

SAFETY DATA SHEET

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

Revision date: 20-Aug-2015

Print date: 28-Aug-2015

Version: 1.0

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

1.1. Product identifier

Trade name/designation:

ORBAT forte

Article No.:

0032336 (20 ml)

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

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 |
|---|----------------------------------|--------------------------|
| Serious eye damage/eye irritation (Eye Dam. 1) | H318: Causes serious eye damage. | |

Additional information:

Contains: Iron(III) sulfate

Precautionary statements:

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

Additional information:

As a medical device 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 skin irritation.

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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.: 10028-22-5 EC No.: 233-072-9 | Iron(III) sulfate Eye Dam. 1, Acute Tox. 4, Skin Irrit. 2  Danger H302-H315-H318 | 20 - 30 Wt % |
| CAS No.: 56-81-5 EC No.: 200-289-5 | Glycerol | 30 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 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. Get immediate medical advice/attention.

After ingestion:

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

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

Causes serious eye damage. 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:

Co-ordinate fire-fighting measures to the fire surroundings.

5.2. Special hazards arising from the substance or mixture

The product itself does not burn. No special fire protection measures are necessary.

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.

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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.

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. 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.

Hints on storage assembly:

Keep away from food, drink and animal feedingstuffs.

Storage class: 12 - non-combustible liquids that cannot be assigned to any of the above storage classes

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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

8.1.1. Occupational exposure limit values

| Limit value type (country of origin) | Substance name | ① Long-term occupational exposure limit value ② Short-term occupational exposure limit value ③ Instantaneous value ④ Monitoring and observation processes ⑤ Remark |
|--------------------------------------|------------------------------|--|
| WEL (GB) | Glycerol CAS No.: 56-81-5 | ① 10 mg/m ³ |

8.1.2. Biological limit values

No data available

8.1.3. DNEL-/PNEC-values

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): ≥ 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 respiratory protection necessary.

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: liquid, viscous

Colour: dark brown

Odour: odourless

Safety relevant basis data

| Parameter | | at °C | Method | Remark |
|--|-----------------------|-------|--------|--------|
| pH | 0.8 - 2 | 20 °C | | |
| Melting point/freezing point | <i>not applicable</i> | | | |
| Freezing point | <i>not determined</i> | | | |
| Initial boiling point and boiling range | ≥ 100 °C | | | |
| Decomposition temperature (°C): | <i>not determined</i> | | | |
| Flash point | <i>not applicable</i> | | | |
| Evaporation rate | <i>not determined</i> | | | |
| Ignition temperature in °C | <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 | 1.4 g/ml | 20 °C | | |
| Bulk density | <i>not applicable</i> | | | |
| Water solubility (g/L) | 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

The product itself does not burn.

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.

10.4. Conditions to avoid

No data available.

10.5. Incompatible materials

Oxidising agent, strong; alkali (lye)

10.6. Hazardous decomposition products

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

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.

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Acute inhalation toxicity:

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

Skin corrosion/irritation:

May cause skin irritation.

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

Eye damage/irritation:

Causes serious eye damage.

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

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.

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.

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:

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

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.

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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. 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.

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).

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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 |
|--|----------------------------------|--------------------------|
| Serious eye damage/eye irritation (<i>Eye Dam. 1</i>) | H318: Causes serious eye damage. | |

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

| Hazard statements | |
|-------------------|----------------------------|
| H302 | Harmful if swallowed. |
| H315 | Causes skin irritation. |
| H318 | Causes serious eye damage. |

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.