

# SAFETY DATA SHEETS

**This SDS packet was issued with item:**

074570206

N/A

# SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010  
Dental Use



Kulzer, LLC  
4315 S. Lafayette Blvd.  
South Bend, IN 46614 USA

Date Issued : 02/16/2018  
SDS No : 138-250.01

## Venus White Activator

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

#### 1.1. Product identifier

**Product code** : 40005211 (XQ/15034)  
**Product name** : Venus White Activator  
**Product description** : Dental Bleaching Gel Activator

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

**Relevant identified uses** : Professional Dental Bleaching Gel Activator

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

##### Manufacturer

Kulzer, LLC (Mitsui Chemicals Group)  
4315 S. Lafayette Blvd.  
South Bend, IN 46614

**Customer Support** : (800) 431-1785

#### 1.4. Emergency telephone number

**CHEMTREC (NORTH AMERICA)** : (800) 424 - 9300  
**(INTERNATIONAL)** : +1(703) 527 - 3887

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture


##### Classification according to Regulation(EC) No 1272/2008 [CLP]

: The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

**Health** : Skin Corrosion, Category 1A  
Acute Toxicity (Oral), Category 4

#### 2.2. Label elements

##### Classification according to Regulation(EC) No 1272/2008 [CLP]

**Hazard pictogram(s)** :   
Corrosive

**Signal Word** : DANGER

**Hazard statement(s)** : H314: Causes severe skin burns and eye damage.  
H302: Harmful if swallowed.

##### Precautionary statement(s)

**Prevention** : P280: Wear protective gloves/protective clothing/eye protection/face protection.

**Response** : P305: IF IN EYES:

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P351: Rinse cautiously with water for several minutes.  
P315: Get immediate medical advice/attention.  
P306+P360: IF ON CLOTHING: Rinse immediately contaminated clothing and skin with plenty of water before removing clothes.  
P313: Get medical advice/attention.  
P363: Wash contaminated clothing before reuse.  
P301: IF SWALLOWED:  
P310: Immediately call a POISON CENTER or doctor/physician.  
P330: Rinse mouth.  
P331: Do NOT induce vomiting.

**Storage** : P273: Avoid release to the environment.

**Disposal** : P501: Dispose of in compliance with governmental regulation. (EC1975L0442-20/11/2003)

### 2.3. Other hazards

**Immediate concerns** : Corrosive. Will cause eye burns and permanent tissue damage.

## SECTION 3: Composition / information on ingredients

### 3.1. Substances

Not Applicable

### 3.2. Mixtures

Chemical Name	CAS	EINECS No.	Wt.%	Classification according to Regulation(EC) No 1272/2008 [CLP]
Potassium Hydroxide	1310-58-3	215-181-3	< 15	Acute Tox. (O),Cat. 4; Skin Corr.,Cat. 1A; H302; H314
Glycerin	56-81-5	200-289-5	< 86	Not classified

For full text of H-statements: see SECTION 16.

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

**Following eyes** : Immediately flush eyes with plenty of water for at least 15 minutes. Get immediate medical attention.

**Following skin** : Immediately flush skin with plenty of water. Remove clothing. Get medical attention immediately. Wash clothing separately before reuse.

**Following ingestion** : If swallowed, rinse mouth with water, Do NOT Induce Vomiting. Give victim a glass of water or milk. Call a physician or poison control center if you feel unwell.

**Following inhalation** : No specific treatment is necessary since this material is not likely to be hazardous by inhalation. If exposed to excessive levels of dusts or fumes, remove to fresh air and get medical attention if cough or other symptoms develop.

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

<b>Eyes</b>	: Causes severe eye burns.
<b>Skin</b>	: Corrosive, causes skin burning.
<b>Ingestion</b>	: Harmful if swallowed.
<b>Inhalation</b>	: None expected for this product.

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

<b>Notes to physician</b>	: Corrosive
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## SECTION 5: Fire fighting measures

### 5.1. Extinguishing media

<b>Extinguishing media</b>	: Water spray, fog, or mist, foam, dry chemical, carbon dioxide (CO <sub>2</sub> )
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### 5.2. Special hazards arising from the substance or mixture

<b>Hazardous combustion products</b>	: None known.
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### 5.3. Advice for firefighters

<b>Fire fighting procedures</b>	: General: Evacuate all personnel; use protective equipment for fire-fighting. Use self-contained breathing apparatus when the product is involved in fire.
<b>Additional information</b>	: Do not use strong water jet for extinguishing - may cause spattering of burning material.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

<b>Special protective equipment</b>	: Wear suitable protective clothing, gloves and eye/face protection.
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### 6.2. Environmental precautions

<b>Water spill</b>	: Do not allow to enter sewers or drains that may lead to waterways.
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### 6.3. Methods and material for containment and cleaning up

<b>Small Spill</b>	: Clean up spills immediately, observing precautions in Protective Equipment section.
<b>Large Spill</b>	: Absorb with inert, damp non-combustible material, then flush area with water.

### 6.4. Reference to other sections

<b>Reference to other sections</b>	: NAP
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## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

<b>General procedures</b>	: Avoid contact with eyes, skin and clothing.
<b>Handling</b>	: Use suitable protective equipment.
<b>Storage</b>	: See product labeling.

### 7.2. Conditions for safe storage, including any incompatibilities

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**Shelf life** : See product labeling

### 7.3. Specific end use(s)

**Specific end use(s)** : Professional Dental Bleaching Gel Activator

## SECTION 8: Exposure controls / personal protection

### 8.1. Control parameters

**Control parameters** : Potassium Hydroxide CAS: 1310-58-3

Control Parameters	Exposure Limits
OSHA PEL	none
ACGIH TLV	2mg/m <sup>3</sup>
AIHA WHEEL	none
NIOSH REL	2mg/m <sup>3</sup>

#### Canada

Alberta	2mg/m <sup>3</sup> Ceiling
British Columbia	2mg/m <sup>3</sup> Ceiling
Ontario	2mg/m <sup>3</sup> Ceiling
Quebec	2mg/m <sup>3</sup> Ceiling

Australia: None

Mexico: None

### 8.2. Exposure controls

**Eye/face protection** : Use chemical splash goggles and face shield (ANSI Z87.1 or approved equivalent).

**Skin protection** : Wear suitable protective clothing and gloves.

**Respiratory protection** : Good general ventilation should be sufficient to control airborne levels.

**Other precautions** : Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.

## SECTION 9: Physical and chemical properties

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

**Physical state** : Gel

**Colour** : Whitish

**Odour** : Odorless or no characteristic odor

**pH** : > 12

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### 9.2. Other information

**Additional information** : No further relevant information available.

### SECTION 10: Stability and reactivity

#### 10.1. Reactivity

**Reactivity** : Stable

#### 10.2. Chemical stability

**Chemical stability** : Stable when stored and handled under recommended conditions.

#### 10.3. Possibility of hazardous reactions

**Hazardous polymerization** : None

#### 10.4. Conditions to avoid

**Conditions to avoid** : Heat, moisture, incompatibles.

#### 10.5. Incompatible materials

**Incompatible materials** : Acids, flammable liquids, organic halogen compounds, trichloroethylene, nitromethane, aluminum, tin, zinc.

#### 10.6. Hazardous decomposition products

**Hazardous decomposition products** : None known.

### SECTION 11: Toxicological information

#### 11.1. Information on toxicological effects

##### Acute

**Dermal LD<sub>50</sub>** : Not determined

**Oral LD<sub>50</sub>** : Not determined

**Inhalation LC<sub>50</sub>** : Not determined

### SECTION 12: Ecological information

#### 12.1. Toxicity

**Toxicity** : Readily biodegradable.

**Aquatic toxicity (acute)** : Do not allow to enter sewers or drains that may lead to waterways.

**96-hour LC<sub>50</sub>** : Not determined

**48-hour EC<sub>50</sub>** : Not determined

**96-hour EC<sub>50</sub>** : Not determined

#### 12.2. Persistence and degradability

**Persistence and degradability** : Not determined

#### 12.3. Bioaccumulative potential

**Bioaccumulative potential** : Not determined

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**12.4. Mobility in soil**

Mobility in soil : Does not bioaccumulate.

**12.5. Results of PBT and vPvB assessment**

Results of PBT and vPvB assessment : Not determined

**12.6. Other adverse effects**

Environmental data : Not defined

**SECTION 13: Disposal considerations**

**13.1. Waste treatment methods**

Disposal method : Dispose of in compliance with governmental regulation.(EC 1975L0442-20/11/2003)

**SECTION 14: Transport information**

**14.1. UN number**

UN number : 1760

**14.2. UN proper shipping name**

UN proper shipping name : Corrosive liquid N.O.S (Potassium Hydroxide Mixture)

**14.3. Transport hazard class(es)**

Primary hazard class/division : 8

**14.4. Packing group**

Packing group : II

**14.5. Environmental hazards**

Marine pollutant #1 : NAP

**14.6. Special precautions for user**

ADR - road : NAP

RID - rail : NAP

IMDG - sea : NAP

IATA - air : NAP

**14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**

Transport in bulk : NAP

**SECTION 15: Regulatory information**

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

General information : Please refer to Medical Devices Directive 93/42/EEC

**15.2. Chemical safety assessment**

Chemical safety assessment : Not Determined

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**SECTION 16: Other information**

<b>Relevant H-statements (number and full-text)</b>	: Acute Tox. (O), Cat. 4: Acute Toxicity (Oral), Category 4 Skin Corr., Cat. 1A: Skin Corrosion, Category 1A H302: Harmful if swallowed. H314: Causes severe skin burns and eye damage.
<b>Prepared by</b>	: Anu Kattoju
<b>General statements</b>	: NAP = Not Applicable NE = Not Established TLV = Threshold Limit Value PEL = Permittable exposure limits MAK = Maximum Workplace Concentration STEL = Short-term exposure limit STEV = Short-term exposure value TWA = Time Weighted Average PPE = Personal Protective Equipment
<b>Manufacturer disclaimer</b>	: FOR DENTAL USE ONLY: Use as directed. The information and recommendations are taken from sources (raw material SDS(s) and manufacturer's knowledge) believed to be accurate; however, the manufacturer, makes no warranty with respect to the accuracy of the information or the suitability of the recommendation and assumes no liability to any user thereof. Each user should review these recommendations in the specific context of the intended use and determine whether they are appropriate.



**Safety Data Sheet**  
*acc. to OSHA HCS*

Printing date 06/13/2018

Reviewed on 04/19/2018

**1 Identification**

- **Product identifier**
- **Trade name:** Gingival Barrier Venus White Max
- **Article number:** 40005202 (10130)
- **Index number:** SDS 93-250.01
- **Application of the substance / the mixture** Professional Light Cure Gingival Barrier
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Kulzer, LLC (Mitsui Chemicals Group)  
4315 S. Lafayette Blvd  
South Bend, IN 46614  
Customer Support : (800) 431-1785
- **Information department:** Customer Service
- **Emergency telephone number:**  
CHEMTREC (NORTH AMERICA) : (800) 424-9300  
(INTERNATIONAL) : +(703) 527-3887

**2 Hazard(s) identification**

- **Classification of the substance or mixture**



Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2A H319 Causes serious eye irritation.

Skin Sens. 1 H317 May cause an allergic skin reaction.

- **Label elements**
- **GHS label elements** The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**



GHS07

- **Signal word** Warning
- **Hazard-determining components of labeling:**  
DUDMA

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**Trade name: Gingival Barrier Venus White Max**

(Contd. of page 1)

*Amine Methacrylate*

· **Hazard statements**

*Causes skin irritation.*

*Causes serious eye irritation.*

*May cause an allergic skin reaction.*

· **Precautionary statements**

*Avoid breathing dust/fume/gas/mist/vapors/spray*

*Wash thoroughly after handling.*

*Contaminated work clothing must not be allowed out of the workplace.*

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

*If on skin: Wash with plenty of water.*

*If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.*

*Continue rinsing.*

*Take off contaminated clothing and wash it before reuse.*

*If skin irritation or rash occurs: Get medical advice/attention.*

*Specific treatment (see on this label).*

*If eye irritation persists: Get medical advice/attention.*

*Wash contaminated clothing before reuse.*

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

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



*Health = 2*

*Fire = 0*

*Reactivity = 0*

· **HMIS-ratings (scale 0 - 4)**



*Health = 2*

*Fire = 0*

*Reactivity = 0*

· **Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

### 3 Composition/information on ingredients

· **Chemical characterization: Mixtures**

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

· **Dangerous components:**

72869-86-4	DUDMA	>50-≤85%
112926-00-8	Synthetic Amorphous Silica	< 11%
12001-26-2	Mica	≤2.5%
	Amine Methacrylate	< 1%

### 4 First-aid measures

· **Description of first aid measures**

· **After inhalation:**

*Seek medical treatment in case of complaints.*

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Supply fresh air and to be sure call for a doctor.

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

· **After skin contact:**

If skin irritation continues, consult a doctor.

Immediately wash with water and soap and rinse thoroughly.

· **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 Fire-fighting measures

· **Extinguishing media**

· **Suitable extinguishing agents:**

Water spray, fog, or mist, foam, dry chemical, carbon dioxide

Use fire fighting measures that suit the environment.

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

· **Advice for firefighters**

· **Protective equipment:** No special measures required.

## 6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures** Not required.

· **Environmental precautions:** No special measures required.

· **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.

· **Protective Action Criteria for Chemicals**

· **PAC-1:**

72869-86-4	DUDMA	120 mg/m <sup>3</sup>
112926-00-8	Synthetic Amorphous Silica	18 mg/m <sup>3</sup>
12001-26-2	Mica	9 mg/m <sup>3</sup>

· **PAC-2:**

72869-86-4	DUDMA	1,300 mg/m <sup>3</sup>
112926-00-8	Synthetic Amorphous Silica	200 mg/m <sup>3</sup>
12001-26-2	Mica	99 mg/m <sup>3</sup>

· **PAC-3:**

72869-86-4	DUDMA	7,900 mg/m <sup>3</sup>
112926-00-8	Synthetic Amorphous Silica	1,200 mg/m <sup>3</sup>
12001-26-2	Mica	590 mg/m <sup>3</sup>

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Trade name: **Gingival Barrier Venus White Max**

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## 7 Handling and storage

- **Handling:**
- **Precautions for safe handling** No special precautions are necessary if used correctly.
- **Information about protection against explosions and fires:** 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 receptacle tightly sealed.
- **Specific end use(s)** Professional Light Cure Gingival Barrier

## 8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**
- **Components with limit values that require monitoring at the workplace:**  
The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit.  
At this time, the other constituents have no known exposure limits.

### 112926-00-8 Synthetic Amorphous Silica

PEL	20mppcf or 80mg/m <sup>3</sup> /%SiO <sub>2</sub>
REL	Long-term value: 6 mg/m <sup>3</sup> See Pocket Guide App. C
TLV	TLV withdrawn

### 12001-26-2 Mica

PEL	Long-term value: 20 mppcf ppm <1% crystalline silica
REL	Long-term value: 3* mg/m <sup>3</sup> *respirable dust; containing < 1% quartz
TLV	Long-term value: 3* mg/m <sup>3</sup> *as respirable fraction

- **Additional information:** The lists that were valid during the creation 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.
- **Breathing equipment:** Not required.
- **Protection of hands:**



Protective gloves

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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 is based 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:**



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>Color:</b>	Blue Green
· <b>Odor:</b>	Acrylic
· <b>Odor threshold:</b>	Not determined.

· **pH-value:** Not applicable (non-aqueous)

· **Change in condition**

· <b>Melting point/Melting range:</b>	Undetermined.
· <b>Boiling point/Boiling range:</b>	Undetermined.

· **Flash point:** Not applicable.

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

· **Decomposition temperature:** Not determined.

· **Auto igniting:** Product is not selfigniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Explosion limits:**

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

· **Vapor pressure:** Not determined.

· <b>Density at 20 °C:</b>	0.92-1.2 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined.
· <b>Vapor density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.

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- |   |  |
|---|--|
| <b>· Solubility in / Miscibility with Water:</b>  | Not miscible or difficult to mix.          |
| <b>· Partition coefficient (n-octanol/water):</b> | Not determined.                            |
| <b>· Viscosity:</b>                               |  |
| <b>Dynamic:</b>                                   | Not determined.                            |
| <b>Kinematic:</b>                                 | Not determined.                            |
| <b>· Solvent content:</b>                         |  |
| <b>VOC content:</b>                               | 0.00 %<br>0.0 g/l / 0.00 lb/gl             |
| <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** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

## 11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**

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

### ATE (Acute Toxicity Estimate)

Oral	LD50	26,667 mg/kg (mouse)
Dermal	LD50	>21,667 mg/kg (rabbit)
Inhalative	LC50/4 h	>17.3 mg/l (rat)

### 72869-86-4 DUDMA

Oral	LD50	>5,000 mg/kg (rat)
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### 112926-00-8 Synthetic Amorphous Silica

Oral	LD50	>5,000 mg/kg (rat)
Dermal	LD50	>5,000 mg/kg (rabbit)
Inhalative	LC50/4 h	>0.69 mg/l (rat)

### 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:**
- **on the skin:** Irritant to skin and mucous membranes.
- **on the eye:** Irritating effect.
- **Sensitization:** Sensitization possible through skin contact.

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· **Additional toxicological information:**

The product shows the following dangers according to internally approved calculation methods for preparations:  
Irritant

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**

64-17-5	Ethyl Alcohol	I
68187-11-1	Co-Cr-AL spinel blue green	2B
14808-60-7	Silica Glass	I

· **NTP (National Toxicology Program)**

14808-60-7	Silica Glass	K
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· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

## 12 Ecological information

· **Toxicity**

· **Aquatic toxicity:**

<b>72869-86-4 DUDMA</b>	
EC50	>0.6 mg/l (Algae) (Toxicity to algae)
	>1.2 mg/l (daphnia) (Toxicity to aquatic invertebrates)
<b>Amine Methacrylate</b>	
EC50	42 mg/l (Algae)

· **Persistence and degradability** No further relevant information available.

· **Behavior in environmental systems:**

· **Bioaccumulative potential** No further relevant information available.

· **Mobility in soil** No further relevant information available.

· **Additional ecological information:**

· **General notes:** Not known to be hazardous to water.

· **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:**

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

· **Uncleaned packagings:**

· **Recommendation:** Disposal must be made according to official regulations.

## 14 Transport information

· **UN-Number**

· **DOT, ADN, IMDG, IATA** not regulated

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- |  |                        |
|--|------------------------|
| <b>· UN proper shipping name</b>   |                        |
| <b>· DOT, ADN, IMDG, IATA</b>  | <i>not regulated</i>   |
| <b>· Transport hazard class(es)</b>  |                        |
| <b>· DOT, ADN, IMDG, IATA</b>  |                        |
| <b>· Class</b>   | <i>not regulated</i>   |
| <b>· Packing group</b>   |                        |
| <b>· DOT, 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>· Stowage Category</b>  | <i>A</i>               |
| <b>· Transport in bulk according to Annex II of MARPOL73/78 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**
- **Sara**

- **Section 355 (extremely hazardous substances):**

*None of the ingredients is listed.*

- **Section 313 (Specific toxic chemical listings):**

1344-28-1 Aluminium Oxide

68187-11-1 Co-Cr-AL spinel blue green

- **TSCA (Toxic Substances Control Act):**

*All ingredients are listed.*

- **TSCA new (21st Century Act) (Substances not listed)**

112926-00-8 Synthetic Amorphous Silica

12001-26-2 Mica

- **Proposition 65**

- **Chemicals known to cause cancer:**

14808-60-7 Silica Glass

- **Chemicals known to cause reproductive toxicity for females:**

*None of the ingredients is listed.*

- **Chemicals known to cause reproductive toxicity for males:**

*None of the ingredients is listed.*

- **Chemicals known to cause developmental toxicity:**

64-17-5 Ethyl Alcohol

- **Carcinogenic categories**

- **EPA (Environmental Protection Agency)**

*None of the ingredients is listed.*

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# Safety Data Sheet

acc. to OSHA HCS

Printing date 06/13/2018

Reviewed on 04/19/2018

**Trade name: Gingival Barrier Venus White Max**

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· <b>TLV (Threshold Limit Value established by ACGIH)</b>		
64-17-5	Ethyl Alcohol	A3
1344-28-1	Aluminium Oxide	A4
14808-60-7	Silica Glass	A2
· <b>NIOSH-Ca (National Institute for Occupational Safety and Health)</b>		
14808-60-7	Silica Glass	

- **GHS label elements** The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**



GHS07

- **Signal word** Warning
- **Hazard-determining components of labeling:**  
DUDMA  
Amine Methacrylate
- **Hazard statements**  
Causes skin irritation.  
Causes serious eye irritation.  
May cause an allergic skin reaction.
- **Precautionary statements**  
Avoid breathing dust/fume/gas/mist/vapors/spray  
Wash thoroughly after handling.  
Contaminated work clothing must not be allowed out of the workplace.  
Wear protective gloves / eye protection / face protection.  
If on skin: Wash with plenty of water.  
If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.  
Continue rinsing.  
Take off contaminated clothing and wash it before reuse.  
If skin irritation or rash occurs: Get medical advice/attention.  
Specific treatment (see on this label).  
If eye irritation persists: Get medical advice/attention.  
Wash contaminated clothing before reuse.  
Dispose of contents/container in accordance with local/regional/national/international regulations.
- **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.

- **Department issuing SDS:** Regulatory Affairs
- **Contact:** Customer Service
- **Date of preparation / last revision** 06/13/2018 / -
- **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  
DOT: US Department of Transportation  
IATA: International Air Transport Association

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**Safety Data Sheet**  
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(Contd. of page 9)

*ACGIH: American Conference of Governmental Industrial Hygienists*  
*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)*  
*NFPA: National Fire Protection Association (USA)*  
*HMIS: Hazardous Materials Identification System (USA)*  
*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*  
*NIOSH: National Institute for Occupational Safety*  
*OSHA: Occupational Safety & Health*  
*TLV: Threshold Limit Value*  
*PEL: Permissible Exposure Limit*  
*REL: Recommended Exposure Limit*  
*Skin Irrit. 2: Skin corrosion/irritation – Category 2*  
*Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A*  
*Skin Sens. 1: Skin sensitisation – Category 1*

US