

<b>Security record</b>  POLYCARBONATE MATERIAL	CODE:	SDS27
	SECTOR:	Development
	PAGE:	Page 1 of 7
	REVIEW:	00

## 1. **PRODUCT AND COMPANY IDENTIFICATION:**

### 1.1 **Product name:**

Aesthetic Orthodontic Fixation System (Brackets - Accessories).

### 1.2 **Model:**

BioCrystal Bracket, Aesthetic Button and Aesthetic Distalizer.

### 1.3 **Purpose of the Product:**

Its purpose is to serve as a support and fitting point for wires, pre-contoured arch wires, orthodontic elastics, or other auxiliary products used in orthodontic treatment.

### 1.4 **Material:**

Polycarbonate.

### **Company Information:**

### 1.6 **European Representative Information:**

Not applicable.

## 2. **HAZARD IDENTIFICATION:**

This substance/mixture does not contain components that can be considered persistent, bio-accumulative and toxic (PBT), or very persistent and very bio-accumulative (vPvB) at levels from 0.1%.

### 2.1 **Label Element:**

Labeling according to ISO 1041:2008, ISO 15223-1:2016.

### 2.2 **Use Restriction:**

These products are designed and manufactured for single use only. Its reuse or reprocessing can cause cross-infection, decrease and loss of mechanical properties due to natural wear and tear.

## 3. **COMPOSITION AND INFORMATION ABOUT INGREDIENTS:**

**Mixture:** Polycarbonate.

Contains no dangerous ingredients as per Regulation (EC) No. 1907/2006.

<b>Security record</b>  <b>POLYCARBONATE MATERIAL</b>	<b>CODE:</b>	SDS27
	<b>SECTOR:</b>	Development
	<b>PAGE:</b>	Page <b>2</b> of <b>7</b>
	<b>REVIEW:</b>	00

#### 4. **FIRST AID ACTIONS:**

**When it comes into contact with the skin:** IN CASE OF CONTACT WITH VERY HOT MELT: Immediately cool with plenty of water. Do not remove product crusts formed on the skin by force or with solvents. Consult a doctor immediately for the treatment of any burns and for gentle cleansing of the skin.

**In case of inhalation:** In case of accidental inhalation of dust or fumes from overheating or combustion, move to fresh air.

**In case of ingestion:** Look for medical care.

#### 5. **FIRE FIGHTING MEASURES:**

**Suitable extinguishing media:** spray water jets, powder extinguishers, carbon dioxide (CO<sub>2</sub>), foam, and dry chemicals.

**Specific hazards arising from the material:** During a fire, it forms carbon monoxide and dioxide, nitric oxides, and traces of hydrocyanic acid (prussic acid). Do not breathe the fumes in the event of a fire and/or explosion.

**Special fire control instructions:** In firefighting, use respiratory apparatus with air intake independent of the environment.

Prevent the penetration of extinguishing water into soil and groundwater or surface water.

#### 6. **CONTROL MEASURES FOR SPILLING OR LEAKING:**

Do not discharge into surface water or the sewage system.

Use mechanical equipment for handling. Avoid forming dust.

#### 7. **HANDLING AND STORAGE:**

Avoid sources of ignition where the product is handled and stored. Do not allow molten material to contact your eyes, skin, or clothing. Handle in accordance with good industrial hygiene and safety practices.

Store the product in its original packaging in a dry, well-ventilated place. Avoid storing it in heat or direct sunlight to maintain its quality. No special storage conditions are required.

#### 8. **EXPOSURE CONTROL AND PERSONAL PROTECTION:**

In the thermal process, it is necessary to observe the instructions for the substances indicated below.

Substance	CAS No.	Basis	Type	Value	maximum limit value	Comments
phenol	108-95-2	BR OEL	TWA 48HRS	4 ppm 15 mg/m <sup>3</sup>		

<b>Security record</b>  <b>POLYCARBONATE MATERIAL</b>	<b>CODE:</b>	SDS27
	<b>SECTOR:</b>	Development
	<b>PAGE:</b>	Page <b>3</b> of <b>7</b>
	<b>REVIEW:</b>	00

phenol	108-95-2	BR OEL				Possible dermal absorption
phenol	108-95-2	EU ELV	TWA	2 ppm 8 mg/m <sup>3</sup>		Indicative
phenol	108-95-2	EU ELV				Possible dermal absorption
phenol	108-95-2	EU ELV	STEL	4 ppm 16 mg/m <sup>3</sup>		Indicative
chlorobenzene	108-90-7	EU ELV	TWA	5 ppm 23 mg/m <sup>3</sup>		Indicative
chlorobenzene	108-90-7	EU ELV	STEL	15 ppm 70 mg/m <sup>3</sup>		Indicative
chlorobenzene	108-90-7	BR OEL	TWA 48HRS	59 ppm 275 mg/m <sup>3</sup>		
2,2-Bis-(4-hydroxyphenyl)-propane	05-80-7	EU ELV	TWA	2 mg/m <sup>3</sup>		Indicative

### Appropriate Engineering Controls

**Hand protection:** Suitable materials for protective gloves. Change contaminated and/or damaged gloves.

**Skin and body protection:** There are no special skin protection requirements during normal handling and use.

**Breath protection:** In the event of dust formation, use a filtering device with a P1 particle filter according to EN 143.

**Eye protection:** Wear protective eye equipment.

### 9. **PHYSICOCHEMICAL PROPERTIES:**

**Appearance:** Solid.

**Odor:** Odorless.

**Odor Threshold:** Not determined.

**pH:** Not applicable.

**Softening point:** 130 – 160°C

**Fusion point:** 220 – 280°C

**Flash point:** Not determined.

**Evaporation rate:** Not determined.

**Flammability (solid, gas):** Not determined.

**Upper/Lower Flammability or Explosive Limits:** Not determined.

**Steam pressure:** Not applicable.

<b>Security record</b>  POLYCARBONATE MATERIAL	<b>CODE:</b>	SDS27
	<b>SECTOR:</b>	Development
	<b>PAGE:</b>	Page 4 of 7
	<b>REVIEW:</b>	00

**Vapor Density:** Not determined.

**Density:** ca 1.2 - 1.4 g/cm<sup>3</sup>

**Apparent density:** 600 - 700 kg/m<sup>3</sup>

**Solubility(ies):** Practically insoluble.

**Partition coefficient:** Not determined.

**Autoignition temperature:** Not applicable.

**Ignition temperature:** > 450°C

**Decomposition temperature:** >=380°C

**Viscosity:** Not determined.

#### 10. **STABILITY AND REACTIVITY:**

**Reactivity:** Information not available.

**Chemical stability:** In the case of thermal decomposition, which occurs in the event of fire or excessive heating, toxic gases, and vapors harmful to health may be formed.

**Instability conditions:** Information not available.

**Possibility of hazardous reactions:** There are no dangerous reactions.

**Conditions to avoid:** Generation of dust clouds.

**Incompatible materials:** Information not available.

**Hazardous decomposition products:** In flameless combustion or incomplete combustion, toxic gas mixtures are formed, which mainly contain CO and CO<sub>2</sub>.

In the thermal process, it is necessary to observe the instructions for the substances indicated below.

phenol

Index No. 604-001-00-2

CAS No.: 108-95-2

GHS classification: Tox. Acute 3 Oral H301 Tox. Acute 3 Inhalant H331 Tox. Acute 3 Dermal H311 Corr. PeleCorr. Skin 1B H314 Eye damage 1 H318 Mutag. 2 H341 Tox. Spec. (repeated) 2 H373 Chronic aquatic 2 H411

chlorobenzene

Index No. 602-033-00-1

CAS No.: 108-90-7

<b>Security record</b>  POLYCARBONATE MATERIAL	CODE:	SDS27
	SECTOR:	Development
	PAGE:	Page 5 of 7
	REVIEW:	00

GHS Rating: Liq. inflame. 3 H226 Tox. Acute 4 Inhalant H332 Irrit. Skin 2 H315 Chronic aquatic 2 H411

4-butylphenol tert.

Index No. 604-090-00-8

CAS No.: 98-54-4

GHS Rating: Irrit. Skin 2 H315 Eye damage 1 H318 Tox. Playback 2 H361f Chronic aquatic 1 H410

2,2-Bis-(4-hydroxyphenyl)-propane

CAS No.: 80-05-7

GHS classification: Tox. Playback 1B H360F Tox. Spec. (single) 3 Inhalant H335 Eye damage 1 H318 Sensib. Skin 1 H317 Chronic aquatic 2 H411

**Hazardous Polymerization:** Hazardous polymerization does not occur.

## 11. **TOXICOLOGICAL INFORMATION:**

**Eyes:** No data available.

**Skin:** No data available.

**Inhalation:** No data available.

**Ingestion:** No data available.

**Carcinogenicity:** No carcinogen as defined by IARC, NTP and/or OSHA.

According to our experience and information, the product has no harmful effects on health if handled correctly.

## 12. **ECOLOGICAL INFORMATION:**

Prevent penetration into water courses, wastewater and soil.

**Environmental ecotoxicity:** No data available.

**Physical:** No data available.

**Persistence and degradability:** No data available.

**Bio accumulative potential:** No data available.

**Mobility on the ground:** No data available.

**Other adverse effects:** The product is practically insoluble in water. Due to its consistency and insolubility in water, ecological problems are not expected. However, the product is not easily biodegradable. gradable.

<b>Security record</b>  POLYCARBONATE MATERIAL	CODE:	SDS27
	SECTOR:	Development
	PAGE:	Page 6 of 7
	REVIEW:	00

**13. CONSIDERATIONS ON TREATMENT AND DISPOSAL:**

In the treatment and disposal of the product, its remains and used packaging, attention must be paid to local, state, and national legislation.

**Waste disposal methods:** The product lends itself to mechanical recycling. After it is properly prepared, it can be melted again and used for molding new parts. An essential condition for mechanical recycling is the specific collection of material and separation by type.

**Disposal of packaging:** the packages can be sent for recovery, according to their nature, to the collection services already implemented by the chemical industry. The recovery of empty packaging must be carried out in accordance with national legislation and regulations on the protection of the environment.

**14. TRANSPORT INFORMATION:**

**Terrestrial**

UN number or ID number:	non-dangerous goods
UN proper shipping name:	non-dangerous goods
Hazard classes for transport purposes:	non-dangerous goods
Packing group:	non-dangerous goods
Hazards to the environment:	non-dangerous goods

**IATA**

UN number or ID number:	non-dangerous goods
UN proper shipping name:	non-dangerous goods
Hazard classes for transport purposes:	non-dangerous goods
Packing group:	non-dangerous goods
Hazards to the environment:	non-dangerous goods

**IMDG**

UN number or ID number:	non-dangerous goods
UN proper shipping name:	non-dangerous goods
Hazard classes for transport purposes:	non-dangerous goods
Packing group:	non-dangerous goods
Marine pollutant:	non-dangerous goods

**Other indications:** Non-hazardous product during transport. Protect from moisture.

**15. REGULATIONS:**

Apply laws, regulations and standards as needed by region, state and country.

**16. OTHER INFORMATION:**

This SDS has been prepared based on current knowledge about the proper handling of the

<b>Security record</b>  <b>POLYCARBONATE MATERIAL</b>	<b>CODE:</b>	SDS27
	<b>SECTOR:</b>	Development
	<b>PAGE:</b>	Page <b>7</b> of <b>7</b>
	<b>REVIEW:</b>	00

product and under normal conditions of use, according to the specified application. Any other use of the product that involves combining it with other materials and ways of use other than those indicated are the responsibility of the user.

**17. REVISION HISTORY:**

First version.

Date: 08/17/2023

Electronically signed as attached	Electronically signed as attached	Electronically signed as attached
-----------------------------------	-----------------------------------	-----------------------------------

<b><i>Security record</i></b>  <b>POLYCARBONATE MATERIAL</b>		<b>CODE:</b>	<b>SDS27</b>
		<b>SECTOR:</b>	<b>Development</b>
		<b>PAGE:</b>	<b>Page 8 of 7</b>
		<b>REVIEW:</b>	<b>00</b>
Designer - Materials Analyst Karina Morais		Reviewer - Quality Assistant Bianca de Alexandre Souza	Approver - Research Director and Development Alexandre Gallo Lopes

## SDS27 - Polycarbonate Material - Rev 00 EN

Código do documento e202b482-209a-422a-872c-3df343086366

### Assinaturas

Alexandre Gallo Lopes  
alex@aditek.com.br Assinou

Karina Oliveira de Moraes  
karina.morais@aditek.com.br  
Assinou

Bianca de Alexandre Souza  
bianca.alexandre@aditek.com.br  
Assinou

### Eventos do documento

#### 18 Aug 2023, 08:33:55

Documento e202b482-209a-422a-872c-3df343086366 **criado** por ADITEK DO BRASIL (9bc671b3-4379-4b17-b681-c191b14c958e).  
Email:documentos@aditek.com.br. - DATE\_ATOM: 2023-08-18T08:33:55-03:00

#### 18 Aug 2023, 08:33:57

Assinaturas **iniciadas** por ADITEK DO BRASIL (9bc671b3-4379-4b17-b681-c191b14c958e). Email: documentos@aditek.com.br. -  
DATE\_ATOM: 2023-08-18T08:33:57-03:00

#### 18 Aug 2023, 08:39:28

KARINA OLIVEIRA DE MORAIS **Assinou** (4b363f5d-6f12-4976-b9e3-a562b37ed93e) - Email:  
karina.morais@aditek.com.br - IP: 45.4.34.253 (mailz.aditek.com.br porta: 10974) - [Geolocalização: -21.3360646](#)  
[-47.7349512](#) - Documento de identificação informado: 442.471.548-50 - DATE\_ATOM: 2023-08-18T08:39:28-03:00

#### 18 Aug 2023, 09:11:30

BIANCA DE ALEXANDRE SOUZA **Assinou** (2e085d97-e652-4542-a1d5-50a504a915cc) - Email:  
bianca.alexandre@aditek.com.br - IP: 45.4.34.253 (mailz.aditek.com.br porta: 20662) - Documento de identificação informado:  
460.692.868-98 - DATE\_ATOM: 2023-08-18T09:11:30-03:00

#### 18 Aug 2023, 09:59:57

ALEXANDRE GALLO LOPES **Assinou** (ed8c269b-7ae0-4e54-9aa9-4e7676daaff6) - Email: alex@aditek.com.br - IP: 200.73.8.126  
(host126.200.73.8.static.ifxnw.cl porta: 30036) - Documento de identificação informado: 030.679.738-01 - DATE\_ATOM: 2023-08-  
18T09:59:57-03:00

9 páginas - Datas e horários baseados em Brasília, Brasil  
**Sincronizado com o NTP.br e Observatório Nacional (ON)**  
Certificado de assinaturas gerado em 18 de August de 2023, 10:00:05

Hash do documento original

(SHA256):935b3d96d34e826d694391a521e4cb12303cdd208c17e63a24b849f16ad3fe3f

(SHA512):f83b26c6cd30ec5983345600561571014e3274b363bb7e9242381c33ea9e633248f76aa563a2a17ae804400e3c7274aa0bbe8fbc402251a03a47b8dce42e5ca4

Esse log pertence **única** e **exclusivamente** aos documentos de HASH acima

**Esse documento está assinado e certificado pela D4Sign**