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SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Commercial product name: Combiloc Plus
CAS No.: --
EG No.: --
INDEX No.: --
REACH No.: --

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

Relevant identified uses: Plastic articles
Uses advised against: Other

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier: al dente Dentalprodukte GmbH
Street / mailbox: Borsigstr. 1
Country code. / postal code / city: D - 38644 Goslar
Phone: 0 53 21 / 80031
Fax: 0 53 21 / 50881
E-mail / Website: info@aldente.de / www.aldente.de
Further information obtainable from: al dente Dentalprodukte GmbH

1.4 Emergency telephone number

al dente Dentalprodukte GmbH: +49 (0) 53 21 / 80031 (Mon-Fri. 8 a.m. – 4 p.m.)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Regulation (EC) No 1272/2008: - No dangerous material! (!)

2.2 Label elements

Classification according to Regulation (EC)

No. 1272/2008 [CLP]:

Hazard pictograms: -

Signal word: -

Hazard statements: -

Precautionary statements: -

Hazardous component(s) for labelling: none

Special labelling of particular preparations: none

2.3 Other hazards:

On basis of test data. This substance is classified as not hazardous according to 67/548/EEC.

SECTION 3: Composition / information on ingredients

3.1 Substances: Polymere

3.2 Mixtures: PET-G / TPU

Composition/information on ingredients

Substance:	EC-no.:	CAS-No.:	REACH-no.:	Concentration:	Classification: EC 1272/2008 (CLP):
Polyethylenterephthal at PET-G	--	25640-14-6	--	50 - 80%	--

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Thermoplastic Polyurethan TPU	--	9018-04-6		20 - 50%	--
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(Full text of H- and EUH-phrases: see section 16.)

SECTION 4: First aid measures

4.1 Description on first aid measures:

General information:

No special measures are necessary.

Following inhalation:

Do not breathe dust. Dust should be exhausted directly at the point of origin. Inhalation of dust may cause irritation of the respiratory system.

Following skin contact:

No special measures are necessary. After contact with molten product, cool skin area rapidly with cold water. Immerse in cold water for a prolonged period. Burns caused by molten material must be treated clinically. Irritating to skin. slightly irritant

After eye contact:

Rinse immediately carefully and thoroughly with eye-bath or water. In case of troubles or persistent symptoms, consult an ophthalmologist. Irritating to eyes. Dust protection goggles.

After ingestion:

No special measures are necessary.

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

No information available.

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

No information available.

SECTION 5: Firefighting measures

5.1 Extinguishing media:

Suitable extinguishing media:

Extinguishing powder. Carbon dioxide. alcohol resistant foam. Water spray.

Unsuitable extinguishing media:

High power water jet.

5.2 Special hazards arising from the substance or mixture:

In case of fire may be liberated: Carbon dioxide (CO₂). Carbon monoxide. Sulphur dioxide (SO₂). Formaldehyde.

5.3 Advice for firefighters:

General information:

Use water spray jet to protect personnel and to cool endangered containers.

Special protective equipment for firefighters:

In case of fire: Wear self-contained breathing apparatus. Protective clothing.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures:

No special measures are necessary.

6.2 Environmental precautions:

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

6.3 Methods and material for containment and cleaning up

Take up mechanically, placing in appropriate containers for disposal.

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6.4 Reference to other sections: Treat the recovered material as prescribed in the section on waste disposal.

SECTION 7: Handling and storage

- 7.1 Precautions for safe handling**
Advices on safe handling: Avoid generation of dust. Dust must be exhausted directly at the point of origin.
Precautions against fire and explosion: Keep away from sources of ignition - No smoking. Keep away from heat.
- 7.2 Conditions for safe storage, including any incompatibilities**
Requirements for storage rooms and vessels: Keep container tightly closed and dry.
Hints on joint storage: Conditions to avoid: UV-radiation/sunlight.
Storage class: 11
- 7.3 Specific end use(s):** Observe instructions for use.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limit value

Substance:	CAS-No.:	Source:	Occupational exposure limit value:[ppm]	Occupational exposure limit value:[mg/m ³]	Limitation of exposure peaks:	Remark:

Substance with a common (EC) occupational exposure limit value

Substance:	CAS-No.:	Source:	Occupational exposure limit value:[ppm]	Occupational exposure limit value:[mg/m ³]	Limitation of exposure peaks:	Remark:

DNEL-/PNEC-values

DNEL value

Substance:	CAS-No.:	DNEL/DMEL

PNEC Value

Substance:	CAS-No.:	PNEC

Remark: none

8.2 Exposure controls
Occupational exposure controls: none

General protection and hygiene measures: When using do not eat, drink, smoke, sniff. Wash hands before breaks and after work. Take off immediately all contaminated clothing.

Personal protection equipment: Minimum standard for preventive measures while handling with working materials are specified in the TRGS 500. Dust protection goggles.

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Respiratory protection:	With correct and proper use, and under normal conditions, breathing protection is not required. Technical ventilation of workplace.
Hand protection:	See chapter 7. No additional measures necessary.
Eye/face protection:	Dust protection goggles.
Body protection:	Not required.
Environmental exposure controls:	Refer to chapter 7. No further action is necessary.
Consumer exposure controls:	Refer to chapter 7. No further action is necessary.
Exposure Scenario:	none

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance:	
Physical state:	solid
Colour:	various
Odour:	characteristically
Odour threshold:	No data available

Safety relevant basis data

	Parameter	Value	Unit	Remark
pH:				not applicable
Melting point/freezing point:	Vicat		80 °C	
Initial boiling point and boiling range:				not determined
Flash point:			>250 °C	
Evaporation rate:				not applicable
Flammability (solid, gas):				not determined
Explosive properties:				not explosive.
Lower flammability or explosive limits:				not applicable
Upper flammability or explosive limits:				not applicable
Vapour pressure:				not applicable
Vapour density:				not applicable
Relative density:				not determined
Density:		1,12 - 1,27	g/cm ³	
Solubility(ies):				not determined
Water solubility:				practically insoluble
Fat solubility:				not determined
Partition coefficient: n-octanol/water:				not determined
Auto-ignition temperature:				not determined
Decomposition temperature:				not determined
Viscosity:				not applicable
Oxidising properties:				not determined
Solvent content:				not applicable

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9.2 Other information: Observe technical data sheet.

SECTION 10: Stability and reactivity

10.1 Reactivity: No hazardous reaction when handled and stored according to provisions.

10.2 Chemical stability: Reacts with : Solvents/Thinner Etchant and acids

10.3 Possibility of hazardous reactions: No data available.

10.4 Conditions to avoid: UV-radiation/sunlight.

10.5 Incompatible materials: Acid Base Oxidizing agent

10.6 Hazardous decomposition products: Hydrocarbons. Carbon dioxide (CO₂) Carbon monoxide. aldehydes

SECTION 11: Toxicological information

11.1 Information on toxicological effects: Medical device product
 Cytotoxtest: no abnormality detected

M-factor: -- **Acute toxicity (dermal):** -
Acute toxicity (oral): -- **Acute toxicity (inhalative):** -

Acute toxicity

Substance:	CAS-No.:	Toxicological information
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Skin corrosion/irritation: In the case of the formation of dust.

Serious eye damage/irritation: Irritating to eyes. In the case of the formation of dust.

Respiratory or skin sensitisation: Toxicological data are not available.

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)
 Carcinogenicity: No indications of human carcinogenicity exist.
 Germ cell mutagenicity: No indications of human germ cell mutagenicity exist.
 Reproductive toxicity: Toxicological data are not available.

STOT-single exposure: No information available.

STOT-repeated exposure: No information available.

Aspiration hazard: Inhalation of dust may cause irritation of the respiratory system.

SECTION 12: Ecological information

12.1 Toxicity: none

Ecotoxicity

Substance:	CAS-No.:	Ecotoxicity
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12.2 Persistence and degradability: No information available.

12.3 Bioaccumulative potential: No information available.

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- 12.4 Mobility in soil:** No information available.
- 12.5 Results of PBT and vPvB assessment:** not applicable
- 12.6 Other adverse effects:** No information available.

SECTION 13: Disposal considerations

- 13.1 Waste treatment methods:**
- Appropriate disposal/Product:** Can be incinerated together with household waste in compliance with applicable technical regulations following consultation with approved waste disposal management companies and authorities in charge.
- Appropriate disposal / Package:** Dispose of waste according to applicable legislation.
- List of proposed waste codes/waste designations in accordance with EWC:** Consult the appropriate local waste disposal expert about waste disposal.
- Waste code product:** --
- Waste code packaging:** --

SECTION 14: Transport information

- 14.1 UN number**
UN No.: --
- 14.2 UN proper shipping name**
ADR / RID: --
IMDG / ICAO-TI / IATA-DGR: --
- 14.3 Transport hazard class(es)**
Hazard label(s): -- **Classification Code:** --
- 14.4 Packing group:** --
- 14.5 Environmental hazards:**
Labelling environmentally hazardous substances
ADR/RID / IMDG-Code / ICAO-TI / IATA-DGR: no
Marine Pollutant: no
- 14.6 Special precautions for user:**
Land transport (ADR/RID)
Transport category: -- **Tunnel restriction code:** --
Special provisions: -- **Limited quantity (LQ):** --
- Sea transport (IMDG)**
EmS-No: --
Special provisions: -- **Limited quantity (LQ):** --
- 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code:** Remark: 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**

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Regulation (EC) No 166/2006 concerning the establishment of a European Pollutant Release and Transfer Register: No information available.

Regulation (EC) No 1005/2009 on substance that deplete the ozone layer: No information available.

Regulation (EC) No 648/2004 on detergents: No information available.

Regulation (EC) No 850/2004 on persistent organic pollutants: No information available.

Regulation (EU) No 649/2012 concerning the export and import of dangerous chemicals: No information available.

Restrictions according to Title VIII of Regulation (EC) No 1907/2006: No information available.

National regulations: Observe in addition any national regulations!

Restrictions of occupation: none

Other regulations, restrictions and prohibition regulations: none

15.2 Chemical safety assessment: For this substance a chemical safety assessment has not been carried out.

SECTION 16: Other information

Relevant H- and EUH-phrases (Number and full text)

Hazard statements

Training advice: none

Recommended restrictions of use: none

Further information:

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

Documentation of changes: none

Key literature references and sources for data: none

Abbreviations and acronyms:

AC: Artikelkategorie (Article Category)

ACGIH: Rat für Arbeitsschutz und Gefahrstoffe, Amerika (American Conference of Government Industrial Hygienists)

ADN: Europäisches Übereinkommen über die internationale Beförderung gefährlicher Güter auf Binnengewässern (Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures)

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AGW:	Arbeitsplatzgrenzwert
AOX:	Adsorbierbare organisch gebundene Halogene (Adsorbable Organic halogen compounds)
Bw:	Körpergewicht (Body weight)
CMR:	Stoffe klassifiziert als Krebserzeugend, Mutagen oder Reproduktionstoxisch (Carcinogenic, Mutagenic, toxic for Reproduction)
CSR:	Stoffsicherheitsbericht (Chemical Safety Report)
DIN:	Deutsches Institut für Normung / Deutsche Industrienorm
DNEL:	Grenzwert, unterhalb dessen der Stoff keine Wirkung ausübt (Derived No Effect Level)
DPD:	Zubereitungsrichtlinie / Richtlinie 1999-45-EC (Dangerous Preparations Directive)
DSD:	Stoffrichtlinie / Richtlinie 67-548-EC (Dangerous Substances Directive)
DU:	Nachgeschalteter Anwender (Downstream User)
EC50:	Wirksame Konzentration 50% (Effective Concentration 50%)
EN:	Europäische Norm
EWC/EWL:	Europäischer Abfallartenkatalog (European Waste Catalogue)
IATA:	Verband für den internationalen Lufttransport (International Air Transport Association)
IBC:	Großpackmittel (Intermediate Bulk Container)
ICAO:	Internationale Zivilluftfahrt-Organisation (International Civil Aviation Organization)
IMDG Code:	Gefahrgutvorschriften für den internationalen Seetransport (International Maritime Dangerous Goods Code)
IMO:	Internationale Seeschiffahrts-Organisation (International Maritime Organization)
ISO:	Internationale Normungsorganisation (International Standards Organisation)
LC50:	Lethale (Tödliche) Konzentration 50%
LD50:	Lethale (Tödliche) Dosis 50%
LEV:	Lokale Absaugung (Local exhaust ventilation)
OEL:	Arbeitsplatzgrenzwert (Occupational Exposure Limit)
PBT:	persistent, bioakkumulierbar, giftig (persistent, bioaccumulative, toxic)
PNEC:	Abgeschätzte Nicht-Effekt-Konzentration (Predicted No Effect Concentration)
PPE/PSA:	Persönliche Schutzausrüstung (Personal Protective Equipment)
REACH:	Registrierung, Bewertung und Zulassung von Chemikalien (Registration, Evaluation and Authorization of Chemicals)
RID:	Gefahrgutvorschriften für den Transport mit der Eisenbahn (Règlement International concernant le transport de marchandises dangereuses par chemin de fer)
STEL:	Grenzwert für Kurzzeitexposition (Short-term Exposure Limit)
SVHC:	Stoff sehr hoher Besorgnis (Substance of Very High Concern)
TLV:	Arbeitsplatzgrenzwert (Threshold Limit Value)
VOC:	Flüchtige organische Kohlenwasserstoffe (Volatile Organic Compounds)
vPvB:	sehr persistent, sehr bioakkumulierbar (very persistent, very bioaccumulative)