

Printing date 23.05.2023 Version number 4 Revision: 23.05.2023

Hazardous according to criteria of Australian Safety and Compensation Council.

1 Identification

- · Product identifier
- · Trade name: OPTIGLAZE color (Clear, Orange, Red, Brown, Grey, Black, Pink, Yellow, Blue, Green, White, I vory_White)
- 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
- Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

GC Australasia Dental Pty Ltd 1753 Botany Road Banksmeadow, NSW 2019

Tel: +61 2 9301 8200

- · Further information obtainable from: Regulatory affairs
- · Emergency telephone number: 24 hours Emergency: 13 11 26.

2 Hazard(s) Identification

Classification of the substance or mixture

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.

Carc. 2 H351 Suspected of causing cancer. Route of exposure: Inhalation.

STOT SE 3 H335 May cause respiratory irritation.

- · Label elements
- · GHS label elements The product is classified and labelled according to the Globally Harmonised System (GHS).
- · 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

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

Methyl methacrylate titanium dioxide

· Hazard statements

Highly flammable liquid and vapour.

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Causes skin irritation.

May cause an allergic skin reaction.

Suspected of causing cancer. Route of exposure: Inhalation.

May cause respiratory irritation.

· Precautionary statements

Keep away from heat/sparks/open flames/hot surfaces. No smoking.

Wear protective gloves/protective clothing/eye protection/face protection.

IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.

IF exposed or concerned: Get medical advice/attention.

Specific treatment (see on this label).

Take off contaminated clothing and wash it before reuse.

Store locked up.

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

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

3 Composition and Information on Ingredients

- · 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	· Dangerous components:		
	Methyl methacrylate	50-<75%	
	Flam. Liq. 2, H225; Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335		
7631-86-9	silicon dioxide	5-<10%	
13463-67-7	titanium dioxide	2.5-<5%	
	Carc. 2, H351		
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	1-<2.5%	
	Repr. 2, H361		

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

4 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 eve contact:

Rinse opened eye for several minutes under running water.

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If symptoms persist consult doctor.

· After swallowing:

Rinse out mouth and then drink plenty of water.

If symptoms persist consult doctor.

- · Information for doctor:
- Most important symptoms and effects, both acute and delayed Allergic reactions
- · Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 Fire Fighting Measures

- · Suitable extinguishing agents: CO2, sand, extinguishing powder. Do not use water.
- · For safety reasons unsuitable extinguishing agents: Water
- · 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.

- · Protective equipment: Wear self-contained respiratory protective device.
- · Additional information

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

6 Accidental Release Measures

· 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.

· 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.

· 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.

· 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.

7 Handling and Storage

- · Handling:
- · Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace.

Do not inhale dust / smoke / mist.

Prevent formation of aerosols.

Avoid contact with the eyes and skin.

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· 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.

- · 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.

· Specific end use(s) No further relevant information available.

8 Exposure controls and personal protection

- · Additional information about design of technical facilities: No further data; see section 7.
- · Ingredients with limit values that require monitoring at the workplace:

80-62-6 Methyl methacrylate

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

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7631-86-9 silicon dioxide

TWA Long-term value: 2 mg/m³

13463-67-7 titanium dioxide

WES Long-term value: 10 mg/m³ inhalable dust

· 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.)

13463-67-7 titanium dioxide

Inhalative DNEL inhalation 10 mg/m3 (man)

- · Additional information: The lists valid during the making were used as basis.
- · 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 soiled and contaminated clothing

· Respiratory protection: Suitable respiratory protective device recommended.

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· Protection of hands:



· 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

9 Physical and Chemical Properties

· General Information

· Appearance:

· Form: Fluid

• Colour: According to product specification

Odour: Pungent
Odour threshold: Not determined.
pH-value: Not determined.

· Change in condition

Melting point/freezing point:

 Initial boiling point and boiling range:
 I01 °C (213.8 °F)

 Flash point:

 I0 °C (50 °F)

 Highly flammable.
 Auto-ignition temperature:

 Undetermined.

 Not determined.

• **Ignition temperature:** Product is not selfigniting.

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

· Explosion limits:

Lower: 2.1 Vol %
Upper: 12.5 Vol %
Vapour pressure: Not determined.

Density at 20 °C (68 °F): 1.06 g/cm³ (8.8457 lbs/gal)

Relative density
 Vapour density
 Evaporation rate
 Not determined.
 Not determined.

· Solubility in / Miscibility with

• water: Insoluble.
• Partition coefficient: n-octanol/water: Not determined.

· Viscosity:

· **Dynamic:** Not determined.

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Trade name: OPTIGLAZE_color_(Clear,_Orange,_Red,_Brown,_Grey,_Black,_Pink,_Yellow,_Blue,_Green,_White,_Ivory _White)

		(Contd. of page 5)
· Kinematic: · Solvent content:	Not determined.	
· VOC (EC)	$0.0~\mathrm{g/l}$	
· Other information	No further relevant information available.	

10 Stability and Reactivity

- · Reactivity No further relevant information available.
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · Possibility of hazardous reactions No dangerous reactions known.
- · Conditions to avoid No further relevant information available.
- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products: No dangerous decomposition products known.

11 Toxicological Information

- Information on toxicological effects
- · Acute toxicity Based on available data, the classification criteria are not met.

· LD/LC50	· LD/LC50 values relevant for classification:			
80-62-6 M	80-62-6 Methyl methacrylate			
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	Oral LD50 10,000 mg/kg (rat (f+m))			
13463-67-	13463-67-7 titanium dioxide			
Oral	LD50	>5,000 mg/kg (mouse) (OECD 420)		
Inhalative	LC50/4 h	>6.82 mg/l (rat male)		

- · Skin corrosion/irritation Causes skin irritation.
- · Serious eye damage/irritation Based on available data, the classification criteria are not met.
- · Respiratory or skin sensitisation May cause an allergic skin reaction.
- Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Suspected of causing cancer. Route of exposure: Inhalation.
- · Reproductive toxicity Based on available data, the classification criteria are not met.
- · STOT-single exposure May cause respiratory irritation.
- · 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.
- · Additional toxicological information:
- Repeated dose toxicity No further relevant information available.
- CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)

No further relevant information available.

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12 Ecological Information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Behaviour in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- · 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

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.

- · Results of PBT and vPvB assessment
- · **PBT**: Not applicable.
- · **vPvB**: Not applicable.
- · Other adverse effects No further relevant information available.

13 Disposal considerations

- · Waste treatment methods
- · Recommendation

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

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

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14 Trans	ρυτιτι	or mui	$\iota U I \iota$

· UN-Numbe	r
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UN1247 · ADG, IMDG, IATA

· UN proper shipping name

 \cdot ADG

1247 METHYL METHACRYLATE MONOMER,

STABILIZED mixture

· IMDG, IATA METHYL METHACRYLATE MONOMER, STABILIZED

mixture

- · Transport hazard class(es)
- $\cdot ADG$



3 (F1) Flammable liquids. · Class

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	(Contd. of page
Label	3
· IMDG, IATA	
3	
Class	3 Flammable liquids.
Label	3
Packing group	
ADG, IMDG, IATA	II
Environmental hazards:	
Marine pollutant:	No
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.
Transport in bulk according to Annex II of Mar	
and the IBC Code	Not applicable.
Transport/Additional information:	
ADG	
Limited quantities (LQ)	IL
Excepted quantities (EQ)	Code: E2
	Maximum net quantity per inner packaging: 30 ml
_	Maximum net quantity per outer packaging: 500 ml
Transport category	2
Tunnel restriction code	<i>D/E</i>
· IMDG	
Limited quantities (LQ)	IL
Excepted quantities (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 MONOMEI
· G ·······	STABILIZED MIXTURE, 3, II

15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Australian Inventory of Industrial Chemicals

All ingredients are listed.

· Standard for the Uniform Scheduling of Medicines and Poisons

80-62-6 Methyl methacrylate

S6, S10 (Contd. on page 9)

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· Australia: Priority Existing Chemicals

None of the ingredients is listed.

- GHS label elements The product is classified and labelled according to the Globally Harmonised System (GHS).
- · Hazard pictograms







GHS07

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

Methyl methacrylate

titanium dioxide

· Hazard statements

Highly flammable liquid and vapour.

Causes skin irritation.

May cause an allergic skin reaction.

Suspected of causing cancer. Route of exposure: Inhalation.

May cause respiratory irritation.

· Precautionary statements

Keep away from heat/sparks/open flames/hot surfaces. No smoking.

Wear protective gloves/protective clothing/eye protection/face protection.

IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.

IF exposed or concerned: Get medical advice/attention.

Specific treatment (see on this label).

Take off contaminated clothing and wash it before reuse.

Store locked up.

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

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

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.

H351 Suspected of causing cancer.

H361 Suspected of damaging fertility or the unborn child.

- · Department issuing SDS: Regulatory affairs
- · Contact: msds@gc.dental

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· 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

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 Flam. Liq. 2: Flammable liquids – Category 2 Skin Irrit. 2: Skin corrosion/irritation – Category 2 Skin San L. Skin sensitivation

Skin Sens. 1: Skin sensitisation – Category 1
Carc. 2: Carcinogenicity – Category 2

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.

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