

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

Printing date 13.05.2020

Revision: 18.07.2019

**1 Identification of the substance/mixture and of the company/undertaking**

- **Product identifier**
- **Trade name:** *Opalescence™ PF, 10-20% Bleaching Gel (Regular, Mint or Melon)*
- **Article number:** 13509, 13514, 13518, 39005, 39009, 39013, 39019, 39025, 39029, 71178, 71179, 71180
- **Index number:** SDS 14-001.18
- **Relevant identified uses of the substance or mixture and uses advised against**  
*Professional Dental Teeth Whitening Gel*
- **Application of the substance / the mixture** *Professional Dental Teeth Whitening Gel*
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
*Ultradent Products Inc.  
505 W. Ultradent Drive (10200 S)  
South Jordan, UT 84095-3942  
USA  
onlineordersupport@ultradent.com*
- 
- EC Responsible Person  
Ultradent Products GmbH  
Am Westhoyer Berg 30  
51149 Cologne Germany  
Email: infoDE@ultradent.com  
Emergency Phone: +49(0)2203-35-92-0*
- **Further information obtainable from:** *Customer Service*
- **Emergency telephone number:**  
*CHEMTREC (NORTH AMERICA) : (800) 424-9300  
(INTERNATIONAL) : +(703) 527-3887*

**2 Hazards identification**

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**



GHS07

- Acute Tox. 4 H332 Harmful if inhaled.*
- Skin Irrit. 2 H315 Causes skin irritation.*
- Eye Irrit. 2 H319 Causes serious eye irritation.*

- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**  
*The Regulation EC 1272/2008 on classification, labeling and packaging of substances and mixtures (CLP) shall not apply to a cosmetic in the finished state used in direct physical contact with the human body according to Art. 1.5 (c). Therefore, the product is exempted from the CLP labeling requirements, and no SDS is required by Regulation 1907/2006, Art. 2 (6b), REACH. Therefore, all given data, classification, and information on this SDS are provided solely on a voluntary basis.*
- **Hazard pictograms** GHS07
- **Signal word** *Warning*
- **Hazard-determining components of labelling:**  
*Carbamide Peroxide  
Sodium Hydroxide*

(Contd. on page 2)

# Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 13.05.2020

Revision: 18.07.2019

**Trade name: Opalescence™ PF, 10-20% Bleaching Gel (Regular, Mint or Melon)**

(Contd. of page 1)

· **Hazard statements**

H332 Harmful if inhaled.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

· **Precautionary statements**

P101 If medical advice is needed, have product container or label at hand.

P102 Keep out of reach of children.

P103 Read label before use.

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P264 Wash thoroughly after handling.

P271 Use only outdoors or in a well-ventilated area.

P280 Wear protective gloves / eye protection / face protection.

P302+P352 IF ON SKIN: Wash with plenty of water.

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P312 Call a POISON CENTER/doctor if you feel unwell.

P321 Specific treatment (see on this label).

P362+P364 Take off contaminated clothing and wash it before reuse.

P332+P313 If skin irritation occurs: Get medical advice/attention.

P337+P313 If eye irritation persists: Get medical advice/attention.

· **Additional information:**

Contains Oils, Peppermint. May produce an allergic reaction.

· **Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

### 3 Composition/information on ingredients

· **Chemical characterisation: Mixtures**

· **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

CAS: 56-81-5 EINECS: 200-289-5	Glycerine substance with a Community workplace exposure limit	>25-≤50%
CAS: 124-43-6 EINECS: 204-701-4	Carbamide Peroxide ⚠ Ox. Sol. 3, H272; ⚠ Skin Corr. 1B, H314	>10-≤20%
CAS: 1310-73-2 EINECS: 215-185-5	Sodium Hydroxide ⚠ Acute Tox. 3, H301; ⚠ Skin Corr. 1A, H314; ⚠ Acute Tox. 4, H312	<5%
	Artificial Watermelon ⚠ Flam. Liq. 3, H226	≤2.5%
CAS: 8006-90-4 EINECS: 282-015-4	Oils, Peppermint ⚠ Asp. Tox. 1, H304; ⚠ Aquatic Chronic 2, H411; ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	≤2.5%
CAS: 7681-49-4 EINECS: 231-667-8	Sodium Fluoride ⚠ Acute Tox. 3, H301; Acute Tox. 2, H310; ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319	0.25%
CAS: 7757-79-1 EINECS: 231-818-8	Potassium Nitrate ⚠ Ox. Sol. 2, H272; ⚠ Skin Irrit. 2, H315; STOT SE 3, H335-H336	<3%

(Contd. on page 3)

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

Printing date 13.05.2020

Revision: 18.07.2019

**Trade name: Opalescence™ PF, 10-20% Bleaching Gel (Regular, Mint or Melon)**

(Contd. of page 2)

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

#### 4 First aid measures

· **Description of first aid measures**

· **General information:**

Immediately remove any clothing soiled by the product.

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

· **After inhalation:**

This product is a viscous gel, therefore chance of inhalation is extremely low.

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.

In case of unconsciousness place patient stably in side position for transportation.

· **After skin contact:**

Immediately wash with water and soap and rinse thoroughly.

If skin irritation continues, consult a doctor.

· **After eye contact:**

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

· **After swallowing:** If swallowed in large quantities seek medical attention.

· **Information for doctor:**

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

· **Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

#### 5 Firefighting measures

· **Extinguishing media**

· **Suitable extinguishing agents:** Water spray

· **Special hazards arising from the substance or mixture** No further relevant information available.

· **Advice for firefighters:**

· **Protective equipment:**

Wear fully protective suit.

Mouth respiratory protective device.

#### 6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures**

Wear protective equipment. Keep unprotected persons away.

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

· **Methods and material for containment and cleaning up:**

Dispose contaminated material as waste according to item 13.

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

Ensure adequate ventilation.

· **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.

GB2

(Contd. on page 4)

# Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 13.05.2020

Revision: 18.07.2019

**Trade name: Opalescence™ PF, 10-20% Bleaching Gel (Regular, Mint or Melon)**

(Contd. of page 3)

## 7 Handling and storage

- **Handling:**
- **Precautions for safe handling:**  
Ensure good ventilation/exhaustion at the workplace.  
Prevent formation of aerosols.
- **Information about fire - and explosion protection:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**  
See product labelling.  
Keep container tightly sealed.
- **Specific end use(s)** Professional Dental Teeth Whitening Gel

## 8 Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **Control parameters**

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

### 56-81-5 Glycerine

WEL (Great Britain) Long-term value: 10 mg/m<sup>3</sup>

### 1310-73-2 Sodium Hydroxide

WEL (Great Britain) Short-term value: 2 mg/m<sup>3</sup>

- **Additional information:** The lists valid during the making were used as basis.
- **Exposure controls**
- **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:**  
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
- **Protection of hands:**



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 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.

(Contd. on page 5)

# Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 13.05.2020

Revision: 18.07.2019

**Trade name: Opalescence™ PF, 10-20% Bleaching Gel (Regular, Mint or Melon)**

(Contd. of page 4)

· **Penetration time of glove material**

The exact breakthrough time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye protection:**



Tightly sealed goggles

· **Body protection:** Protective work clothing

## 9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

<b>Form:</b>	Gel
<b>Colour:</b>	Colourless
<b>Odour:</b>	Product specific
<b>Odour threshold:</b>	Not determined.

· **pH-value at 20 °C:** 5.3-7.5

· **Change in condition**

<b>Melting point/freezing point:</b>	Undetermined.
<b>Initial boiling point and boiling range:</b>	Undetermined.

· **Flash point:** Not applicable.

· **Flammability (solid, gas):** Not applicable.

· **Decomposition temperature:** Not determined.

· **Auto-ignition temperature:** Product is not selfigniting.

· **Explosive properties:** Product does not present an explosion hazard.

· **Explosion limits:**

<b>Lower:</b>	Not determined.
<b>Upper:</b>	Not determined.

· **Vapour pressure:** Not determined.

<b>Density at 20 °C:</b>	1.2-1.3 g/cm <sup>3</sup>
<b>Relative density</b>	Not determined.
<b>Vapour density</b>	Not determined.
<b>Evaporation rate</b>	Not determined.

· **Solubility in / Miscibility with water:** Partly soluble.

· **Partition coefficient: n-octanol/water:** Not determined.

· **Viscosity:**

<b>Dynamic:</b>	Not determined.
<b>Kinematic:</b>	Not determined.

· **Solvent content:**

<b>Organic solvents:</b>	<60 %
<b>Water:</b>	<50 %

(Contd. on page 6)

**Safety data sheet**  
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Revision: 18.07.2019

**Trade name: Opalescence™ PF, 10-20% Bleaching Gel (Regular, Mint or Melon)**

(Contd. of page 5)

<b>VOC (EC)</b>	<1 %
<b>Solids content:</b>	<60.0 %
<b>Other information</b>	No further relevant information available.

### 10 Stability and reactivity

- **Reactivity Stable**
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions:** No dangerous reactions known.
- **Conditions to avoid:** Excess heat
- **Incompatible materials:**  
Strong Alkalis  
Metals
- **Hazardous decomposition products:** No dangerous decomposition products known.

### 11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity**  
Harmful if inhaled.

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

<b>ATE (Acute Toxicity Estimates)</b>		
Oral	LD50	3,688-7,498 mg/kg
Dermal	LD50	27,959 mg/kg (rabbit)
Inhalative	LC50/4 h	>0.403 mg/l (rat)
<b>56-81-5 Glycerine</b>		
Oral	LD50	7,750 mg/kg (Guinea pig)
		4,100 mg/kg (mouse)
		5,570 mg/kg (rat)
		27,000 mg/kg (rabbit)
Dermal	LC50 Fish	>5,000 mg/l (Fish)
	LD50	>21,900 mg/kg (rat)
Inhalative	LC50/4 h	10,000 mg/kg (rabbit)
		>0.1425 mg/l (rat)
<b>124-43-6 Carbamide Peroxide</b>		
Oral	LD50	>2,000 mg/kg (rat)
<b>1310-73-2 Sodium Hydroxide</b>		
Oral	LD50	130-340 mg/kg (rat)
	LC50 Fish	160 mg/l (Fish)
Dermal	LD50	1,350 mg/kg (rabbit)
	Absolute lethal concentration	180 ppm (Fish)
<b>8006-90-4 Oils, Peppermint</b>		
Oral	LD50	2,490 mg/kg (mouse)

(Contd. on page 7)

# Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 13.05.2020

Revision: 18.07.2019

**Trade name: Opalescence™ PF, 10-20% Bleaching Gel (Regular, Mint or Melon)**

(Contd. of page 6)

		2,426 mg/kg (rat)
<b>7681-49-4 Sodium Fluoride</b>		
Oral	LD50	52 mg/kg (mouse)
	LC50 Fish (static)	17 mg/l (Fish)
Dermal	LD50	175 mg/kg (rat)

- **Primary irritant effect:**
- **Skin corrosion/irritation**  
Causes skin irritation.
- **Serious eye damage/irritation**  
Causes serious eye irritation.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **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.

## 12 Ecological information

- **Toxicity**

· <b>Aquatic toxicity:</b>	
<b>56-81-5 Glycerine</b>	
EC50	>10,000 mg/l (Bacteria) >10,000 mg/l (daphnia)
<b>1310-73-2 Sodium Hydroxide</b>	
EC50	40.38 mg/l (Water Flea)
<b>7681-49-4 Sodium Fluoride</b>	
EC50	272 mg/kg (Algae) 98 mg/kg (daphnia)
Algae Toxicity (static)	7 mg/l (Algae)

- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**  
Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water  
Do not allow product to reach ground water, water course or sewage system.  
Danger to drinking water if even small quantities leak into the ground.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

GB2

(Contd. on page 8)

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

Printing date 13.05.2020

Revision: 18.07.2019

**Trade name: Opalescence™ PF, 10-20% Bleaching Gel (Regular, Mint or Melon)**

(Contd. of page 7)

### 13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**  
Must not be disposed together with household garbage. Do not allow product to reach sewage system.

- **European waste catalogue**

HP8	Corrosive
-----	-----------

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

### 14 Transport information

- |  |                 |
|--|-----------------|
| · <b>UN-Number</b><br>· <b>ADR, IMDG, IATA</b>   | not regulated   |
| · <b>UN proper shipping name</b><br>· <b>ADR, IMDG, IATA</b>                           | not regulated   |
| · <b>Transport hazard class(es)</b><br>· <b>ADR, ADN, IMDG, IATA</b><br>· <b>Class</b> | not regulated   |
| · <b>Packing group</b><br>· <b>ADR, IMDG, IATA</b>                                     | not regulated   |
| · <b>Environmental hazards:</b>  | Not applicable. |
| · <b>Special precautions for user</b>  | Not applicable. |
| · <b>Transport in bulk according to Annex II of Marpol and the IBC Code</b>            | Not applicable. |
| · <b>UN "Model Regulation":</b>  | not regulated   |

### 15 Regulatory information

- **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.
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3
- **Chemical safety assessment:**  
The 10-16% products meet the toxicological profile required for cosmetics per the EU cosmetic regulation, Regulation (EC) No. 1223/2009.

### 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.

- **Relevant phrases**  
H226 Flammable liquid and vapour.

(Contd. on page 9)



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

Printing date 13.05.2020

Revision: 18.07.2019

**Trade name: Opalescence™ PF, 10-20% Bleaching Gel (Regular, Mint or Melon)**

(Contd. of page 8)

H272 May intensify fire; oxidiser.  
 H301 Toxic if swallowed.  
 H304 May be fatal if swallowed and enters airways.  
 H310 Fatal in contact with skin.  
 H312 Harmful in contact with skin.  
 H314 Causes severe skin burns and eye damage.  
 H315 Causes skin irritation.  
 H317 May cause an allergic skin reaction.  
 H319 Causes serious eye irritation.  
 H335 May cause respiratory irritation.  
 H336 May cause drowsiness or dizziness.  
 H411 Toxic to aquatic life with long lasting effects.

· **Department issuing SDS:** Regulatory Affairs

· **Contact:** Customer Service

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport 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)

VOC: Volatile Organic Compounds (USA, EU)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Flam. Liq. 3: Flammable liquids – Category 3

Ox. Sol. 2: Oxidizing solids – Category 2

Ox. Sol. 3: Oxidizing solids – Category 3

Acute Tox. 3: Acute toxicity - oral – Category 3

Acute Tox. 2: Acute toxicity - dermal – Category 2

Acute Tox. 4: Acute toxicity - dermal – Category 4

Skin Corr. 1A: Skin corrosion/irritation – Category 1A

Skin Corr. 1B: Skin corrosion/irritation – Category 1B

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Skin Sens. 1: Skin sensitisation – Category 1

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

Asp. Tox. 1: Aspiration hazard – Category 1

Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2

GB2

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

Printing date 16.11.2022

Version number 1

Revision: 16.11.2022

**1 Identification of the substance/mixture and of the company/undertaking**

- **Product identifier**
- **Trade name:** *Opalescence™ Whitening Toothpaste*
- **Article number:** *SDS 12-001.12, 1008310, 11577*
- **Relevant identified uses of the substance or mixture and uses advised against** *Toothpaste*
- **Application of the substance / the mixture** *Toothpaste*
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
*Ultradent Products Inc.  
505 W. Ultradent Drive (10200 S)  
South Jordan, UT 84095-3942  
USA  
onlineordersupport@ultradent.com*
- **EC Responsible Person**  
*Ultradent Products GmbH  
Am Westhover Berg 30  
51149 Cologne Germany  
Email: infoDE@ultradent.com  
Emergency Phone: +49(0)2203-35-92-0*
- **Further information obtainable from:** *Customer Service*
- **Emergency telephone number:**  
*CHEMTREC (NORTH AMERICA) : (800) 424-9300  
(INTERNATIONAL) : +(703) 527-3887*

**2 Hazards identification**

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**



*Eye Irrit. 2 H319 Causes serious eye irritation.*

- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** *Void*
- **Hazard pictograms** *GHS07*
- **Signal word** *Warning*
- **Hazard statements**  
*H319 Causes serious eye irritation.*
- **Precautionary statements**  

<i>P101</i>	<i>If medical advice is needed, have product container or label at hand.</i>
<i>P102</i>	<i>Keep out of reach of children.</i>
<i>P103</i>	<i>Read carefully and follow all instructions.</i>
<i>P264</i>	<i>Wash thoroughly after handling.</i>
<i>P280</i>	<i>Wear eye protection / face protection.</i>
<i>P305+P351+P338</i>	<i>IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</i>

(Contd. on page 2)

# Safety data sheet

## according to 1907/2006/EC, Article 31

Printing date 16.11.2022

Version number 1

Revision: 16.11.2022

**Trade name: Opalescence™ Whitening Toothpaste**

P337+P313

If eye irritation persists: Get medical advice/attention.

(Contd. of page 1)

### 3 Composition/information on ingredients

- **Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

- **Dangerous components:**

CAS: 56-81-5 EINECS: 200-289-5	Glycerin substance with a Community workplace exposure limit	>20-<40%
CAS: 112926-00-8 EC number: 601-214-2	Synthetic Amorphous Silica ⚠ Acute Tox. 3, H331	>10-<30%
CAS: 119-36-8 EINECS: 204-317-7	Methyl Salicylate ⚠ Acute Tox. 4, H302	>1-<5%
CAS: 151-21-3 EINECS: 205-788-1	Sodium Lauryl Sulfate ⚠ Eye Dam. 1, H318; ⚠ Acute Tox. 4, H302; Skin Irrit. 2, H315; Aquatic Chronic 3, H412	≥1-<2.5%
CAS: 8006-90-4 EINECS: 282-015-4	Oils, Peppermint ⚠ Asp. Tox. 1, H304; ⚠ Aquatic Chronic 2, H411; ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	<1%
CAS: 7681-49-4 EINECS: 231-667-8	Sodium Fluoride ⚠ Acute Tox. 3, H301; Acute Tox. 2, H310; ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319, EUH032	<1%
CAS: 1310-73-2 EINECS: 215-185-5	Sodium Hydroxide ⚠ Acute Tox. 3, H301; ⚠ Skin Corr. 1A, H314; Eye Dam. 1, H318; ⚠ Acute Tox. 4, H312	<1%

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

### 4 First aid measures

- **Description of first aid measures**
- **After inhalation:** This product is a viscous gel, therefore chance of inhalation is extremely low.
- **After skin contact:** Rinse with water and soap.
- **After eye contact:**  
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing:** If swallowed in large quantities seek medical attention.
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

### 5 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**  
Dry Chemical  
Water spray  
Water mist  
Water fog  
Foam, dry chemical, carbon dioxide  
Use fire extinguishing methods suitable to surrounding conditions.

(Contd. on page 3)

# Safety data sheet

## according to 1907/2006/EC, Article 31

Printing date 16.11.2022

Version number 1

Revision: 16.11.2022

**Trade name: Opalescence™ Whitening Toothpaste**

(Contd. of page 2)

- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters:**
- **Protective equipment:** Wear fully protective suit.

### 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Wear protective clothing.
- **Environmental precautions:**
  - Dilute with plenty of water.
  - Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
  - Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **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.

### 7 Handling and storage

- **Precautions for safe handling:** No special precautions are necessary if used correctly.
- **Information about fire - and explosion protection:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
  - See product labelling.
  - Keep container tightly sealed.
- **Specific end use(s)** Toothpaste

### 8 Exposure controls/personal protection

- **Control parameters**

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

#### 56-81-5 Glycerin

WEL Long-term value: 10 mg/m<sup>3</sup>

#### 1310-73-2 Sodium Hydroxide

WEL Short-term value: 2 mg/m<sup>3</sup>

- **Additional information:** The lists valid during the making were used as basis.
- **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.
  - Avoid contact with the eyes and skin.
- **Respiratory protection:** Not required.

(Contd. on page 4)

# Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 16.11.2022

Version number 1

Revision: 16.11.2022

Trade name: Opalescence™ Whitening Toothpaste

(Contd. of page 3)

### · 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 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 breakthrough time has to be found out by the manufacturer of the protective gloves and has to be observed.

### · Eye/face protection



Tightly sealed goggles

· **Body protection:** Protective work clothing

## 9 Physical and chemical properties

### · Information on basic physical and chemical properties

#### · General Information

· Physical state	Fluid
· Colour:	According to product specification
· Odour:	Characteristic
· 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:	Not determined.
· Upper:	Not determined.
· Flash point:	177 °C
· Decomposition temperature:	Not determined.
· pH at 20 °C	6.3-7.6
· Viscosity:	
· Kinematic viscosity	Not determined.
· Dynamic:	Not determined.
· Solubility	
· water:	Partly soluble.
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure:	Not determined.
· Density and/or relative density	
· Density at 20 °C:	1.214 g/cm <sup>3</sup>
· Relative density	Not determined.
· Vapour density	Not determined.

(Contd. on page 5)

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

Printing date 16.11.2022

Version number 1

Revision: 16.11.2022

Trade name: Opalescence™ Whitening Toothpaste

(Contd. of page 4)

- **Other information**
  - **Appearance:**
  - **Form:** Fluid
  - **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
  - **Pyrophoric liquids** Void
  - **Pyrophoric solids** Void
  - **Self-heating substances and mixtures** Void
  - **Substances and mixtures, which emit flammable gases in contact with water** Void
  - **Oxidising liquids** Void
  - **Oxidising solids** Void
  - **Organic peroxides** Void
  - **Corrosive to metals** Void
  - **Desensitised explosives** Void

## 10 Stability and reactivity

- **Reactivity** Stable
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions:** No dangerous reactions known.
- **Conditions to avoid:**  
Light  
Ignition sources  
Heat
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

## 11 Toxicological information

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

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

**ATE (Acute Toxicity Estimates)**

Oral	LD50	11,104-12,270 mg/kg
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(Contd. on page 6)

GB

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

Printing date 16.11.2022

Version number 1

Revision: 16.11.2022

**Trade name: Opalescence™ Whitening Toothpaste**

(Contd. of page 5)

Dermal	LD50	70,000 mg/kg
Inhalative	LC50/4 h	2.58 mg/l

**56-81-5 Glycerin**

Oral	LD50	7,750 mg/kg (Guinea pig) 4,100 mg/kg (mouse) 5,570 mg/kg (rat) 27,000 mg/kg (rabbit)
Dermal	LC50 Fish	>5,000 mg/l (Fish)
	LD50	>21,900 mg/kg (rat) 10,000 mg/kg (rabbit)

**112926-00-8 Synthetic Amorphous Silica**

Oral	LD50	>5,000 mg/kg (rat)
Dermal	LD50	>5,000 mg/kg (rabbit)

**119-36-8 Methyl Salicylate**

Oral	LD50	887 mg/kg (rat) 2,800 mg/kg (rabbit)
	LC50 Fish	19.8 mg/l (Fish)
Dermal	LD50	>5,000 mg/kg (rabbit)

**151-21-3 Sodium Lauryl Sulfate**

Oral	LD50	1,288 mg/kg (rat)
	LC50 Fish	14.67-15.51 mg/l (Fish)
	LC50(Daphnia magna) (static)	1.8 mg/l (daphnia)

**8006-90-4 Oils, Peppermint**

Oral	LD50	2,490 mg/kg (mouse) 2,426 mg/kg (rat)
------	------	--

**7681-49-4 Sodium Fluoride**

Oral	LD50	52 mg/kg (mouse)
	LC50 Fish (static)	17 mg/l (Fish)
Dermal	LD50	175 mg/kg (rat)

**1310-73-2 Sodium Hydroxide**

Oral	LD50	130-340 mg/kg (rat)
	LC50 Fish	160 mg/l (Fish)
Dermal	LD50	1,350 mg/kg (rabbit)
	Absolute lethal concentration	180 ppm (Fish)

· **Serious eye damage/irritation** Causes serious eye irritation.

· **Information on other hazards**

· **Endocrine disrupting properties**

None of the ingredients is listed.

GB

(Contd. on page 7)

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

Printing date 16.11.2022

Version number 1

Revision: 16.11.2022

Trade name: Opalescence™ Whitening Toothpaste

(Contd. of page 6)

## 12 Ecological information

- **Toxicity**

· <b>Aquatic toxicity:</b>	
<b>56-81-5 Glycerin</b>	
EC50	>10,000 mg/kg (Bacteria)
<b>119-36-8 Methyl Salicylate</b>	
EC50	28 mg/kg (daphnia)
Aqua toxicity	1.6 mg/l (Algae)
<b>151-21-3 Sodium Lauryl Sulfate</b>	
EC50 (static)	16.5 mg/kg (Crustacean)
	50.6-52.3 mg/kg (daphnia)
<b>7681-49-4 Sodium Fluoride</b>	
EC50	272 mg/kg (Algae)
	98 mg/kg (daphnia)
Algae Toxicity (static)	7 mg/l (Algae)
<b>1310-73-2 Sodium Hydroxide</b>	
EC50	40.38 mg/kg (Water Flea)

- **Persistence and degradability** No further relevant information available.
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Endocrine disrupting properties** The product does not contain substances with endocrine disrupting properties.
- **Other adverse effects**
- **Additional ecological information:**
- **General notes:**  
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water  
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

## 13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**  
Dispose of contents/container in accordance with international, federal, state, and local regulations.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

## 14 Transport information

- **UN number or ID number**
- **ADR, IMDG, IATA** not regulated

(Contd. on page 8)

GB



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

Printing date 16.11.2022

Version number 1

Revision: 16.11.2022

**Trade name: Opalescence™ Whitening Toothpaste**

(Contd. of page 7)

· <b>UN proper shipping name</b> · <b>ADR, IMDG, IATA</b>	<i>not regulated</i>
· <b>Transport hazard class(es)</b> · <b>ADR, ADN, IMDG, IATA</b> · <b>Class</b>	<i>not regulated</i>
· <b>Packing group</b> · <b>ADR, IMDG, IATA</b>	<i>not regulated</i>
· <b>Environmental hazards:</b>	<i>Not applicable.</i>
· <b>Special precautions for user</b>	<i>Not Applicable</i>
· <b>Maritime transport in bulk according to IMO instruments</b>	<i>Not applicable.</i>
· <b>UN "Model Regulation":</b>	<i>not regulated</i>

### 15 Regulatory information

- **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.
- **Chemical safety assessment:**  
*The product meets the toxicological profile required for cosmetics per the EU cosmetic regulation, Regulation (EC) No. 1223/2009.*

### 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.*

- **Relevant phrases from Section 3**
  - H301 Toxic if swallowed.
  - H302 Harmful if swallowed.
  - H304 May be fatal if swallowed and enters airways.
  - H310 Fatal in contact with skin.
  - H312 Harmful 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.
  - H331 Toxic if inhaled.
  - H411 Toxic to aquatic life with long lasting effects.
  - H412 Harmful to aquatic life with long lasting effects.
  - EUH032 Contact with acids liberates very toxic gas.
- **Department issuing SDS:** Environmental, Health, and Safety
- **Contact:** Customer Service
- **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

(Contd. on page 9)

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

Printing date 16.11.2022

Version number 1

Revision: 16.11.2022

**Trade name: Opalescence™ Whitening Toothpaste**

(Contd. of page 8)

*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**Acute Tox. 4: Acute toxicity – Category 4**Acute Tox. 2: Acute toxicity – Category 2**Acute Tox. 3: Acute toxicity – Category 3**Skin Corr. 1A: Skin corrosion/irritation – Category 1A**Skin Irrit. 2: Skin corrosion/irritation – Category 2**Eye Dam. 1: Serious eye damage/eye irritation – Category 1**Eye Irrit. 2: Serious eye damage/eye irritation – Category 2**Skin Sens. 1: Skin sensitisation – Category 1**Asp. Tox. 1: Aspiration hazard – Category 1**Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2**Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3***\* Data compared to the previous version altered.**

GB

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

Printing date 22.04.2020

Revision: 22.11.2019

**1 Identification of the substance/mixture and of the company/undertaking**

- **Product identifier**
- **Trade name:** Ultradent™ LC Block-Out Resin
- **Article number:** 10318
- **Index number:** SDS 30-001.11
- **Relevant identified uses of the substance or mixture and uses advised against** Dental Laboratory Resin
- **Application of the substance / the mixture** Dental Laboratory Resin
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Ultradent Products Inc.  
505 W. Ultradent Drive (10200 S)  
South Jordan, UT 84095-3942  
USA  
onlineordersupport@ultradent.com
- **EC Responsible Person**  
Ultradent Products GmbH  
Am Westhoyer Berg 30  
51149 Cologne Germany  
Email: infoDe@ultradent.com  
Emergency Phone: +49(0)2203-35-92-0
- **Further information obtainable from:** Customer Service
- **Emergency telephone number:**  
CHEMTREC (NORTH AMERICA) : (800) 424-9300  
(INTERNATIONAL) : +(703) 527-3887

**2 Hazards identification**

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**



GHS07

Acute Tox. 4 H332 Harmful if inhaled.  
Skin Sens. 1 H317 May cause an allergic skin reaction.

- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Hazard pictograms**



GHS07

- **Signal word** Warning
- **Hazard-determining components of labelling:**  
Diurethane Dimethacrylate  
Triethylene Glycol Dimethacrylate  
Amine Methacrylate

(Contd. on page 2)

# Safety data sheet

## according to 1907/2006/EC, Article 31

Printing date 22.04.2020

Revision: 22.11.2019

Trade name: **Ultradent™ LC Block-Out Resin**

(Contd. of page 1)

- **Hazard statements**

H332 Harmful if inhaled.

H317 May cause an allergic skin reaction.

- **Precautionary statements**

P101 If medical advice is needed, have product container or label at hand.

P102 Keep out of reach of children.

P103 Read label before use.

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P271 Use only outdoors or in a well-ventilated area.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves.

P302+P352 IF ON SKIN: Wash with plenty of water.

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P312 Call a POISON CENTER/doctor if you feel unwell.

P321 Specific treatment (see on this label).

P362+P364 Take off contaminated clothing and wash it before reuse.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- **Other hazards**

- **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.

- **vPvB:** Not applicable.

### 3 Composition/information on ingredients

- **Chemical characterisation: Mixtures**

- **Description:** Mixture of substances listed below with nonhazardous additions.

- **Dangerous components:**

CAS: 72869-86-4	Diurethane Dimethacrylate	<90%
EINECS: 276-957-5	⚠ Skin Sens. 1, H317	
CAS: 109-16-0	Triethylene Glycol Dimethacrylate	<25%
EINECS: 203-652-6	⚠ Skin Sens. 1, H317	
	Amine Methacrylate	<1%
	⚠ Acute Tox. 4, H302; Acute Tox. 4, H312; Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	

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

### 4 First aid measures

- **Description of first aid measures**

- **General information:**

Immediately remove any clothing soiled by the product.

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

- **After inhalation:**

This product is a viscous gel, therefore chance of inhalation is extremely low.

Seek medical treatment 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.

- **After swallowing:**

Rinse out mouth and then drink plenty of water.

(Contd. on page 3)

# Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 22.04.2020

Revision: 22.11.2019

**Trade name: Ultradent™ LC Block-Out Resin**

(Contd. of page 2)

- *Seek medical treatment.*
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** *No further relevant information available.*
- **Indication of any immediate medical attention and special treatment needed**  
*No further relevant information available.*

## 5 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
  - Water spray*
  - Foam*
  - Fire-extinguishing powder*
  - Use fire extinguishing methods suitable to surrounding conditions.*
- **Special hazards arising from the substance or mixture**
  - Carbon monoxide (CO)*
  - Nitrogen oxides (NO<sub>x</sub>)*
  - During fire, gases hazardous to health may be formed.*
- **Advice for firefighters:**
- **Protective equipment:**
  - Wear fully protective suit.*
  - Mouth respiratory protective device.*

## 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** *Not required.*
- **Environmental precautions:** *Do not allow to enter sewers/ surface or ground water.*
- **Methods and material for containment and cleaning up:**
  - Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).*
  - Dispose contaminated material as waste according to item 13.*
  - Ensure adequate ventilation.*
- **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.*

## 7 Handling and storage

- **Handling:**
- **Precautions for safe handling:**
  - Keep receptacles tightly sealed.*
  - Ensure good ventilation/exhaustion at the workplace.*
  - Prevent formation of aerosols.*
- **Information about fire - and explosion protection:** *No special measures required.*
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**
  - Store in a cool location.*
  - Store only in the original receptacle.*
- **Information about storage in one common storage facility:**
  - Store away from oxidising agents.*

(Contd. on page 4)

# Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 22.04.2020

Revision: 22.11.2019

**Trade name: Ultradent™ LC Block-Out Resin**

(Contd. of page 3)

Store away from foodstuffs.

· **Further information about storage conditions:**

Protect from heat and direct sunlight.

See product labelling.

Keep container tightly sealed.

· **Specific end use(s)** Dental Laboratory Resin

## 8 Exposure controls/personal protection

· **Additional information about design of technical facilities:** No further data; see item 7.

· **Control parameters**

· **Ingredients with limit values that require monitoring at the workplace:**

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

· **Additional information:** The lists valid during the making were used as basis.

· **Exposure controls**

· **Personal protective equipment:**

· **General protective and hygienic measures:**

Do not eat or drink while working.

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

· **Respiratory protection:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

· **Protection of hands:**



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 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 breakthrough time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye protection:** Goggles recommended during refilling

· **Body protection:** Protective work clothing

## 9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

**Form:** Gel

**Colour:** Blue

(Contd. on page 5)

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

Printing date 22.04.2020

Revision: 22.11.2019

Trade name: **Ultradent™ LC Block-Out Resin**

(Contd. of page 4)

· <b>Odour:</b>	Methacrylate
· <b>Odour threshold:</b>	Not determined.
· <b>pH-value:</b>	Not applicable (non-aqueous)
· <b>Change in condition</b>	
<b>Melting point/freezing point:</b>	<25 °C
<b>Initial boiling point and boiling range:</b>	>100 °C
· <b>Flash point:</b>	Not applicable.
· <b>Flammability (solid, gas):</b>	Not applicable.
· <b>Decomposition temperature:</b>	260 °C (TGA trace)
· <b>Auto-ignition temperature:</b>	Product is not selfigniting.
· <b>Explosive properties:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b>	
<b>Lower:</b>	Not determined.
<b>Upper:</b>	Not determined.
· <b>Vapour pressure:</b>	Not determined.
· <b>Density at 20 °C:</b>	1.1-1.2 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with water:</b>	Insoluble.
· <b>Partition coefficient: n-octanol/water:</b>	Not determined.
· <b>Viscosity:</b>	
<b>Dynamic at 20 °C:</b>	46,000 cps
<b>Kinematic:</b>	Not determined.
· <b>Solvent content:</b>	
<b>VOC (EC)</b>	<1%
<b>Solids content:</b>	<30.0 %
· <b>Other information</b>	No further relevant information available.

### 10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions:** No dangerous reactions known.
- **Conditions to avoid:**
  - Light
  - UV light
- **Incompatible materials:** Strong oxidizing agents
- **Hazardous decomposition products:** No dangerous decomposition products known.

GB2

(Contd. on page 6)

# Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 22.04.2020

Revision: 22.11.2019

Trade name: **Ultradent™ LC Block-Out Resin**

(Contd. of page 5)

## 11 Toxicological information

- **Information on toxicological effects**

- **Acute toxicity**

Harmful if inhaled.

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

**ATE (Acute Toxicity Estimates)**

Inhalative	LC50/4 h	3.71 mg/l (rat)
------------	----------	-----------------

**72869-86-4 Diurethane Dimethacrylate**

Oral	LD50	>5,000 mg/kg (rat)
------	------	--------------------

**109-16-0 Triethylene Glycol Dimethacrylate**

Oral	LD50	>5,000 mg/kg (rat)
	LC50 Fish	16.4 mg/l (Fish) (Toxicity to fish)
Dermal	LD50	>2,000 mg/kg (mouse)

**Amine Methacrylate**

Oral	LD50	1,550 mg/kg (rat)
	LC50 Fish	19 mg/l (Fish)
Dermal	LD50	2,000 mg/kg (rabbit)
Inhalative	LC50/4 h	96 mg/l (rat)

- **Primary irritant effect:**

- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.

- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.

- **Respiratory or skin sensitisation**

May cause an allergic skin reaction.

- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**

- **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.

## 12 Ecological information

- **Toxicity**

- **Aquatic toxicity:**

**72869-86-4 Diurethane Dimethacrylate**

Biodegradability	28 days (Aerobic) (Biodegradability testing)
EC50	>0.6 mg/l (Algae) (Toxicity to algae)
	>1.2 mg/l (daphnia) (Toxicity to aquatic invertebrates)

**109-16-0 Triethylene Glycol Dimethacrylate**

Biodegradability	28 days (Aerobic) (Biodegradability testing)
Aqua toxicity	32 mg/l (daphnia) (No Observed Effect Concentration)
EC50	>100 mg/l (Algae) (Toxicity to algae)

**Amine Methacrylate**

EC50	42 mg/l (Algae)
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(Contd. on page 7)



# Safety data sheet

## according to 1907/2006/EC, Article 31

Printing date 22.04.2020

Revision: 22.11.2019

**Trade name: Ultradent™ LC Block-Out Resin**

(Contd. of page 6)

- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**  
*Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water*  
*Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.*
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

### 13 Disposal considerations

- **Waste treatment methods**
- **Recommendation** Do not allow product to reach sewage system.

· <b>European waste catalogue</b>
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HP13	Sensitising
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- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

### 14 Transport information

- |   |                        |
|---|------------------------|
| · <b>UN-Number</b>  |                        |
| · <b>ADR, IMDG, IATA</b>  | <i>not regulated</i>   |
| · <b>UN proper shipping name</b>  |                        |
| · <b>ADR, IMDG, IATA</b>  | <i>not regulated</i>   |
| · <b>Transport hazard class(es)</b>   |                        |
| · <b>ADR, ADN, IMDG, IATA</b>   |                        |
| · <b>Class</b>  | <i>not regulated</i>   |
| · <b>Packing group</b>  |                        |
| · <b>ADR, IMDG, IATA</b>  | <i>not regulated</i>   |
| · <b>Environmental hazards:</b>   | <i>Not applicable.</i> |
| · <b>Special precautions for user</b>                                       | <i>Not applicable.</i> |
| · <b>Transport in bulk according to Annex II of Marpol and the IBC Code</b> | <i>Not applicable.</i> |
| · <b>UN "Model Regulation":</b>   | <i>not regulated</i>   |

### 15 Regulatory information

- **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.
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3

(Contd. on page 8)

GB2

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

Printing date 22.04.2020

Revision: 22.11.2019

**Trade name: Ultradent™ LC Block-Out Resin**

(Contd. of page 7)

· **Chemical safety assessment:**

Device is biocompatible when used as directed by dental professionals per ISO 10993-1

## 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.*

· **Relevant phrases**

H302 Harmful if swallowed.

H312 Harmful in contact with skin.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

· **Department issuing SDS:** Regulatory Affairs

· **Contact:** Customer Service

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport 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)

VOC: Volatile Organic Compounds (USA, EU)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Acute Tox. 4: Acute toxicity - oral – Category 4

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Skin Sens. 1: Skin sensitisation – Category 1