

# Safety Data Sheet

According to Regulation (EC) No 1272/2008

Revision 0: 29/12/2021

## SECTION 1. PRODUCT/ MIXTURE AND COMPANY IDENTIFICATION

### *1.1 Product Identifier*

<b>Product name</b>	BLANCONE Gingival Barrier
<b>Other means of identification</b>	Ref: 019002

### *1.2 Details of the supplier of the safety data sheet*

<b>Manufacturer/Supplier</b>	IDS S.p.A.
<b>Address</b>	Via S. Cristoforo 28/10 17100 Savona (SV) ITALY
<b>Telephone</b>	+39 019 862080
<b>Fax</b>	+39 019 2304865
<b>Website</b>	<a href="http://www.idsdental.it">www.idsdental.it</a>
<b>Email</b>	<a href="mailto:info@idsdental.it">info@idsdental.it</a>
<b>Emergency Telephone</b>	+39 019 862080

### *1.3 Description of the Product*

Light cured resin barrier

## SECTION 2. HAZARDS IDENTIFICATION

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

<b>Classification according to regulation (EC) No 1272/2008 [CLP]</b>	<b>Health</b> Eye Irritation Skin Irritation,
-----------------------------------------------------------------------	-----------------------------------------------------

Classification drawn from EC Directive  
1272/2008 - Annex VI

### *2.2 Label element(s)*

CLP label element  
Pictogram GHS07



**SIGNAL WORD**

**WARNING**

### Hazard statement(s)

<b>H319 H315</b>	Causes serious irritation on eye and skin
<b>H317</b>	May cause an allergic skin reaction
<b>H335</b>	May cause respiratory irritation
<b>H411</b>	Toxic to aquatic life with long lasting effects

### Supplementary statement(s)

Not Applicable

# Safety Data Sheet

According to Regulation (EC) No 1272/2008

Revision 0: 29/12/2021

## **Precautionary statement(s) Prevention**

**P280**

Wear protective gloves/protecting clothing/eye protection/face protection

## **Precautionary statement(s) Response**

**P305+P351+P338+P313**

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical advice/attention

**P302+P352**

IF ON SKIN: Wash with plenty of soap and water

**P337+P313**

If eye irritation persists: Get medical advice/attention.

## **Precautionary statement(s) Storage**

<b>P273</b>	Avoid release to the environment
-------------	----------------------------------

## **Precautionary statement(s) Disposal**

<b>P501</b>	Dispose of in compliance with governmental regulation. (EC1975L0442-10/11/2003)
-------------	---------------------------------------------------------------------------------

### ***2.3 Other hazards***

Cumulative effects may result following exposure\*.

May produce skin discomfort\*.

**REACH** - Art.57-59: The mixture does not contain Substances of Very High Concern (SVHC) at the SDS print date.

## **SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

### **Description**

Gel for application on teeth and gums.

### **3.1 Substances**

Not Applicable

### 3.2 Mixtures/ Chemical characterization

---

**Hazardous components**

CAS No	EC No	REACH No	Description	% w/w	Classification according to Regulation EC No 1272/2008 (GLP)
36653-82-4	253-149-0	Not Available	Cetyl alcohol	≤10	H335, H315, H319, H412 [1]
72869-86-4	276-957-5	Not Available	Diurethane Dimethacrylate	< 89	H317, H319, H315, H335, H411 [1]

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

## **SECTION 4. FIRST AID MEASURES**

### **General information**

The intended use is for application for the patient at dental office and patient home following the instructions of the dentist.

### **Skin contact**

Immediately rinse with a lot of water and a mild soap. If irritation develops consult a doctor.

### **Eye contact**

Rinse opened eye for several minutes under running water. Then consult a doctor.

### **After swallowing**

No risk at small doses at intended use. Rinse out mouth and then drink plenty of water. In case of high dose consult doctor.

## **SECTION 5. FIREFIGHTING MEASURES**

### **Suitable extinguishing agents**

Water spray. Use fire extinguishing methods suitable to surrounding conditions.

### **For safety reasons unsuitable extinguishing agents**

Water with full jet, CO<sub>2</sub>

### **Protective equipment**

Use self-contained breathing apparatus when the product is involved in fire.

## **SECTION 6. ACCIDENTAL RELEASE MEASURES**

### **Person-related safety precautions**

# Safety Data Sheet

According to Regulation (EC) No 1272/2008

Revision 0: 29/12/2021

Wear protective equipment. Keep unprotected persons away. Dilute with plenty of water.

## **Measures for cleaning/collecting.**

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

## **Measures for environmental protection (see section 12)**

Prevent any spillage from entering waterways, drains or sewage system. Dispose contaminated material as waste according to item 13.

## **SECTION 7. HANDLING AND STORAGE**

### **Handling**

#### **Safe Handling**

- For use by trained dental professionals
- Avoid all personal contact, including inhalation.
- When handling, DO NOT eat, drink or smoke.
- Keep containers securely sealed when not in use.
- Avoid physical damage to containers.
- Use good occupational work practice.
- Observe manufacturer's storage and handling recommendations contained within this SDS.

#### **Information about fire - and explosion protection**

Ensure good ventilation/exhaustion at the workplace. No special measures required.

### **Storage**

#### **Requirements to be met by storerooms and receptacles**

Store in dry and well-ventilated area at 5°C to 25°C. Avoid the direct contact with light and heat

#### **Information about storage in one common storage facility**

- Store away from flammable substances.

#### **Further information about storage conditions**

- Keep receptacle tightly sealed.
- Protect from heat and direct sunlight.
- Store in a cool place.
- Heat can cause polymerization with rapid release of energy which may melt the container.

## **SECTION 8. EXPOSURE CONTROLS/ PERSONAL PROTECTION**

### **General protective measures**

Avoid contact with eyes and skin

# Safety Data Sheet

According to Regulation (EC) No 1272/2008

Revision 0: 29/12/2021

## Hygienic measures

Immediately remove all soiled and contaminated clothing

<b>8.1 Control parameters</b>
Not Determined

## 8.2. Personal Protective Equipment (PPE) Information

**Eyes:** Wear appropriate protective eyeglasses.

**Skin:** S36/37: Wear suitable protective clothing and gloves.

**Clothing:** Wear appropriate protective clothing to prevent skin exposure.

**Respiratory:** S38: In case of insufficient ventilation, wear suitable respiratory equipment.

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

**Physical State:** Viscous flowable paste

**Colour:** Blue -Green

**Odour:** Characteristic

	Value	Temperature
pH-value	N/A	
Boiling point	Gel before Boiling	
Vapour pressure	n/a	20°C
Density	1.000-1.800 g/cm <sup>3</sup>	25°C
Solubility in water	insoluble	
Viscosity	30,000-70,000 cPs	25°C

## SECTION 10. STABILITY AND REACTIVITY

### Stability

Product is stable at room temperature in closed containers under normal storage and handling conditions. Heat and intense light can cause polymerization

### Dangerous reactions

# Safety Data Sheet

According to Regulation (EC) No 1272/2008

Revision 0: 29/12/2021

None known

## **Hazardous decomposition products**

None known

## **SECTION 11. TOXICOLOGICAL INFORMATION**

### *11.1 Information on toxicological effects*

Inhaled	None expected
Ingestion	No data available Diurethane Dimethacrylate Oral (rat) LD 50> 2000mg/Kg
Skin contact	Possible skin irritant
Eye	May be irritating the eyes
Acute Toxicity	May be sensitizing to skin
Teratogenicity	No data available
Reproductive Effects	No data available
Mutagenicity	No data available

**Note: Device is biocompatible when used as directed by dental professionals**

## **SECTION 12. ECOLOGICAL/ENVIROMENTAL INFORMATION**

Eco toxicity	Water pollutant
Persistence and biodegradability	No data available
Bioaccumulative potential	No data available
Mobility in soil	Not derermined
Results of PBT and VPvB assessment	No data available
Other adverse effects	No data available

## **SECTION 13. DISPOSAL CONSIDERATIONS**

<b>Product</b>	<b>Dispose of in accordance with governmental regulation. (EC 1975L0442-20/11/2003).</b>
<b>Uncleaned packaging</b>	Dispose of contaminated packaging as hazardous waste in accordance with local official regulations
<b>Waste treatment options</b>	Not Available
<b>Sewage disposal options</b>	Not Available

# Safety Data Sheet

According to Regulation (EC) No 1272/2008

Revision 0: 29/12/2021

## SECTION 14. TRANSPORT INFORMATION

### *14.1 Labels Required*

<b>Marine Pollutant</b>	NO
<b>HAZCHEM</b>	Not Applicable

### *14.2 General transport information*

<b>Land transport ADR/RID (GGV SE)</b>	No dangerous good in sense of these transport regulations
<b>Inland waterways transport (ADN)</b>	No dangerous good in sense of these transport regulations
<b>Sea transport IMDG (GGV See)</b>	No dangerous good in sense of these transport regulations
<b>Air transport (ICAO)</b>	No dangerous good in sense of these transport regulations

## SECTION 15. REGULATORY INFORMATION

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

This Product is regulated by Medical Device Regulation (EU) 2017/745

## SECTION 16. OTHER INFORMATION

### *16.1 Full text Hazard (H) and Risk (R) codes (not classification of ready mixed product)*

#### **H-phrases**

H315	Causes skin irritation.
H317	May cause an allergic skin reaction
H319	Causes serious eye damage
H411	Toxic to aquatic life with long lasting effects
H335	May cause respiratory irritation.

**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.**