

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006 (REACH)

**Revision date:** 15-Mar-2017

**Print date:** 15-Mar-2017

**Version:** 1.0

Page 1/8



## HISTOLITH NaOCl 1%

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

#### 1.1 Product identifier

**Trade name/designation:**

HISTOLITH NaOCl 1%

**Article No.:**

0032342 (200 ml), 0032343 (500 ml)

**Additional information:**

Voluntary safety information following the Safety Data Sheet format according to Regulation (EC) No. 1907/2006 (REACH). As a medical device this product is not subject to Regulation (EC) no. 1272/2008 [CLP] and do not require labeling according this regulation.

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

**Use of the substance/mixture:**

Medical device for dental application. Observe instructions for use.  
For professional use only.

#### 1.3 Details of the supplier of the safety data sheet

**Manufacturer/Supplier:**

**lege artis Pharma GmbH + Co. KG**

Breitwasenring 1  
72135 Dettenhausen  
GERMANY

**Telephone:** +49 (0) 71 57 / 56 45 - 0

**Telefax:** +49 (0) 71 57 / 56 45 - 50

**E-mail:** info@legeartis.de

**Website:** www.legeartis.de

**E-mail (competent person):** sicherheitsdatenblaetter@legeartis.de

#### 1.4 Emergency phone number

24h: +49 (0) 551 / 192 40, +49 (0) 71 57 / 56 45 - 0 (Only available during office hours.)

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

**Classification according to Regulation (EC) No. 1272/2008 [CLP]:**

Hazard classes and hazard categories	Hazard statements	Classification procedure
Skin corrosion/irritation ( <i>Skin Irrit. 2</i> )	H315: Causes skin irritation.	Calculation
Serious eye damage/eye irritation ( <i>Eye Irrit. 2</i> )	H319: Causes serious eye irritation.	Calculation

**Additional information:**

Contains: Sodium hypochlorite solution

Warning! Do not use together with other products. May release dangerous gases (chlorine).

Precautionary statements:

Avoid release to the environment. Wear protective gloves/protective clothing/eye protection/face protection. IF ON SKIN: Wash with plenty of water. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get immediate medical advice/attention.

#### 2.2 Label elements

**Labelling according to Regulation (EC) No. 1272/2008 [CLP]**

According to EC directives or the corresponding national regulations the product does not have to be labelled.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006 (REACH)

**Revision date:** 15-Mar-2017

**Print date:** 15-Mar-2017

**Version:** 1.0

Page 2/8



## HISTOLITH NaOCl 1%

### 2.3 Other hazards

#### Adverse environmental effects:

Harmful to aquatic organisms.

## SECTION 3: Composition / information on ingredients

### 3.2 Mixtures

#### Description:

Sodium hypochlorite (NaOCl) in aqueous solution, alkaline

#### Ingredients:

Product identifiers	Substance name Classification according to Regulation (EC) No. 1272/2008 [CLP]	Content
<b>CAS No.:</b> 7681-52-9 <b>EC No.:</b> 231-668-3	<b>Sodium hypochlorite (active chlorine)</b> Skin Corr. 1B, Met. Corr. 1, Aqua. Acute 1, Aqua. Chronic 2 <b>Danger</b> H290-H314-H400-H411-EUH031 M-factor: 10	≈ 1 Wt %

Full text of H- and EUH-phrases: see section 16.

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

#### General information:

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible). Take off immediately all contaminated clothing. If unconscious place in recovery position and seek medical advice. Do not leave affected person unattended.

#### Following inhalation:

No special measures are necessary.

In case of inhaling spray mist, consult a physician. Provide fresh air.

#### In case of skin contact:

Wash with plenty of water. In case of skin irritation, consult a physician.

#### After eye contact:

Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.

Continue rinsing. Get immediate medical advice/attention.

#### After ingestion:

Rinse mouth thoroughly with water. Let water be drunk in little sips (dilution effect). Get medical advice/attention if you feel unwell.

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

Causes serious eye irritation. Causes skin irritation.

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

Treat symptomatically.

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

#### Suitable extinguishing media:

Product does not burn. Use extinguishing measures to suit surroundings.

### 5.2 Special hazards arising from the substance or mixture

No special fire protection measures are necessary.

#### Hazardous combustion products:

In case of fire may be liberated: hydrogen chloride (HCl), Chlorine (Cl<sub>2</sub>), Sodium hydroxide.

### 5.3 Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing.

Suppress gases/vapours/mists with water spray jet.

### 5.4 Additional information

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006 (REACH)

**Revision date:** 15-Mar-2017

**Print date:** 15-Mar-2017

**Version:** 1.0

Page 3/8



## HISTOLITH NaOCI 1%

### SECTION 6: Accidental release measures

#### 6.1 Personal precautions, protective equipment and emergency procedures

##### 6.1.1 For non-emergency personnel

**Personal precautions:**

Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid contact with eyes and skin. Special danger of slipping by leaking/spilling product. Remove persons to safety.

**Protective equipment:**

Wear protective gloves/protective clothing/eye protection/face protection.

##### 6.1.2 For emergency responders

**Personal protection equipment:**

Personal protection equipment: see section 8

#### 6.2 Environmental precautions

Do not allow to enter into surface water or drains.

#### 6.3 Methods and material for containment and cleaning up

**For containment:**

Wipe up with absorbent material (eg. cloth, fleece). Handling larger quantities: Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents).

**For cleaning up:**

Water (with cleaning agent)

#### 6.4 Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

#### 6.5 Additional information

Use appropriate container to avoid environmental contamination.

### SECTION 7: Handling and storage

#### 7.1 Precautions for safe handling

**Protective measures**

**Advices on safe handling:**

Avoid contact with eyes and skin. Take off immediately all contaminated clothing. Wear personal protection equipment (refer to section 8).

**Fire prevent measures:**

No special measures are necessary.

**Environmental precautions:**

Discharge into the environment must be avoided.

**Advices on general occupational hygiene**

When using do not eat, drink or smoke. Wash hands and face before breaks and after work and take a shower if necessary. Wash contaminated clothing before reuse. Apply skin care products after work.

#### 7.2 Conditions for safe storage, including any incompatibilities

**Technical measures and storage conditions:**

Keep container tightly closed in a cool, well-ventilated place.

Conditions to avoid: Heat, Light, UV-radiation/sunlight, Temperature > 25 °C (slow decomposition).

Recommended storage temperature: ≤ 25 °C

**Requirements for storage rooms and vessels:**

Floors should be impervious, resistant to liquids and easy to clean. Do not store together with: Acids.

Keep/Store only in original container.

**Hints on storage assembly:**

Do not store together with: Acids, Reducing agent

Keep away from food, drink and animal feedingstuffs.

**Storage class:** 8B - Non-combustible corrosive substances

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006 (REACH)

Revision date: 15-Mar-2017

Print date: 15-Mar-2017

Version: 1.0

Page 4/8



## HISTOLITH NaOCI 1%

### 7.3 Specific end use(s)

#### Recommendation:

Medical device for dental application.  
Observe instructions for use.

## SECTION 8: Exposure controls / Personal protection

### 8.1 Control parameters

No data available.

### 8.2 Exposure controls

#### 8.2.1 Appropriate engineering controls

Technical measures and the application of suitable work processes have priority over personal protection equipment.

#### 8.2.2 Personal protection equipment



#### Eye/face protection:

Eye glasses with side protection (EN 166).

#### Skin protection:

Tested protective gloves must be worn (EN 374).

Suitable material: NBR (Nitrile rubber)

Thickness of the glove material:  $\geq 0,11$  mm

Breakthrough time (maximum wearing time):  $\geq 480$  min

The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. The exact break trough time has to be obtained from the protective glove manufacturer and must be observed. Check leak tightness/ impermeability prior to use. In the case of wanting to use the gloves again, clean them before taking off and air them well.

#### Respiratory protection:

Usually no personal respirative protection necessary. Provide adequate ventilation.

Wear breathing apparatus if exposed to vapours/dusts/aerosols.

#### Other protection measures:

Wear suitable protective clothing.

#### 8.2.3 Environmental exposure controls

No data available.

### 8.3 Additional information

No data available.

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

**Physical state:** liquid

**Colour:** colourless - light yellow

**Odour:** easily perceived like Chlorine (Cl<sub>2</sub>)

#### Safety relevant basic data

Parameter		at	Method	Remark
pH	11.8	20 °C		
Melting point	<i>not determined</i>			
Freezing point	<i>not determined</i>			
Initial boiling point and boiling range	$\geq 100$ °C			
Decomposition temperature	<i>not determined</i>			
Flash point	<i>not applicable</i>			
Evaporation rate	<i>not determined</i>			

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006 (REACH)

**Revision date:** 15-Mar-2017

**Print date:** 15-Mar-2017

**Version:** 1.0



Page 5/8

## HISTOLITH NaOCl 1%

Parameter		at	Method	Remark
Ignition temperature	<i>not applicable</i>			
Upper/lower flammability or explosive limits	<i>not applicable</i>			
Vapour pressure	<i>not determined</i>			
Vapour density	<i>not determined</i>			
Density	1.02 g/ml	20 °C		
Bulk density	<i>not applicable</i>			
Water solubility	completely miscible			
Partition coefficient: n-octanol/water	<i>not determined</i>			
Dynamic viscosity	<i>not determined</i>			
Kinematic viscosity	<i>not determined</i>			

### 9.2 Other information

No data available.

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

See section 10.3

### 10.2 Chemical stability

Slow decomposition: > 25 °C

### 10.3 Possibility of hazardous reactions

No hazardous reaction when handled and stored according to provisions.

Reaction / Violent reaction with: Acids. Formation of: Chlorine (Cl<sub>2</sub>)!

Reaction with: Reducing agent, metals (including their alloys)

### 10.4 Conditions to avoid

Light, UV-radiation/sunlight, Temperature > 25 °C (slow decomposition).

Impurities may cause catalytic decomposition.

### 10.5 Incompatible materials

Acids; Reducing agent; Metals (including their alloys): Cu, Ni, Co. Fabrics, textiles and apparel.

### 10.6 Hazardous decomposition products

In case of fire may be liberated: hydrogen chloride (HCl), Chlorine (Cl<sub>2</sub>), Sodium hydroxide.

### Further information

No data available.

## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

#### Acute oral toxicity:

Based on available data, the classification criteria are not met.

#### Acute dermal toxicity:

Based on available data, the classification criteria are not met.

#### Acute inhalation toxicity:

Based on available data, the classification criteria are not met.

#### Skin corrosion/irritation:

Causes skin irritation.

#### Eye damage/irritation:

Causes serious eye irritation.

#### Respiratory or skin sensitisation:

Based on available data, the classification criteria are not met.

#### Germ cell mutagenicity:

Based on available data, the classification criteria are not met.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006 (REACH)

**Revision date:** 15-Mar-2017

**Print date:** 15-Mar-2017

**Version:** 1.0

Page 6/8



## HISTOLITH NaOCl 1%

### **Carcinogenicity:**

Based on available data, the classification criteria are not met.

### **Reproductive toxicity:**

Based on available data, the classification criteria are not met.

### **STOT-single exposure:**

Based on available data, the classification criteria are not met.  
aerosol or mist formation: May cause respiratory irritation.

### **STOT-repeated exposure:**

Based on available data, the classification criteria are not met.

### **Aspiration hazard:**

Based on available data, the classification criteria are not met.

### **Additional information:**

No data available.

## SECTION 12: Ecological information

### **12.1 Toxicity**

#### **Aquatic toxicity:**

Harmful to aquatic organisms.

### **12.2 Persistence and degradability**

No data available.

### **12.3 Bioaccumulative potential**

#### **Accumulation / Evaluation:**

No indication of bioaccumulation potential.

### **12.4 Mobility in soil**

No data available.

### **12.5 Results of PBT and vPvB assessment**

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

### **12.6 Other adverse effects**

No data available.

## SECTION 13: Disposal considerations

### **13.1 Waste treatment methods**

#### **Waste treatment options**

#### **Appropriate disposal / Product:**

Dispose of waste according to applicable legislation. Consult the appropriate local waste disposal expert about waste disposal.

#### **Appropriate disposal / Package:**

Completely emptied packages can be recycled.

#### **Other disposal recommendations:**

The allocation of waste code numbers / waste names must be carried out in accordance with the European Waste Catalogue (EWC). Collect in closed and suitable containers for disposal.

### **13.2 Additional information**

Waste for disposal is to be classified and labelled.

## SECTION 14: Transport information

Land transport (ADR / RID)	Inland waterway craft (ADN)	Sea transport (IMDG)	Air transport (ICAO-TI / IATA-DGR)
<b>14.1 UN-No.</b>			
1791	1791	1791	1791

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006 (REACH)

Revision date: 15-Mar-2017





Print date: 15-Mar-2017

Version: 1.0

Page 7/8



## HISTOLITH NaOCl 1%

Land transport (ADR / RID)	Inland waterway craft (ADN)	Sea transport (IMDG)	Air transport (ICAO- TI / IATA-DGR)
<b>14.2 UN proper shipping name</b>			
HYPOCHLORITE SOLU- TION	HYPOCHLORITE SOLU- TION	HYPOCHLORITE SOLU- TION	HYPOCHLORITE SOLU- TION
<b>14.3 Transport hazard class(es)</b>			
 8	 8	 8	 8
<b>14.4 Packing group</b>			
III	III	III	III
<b>14.5 Environmental hazards</b>			
No	No	No	No
<b>14.6 Special precautions for user</b>			
<b>Special provisions:</b> 521 <b>Limited Quantity (LQ):</b> 5 L <b>Hazard identification number (KemlerNo.):</b> 80 <b>Classification code:</b> C9 <b>Tunnel restriction code:</b> E <b>Remark:</b> -	<b>Special provisions:</b> not determined <b>Limited Quantity (LQ):</b> not determined <b>Classification code:</b> C9 <b>Remark:</b> -	<b>Special provisions:</b> not determined <b>Limited Quantity (LQ):</b> not determined <b>EmS-No.:</b> F-A; S-B <b>Remark:</b> -	<b>Special provisions:</b> not determined <b>Limited Quantity (LQ):</b> not determined <b>Remark:</b> -

### 14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code

not applicable

#### Additional information:

Small amounts: Transport as "Limited Quantity" according to chapter 3.4 ADR/RID / Transport as "Excepted Quantity" according to chapter 3.5 ADR/RID.

## SECTION 15: Regulatory information

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

#### 15.1.1 EU legislation

##### Other EU regulations:

Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work Observe restrictions to employment for juvenils according to the 'juvenile work protection guideline' (94/33/EC). Directive 93/42/EEC concerning medical devices.

#### 15.1.2 National regulations

No data available.

### 15.2 Chemical Safety Assessment

No data available.

### 15.3 Additional information

No data available.



# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006 (REACH)

**Revision date:** 15-Mar-2017

**Print date:** 15-Mar-2017

**Version:** 1.0

Page 8/8



## HISTOLITH NaOCl 1%

### SECTION 16: Other information

#### 16.1 Indication of changes

No data available.

#### 16.2 Abbreviations and acronyms

See overview table at [www.euphrac.eu](http://www.euphrac.eu)

#### 16.3 Key literature references and sources for data

European Chemicals Agency (ECHA): <http://www.echa.europa.eu>

ECHA, C&L Inventory: <http://echa.europa.eu/information-on-chemicals/cl-inventory-database>

ECHA, Registered substances: <http://echa.europa.eu/information-on-chemicals/registered-substances>

GESTIS (Gefahrstoffinformationssystem der DGUV): <http://www.dguv.de/ifa/GESTIS/index.jsp>

Hörrath Gefährliche Stoffe und Gemische, 8. Auflage, Dr. Angela Schulz

Safety data sheets of the manufacturers

#### 16.4 Classification for mixtures and used evaluation method according to regulation (EC) No. 1272/2008 [CLP]

##### Classification according to Regulation (EC) No. 1272/2008 [CLP]:

Hazard classes and hazard categories	Hazard statements	Classification procedure
Skin corrosion/irritation ( <i>Skin Irrit. 2</i> )	H315: Causes skin irritation.	Calculation
Serious eye damage/eye irritation ( <i>Eye Irrit. 2</i> )	H319: Causes serious eye irritation.	Calculation

#### 16.5 Relevant H- and EUH-phrases

Hazard statements	
H290	May be corrosive to metals.
H314	Causes severe skin burns and eye damage.
H400	Very toxic to aquatic life.
H411	Toxic to aquatic life with long lasting effects.

#### 16.6 Training advice

No data available.

#### 16.6 Additional information

The information in this data sheet has been established to our best knowledge and was up-to-date at time of revision. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. It does not represent a guarantee for the properties of the product described in terms of the legal warranty regulations.