HOLOGIC®

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

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.
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1-508-263-2900

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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

This mixture is classified as hazardous according to regulation (EC) No. 1272/2008 [CLP]

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

2.2. Label Elements
Contains Methanol

This mixture is classified as hazardous according to regulation (EC) No. 1272/2008 [CLP].

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
P280 - Wear protective gloves and protective clothing
P260 - Do not breathe dust/fume/gas/mist/vapours/spray
P301 + P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P302 + P350 - IF ON SKIN: Gently wash with plenty of soap and water
P308 + P311 - IF exposed or concerned: Call a POISON CENTER or doctor
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

Mixtures 3.2
Mixtures

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

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 Treat symptomatically.

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

Chemical name	European Union	United Kingdom	France	Spain	Germany
Methanol 67-56-1	TWA: 200 ppm TWA: 260 mg/m³ Skin	STEL: 250 ppm STEL: 333 mg/m³ TWA: 200 ppm TWA: 266 mg/m³ Skin	TWA: 200 ppm TWA: 260 mg/m³ STEL: 1000 ppm STEL: 1300 mg/m³	S* TWA: 200 ppm TWA: 266 mg/m³	TWA: 200 ppm TWA: 270 mg/m³ Ceiling / Peak: 800 ppm Ceiling / Peak: 1080 mg/m³ Skin

Chemical name	Italy	Portugal	Netherlands	Finland	Denmark
Methanol 67-56-1	TWA: 200 ppm TWA: 260 mg/m³ Skin	STEL: 250 ppm TWA: 200 ppm TWA: 260 mg/m³	Skin TWA: 133 mg/m³ TWA: 100 ppm	TWA: 200 ppm TWA: 270 mg/m³ STEL: 250 ppm STEL: 330 mg/m³ Skin	TWA: 200 ppm TWA: 260 mg/m³ Skin

Chemical name	Austria	Switzerland	Poland	Norway	Ireland
Methanol 67-56-1	Skin STEL 800 ppm STEL 1040 mg/m³ TWA: 200 ppm TWA: 260 mg/m³	Skin STEL: 800 ppm STEL: 1040 mg/m³ TWA: 200 ppm TWA: 260 mg/m³	STEL: 300 mg/m³ TWA: 100 mg/m³	TWA: 100 ppm TWA: 130 mg/m³ Skin STEL: 150 ppm STEL: 162.5 mg/m³	TWA: 200 ppm TWA: 260 mg/m³ Skin

Derived No Effect Level (DNEL) No information available

Predicted No Effect Concentration (PNEC) No information available.

8.2. Exposure controls

Engineering Controls Showers. Eyewash stations. Provide adequate ventilation.

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.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Liquid		
appearance	colourless, clear, Liquid	**Odour**	Alcohol
colour	colourless	**odour threshold**	No information available

Property	**Values**	**Remarks • Method**
pH	5.5	
Melting point/freezing point	-48 °C / -54 °F	
Boiling point / boiling range	71 °C / 159 °F	
Flash Point	26 °C / 78 °F	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%	
vapour pressure		No information available
Vapour Density		No information available
Specific gravity		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
Kinematic viscosity		No information available
Dynamic viscosity		No information available
Percent Volatile	> 99%	

9.2. Other information

molecular weight	No information available
VOC content (%)	53
density	No information available
Bulk Density	No information available

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

Conditions to Avoid Heat, flames and sparks.

10.5. Incompatible materials

Incompatible Materials Strong oxidising agents. Acids. Metals.

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

ATEmix (oral)	94.00
ATEmix (dermal)	283.00
ATEmix (inhalation-vapour)	2.83

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	Not Applicable
Target organ effects	Central nervous system, Eyes, Gastrointestinal tract (GI), Respiratory system, Skin.
Aspiration hazard	Not Applicable

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.

Chemical name	Partition coefficient
Methanol	-0.77

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
14.3 Hazard Class	3
Subsidiary hazard class	6.1
14.4 Packing Group	III
Description	UN1992, FLAMMABLE LIQUID, TOXIC, N.O.S (Methanol), 3 (6.1), III, (26°C C.C.)
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
14.3 Hazard Class	3
Labels	3 + 6.1
14.4 Packing Group	III
Description	UN1992, FLAMMABLE LIQUID, TOXIC, N.O.S (Methanol), 3 (6.1), 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
14.3 Hazard Class	3
Labels	3 + 6.1
14.4 Packing Group	III
Description	UN1992, FLAMMABLE LIQUID, TOXIC, N.O.S (Methanol), 3 (6.1), 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
14.3 Hazard Class	3
Subsidiary hazard class	6.1
14.4 Packing Group	III
Description	UN1992, FLAMMABLE LIQUID, TOXIC, N.O.S (Methanol), 3 (6.1), III
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
Description	UN1992, Flammable liquid, toxic, n.o.s (Methanol), 3 (6.1), 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

SVHC

This product does not contain candidate substances of very high concern at a concentration >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59)

Chemical name	French RG number	Title
Methanol 67-56-1	RG 84	

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 .

Chemical 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	-	-

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

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

SECTION 16: Other information

Prepared by Hologic Inc

Revision date 30-May-2018

Version 3

This 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