) and IARC Group 1 (carcinogenic to humans). This material is in a pelletized desiccant sealed packet within the plate pouch, which is unlikely to generate significant dust under normal conditions of use and is thus not typically considered a health hazard. However, health hazards could result from dusts generated if the packet is cut, split or otherwise compromised and a significant number of pellets were crushed to a powder form. Keep the desiccant packet intact as received in the microwell plate component package.
- 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 over exposure may include headache, dizziness, and congestion. Skin contact may result in dermatitis and may cause allergic skin reaction upon repeated exposure. May be toxic to developing fetus, generally at concentrations and volumes that greatly exceed that of this kit. |
| Eye Contact: | Flush eyes with copious water for at least 15 minutes. Ensure adequate flushing by separating the eyelids with fingers while flushing with water. OBTAIN MEDICAL ATTENTION. |
| Skin Contact: | Remove contaminated clothing. Flush skin with copious water and wash affected area with soap and water. If blood-to-blood contact occurs, or if more severe symptoms develop, consult a physician. |
| Inhalation: | Remove person from exposure area to fresh air. If breathing becomes difficult, immediately call for emergency medical assistance. Treat symptomatically and supportively. Generally, this aqueous product is not a significant inhalation hazard in the kit volumes and concentrations present. |
| If Swallowed: | If ingested, rinse out mouth thoroughly with water, provided the person is conscious, and OBTAIN MEDICAL ATTENTION. Call a physician or the local poison control center. Treat symptomatically and supportively. If vomiting occurs, keep head lower than hips to prevent aspiration. |
| Notes to Physician | According to the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030), Universal Precautions apply. Persons handling human blood source samples should be offered hepatitis B vaccination prior to working with human source material**.** |

## SECTION 5: FIREFIGHTING MEASURES

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

## SECTION 6: ACCIDENTAL RELEASE MEASURES

- Avoid direct contact with skin, eyes, mucous membranes and clothing by wearing appropriate lab Personal Protective Equipment (PPE), including gloves, lab coat and eye/face protection.
- In the event of a hazardous material spill, contain the spill if it is safe to do so and immediately move to a safe area, free from potential aerosols, to decontaminate and/or safely remove any contaminated clothing, as necessary. IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. Isolate the hazard area and ventilate if appropriate. Ensure that appropriate spill cleanup materials and PPE are available and used.
- Prevent material from entering sewers, waterways or confined spaces.
- Follow established laboratory policy and applicable 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.).
- 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: | 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.<br>Do not smoke, eat, or drink in areas where patient samples and kit reagents are handled. Wash your hands after use. Wear appropriate personal protective equipment (PPE), including gloves, lab coat or equivalent and eye/face protection.<br>Keep containers tightly closed; avoid splashing, spills and the generation of aerosols.<br>Handle all human source specimens, materials and equipment used to perform the operations as though they were capable of transmitting infectious disease, as per *Standard* and *Universal Precautions*.<br>All personal protective equipment should be removed before leaving the work area. Refer to Section 8 for more specifics.<br>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.<br>Consult with your Environmental Health & Safety Office for assistance. |
| Storage: | Store according to product and label instructions (generally at 2-8°C or at ambient temperature (15-30°C)). |
| Caution, consult accompanying documents. Read and follow all the Precautions and Warnings in the kit product instructions. Refer to the *Instructions For Use / Package Insert* for additional product information. | |
| For *in vitro* diagnostic use. | |

## SECTION 8: EXPOSURE CONTROL / PERSONAL PROTECTION MEASURES

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

| Chemical | CAS-No. | Value | Control parameter | Update | Basis |
|---|---|---|---|---|---|
| ***Hydrochloric acid*** | ***7647-01-0*** | TLV – C | 2 ppm | 2007-01-01 | USA. ACGIH Threshold Limit Values (TLV) |
| | | PEL – C | 7 mg/m$^3$ *<br>5 ppm | 2006-02-28 | USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants |
| | | REL – C<br><br>IDLH | 7 mg/m$^3$<br>5 ppm<br>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.<br>***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$^3$ *<br>1 ppm | 1997-08-04 | USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants |
| | | REL<br><br>IDLH | 1.4 mg/m$^3$<br>1 ppm<br>75 ppm | 2005-149 [SEP-2007] | USA. National Institute for Occupational Safety and Health (NIOSH) |
| | * The value in mg/m$^3$ is approximate<br>***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. | | | | |
| ***Dimethyl sulfoxide*** | ***67-68-5*** | TWA-WEEL | 250 ppm | 2014 | USA: Workplace Environmental Exposure Levels |
| | | MAK | 50 ppm (160 mg/m$^3$) | 2011 | GERMANY: |
| *Source: RTECS September 2013 Update and Raw Material Vendor Safety Data Sheet* | | | | | |

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

The following personal protective equipment (PPE) is recommended to prevent blood or other potentially infectious or hazardous materials from reaching the user's work or street clothes, skin, mouth, mucous membranes and eyes, or 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 / 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

| | | | |
|---|---|---|---|
| **Appearance:** | Variable, generally aqueous liquids. Exceptions are the solid microtiter plate and related materials. | | |
| **Odor/odour:** | No applicable information was found. | **Odor/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, **and *Chromogen*** at pH ~1.5. | | |
| **Boiling point:** | Undetermined. | **Melting point:** | Undetermined. |
| **Flash point:** | Not Applicable.<br>Flammable limits: LEL/LFL is Not Applicable; UEL/UFL is Not Applicable | | |
| **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/vapour pressure:** | No applicable information was found. | | |
| **Vapor/vapour density:** | No applicable information was found. | | |
| **Relative density:** | Variable, approximately 1-2. | | |
| **Solubility:** | The liquid chemical components are soluble in water. | | |
| **Partition coefficient (n-octanol/water):** | No applicable information was found. | | |
| **Auto igniting:** | Product is not known to be self-igniting. | | |
| **Decomposition temperature:** | No applicable information was found. | | |

| | |
|---|---|
| **Viscosity:** | No applicable information was found. |
| **Danger of explosion:** | 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. |
| Conditions and/or Materials to Avoid: | None known when used as intended. |
| Hazardous Decomposition Products: | May emit toxic oxides of carbon and nitrogen under fire conditions. |
| 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 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: | May slightly irritate eyes or skin, depending on amount and contact time. |
| Skin Corrosivity / Metal Corrosion: | The **EIA Chromogen (11X)** solution in this product has been evaluated with the CORROSITEX® test method to determine its corrosive potential. The results of this testing classified this solution as non-corrosive. |
| Serious Eye Damage / Irritation: | May slightly irritate eyes depending on amount and contact time. |
| STOT-Single Exposure: | No applicable information was found. |
| Aspiration Hazard: | No applicable information was found. |
| Other Acute Health Effects: | No significant other acute health effect known. |

Biohazard Potential:

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). The ***Positive Controls*** contain purified HBsAg (human ad and ay subtypes) in synthetic diluent. 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

| | |
|---|---|
| Respiratory or Skin Sensitization: | Contains a small volume of very dilute, potentially skin-contact sensitizing preservatives, ***ProClin*** and ***Gentamicin sulfate*** (an antimicrobial biocide that is also a photosensitizer); prolonged or repeated exposure may cause allergic reaction in certain sensitive individuals. Though the potential for an allergic response is greatly reduced by the dilution, sensitization threshold is unknown; thus handle accordingly. |
| Carcinogenicity: | Component **R1** contains **< 0.1%** ***Cobalt (II) chloride*** (CAS# 7646-79-9, IARC Group 2B and EU Category 2 carcinogen) and ***silica quartz*** (CAS# 14808-60-7, ACGIH class A2 and IARC Group 1 carcinogen) sealed in a pelletized desiccant packet. Keep the desiccant packet intact as received in the microwell plate component package. |
| Germ Cell Mutagenicity: | No applicable information was found. |
| Reproductive hazard: | Reasonably anticipated to be a reproductive toxin. May cause harm to unborn child. ***Gentamicin sulfate*** is known to the State of California to cause developmental toxicity (teratogen), classified under the generic class of aminoglycosides. (Designation is for concentrated gentamicin sulfate, which is diluted to 0.005% in kit components.) |
| 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: | **Concentrated *Hydrochloric acid*** [CAS# 7647-01-0]*:<br>Fish $LC_{50}$ - Bluegill/Sunfish – 282 mg/l - 48 h<br>**Concentrated *2-methyl-4-isothiazolin*** [CAS# 2682-20-4]**:<br>Fish $LC_{50}$ – Lepomis macrochirus (Bluegill) – 300 µg/l [min. 240 µg/l, max. 320 µg/l] - 96 h<br>Fish $LC_{50}$ - Oncorhynchus mykiss (rainbow trout) – 190 µg/l [min. 130 µg/l, max. 310 µg/l] - 96 h<br>Fish $LC_{50}$ - Oncorhynchus mykiss (rainbow trout) – 70 µg/l [min. 60 µg/l, max. 90 µg/l] - 96 h<br>**Concentrated *Citric acid*** [CAS#: 77-92-9]*:<br>Toxicity to fish mortality $LC_{50}$ - Leuciscus idus melanotus - 440 mg/l - 48 h<br>Method: OECD Test Guideline 203<br>Toxicity to daphnia and other aquatic invertebrates: static test - Daphnia magna (Water flea) - 1,535 mg/l - 24 h<br>** Source: Raw Material Vendor Safety Data Sheets, RTECS and/or CCOHS*<br>***Source: PAN Pesticides Database – Chemical Studies on Aquatic Organisims [obtained 3/7/2012]* |
| 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: | Components **R8 (pH 4) and R9 (pH 1.5)** may be hazardous for drinking water and toxic to aquatic organisms by pH modification if not neutralized generally at concentrations and volumes that greatly exceed that of this kit. 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:**

- All ***human source*** and other potentially infectious material must be appropriately decontaminated or disposed of as infectious material; check your applicable ordinances accordingly.
- ***Chromogen*** (pH ~1.5), and ***Substrate Buffer*** (pH ~4.0) wastes should 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 a 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.

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 & Safety Office for your specific shipping procedures.

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

Note: The **EIA Chromogen (11X)** solution in this product 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.

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

Acidic ***Chromogen*** is at pH ~1.5, 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 which corrodes Steel (NACE Standard TM-01-69)) must be transported as follows:

Proper Shipping name: **Waste Corrosive Liquid**
Hazard Class or Division: **8**
UN ID Number: **UN 1760**
Packing group **III**


**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 R1*** contains < 0.1% ***Cobalt (II) chloride*** (CAS# 7646-79-9, IARC Group 2B and EU Category 2 carcinogen) and ***silica quartz*** (CAS# 14808-60-7, in dust form is an ACGIH class A2 and IARC Group 1 carcinogen) in a pelletized desiccant sealed packet. Keep the desiccant packet intact as received in the component package.

**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) 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: ***Hydrogen peroxide*****,** CAS# 7722-84-1; Revision Date: 1993-04-24

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

***California Proposition 65 (California Safe Drinking Water and Toxic Enforcement Act of 1986)***: WARNING: This Product Contains a Chemical(s) Known to the State of California to Cause Reproductive Toxicity.

Chemicals known to cause reproductive Toxicity: ***Gentamicin Sulfate*** CAS# 1405-41-0; classified under the generic class of Aminoglycosides. (Listed October 1, 1992)

## SECTION 16: OTHER INFORMATION

**Hazard statement abreviation(s):**

| | |
|---|---|
| Acute Tox. – oral. | Acute toxicity – ingested (swallowed) |
| Acute Tox. – inhl. | Acute toxicity - inhaled |
| Resp. Sens. | Respiratory sensitization |
| Skin Sens. | Skin sensitisation |
| Skin Corr. | Skin corrosion |
| Eye Damage. | Serious eye damage |
| STOT SE | Specific target organ toxicity - single exposure |
| Aquatic Acute | Acute aquatic toxicity |
| Aquatic Chronic | Chronic aquatic toxicity |
| Met. Corr | Corrosive to Metals |
| Fla. Liq. | Flammable liquid |
| Cat. | Category |
| | |
| H227 | Combustible liquid. |
| H290 | May be corrosive to metals. |
| H302 | Harmful if swallowed. |
| H314 | Causes severe skin burns and eye damage. |
| H317 | May cause an allergic skin reaction. |
| H331 | Toxic if inhaled. |
| H334 | May cause allergy or asthma symptoms or breathing difficulties if inhaled. |
| H335 | May cause respiratory irritation. |
| H410 | Very toxic to aquatic life with long lasting effects. |
| | |
| P210 | Keep away from heat. |
| P234 | Keep only in original container. |
| P261 | Avoid breathing mist / vapors/vapours / spray. |
| P264 | Wash skin thoroughly after handling. |
| P270 | Do not eat, drink or smoke when using this product. |
| P271 | Use only outdoors or in a well-ventilated area. |
| 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. |
| P285 | In case of inadequate ventilation wear respiratory 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 + P352 | IF ON SKIN: 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. |
| P304 + P341 | IF INHALED: If breathing is difficult, 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. |
| P333 + P313 | If skin irritation or rash occurs: Get medical advice/ attention. |
| P342 + P311 | If experiencing respiratory symptoms: Call a POISON CENTER or doctor/ physician. |
| P363 | Wash contaminated clothing before reuse. |
| P370 + P378 | In case of fire: Use dry sand, dry chemical or alcohol-resistant foam for extinction. |
| P390 | Absorb spillage to prevent material damage. |
| P391 | Collect spillage. |
| P403 + P233 | Store in a well-ventilated place. Keep container tightly closed. |
| P403 + P235 | Store in a well-ventilated place. Keep cool. |
| P405 | Store locked up. |
| P406 | Store in corrosive resistant stainless steel container with a resistant inner liner. |
| P501 | Dispose of contents and container in accordance to local, regional, national and international regulations. |
| P501 | Dispose of this material and its container to hazardous or special waste collection point. |
| Caution: | Contains human source material. Handle as if capable of transmitting potentially infectious agents (*Standard* and *Universal Precautions*). |

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

For *in vitro* diagnostic use.

**Chemical safety assessment:** Mixtures covered in this SDS were classified using the US HCS, EC CLP and/or UN Globally Harmonized System of Classification and 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 if available 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)
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*
PAN Pesticides Database – Chemical Studies on Aquatic Organisims
*Australian Inventory of Chemical Substances* (ACIS) Listing
California Proposition 65

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

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

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

**This Revision:** Updated, reformatted and added new GHS information.

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