

Safety Data Sheet

ThinPrep® CytoLyt Solution

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

Product identifier

Product Name ThinPrep® CytoLyt Solution

Safety data sheet number 85092-001

Recommended use of the chemical and restrictions on use

Specific use(s)

A methanol based, buffered preservative solution used to support cells during transport

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 4
Acute toxicity - Dermal	Category 4
Acute toxicity - Inhalation (Dusts/Mists)	Category 4
Specific target organ toxicity (single exposure)	Category 1
Flammable liquids	Category 3

Emergency Overview

Label elements



Signal word Danger

Hazard statements

H302 - Harmful if swallowed

H312 - Harmful in contact with skin

H332 - Harmful if inhaled

H370 - Causes damage to organs

H225 - Highly flammable liquid and vapor

<u>Precautionary Statements - Prevention</u>

P210 - Keep away from heat/sparks/open flames/hot surfaces. — No smoking

P280 - Wear protective gloves/protective clothing/eye protection/face protection

P264 - Wash face, hands and any exposed skin thoroughly after handling

P270 - Do not eat, drink or smoke when using this product

P260 - Do not breathe dust/fume/gas/mist/vapors/spray

P243 - Take precautionary measures against static discharge

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

Call a POISON CENTER or doctor/physician if you feel unwell

P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell

P330 - Rinse mouth

Fire

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

<u>Precautionary Statements - Storage</u>

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

OSHA Hazard Classification

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

Component name	CAS No	%
Methanol	67-56-1	14 - 25

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.

Indication of any immediate medical attention and special treatment needed

Note to physicians Effects of exposure (inhalation, ingestion or skin contact) to substance may be delayed.

Keep victim warm and quiet. Treat for CNS depression and possible renal failure. Provide general supportive measures and treat symptomatically. Symptons 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, CO2, water spray or alcohol-resistant foam. Water spray, fog or

alcohol-resistant foam. Move containers from fire area if you can do it without risk. Dike fire control water for later disposal; do not scatter the material. Use water spray or fog; do not

use straight streams.

Unsuitable Extinguishing Media CAUTION: All these products have a very low flash point. Use of water spray when fighting

fire may be inefficient.

Specific hazards arising from the

chemical

Vapors may form explosive mixtures with air. Vapors may travel to source of ignition and flash back. Most vapors are heavier than air. They will spread along ground and collect in low or confined areas (sewers, basements, tanks). Vapor explosion hazard indoors, outdoors or in sewers. Those substances designated with a "P" may polymerize explosively when heated or involved in a fire. Runoff to sewer may create fire or explosion hazard.

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

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.

Other Information Water spray may reduce vapor; but may not prevent ignition in closed spaces.

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.

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

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).

Incompatible materials. Strong oxidizing agents. Acids. Aluminum.

SECTION 8: Exposure Controls/Personal Protection.

Exposure Guidelines

United States of America

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

Canada

Component name	British Columbia OEL	Quebec OEL	Ontario TWA
Methanol 67-56-1	TWA: 200 ppm STEL: 250 ppm	TWA: 200 ppm TWA: 262 mg/m ³	TWA: 200 ppm STEL: 250 ppm
07-30-1	Stell 250 ppill Skin	STEL: 250 ppm	Stel. 250 ppm Skin
		STEL: 328 mg/m ³	
		Skin	

Mexico

Component	Carcinogenicity	Exposure Limits
Methanol	-	Mexico: TWA 200 ppm
67-56-1 (14 - 25)		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 protectionTight sealing safety goggles.Skin and body protectionWear suitable protective clothing.Hand ProtectionWear protective gloves.

Not Applicable

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. Handle in

accordance with good industrial hygiene and safety practice.

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, Liquid
Color Colorless
Odor Alcohol-like

Odor threshold No information available

<u>Property</u> <u>Values</u>

pH 7

Melting point/freezing pointNo information availableBoiling point / boiling range64 °C / 147 °FFlash point43 °C / 109 °FMethodCC (closed cup)

Evaporation rate > 1

Flammability (solid, gas) No information available

Flammability Limits in Air

Upper flammability limits 36% Lower flammability limit 6.7%

Vapor pressure127 mmHgVapor density1.1 (Air=1)

Relative density
Specific Gravity
0.97

Water solubility 0.97
Water solubility

Solubility(ies) No information available

Partition coefficient No information available

Autoignition temperature385 °C / 725 °FDecomposition temperatureNo information availableViscosityNo information availableExplosive propertiesNo 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. Avoid temperatures exceeding the flash point. Incompatible

materials.

Incompatible materials. Strong oxidizing agents. Acids. Aluminum.

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 May be harmful by inhalation, ingestion, or skin absorption.

InhalationNone under normal use conditions.Eye contactRisk of serious damage to eyes.Skin ContactNone under normal use conditions.IngestionNone 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.

Irritation May cause skin and eye irritation.

SensitizationNo information available.Germ cell mutagenicityNo information available.CarcinogenicityNo information available.

Reproductive toxicity
STOT - single exposure
STOT - repeated exposure
No information available.
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.

Component name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Sodium Chloride 7647-14-5		12946: 96 h Lepomis macrochirus mg/L LC50 static		1000: 48 h Daphnia magna mg/L EC50 340.7 - 469.2: 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.

Component name	Partition coefficient
Methanol 67-56-1	-0.77
07 00 1	

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

U154 D001

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

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	Toxic	
67-56-1	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: R

Emergency Response Guide

Number

Methanol: RQ kg= 10809.52

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<u>TDG</u>

UN/ID No UN1993

Proper shipping name Flammable liquids, n.o.s. (Methanol)

Hazard Class 3
Packing Group III
Marine pollutant D.

<u>IATA</u>

UN/ID No UN1993

Proper shipping name Flammable liquids, n.o.s. (Methanol)

Hazard Class 3
Packing Group III
ERG Code 3L

<u>IMDG</u>

UN/ID No UN1993

Proper shipping name Flammable liquids, n.o.s. (Methanol)

Hazard Class3Packing GroupIIIEmS-NoF-E, S-E

SECTION 15: Regulatory information

International Inventories

Component name	TSCA	EINECS/ELINCS	DSL/NDSL	PICCS
Water 7732-18-5	Present	X	X	X
Methanol 67-56-1	Present	X	Х	Х

ThinPrep® CytoLyt Solution Magnesium Acetate Present X X X X X 142-72-3

142-72-3	rieseni	^	^	^
Sodium Chloride 7647-14-5	Present	X	X	X
Potassium Chloride 7447-40-7	Present	X	X	X

Component name	ENCS	IECSC	AICS	KECL
Water 7732-18-5	-	X	Х	Present
Methanol 67-56-1	Present	X	Х	Present
Magnesium Acetate 142-72-3	Present	X	X	Present
Sodium Chloride 7647-14-5	Present	X	Х	Present
Potassium Chloride 7447-40-7	Present	X	Х	Present
Calcium Acetate 5743-26-0	-	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	14 - 25	1.0

SARA 311/312 Hazard Categories

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, contains one or more substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302).

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

US State Regulations

California Proposition 65

This product contains the following Proposition 65 chemicals.

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

U.S. State Right-to-Know Regulations

This product may contain substances regulated by state right-to-know regulations.

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

U.S. EPA Label Information

EPA Pesticide Registration Number Not Applicable

International Regulations

Mexico - Grade	Moderate risk, Grade 2		
Comp	onent name	Carcinogenicity	Exposure Limits
M	ethanol	-	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