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Safety data sheet according to 1907/2006/EC, Article 31

Printing date 23.05.2023

Version number 4 (replaces version 3)

Revision: 23.05.2023

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

· 1.1 Product identifier

· Trade name:

OPTIGLAZE_color_(Clear_HV, A_shades, B_shades, C_shades, D_shades)

Nanoform

• 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 Auxiliary 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

· Information department: Regulatory affairs

· 1.4 Emergency telephone number: International: +01-813-248-0585 (ChemTel Inc.)

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.

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 labeled according to the 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



· Signal word Danger

- · Hazard-determining components of labeling:
- Methyl methacrylate • Hazard statements
- H225 Highly flammable liquid and vapour.

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H315 Causes skin in	ritation.
H317 May cause an	allergic skin reaction.
H335 May cause re.	spiratory irritation.
· Precautionary state	ments
P210	Keep away from heat/sparks/open flames/hot surfaces No smoking.
P272	Contaminated work clothing must not be allowed out of the workplace.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P303+P361+P353	If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/
	shower.
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

·R · **PBT:** Not applicable.

· vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

· 3.2 Chemical characterization: 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:	
	Methyl methacrylate	25-<50%
	Flam. Liq. 2, H225; Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	
7631-86-9	silicon dioxide	5-<10%
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	1-<2.5%
	Repr. 2, H361f	
· Additional i	nformation: For the wording of the listed hazard phrases refer to section 16	

ine woraing of the listed hazard phras

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.

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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* Wear protective equipment. Keep unprotected persons away. 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. Do not allow to enter sewers/ surface or ground water. - 6.3 Methods and material for containment and cleaning up: Ensure adequate ventilation. Allow to evaporate. Absorb liquid components with liquid-binding material. Dispose of the collected material 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.

SECTION 7: Handling and storage

See Section 13 for disposal information.

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 protection against explosions and fires: Keep ignition sources away - Do not smoke. Protect against electrostatic charges. Do not spray on a naked flame or any incandescent material.

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- 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 receptacle 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

· Components with limit values that require monitoring at the workplace:

80-62-6 Methyl methacrylate

IOELV Short-term value: 100 ppm

Long-term value: 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 that were valid during the creation were used as basis.

· 8.2 Exposure controls

• Additional information about design of technical systems: No further data; see section 7.

• Personal protective equipment:

- General protective and hygienic measures:
- The usual precautionary measures for handling chemicals should be followed.
- Avoid contact with the eyes and skin.

Wash hands before breaks and at the end of work.

Avoid contact with the skin.

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing.

• Breathing equipment:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

Suitable respiratory protective device recommended.

Protection of hands:

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.



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.

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· 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:



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Tightly sealed goggles

SECTION 9: Physical and chemical properties

• 9.1 Information on basic physical and chemica	al properties
· General Information	
· Physical state	Fluid
· Color:	According to product specification
· Odor:	Pungent
· Odor threshold:	Not determined.
• Melting point/Melting range:	Undetermined.
· Boiling point/Boiling range:	Undetermined.
· Flammability (solid, gaseous):	Highly flammable.
• Explosion limits:	
· Lower:	2.1 Vol %
· Upper:	12.5 Vol %
· Flash point:	10 °C
· Auto igniting:	Undetermined.
· Decomposition temperature:	Not determined.
· pH-value:	Not determined.
· Viscosity:	
· Kinematic:	Not determined.
Dynamic:	Not determined.
· Solubility in / Miscibility with	
· Water:	Insoluble.
· Partition coefficient (n-octanol/water):	Not determined.
· Vapor pressure:	Not determined.
• Density and/or relative density	
Density at 20 °C:	1.06 g/cm ³
· Relative density	Not determined.
· Vapor density	Not determined.
· Particle characteristics	SiO2: Diameter particle structure = $2.5 - 50$ nm (TEM)
	d50, number-based)
	Diameter agglomerate = $5 - 50$ mm (laser diffraction dry
	module, d50, volume based)
	7631-86-9 silicon dioxide: Spheroidal, amorphou.
	nanoform, set including amorphous nanoforms
	amorphous forms, non-surface-treated nanoforms
	unorphous jorms, non-surjuce-treated nanojorms
• 9.2 Other information	
· Appearance:	
· Form:	Fluid
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Important information on protection of hea	llth and	
environment, and on safety.		
Ignition temperature:	Product is not selfigniting.	
Danger of explosion:	Product does not present an explosion hazard.	
Solvent content:		
VOC (EC)	$0.0 \ g/l$	
Change in condition	, and the second s	
Evaporation rate	Not determined.	
Information with regard to physical hazard cla	isses	
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 flammab	le 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.

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 that are 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))
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7631-86-9 silicon dioxide

Oral LD50 10,000 mg/kg (rat (f+m))

• on the skin: Causes skin irritation.

• on the eye: Based on available data, the classification criteria are not met.

· Sensitization: May cause an allergic skin reaction.

· 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.

• Specific target organ toxicity - single exposure May cause respiratory irritation.

• Specific target organ toxicity - repeated exposure Based on available data, the classification criteria are not met.

• Aspiration hazard Based on available data, the classification criteria are not met.

• Additional toxicological information:

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

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 (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 of together with household garbage. Do not allow product to reach sewage system.

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· Uncleaned packagings:

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

14.1 UN-Number ADR, IMDG, IATA	UN1247
14.2 UN proper shipping name	
DOT	Methyl methacrylate monomer, stabilized mixture
ADR	1247 METHYL METHACRYLATE MONOMER, STABILIZE
	mixture
IMDG, IATA	METHYL METHACRYLATE MONOMER, STABILIZE, mixture
14.3 Transport hazard class(es)	
ADR	
Class	3 (F1) Flammable liquids
Label	3
IMDG, IATA	
Class	3 Flammable liquids
Label	3
14.4 Packing group ADR, IMDG, IATA	Ш
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 Stowage Code	C SWI Protected from sources of heat.
Stowage Code	SW1 Frotected from sources of near. SW2 Clear of living quarters.
14.7 Transport in bulk according to Annex II o MARPOL73/78 and the IBC Code	f Not applicable.
Transport/Additional information:	
ADR	
Limited quantities (LQ)	1L

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Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml 2
Maximum net quantity per outer packaging: 500 ml 2
2
D/E
1L
Code: E2
Maximum net quantity per inner packaging: 30 ml
Maximum net quantity per outer packaging: 500 ml
UN 1247 METHYL METHACRYLATE MONOMER STABILIZED MIXTURE, 3, II

SECTION 15: Regulatory information

 \cdot 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture \cdot Sara

Section 313 (Specific toxic chemical listings):	
80-62-6 Methyl methacrylate	
Proposition 65	
Chemicals known to cause cancer:	
None of the ingredients is listed.	
Chemicals known to cause reproductive toxicity for females:	
None of the ingredients is listed.	
Chemicals known to cause reproductive toxicity for males:	
None of the ingredients is listed.	
Chemicals known to cause developmental toxicity:	
None of the ingredients is listed.	
Carcinogenic categories	
EPA (Environmental Protection Agency)	
80-62-6 Methyl methacrylate	<i>E</i> , <i>N</i>
	·
TLV (Threshold Limit Value)	A
TLV (Threshold Limit Value) 80-62-6 Methyl methacrylate	71
80-62-6 Methyl methacrylate	
80-62-6 Methyl methacrylate MAK (German Maximum Workplace Concentration)	

• Qualifying quantity (tonnes) for the application of lower-tier requirements 5,000 t

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- Qualifying quantity (tonnes) for the application of upper-tier requirements 50,000 t • REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3
- 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.

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
- Date of previous version 23.05.2023
- Version number of previous version: 3
- 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
- DOT: US Department of Transportation
- 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)
- *VOC: Volatile Organic Compounds (USA, EC 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*
- NIOSH: National Institute for Occupational Safety

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OSHA: Occupational Safety & Health 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 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 limits our liability for death or personal injury caused by our negligence or for fraudulent misrepresentation.

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