



# Safety Data Sheet

## Enzyme Reconstitution Solution

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### Product Identifier

**Product Name** Enzyme Reconstitution Solution

#### Recommended use of the chemical and restrictions on use

**Specific use(s)** Aptima CT Assay, Aptima GC Assay, Aptima COMBO 2 Assay, Aptima Trichomonas vaginalis Assay, Aptima HPV Assays, Aptima Mycoplasma genitalium Assay

**Recommended Use** In vitro diagnostic

#### Details of the supplier of the safety data sheet

**United States of America Distributor** Hologic, Inc.  
10210 Genetic Center Drive  
San Diego, CA 92121-4362  
USA

**Canadian Distributor** Hologic Canada Limited  
130 Spadina Avenue, Suite 401  
Toronto, ON, M5V-2L4  
Canada  
1-877-209-7192

#### **Emergency Telephone - United States of America**

**24 Hour Emergency Phone Number** Chemtrec, U.S. and Canada 1-800-424-9300; Chemtrec International +1-703-527-3887

**For further information, please contact:** MolecularSupport@hologic.com

### SECTION 2: Hazards identification

#### Classification

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200).

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [GHS]

#### Emergency Overview

The product contains no substances, which at their given concentration, are considered to be hazardous to health.

#### Label Elements

#### ERG Code

#### Hazards not otherwise classified (HNOC)

##### **Unknown Acute Toxicity**

11% of the mixture consists of ingredient(s) of unknown toxicity

**SECTION 3: Composition/information on ingredients****Substances**

Not applicable

**Mixtures**

Mixtures

**OSHA Hazard Classification**

The product contains no substances, which at their given concentration, are considered to be hazardous to health.

Component name	CAS No	%
HEPES	7365-45-9	1 - 5

**SECTION 4: First aid measures****First aid measures**

<b>Eye contact</b>	In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice. If symptoms persist, call a physician.
<b>Skin Contact</b>	Wash skin with soap and water. If symptoms persist, call a physician.
<b>Inhalation</b>	Remove to fresh air. If symptoms persist, call a physician.
<b>Ingestion</b>	Clean mouth with water and drink afterwards plenty of water. If symptoms persist, call a physician.

**Indication of any immediate medical attention and special treatment needed**

**Note to physicians** Treat symptomatically.

**SECTION 5: Firefighting measures**

<b>Flammability</b>	Not flammable.
<b>Suitable Extinguishing Media</b>	Use extinguishing agent suitable for type of surrounding fire.
<b>Protective equipment and precautions for firefighters</b>	As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

**SECTION 6: Accidental release measures****Personal precautions, protective equipment and emergency procedures**

<b>Personal precautions</b>	Use personal protective equipment as required.
<b><u>Environmental precautions</u></b>	See Section 12 for additional ecological information.

**Methods and material for containment and cleaning up**

<b>Methods for containment</b>	Cover with absorbent or contain.
<b>Methods for cleaning up</b>	Soak up with inert absorbent material. Dispose of contents/containers in accordance with local regulations.

**SECTION 7: Handling and storage**

<b>Precautions for safe handling</b>	Avoid prolonged contact with eyes, skin, and clothing. No known effects under normal use conditions.
<b>Advice on safe handling</b>	Handle in accordance with good industrial hygiene and safety practice. Avoid contact with

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skin and eyes. Wash hands thoroughly after handling. Use personal protection recommended in Section 8.

### Conditions for safe storage, including any incompatibilities

**Storage** Store in accordance with local regulations. Use appropriate containment to avoid environmental contamination.

## SECTION 8: Exposure Controls/Personal Protection.

### Exposure Guidelines

#### United States of America

Component name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Glycerol 56-81-5	-	TWA: 15 mg/m <sup>3</sup> mist, total particulate TWA: 5 mg/m <sup>3</sup> mist, respirable fraction (vacated) TWA: 10 mg/m <sup>3</sup> mist, total particulate (vacated) TWA: 5 mg/m <sup>3</sup> mist, respirable fraction	-

#### Canada

Component name	British Columbia OEL	Quebec OEL	Ontario TWA
Glycerol 56-81-5	TWA: 10 mg/m <sup>3</sup> TWA: 3 mg/m <sup>3</sup>	TWA: 10 mg/m <sup>3</sup>	-

#### Mexico

### Appropriate engineering controls

**Engineering Controls** Provide adequate ventilation. Showers. Eyewash stations.

### Individual protection measures, such as personal protective equipment

**Eye/face protection** Wear safety glasses with side shields (or goggles).  
**Skin and body protection** Wear suitable protective clothing.  
**Hand Protection** Wear protective gloves.  
**Respiratory protection** Not applicable

### Other Information

**Environmental exposure controls** No information available.

## SECTION 9: Physical and chemical properties

### Information on basic physical and chemical properties

**Physical State @20°C** Liquid  
**Color** Colorless  
**Odor** No information available  
**Odor threshold** No information available

### Property

### Values

**pH** ~ 7.0  
**Melting point/freezing point**  
**Boiling point / boiling range** No information available  
**Flash point**  
**Method** No information available  
**Evaporation rate** No information available

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<b>Flammability (solid, gas)</b>	No information available
<b>Flammability Limits in Air</b>	
<b>Upper flammability limits</b>	No information available
<b>Lower flammability limit</b>	No information available
<b>Vapor pressure</b>	No information available
<b>Vapor density</b>	No information available
<b>Relative density</b>	
<b>Specific Gravity</b>	1.071
<b>Water solubility</b>	No information available
<b>Solubility(ies)</b>	No information available
<b>Partition coefficient</b>	No information available
<b>Autoignition temperature</b>	No information available
<b>Decomposition temperature</b>	No information available
<b>Viscosity</b>	No information available
<b>Explosive properties</b>	No information available
<b>Oxidizing properties</b>	No information available

## SECTION 10: Stability and reactivity

<b>Reactivity</b>	None under normal use conditions.
<b>Stability</b>	Stable under normal conditions.
<b>Possibility of Hazardous Reactions</b>	None under normal use conditions.
<b>Hazardous polymerization</b>	None under normal use conditions.
<b>Conditions to avoid</b>	None under normal use conditions.
<b>Incompatible materials</b>	None under normal use conditions.
<b>Hazardous Decomposition Products</b>	None under normal use conditions.
<b>Materials to avoid</b>	None under normal use conditions.

## SECTION 11: Toxicological information

### Information on likely routes of exposure

<b>Product Information</b>	Product does not present an acute toxicity hazard based on known or supplied information.
<b>Inhalation</b>	None under normal use conditions.
<b>Eye contact</b>	None under normal use conditions.
<b>Skin Contact</b>	None under normal use conditions.
<b>Ingestion</b>	None under normal use conditions.

Component name	LD50/oral/rat - (mg/kg)	LD50/dermal/rat - (mg/kg)	Inhalation LC50
Triton X-100 9002-93-1	= 1800 mg/kg ( Rat )	-	-

### Information on toxicological effects

#### Delayed and immediate effects as well as chronic effects from short and long-term exposure

<b>Skin corrosion/irritation</b>	No information available.
<b>Serious eye damage/eye irritation</b>	No information available.
<b>Sensitization</b>	No information available.
<b>Germ cell mutagenicity</b>	No information available.
<b>Carcinogenicity</b>	No information available.
<b>Reproductive toxicity</b>	No information available.
<b>STOT - single exposure</b>	No information available.
<b>STOT - repeated exposure</b>	No information available.

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**Aspiration hazard** No information available.

### Numerical measures of toxicity - Product Information

**Unknown Acute Toxicity** 11% of the mixture consists of ingredient(s) of unknown toxicity

The following values are calculated based on chapter 3.1 of the GHS document .

**ATEmix (oral)** 16529 mg/kg  
**ATEmix (dermal)** 42827  
**ATEmix (inhalation-dust/mist)** 0.6

## SECTION 12: Ecological information

### Ecotoxicity

20 - 50% of the mixture consists of components(s) of unknown hazards to the aquatic environment.

Component name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Potassium Chloride 7447-40-7	2500: 72 h <i>Desmodesmus subspicatus</i> mg/L EC50	1060: 96 h <i>Lepomis macrochirus</i> mg/L LC50 static		825: 48 h <i>Daphnia magna</i> mg/L EC50 83: 48 h <i>Daphnia magna</i> mg/L EC50 Static
EDTA 60-00-4	1.01: 72 h <i>Desmodesmus subspicatus</i> mg/L EC50	34 - 62: 96 h <i>Lepomis macrochirus</i> mg/L LC50 static		113: 48 h <i>Daphnia magna</i> mg/L EC50 Static

**Persistence and degradability** No information available.

**Bioaccumulation** No information available.

**Mobility** No information available.

**Other adverse effects** No information available.

## SECTION 13: Disposal Considerations.

### Waste treatment methods

**Disposal of wastes** Disposal should be in accordance with applicable regional, national and local laws and regulations.

**Waste from residues/unused products** Disposal should be in accordance with applicable regional, national and local laws and regulations.

**Contaminated packaging** Disposal should be in accordance with applicable regional, national and local laws and regulations.

## SECTION 14: Transport information

**DOT** Not regulated

**TDG** Not regulated

**IATA** Not regulated

**IMDG** Not regulated

**SECTION 15: Regulatory information****International Inventories**

Component name	TSCA	EINECS/ELINCS	DSL/NDSL	PICCS
Water 7732-18-5	Present	X	X	X
Glycerol 56-81-5	Present	X	X	X
Triton X-100 9002-93-1	Present	-	X	X
HEPES 7365-45-9	Present	X	X	X
Potassium Chloride 7447-40-7	Present	X	X	X
EDTA 60-00-4	Present	X	X	X

Component name	ENCS	IECSC	AICS	KECL
Water 7732-18-5	Present	X	X	Present
Glycerol 56-81-5	Present	X	X	Present
Triton X-100 9002-93-1	-	X	X	Present
HEPES 7365-45-9	-	X	X	-
Potassium Chloride 7447-40-7	Present	X	X	Present
EDTA 60-00-4	Present	X	X	Present

Legend

X - Present

- Not Listed

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

PICCS - Philippines Inventory of Chemicals and Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

AICS - Australian Inventory of Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

**US Federal Regulations****SARA 313**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

**SARA 311/312 Hazard Categories**

<b>Acute health hazard</b>	No
<b>Chronic Health Hazard</b>	No
<b>Fire hazard</b>	No
<b>Sudden release of pressure hazard</b>	No
<b>Reactive Hazard</b>	No

**CWA (Clean Water Act)**

This product contains the following substances which are regulated pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

**CERCLA**

This material, as supplied, contains one or more substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302).

**US State Regulations****California Proposition 65**

This product does not contain any Proposition 65 chemicals.

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**U.S. State Right-to-Know Regulations**

This product may contain substances regulated by state right-to-know regulations.

Component name	New Jersey	Massachusetts	Pennsylvania
Glycerol 56-81-5	X	X	X
EDTA 60-00-4	X	X	X

**U.S. EPA Label Information**

**EPA Pesticide Registration Number** Not applicable

**International Regulations**

**Canada**

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the SDS contains all the information required by the CPR.

**WHMIS Hazard Class**

Non-controlled

**Mexico**

No information available

**SECTION 16: Other information**

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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

**End of Safety Data Sheet**