

Safety Data Sheet

ThinPrep® PreservCyt Solution

SECTION 1: Identification of the substance/preparation and of the Company/undertaking

Product identifier

Product Name ThinPrep® PreservCyt Solution

Safety data sheet number 85093-001

Recommended use of the chemical and restrictions on use

Specific use(s) A methanol based, buffered preservative solution used to support cells during transport and slide preparation

Recommended Use In vitro diagnostic

Details of the supplier of the safety data sheet

Manufacturer Hologic Inc.
250 Campus Drive
Marlborough, MA 01752
United States
1-508-263-2900

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

For further information, please contact: sds@hologic.com

SECTION 2: Hazards identification

Classification

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200).

| | |
|--|------------|
| Acute toxicity - Oral | Category 3 |
| Acute toxicity - Dermal | Category 3 |
| Acute toxicity - Inhalation (Vapors) | Category 3 |
| Specific target organ toxicity (single exposure) | Category 1 |
| Flammable liquids | Category 3 |

Emergency Overview

Label elements



Signal word
Danger

Hazard statements

H301 - Toxic if swallowed
H311 - Toxic in contact with skin
H331 - Toxic if inhaled
H370 - Causes damage to organs
Flammable liquid and vapor

Precautionary Statements - Prevention

P210 - Keep away from heat/sparks/open flames/hot surfaces. — No smoking
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P264 - Wash face, hands and any exposed skin thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P403 + P233 - Store in a well-ventilated place. Keep container tightly closed

Precautionary Statements - Response

P307 + P311 - IF exposed: Call a POISON CENTER or doctor/physician
P303 + P361 + P353 - IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower
P363 - Wash contaminated clothing before reuse
P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
P311 - Call a POISON CENTER or doctor/physician
P301 + P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician
P330 - Rinse mouth

Fire

In case of fire: Use CO2, dry chemical, or foam for extinction.

Precautionary Statements - Storage

P403 + P233 - Store in a well-ventilated place. Keep container tightly closed

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant.

Hazards not otherwise classified (HNOC)

Not Applicable

Other Information

Not Applicable

SECTION 3: Composition/information on ingredients

Substances

Not Applicable

Mixtures

Mixtures

| Component name | CAS No | % |
|----------------|---------|-------|
| Methanol | 67-56-1 | 35-55 |

SECTION 4: First aid measures

First aid measures

General advice

Immediate medical attention is required. In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

Eye contact

Immediately flush with plenty of water. After initial flushing, remove any contact lenses and continue flushing for at least 15 minutes. Keep eye wide open while rinsing. Call a physician immediately.

| | |
|---|---|
| Skin Contact | Wash off immediately with plenty of water. |
| Inhalation | Immediate medical attention is required. Remove to fresh air. If not breathing, give artificial respiration. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation. |
| Ingestion | Do NOT induce vomiting. Call a physician or poison control center immediately. Never give anything by mouth to an unconscious person. Drink plenty of water. Rinse mouth. |
| Self-protection of the first aider | Remove all sources of ignition. |
| Symptoms | May cause gastrointestinal irritation with nausea, vomiting and diarrhea, central nervous system depression, headaches, and dizziness. May be fatal or cause blindness if swallowed in large amounts. |

Indication of any immediate medical attention and special treatment needed

| | |
|---------------------------|---|
| Note to physicians | Treat for CNS depression and possible renal failure. Provide general supportive measures and treat symptomatically. Symptoms may be delayed. Ethanol and fomepizole are effective antidotes for methanol poisoning, although fomepizole is preferred. |
|---------------------------|---|

SECTION 5: Firefighting measures

| | |
|--|--|
| Flammability | Flammable liquid and vapor. |
| Suitable Extinguishing Media | Dry chemical, Foam, Carbon dioxide (CO2). |
| Unsuitable Extinguishing Media | Do not use a solid water stream as it may scatter and spread fire. |
| Specific hazards arising from the chemical | Most vapors are heavier than air. They will spread along ground and collect in low or confined areas (sewers, basements, tanks). Vapors may form explosive mixtures with air. 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

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|---|---|
| Personal precautions | Remove all sources of ignition. Evacuate personnel to safe areas. Ensure adequate ventilation, especially in confined areas. Use personal protective equipment as required. |
| <u>Environmental precautions</u> | Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. Do not flush into surface water or sanitary sewer system. |

Methods and material for containment and cleaning up

| | |
|--------------------------------|--|
| Methods for containment | Prevent further leakage or spillage if safe to do so. Cover powder spill with plastic sheet or tarp to minimize spreading. Dike far ahead of liquid spill for later disposal. |
| Methods for cleaning up | Dam up. Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust). Pick up and transfer to properly labeled containers. Soak up with inert absorbent material. |

SECTION 7: Handling and storage

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|--------------------------------------|--|
| Precautions for safe handling | Keep away from heat, sparks, flame and other sources of ignition (i.e., pilot lights, electric motors and static electricity). Keep container tightly closed. Ensure adequate ventilation, especially in confined areas. |
| Advice on safe handling | Ensure adequate ventilation, especially in confined areas. Keep away from heat, sparks, flame and other sources of ignition (i.e., pilot lights, electric motors and static electricity). Take precautionary measures against static discharges. Use spark-proof tools and explosion-proof equipment. All equipment used when handling the product must be grounded. |

Conditions for safe storage, including any incompatibilities

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

Storage Conditions Keep tightly closed in a dry and cool place. Keep in properly labeled containers. Keep away from heat, sparks, flame and other sources of ignition (i.e., pilot lights, electric motors and static electricity).

SECTION 8: Exposure Controls/Personal Protection.**Exposure Guidelines****United States of America**

| Component name | ACGIH TLV | OSHA PEL | NIOSH IDLH |
|---------------------|-------------------------------------|--|--|
| Methanol 67-56-1 | STEL: 250 ppm TWA: 200 ppm S* | TWA: 200 ppm TWA: 260 mg/m ³ (vacated) TWA: 200 ppm (vacated) TWA: 260 mg/m ³ (vacated) STEL: 250 ppm (vacated) STEL: 325 mg/m ³ (vacated) S* | IDLH: 6000 ppm TWA: 200 ppm TWA: 260 mg/m ³ STEL: 250 ppm STEL: 325 mg/m ³ |

Canada

| Component name | British Columbia OEL | Quebec OEL | Ontario TWA |
|---------------------|---------------------------------------|--|---------------------------------------|
| Methanol 67-56-1 | TWA: 200 ppm STEL: 250 ppm Skin | TWA: 200 ppm TWA: 262 mg/m ³ STEL: 250 ppm STEL: 328 mg/m ³ Skin | TWA: 200 ppm STEL: 250 ppm Skin |

Mexico

| Component | Carcinogenicity | Exposure Limits |
|-------------------------------|-----------------|--|
| Methanol 67-56-1 (35-55) | - | Mexico: TWA 200 ppm Mexico: TWA 260 mg/m ³ Mexico: STEL 250 ppm Mexico: STEL 310 mg/m ³ |

NIOSH IDLH *Immediately Dangerous to Life or Health*

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 Tight sealing safety goggles.
Skin and body protection Wear suitable protective clothing.
Hand Protection Wear protective nitrile rubber gloves.
Respiratory protection Not Applicable

General Hygiene Considerations Regular cleaning of equipment, work area and clothing is recommended. Do not eat, drink or smoke when using this product. Wash contaminated clothing before reuse.

Other Information

Environmental exposure controls No information available.

SECTION 9: Physical and chemical properties**Information on basic physical and chemical properties**

Physical state Liquid
Appearance Colorless, clear, Liquid
Color Colorless

Odor Alcohol
Odor threshold No information available

| <u>Property</u> | <u>Values</u> |
|--------------------------------------|--|
| pH | 5.5 |
| Melting point/freezing point | -48 °C / -54 °F No information available |
| Boiling point / boiling range | 64 °C / 147 °F |
| Flash point | 27 °C / 81 °F |
| Method | CC (closed cup) |
| Evaporation rate | No information available |
| Flammability (solid, gas) | No information available |
| Flammability Limits in Air | |
| Upper flammability limits | 36% |
| Lower flammability limit | 6.7% |
| Vapor pressure | No information available |
| Vapor density | No information available |
| Relative density | No information available |
| Water solubility | Miscible in water |
| Solubility(ies) | No information available |
| Partition coefficient | No information available |
| Autoignition temperature | 385 °C / 725 °F |
| Decomposition temperature | No information available |
| Viscosity | No information available |
| Explosive properties | No information available |
| Oxidizing properties | No information available |
| Percent Volatile | > 99% |

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 Heat, flames and sparks.

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 Repeated or prolonged exposure may cause central nervous system damage. May be harmful by inhalation, ingestion, or skin absorption.

Inhalation Harmful by inhalation.

Eye contact Risk of serious damage to eyes.

Skin Contact Harmful in contact with skin.

Ingestion Harmful if swallowed.

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** Central nervous system, Eyes, Gastrointestinal tract (GI), Respiratory system, Skin.**Aspiration hazard** No information available.**Numerical measures of toxicity - Product Information**

The following values are calculated based on chapter 3.1 of the GHS document . mg/kg mg/l

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.

| Component name | Partition coefficient |
|---------------------|-----------------------|
| Methanol 67-56-1 | -0.77 |

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.**US EPA Waste Number** D001 U154

| Component name | RCRA | RCRA - Basis for Listing | RCRA - D Series Wastes | RCRA - U Series Wastes |
|---------------------|------|-----------------------------------|------------------------|------------------------|
| Methanol 67-56-1 | | Included in waste stream: F039 | | U154 |

This product contains one or more substances that are listed with the State of California as a hazardous waste.

| Component name | California Hazardous Waste Status |
|---------------------|-----------------------------------|
| Methanol 67-56-1 | Toxic Ignitable |

SECTION 14: Transport information

DOT

UN/ID No UN1993
Proper shipping name Flammable liquids, n.o.s. (Methanol)
Hazard Class 3
Packing Group III
Reportable Quantity (RQ) Methanol: RQ kg= 4283.02
Emergency Response Guide Number 128

TDG

UN/ID No UN1993
Proper shipping name Flammable liquids, n.o.s. (Methanol)
Hazard Class 3
Packing Group III

IATA

UN/ID No UN1993
Proper shipping name Flammable liquids, n.o.s. (Methanol)
Hazard Class 3
Packing Group III
ERG Code 3L

IMDG

UN/ID No UN1993
Proper shipping name Flammable liquids, n.o.s. (Methanol)
Hazard Class 3
Packing Group III
EmS-No F-E, S-E

| |
|---|
| SECTION 15: Regulatory information |
|---|

International Inventories

| Component name | TSCA | EINECS/ELINCS | DSL/NDSL | PICCS |
|---------------------------------|---------|---------------|----------|-------|
| Methanol 67-56-1 | Present | X | X | X |
| EDTA Disodium Salt 6381-92-6 | - | - | X | X |
| Glacial Acetic Acid 758-12-3 | - | X | - | - |

| Component name | ENCS | IECSC | AICS | KECL |
|---------------------------------|---------|-------|------|---------|
| Methanol 67-56-1 | Present | X | X | Present |
| EDTA Disodium Salt 6381-92-6 | - | X | X | - |

Legend:

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

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

US Federal Regulations**SARA 313**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product contains a chemical or chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

| Component name | CAS No | % | SARA 313 - Threshold Values % |
|--------------------|---------|-------|-------------------------------|
| Methanol - 67-56-1 | 67-56-1 | 35-55 | 1.0 |

SARA 311/312 Hazard Categories

ThinPrep® PreservCyt Solution

| | |
|-----------------------------------|-----|
| Acute health hazard | Yes |
| Chronic Health Hazard | No |
| Fire hazard | Yes |
| 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.

| Component name | Hazardous Substances RQs | CERCLA/SARA RQ | Reportable Quantity (RQ) |
|---------------------|--------------------------|----------------|--|
| Methanol 67-56-1 | 5000 lb | | RQ 5000 lb final RQ RQ 2270 kg final RQ |

US State Regulations

California Proposition 65

This product contains the following Proposition 65 chemicals.

| Component name | California Proposition 65 |
|--------------------|---------------------------|
| Methanol - 67-56-1 | Developmental |

U.S. State Right-to-Know Regulations

| Component name | New Jersey | Massachusetts | Pennsylvania |
|---------------------|------------|---------------|--------------|
| Methanol 67-56-1 | X | X | X |

U.S. EPA Label Information

EPA Pesticide Registration Number Not Applicable

International Regulations

Mexico - Grade Serious risk, Grade 3

| Component name | Carcinogenicity | Exposure Limits |
|----------------|-----------------|--|
| Methanol | - | Mexico: TWA 200 ppm Mexico: TWA 260 mg/m ³ Mexico: STEL 250 ppm Mexico: STEL 310 mg/m ³ |

SECTION 16: Other information

Revision Date 20-May-2015

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