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

1.1 Product identifier

Trade name: PHYSIOSET CT, CONDYLOFORM CT, BONARTIC CT

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

No further relevant information available.

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:
CANDULOR AG
Boulevard Lilienthal 8
CH-8152 Glattpark (Opfikon)
SWITZERLAND

Tel. +41 (0) 44 805 9000
Fax +41 (0) 44 805 9090

Further information obtainable from:
Regulatory Affairs
info@candulor.ch

1.4 Emergency telephone number: +423 / 235 33 13 (Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein)

SECTION 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

2.3 Other hazards

Mechanical processing:
Avoid breathing sANDING dust /swarf.

RESULTS OF PBT AND vPvB ASSESSMENT

PBT: Not applicable.
vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

3.2 Chemical characterisation: Mixtures

Description: Ceramic denture teeth

Dangerous components: Void

SECTION 4: First aid measures

4.1 Description of first aid measures

General information: No special measures required.

After inhalation:
Grinding dust: Supply fresh air; consult doctor in case of complaints.
In case of unconsciousness place patient stably in side position for transportation.

After skin contact: Generally the product does not irritate the skin.

(Contd. on page 2)
· **After eye contact:**
  Rinse opened eye for several minutes under running water. Then consult a doctor.
  Mechanical effects only.
· **After swallowing:** Seek medical treatment.
· **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.

**SECTION 5: Firefighting measures**

· **5.1 Extinguishing media**
  Suitable extinguishing agents:
  CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
· **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.

**SECTION 6: Accidental release measures**

· **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
· **6.2 Environmental precautions:** No special measures required.
· **6.3 Methods and material for containment and cleaning up:** Pick up mechanically.
· **6.4 Reference to other sections**
  No dangerous substances are released.
  See Section 7 for information on safe handling.
  See Section 8 for information on personal protection equipment.
  See Section 13 for disposal information.

**SECTION 7: Handling and storage**

· **7.1 Precautions for safe handling**
  For use in dentistry only.
  Only adequately trained personnel should handle this product.
· **7.2 Conditions for safe storage, including any incompatibilities**
  Storage:
  Requirements to be met by storerooms and receptacles: Store only in the original receptacle.
· **7.3 Specific end use(s)** No further relevant information available.

**SECTION 8: Exposure controls/personal protection**

· **Additional information about design of technical facilities:** No further data; see item 7.
· **8.1 Control parameters**
  Ingredients with limit values that require monitoring at the workplace: Not required.
  Additional information: The lists valid during the making were used as basis.
8.2 Exposure controls

Personal protective equipment:

General protective and hygienic measures:
Usual hygienic measures for dental practice and dental laboratories.

Respiratory protection: Use respiratory protective device against the effects of dust.

Protection of hands:
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 can not 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 protection:
Always wear safety goggles during mechanical processing (grinding, sawing /cutting, drilling, milling).

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SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Appearance:
Form: Solid
Colour: According to product specification
Odour: Odourless
Odour threshold: Not determined.

pH-value: Not applicable.

Change in condition
Melting point/Melting range: Undetermined.
Boiling point/Boiling range: Undetermined.

Flash point: Not applicable.

Flammability (solid, gaseous): Product is not flammable.

Self-igniting: Not determined.

Danger of explosion: Product does not present an explosion hazard.

Explosion limits:
Lower: Not determined.
Upper: Not determined.

Vapour pressure: Not applicable.

Density: Not determined.
Relative density Not determined.
Vapour density Not applicable.
Evaporation rate Not applicable.
Section 10: Stability and Reactivity

- 10.1 Reactivity: No further relevant information available.
- 10.2 Chemical stability: Stable under normal handling and storage conditions.
- 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: None under normal conditions of storage and use.

Section 11: Toxicological Information

- 11.1 Information on toxicological effects
  - 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.
  - Additional toxicological information: No further relevant information available.
  - 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.

Section 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
    - PBT: Not applicable.
    - vPvB: Not applicable.
  - 12.6 Other adverse effects: No further relevant information available.
SECTION 13: Disposal considerations

- 13.1 Waste treatment methods
  - Recommendation: Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

- Uncleaned packaging:
  - Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information

- 14.1 UN-Number
  - ADR, RID, ADN, ADN, IMDG, IATA: Void

- 14.2 UN proper shipping name
  - ADR, RID, ADN, ADN, IMDG, IATA: Void

- 14.3 Transport hazard class(es)
  - ADR, RID, ADN, ADN, IMDG, IATA: Void

- 14.4 Packing group
  - ADR, RID, ADN, IMDG, IATA: Void

- 14.5 Environmental hazards:
  - Marine pollutant: No

- 14.6 Special precautions for user
  - Not applicable.

- 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
  - Not applicable.

- Transport/Additional information:
  - Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).

- UN "Model Regulation": Void

SECTION 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
  - National regulations:
  - Other regulations, limitations and prohibitive regulations: The product is a medical device according to the Directive 93/42/EEC.

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

SECTION 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.

- Abbreviations and acronyms:
  - ADR: Accord européen sur le transport 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
Trade name: PHYSIOSET CT, CONDYLOFORM CT, BONARTIC CT

CAS: Chemical Abstracts Service (division of the American Chemical Society)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative

* Data compared to the previous version altered.