

# SAFETY DATA SHEET

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

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Version: 1.0

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## TOXAVIT

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

#### 1.1. Product identifier

Trade name/designation:

TOXAVIT

Article No.:

0032119 (2 g)

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

Use of the substance/mixture:

Medicinal product for dental application. Observe instructions for use.

For professional use only,

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

Supplier (manufacturer/importer/only representative/downstream user/distributor):

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 telephone 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
Acute toxicity (oral) ( <i>Acute Tox. 4</i> )	H302: Harmful if swallowed.	
Skin corrosion/irritation ( <i>Skin Irrit. 2</i> )	H315: Causes skin irritation.	
Respiratory or skin sensitisation ( <i>Skin Sens. 1</i> )	H317: May cause an allergic skin reaction.	
Serious eye damage/eye irritation ( <i>Eye Dam. 1</i> )	H318: Causes serious eye damage.	
Acute toxicity (inhalative) ( <i>Acute Tox. 4</i> )	H332: Harmful if inhaled.	
Respiratory or skin sensitisation ( <i>Resp. Sens. 1</i> )	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.	

#### Additional information:

Contains: Paraformaldehyde, Lidocaine hydrochloride monohydrate, Eugenole, m-Cresol

Precautionary statements:

Do not breathe dust/fume/gas/mist/vapours/spray. Wear protective gloves/protective clothing/eye protection/face protection. IF SWALLOWED: Call a POISON CENTER if you feel unwell. IF ON SKIN: Gently wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention. 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.

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### 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.

#### Additional information:

As a medicinal product this article is not subject to Regulation (EC) no. 1272/2008 [CLP] and do not require labeling according to this regulation.

### 2.3. Other hazards

No data available

## SECTION 3: Composition / information on ingredients

### 3.2. Mixtures

#### Hazardous ingredients / Hazardous impurities / Stabilisers:

Product identifiers	Substance name Classification according to Regulation (EC) No. 1272/2008 [CLP]	Concentration
CAS No.: 30525-89-4	<b>Paraformaldehyde</b> Eye Dam. 1, Flam. Sol. 2, Acute Tox. 4, Skin Irrit. 2, Resp. Sens. 1, Sk in Sens. 1 <b>Danger</b> H228-H302-H315-H317-H318-H332-H334	40 - 60 Wt %
CAS No.: 6108-05-0 EC No.: 200-803-8	<b>Lidocaine hydrochloride monohydrate</b> Acute Tox. 3 <b>Danger</b> H301	30 - 50 Wt %
CAS No.: 97-53-0 EC No.: 202-589-1	<b>Eugenol</b> Eye Irrit. 2, Skin Sens. 1 <b>Warning</b> H317-H319	1 - 5 Wt %
CAS No.: 108-39-4 EC No.: 203-577-9	<b>m-Cresol</b> Skin Corr. 1B, Acute Tox. 3, Aquatic Chronic 3 <b>Danger</b> H301-H311-H314-H412	1 - 5 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:

Provide fresh air.

#### In case of skin contact:

Gently wash with plenty of soap and 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. If eye irritation persists: Get medical advice/attention.

#### After ingestion:

Rinse mouth. Call a POISON CENTER if you feel unwell.

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

Harmful if swallowed or if inhaled. Causes serious eye damage. Causes skin irritation. May produce an allergic reaction.

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

Treat symptomatically.

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### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

**Suitable extinguishing media:**

Water spray jet, alcohol resistant foam, Extinguishing powder, Carbon dioxide (CO<sub>2</sub>).

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

This material is combustible, but will not ignite readily.

**Hazardous combustion products:**

In case of fire may be liberated: Gases/vapours, toxic

#### 5.3. Advice for firefighters

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

#### 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:**

Do not breathe 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: Take up mechanically.

**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:**

Do not breathe dust/fume/gas/mist/vapours/spray. Avoid contact with eyes and skin. Take off immediately all contaminated clothing. Do not mix with other chemicals. 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.

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### 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. Take off contaminated clothing and wash it 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: Light, Heat

Recommended storage temperature: 2 - 8 °C

#### Requirements for storage rooms and vessels:

Floors should be impervious, resistant to liquids and easy to clean. Keep/Store only in original container.

#### Hints on storage assembly:

Keep away from food, drink and animal feedingstuffs.

**Storage class:** 11 - Combustible solids that cannot be assigned to any of the above storage classes

### 7.3. Specific end use(s)

#### Recommendation:

Medicinal product 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 (DIN EN 166).

#### Skin protection:

Tested protective gloves must be worn (DIN 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.

Filtering device (full mask or mouthpiece) with filter: A

#### Other protection measures:

Wear suitable protective clothing.

#### 8.2.3. Environmental exposure controls

No data available

### 8.3. Additional information

No data available

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### SECTION 9: Physical and chemical properties

#### 9.1. Information on basic physical and chemical properties

##### Appearance

**Physical state:** solid, pasty

**Colour:** dark grey

**Odour:** like Paraformaldehyde, m-Cresol

##### Safety relevant basis data

Parameter		at °C	Method	Remark
pH	4.2	20 °C		(10 %)
Melting point/freezing point	≥ 74 °C			(Lidocaine hydrochloride monohydrate)
Freezing point	<i>not determined</i>			
Initial boiling point and boiling range	<i>not determined</i>			
Decomposition temperature (°C):	<i>not determined</i>			
Flash point	<i>not determined</i>			
Evaporation rate	<i>not determined</i>			
Ignition temperature in °C	300 °C			(Paraformaldehyde)
Upper/lower flammability or explosive limits	<i>not determined</i>			
Vapour pressure	1.93 hPa	25 °C		(Paraformaldehyde)
Vapour density	<i>not determined</i>			
Density	1 g/ml	20 °C		
Bulk density	<i>not applicable</i>			
Water solubility (g/L)	partially soluble			
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

This material is combustible, but will not ignite readily.

#### 10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

#### 10.3. Possibility of hazardous reactions

No hazardous reaction when handled and stored according to provisions.

Possibility of hazardous reactions with alkali (lye); Amines; Acids; Oxidising agent, strong (Formation of: Gases/vapours, toxic)

#### 10.4. Conditions to avoid

Light, Heat.

#### 10.5. Incompatible materials

alkali (lye); Amines; Acids; Oxidising agent, strong; metals (including their alloys): Fe, Cu, Ni, Zn

#### 10.6. Hazardous decomposition products

Decomposition takes place from temperatures above: 300 °C Formation of: Gases/vapours, toxic

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### SECTION 11: Toxicological information

#### 11.1. Information on toxicological effects

CAS No.	Substance name	Toxicological information
6108-05-0	Lidocaine hydrochloride monohydrate	<b>LD<sub>50</sub> oral:</b> 292 mg/kg (Rat)
30525-89-4	Paraformaldehyde	<b>LD<sub>50</sub> oral:</b> 592 mg/kg (Rat) <b>LC<sub>50</sub> inhalative:</b> 1.07 mg/l 4 h (Rat)
108-39-4	m-Cresol	<b>LD<sub>50</sub> oral:</b> 242 mg/kg (Rat)

**Acute oral toxicity:**

Harmful if swallowed.

**Acute dermal toxicity:**

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

**Acute inhalation toxicity:**

Harmful if inhaled.

**Skin corrosion/irritation:**

Causes skin irritation.

**Eye damage/irritation:**

Causes serious eye damage.

**Respiratory or skin sensitisation:**

May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled.

**Germ cell mutagenicity:**

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

**Carcinogenicity:**

Paraformaldehyde: Evidence for possible carcinogenic effects in experimental animals existent. Suspected of causing cancer.

**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.

**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.

### SECTION 12: Ecological information

#### 12.1. Toxicity

**Aquatic toxicity:**

The substance/mixture does not fulfill the criteria of the acute aquatic toxicity according to Regulation (EC) No 1272/2008 [CLP], Annex I. On the basis of existing data about the elimination/degradation and bioaccumulation potential longer term damage to the environment is unlikely.

#### 12.2. Persistence and degradability

**Biodegradation:**

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.

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### 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 identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process. 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

No dangerous good in sense of these transport regulations.

### 14.1. UN-No.

not relevant

### 14.2. UN proper shipping name

not relevant

### 14.3. Transport hazard class(es)

not relevant

### 14.4. Packing group

not relevant

### 14.5. Environmental hazards

not relevant

### 14.6. Special precautions for user

not relevant

### 14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

not applicable

## SECTION 15: Regulatory information

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

#### 15.1.1. EU legislation

##### Other regulations (EU):

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). Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers. Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

#### 15.1.2. National regulations

No data available



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### 15.2. Chemical Safety Assessment

No data available.

### 15.3. Additional information

No data available.

## SECTION 16: Other information

### 16.1. Indication of changes

No data available.

### 16.2. Abbreviations and acronyms

For abbreviations and acronyms, see: ECHA Guidance on information requirements and chemical safety assessment, chapter R.20 (Table of terms and abbreviations).

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

No data available.

### 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
Acute toxicity (oral) ( <i>Acute Tox. 4</i> )	H302: Harmful if swallowed.	
Skin corrosion/irritation ( <i>Skin Irrit. 2</i> )	H315: Causes skin irritation.	
Respiratory or skin sensitisation ( <i>Skin Sens. 1</i> )	H317: May cause an allergic skin reaction.	
Serious eye damage/eye irritation ( <i>Eye Dam. 1</i> )	H318: Causes serious eye damage.	
Acute toxicity (inhalative) ( <i>Acute Tox. 4</i> )	H332: Harmful if inhaled.	
Respiratory or skin sensitisation ( <i>Resp. Sens. 1</i> )	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.	

### 16.5. Relevant R-, H- and EUH-phrases (Number and full text)

Hazard statements	
H228	Flammable solid.
H301	Toxic if swallowed.
H302	Harmful if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H412	Harmful to aquatic life with long lasting effects.

### 16.6. Training advice

No data available.

### 16.7. 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.