



Safety Data Sheet

Cleavase Enzyme Solution

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

Product Identifier

Product Name Cleavase Enzyme Solution

Recommended use of the chemical and restrictions on use

Specific use(s) Cervista HPV 16/18, Cervista HPV HR

Recommended Use In vitro diagnostic

Details of the supplier of the safety data sheet

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

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

Manufacturer Hologic, Inc.
10210 Genetic Center Drive
San Diego, CA 92121-4362

Emergency Telephone - United States of America

24 Hour Emergency Phone Number Chemtrec, U.S. and Canada 1-800-424-9300; Chemtrec International + 1-703-741-5970

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).

Not a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Emergency Overview

Label Elements

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

Hazards not otherwise classified (HNOC)

Other Information

1.6% of the mixture consists of ingredient(s) of unknown toxicity

SECTION 3: Composition/information on ingredients

Substances

Not Applicable

Mixtures Mixtures

Mixtures

OSHA Hazard Classification

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

SECTION 4: First aid measures

First aid measures

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

Flammability	Not flammable.
Suitable Extinguishing Media	Use extinguishing agent suitable for type of surrounding fire.
Protective equipment and precautions for firefighters	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

Personal precautions	Use personal protective equipment as required.
-----------------------------	--

Methods and material for containment and cleaning up

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

SECTION 7: Handling and storage

Precautions for safe handling	Avoid prolonged contact with eyes, skin, and clothing. No known effects under normal use conditions.
Advice on safe handling	Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin and eyes. Wash hands thoroughly after handling. Use personal protection recommended in Section 8.

Cleavase Enzyme Solution

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

Table with 4 columns: Component name, ACGIH TLV, OSHA PEL, NIOSH IDLH. Row 1: Glycerol 56-81-5, -, TWA: 15 mg/m³ mist, total particulate; TWA: 5 mg/m³ mist, respirable fraction; (vacated) TWA: 10 mg/m³ mist, total particulate; (vacated) TWA: 5 mg/m³ mist, respirable fraction; -

Canada

Table with 4 columns: Component name, British Columbia OEL, Quebec OEL, Ontario TWA. Row 1: Glycerol 56-81-5, TWA: 10 mg/m³; TWA: 3 mg/m³; TWA: 10 mg/m³; TWA: 10 mg/m³

Mexico

Other Information Vacated limits revoked by the Court of Appeals decision in AFL-CIO v. OSHA, 965 F.2d 962 (11th Cir., 1992).

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: No information available
Melting point/freezing point: No information available
Boiling point / boiling range: No information available
Flash point: No information available
Method: No information available
Evaporation rate: No information available
Flammability (solid, gas): No information available

Flammability Limits in Air	
Upper flammability limits	No information available
Lower flammability limit	No information available
Vapor pressure	No information available
Vapor density	No information available
Relative density	No information available
Water solubility	No information available
Solubility(ies)	No information available
Partition coefficient	No information available
Autoignition temperature	No information available
Decomposition temperature	No information available
Viscosity	No information available
Explosive properties	No information available
Oxidizing properties	No information available

SECTION 10: Stability and reactivity

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

SECTION 11: Toxicological information

Information on likely routes of exposure

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

Information on toxicological effects

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

Skin corrosion/irritation	No information available.
Serious eye damage/eye irritation	No information available.
Sensitization	No information available.
Germ cell mutagenicity	No information available.
Carcinogenicity	No information available.

Reproductive toxicity	No information available.
STOT - single exposure	No information available.
STOT - repeated exposure	No information available.

Target Organ Effects Eyes, kidney, Respiratory system, Skin.

Aspiration hazard	No information available.
--------------------------	---------------------------

Numerical measures of toxicity - Product Information

Unknown Acute Toxicity	1.6% of the mixture consists of ingredient(s) of unknown toxicity
-------------------------------	---

Cleavase Enzyme Solution

ATEmix (dermal)

16926

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 Desmodesmus subspicatus mg/L EC50	1060: 96 h Lepomis macrochirus mg/L LC50 static		825: 48 h Daphnia magna mg/L EC50 83: 48 h Daphnia magna mg/L EC50 Static
Magnesium Chloride 7786-30-3	2200: 72 h Desmodesmus subspicatus mg/L EC50			140: 48 h Daphnia magna 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
Glycerol 56-81-5	Present	X	X	X
Water 7732-18-5	Present	X	X	X
Tween 20	Present	X	X	X

Cleavase Enzyme Solution

9005-64-5				
Triton X-100 9002-93-1	Present	-	X	X
Potassium Chloride 7447-40-7	Present	X	X	X
Trizma Hydrochloride 1185-53-1	Present	X	X	X
Magnesium Chloride 7786-30-3	Present	X	X	X
BSA, 20 mg/mL 9048-46-8	Present	X	X	X

Component name	ENCS	IECSC	AICS	KECL
Glycerol 56-81-5	Present	X	X	Present
Water 7732-18-5	-	X	X	Present
Tween 20 9005-64-5	Present	X	X	Present
Triton X-100 9002-93-1	Present	X	X	Present
Potassium Chloride 7447-40-7	Present	X	X	Present
Trizma Hydrochloride 1185-53-1	-	X	X	Present
Magnesium Chloride 7786-30-3	Present	X	X	Present
BSA, 20 mg/mL 9048-46-8	-	X	X	Present

Legend

X - Present

- Not Listed

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

Acute health hazard	No
Chronic Health Hazard	No
Fire hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	No

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

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

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

SECTION 16: Other information

Revision Date 18-Oct-2016

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