Globally Harmonised System (GHS) (European Union)

SAFETY DATA SHEET
ThinPrep® PreservCyt Solution

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

Product Identifier

Product Name ThinPrep® PreservCyt Solution

Safety data sheet number 85952-001

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 testing

Details of the supplier of the safety data sheet

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

Supplier Address Hologic, Ltd.
Heron House Oaks Business Park
Crewe Road
Wythenshawe, Manchester
M23 9HZ, United Kingdom
+44 (0) 161 946 2206

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 sds@hologic.com

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

<table>
<thead>
<tr>
<th>Classification</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity - Oral</td>
<td>Category 3</td>
</tr>
<tr>
<td>Acute toxicity - Dermal</td>
<td>Category 3</td>
</tr>
<tr>
<td>Acute toxicity - Inhalation (Vapours)</td>
<td>Category 3</td>
</tr>
<tr>
<td>Specific target organ toxicity (single exposure)</td>
<td>Category 1</td>
</tr>
<tr>
<td>Flammable liquids</td>
<td>Category 3</td>
</tr>
</tbody>
</table>

Classification according to Directive 67/548/EEC or 1999/45/EC

Full text of R-phrases: see section 16

Hazard symbols

T - Toxic

R-code(s)

R10 - T;R39/23/24/25 - T;R23/24/25

2.2. Label Elements
Product Identifier
Contains Methanol

Signal Word
DANGER

hazard statements
H301 - Toxic if swallowed
H311 - Toxic in contact with skin
H331 - Toxic if inhaled
H370 - Causes damage to organs
H226 - Flammable liquid and vapour

Precautionary Statements - EU (§28, 1272/2008)
P210 - Keep away from heat/sparks/open flames/hot surfaces. — No smoking
P260 - Do not breathe dust/fume/gas/mist/vapours/spray
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P301 + P310 - IF SWALLOWED: Immediately call a POISON CENTRE or doctor/physician
P307 + P311 - IF exposed: Call a POISON CENTRE or doctor/physician
P309 - IF exposed or if you feel unwell
P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
P303 + P361 + P353 - IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower
P370 + P378 - In case of fire: Use dry sodium carbonate to extinguish
P403 + P233 - Store in a well-ventilated place. Keep container tightly closed

2.3. Other Hazards
No information available.

SECTION 3: Composition/information on ingredients

3.1 Substances
Not Applicable

3.2 Mixtures
Mixtures

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS No</th>
<th>%</th>
<th>EC No</th>
<th>Classification according to Regulation (EC) No. 1272/2008 [CLP]</th>
<th>REACH registration number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methanol</td>
<td>67-56-1</td>
<td>35-55</td>
<td>Present</td>
<td>Acute Tox. 3 (H301) Acute Tox. 3 (H311) Acute Tox. 3 (H331) STOT SE 1 (H370) Flam. Liq. 2 (H225)</td>
<td>01-2119433307-44-0135</td>
</tr>
</tbody>
</table>

SECTION 4: First aid measures

4.1 Description of first aid measures

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

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.
Skin contact
Wash off immediately with plenty of water.

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 doctor immediately.

Ingestion
Do NOT induce vomiting. Call a doctor or poison control centre immediately. Never give anything by mouth to an unconscious person. Drink plenty of water.

Self-protection of the first aider
Remove all sources of ignition.

4.2. Most important symptoms and effects, both acute and delayed
Symptoms
No information available.

4.3. Indication of any immediate medical attention and special treatment needed
Note to doctors
Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media
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.

5.2. Special hazards arising from the substance or mixture
Specific hazards arising from the chemical
Most vapours are heavier than air. They will spread along ground and collect in low or confined areas (sewers, basements, tanks). Vapours may form explosive mixtures with air. Flammable.

5.3. Advice for firefighters
Special protective equipment for fire-fighters
As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear. Evacuate area and fight fire from a safe distance. Prevent fire extinguishing water from contaminating surface water or the ground water system.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures
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.

6.2. Environmental precautions
Environmental Precautions
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.

6.3. 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 minimise spreading. Dyke 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 labelled containers. Soak up with inert absorbent material.

6.4. Reference to other sections
Reference to other sections
SECTION 8: Exposure controls/personal protection, SECTION 13: Disposal considerations.

SECTION 7: Handling and storage

7.1. Precautions for safe handling
**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.

**General Hygiene Considerations**

Regular cleaning of equipment, work area and clothing is recommended. When using do not eat, drink or smoke.

**7.2. Conditions for safe storage, including any incompatibilities**

**Storage Conditions**

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

**7.3. Specific end use(s)**

**Specific use(s)**

In vitro diagnostic testing

**Risk Management Methods (RMM)**

The information required is contained in this Safety Data Sheet.

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>European Union</th>
<th>United Kingdom</th>
<th>France</th>
<th>Spain</th>
<th>Germany</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methanol 67-56-1</td>
<td>TWA: 200 ppm TWA: 260 mg/m³</td>
<td>TWA: 200 ppm TWA: 260 mg/m³</td>
<td>TWA: 200 ppm TWA: 260 mg/m³</td>
<td>TWA: 200 ppm TWA: 260 mg/m³</td>
<td>TWA: 200 ppm TWA: 260 mg/m³</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Italy</th>
<th>Portugal</th>
<th>Netherlands</th>
<th>Finland</th>
<th>Denmark</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methanol 67-56-1</td>
<td>TWA: 200 ppm TWA: 260 mg/m³</td>
<td>TWA: 200 ppm TWA: 260 mg/m³</td>
<td>Skin</td>
<td>TWA: 200 ppm TWA: 260 mg/m³</td>
<td>TWA: 200 ppm TWA: 260 mg/m³</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Austria</th>
<th>Switzerland</th>
<th>Poland</th>
<th>Norway</th>
<th>Ireland</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methanol 67-56-1</td>
<td>Skin</td>
<td>Skin</td>
<td>STEL 300 mg/m³ TWA: 100 mg/m³</td>
<td>STEL 100 mg/m³</td>
<td>STEL 162.5 mg/m³</td>
</tr>
</tbody>
</table>

**Derived No Effect Level (DNEL)**  
No information available

**Predicted No Effect Concentration (PNEC)**  
No information available.

#### 8.2. Exposure controls

**Engineering Controls**


**Personal Protective Equipment**

- **Eye/face Protection**
  Wear safety glasses with side shields (or goggles).

- **Hand Protection**
  Wear protective nitrile rubber gloves.

- **Skin and body protection**
  Gloves made of plastic or rubber. Wear suitable protective clothing.
**Respiratory protection**

No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required. In case of inadequate ventilation wear respiratory protection.

**Environmental exposure controls**

Use appropriate containment to avoid environmental contamination.

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### SECTION 9: Physical and chemical properties

**9.1. Information on basic physical and chemical properties**

<table>
<thead>
<tr>
<th>Property</th>
<th>Values</th>
<th>Remarks • Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>Liquid</td>
<td></td>
</tr>
<tr>
<td>appearance</td>
<td>colourless, clear, Liquid</td>
<td></td>
</tr>
<tr>
<td>colour</td>
<td>Odour</td>
<td>Alcohol</td>
</tr>
<tr>
<td>odour threshold</td>
<td>No information available</td>
<td></td>
</tr>
<tr>
<td><strong>Property</strong></td>
<td><strong>Values</strong></td>
<td><strong>Remarks • Method</strong></td>
</tr>
<tr>
<td><strong>pH</strong></td>
<td>5.5</td>
<td></td>
</tr>
<tr>
<td><strong>Melting point/freezing point</strong></td>
<td>-48 °C / -54 °F</td>
<td></td>
</tr>
<tr>
<td><strong>Boiling point / boiling range</strong></td>
<td>71 °C / 159 °F</td>
<td></td>
</tr>
<tr>
<td><strong>Flash Point</strong></td>
<td>26 °C / 78 °F</td>
<td>CC (closed cup)</td>
</tr>
<tr>
<td><strong>Evaporation Rate</strong></td>
<td></td>
<td>No information available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td></td>
<td>No information available</td>
</tr>
<tr>
<td>Flammability Limits in Air</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Upper flammability limit</td>
<td>36%</td>
<td>No information available</td>
</tr>
<tr>
<td>Lower Flammability Limit</td>
<td>6.7%</td>
<td>No information available</td>
</tr>
<tr>
<td><strong>vapour pressure</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Vapour Density</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Specific gravity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Water solubility</strong></td>
<td>Miscible in water</td>
<td></td>
</tr>
<tr>
<td>solubility(ies)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Autoignition temperature</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>decomposition temperature</strong></td>
<td>385 °C / 725 °F</td>
<td></td>
</tr>
<tr>
<td><strong>Kinematic viscosity</strong></td>
<td></td>
<td>No information available</td>
</tr>
<tr>
<td><strong>Dynamic viscosity</strong></td>
<td></td>
<td>No information available</td>
</tr>
<tr>
<td><strong>Percent Volatile</strong></td>
<td>&gt; 99%</td>
<td></td>
</tr>
</tbody>
</table>

**9.2. Other information**

| Molecular weight                | No information available | |
| VOC content (%)                 | 53                       | |
| **density**                     | No information available |
| **Bulk Density**                | No information available |

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### SECTION 10: Stability and reactivity

**10.1. Reactivity**

Reactivity

None under normal use conditions

**10.2. Chemical stability**

Stability

Stable under normal conditions.

**Explosion data**

| Sensitivity to Mechanical Impact | None |
| Sensitivity to Static Discharge  | None |

**10.3. Possibility of hazardous reactions**

Possibility of Hazardous Reactions

None under normal use conditions.

**10.4. Conditions to avoid**
ThinPrep® PreservCyt Solution

**Conditions to Avoid**
Heat, flames and sparks.

10.5. Incompatible materials

**Incompatible Materials**

10.6. Hazardous decomposition products

**Hazardous Decomposition Products**
None under normal use conditions.

---

**SECTION 11: Toxicological information**

11.1. Information on toxicological effects

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

**Irritation**
None under normal use conditions

**inhalation**
Harmful by inhalation

**Eye contact**
May cause irritation

**Skin contact**
Harmful in contact with skin

**Ingestion**
Harmful if swallowed

The following values are calculated based on chapter 3.1 of the GHS document

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ATEmix (oral)</td>
<td>94.00</td>
</tr>
<tr>
<td>ATEmix (dermal)</td>
<td>282.00</td>
</tr>
<tr>
<td>ATEmix (inhalation-vapour)</td>
<td>2.82</td>
</tr>
</tbody>
</table>

**Skin corrosion/irritation**
Not Applicable

**Serious eye damage/eye irritation**
Not Applicable

**Sensitisation**
Not Applicable

**Germ cell mutagenicity**
Not Applicable

**Carcinogenicity**
Not Applicable

**Reproductive toxicity**
Not Applicable

**STOT - single exposure**
Not Applicable

**STOT - repeated exposure**
Central nervous system, Eyes, Gastrointestinal tract (GI), Respiratory system, Skin.

**Aspiration hazard**
Not Applicable

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**SECTION 12: Ecological information**

12.1. Toxicity

50.133% of the mixture consists of components(s) of unknown hazards to the aquatic environment

12.2. Persistence and degradability
No information available.

12.3. Bioaccumulative potential
No information available.

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Partition coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methanol</td>
<td>-0.77</td>
</tr>
</tbody>
</table>

12.4. Mobility in soil
No information available.
12.5. Results of PBT and vPvB assessment
This preparation contains no substance considered to be persistent, bio-accumulating nor toxic (PBT). This preparation contains no substance considered to be very persistent nor very bio-accumulating (vPvB).

12.6. Other adverse effects
None

SECTION 13: Disposal considerations

13.1. Waste treatment methods
Waste from Residues / Unused Products
Disposal should be in accordance with applicable regional, national and local laws and regulations.

Contaminated packaging
Dispose of in accordance with federal, state and local regulations.

Other Information
Waste codes should be assigned by the user based on the application for which the product was used.

SECTION 14: Transport information

IMDG
14.1 UN/ID no UN1992
14.2 Proper Shipping Name Flammable liquid, toxic, n.o.s. (Methanol)
14.3 Hazard Class 3
   Subsidiary hazard class 6.1
14.4 Packing Group III
14.5 Marine pollutant Not Applicable
14.6 Special Provisions None
   EmS-No F-E, S-D
14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
   No information available

RID
14.1 UN/ID no UN1992
14.2 Proper Shipping Name Flammable liquid, toxic, n.o.s. (Methanol)
14.3 Hazard Class 3
   Labels 6.1
14.4 Packing Group III
14.5 Environmental Hazard Not Applicable
   Classification code FT1
14.6 Special Provisions None

ADR
14.1 UN/ID no UN1992
14.2 Proper Shipping Name Flammable liquid, toxic, n.o.s. (Methanol)
14.3 Hazard Class 3
   Labels 3 + 6.1
14.4 Packing Group III
14.5 Environmental Hazard Not Applicable
14.6 Special Provisions None
   Classification code FT1
   Tunnel restriction code (D/E)

ICAO (air)
14.1 UN/ID no UN1992
14.2 Proper Shipping Name Flammable liquid, toxic, n.o.s. (Methanol)
14.3 Hazard Class 3
   Subsidiary hazard class 6.1
14.4 Packing Group III
**ThinPrep® PreservCyt Solution**

14.5 Environmental Hazard  
Not Applicable

14.6 Special Provisions  
None

**IATA**

14.1 UN/ID no  
UN1992

14.2 Proper Shipping Name  
Flammable liquid, toxic, n.o.s. (Methanol)

14.3 Hazard Class  
3

Subsidiary hazard class  
6.1

14.4 Packing Group  
III

14.5 Environmental Hazard  
Not Applicable

14.6 Special Provisions  
None

ERG Code  
3P

---

**SECTION 15: Regulatory information**

**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

EU - REACH (1907/2006) - Submitted Annex XV Dossiers for Proposals for Substances of Very High Concern

This product complies with SVHC

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>TSCA</th>
<th>EINECS/ELINCS</th>
<th>DSL/NDSL</th>
<th>PICCS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methanol 67-56-1</td>
<td>Present</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>EDTA Disodium Salt 6381-92-6</td>
<td>-</td>
<td>-</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Glacial Acetic Acid 758-12-3</td>
<td>X</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

Water hazard class (WGK)  
Not determined

TA Luft (German Air Pollution Control Regulation)  
Not determined

**International Inventories**

All of the components in the product are on the following Inventory lists.

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>ENCS</th>
<th>IECSC</th>
<th>AICS</th>
<th>KECL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methanol 67-56-1</td>
<td>Present</td>
<td>X</td>
<td>X</td>
<td>Present</td>
</tr>
<tr>
<td>EDTA Disodium Salt 6381-92-6</td>
<td>-</td>
<td>X</td>
<td>X</td>
<td>-</td>
</tr>
</tbody>
</table>

**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

**15.2. Chemical safety assessment**

Chemical Safety Report  
No information available

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**SECTION 16: Other information**
ThinPrep® PreservCyt Solution

Full text of R-phrases referred to under sections 2 and 3
R10 - Flammable
R23/24/25 - Toxic by inhalation, in contact with skin and if swallowed
R39/23/24/25 - Toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed

Revision date 19-May-2015
Version 1

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

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