



Safety Data Sheet

Amplification Reagent

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

Product Identifier

Product Name Amplification Reagent

Recommended use of the chemical and restrictions on use

Specific use(s) Aptima HIV-1 Quant Dx Assay, Aptima HCV Quant Dx Assay, Aptima HBV Quant Assay, Aptima HSV 1 & 2 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).

Emergency Overview

Label Elements

ERG Code

Hazards not otherwise classified (HNOC)

H412 - Harmful to aquatic life with long lasting effects. H402 - Harmful to aquatic life.

Unknown Acute Toxicity

100.01% of the mixture consists of ingredient(s) of unknown toxicity

SECTION 3: Composition/information on ingredients

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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	%
Magnesium Chloride	7786-30-3	60 - 65

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.
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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.
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

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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

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	Solid
Appearance	Lyophilized Cake
Color	White to off-white
Odor	No information available
Odor threshold	No information available

<u>Property</u>	<u>Values</u>
pH	~ 8.3 Not applicable
Melting point/freezing point	
Boiling point / boiling range	No information available
Flash point	
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	Not applicable
Water solubility	No information available
Solubility(ies)	No information available
Partition coefficient	No information available
Autoignition temperature	No information available

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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.

Component name	LD50/oral/rat - (mg/kg)	LD50/dermal/rat - (mg/kg)	Inhalation LC50
Magnesium Chloride 7786-30-3	= 2800 mg/kg (Rat)	-	-
Trizma Base 77-86-1	= 5900 mg/kg (Rat)	-	-

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.

Aspiration hazard No information available.

Numerical measures of toxicity - Product Information

Unknown Acute Toxicity 100.01% 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) 3074 mg/kg

SECTION 12: Ecological information**Ecotoxicity**

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

Component name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Magnesium Chloride 7786-30-3	82.7: 72 h Pseudokirchneriella subcapitata 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
Magnesium Chloride 7786-30-3	Present	X	X	X
Trizma Hydrochloride 1185-53-1	Present	X	X	X
Trizma Base 77-86-1	Present	X	X	X

Component name	ENCS	IECSC	AICS	KECL
Magnesium Chloride 7786-30-3	Present	X	X	Present
Trizma Hydrochloride	Present	X	X	Present

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1185-53-1				
Trizma Base 77-86-1	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

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

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

D2B - Toxic materials

Mexico

No information available

SECTION 16: Other information

Version

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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