

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 28.10.2022

Version number 6 (replaces version 5)

Revision: 28.10.2022

Start

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

- **1.1 Product identifier**
- **Trade name: *Illuminé 15 %***
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the mixture** *Tooth whitening gel*
- **Uses advised against** *No further relevant information available.*
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
*Dentsply DeTrey GmbH
De-Trey-Str. 1
D-78467 Konstanz
GERMANY
Tel.: +49-(0)7531-583-0
Fax: +49-(0)7531-583-104
email: KonstanzDEU.info-sdb@dentsplysirona.com*
- **Further information obtainable from:** *Research and Development*
- **1.4 Emergency telephone number:** *+49-(0)7531-583-0 8:00 - 17:00 (GMT + 1:00)*

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
*Skin Irrit. 2 H315 Causes skin irritation.
Eye Irrit. 2 H319 Causes serious eye irritation.*
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the GB CLP regulation.
- **Hazard pictograms**



GHS07

- **Signal word** *Warning*
- **Hazard statements**
*H315 Causes skin irritation.
H319 Causes serious eye irritation.*
- **Precautionary statements**
*P264 Wash thoroughly after handling.
P280 Wear protective gloves / eye protection / face protection.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P332+P313 If skin irritation occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before reuse.
P337+P313 If eye irritation persists: Get medical advice/attention.*
- **Additional information:**
As this product is a cosmetic product in the meaning of regulation 1223/2009 and is intended for use by the end consumer, the finished products are exempt from the labelling requirements according to regulation 1272/2008.
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** *Not applicable.*
- **vPvB:** *Not applicable.*

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SECTION 3: Composition/information on ingredients

3.2 Mixtures

Description: Mixture of substances listed below with nonhazardous additions.

Dangerous components:

| | | |
|-------------------------------------|---|--------------------|
| CAS: 56-81-5 EINECS: 200-289-5 | glycerol substance with a Community workplace exposure limit | 50 – 100% |
| CAS: 124-43-6 EINECS: 204-701-4 | urea peroxide Ox. Sol. 2, H272; Skin Irrit. 2, H315 | 10 – 25% |
| CAS: 9003-01-4 | Poly acrylic acid Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335 | ≤ 2.5% |
| CAS: 1310-73-2 EINECS: 215-185-5 | sodium hydroxide Skin Corr. 1A, H314; Acute Tox. 4, H302 Specific concentration limits: Skin Corr. 1A; H314: $C \geq 5\%$ Skin Corr. 1B; H314: $2\% \leq C < 5\%$ Skin Irrit. 2; H315: $0.5\% \leq C < 2\%$ Eye Irrit. 2; H319: $0.5\% \leq C < 2\%$ | $\geq 0.5 - < 2\%$ |
| CAS: 7681-49-4 EINECS: 231-667-8 | sodium fluoride Acute Tox. 3, H301; Skin Irrit. 2, H315; Eye Irrit. 2, H319, EUH032 | ≤ 2.5% |

Additional information For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General information Immediately remove any clothing soiled by the product.

After inhalation Supply fresh air; consult doctor in case of complaints.

After skin contact Immediately wash with water and soap and rinse thoroughly.

After eye contact Rinse opened eye for several minutes under running water. Then consult a doctor.

After swallowing

Rinse out mouth and then drink plenty of water.

Drink plenty of water and provide fresh air. Call for a doctor immediately.

Information for doctor No further relevant information available.

4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing agents

CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

For safety reasons unsuitable extinguishing agents Water with full jet.

5.2 Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire.

5.3 Advice for firefighters

Protective equipment: Self-contained respiratory protective device.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.

6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

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- Dispose contaminated material as waste according to item 13.
- **6.4 Reference to other sections**
See Section 7 for information on safe handling
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** Observe normal care for working with chemicals.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage**
- **Requirements to be met by storerooms and receptacles:** Store only in the original receptacle.
- **Information about storage in one common storage facility:** Store away from foodstuffs.
- **Further information about storage conditions:**
Keep receptacle tightly sealed.
Store in a cool place.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**

CAS: 56-81-5 glycerol

WEL Long-term value: 10 mg/m³

- **Regulatory information** WEL: EH40/2020
- **Additional information:** The lists valid during the making were used as basis.

- **8.2 Exposure controls**
- **Appropriate engineering controls** No further data; see item 7.
- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures**
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.
- **Respiratory protection:** Not necessary if room is well-ventilated.
- **Hand protection**



Protective gloves.

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
- **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

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· **Eye/face protection**

Tightly sealed goggles.

· **Body protection:** Protective work clothing.

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

| | |
|---|----------------------------------|
| · Physical state | Fluid |
| · Colour: | Colourless |
| · Odour: | Product specific |
| · Odour threshold: | Not determined. |
| · Melting point/freezing point: | undetermined |
| · Boiling point or initial boiling point and boiling range | Undetermined. |
| · Flammability | Not applicable. |
| · Lower and upper explosion limit | |
| · Lower: | 2.6 Vol % |
| · Upper: | 11.3 Vol % |
| · Flash point: | Not applicable |
| · Ignition temperature: | Not applicable |
| · Decomposition temperature: | Not determined. |
| · pH at 20 °C | 6 |
| · Viscosity: | |
| · Kinematic viscosity | Not determined. |
| · dynamic: | Not determined. |
| · Solubility | |
| · Water: | Not miscible or difficult to mix |
| · Partition coefficient n-octanol/water (log value) | Not determined. |
| · Vapour pressure: | Not determined. |
| · Density and/or relative density | |
| · Density: | Not determined |
| · Relative density | Not determined. |
| · Vapour density | Not determined. |

· 9.2 Other information

| | |
|--|---|
| · Appearance: | |
| · Form: | paste |
| · Important information on protection of health and environment, and on safety. | |
| · Auto-ignition temperature: | Product is not selfigniting. |
| · Explosive properties: | Product does not present an explosion hazard. |
| · Change in condition | |
| · Evaporation rate | Not determined. |

· Information with regard to physical hazard classes

| | |
|--|------|
| · Explosives | Void |
| · Flammable gases | Void |
| · Aerosols | Void |
| · Oxidising gases | Void |
| · Gases under pressure | Void |
| · Flammable liquids | Void |
| · Flammable solids | Void |
| · Self-reactive substances and mixtures | Void |

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| | |
|--|-------------|
| · <i>Pyrophoric liquids</i> | <i>Void</i> |
| · <i>Pyrophoric solids</i> | <i>Void</i> |
| · <i>Self-heating substances and mixtures</i> | <i>Void</i> |
| · <i>Substances and mixtures, which emit flammable gases in contact with water</i> | <i>Void</i> |
| · <i>Oxidising liquids</i> | <i>Void</i> |
| · <i>Oxidising solids</i> | <i>Void</i> |
| · <i>Organic peroxides</i> | <i>Void</i> |
| · <i>Corrosive to metals</i> | <i>Void</i> |
| · <i>Desensitised explosives</i> | <i>Void</i> |

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** Oxygen

SECTION 11: Toxicological information

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

- **Acute toxicity**

- **LD/LC50 values relevant for classification:**

ATE (Acute Toxicity Estimate)

| | | |
|------|------|--------------------|
| Oral | LD50 | 23,636 mg/kg (rat) |
|------|------|--------------------|

CAS: 56-81-5 glycerol

| | | |
|------|------|--------------------|
| Oral | LD50 | 12,600 mg/kg (rat) |
|------|------|--------------------|

| | | |
|--------|------|-------------------------|
| Dermal | LD50 | > 18,700 mg/kg (rabbit) |
|--------|------|-------------------------|

CAS: 9003-01-4 Poly acrylic acid

| | | |
|------|------|-------------------|
| Oral | LD50 | 2,500 mg/kg (rat) |
|------|------|-------------------|

CAS: 1310-73-2 sodium hydroxide

| | | |
|------|------|-------------------|
| Oral | LD50 | 2,000 mg/kg (rat) |
|------|------|-------------------|

CAS: 7681-49-4 sodium fluoride

| | | |
|------|------|----------------|
| Oral | LD50 | 52 mg/kg (rat) |
|------|------|----------------|

- **Skin corrosion/irritation** Causes skin irritation.
- **Serious eye damage/irritation** Causes serious eye irritation.
- **11.2 Information on other hazards**

- **Endocrine disrupting properties**

None of the ingredients is listed.

SECTION 12: Ecological information

- **12.1 Toxicity**

- **Aquatic toxicity:**

CAS: 56-81-5 glycerol

| | |
|----------|--|
| LC50/24h | > 5,000 mg/l (Fish acute toxicity study) |
|----------|--|

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| | |
|---|--|
| EC50/24h | > 10,000 mg/L (daphnia magna) |
| CAS: 9003-01-4 Poly acrylic acid | |
| LC50/96h | 168 – 280 mg/l (daphnia magna) 580 – 2,000 mg/l (Fish acute toxicity study) |
| CAS: 7681-49-4 sodium fluoride | |
| LC50/96h | > 100 mg/l (Fish acute toxicity study) |

- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties**
The product does not contain substances with endocrine disrupting properties.
- **12.7 Other adverse effects**
- **Additional ecological information:**
- **General notes:** Do not allow product to reach ground water, water course or sewage system.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**



Must not be disposed together with household garbage. Do not allow product to reach sewage system.

- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

SECTION 14: Transport information

| | |
|---|-----------------|
| · 14.1 UN number or ID number · ADR, IMDG, IATA | Void |
| · 14.2 UN proper shipping name · ADR, IMDG, IATA | Void |
| · 14.3 Transport hazard class(es) · ADR, ADN, IMDG, IATA · Class | Void |
| · 14.4 Packing group · ADR, IMDG, IATA | Void |
| · 14.5 Environmental hazards: | Not applicable. |
| · 14.6 Special precautions for user | Not applicable. |
| · 14.7 Maritime transport in bulk according to IMO instruments | Not applicable. |
| · UN "Model Regulation": | Void |

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SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

The attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer.

For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product is given in the DFU.

· **Relevant phrases**

- H272 May intensify fire; oxidiser.
- H301 Toxic if swallowed.
- H302 Harmful if swallowed.
- H314 Causes severe skin burns and eye damage.
- H315 Causes skin irritation.
- H319 Causes serious eye irritation.
- H335 May cause respiratory irritation.
- EUH032 Contact with acids liberates very toxic gas.

· **Department issuing SDS:** Research & Development

· **Contact:** HotLine for urgent technical support: +49-7531-583-350

· **Abbreviations and acronyms:**

- ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
- IMDG: International Maritime Code for Dangerous Goods
- IATA: International Air Transport Association
- GHS: Globally Harmonised System of Classification and Labelling of Chemicals
- EINECS: European Inventory of Existing Commercial Chemical Substances
- ELINCS: European List of Notified Chemical Substances
- CAS: Chemical Abstracts Service (division of the American Chemical Society)
- LC50: Lethal concentration, 50 percent
- LD50: Lethal dose, 50 percent
- PBT: Persistent, Bioaccumulative and Toxic
- vPvB: very Persistent and very Bioaccumulative
- Ox. Sol. 2: Oxidizing solids – Category 2
- Acute Tox. 3: Acute toxicity – Category 3
- Acute Tox. 4: Acute toxicity – Category 4
- Skin Corr. 1A: Skin corrosion/irritation – Category 1A
- Skin Irrit. 2: Skin corrosion/irritation – Category 2
- Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
- STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

· *** Data compared to the previous version altered.**