

Date of issue 23.04.2015

Date of revision 22.01.18

Valid from 01.01.15

Version: 2

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

Combiloc Plus - Thermoforming Sheet

581-012-093, 581-012-174,

581-012-095, 581-012-176

dentalprodukte

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

Replaces Version: 1

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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

Am Tobel 15

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 Australian Distributor:

Ultimate Dental Supplies, 660A South Rd, MOORABBIN VIC 3189

Phone / Fax / Email:

03 9532 1799/ 03 9555 9458/info@ultimatedental.com.au

Emergency Phone:

13 11 26 Poisons Hotline (24 hours/7 days)

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 pictograms: NONE

Signal word: NONE

Hazardous component(s) for labelling:

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Hazard statements: NONE

Precautionary statements: NONE

Supplemental Hazard information (EU):

NONE

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

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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

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 (CO₂), sulphur dioxide (SO₂), 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.

7.3 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.

7.4 Specific end uses

Sector specific guidelines: dental / orthodontic laboratories, clinics

Section 8: Exposure controls / personal protection

8.1 Control parameters

Limit value type (country) n.a.

Substances: .

Specificatio .

Peak limitation: n.a.

Toxic to reproduction: n.a.

Source (TRGS) n.a.

Occupational exposure limits

PET-G, TPU ; CAS-no. : see section 3.1

Does not contain any substances - according to the common EU lists - that have to be monitored at workplaces.

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.

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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 ³
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.

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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 (CO₂), 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.

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

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.:

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

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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