

Printing date 22.05.2023 Version number 4 (replaces version 3) Revision: 22.05.2023

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

- · 1.1 Product identifier
- · Trade name: OPTIGLAZE
- · 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
- · 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

Flam. Liq. 2 H225 Highly flammable liquid and vapour.

Skin Irrit. 2 H315 Causes skin irritation.

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

Repr. 2 H361f Suspected of damaging fertility.

STOT SE 3 H335 May cause respiratory irritation.

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

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

· Exemptions

The product, regulated as an invasive medical device by the Regulation (EC) 2017/745, is exempted from labelling requirements for substances and mixtures (according to the provision of the Art 1.5).

· Hazard pictograms







GHS02 GHS07

GHS08

· Signal word Danger

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· Hazard-determining components of labelling:

Methyl methacrylate

diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

· Hazard statements

H225 Highly flammable liquid and vapour.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H361f Suspected of damaging fertility.

H335 May cause respiratory irritation.

· Precautionary statements

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No

smoking.

P280 Wear protective gloves / eye protection / face protection.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water

[or shower].

P308+P313 IF exposed or concerned: Get medical advice/attention.

P321 Specific treatment (see on this label).

P362+P364 Take off contaminated clothing and wash it before reuse.

P405 Store locked up.

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. · **vPvB**: Not applicable.

SECTION 3: Composition/information on ingredients

- · 3.2 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: 80-62-6	Methyl methacrylate	25-<50%
EINECS: 201-297-1 Index number: 607-035-00-6	Flam. Liq. 2, H225; Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	
	substance with a Community workplace exposure limit	
CAS: 7631-86-9 EINECS: 231-545-4	silicon dioxide Nanoform: Spheroidal, amorphous nanoform, set including amorphous nanoforms, amorphous forms, non-surface-treated nanoforms	
CAS: 75980-60-8 EINECS: 278-355-8 Index number: 015-203-00-X	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide Repr. 2, H36If	≥3-<5%

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

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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.

· 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:

Rinse opened eye for several minutes under running water.

If symptoms persist consult 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, sand, extinguishing powder. Do not use water.
- · For safety reasons unsuitable extinguishing agents: Water
- 5.2 Special hazards arising from the substance or mixture

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

No further relevant information available.

- 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.

Keep away from ignition sources.

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.

Do not allow to penetrate the ground/soil.

· 6.3 Methods and material for containment and cleaning up:

Ensure adequate ventilation.

Absorb liquid components with liquid-binding material.

Dispose of the material collected according to regulations.

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· 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

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

Avoid contact with the eyes and skin.

· Information about fire - and explosion protection:

Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.

Do not spray onto a naked flame or any incandescent material.

· 7.2 Conditions for safe storage, including any incompatibilities

- · Storage:
- Requirements to be met by storerooms and receptacles:

Store in a cool location.

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.

Store in cool, dry conditions in well sealed receptacles.

Protect from heat and direct sunlight.

Store in a cool place.

· 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 workp	lace:
80-62-6 Methyl methacrylate	

WEL Short-term value: 416 mg/m³, 100 ppm Long-term value: 208 mg/m³, 50 ppm

· DNELs

80-62-6 Methyl methacrylate

Dermal	DNEL dermal	13.67 mg/kg bw/day (man) (worker, l. te., syst.)
Inhalative	DNEL inhalation	208 mg/m3 (air) (worker, l. te., syst.)

- · Additional information: The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- · Appropriate engineering controls No further data; see section 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.

Avoid contact with the eyes and skin.

Wash hands before breaks and at the end of work.

Keep away from foodstuffs, beverages and feed.

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Immediately remove all soiled and contaminated clothing

- · Respiratory protection: Suitable respiratory protective device recommended.
- · Hand protection



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/face protection



Tightly sealed goggles

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Physical state Fluid

· Colour: According to product specification

Odour: Characteristic
 Odour threshold: Not determined.
 Melting point/freezing point: Undetermined.

· Boiling point or initial boiling point and boiling range 101 °C

· Flammability Highly flammable.

· Lower and upper explosion limit

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

· Flash point: 10 °C

· Auto-ignition temperature:
 Decomposition temperature:
 Not determined.
 PH
 Not determined.

· Viscosity:

Kinematic viscosity
 Dynamic:
 Not determined.
 Not determined.

·Solubility

• water:
• Partition coefficient n-octanol/water (log value)
• Vapour pressure:

Insoluble.

Not determined.

Not determined.

· Density and/or relative density

Density: Not determined.Relative density Not determined.

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Vapour density	Not determined.
Particle characteristics	SiO2: Diameter particle structure = 2.5 - 50 nm (TEM d50, number-based)
	Diameter agglomerate = $5 - 50$ mm (laser diffraction di
	module, d50, volume based)
	7631-86-9 silicon dioxide: Spheroidal, amorphou
	nanoform, set including amorphous nanoforms
	amorphous forms, non-surface-treated nanoforms
9.2 Other information	
Appearance:	
Form:	Fluid
Important information on protection of hea	alth and
environment, and on safety.	
Ignition temperature:	Product is not selfigniting.
Explosive properties:	Product does not present an explosion hazard.
Solvent content:	
VOC (EC)	$0.0~\mathrm{g/l}$
Change in condition	
Evaporation rate	Not determined.
Information with regard to physical hazard cla	asses
Explosives	Void
Flammable gases	Void
Aerosols	Void
Oxidising gases	Void
Gases under pressure	Void
Flammable liquids	Highly flammable liquid and vapour.
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 flammat	ble gases
in contact with water	Void
Oxidising liquids	Void
Oxidising solids	Void
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 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.

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SECTION 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.

· LD/LC50	· LD/LC50 values relevant for classification:		
80-62-6 M	ethyl meth	acrylate	
Oral	LD50	6,000 mg/kg (rabbit)	
Dermal	LD50	>5,000 mg/kg (rab)	
Inhalative	LC50/4 h	29.8 mg/l (rat (f+m))	
7631-86-9	7631-86-9 silicon dioxide		
Oral	LD50	10,000 mg/kg (rat (f+m))	

- · Skin corrosion/irritation Causes skin irritation.
- · Respiratory or skin sensitisation May cause an allergic skin reaction.
- · Reproductive toxicity Suspected of damaging fertility.
- · STOT-single exposure May cause respiratory irritation.
- · Additional toxicological information:
- · Repeated dose toxicity No further relevant information available.
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)

No further relevant information available.

- · 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

The product does not contain substances with endocrine disrupting properties.

- · 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.

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.

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

14.1 UN www.bon.on ID	
14.1 UN number or ID number ADR, IMDG, IATA	UN1247
14.2 UN proper shipping name	
ADR	1247 METHYL METHACRYLATE MONOME
HAD C LATA	STABILIZED mixture
IMDG, IATA	METHYL METHACRYLATE MONOMER, STABILIZE mixture
14.3 Transport hazard class(es)	
ADR	
3	
Class	3 (F1) Flammable liquids.
Label	3
IMDG, IATA	
3	
Class	3 Flammable liquids.
Label	3
14.4 Packing group	
ADR, IMDG, IATA	II
14.5 Environmental hazards:	
Marine pollutant:	No
14.6 Special precautions for user	Warning: Flammable liquids.
Hazard identification number (Kemler code):	33
EMS Number:	F- E , S - D
Stowage Category	C
Stowage Code	SWI Protected from sources of heat.
	SW2 Clear of living quarters.
14.7 Maritime transport in bulk according to IM	
instruments	Not applicable.
Transport/Additional information:	
ADR	
Limited quantities (LQ)	
Excepted quantities (EQ)	Code: E2
	Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml

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· Transport category	2
· Tunnel restriction code	D/E
· IMDG	
· Limited quantities (LQ)	1L
\cdot Excepted quantities (\widetilde{EQ})	Code: E2
	Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per outer packaging: 500 ml
· UN "Model Regulation":	UN 1247 METHYL METHACRYLATE MONOMER STABILIZED MIXTURE, 3, II

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 P5c FLAMMABLE LIQUIDS
- Qualifying quantity (tonnes) for the application of lower-tier requirements 5,000 t
- · Qualifying quantity (tonnes) for the application of upper-tier requirements 50,000 t
- · 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

· Relevant phrases

H225 Highly flammable liquid and vapour.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H335 May cause respiratory irritation.

H361f Suspected of damaging fertility.

- · Classification according to Regulation (EC) No 1272/2008 Calculation method
- · Department issuing SDS: Regulatory affairs
- · Contact: msds@gc.dental
- · 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)

DNEL: Derived No-Effect Level (UK REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Flam. Liq. 2: Flammable liquids – Category 2

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Skin Sens. 1: Skin sensitisation – Category 1

Repr. 2: Reproductive toxicity - Category 2

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

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- ·Sources
- ECHA (http://echa.europa.eu/)
- EnviChem (www.echemportal.org)
- * * Data compared to the previous version altered.

This version replaces all previous versions.

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