

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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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 ³
112926-00-8	Synthetic Amorphous Silica	18 mg/m ³
12001-26-2	Mica	9 mg/m ³

· **PAC-2:**

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

· **PAC-3:**

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

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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 ³ /%SiO ₂
REL	Long-term value: 6 mg/m ³ 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 ³ *respirable dust; containing < 1% quartz
TLV	Long-term value: 3* mg/m ³ *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:**

Form:	Gel
Color:	Blue Green
Odor:	Acrylic
Odor threshold:	Not determined.

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

· **Change in condition**

Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	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:**

Lower:	Not determined.
Upper:	Not determined.

· **Vapor pressure:** Not determined.

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

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- | | |
|---|--|
| · Solubility in / Miscibility with Water: | Not miscible or difficult to mix. |
| · Partition coefficient (n-octanol/water): | Not determined. |
| · Viscosity: | |
| Dynamic: | Not determined. |
| Kinematic: | Not determined. |
| · Solvent content: | |
| VOC content: | 0.00 %
0.0 g/l / 0.00 lb/gl |
| · Other information | 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:**

72869-86-4 DUDMA

EC50	>0.6 mg/l (Algae) (Toxicity to algae)
	>1.2 mg/l (daphnia) (Toxicity to aquatic invertebrates)

Amine Methacrylate

EC50	42 mg/l (Algae)
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· **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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- | | |
|--|------------------------|
| · UN proper shipping name | |
| · DOT, ADN, IMDG, IATA | <i>not regulated</i> |
| · Transport hazard class(es) | |
| · DOT, ADN, IMDG, IATA | |
| · Class | <i>not regulated</i> |
| · Packing group | |
| · DOT, IMDG, IATA | <i>not regulated</i> |
| · Environmental hazards: | <i>Not applicable.</i> |
| · Special precautions for user | <i>Not applicable.</i> |
| · Stowage Category | <i>A</i> |
| · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | <i>Not applicable.</i> |
| · UN "Model Regulation": | <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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· TLV (Threshold Limit Value established by ACGIH)		
64-17-5	Ethyl Alcohol	A3
1344-28-1	Aluminium Oxide	A4
14808-60-7	Silica Glass	A2
· NIOSH-Ca (National Institute for Occupational Safety and Health)		
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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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