

SAFETY DATA SHEET

(REACH regulation (EC) n° 1907/2006 - n° 2015/830)

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product name: UNISEPTA® LIGHT

Product code: 1700000.

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

Disinfection of medical devices

For further information on product indication, please see the label.

1.3. Details of the supplier of the safety data sheet

Registered company name: USF HEALTHCARE S.A.

Address: Rue François-Perreard 18.CH-1225.CHENE-BOURG.SWITZERLAND.

Telephone: +41 22 839 79 00. Fax: +41 22 839 79 10.

e-mail:info@usfhc.com www.usfhealthcare.com

1.4. Emergency telephone number: 145 ou +41 1 251 51 51.

Association/Organisation: CSIT (Tox) / STIZ (Tox-Zentrum) / STIC (The Tox).

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

In compliance with EC regulation No. 1272/2008 and its amendments.

Flammable liquid, Category 3 (Flam. Liq. 3, H226).

Hazardous to the aquatic environment - Chronic hazard, Category 3 (Aquatic Chronic 3, H412).

This mixture does not present a health hazard with the exception of possible occupational exposure thresholds (see paragraphs 3 and 8).

2.2. Label elements

In compliance with EC regulation No. 1272/2008 and its amendments.

Hazard pictograms :



GHS02

Signal Word:

WARNING

Hazard statements :

H226 Flammable liquid and vapour.

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements - General:

P102 Keep out of reach of children.

Precautionary statements - Prevention :

P210 Keep away from sparks and open flames. No smoking.

P261 Avoid breathing product from spraying.
P273 Avoid release to the environment.

P280 Wear protective gloves.

Precautionary statements - Storage:

P403 Store in a well-ventilated place.

Precautionary statements - Disposal:

P501 Dispose of unused product and its container as hazardous waste.

2.3. Other hazards

The mixture does not contain substances classified as 'Substances of Very High Concern' (SVHC) >= 0.1% published by the European CHemicals Agency (ECHA) under article 57 of REACH: http://echa.europa.eu/fr/candidate-list-table

No other hazard identified in the current state of knowledge.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Title for H and EUH statements: see § 16.

3.2. Mixtures

Composition:

Identification	(EC) 1272/2008	Note	%
CAS: 64-17-5	GHS07, GHS02	[1]	10 <= x % < 25
EC: 200-578-6	Dgr		
REACH: 01-2119457610-43	Flam. Liq. 2, H225		
	Eye Irrit. 2, H319		
ETHYL ALCOHOL			
CAS: 27083-27-8	GHS06, GHS05, GHS09, GHS08	[2]	0 <= x % < 2.5
	Dgr		
POLYHEXAMETHYLENE BIGUANIDE	Acute Tox. 4, H302		
HYDROCHLORIDE	Skin Sens. 1, H317		
	Eye Dam. 1, H318		
	Acute Tox. 2, H330		
	Carc. 2, H351		
	STOT RE 1, H372		
	Aquatic Acute 1, H400		
	M Acute = 10		
	Aquatic Chronic 1, H410		
	M Chronic = 10		
CAS: 7173-51-5	GHS06, GHS05, GHS09		0 <= x % < 2.5
EC: 230-525-2	Dgr		
	Acute Tox. 3, H301		
DIDECYLDIMETHYLAMMONIUM	Skin Corr. 1B, H314		
CHLORIDE	Aquatic Acute 1, H400		
	M Acute = 10		
	Aquatic Chronic 1, H410		
	M Chronic = 1		

Information on ingredients :

[1] Substance for which maximum workplace exposure limits are available.

[2] Carcinogenic, mutagenic or reprotoxic (CMR) substance.

CAS: 67-63-0	PROPAN-2-OL
EC: 200-661-7	
CAS: 67-63-0 REACH:	[1]
01-2119457558-25 : GHS02,	
GHS07 Dgr Flam. Liq. 2:	
H225 ; Eye Irrit. 2 : H319	
; STOT SE 3 : H336	
x % < 1	

SECTION 4: FIRST AID MEASURES

As a general rule, in case of doubt or if symptoms persist, always call a doctor.

NEVER induce swallowing by an unconscious person.

4.1. Description of first aid measures

In the event of exposure by inhalation:

Move the person away from the place of exposure and take him/her outside.

In the event of splashes or contact with eyes :

If applicable, remove contact lenses.

Wash thoroughly with soft clean water for 15 minutes, holding the eyelids open.

If there is any redness, pain or visual impairment, consult an ophthalmologist. Show this container or label.

In the event of splashes or contact with skin:

Remove all contaminated or stained clothing immediately. Do not use them again until they have been decontaminated.

Rinse immediately and thoroughly with water.

In the event of skin irritation, seek medical advice. Show this container or label.

In the event of swallowing:

Rinse out the mouth, do not induce vomiting, keep the person calm and take him/her to a clinic or a doctor's. Show the container or label.

4.2. Most important symptoms and effects, both acute and delayed

Cf. § 11

4.3. Indication of any immediate medical attention and special treatment needed

Refer to the recommendation of the doctor.

SECTION 5: FIREFIGHTING MEASURES

Flammable.

Move oxidising products away from the fire.

Move any flammable materials away from the fire.

5.1. Extinguishing media

Suitable methods of extinction

Prevent the effluent of fire-fighting measures from entering drains or waterways.

Use powder or foam extinguishers.

Special foams for polar liquids, powders and carbon dioxide.

Unsuitable methods of extinction

In the event of a fire, do not use:

- water jet

5.2. Special hazards arising from the substance or mixture

A fire will often produce a thick black smoke. Exposure to decomposition products may be hazardous to health.

Do not breathe in smoke.

5.3. Advice for firefighters

Fire-fighting personnel are to be equipped with autonomous insulating breathing apparatus.

Full protective suit.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Consult the safety measures listed under headings 7 and 8.

Keep away any unprotected person.

Move all flammable sources out of danger and keep them away from the scene.

Eliminate any possible source of ignition and ventilate the premises.

6.2. Environmental precautions

Contain and control the leaks or spills with non-combustible absorbent materials such as sand, earth, vermiculite, diatomaceous earth in drums for waste disposal.

Do not get rid in natural spaces (waterways, ground and vegetations...)

6.3. Methods and material for containment and cleaning up

Absorb any spilled product with absorbent non-combustible materials, and sweep away or remove with a shovel. Put any waste in drums for disposal. Do not mix with any other waste. Wash the contaminated surface thoroughly with water.

For small quantities, dilute the product with large quantities of water and rinse away.

Do not collect the product for re-use.

Do not get rid in natural spaces.

6.4. Reference to other sections

Disposal considerations: see section 13.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Avoid all contact with skin or eyes.

Handle in accordance with user instructions on label

Handle at a temperature not exceeding 45° C.

During spray, handle in a well ventilated place (10 to 15 air changes per hour).

Do not breathe in the aerosols and spray mists.

Fire prevention:

Keep packages tightly closed and away from sources of heat, sparks and naked flames.

Do not use tools which may produce sparks. Do not smoke.

Prevent access by unauthorised personnel.

Keep away from sources of ignition - no smoking.

Keep away from flammable materials

Recommended equipment and procedures :

For personal protection, see section 8.

Observe precautions stated on label and also industrial safety regulations.

Packages which have been opened must be reclosed carefully and stored in an upright position.

Water source nearby.

Ensure room is well ventilated.

Prohibited equipment and procedures :

No smoking, eating or drinking in areas where the mixture is used.

7.2. Conditions for safe storage, including any incompatibilities

Keep the container tightly closed

Keep in the original container only, in a cool and well-ventilated place, away from all sources of ignition, heat and direct sunlight.

Recommended storage temperature: from +5°C to +25°C.

Do not use after the expiry date mentioned on the packaging.

Keep out of the reach of children

Store away from incompatible materials (see section 10)

7.3. Specific end use(s)

For professional use only

Refer to paragraph 1 for product indication

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

The information in this chapter refers to the product specifically described in this document. If the product is handled and/or exposed simultaneously with other chemical agents, these must be taken into consideration when choosing personal safety equipment.

The Exposure Threshold Limit Value and the Average Exposure Value given below are quoted by the CAS number of the substance. Paragraph 3 details the chemical name corresponding to the CAS number.

8.1. Control parameters

Occupational exposure limits :

- Germany - AGW (BAuA - TRGS 900, 21/06/2010) :

CAS	VME:	VME:	Excess	Notes		
67-63-0	200 ml/m3	500 mg/m3	2(II)	DFG, Y		
64-17-5		500 ppm		2(II)		
		960 mg/m3				
- Belgium	(Order of 19/05/2009, 2	2010) :				
CAS	TWA:	STEL:	Ceiling:	Definition :	Criteria :	
67-63-0	400 ppm	500 ppm	-	-	-	
64-17-5	1000 ppm					
	1907 mg/m3					
- France (INRS - ED984 :2012) :	•		·		
CAS	VME-ppm:	VME-mg/m3:	VLE-ppm:	VLE-mg/m3:	Notes:	TMP No:
67-63-0	-	-	400	980	-	84
64-17-5	1000	1900	5000	9500	-	84
- Spain (Ir	nstituto Nacional de Seg	guridad e Higiene en	el Trabajo (INSHT),	Mayo 2010):	·	·
CAS	TWA:	STEL:	Ceiling:	Definition :	Criteria :	
67-63-0	400 ppm	500 ppm	-	-	-	
64-17-5	1000 ppm					

	1910 mg/m3
- Poland (2014)	

CAS	TWA:	STEL:	Ceiling:	Definition :	Criteria :
67-63-0	900 mg/m3	1200 mg/m3	-	-	-
64-17-5	1900 mg/m3				

- Czech Republic (Regulation No. 361/2007) :

CAS	TWA:	STEL:	Ceiling :	Definition :	Criteria :
67-63-0	500 mg/m3	1000 mg/m3	-	-	-
64-17-5	1000 mg/m3	3000 mg/m3			

- Slovakia (Regulation No. 300/2007) :

- Siovakia (Neg	guiation 190. 300/2007	<i>)</i> ·			
CAS	TWA:	STEL:	Ceiling :	Definition :	Criteria :
67-63-0	200 ppm	500 mg/m3	II1		
64-17-5	500 ppm	1920 mg/m3			
	960 mg/m3				

⁻ Switzerland (SUVA 2015) :

UNISEPTA® LIGHT - 1700000

CAS	VME	VLE	Valeur plafond	Notations		
67-63-0	500	200	1000	400	4x15	В
64-17-5	500 ppm	1000 ppm		SSC		
	960 mg/m3	1920 mg/m3				

- UK / WEL (Workplace exposure limits, EH40/2005, 2007):

CAS	TWA:	STEL:	Ceiling :	Definition :	Criteria :	
64-17-5	1000 ppm					
	1920 mg/m3					

8.2. Exposure controls

Appropriate engineering controls

Ensure the rooms are well-ventilated. Atmospheric concentrations at the workplace must not exceed the limit values given for normal conditions of use

- Eye / face protection

Avoid contact with eyes.

Water source nearby.

- Hand protection

Recommended properties:

- Impervious gloves in accordance with standard EN374

Due to the solvents present neoprene or nitrile type gloves are recommended.

Gloves must be replaced immediately if they show signs of wear and tear.

- Body protection

Work clothing worn by personnel shall be laundered regularly.

After contact with the product, all parts of the body that have been soiled must be washed.

- Respiratory protection

In case of insufficient ventilation, with the risk of exceeding the TLVs (Treshold Limit Values)/TWA, wear suitable breathing apparatus.

Particularly breathing apparatus, A2P2 type

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

General information :

Physical state :	Fluid liquid.
Colour:	colourless
Odour:	sweet-smelling

Important health, safety and environmental information

pH:	5.40 .
	Neutral.
Boiling point/boiling range :	Not specified.
Flash Point Interval :	23°C <= FP <= 55°C
Vapour pressure (50°C):	Not relevant.
Density:	+/- 1.0
Water solubility:	Soluble.
Melting point/melting range :	Not specified.
Self-ignition temperature :	Not specified.
Decomposition point/decomposition range :	Not specified.

9.2. Other information

The pH stated in section 9.1 is an indicative value. Below the minimum and maximum product pH:

pri paro produot.	pH pure product:	4,7 - 6,1
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SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

No hazardous reaction if the instructions/indications for storage and handling are respected.

10.2. Chemical stability

This mixture is stable under the recommended handling and storage conditions in section 7.

10.3. Possibility of hazardous reactions

Cf. § 10.1 and 10.2

10.4. Conditions to avoid

Avoid .

- frost

UNISEPTA® LIGHT - 1700000

Do not spray onto a flame or any other incandescent objects.

Avoid exposure to heat.

10.5. Incompatible materials

Any material sensitive to alcohols

Do not mix with other products.

10.6. Hazardous decomposition products

At high temperatures, dangerous decomposition products may be produced, such as fumes, carbon dioxide and carbon monoxide, nitrogen oxide.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

11.1.1. Substances

Not specified

11.1.2. Mixture

The toxicological data of the mixture (resulting from studies or in accordance with conventional methods) are outlined below.

Acute toxicity:

Acute toxicity estimate (ATE)*:

Oral ATE:

> 2000 mg/kg

* according to the method of calculation describe in the CLP regulation (Classification, Labelling, Packaging) Part 3 Chapter 3.1 based on the data of the different components present in the product.

Ingestion may lead to irritation of the buccal cavity.

Sore throat, abdominal pain, nausea.

Skin corrosion/skin irritation:

Possibility of itching with light to moderate local redness.

Serious damage to eyes/eye irritation :

May lead to slight ocular irritation: redness of the conjonctiva and lacrimation.

Respiratory or skin sensitisation:

Product not classified in this hazard category.

Germ cell mutagenicity:

Product not classified in this hazard category.

Carcinogenicity:

Product not classified in this hazard category.

Reproductive toxicant:

Product not classified in this hazard category.

Specific target organ systemic toxicity - single exposure :

Product not classified in this hazard category.

Specific target organ systemic toxicity - repeated exposure :

Product not classified in this hazard category.

Aspiration hazard :

Product not classified in this hazard category.

SECTION 12: ECOLOGICAL INFORMATION

Following information is based on data from the compounds.

Avoid any product release into waterways.

12.1. Toxicity

12.1.1. Substances

Not specified

12.1.2. Mixtures

Chronic toxicity:

Harmful to aquatic life with long lasting effects.

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available

12.5. Results of PBT and vPvB assessment

No data available.

12.6. Other adverse effects

No data available.

SECTION 13: DISPOSAL CONSIDERATIONS

Proper waste management of the mixture and/or its container must be determined in accordance with Directive 2008/98/EC.

The packages must not be reused.

Do not pour into waterways.

13.1. Waste treatment methods

Waste:

Waste management is carried out without endangering human health, without harming the environment and, in particular without risk to water, air, soil, plants or animals.

Recycle or dispose of waste in compliance with current legislation, preferably via a certified collector or company.

Soiled packaging:

Empty container completely. Keep label(s) on container.

Give to a certified disposal contractor.

Codes of wastes (Decision 2001/573/EC, Directive 2006/12/EEC, Directive 94/31/EEC on hazardous waste):

18 01 06 * chemicals consisting of or containing dangerous substances

For information:

The waste code is given for indicative purposes.

The waste code must be determined by the user, according to the application of the product.

18 = Wastes from human or animal health care and/or related research (except kitchen and restaurant wastes not arising from immediate health care)

SECTION 14: TRANSPORT INFORMATION

Transport product in compliance with provisions of the ADR for road, RID for rail, IMDG for sea and ICAO/IATA for air transport (ADR 2015 - IMDG 2014 - ICAO/IATA 2015).

14.1. UN number

1170

14.2. UN proper shipping name

UN1170=ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)

14.3. Transport hazard class(es)

- Classification :



3

14.4. Packing group

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14.5. Environmental hazards

14.6. Special precautions for user

ADR/RID	Class	Code	Pack gr.	Label	Ident.	LQ	Provis.	EQ	Cat.	Tunnel
	3	F1	III	3	30	5 L	144 601	E1	3	D/E
IMDG	Class	2°Label	Pack gr.	LQ	EMS	Provis.	EQ		·	
	3	-	III	5 L	F-E,S-D	144 223	E1			
IATA	Class	2°Label	Pack gr.	Passager	Passager	Cargo	Cargo	note	EQ	
	3	-	III	355	60 L	366	220 L	A3 A58 A180	E1	
	3	-	III	Y344	10 L	-	-	A3 A58 A180	E1	

For limited quantities, see part 2.7 of the OACI/IATA and chapter 3.4 of the ADR and IMDG.

For excepted quantities, see part 2.6 of the OACI/IATA and chapter 3.5 of the ADR and IMDG.

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

SECTION 15: REGULATORY INFORMATION

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

- Classification and labelling information included in section 2:

The following regulations have been used:

Regulation (EC) No. 1272/2008 and its amendments.

15.2. Chemical safety assessment

Information from the chemical safety assessment of substances present in the product is included in the appropriate sections of this safety data sheet, whenever necessary.

SECTION 16: OTHER INFORMATION

Since the user's working conditions are not known by us, the information supplied on this safety data sheet is based on our current level of knowledge and on national and community regulations.

It is at all times the responsibility of the user to take all necessary measures to comply with legal requirements and local regulations.

The information in this safety data sheet must be regarded as a description of the safety requirements relating to the mixture.

It is recommended that the information contained in this safety data sheet is provided to the users, if necessary in an appropriate form.

This information relates to the specifically designated product and may not be valid in combination with any another product. The product must not be used for applications other than those specified in heading 1 without having first obtained written handling instructions.

UPDATES SINCE PREVIOUS VERSION

- § 1

Wording of the phrases mentioned in section 3:

	•					
H225	Highly flammable liquid and vapour.					
H301	Toxic if swallowed.					
H302	Harmful if swallowed.					
H314	Causes severe skin burns and eye damage.					
H317	May cause an allergic skin reaction.					
H318	Causes serious eye damage.					
H319	Causes serious eye irritation.					
H330	Fatal if inhaled.					
H351	Suspected of causing cancer .					
H372	Causes damage to organs through prolonged or repeated exposure .					
H400	Very toxic to aquatic life.					
H410	Very toxic to aquatic life with long lasting effects.					

H336 May cause drowsiness or dizziness.

Abbreviations :

CMR: Carcinogenic, mutagenic or reprotoxic.

ADR: European agreement concerning the international carriage of dangerous goods by Road.

IMDG: International Maritime Dangerous Goods. IATA: International Air Transport Association. ICAO: International Civil Aviation Organisation

RID: Regulations concerning the International carriage of Dangerous goods by rail.

GHS02 : Flame