Safety Data Sheet

according to regulation (EU) No. 1907/2006 (REACH) Article 31, Annex II as amended

1. Identification of the substance/mixture and of the company/undertaking *

1.1. Product identifier
Trade name: picodent twinduo / twinduo extrahart / twinduo soft

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

Use of the substance/mixture Product for dental technology

1.3. Details about the supplier of the safety data sheet
Manufacturer/Supplier:
Company name: picodent GmbH
Street: Lüdenscheider Str. 24-26
City: D-51688 Wipperfürth
Telephone: +49 2267 6580-0
E-Mail: picodent@picodent.de
Internet: www.picodent.de
Department for information: picodent Dental Produktions- und Vertriebs-GmbH
Telephone No. +49 2267 6580-0

1.4. Emergency contact number:

Medical Emergency information in case of poisoning: -24 h – Phone: +49 6131 19240
advisory service in German or English language
Poison Information Center Mainz

2. Hazards identification

2.1. Classification of the substance or mixture
Classification according to Regulation (EC) No 1272/2008 The product is not classified, according to the CLP regulation.

2.2. Label elements
Labelling according to Regulation (EC) No 1272/2008 Void
Hazard pictograms Void
Signal word Void
Hazard statements Void

Additional information: This Product contains a substance which is classified as STOT RE 1. Due to its physical form, exposure through inhalation is not expected (Regulation (EC) No 1272/2008 (CLP) - Annex I, 1.1.1.5).

2.3. Other hazards
Results of PBT and vPvB assessment This substance/mixture does not contain components classified as either persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

PBT: Not applicable.
vPvB: Not applicable.

Determination of endocrine-disrupting properties

Endocrine disrupting properties - human health: The substance/ mixture does not contain any components that exhibit endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated Regulation (EU) 2017/2100 or Commission Delegated Regulation (EU) 2018/605 in quantities of 0.1% or more.

Endocrine disrupting properties - Environment: The substance/ mixture does not contain any components that exhibit endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated Regulation (EU) 2017/2100 or Commission Delegated Regulation (EU) 2018/605 in quantities of 0.1% or more.

3. Composition/information on ingredients

3.2. Mixtures

Description: Mixture of substances listed below with nonhazardous additions.

Dangerous components:

EINECS: 238-455-4	Cristobalite (CAS 14464-46-1)	STOT RE 1,	H372	50-100%

Additional information: For the wording of the listed hazard phrases refer to section 16.

4. First aid measures

4.1. Description of first aid measures

General information: No special measures required.
After inhalation: Supply fresh air; consult doctor in case of complaints.
After skin contact: Generally the product does not irritate the skin.
After eye contact: Rinse opened eye for several minutes under running water.
After swallowing: If symptoms persist consult doctor.

4.2. Most important symptoms and effects, both acute and delayed No further relevant information available.

4.3. Indication of any immediate medical attention and special treatment needed No further relevant information available.

5. Firefighting measures

5.1. Extinguishing media Suitable extinguishing agents: Use fire extinguishing methods suitable to surrounding conditions.

5.2. Special hazards arising from the substance or mixture No further relevant information available.

5.3. Advice for firefighters Protective equipment: No special measures required.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures Not required.

6.2. Environmental precautions: Do not allow to enter sewers/surface or ground water

6.3. Methods and material for containment and cleaning up: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

6.4. Reference to other sections See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7. Handling and storage

7.1. Precautions for safe handling No special measures required.
Information about fire and explosion protection: No special measures required.

7.2. Conditions for safe storage, including any incompatibilities
Storage:
Requirements to be met by storerooms and receptacles: No special requirements.
Information about storage in one common storage facility: Not required.
Further information about storage conditions: None.

7.3. Specific end use(s) No further relevant information available.

8. Exposure controls/personal protection

8.1. Control parameters
Ingredients with limit values that require monitoring at the workplace: The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
Additional information: The lists valid during the making were used as basis.

8.2. Exposure controls
Appropriate engineering controls No further data; see item 7.
Individual protection measures, such as personal protective equipment
General protective and hygienic measures: The usual precautionary measures are to be adhered to when handling chemicals.
Respiratory protection: Not required.

Hand protection The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

Material of gloves	The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material cannot be calculated in advance and has therefore to be checked prior to the application.
Penetration time of glove material	The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
Eye/face protection	Goggles recommended during refilling

9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

General Information	
Physical state	Fluid
Colour:	according to product description
Odour:	Characteristic
Odour threshold:	Not determined.
Melting point/freezing point:	Undetermined.
Boiling point or initial boiling point and boiling range	Undetermined.
Flammability	Not applicable.
Lower and upper explosion limit	
Lower:	Not determined.
Upper:	Not determined.
Flash point:	Not applicable.
Ignition temperature:	Not determined.
Decomposition temperature:	Not determined.
pH	Not determined.
Viscosity:	
Kinematic viscosity	Not determined.
Dynamic:	Not determined.
Solubility	
water:	Not miscible or difficult to mix.
Partition coefficient n-octanol/water (log value)	Not determined.
Vapour pressure:	Not determined.
Density and/or relative density	
Density:	Not determined.
Relative density	Not determined.
Vapour density	Not determined.

9.2. Other information

Appearance:	
Form:	Solid
Important information on protection of health and environment, and on safety.	
Auto-ignition temperature:	Product is not self-igniting.
Explosive properties:	Product does not present an explosion hazard.
Solvent content:	
VOC (EC)	0.00 %
Solids content:	80.0 %

Change in condition	
Evaporation rate	Not determined.
Information with regard to physical hazard classes	
Explosives	Void
Flammable gases	Void
Aerosols	Void
Oxidising gases	Void
Gases under pressure	Void
Flammable liquids	Void
Flammable solids	Void
Self-reactive substances and mixtures	Void
Pyrophoric liquids	Void
Pyrophoric solids	Void
Self-heating substances and mixtures	Void
Substances and mixtures, which emit flammable gases in contact with water	Void
Oxidising liquids	Void
Oxidising solids	Void
Organic peroxides	Void
Corrosive to metals	Void
Desensitised explosives	Void

10. Stability and reactivity

10.1. Reactivity — No further relevant information available.

10.2. Chemical stability — Thermal decomposition / conditions to be avoided:
No decomposition if used according to specifications.

10.3. Possibility of hazardous reactions — No dangerous reactions known.

10.4. Conditions to avoid — No further relevant information available.

10.5. Incompatible materials: — No further relevant information available.

10.6. Hazardous decomposition products: — No dangerous decomposition products known.

11. Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity	Based on available data, the classification criteria are not met.
Skin corrosion/irritation	Based on available data, the classification criteria are not met.
Serious eye damage/irritation	Based on available data, the classification criteria are not met.
Respiratory or skin sensitisation	Based on available data, the classification criteria are not met.
Germ cell mutagenicity	Based on available data, the classification criteria are not met.
Carcinogenicity	Based on available data, the classification criteria are not met.
Reproductive toxicity	Based on available data, the classification criteria are not met.
STOT-single exposure	Based on available data, the classification criteria are not met.
STOT-repeated exposure	Based on available data, the classification criteria are not met.
Aspiration hazard	Based on available data, the classification criteria are not met.

11.2. Information on other hazards

Endocrine disrupting properties

Endocrine disrupting properties - human health: The substance/ mixture does not contain any components that exhibit endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated Regulation (EU) 2017/2100 or Commission Delegated Regulation (EU) 2018/605 in quantities of 0.1% or more.

None of the ingredients is listed.

12. Ecological information

12.1. Toxicity

Aquatic toxicity: No further relevant information available.

12.2. Persistence and degradability No further relevant information available.

12.3. Bioaccumulative potential No further relevant information available.

12.4. Mobility in soil No further relevant information available.

12.5. Results of PBT and vPvB assessment This substance/mixture does not contain components classified as either persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

PBT: Not applicable.
vPvB: Not applicable.

12.6. Endocrine disrupting properties Endocrine disrupting properties - Environment: The substance/ mixture does not contain any components that exhibit endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated Regulation (EU) 2017/2100 or Commission Delegated Regulation (EU) 2018/605 in quantities of 0.1% or more.

12.7. Other adverse effects

Additional ecological information:

General notes: Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

13. Disposal considerations

13.1. Waste treatment methods

Recommendation Smaller quantities can be disposed of with household waste.

Uncleaned packaging:

Recommendation: Disposal must be made according to official regulations.

14. Transport information

14.1. UN number or ID number
ADR, IMDG, IATA Void

14.2. UN proper shipping name
ADR, IMDG, IATA Void

14.3. Transport hazard class(es)
ADR, ADN, IMDG, IATA
Class Void

14.4. Packing group
ADR, IMDG, IATA Void

14.5. Environmental hazards: Not applicable.

14.6. Special precautions for user Not applicable.

14.7. Maritime transport in bulk according to
IMO instruments Not applicable.
UN "Model Regulation": Void

15. Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture
Directive 2012/18/EU
Named dangerous substances - ANNEX I None of the ingredients is listed.

DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II None of the ingredients is listed.

REGULATION (EU) 2019/1148
Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3)) None of the ingredients is listed.

Annex II - REPORTABLE EXPLOSIVES PRECURSORS None of the ingredients is listed.

Regulation (EC) No 273/2004 on drug precursors None of the ingredients is listed.

Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors None of the ingredients is listed.

15.2. Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16. Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Relevant phrases
H372 Causes damage to organs through prolonged or repeated exposure.

Abbreviations and acronyms:
ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
VOC: Volatile Organic Compounds (USA, EU)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1

Sources
The data for the hazardous ingredients were taken respectively from the last version of Safety Data Sheets of suppliers.

* Data compared to the previous version Rev.-No. 2.1 altered.