



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) Amplified Mycobacterium Tuberculosis Direct (MTD) Test

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

EUH210 - Safety data sheet available on request

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

Hazards not otherwise classified (HNOC)

Other Information

8.3% 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 | % |
|--------------------|-----------|-------|
| Potassium Chloride | 7447-40-7 | 1 - 5 |

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. |
| 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

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 |

| Property | Values |
|--------------------------------------|--------------------------|
| pH | Not Applicable |
| 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 | No information available |
| 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 |

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| | |
|----------------------------------|--------------------------|
| 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. |

*IARC (International Agency for Research on Cancer)
Not classifiable as a human carcinogen*

| | |
|---------------------------------|---------------------------|
| 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 | 8.3% 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) 32886 mg/kg

SECTION 12: Ecological information

Ecotoxicity

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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 |
|------------------------------|--|---|----------------------------|---|
| Magnesium Chloride 7786-30-3 | 2200: 72 h Desmodesmus subspicatus mg/L EC50 | | | 140: 48 h Daphnia magna mg/L EC50 Static |
| 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 |

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 |
|--------------------------------|---------|---------------|----------|-------|
| Polyvinylpyrrolidone 9003-39-8 | Present | - | X | X |
| Trizma Base 77-86-1 | Present | X | X | X |
| Magnesium Chloride 7786-30-3 | Present | X | X | X |
| Potassium Chloride 7447-40-7 | Present | X | X | X |

| Component name | ENCS | IECSC | AICS | KECL |
|--------------------------------|---------|-------|------|---------|
| Polyvinylpyrrolidone 9003-39-8 | Present | X | X | Present |

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| | | | | |
|---------------------------------|---------|---|---|---------|
| Trizma Base 77-86-1 | Present | X | X | Present |
| Magnesium Chloride 7786-30-3 | Present | X | X | Present |
| Potassium Chloride 7447-40-7 | Present | 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

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

Amplification Reagent

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