

# Safety data sheet in accordance with regulation (EC) no. 1907/2006



(amended by regulation (EU) no. 453/2010)

Date of issue 23.04.2015  
Date of revision 22.01.18  
Valid from 01.01.15  
Version: 2

Combiloc Plus – Thermoforming Sheet  
581-012-093, 581-012-174,  
581-012-095, 581-012-176

Replaces Version: 1

## **Section 1: Identification of the substance/mixture and of the company**

### **1.1 Product Identifier**

Substances: PET-G polyethylene terephthalate (hard side), TPU thermoplastic polyurethane (soft side)  
Index-no.: void  
EC-no.: void  
CAS-no.: 25640-14-6 PET-G, 9018-04-6 TPU  
REACH-registration no.: The substance does not require registration according to regulation (EC) no. 1907/2006 (REACH)

**Other means or identification:** sheets for orthodontics

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

Relevant identified uses: to be used in dental labs exclusively

Uses advised against: should not be used by untrained personnel

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

#### **Supplier:**

al dente Dentalprodukte GmbH

#### **Street:**

Am Tobel 15

#### **Address / zip-code / town / country:**

88263 Horgenzell Germany

#### **Phone / Fax / Email:**

+49 (0) 7504 – 9 70 91-0 / +49 (0) 7504 – 9 70 91-20 / E-Mail: info@aldente.de

### **1.4 Emergency Telephone Number:**

+49 (0) 171 7508 130

## **Section 2: Hazards identification:**

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

Classification according to regulation (EC) no. 1272/2008 (CLP)

This substance does not meet the criteria for classification according to regulation (EC) no. 1272/2008 (CLP).

### **2.2 Label Elements**

#### **Labelling according to regulation (EC) no. 1272/2008 (CLP/GHS)**

**Hazard pictorams:** NONE

**Signal word:** NONE

**Hazardous component(s) for labelling:**

**Hazard statements:** NONE

**Precautionary statements:** NONE

**Supplemental Hazard information (EU):**

NONE

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## 2.3 Other Hazards:

Results of PBT and vPvP assessment:

PBT not applicable

vPvP not applicable

## Section 3: Composition/information on ingredients

### 3.1 Substances

Principal component of the substance:

**Substance I** name: Polyethylene terephthalate PET-G

Index-no.: void

EC-no.: void

CAS-no.: 25640-14-6

**Substance II** name: Thermoplastic polyurethane TPU

Index-no.: void

EC-no.: void

CAS-no.: 9018-04-6

Impurities, stabilizers: none

### 3.2 Mixtures none

Description of the mixture:

EG-no.: CAS-no.: Index-Nno.: REACH-registration no.:

Content ration: %

Classification according to regulation (EC) no. 1272/2008 (CLP)

none

(Full text of H- and EUH-phrases: see SECTION 16)

## Section 4: First aid measures

### 4.1 Description of first aid measures: No necessity of special measures

**Following inhalation:** Do not breathe dust when working the sheets. Inhalation of dust may cause irritation of the respiratory system. Dust should be exhausted at the point of origin.

**Following skin contact:** There are no special measures necessary. In case of contact with melted product, cool down the affected skin by means of cool water. Burnt areas should be immersed in cool water for a length of time and should be clinically treated.

**Following eye contact:** Rinse thoroughly with water, if necessary seek for medical advice. In case of Persistent symptoms, consult an ophthalmologist. May cause irritations to eyes. Wear dust protection glasses.

**Following ingestion:** No necessity of special measures

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

Symptoms: none available

Effects: none available

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

Notes for the doctor: no information available

Special treatment: no information available

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## **Section 5: Firefighting measures**

### **5.1 Extinguishing media**

Suitable: extinguishing powder, water spray, alcohol resistant foam, carbon dioxide  
Unsuitable: Water jet (high power)

### **5.2 Special hazards arising from the substance or mixture**

In case of fire fumes are possible: carbon dioxide (CO<sub>2</sub>), sulphur dioxide (SO<sub>2</sub>), formaldehyde.

### **5.3 Advice for fire-fighters**

Respiratory protection independent of ambient environment – in case of fumes. Protective clothing.

### **5.4 Additional indication:**

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

## **Section 6: Accidental release measures**

### **6.1 Personal precautions, protective equipment and emergency procedures**

**For non-emergency personnel**

Protective equipment: no special measures are to be taken.

Emergency procedures: no special measures are to be taken.

**For emergency responders**

Personal protective equipment: see section 5.3

### **6.2 Environmental precautions**

Do not empty into drains or the aquatic environment. Do not allow to enter into soil/subsoil.

### **6.3 Methods and material for containment and cleaning up**

Clean up mechanically.

### **6.4 Reference to other sections**

More information on disposal see section 13.

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## **Section 7: Handling and storage**

### **7.1 Precautions for safe handling**

**Fire preventions:** Keep away from sources of ignition and heat. Do not smoke.

**Aerosol and dust generation preventions:** Avoid generation of dust – work under fume hood.

**Environmental precautions:** No special precautions necessary.

**Advice on general occupational hygiene:** Observe general hygiene rules.

### **7.2 Conditions for safe storage, including any incompatibilities**

**Storage conditions:** No special measures are necessary.

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## Requirements for storage rooms and vessels

Store in original bundles. Store in a dry place. Keep away from sunlight. Store in original container.

**Storage class:** 11 (TRGS 510)    Materials to avoid: n.a.

## 7.3 Specific end uses

**Sector specific guidelines:** dental / orthodontic laboratories, clinics

## Section 8: Exposure controls / personal protection

### 8.1 Control parameters

#### Occupational exposure limits

Substances:    PET-G, TPU                                 ; CAS-no. : see section 3.1  
Specification :                                 Does not contain any substances - according to the common EU lists – that have to be monitored at work-places.  
Limit value type (country of origin) :                                 n.a.  
Peak limitation:                                 n.a.  
Toxic to reproduction:                                 n.a.  
Source (TRGS)                                 n.a.

#### 8.1.2 DNEL- and PNEC- values                                 none

Substance:    PET-G, TPU                                 ; CAS-No. : see section 3.1  
Specification :    n.a.  
Value:                                 n.a.

#### 8.1.3 Control-Banding (e.g. ILO, EMKG)                                 none

### 8.2 Exposure controls    The type and extent of usage determine the choice of protective measures.

**Appropriate engineering controls**    Provide good ventilation

#### Personal protective equipment

#### Eye / face protection

Safety glasses – to protect from dusts when working the sheets.

**Skin protection:** not required

**Hand protection:** not required

#### Body protection

Appropriate – do not eat, drink, smoke while working. Wash your hands after work.

#### Respiratory protection

Not required under normal use. Ventilation of workplace.

#### Thermal hazards

Not required under normal use.

#### Environmental exposure controls

Do not allow to get into sewer system, surface or ground water.

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## Section 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties:

Physical state:	
- Aggregate state:	Solid
- colour :	Transparent – opaque (as an exception: blue – green)
Odour :	Characteristic
Odour threshold :	No information available
pH-value:	n.a.
Freezing point :	n.a.
Initial boiling point/boiling range :	n.a.
Flash point:	> 200°C
Melting point:	180 – 220°C
Evaporation rate :	n.a.
Flammability:	Not determined
Upper/lower explosive limits	Not applicable
Vapour pressure :	n.a.
Vapour density:	n.a.
Relative density:	n.a.
Solubility:	Not soluble in water
Partition coefficient:	n.a.
Auto-ignition temperature:	Not applicable
Decomposition temperature:	> 230°C
Viscosity:	n.a.
Density:	117 g/cm <sup>3</sup>
explosive properties:	none
Oxidising properties:	none

### Other information

9.2 No further information available

### Physical hazards Explosives

## Section 10: Stability and reactivity

10.1 Reactivity: no known unusual reactivity

10.2 Chemical stability: reacts with solvents, thinner, acids.

10.3 Possibility of hazardous reactions: no known hazardous reactions

10.4 Conditions to avoid: sunlight

10.5 Incompatible materials: Oxidizing agents, acids, bases.

10.6 Hazardous decomposition products: Hydrocarbons, carbon dioxide (CO<sub>2</sub>), carbon monoxide, aldehydes

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## **Section 11: Toxicological information**

### **11.1 Information on toxicological effects**

When used appropriately no dangers to health are currently known appearing from this medical device product.

#### **Acute toxicity**

No information available

#### **Skin irritation**

Danger of burns when in properly used.

#### **Eye irritation**

No irritation due to dusts when wearing eye protection glasses.

#### **Sensitisation to the respiratory tract / skin**

Work on ventilated places in order to avoid dust enter the respiratory tract which may cause irritation.

Germ cell mutagenicity

No information available

Carcinogenicity

No existing information on human carcinogenicity

Reproductive toxicity

No information available

Specific target organ toxicity (single exposure) none

Specific target organ toxicity (repeated exposure) none

#### **Aspiration hazard**

void

#### **Symptoms related to the physical, chemical and toxicological characteristics:**

In case of ingestion: none

In case of skin contact: may cause burns when hot

In case of inhalation: irritation of the respiratory tract (only when working in not ventilated places)

In case of eye contact: dust may cause irritation – rinse with water – seek for a doctor's advice.

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## **Section 12: Ecological information**

### **12.1 Toxicity**

None

### **12.2 Persistence and degradability**

No data available. As to consistency and non-solubility a bioavailability is very unlikely.

### **12.3 Bioaccumulative potential**

Not bioaccumulative

### **12.4 Mobility in soil**

No data available.

### **12.5 Results of PBT- and vPvB assessment**

Not applicable.

### **12.6 Other adverse effects**

None

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## **Section 13: Disposal considerations**

### **13.1 Waste treatment methods**

Contaminated packaging disposal  
Recycle according to official regulations.

### **Waste codes / waste designations according to EWC / AVV:**

20 01 39 - plastics

### **Special precautions**

None

### **Other relevant provisions for waste treatment national or EC**

Dispose of waste according to applicable legislation

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## **Section 14: Transport information**

### **14.1 UN-no.**

Not applicable

### **14.2 UN proper shipping name**

#### **ADR/RID**

The product is not defined under ADR/RID regulations.

#### **IMDG-Code / ICAO-TI / IATA-DGR**

The product is not defined under IMDG regulations.

### **14.3 Transport hazard class(es) / hazard labels**

Not relevant

### **14.4 Packing group**

Not relevant

### **14.5 Environmental hazards**

#### **Environmentally hazardous substance marking**

ADR/RID / IMDG-Code / ICAO-TI / IATA-DGR:  yes / XXX no

Marine Pollutant:  yes / XXX no

### **14.6 Special precautions for user**

No additional information available.

### **14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Pollution category (X, Y or Z) : not applicable

Type of ship (1, 2 or 3) : not applicable

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## **Section 15: Regulatory information**

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

**EU-regulations, e.g.:**

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**Directive /EC) no. 2037/2000 (substances that deplete the ozone layer): not listed**

**Directive (EC) no. 850/2004 (persistent organic pollutants): not listed**

**Directive (EC) no. 689/2008 (Import and export of dangerous chemicals): not listed**

**Directive (EC) no. 648/2004 (Detergents Regulation): not listed**

**National regulations, e.g.:**

**Water hazard class (VwVwS) : not water pollutant / registration no. 268**

**Technical instructions on Air Quality Control (TA-Luft): not applicable**

**Other relevant regulations:** TRGS 500, 510 (Germany): storage class: 11 (combustible solids)

## 15.2 Chemical safety assessment

For this product a chemical safety assessment was not carried out.

## **Section 16: Other information**

### **Indication of changes**

Regulation (EC) no. 1272/2008 (CLP, EU\_GHS)  
Section1: Emergency number, editorial revision

### **Abbreviations and acronyms**

n.a. Not applicable

### **Key literature references and sources for data**

Gestis Stoffdatenbank - <http://gestis.itrust.de/>  
Authority for chemicals [www.baua.de](http://www.baua.de)

### **Classification for mixtures and used evaluation method according to regulation (EC) 1207/2008 [CLP]:**

No classification

### **Relevant R-, H- and EUH-phrases (number and full text):**

No phrases relevant – therefore no listing of these phrases.

### **Training advice**

Not applicable for qualified dental technicians.

### **Further information**

none

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