

Material Safety Data Sheet

HCUTM - Specimen transport and storage container, prefilled with Multipurpose Medium

Version 01

Revision Date 2020. 03. 30

Date of issue : 20. 06. 2019

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

1.1 Product identifier

Trade name :

HCUTM, Specimen transport and storage container, prefilled with Multipurpose Medium

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/Mixture : A specimen transport and storage container, prefilled with multipurpose medium for specimen collection.

1.3 Detail of the supplier of the safety data sheet

Manufacturer/supplier :

Han Chang Medic

79-35, Jang San 2-gil, Susin-myeon Dongnam-gu, Cheonahn-si,

Chungcheongnam- do, Republic of Korea

E-mail address of person in charge; hanchangmedic@gmail.com, +82-41-569-8898

SDS/Contact Person : Mr. OH SE YOUNG

SECTION 2 : Hazard identification

2.1 Classification of the substance or mixture

Classification (Specimen transport and storage container for Medical Device)

Not a hazardous substance or mixture

According to OSHA & TSCA

2.2 Label elements

Labeling (Regulation(EC)No1272/2008)

Not a hazardous substance or mixture according to Regulation(EC) No. 1272/2008

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic(PBT), or very persistent and very bioaccumulate(vPvB) at levels of 0.1%, or Higher No special risks known.

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SECTION 3 : Composition/Information on Ingredients

3.2 Mixtures

Chemical nature : Aqueous solution

Components (1L Per)

Chemical name	CAS-No. Index-No. Registration No,	Concentration
Hank's balanced salt solution		10.33%
BSA (Bovine Serum Albumin)	9048-46-8	10.54%
L-cysteine	616-91-1	0.43%
Gelatin	9000-70-8	0.79%
Sucrose	57-50-1	72.19%
L-glutamic acid	56-86-0	0.74%
HEPES	7365-45-9	3.17%
Sodium bicarbonate	144-55-8	0.37%
Vancomycin	1404-93-9	0.10%
Amphotericin B	1397-89-3	1.31%
Colistin	1264-72-8	0.02%
Phenol Red	143-74-8	0.01%

SECTION 4 : First aid measures

4.1 Description of first aid measure

In case of eye contact : Flush eyes with water as a precaution.

If swallowed : Do NOT induce vomiting
Drink water as a precaution.
Consult a physician if it is necessary

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : Gastrointestinal discomfort

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : No information available

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SECTION 5 : Fire fighting measures

Not applicable due to contain non fire or burning materials.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personnel Precautions : No special precautions required.

6.2 Environmental precautions

Environmental precautions : Avoid subsoil penetration.

6.3 Methods and material for containment and clean up

Method of cleaning up : Wipe up with absorbent materials (e.g. cloth..)

6.4 Reference to other sections

See chapter 13

SECTION 7 : Handling and storage

7.1 Precaution for safe handling : not required under normal use

Advice on safe handling : No special protective measures against fire required.

Hygiene measures : Keep away from food and drink. Keep away from children.

7.2 Condition for safe storage, including any incompatibilities

Requirement for storage : Store at room temperature in the original container.

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Further information on storage : Do not freeze, Keep away from direct sunlight.

Recommended storage temperature : 15 ~ 25°C

Advice on common storage : No materials to be especially mentioned

SECTION 8 : Exposure Controls/Personal protection

8.1 Control Parameters

Substance name	End use	Exposure routes	Potential health effects	Value
Sodium Chloride	Workers	Inhalation	Long term systemic effects, Long term local effects	LD50>10.5mg/L 4hr Rat
	Workers	Skin contact	Long Term systemic effects	LD50>10000mg/kg Rabbit
	Consumers	Inhalation	Long term exposure Short term exposure Local effects	LD50>10.5mg/L 4hr Rat
	Consumers	Skin contact	Long term local effects	LD50>10000mg/kg Rabbit
	Consumers	Injection	Long term exposure Short term exposure Local effects	LD50>3000mg Rat

Derived No Effect Level(DNEL) according to Regulation (EC).No.1907/2006:

Substance name	Environment Compartment	Value
Sodium chloride	Fresh water	10mg/L
	marine water	NA
	Fresh water sediment	7.2 mg/kg
	Marin sediment	0.72mg/kg
	Soil	1.26mg/kg
	Intermittent use/release	3.44mg/L
	Sewage treatment plant	24.5mg/L

Predicted No Effects Concentration according to Regulation (EC) No.1907/2006:

8.2 Exposure control

Personal protective equipment

Protective measures : Avoid contact with eyes

SECTION 9 : Physical and chemical properties

9.1 Information on basic physical properties

Appearance : Liquid
Color : Pink red
Odor : Nearly odorless
Odor Threshold : Not determined
pH : 7.3 ± 0.2 at 25°C

Melting point/freezing point	: ca. 0 °C
Decomposition temperature.	: Not applicable
Flammability (solid, gas)	: Not applicable
Upper explosion limit	: Not applicable
Lower explosion limits	: Not applicable
Vapor pressure	: ca. 25hPa(20 °C) similar to water
Vapor density	: No data available
Relative density.	: ca. 1,005g/cm ³ (20 °C)
Solubility Water solubility	: In all proportions (20 °C)
Partition coefficient (n-octanol/water)	: Not applicable
Auto-ignition temperature	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available

9.2 Other information

No data available

SECTION 10 : Stabilities and reactivity

10.1 Reactivity

No dangerous reaction known under conditions of normal use.

10.2 Chemical stability

The product is chemically stable.

10.3 Possibilities of hazardous reactions

Hazardous reactions : None reasonable foreseeable

10.4 Condition to avoid

Condition to avoid : Do not store at temperature above 30 °C

10.5 Incompatible materials

Materials to avoid : Do not mix with other products

10.6 Hazardous decomposition products

None reasonably foreseeable.

SECTION 11 : Toxicological information

11.1 Information on toxicological effects

Product:

Acute oral toxicity : Not applicable

Components :

Sodium bicarbonate

Acute oral toxicity : LD50>10,000mg/kg Rabbit

Acute inhalation toxicity : LD50>10.5mg/L 4hr Rat

Acute dermal toxicity : LD50>10000mg/kg Rabbit

BSA

Acute oral toxicity : Not applicable

Acute inhalation toxicity : Not applicable

Acute dermal toxicity : Not applicable

11.2 Skin corrosion/irritation

Product:

Result : No skin irritation

Components :

Sodium bicarbonate

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

BSA

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

11.3 Serious eye damage/eye irritation

Product :

Result : Assessment of eye tolerance in rabbits – slightly irritating

Remarks : According to the classification criteria of the EC the product is not considered as an eye irritant.

SECTION 12: Ecological information

12.1 Toxicity

Product:

Toxicity to microorganisms : EC50:> 3.200mg/L

Method : OECD 209

Components:

Sodium chloride

Toxicity to fish : LC50(Leucis idus (Golden orfe)): NA

Exposure time : 96h

Toxicity to daphnia and : EC50:>500mg/L

Other aquatic invertebrates : Exposure time : 48h

Toxicity to algae : EC50(Desmodesmus subspicatus(green algae))
500mg/L, Exposure time : 72h

Toxicity to fish(Chronic toxicity) : NOEC:23mg/L
Exposure time : 34d

Species : Pimephales promelas (fathead minnow)

Toxicity to daphnia and : NOEC: 9.43 mg/L

Other aquatic invertebrates : Exposure time : 34d

(Chronic toxicity) Species : Daphnia magna (Water flea)

BSA

Toxicity to daphnia and : No data

Other aquatic invertebrates

Toxicity to algae : No data

Toxicity to fish(Chronic toxicity). : No data

Toxicity to daphnia and : No data

Other aquatic invertebrates

(Chronic toxicity)

12.2 Persistence and degradability

Product:

Biodegradability : Biodegradation : 90 ~ 100%

Exposure time: 15d

Method: OECD Test Guideline 301A

According to the result of tests of Biodegradability

this product is considered as being readily Biodegradable

Chemical Oxygen Demand : 594 mg/L(COD)

Test substance : 1 % solution.

Components:**Sodium chloride**

Biodegradability : The methods of determining Biodegradability are not applicable to inorganic substance

BSA

Biodegradability : Biodegradation : 90 ~ 100%
Exposure time: 15d

Method: OECD Test Guideline 301A

According to the result of tests of Biodegradability this product is considered as being readily Biodegradable

12.3 Other adverse effects

Product:

Additional ecological : none information

SECTION 13 : Disposal considerations**13.1 Waste treatment methods**

Product : Dispose of the product according to the defined EWC
(European Waste Code)

Contaminated packaging : Take empty packaging to the recycling plant.

Waste key for the unused : European waste catalogue (EWC) 070601

SECTION 14: Transport information**14.1 UN number**

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good

14.3 Transport hazard class(es)

Not regulated as a dangerous good

14.4 Packing group

Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precaution for user

Not applicable

SECTION 15: Regulatory information

15.1 Safety, health and environment regulation/legislation specific for the substance or mixture

REACH – Candidate List of Substance of very High : Not applicable

Concern for Authorization (Article 59)

Regulation (EC) No 850/2004 on persistent organic pollutants : Not applicable

Seveso III : Directive 2012/18/EU of the European Parliament and of the Council on the control of major accident hazards involving dangerous substance.
Not applicable.

Volatile organic compounds : Volatile organic compound(VOC) content: < 3%
Directive 2010/75/EC on the limitation of emission of volatile organic compound.
Not applicable.

Other regulations:

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Take note of Directive 2000/39/EC establishing a first list of indicative occupational exposure limit values

15.2 Chemical safety assessment

Exempt

SECTION 16: Other information

Full text of H-Statement

H302 : Harmful if swallowed

H315 : Cause skin irritation

H319 : Cause skin irritation

H400 : Very toxic to aquatic life
H410 : Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox. : Acute toxicity
Aquatic Acute : Short-term(acute) aquatic hazard
Aquatic Chronic : Long-term(chronic) aquatic hazard
Eye irritation : Eye irritation
Skin irritation : Skin irritation

ADN–European Agreement concerning the international Carriage of Dangerous Goods by inland Waterway; ADR-European Agreement concerning the international Carriage of Dangerous goods by Road; AICS-Austrian Inventory of Chemical Substance; ASTM-American Society for the Testing Materials; bw-Body weight; CLP-Classification Labeling Packaging Regulation; Regulation(EC) No 1272/2008; OECD-Organization for Economic Co-operation and Development REACH-Regulation (EC) 1907/2006 of the European parliament and of the Council concerning the Registration. TSCA-Toxic Substances Control Act(U.S.A): UN-United Nations.

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