

# SAFETY DATA SHEET

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

**Revision date:** 19 Jun 2026

**Print date:** 19 Jun 2026

**Version:** 1.1



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## durimplant

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

#### 1.1 Product identifier

**Trade name/designation:**

durimplant

**Other means of identification:**

Article No. : 0032207 (10 ml)

**Additional information:**

Voluntary safety information following the Safety Data Sheet format according to Regulation (EC) No. 1907/2006 (REACH). As a cosmetic 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:**

Cosmetic product for dental application.

Observe instructions for use.

#### 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 |
|----------------------------------------------------------------------|----------------------------------------------------------|--------------------------|
| Respiratory or skin sensitisation<br>( <i>Skin Sens. 1</i> )         | H317: May cause an allergic skin reaction.               | Calculation              |
| Hazardous to the aquatic environment<br>( <i>Aquatic Chronic 3</i> ) | H412: Harmful to aquatic life with long lasting effects. | Calculation              |

**Additional information:**

Contains: Sage oil, Mentha arvensis, ext.

Precautionary statements:

Avoid release to the environment. Wear protective gloves/protective clothing/eye protection/face protection. IF ON SKIN: Gently wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention. IF IN EYES: Wipe up with absorbent material (eg. cloth, fleece). 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.

#### 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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### Additional information:

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

### 2.3 Other hazards

#### Adverse human health effects and symptoms:

May cause eye irritation. May cause skin irritation.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Description:

A mixture of the substances listed below, containing non-hazardous additives.

#### Ingredients:

| Product identifiers                      | Substance name<br>Classification according to Regulation (EC) No. 1272/2008 [CLP]                                                                                                                                                                                                                                                                                                         | Content           |
|------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| CAS No.: 90106-49-3<br>EC No.: 290-272-9 | <b>Sage, Salvia lavandulifolia, ext.</b><br>Acute Tox. 4 (H332), Aquatic Acute 1 (H400), Aquatic Chronic 1 (H410),<br>Asp. Tox. 1 (H304), STOT SE 2 (H371), Skin Sens. 1 (H317)<br> Danger<br><b>Acute Toxicity Estimate</b><br>ATE (inhalation, vapour) 11 mg/L<br>ATE (inhalation, dust/mist) 1.5 mg/L | 1 – 2<br>weight-% |
| CAS No.: 90063-97-1<br>EC No.: 290-058-5 | <b>Mentha arvensis, ext.</b><br>Acute Tox. 4 (H302), Aquatic Chronic 2 (H411), Eye Irrit. 2 (H319),<br>Skin Irrit. 2 (H315), Skin Sens. 1 (H317)<br> Warning<br><b>Acute Toxicity Estimate</b><br>ATE (oral) 500 mg/kg                                                                                 | < 1<br>weight-%   |

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 but breathing normally, place in recovery position and seek medical advice. Do not leave affected person unattended.

#### Following inhalation:

No special measures are necessary.

#### In case of skin contact:

Gently wash with plenty of soap and water. In case of skin irritation, consult a physician.

#### After eye contact:

Wipe with absorbent material (e.g. cloth, fleece). 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.

#### Following ingestion:

Rinse mouth. Get medical advice/attention if you feel unwell.

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

May cause an allergic skin reaction. May cause eye irritation. May cause 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:

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

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### 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. 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 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. Do not allow to enter into soil/subsoil.

### 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 (sand, diatomaceous earth, acid- or universal binding agents). Collect in closed and suitable containers for disposal.

#### For cleaning up:

Solvent

### 6.4 Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

## 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:

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

##### 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. 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.

Recommended storage temperature: 15 - 25 °C

#### Requirements for storage rooms and vessels:

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

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### Hints on storage assembly:

Keep away from food, drink and animal feedingstuffs.

### 7.3 Specific end use(s)

#### Recommendation:

Cosmetic 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 (EN 166).

##### Skin protection:

Tested protective gloves must be worn (EN ISO 374).

Suitable material: NBR (Nitrile rubber)

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

Breakthrough 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 breakthrough time must be requested 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 respiratory protection necessary.

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.

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

**Physical state:** liquid

**Form:** liquid, Gel

**Colour:** beige

**Odour:** aromatic

**Flammability:** Yes

#### Safety relevant basic data

| Parameter                               | Value                     | at    | ① Method<br>② Remark |
|-----------------------------------------|---------------------------|-------|----------------------|
| pH                                      | 5.8                       | 20 °C | ② (10 %)             |
| Melting point                           | <i>Not applicable.</i>    |       |                      |
| Freezing point                          | <i>No data available.</i> |       |                      |
| Initial boiling point and boiling range | <i>No data available.</i> |       |                      |
| Flash point                             | <i>No data available.</i> |       |                      |

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| Parameter                                    | Value              | at    | ① Method<br>② Remark |
|----------------------------------------------|--------------------|-------|----------------------|
| Evaporation rate                             | No data available. |       |                      |
| Auto-ignition temperature                    | No data available. |       |                      |
| Upper/lower Flammability or explosive limits | Not applicable.    |       |                      |
| Vapour pressure                              | No data available. |       |                      |
| Vapour density                               | No data available. |       |                      |
| Density                                      | 0.9 g/mL           | 20 °C |                      |
| Bulk density                                 | Not applicable.    |       |                      |
| Water solubility                             | Immiscible         |       |                      |
| Dynamic viscosity                            | No data available. |       |                      |
| Kinematic viscosity                          | No data available. |       |                      |

### 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 chemically stable under recommended conditions of storage, use and temperature.

### 10.3 Possibility of hazardous reactions

No hazardous reaction when handled and stored according to provisions.

### 10.4 Conditions to avoid

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

### 10.5 Incompatible materials

oxidizing agent, strong

### 10.6 Hazardous decomposition products

No known hazardous decomposition products. In case of fire may be liberated: Gases/vapours, toxic

## SECTION 11: Toxicological information

### 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

#### 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:

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

May cause skin irritation.

#### Serious eye damage/irritation:

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

May cause eye irritation.

#### Respiratory or skin sensitisation:

May cause an allergic skin reaction.

#### Germ cell mutagenicity:

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

#### Carcinogenicity:

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

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### 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.

## 11.2 Information on other hazards

### Endocrine disrupting properties:

This product does not contain a substance that has endocrine disrupting properties with respect to humans as no components meets the criteria.

## SECTION 12: Ecological information

### 12.1 Toxicity

#### Aquatic toxicity:

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

#### Assessment/classification:

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:

Some of the components are poorly biodegradable.

### 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

|                                                                                |
|--------------------------------------------------------------------------------|
| <b>Mentha arvensis, ext.</b> CAS No.: 90063-97-1 EC No.: 290-058-5             |
| <b>Results of PBT and vPvB assessment:</b> —                                   |
| <b>Sage, Salvia lavandulifolia, ext.</b> CAS No.: 90106-49-3 EC No.: 290-272-9 |
| <b>Results of PBT and vPvB assessment:</b> —                                   |

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

### 12.6 Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

### 12.7 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.

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### Other disposal recommendations:

The allocation of waste code numbers / waste names must be carried out in accordance with the European Waste Catalogue (EWC). Do not allow to enter into surface water or drains. Collect in closed and suitable containers for disposal. Waste for disposal is to be classified and labelled.

## SECTION 14: Transport information

| Land transport<br>(ADR/RID)                                | Inland waterway craft<br>(ADN)                             | Sea transport<br>(IMDG)                                    | Air transport<br>(ICAO-TI-/IATA-DGR)                       |
|------------------------------------------------------------|------------------------------------------------------------|------------------------------------------------------------|------------------------------------------------------------|
| <b>14.1 UN number or ID number</b>                         |                                                            |                                                            |                                                            |
| No dangerous good in sense of these transport regulations. | No dangerous good in sense of these transport regulations. | No dangerous good in sense of these transport regulations. | No dangerous good in sense of these transport regulations. |
| <b>14.2 UN proper shipping name</b>                        |                                                            |                                                            |                                                            |
| No dangerous good in sense of these transport regulations. | No dangerous good in sense of these transport regulations. | No dangerous good in sense of these transport regulations. | No dangerous good in sense of these transport regulations. |
| <b>14.3 Transport hazard class(es)</b>                     |                                                            |                                                            |                                                            |
| not relevant                                               | not relevant                                               | not relevant                                               | not relevant                                               |
| <b>14.4 Packing group</b>                                  |                                                            |                                                            |                                                            |
| not relevant                                               | not relevant                                               | not relevant                                               | not relevant                                               |
| <b>14.5 Environmental hazards</b>                          |                                                            |                                                            |                                                            |
| not relevant                                               | not relevant                                               | not relevant                                               | not relevant                                               |
| <b>14.6 Special precautions for user</b>                   |                                                            |                                                            |                                                            |
| not relevant                                               | not relevant                                               | not relevant                                               | not relevant                                               |

### 14.7 Maritime transport in bulk according to IMO instruments

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

##### Authorisations:

Contains no substances listed in REACH Annex XIV.

##### Restrictions on use:

Contains no substances subject to the restrictions of Annex XVII of the REACH Regulation.

##### 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 juveniles 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 1223/2009 on cosmetic products.

#### 15.1.2 National regulations

No data available.

### 15.2 Chemical Safety Assessment

No data available.

## SECTION 16: Other information

### 16.1 Indication of changes

Changes executed in version 1.1:  
General revision of all sections

### 16.2 Abbreviations and acronyms

ADN = Accord européen relatif au transport international des marchandises dangereuses par voie de navigation intérieure

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ADR = Accord européen relatif au transport international des marchandises Dangereuses par Route

ATE = acute toxicity estimate

CAS = Chemical Abstracts Service

CLP = Classification, Labelling and Packaging

DMEL = Derived Minimum Effect Level

DNEL = Derived No Effect Level

EC<sub>50</sub> = Median effective concentration

ECB = European Chemicals Bureau

EEC = European Economic Community

EINECS = European Inventory of Existing Commercial Chemical Substances

ELINCS = European List of Notified Chemical Substances

GHS = Globally Harmonized System of Classification and Labelling of Chemicals

IATA = International Air Transport Association

IBC-Code = International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk

IC<sub>50</sub> = Inhibition concentration, 50%

IMDG = International Maritime Code for Dangerous Goods

IUCLID = International Uniform Chemical Information Database

LC<sub>50</sub> = Lethal concentration, 50%

LD<sub>50</sub> = Median lethal dose

LC0 = lethal concentration, 0%

LOAEL = lowest-observed-adverse-effect level

MARPOL = International Convention for the Prevention of Marine Pollution from Ships

NOAEL = No Observed Adverse Effect Level

NOEC = No Observed Effect Content

PBT = Persistent, Bioaccumulative and Toxic substance

PNEC = Predicted No-Effect Content

RID = Règlement concernant le transport international ferroviaire de marchandises dangereuses

REACH = Registration, Evaluation, Authorisation and Restriction of Chemicals

STP = Sewage Treatment Plant

TLV®/TWA = Threshold limit value - time-weighted average

TLV®STEL = Threshold limit value - short-time exposure limit

VOC = Volatile Organic Compounds

vPvB = very Persistent and very Bioaccumulative

### 16.3 Key literature references and sources for data

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

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

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

GESTIS, Information system on hazardous substances: <https://www.gestis.dguv.de/search>

GESTIS, International Limit Values: <https://limitvalue.ifa.dguv.de>

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]

| Hazard classes and hazard categories                                 | Hazard statements                                        | Classification procedure |
|----------------------------------------------------------------------|----------------------------------------------------------|--------------------------|
| Respiratory or skin sensitisation<br>( <i>Skin Sens. 1</i> )         | H317: May cause an allergic skin reaction.               | Calculation              |
| Hazardous to the aquatic environment<br>( <i>Aquatic Chronic 3</i> ) | H412: Harmful to aquatic life with long lasting effects. | Calculation              |

### 16.5 List of relevant hazard statements and/or precautionary statements from sections 2 to 15

| Hazard statements |                                               |
|-------------------|-----------------------------------------------|
| H302              | Harmful if swallowed.                         |
| H304              | May be fatal if swallowed and enters airways. |
| H315              | Causes skin irritation.                       |

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| Hazard statements |                                                       |
|-------------------|-------------------------------------------------------|
| H317              | May cause an allergic skin reaction.                  |
| H319              | Causes serious eye irritation.                        |
| H332              | Harmful if inhaled.                                   |
| H371              | May cause damage to organs.                           |
| H400              | Very toxic to aquatic life.                           |
| H410              | Very toxic to aquatic life with long lasting effects. |
| H411              | Toxic to aquatic life with long lasting effects.      |

### 16.6 Training advice

No data available.

### 16.7 Additional information

The information in this safety 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 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.