

Safety Data Sheet

Calibrators

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

Product Identifier

Product Name Calibrators

Recommended use of the chemical and restrictions on use

Specific use(s) Progensa PCA3 Assay, Aptima HPV Assays, Aptima Trichomonas vaginalis Assay, 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

2.99% of the mixture consists of ingredient(s) of unknown toxicity

SECTION 3: Composition/information on ingredients

Substances

Not applicable

<u>Mixtures</u>

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

SECTION 5: Firefighting measures

Flammability Not flammable.

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 precautionsUse personal protective equipment as required.

Environmental precautions See Section 12 for additional ecological information.

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.

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

This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

United States of America

Canada

<u>Mexico</u>

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 ~ 6.7

Melting point/freezing point

Boiling point / boiling range No information available

Flash point

MethodNo information availableEvaporation rateNo information availableFlammability (solid, gas)No information available

Flammability Limits in Air

Upper flammability limits
Lower flammability limit
Vapor pressure
Vapor density

No information available
No information available
No information available
No information available

Relative density

Specific Gravity 1.003

Water solubility
Solubility(ies)
Partition coefficient
Autoignition temperature
Decomposition temperature
No information available
No information available
No information available
No information available

ViscosityNo information availableExplosive propertiesNo information availableOxidizing propertiesNo 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 polymerizationNone under normal use conditions.

Conditions to avoidNone under normal use conditions.

Incompatible materialsNone 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.

InhalationNone under normal use conditions.Eye contactNone under normal use conditions.

Skin ContactNone under normal use conditions.IngestionNone 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
Serious eye damage/eye irritation
Sensitization
Sensitization
No information available.
No information available.
No information available.

Germ cell mutagenicityNo information available.
Carcinogenicity
No information available.

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

Numerical measures of toxicity - Product Information

Unknown Acute Toxicity 2.99% of the mixture consists of ingredient(s) of unknown toxicity

SECTION 12: Ecological information

Ecotoxicity

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

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
Lauryl Sulfate Lithium Salt 2044-56-6	Present	X	X	-
Sodium Phosphate, Monobasic, Monohydrate 10049-21-5	-	-	-	X
Sodium Phosphate Dibasic 7558-79-4	Present	Х	X	Х
EDTA Disodium Dihydrate 6381-92-6	-	-	X	X
EGTA Free Acid 67-42-5	Present	X	X	X

Component name	ENCS	IECSC	AICS	KECL
Water 7732-18-5	Present	X	X	Present
Lauryl Sulfate Lithium Salt 2044-56-6	Present	X	X	Present
Sodium Phosphate, Monobasic, Monohydrate 10049-21-5	-	Х	X	-
Sodium Phosphate Dibasic 7558-79-4	Present	Х	X	Present
EDTA Disodium Dihydrate 6381-92-6	-	X	X	-

EGTA Free Acid	_	Y	Y	_
67-42-5	_	X	^	_

<u>Legend</u>

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

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 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.

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
Sodium Phosphate Dibasic	X	X	X
7558-79-4			

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

International Regulations

<u>Canada</u>

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

Revision Date 12-Nov-2021

Version

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