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**1. Product and Company Identification:**

**1.1. Product name:**

Aesthetic Orthodontic Fixation System (Brackets - Accessories).

**1.2. Models:**

BioCrystal Bracket, Aesthetic Button and Aesthetic Distalizer.

**1.3. Purpose of the Product:**

Its purpose is to serve as a support and fitting for wires, preformed archwires, orthodontic elastics or other auxiliary products used in orthodontic treatment.

**1.4. Material:**

Polycarbonate.

**1.5. Company Information:**

Modern Arch, 1402 Penn Ave, Wyomissing, PA 19610

**1.6. Information of the European Representative:**

Not applicable.

**2. Hazard Identification:**

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

**2.1. Label element:**

Labeling in accordance with EN ISO 20417:2021, ISO 15223-1:20 21.

The list of symbols and their meanings can be viewed at [www.Modern Arch.com.br](http://www.Modern Arch.com.br).

**2.2. Use restriction:**

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

**3. Composition and Information about the Ingredients:**

**Mixture:** Polycarbonate.

Does not contain dangerous ingredients according to Regulation (EC) No. 1907/2006

**4. First Aid Measures:**

**In contact with the skin:**

IN CASE OF CONTACT WITH VERY HOT MELT: Cool immediately with plenty of water. Product crusts formed on the skin should not be removed by force or with solvents. For the treatment of possible burns and for a gentle cleansing of the skin, immediately consult a doctor.

In case of inhalation: Go to the fresh air in case of accidental inhalation of dust or smoke from overheating or combustion.

If swallowed: Seek medical attention.

**5. Fire-Fighting Measures:**

Suitable extinguishing media: water spray, extinguishing powder, Carbon dioxide (CO<sub>2</sub>), Foam, Dry chemical substance.

**Specific hazards arising from the material:** During fire, carbon monoxide and dioxide, nitric oxides, and traces of hydrocyanic acid (prussic acid) are formed. Do not breathe vapors in cases of fire and/or explosions.

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

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

**6. Control Measures for Spills or Leakage:**

**Do not discharge into surface water or the sanitary sewer system.**  
**Use mechanical equipment for handling. Avoid dust formation.**

**7. Handling and Storage:**

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

Store the product in its packaging in a dry and well-ventilated place. To maintain product quality, do not store it in heat or direct sunlight. No special storage conditions are required.

**8. Exposure Control and Personal Protection: According to Annex I.**

**9. Physicochemical Properties:**

**Appearance:** Solid;

**Odor:** Odorless;

**Odor threshold:** Not determined;

**pH:** Not applicable;

**Softening point:** 130 – 160 °C;

**Melting 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;

**Vapor pressure:** Not applicable;

**Vapor density:** Not determined;

**Relative density:** Not determined;

**Density:** ca. 1.2 – 1.4 g/cm<sup>3</sup>;

**Bulk density:** 600 – 700 kg/m<sup>3</sup>;

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

**Partition coefficient:** Not determined;

**Auto-ignition 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 that are harmful to health can be formed.

**Instability conditions:** Information not available.

**Possibility of dangerous reactions:** No dangerous reactions known.

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

**Incompatible materials:** Information not available.

**Dangerous decomposition products:** In the case of combustion without a flame or incomplete combustion, toxic mixtures of gases are formed, which contain mainly 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. SkinCorr. Skin 1B H314 Eye damage 1 H318 Mutag. 2 H341 Tox. Spec. (repeated) 2 H373 Aquatic chronic 2 H411

**Chlorobenzene**

Index No. 602-033-00-1 CAS No.: 108-90-7

GHS Classification: Liq. Inflammation. 3 H226 Tox. Acute 4 Inhalant H332 Irrit. Skin 2 H315 Aquatic Chronic 2 H411

**4-butylphenol tert.**

Index No. 604-090-00-8 CAS No.: 98-54-4

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

**2,2-Bis-(4- hydroxyphenyl)-propane** CAS No.: 80-05-7

GHS Classification: Tox. Reproduction. 1B H360F Tox. Spec. (single) 3 Inhalant H335 Eye damage 1 H318 Sensitivity. Skin 1 H317 Aquatic Chronic 2 H411

**Hazardous Polymerization:** No hazardous polymerization occurs.

**11. Toxicological Information:**

**Eyes:** No data available.

**Skin:** No data available.

**Inhalation:** No data available.

**Ingestion:** No data available.

**Carcinogenicity:** No carcinogens 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 watercourses, wastewater and soil.

**Environmental ecotoxicity:** No data available.

**Physics:** No data available.

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

**Bioaccumulative potential:** No data available.

**Soil mobility:** No data available.

**Other adverse effects:** The product is practically insoluble in water. Due to its consistency and insolubility in water, no ecological problems are expected. The product is not easily biodegradable.

**13. Treatment and Disposition**

**Considerations:**

When treating and disposing of the product, its remains and used packaging, attention must be paid to local, state and national legislation.

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**Waste disposal methods:** The product can be mechanically recycled. Once properly prepared, it can be re-cast and used for new parts. An essential condition for mechanical recycling is the specific collection of material and separation by types.

**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 environmental protection standards.

**14. Transportation Information:**

**Terrestrial**

UN number or ID number: Non-dangerous goods

Official UN shipping name: Non-dangerous goods

Hazard classes for transport purposes: Non-dangerous goods

Packing group: Non- dangerous goods Environmental hazards: Non-dangerous goods

**IATA (International Air Transport Association)**

UN number or ID number: Non-dangerous goods

Official UN shipping name: Non-dangerous goods

Hazard classes for transport purposes: Non-dangerous goods

Packing group: Non- dangerous goods

Environmental hazards: Non-dangerous goods

**IMDG (International Maritime Code for Dangerous Goods)**

UN number or ID number: Non-dangerous goods

Official UN shipping name: Non-dangerous goods

Hazard classes for transport purposes: Non-dangerous goods

Packing group: Non- dangerous goods

Marine pollutant: Non- hazardous goods

**Other indications:** Product not dangerous during transport. Protect from moisture.

**15. Regulations:**

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

**16. Other Information:**

This SDS has been developed based on current knowledge about the proper handling of the product and under normal conditions of use, according to the specified application. Any

other use of the product that involves its combination with other materials, and forms of use other than those indicated, are the responsibility of the user.

**17. Review History:**

Changes: Content highlighted in gray. Exclusions: N/A

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## ANEXXI

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

Substance	CAS No.	Base	Type	Value	Maximum Limit Value	Comments
Phenol	108-95-2	BR-OEL	TWA 48HRS	4 ppm 15 mg/ m <sup>3</sup>	N.A.	N.A.
Phenol	108-95-2	BR-OEL	N.A.	-	N.A.	Possible dermal absorption
Phenol	108-95-2	EU-ELV	TWA	2 ppm 8 mg/ m <sup>3</sup>	N.A.	Indicative
Phenol	108-95-2	EU-ELV	N.A.	-	N.A.	Possible dermal absorption
Phenol	108-95-2	EU-ELV	STEL	4 ppm 16 mg/ m <sup>3</sup>	N.A.	Indicative
Chlorobenzene	108-90-7	EU-ELV	TWA	5 ppm 23 mg/ m <sup>3</sup>	N.A.	Indicative
Chlorobenzene	108-90-7	EU-ELV	STEL	15 ppm 70 mg/ m <sup>3</sup>	N.A.	Indicative
Chlorobenzene	108-90-7	BR-OEL	TWA 48HRS	59 ppm 275 mg/ m <sup>3</sup>	N.A.	N.A.
2,2-Bis-(4-hydroxyphenyl)-propane	80-05-7	EU-ELV	TWA	2 mg/ m <sup>3</sup>	N.A.	Indicative

### Appropriate Engineering Controls

**Hand protection:** Materials suitable for protective gloves. Change contaminated and/or damaged gloves.

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

**Respiratory protection:** In case of dust formation, use a filter apparatus with P1 type particulate filter according to EN 143.

**Eye protection:** Use protective equipment for the eyes.