

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

Gingival Barrier Venus White Max

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

1.1. Product identifier

Product code : 40005202
Product name : Gingival Barrier Venus White Max
Product description : Light cure gingival barrier resin gel

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

Relevant identified uses : Professional Light Cure Gingival Barrier

1.3. Details of the supplier of the safety data sheet

Manufacturer

Heraeus Kulzer, LLC (Mitsui Chemicals Group)
300 Heraeus Way
South Bend, IN 46614-2517
USA
(800) 431-1785

Distributor

Heraeus Kulzer, LLC (Mitsui Chemicals Group)
300 Heraeus Way
South Bend, IN 46614-2517
USA
(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 Directive 1999/45/EC

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

Danger symbols Xi

R phrases : R36/38

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

Health : Eye Irritation
Skin Irritation

2.2. Label elements

Classification according to Directive 1999/45/EC

Hazard pictogram(s) : Xi




Irritant

R&S statement(s) : R36/38: Irritating to eyes and skin.

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

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Hazard pictogram(s)	:	
		Exclamation mark
Signal Word	:	WARNING
Hazard statement(s)	:	H315: Causes skin irritation.
Precautionary statement(s)	:	
Prevention	:	P280: Wear protective gloves/protective clothing/eye protection/face protection.
Response	:	P305: IF IN EYES: P351: Rinse cautiously with water for several minutes. P313: Get medical advice/attention. P302+P352: IF ON SKIN: Wash with plenty of soap and water.
Storage	:	P273: Avoid release to the environment.
Disposal	:	P501: Dispose of in compliance with governmental regulation. (EC 1975L0442-20/11/2003)

2.3. Other hazards

Immediate concerns : None

SECTION 3: Composition / information on ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

Chemical Name	CAS	EINECS No.	Wt. %	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No 1272/2008 [CLP]
Cetyl Alcohol	36653-82-4	253-149-0	< 15	Xi; R36/37/38	Not classified
Diurethane Dimethacrylate	72869-86-4	276-957-5	< 85	Xi; R36/37/38	Skin Sens., Cat. 1; H317

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

SECTION 4: First aid measures

4.1. Description of first aid measures

Following eyes : Hold eyelids apart and flush eyes with plenty of water for at least 15

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minutes.

- Following skin** : Wash with soap and water.
- Following ingestion** : If swallowed in small quantity the product is harmless, otherwise consult a doctor.
- 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.

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

- Eyes** : May cause mild irritation.
- Skin** : May cause skin irritation and sensitization.
- Ingestion** : None expected for this product.
- Inhalation** : None expected for this product.

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

- Notes to physician** : Not Applicable

SECTION 5: Fire fighting measures

5.1. Extinguishing media

- Extinguishing media** : Please see Fire Fighting Equipment under Section 5.3.

5.2. Special hazards arising from the substance or mixture

- Hazardous combustion products** : Not Determined
- Explosion hazards** : Not Determined
- Fire explosion** : Not Determined
- Sensitive to static discharge** : Not Determined
- Sensitivity to impact** : Not Determined

5.3. Advice for firefighters

- Fire fighting procedures** : General: Evacuate all personnel; use protective equipment for fire-fighting. Use self-contained breathing apparatus when the product is involved in fire.
- Fire fighting equipment** : Water spray, fog, or mist, foam, dry chemical, carbon dioxide(CO₂)

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- General procedures** : Refer to Section 8 for Personal Protective Equipment.

6.2. Environmental precautions

- Water spill** : Do not allow to enter sewers or drains that may lead to waterways.

6.3. Methods and material for containment and cleaning up

- Small spill** : Wipe up with cloth, soap and water.

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Large spill : Collect in tightly closed containers.

6.4. Reference to other sections

Reference to other sections : Not Applicable

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Handling : Keep away from heat sources and direct sunlight.

Storage : See product labeling.

7.2. Conditions for safe storage, including any incompatibilities

Shelf life : See product labeling

7.3. Specific end use(s)

Specific end use(s) : Professional Light Cure Gingival Barrier

SECTION 8: Exposure controls / personal protection

8.1. Control parameters

Control parameters : Not Determined

8.2. Exposure controls

Eye/face protection : Wear eye protection

Skin protection : Wear suitable protective clothing.

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

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Gel

Colour : Blue green

Odour : Acrylic

9.2. Other information

Percent volatile : Not Determined

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity : Polymerization occurs when exposed to visible light, ultraviolet light or extreme heat.

10.2. Chemical stability

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

10.3. Possibility of hazardous reactions

Hazardous polymerization : None

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10.4. Conditions to avoid

Conditions to avoid : Avoid light exposure, excessive heat

10.5. Incompatible materials

Incompatible materials : Strong oxidizing agents

10.6. Hazardous decomposition products

Hazardous decomposition products : None known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute

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

SECTION 12: Ecological information

12.1. Toxicity

Toxicity : Not Determined

Aquatic toxicity (acute)

96-hour LC₅₀ : Not Determined

48-hour EC₅₀ : Not Determined

96-hour EC₅₀ : Not Determined

12.2. Persistence and degradability

Persistence and degradability : Not Determined

12.3. Bioaccumulative potential

Bioaccumulative potential : Not Determined

12.4. Mobility in soil

Mobility in soil : Not Determined

12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment : Not Determined

12.6. Other adverse effects

Environmental data : Not readily degradable.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

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

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SECTION 14: Transport information

14.1. UN number

UN number : N/A

14.2. UN proper shipping name

UN proper shipping name : Not Dangerous Goods

14.3. Transport hazard class(es)

Hazard classification : N/A

14.4. Packing group

Packing group : N/A

14.5. Environmental hazards

Marine pollutant #1 : N/A

14.6. Special precautions for user

ADR - road : Not Dangerous Goods

RID - rail : Not Dangerous Goods

IMDG - sea : Not Dangerous Goods

IATA - air : Not Dangerous Goods

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

Transport in bulk : Not Dangerous Goods

SECTION 15: Regulatory information

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

RoHS : Please refer to Medical Devices Directive 93/42/EEC

15.2. Chemical safety assessment

Chemical safety assessment : See Section 11

Additional information : This product is not considered dangerous for transportation

SECTION 16: Other information

Relevant R-phrases and/or H-statements (number and full text) : R36/37/38: Irritating to eyes, respiratory system and skin.
Skin Sens., Cat. 1: Skin Sensitization, Category 1
H317: May cause an allergic skin reaction.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 08/18/2014 SDS. Revised: **Section 1:** . **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS. **Section 10:** HAZARDOUS POLYMERIZATION, INCOMPATIBLE MATERIALS, STABLE, POSSIBILITY OF HAZARDOUS REACTIONS. **Section 11:** ACUTE (ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat) ACUTE. **Section 12:** ECOTOXICOLOGICAL INFORMATION. **Section 14:** . **Section 15:** SECTION 15: Regulatory

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information. **Section 16: GENERAL STATEMENTS.**

General statements

: N/A= Not Applicable

Manufacturer disclaimer

: We believe that the information contained herein is current as of the date of this Safety Data Sheet. Since the use of this information and these opinions and the conditions of use of the product are not within our control, it is the user's obligation to determine the conditions of safe use of the product.