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

Revision date: 15-Mar-2017
Print date: 15-Mar-2017
Version: 1.0
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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]:

<table>
<thead>
<tr>
<th>Hazard classes and hazard categories</th>
<th>Hazard statements</th>
<th>Classification procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin corrosion/irritation (Skin Irrit. 2)</td>
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<td>Calculation</td>
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<td>Serious eye damage/eye irritation (Eye Irrit. 2)</td>
<td>H319: Causes serious eye irritation.</td>
<td>Calculation</td>
</tr>
</tbody>
</table>

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.

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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:

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

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 drunken 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 (Cl2), 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.
 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:
Wear protective gloves/protective clothing/eye protection/face protection.

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

Advises 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.

Advises 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
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: ≥ 0,11 mm
Breakthrough time (maximum wearing time): ≥ 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
Odour: easily perceived like Chlorine (Cl2)

Colour: colourless - light yellow

Safety relevant basic data

<table>
<thead>
<tr>
<th>Parameter</th>
<th>at</th>
<th>Method</th>
<th>Remark</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH</td>
<td>11.8</td>
<td>20 °C</td>
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</tr>
<tr>
<td>Melting point</td>
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<tr>
<td>Freezing point</td>
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<td>Initial boiling point and boiling range</td>
<td>≥ 100 °C</td>
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<td>Decomposition temperature</td>
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<tr>
<td>Flash point</td>
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</tr>
<tr>
<td>Evaporation rate</td>
<td>not determined</td>
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</tbody>
</table>

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### Parameter

<table>
<thead>
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<th>Parameter</th>
<th>at</th>
<th>Method</th>
<th>Remark</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ignition temperature</td>
<td>not applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Upper/lower flammability or explosive limits</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>not determined</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vapour density</td>
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<td></td>
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<tr>
<td>Density</td>
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<tr>
<td>Bulk density</td>
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<tr>
<td>Water solubility</td>
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<tr>
<td>Partition coefficient: n-octanol/water</td>
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<tr>
<td>Dynamic viscosity</td>
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<td></td>
</tr>
<tr>
<td>Kinematic viscosity</td>
<td>not determined</td>
<td></td>
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</tr>
</tbody>
</table>

### 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 (Cl2)!

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 (Cl2), 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.
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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

<table>
<thead>
<tr>
<th>Land transport (ADR / RID)</th>
<th>Inland waterway craft (ADN)</th>
<th>Sea transport (IMDG)</th>
<th>Air transport (ICAO-TI / IATA-DGR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>14.1 UN-No.</td>
<td>1791</td>
<td>1791</td>
<td>1791</td>
</tr>
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Land transport (ADR / RID) | Inland waterway craft (ADN) | Sea transport (IMDG) | Air transport (ICAO-TI / IATA-DGR)
---|---|---|---
14.2 UN proper shipping name | HYPOCHLORITE SOLUTION | HYPOCHLORITE SOLUTION | HYPOCHLORITE SOLUTION | HYPOCHLORITE SOLUTION
14.3 Transport hazard class(es) | 8 | 8 | 8 | 8
14.4 Packing group | III | III | III | III
14.5 Environmental hazards | No | No | No | No
14.6 Special precautions for user | Special provisions: 521 | Special provisions: not determined | Special provisions: not determined | Special provisions: not determined
Limited Quantity (LQ): 5 L | Limited Quantity (LQ): not determined | Limited Quantity (LQ): not determined | Limited Quantity (LQ): not determined
Hazard identification number (KemlerNo.): 80 | Classification code: C9 | EmS-No.: F-A; S-B | Remark: -
Classification code: C9 | Tunnel restriction code: E | | | Remark: -
Tunnel restriction code: E | Remark: - | | | |
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.
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

16.3 Key literature references and sources for data
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
Hörath 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]
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16.5 Relevant H- and EUH-phrases

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</tr>
<tr>
<td>H314</td>
</tr>
<tr>
<td>H400</td>
</tr>
<tr>
<td>H411</td>
</tr>
</tbody>
</table>

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.