

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 ${\tt sds@hologic.com}$

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

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

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

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. Lig. 2 (H225)	01-2119433307-44-0 135

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.

Wash off immediately with plenty of water. Skin contact

Eve 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

No information available. **Symptoms**

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 Unsuitable Extinguishing Media Dry chemical, Foam, Carbon dioxide (CO2).

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.

Dam up. Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal Methods for cleaning up

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	TWA: 200 ppm	STEL: 250 ppm	TWA: 200 ppm	S*	TWA: 200 ppm
67-56-1	TWA: 260 mg/m ³	STEL: 333 mg/m ³	TWA: 260 mg/m ³	TWA: 200 ppm	TWA: 270 mg/m ³
	Skin	TWA: 200 ppm	STEL: 1000 ppm	TWA: 266 mg/m ³	Ceiling / Peak: 800
		TWA: 266 mg/m ³	STEL: 1300 mg/m ³		ppm
		Skin			Ceiling / Peak: 1080
					mg/m³
					Skin
		l			

Chemical name	Italy	Portugal	Netherlands	Finland	Denmark
Methanol	TWA: 200 ppm	STEL: 250 ppm	Skin	TWA: 200 ppm	TWA: 200 ppm
67-56-1	TWA: 260 mg/m ³	TWA: 200 ppm	TWA: 133 mg/m ³	TWA: 270 mg/m ³	TWA: 260 mg/m ³
	Skin	TWA: 260 mg/m ³	TWA: 100 ppm	STEL: 250 ppm	Skin
				STEL: 330 mg/m ³	
				Skin	

Chemical nar	ne Austria	Switzerland	Poland	Norway	Ireland
Methanol	Skin	Skin	STEL: 300 mg/m ³	TWA: 100 ppm	TWA: 200 ppm
67-56-1	STEL 800 ppm	STEL: 800 ppm	TWA: 100 mg/m ³	TWA: 130 mg/m ³	TWA: 260 mg/m ³
	STEL 1040 mg/m ³	STEL: 1040 mg/m ³		Skin	Skin
	TWA: 200 ppm	TWA: 200 ppm		STEL: 150 ppm	
	TWA: 260 mg/m ³	TWA: 260 mg/m ³		STEL: 162.5 mg/m ³	

Derived No Effect Level (DNEL) No information available

Predicted No Effect Concentration No information available.

(PNEC)

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

Values Remarks • Method Property

5.5 pН

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%

No information available **Lower Flammability Limit** 6.7% vapour pressure No information available

Vapour Density No information available No information available Specific gravity

Water solubility Miscible in water

solubility(ies) No information available No information available

Partition coefficient

Autoignition temperature 385 °C / 725 °F decomposition temperature No information available

Kinematic viscosity No information available **Dvnamic viscosity** No information available **Percent Volatile** > 99%

9.2. Other information

No information available molecular weight VOC content (%) 53

density No information available

Bulk Density No information available

SECTION 10: Stability and reactivity

10.1. Reactivity

None under normal use conditions Reactivity

10.2. Chemical stability

Stable under normal conditions. stability

Explosion data

None Sensitivity to Mechanical Impact 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

inhalationHarmful by inhalationEye contactMay cause irritationSkin contactHarmful in contact with skinIngestionHarmful if swallowed

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

ATEmix (oral) 94.00 ATEmix (dermal) 282.00 ATEmix (inhalation-vapour) 2.82

Skin corrosion/irritationNot ApplicableSerious eye damage/eye irritationNot ApplicableSensitisationNot ApplicableGerm cell mutagenicityNot ApplicableCarcinogenicityNot Applicable

Reproductive toxicity
STOT - single exposure
STOT - repeated exposure
Not Applicable
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. (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 No information available

Annex II of MARPOL 73/78 and the

IBC Code

<u>RID</u>

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

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

Chemi	cal name	French RG number	Title
Me	thanol	RG 84	
67	7-56-1		

Water hazard class (WGK)

TA Luft (German Air Pollution Control Regulation)

Not determined 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	-	Х	-	-

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

<u>Legend</u>

X - Present

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

⁻ Not Listed

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