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

· 1.1 Product identifier

· Trade name: Ceka Multi Composite

· Article number: 6701B

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

No further relevant information available.

· Application of the substance / the mixture Dental Cement

· 1.3 Details of the supplier of the safety data sheet

· Manufacturer/Supplier:

Alphadent NV

Mannebeekstraat 33

8790 Waregem

Belgium

· Further information obtainable from: F&E GDF GmbH, Tel. +49 (0)6003/814-100

· 1.4 Emergency telephone number:

+49 (0) 6003 814-100 GDF GmbH (8:00 - 17:00 Uhr) or

+49 (0) 6131 19240 Poison Information Center, University Mainz (24 h)

SECTION 2: Hazards identification

- · 2.1 Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008

Acute Tox. 4 H332 Harmful if inhaled.

Skin Sens. 1 H317 May cause an allergic skin reaction.

Aquatic Chronic 2 H411 Toxic to aquatic life with long lasting effects.

- · 2.2 Label elements
- · Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the GB CLP regulation.

· Hazard pictograms





GHS07

GHS09

- · Signal word Warning
- · Hazard-determining components of labelling:

di-urethane dimethacrylate

2-[[(butylamino)carbonyl]oxy]ethyl acrylate

dibenzoyl peroxide

· Hazard statements

H332 Harmful if inhaled.

H317 May cause an allergic skin reaction.

H411 Toxic to aquatic life with long lasting effects.

· Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P280 Wear protective gloves.

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P312 Call a POISON CENTER/doctor if you feel unwell.

P321 Specific treatment (see on this label).

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· 2.3 Other hazards

- · Results of PBT and vPvB assessment
- · PBT: Not applicable.

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· vPvB: Not applicable.

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SECTION 3: Composition/information on ingredients

- · 3.2 Mixtures
- · Description: Adhesive material for dental use.

| · Dangerous components: | | | | |
|-------------------------|--|---------|--|--|
| CAS: 41137-60-4 | di-urethane dimethacrylate | 25-50% | | |
| | 🕸 Aquatic Chronic 2, H411; 🚺 Skin Sens. 1B, H317 | | | |
| CAS: 63225-53-6 | | 2.5-10% | | |
| | 🕸 Aquatic Chronic 2, H411; 🐠 Acute Tox. 4, H332; Skin Sens. 1A, H317 | | | |
| CAS: 94-36-0 | dibenzoyl peroxide | <2.5% | | |
| EINECS: 202-327-6 | ♦ Ø Org. Perox. B, H241; Aquatic Chronic 1, H410; Eye Irrit. 2, H319; Skin Sens. 1, H317 | | | |

[·] Additional information For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

- · 4.1 Description of first aid measures
- · After inhalation Supply fresh air; consult doctor in case of complaints.
- · After skin contact

Immediately wash with water and soap and rinse thoroughly.

If skin irritation continues, consult a doctor.

- · After eye contact Rinse opened eye for several minutes under running water. Then consult a doctor.
- · After swallowing

Rinse out mouth and then drink plenty of water.

Call a doctor immediately.

- · 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.

- · For safety reasons unsuitable extinguishing agents Water with full jet.
- 5.2 Special hazards arising from the substance or mixture No further relevant information available.
- · 5.3 Advice for firefighters
- · Protective equipment: Adapt to environment.

SECTION 6: Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures

Avoid eye and skin contact with the substance.

- · 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

No dangerous substances are released.

See Section 7 for information on safe handling

See Section 8 for information on personal protection equipment.

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See Section 13 for disposal information.

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SECTION 7: Handling and storage

- · 7.1 Precautions for safe handling Store in cool, dry place in tightly closed receptacles.
- · 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: Store in refrigerator.
- · Information about storage in one common storage facility: Store away from foodstuffs.
- · Further information about storage conditions: None.
- · 7.3 Specific end use(s) No further relevant information available.

SECTION 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 necessary if room is well-ventilated.
- · Hand protection Solvent resistant gloves
- · Material of gloves

Butyl rubber, BR

Nitrile rubber, NBR

· Penetration time of glove material

0.11 mm

Penetration time 10 min.

 $0.3 \, mm$

Penetration time 60 min.

- · Eve/face protection Goggles recommended during refilling.
- · Body protection: Protective work clothing.

SECTION 9: Physical and chemical properties

- · 9.1 Information on basic physical and chemical properties
- · General Information

Physical stateColour:FluidColourless

Odour: Weak, characteristic
 Odour threshold: Not determined.
 Melting point/freezing point: undetermined

· Boiling point or initial boiling point and boiling

range 251 °C

· Flammability Not applicable.

· Lower and upper explosion limit

· Lower: Not determined. · Upper: Not determined.

· Flash point: 151 °C

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400 °C · Ignition temperature: · Decomposition temperature: Not determined. $\cdot pH$ Not determined. · Viscosity:

· Kinematic viscosity Not determined. · dvnamic: Not determined.

·Solubility · Water: Partition coefficient n-octanol/water (log value)

Not miscible or difficult to mix Not determined. 1,3 mbar (110 ° C)

· Vapour pressure: Density and/or relative density

· Density: Not determined · Relative density Not determined. · Vapour density Not determined.

9.2 Other information

· Appearance:

· Form: Viscous

· Important information on protection of health and environment, and on safety.

Product is not selfigniting. · Auto-ignition temperature:

· Explosive properties: Product does not present an explosion hazard.

· Solvent content:

00% · Solids content:

· Change in condition

Not determined. · Evaporation rate

· Information with regard to physical hazard classes · Explosives Void

· Flammable gases Void · Aerosols Void Void · Oxidising gases Void · Gases under pressure · Flammable liquids Void Void · Flammable solids Void · Self-reactive substances and mixtures Void · Pyrophoric liquids · Pyrophoric solids Void · Self-heating substances and mixtures Void · Substances and mixtures, which emit flammable Void gases in contact with water · Oxidising liquids Void Void

· Oxidising solids · Organic peroxides Void · Corrosive to metals Void · Desensitised explosives Void

SECTION 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 Exothermic polymerization
- 10.4 Conditions to avoid No further relevant information available.
- · 10.5 Incompatible materials:

In presence of radical formers (e. g. peroxides), deoxidizing substances, and/or heavy metal ions, polymerization with heat release is possible.

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· 10.6 Hazardous decomposition products: No dangerous decomposition products known

SECTION 11: Toxicological information

- · 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
- · Acute toxicity Harmful if inhaled.
- · LD/LC50 values relevant for classification:

dibenzoyl peroxide: 78 % in water oral > 5000 mg/kg rat

inhalation > 24,3 mg/1/4h rat

N,N-Bis(2-hydroxyethyl)-p-toluidine LD-50 oral 300 mg/kg rat

- · Respiratory or skin sensitisation May cause an allergic skin reaction.
- 11.2 Information on other hazards
- Endocrine disrupting properties

None of the ingredients is listed.

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 Endocrine disrupting properties For information on endocrine disrupting properties see section 11.
- · 12.7 Other adverse effects
- · Remark: Toxic for fish
- · Additional ecological information:
- · General notes:

Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water.

Do not allow product to reach ground water, water course or sewage system.

Danger to drinking water if even small quantities leak into the ground.

Also poisonous for fish and plankton in water bodies.

Toxic for aquatic organisms

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- **Recommendation** Must be specially treated adhering to official regulations.
- · Uncleaned packaging:
- · Recommendation:

Empty contaminated packagings thoroughly. They may be recycled after thorough and proper cleaning. Packagings that may not be cleansed are to be disposed of in the same manner as the product.

· Recommended cleansing agents: Ethyl acetate

| CECTION | 1 4 700 | |
|---------|---------------|-------------|
| SECTION | 14: Transport | intormation |

| · 14.1 UN num | ber or ID | number |
|---------------|-----------|--------|
|---------------|-----------|--------|

· ADR, IMDG, IATA UN3082

· 14.2 UN proper shipping name

ADR 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (di-urethane

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| | (Contd. of pag |
|---|--|
| | dimethacrylate, 2-[[(butylamino)carbonyl]oxy]eth |
| · IMDG | acrylate) ENVIRONMENTALLY HAZARDOUS SUBSTANC |
| IMDG | LIQUID, N.O.S. (di-urethane dimethacrylate, |
| | [[(butylamino)carbonyl]oxy]ethyl acrylate), MARII |
| | POLLUTANT |
| IATA | ENVIRONMENTALLY HAZARDOUS SUBSTANC |
| | LIQUID, N.O.S. (di-urethane dimethacrylate, |
| | [[(butylamino)carbonyl]oxy]ethyl acrylate) |
| 14.3 Transport hazard class(es) | |
| ADR | |
| | |
| Class | 9 (M6) Miscellaneous dangerous substances and articl |
| Label | 9 |
| IMDG, IATA | |
| A | |
| | |
| Class | 9 Miscellaneous dangerous substances and articles. |
| Label | 9 |
| 14.4 Packing group | |
| ADR, IMDG, IATA | III |
| 14.5 Environmental hazards: | |
| Marine pollutant: | No |
| | Symbol (fish and tree) |
| Special marking (ADR): | Symbol (fish and tree) |
| Special marking (IATA): | Symbol (fish and tree) |
| 14.6 Special precautions for user | Warning: Miscellaneous dangerous substances a |
| | articles. |
| Hazard identification number (Kemler code): | 90 E A S E |
| EMS Number: Stowage Category | F-A,S-F A |
| | |
| 14.7 Maritime transport in bulk according to IM | |
| instruments | Not applicable. |
| Transport/Additional information: | |
| ADR | |
| Limited quantities (LQ) | 5L |
| Excepted quantities (EQ) | Code: E1 |
| | Maximum net quantity per inner packaging: 30 ml |
| Transport category | Maximum net quantity per outer packaging: 1000 ml |
| Transport category Tunnel restriction code | (-) |
| | |
| · IMDG · Limited quantities (LQ) | 5L |
| Limited quantities (LQ) | (Contd. on pag |

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|----------------------------|---|
| · Excepted quantities (EQ) | Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml |
| · UN "Model Regulation": | UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (DI-URETHANE DIMETHACRYLATE, 2-[[(BUTYLAMINO)CARBONYL] OXYJETHYL ACRYLATE), 9, III |

SECTION 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.
- · Seveso category E2 Hazardous to the Aquatic Environment
- Qualifying quantity (tonnes) for the application of lower-tier requirements 200 t
- · Qualifying quantity (tonnes) for the application of upper-tier requirements 500 t
- · National regulations
- · Waterhazard class: Water hazard class 2 (Self-assessment): hazardous for water.
- · 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.

· Relevant phrases

H241 Heating may cause a fire or explosion.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H332 Harmful if inhaled.

H410 Very toxic to aquatic life with long lasting effects.

H411 Toxic to aquatic life with long lasting effects.

- · Department issuing SDS: F&E GDF GmbH
- · Contact: Dr. U. Krichbaum
- Abbreviations and acronyms:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)

ICAO: International Civil Aviation Organisation

ICAO-TI: Technical Instructions by the "International Civil Aviation Organisation" (ICAO)

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)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Org. Perox. B: Organic peroxides – Type B Acute Tox. 4: Acute toxicity – Category 4

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Skin Sens. 1: Skin sensitisation – Category 1

Skin Sens. 1A: Skin sensitisation - Category 1A

Skin Sens. 1B: Skin sensitisation – Category 1B

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard - Category 1

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Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2 ·* **Data compared to the previous version altered.**