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Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 03.08.2018

Version number 2

Revision: 20.01.2016

SECTION 1: Identification of the substance/mixture and of the company/undertaking · 1.1 Product identifier · Trade name: GC G-CEM LinkAce Paste B · 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 Auxillary for dental technology \cdot 1.3 Details of the supplier of the safety data sheet · Manufacturer/Supplier: GC EUROPE N.V. Interleuvenlaan 33 B-3001 Leuven Tel. +32/(0)16/74.10.00 Fax +32/(0)16/40.26.84 msds@gc.dental · Further information obtainable from: Regulatory affairs · 1.4 Emergency telephone number: National poison center for United Kingdom of Great Britain and Northern Ireland: Belfast: +44 28 90 63 2032 Birmingham: +44 121 507 4123 Edinburgh: +44 131 242 1383 Newcastle Upon Tyne: +44 191 2606182/+44 191 2606180 Penarth: +44 292 071 55 54

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
Classification according to Regulation (EC) No 1272/2008
Exempt from requirements - product regulated as a medical device or an in vitro diagnostic medical device.
Skin Irrit. 2 H315 Causes skin irritation.
Eye Irrit. 2 H319 Causes serious eye irritation.
Skin Sens. 1 H317 May cause an allergic skin reaction.
2.2 Label elements
Labelling according to Regulation (EC) No 1272/2008
Exempt from requirements - product regulated as a medical device or an in vitro diagnostic medical device.
The product is classified and labelled according to the CLP regulation.

· Hazard pictograms



· Signal word Warning

• *Hazard-determining components of labelling:* Urethane Dimethacrylate (UDMA)

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· Hazard stateme	nts
H315 Causes sk	in irritation.
H319 Causes se	rious eye irritation.
	e an allergic skin reaction.
· Precautionary s	tatements
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves / eye protection / face protection.
P305+P351+P.	338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if
	present and easy to do. Continue rinsing.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.
· 2.3 Other hazar	

· 2.3 Other hazards

· Results of PBT and vPvB assessment

• **PBT:** Not applicable.

· vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

· 3.2 Chemical characterisation: Mixtures

· Description:

Only substances required to be mentioned according to Annex II of regulation 1907/2006 are listed. Information on the other substances that may be present can be obtained upon request.

• Dangerous components:		
CAS: 72869-86-4	Urethane Dimethacrylate (UDMA)	25-<50%
EINECS: 276-957-5	Skin Sens. 1, H317	
CAS: 1830-78-0	2-Hydroxy-1,3 dimethacryloxypropane	5-<10%
EINECS: 217-388-4	Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	
CAS: 85590-00-7	methacryloyloxydecyl dihydrogen phosphate	2.5-<5%
	Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	
CAS: 80-15-9	α,α -dimethylbenzyl hydroperoxide	0.5-<1%
EINECS: 201-254-7	Org. Perox. E, H242; Acute Tox. 3, H331; STOT RE 2, H373; Skin	
Index number: 617-002-00-8	Corr. 1B, H314; Aquatic Chronic 2, H411; Acute Tox. 4, H302;	
	Acute Tox. 4, H312	
CAS: 1879-09-0	6-tert-butyl-2,4-xylenol	≥0.2-<0.25%
EINECS: 217-533-1	Acute Tox. 2, H310; STOT RE 2, H373; Aquatic Chronic 2, H411; Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319	
· 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

· General information:

Immediately remove any clothing soiled by the product.

If symptoms persist consult doctor.

• After inhalation:

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist. Take affected persons into fresh air and keep quiet.

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• After skin contact:

Immediately wash with water and soap and rinse thoroughly. Seek medical treatment. If skin irritation continues, consult a doctor.

After eye contact: Protect unharmed eye. Rinse opened eye for several minutes under running water. Then consult a doctor. After swallowing:

Rinse out mouth and then drink plenty of water. If symptoms persist consult doctor.

• 4.2 Most important symptoms and effects, both acute and delayed Allergic reactions

• 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. Use fire extinguishing methods suitable to surrounding conditions.

- · For safety reasons unsuitable extinguishing agents: Water with full jet
- · 5.2 Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire.

- 5.3 Advice for firefighters
- · Protective equipment: Wear self-contained respiratory protective device.
- · Additional information

Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

SECTION 6: Accidental release measures

• 6.1 Personal precautions, protective equipment and emergency procedures Remove persons from danger area.
Avoid contact with the eyes and skin.
Wear protective clothing.
· 6.2 Environmental precautions:
Do not allow product to reach sewage system or any water course.
Inform respective authorities in case of seepage into water course or sewage system.
Do not allow to penetrate the ground/soil.
In case of seepage into the ground inform responsible authorities.
· 6.3 Methods and material for containment and cleaning up:
Absorb liquid components with liquid-binding material.
Dispose of the material collected according to regulations.
· 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.

SECTION 7: Handling and storage

• 7.1 Precautions for safe handling Avoid contact with the eyes and skin.

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· Information about fire - and explosion protection: No special measures required.

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· 7.2 Conditions for safe storage, including any incompatibilities

· Storage:

• Requirements to be met by storerooms and receptacles: Store only in unopened original receptacles.

- · Information about storage in one common storage facility: Store away from foodstuffs.
- Further information about storage conditions: Keep container tightly sealed.
- 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:
- The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

· DNELs

1879-09-0 6-tert-butyl-2,4-xylenol

Inhalative DNEL inhalation 0.14 mg/m3 (man)

- Additional information: The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- · Personal protective equipment:
- General protective and hygienic measures: The usual precautionary measures are to be adhered to when handling chemicals. Avoid contact with the eyes and skin. Wash hands before breaks and at the end of work. Keep away from foodstuffs, beverages and feed. Immediately remove all solid and contaminated electhing.
- Immediately remove all soiled and contaminated clothing
- · Respiratory protection: Suitable respiratory protective device recommended.
- Protection of hands:



Protective gloves

· 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:



Tightly sealed goggles

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SECTION 9: Physical and chem	• •
9.1 Information on basic physical and c	chemical properties
General Information	
Appearance: Form:	D
Form: Colour:	Pasty White
Colour: Odour:	white Odourless
Odour: Odour threshold:	Not determined.
pH-value:	Not determined.
-	
Change in condition	
Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range	
Flash point:	93 °C
Flammability (solid, gas):	Not applicable.
Ignition temperature:	Undetermined.
Decomposition temperature:	Not determined.
Auto-ignition temperature:	Product is not selfigniting.
Explosive properties:	Product does not present an explosion hazard.
Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
Vapour pressure:	Not determined.
Density:	Not determined.
Relative density	Not determined.
Vapour density	Not determined.
Evaporation rate	Not determined.
Solubility in / Miscibility with	
water:	Insoluble.
Partition coefficient: n-octanol/water:	Not determined.
Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
Solvent content:	
Organic solvents:	0.0 %
VOC (EC)	0.0 g/l
9.2 Other information	No further relevant information available.

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 No dangerous reactions known.

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• 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.

SECTION 11: Toxicological information

· 11.1 Information on toxicological effects

• Acute toxicity Based on available data, the classification criteria are not met.

· LD/LC50 values relevant for classification:

72869-86-4 Urethane Dimethacrylate (UDMA)

Oral LD50 > 5000 mg/kg (rat female) (OECD 401)

80-15-9 a,a -dimethylbenzyl hydroperoxide

 Oral
 LD50
 382 mg/kg (rat (f+m))

 Dermal
 LD50
 500 mg/kg (rat (f+m))

Inhalative LC50/4 h 220 mg/l (rat (f+m))

1879-09-0 6-tert-butyl-2,4-xylenol

Oral	LD50	910 mg/kg (rat (f+m)) (OECD 401)
Dermal	LD50	< 200 mg/kg (rabbit) (OECD 402)

- Primary irritant effect:
- Skin corrosion/irritation Causes skin irritation.
- Serious eye damage/irritation
- Causes serious eye irritation.
- · Respiratory or skin sensitisation
- May cause an allergic skin reaction.
- **Repeated dose toxicity** No further relevant information available.
- **CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)** 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:

72869-86-4 Urethane Dimethacrylate (UDMA)

|EC50/48h (static)| > 1.2 mg/l (daphnia magna) (OECD 202)

- · 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.
- Additional ecological information:

· General notes:

Water hazard class 3 (German Regulation) (Self-assessment): extremely hazardous for water

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Do not allow product to reach ground water, water course or sewage system, even in small quantities. Danger to drinking water if even extremely small quantities leak into the ground.

· 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

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

• European waste catalogue 18 00 00 WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (except kitchen and restaurant wastes not arising from immediate health care) 18 01 00 wastes from natal care, diagnosis, treatment or prevention of disease in humans 18 01 06* chemicals consisting of or containing dangerous substances

• Uncleaned packaging:

• Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information				
· 14.1 UN-Number · ADR, ADN, IMDG, IATA	not regulated			
· 14.2 UN proper shipping name · ADR, ADN, IMDG, IATA	not regulated			
· 14.3 Transport hazard class(es)				
· ADR, ADN, IMDG, IATA · Class	not regulated			
· 14.4 Packing group · ADR, IMDG, IATA	not regulated			
 14.5 Environmental hazards: Marine pollutant: 	No			
· 14.6 Special precautions for user	Not applicable.			
· 14.7 Transport in bulk according to Anno Marpol and the IBC Code	ex II of Not applicable.			
· UN ''Model Regulation'':	not regulated			

SECTION 15: Regulatory information

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

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SECTION 16: Other information · Relevant phrases H242 Heating may cause a fire. H302 Harmful if swallowed. H310 Fatal in contact with skin. H312 Harmful in contact with skin. H314 Causes severe skin burns and eye damage. H315 Causes skin irritation. H317 May cause an allergic skin reaction. H319 Causes serious eye irritation. H331 Toxic if inhaled. H335 May cause respiratory irritation. H373 May cause damage to organs through prolonged or repeated exposure. H411 Toxic to aquatic life with long lasting effects. · Classification according to Regulation (EC) No 1272/2008 Calculation method · Department issuing SDS: Regulatory affairs · Contact: msds@gc.dental · 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 CAS: Chemical Abstracts Service (division of the American Chemical Society) VOC: Volatile Organic Compounds (USA, EU) DNEL: Derived No-Effect Level (REACH) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative Org. Perox. E: Organic peroxides - Type E/F Acute Tox. 4: Acute toxicity - Category 4 Acute Tox. 2: Acute toxicity – Category 2 Acute Tox. 3: Acute toxicity – Category 3 Skin Corr. 1B: Skin corrosion/irritation - Category 1B Skin Irrit. 2: Skin corrosion/irritation - Category 2 Eye Irrit. 2: Serious eye damage/eye irritation – Category 2 Skin Sens. 1: Skin sensitisation – Category 1 STOT SE 3: Specific target organ toxicity (single exposure) – Category 3 STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2 Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard - Category 2 · Sources • ECHA (http://echa.europa.eu/) • EnviChem (www.echemportal.org) • * Data compared to the previous version altered. This version replaces all previous versions. Disclaimer: The information contained herein is believed to be true and accurate. However, all statements, recommendations or suggestions are made without any guarantee, representation or warranty, express or implied, on our part. Therefore, no warranty is made or to be implied that the information set out in this document is accurate or complete, and we accordingly exclude all liability in connection with the use of this information or the products referred to herein. All such risks are assumed by the purchaser/user. The information contained herein is also subject to change without notice. For the avoidance of doubt, however, nothing in this document excludes or

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