

SAFETY DATA SHEET

according with Regulation (EC) No 1907/2006 (REACH), Annex II

Introductory Details

Revision: 04
Date of revision: 30/10/2025

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Date of preparation: 30/10/2025
Printing date: 30/10/2025

Section 1: Identification

1.1. Product Details

Product Name : Gingiva Barrier
Trade Name : Kulzer Vivida Gingiva Barrier
Use : Light-curing gingiva guard for isolating the gingiva from the teeth requiring treatment.

1.2. Company Identification

Manufacturer's Name : Sanctuary Health Sdn Bhd
Manufacturer's Address : No.16, Persiaran Perindustrian Kanthan 1, Kawasan Perindustrian Kanthan, 31200 Chemor, Perak, Malaysia.
Telephone Number : +605-2012800
Email : info@sanctuaryhealth.com.my
Importer's / Distributer's Name & Address: -

1.3. Emergency Contact Details

Emergency Contact Person : Chee Poi Leng
Position : Person Responsible for Regulatory Compliance (PRRC)
Tel. No. : +605-2012800
Email : poi.leng@sanctuaryhealth.com.my

Section 2: Hazard(s) Identification

2.1 Classification of the substance or mixture

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

- Skin Sensitisation Category 1B (H317)
- Aquatic Chronic Category 2 (H411)

2.2 Label Elements

▪ Pictograms:



GHS07



GHS09

- Signal Word: *Warning*

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■ Hazard Statements:

- H317: May cause an allergic skin reaction
- H411: Toxic to aquatic life with long lasting effects.

■ Precautionary Statements:

- P261 : Avoid breathing vapours.
- P280 : Wear protective gloves/eye protection.
- P302+P352 : IF ON SKIN: Wash with plenty of soap and water.
- P333+P313 : If skin irritation or rash occurs: Get medical advice/attention.
- P273 : Avoid release to the environment.
- P501 : Dispose of contents/container in accordance with local regulations.

2.3 Other Hazards

- Uncured material may irritate eyes and skin.
- Not for use in persons allergic to product ingredients.
- No nanomaterials present (per EU 2011/696/EU)
- No endocrine disruptors present (per EU 2017/2100, 2018/605)

Section 3: Composition/Information on Ingredients

Chemical Characterization

Chemical	CAS No.	EC No.	Hazard Statements
Urethane dimethacrylate (UDMA)	72869-86-4	276-957-5	Skin Sensitisation (Category 1B, H317) Aquatic Chronic (Category 2, H411)
Triethylene glycol dimethacrylate (TEGDMA)	109-16-0	203-652-6	Skin Sensitization (Category 1B, H317)

Section 4: First-Aid Measures

- 4.1 Ingestion : No hazards anticipated from swallowing small amount accidentally during normal handling.
- 4.2 Eye Contact : Rinse with generous water amount of clean water. Consult a physician if irritation persists.
- 4.3 Skin Contact : Immediately wash with water and soap and rinse thoroughly.
- 4.4 Inhalation : Supply fresh air
- 4.5 Further information : If you experience any signs of illness, seek medical advice/attention immediately.

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Section 5: Fire-Fighting Measures

- 5.1 Extinguishing Media : Water haze, foam, carbon dioxide, fire-extinguisher powder
5.2 Fire Fighting Instruction : Protective equipment and self-contained equipment should be available to fireman.
5.3 Special Hazards : NA

Section 6: Accidental Release Measures

- 6.1 Leak/ Spill: Clean up mechanically. Dispose off according to local and national regulations.

Section 7: Handling and Storage

- 7.1 Handling : For professional use only. Keep out of reach of children.
7.2 Storage : Store in dark place avoided from heat and direct sunlight, below 3-25°C
7.3 Industrial hygiene : Usual hygienic measures for dental practices.
7.4 Fire-and-explosion-protection : Not required.
7.5 Storage Class (Lagerklasse) : LGK 10 (Flammable liquids)

Section 8: Exposure Controls/Personal Protection

- 8.1 Exposure Limit : None
8.2 Engineering measures : None
8.3 Personal protection equipment : The usual precautionary measures are to be adhered to when handling the chemicals.
8.4 Eye protection :Wear eye protective (goggles) when handling UV curing light.

Section 9: Physical and Chemical Properties

- Appearance : Blue paste
Odor : Practically odorless
Solubility : Not soluble in water
Boiling Point : Not determined
Melting Point (°C) : Not determined
Vapor Pressure (mm of Hg at 25 °C) : Not determined
Percentage Volatiles : NA
Evaporation Rate : Not determined

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Vapor Density	: Not determined
Specific Gravity	: NA
Flash point	: Not determined
Autoignition temperature	: Product is not self-igniting
Flammable limit (%)	: NA
Other properties if applicable	: NA

Section 10: Stability and Reactivity

10.1 Thermal decomposition : None, if used in accordance to instructions.
10.2 Hazardous Decomposition Products : None under normal conditions of storage and use.
10.3 Hazardous reaction : None.
10.4 Further information : Avoid exposure of product to direct light.

Section 11: Toxicological Information

11.1 Acute toxicity : The oral LD-50 for rats is > 5000 mg/kg
Primary eye irritation test according to EEC Directive
(Rabbit eye): not irritant
11.2 Subacute / Chronic toxicity : Uncured material: Direct contact may cause eye irritation.
Prolonged or frequently repeated skin
contact may cause allergic skin reactions.
11.3 Further information : No hazards anticipated from swallowing small amounts
accidentally during normal handling.
No endocrine disruptors present (per EU 2017/2100,
2018/605).
No nanomaterials present (per EU 2011/696/EU)

Section 12: Ecological Information

No ecological issues are expected when the product is handled and used appropriately.
No endocrine disruptors present (per EU 2017/2100, 2018/605).
No nanomaterials present (per EU 2011/696/EU)

Section 13: Disposal Considerations

Disposal in waste incineration plant, under conditions approved by the local authority.

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Section 14: Transport Information

- 14.1 Classification and restriction according to air and marine transportation and storage of hazardous substance under the airline and ship safety : Not available
- 14.2 Classification and restriction according to other foreign transportation law : Not available
- 14.3 IATA not regulated
- 14.4 Notice : Observed the federal and local government regulation.

No hazardous materials with respect to these transportation regulations.

Section 15: Regulatory Information

This product is a medical device according to the EU MDR 2017/745.
Classification: Class I, Rule 5- Medical Device, non-sterile and non-measuring.

Product compliance to California Proposition 65—*Safe Drinking Water and Toxic Enforcement Act of 1986*

Product does not contain substances subject to restrictions under REACH Regulation (EC) No. 1907/2006, Annex XV11

Product does not contain Phthalates, RoHS (Restriction of Hazardous Substances), or PAHs (Polycyclic Aromatic Hydrocarbons).

Section 16: Other Information

The information and recommendations set forth herein are presented in good faith and are believed to be correct as of the date hereof Sanctuary Health Sdn Bhd. However, it makes no representations as to the completeness of security of this information and supplies it on the condition that the persons receiving same will make their own determination as to its suitability of their purposes prior to use. In no event will Sanctuary Health Sdn Bhd be responsible for damages of any nature whatsoever resulting from use of or reliance upon information.