Ruthinium® Group
We take care of your smile

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

Printing date 06.07.2023 | Version number 1 | Revision: 06.07.2023

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

· **1.1 Product identifier**

· **Trade name: OPAKER**
· **1.2 Relevant identified uses of the substance or mixture and uses advised against**
· **Life cycle stages** PW Widespread use by professional workers
· **Application of the substance / the mixture** Material for dental use
· **Uses advised against** Any use other than those identified is not recommended.

· **1.3 Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
Dental Manufacturing S.p.a.
Via Cà Mignola Nuova, 1699
45021 - Badia Polesine (RO) - Italy
Tel. +39 0425 51628 - Fax +39 0425 590156

· **Further information obtainable from:** info@ruthinium.it
· **1.4 Emergency telephone number:**
Dental Manufacturing S.p.a. - Tel. +39 0425 51628 (Office Hours)

SECTION 2: Hazards identification

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

GHS02 flame

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

GHS07

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 labelled according to the CLP regulation.
· **Hazard pictograms**

GHS02 GHS07

· **Signal word** Danger

· **Hazard-determining components of labelling:**
methyl methacrylate
· **Hazard statements**
H225 Highly flammable liquid and vapour.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H335 May cause respiratory irritation.
· **Precautionary statements**
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

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P280 Wear protective gloves / eye protection / face protection.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.
P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P332+P313 If skin irritation occurs: Get medical advice/attention.
P404 Store in a closed container.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Labelling of packages where the contents do not exceed 125 ml**
· **Hazard pictograms**

GHS02 GHS07

· **Signal word** Danger

· **Hazard-determining components of labelling:**
methyl methacrylate
· **Hazard statements**
H317 May cause an allergic skin reaction.
· **Precautionary statements**
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P280 Wear protective gloves.
P302+P352 IF ON SKIN: Wash with plenty of water.
P332+P313 If skin irritation occurs: Get medical advice/attention.
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:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

CAS: 80-62-6 EINECS: 201-297-1 Index number: 607-035-00-6 Reg.nr.: 01-2119452498-28-xxxx	methyl methacrylate Flam. Liq. 2, H225; Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	60-80%
CAS: 94-36-0 EINECS: 202-327-6 Index number: 617-008-00-0	dibenzoyl peroxide Self-react. B, H241; Org. Perox. B, H241; Aquatic Acute 1, H400 (M=10); Aquatic Chronic 1, H410 (M=10); Eye Irrit. 2, H319; Skin Sens. 1B, H317, EUH208	0.01-0.1%

· **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:**
Rescue workers must wear the protective equipment described in section 8.2 of this safety data sheet.

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· ***IF INHALATED:***
Supply fresh air and to be sure call for a doctor.
In case of unconsciousness place patient stably in side position for transportation.
· ***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. If symptoms persist, consult a doctor.
· ***After swallowing:***
Rinse out mouth and then drink plenty of water.
If ingested do not induce vomiting, seek medical assistance showing the safety data sheet or the hazard label
· ***4.2 Most important symptoms and effects, both acute and delayed*** *Skin: irritation*
· ***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.*
· ***For safety reasons unsuitable extinguishing agents:*** *Water with full jet*
· ***5.2 Special hazards arising from the substance or mixture***
Under certain fire conditions, traces of other toxic gases cannot be excluded.
Carbon monoxide (CO)
· ***5.3 Advice for firefighters***
· ***Protective equipment:***
Use respiratory protection
Wear personal protective clothing.
See Section 8 for information on personal protection equipment.

SECTION 6: Accidental release measures

· ***6.1 Personal precautions, protective equipment and emergency procedures***
See Section 8 for information on personal protection equipment.
Wear protective equipment. Keep unprotected persons away.
· ***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).
Ensure adequate ventilation.
· ***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***
You should follow the usual precautions for handling chemical products
Ensure good ventilation/exhaustion at the workplace.
· ***Information about fire - and explosion protection:***
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.

· ***7.2 Conditions for safe storage, including any incompatibilities***
· ***Storage:***
· ***Requirements to be met by storerooms and receptacles:***
Store only in the original receptacle.

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Store in a cool location.
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:**
Keep container tightly sealed.
Store in cool, dry conditions in well sealed receptacles.
· **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:**	
CAS: 80-62-6 methyl methacrylate (60-80%)	
OEL	Short-term value: 100 ppm Long-term value: 50 ppm IOELV, Sens

· **DNELs**		
CAS: 80-62-6 methyl methacrylate		
Dermal	Long term, local effect	1.5 mg/kg (general population)
		1.5 mg/kg (professional workers)
	Long term, systemic effect	13.67 mg/kg (professional workers)
	Long term, systemic effect	8.2 mg/kg bw/day (general population)
Inhalative	Long term, local effect	105 mg/m3 (general population)
		210 mg/m3 (professional workers)
	Long term, systemic effect	74.3 mg/m3 (general population)
		210 mg/m3 (professional workers)

· **PNECs**	
CAS: 80-62-6 methyl methacrylate	
PNEC	5.74 mg/kg (fresh water sediments)
PNEC	0.94 mg/l (freshwater)
	0.094 mg/l (marine water)

· **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:**
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
Do not inhale gases / fumes / aerosols.
Avoid contact with the eyes and skin.
· **Respiratory protection:**
Use suitable respiratory protective device in case of insufficient ventilation.
Short term filter device:
Filter AX
· **Hand protection**

Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

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Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· **Material of gloves**
Butyl rubber, BR
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 trough time has to be found out by the manufacturer of the protective gloves and has to be observed.
Breakthrough time:> = 480 min - Material thickness:> = 0.7 mm
Breakthrough time:> = 60 min - Material thickness:> = 0.5 mm
Breakthrough time:> = 30 min - Material thickness:> = 0.2 mm

· **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**	*Liquid*
· **Colour:**	*Various colours*
· **Odour:**	*Characteristic*
· **Odour threshold:**	*Not determined.*
· **Melting point/freezing point:**	*-48 °C*
· **Boiling point or initial boiling point and boiling range**	*100 °C*
· **Flammability**	*Highly flammable.*
· **Lower and upper explosion limit**	
· **Lower:**	*2.1 Vol %*
· **Upper:**	*12.5 Vol %*
· **Flash point:**	*10 °C*
· **Auto-ignition temperature:**	*430 °C*
· **pH**	*Not applicable*
· **Viscosity:**	
· **Kinematic viscosity**	*Not determined.*
· **Dynamic:**	*Not determined.*
· **Solubility**	
· **water at 20 °C:**	*1.6 g/l* *Soluble.*
· **Partition coefficient n-octanol/water (log value)**	*1.38 log POW*
· **Vapour pressure at 20 °C:**	*47 hPa*
· **Density and/or relative density**	
· **Density at 20 °C:**	*1.01 g/cm³*
· **Relative density**	*Not determined.*
· **Vapour density**	*Not determined.*

· **9.2 Other information**	
· **Appearance:**	
· **Form:**	*Liquid*

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· **Important information on protection of health and environment, and on safety.**	
· **Ignition temperature:**	Product is not selfigniting.
· **Explosive properties:**	Product is not explosive. However, formation of explosive air/vapour mixtures are possible.
· **Change in condition**	
· **Evaporation rate**	Not determined.

· **Information with regard to physical hazard classes**	
· **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 flammable 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 hazardous reactions when stored and handled according to instructions
· **10.2 Chemical stability** The product is stable under normal conditions of use and storage
· **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:** Avoid contact with acids and oxidants.
· **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** Based on available data, the classification criteria are not met.

· **LD/LC50 values relevant for classification:**

CAS: 80-62-6 methyl methacrylate		
Oral	LD50	7,872 mg/kg (rat)
Dermal	LD50	>5,000 mg/kg (rabbit)
Inhalative	LC50/4 h	33 mg/l (mouse)
		29.8 mg/l (rat)
CAS: 94-36-0 dibenzoyl peroxide		
Oral	LD50	6,400 mg/kg (rat)

· **Skin corrosion/irritation** Causes skin irritation.
· **Serious eye damage/irritation** Based on available data, the classification criteria are not met.

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· **Respiratory or skin sensitisation** 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.
· **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.
· **11.2 Information on other hazards**

· **Endocrine disrupting properties**
None of the ingredients is listed.

SECTION 12: Ecological information

· **12.1 Toxicity**

· **Aquatic toxicity:**	
CAS: 80-62-6 methyl methacrylate	
CL50	>79 mg/l (fish) (Esposizione 96 h)
EC50	69 mg/kg (daphnia)
EC50	>110 mg/l (algae) (Esposizione 72 h)
	69 mg/l (daphnia) (Esposizione 48 h)
NOEC	37 mg/l (daphnia)
	9.4 mg/l (fish)
CAS: 94-36-0 dibenzoyl peroxide	
CL50	0.06 mg/l (fish) (Esposizione 96 h)
EC50	0.06 mg/l (algae) (Esposizione 72 h)
	0.11 mg/l (daphnia) (Esposizione 48 h)

· **12.2 Persistence and degradability**
The product does not contain surfactants. The organic matter can be eliminated in the normal waste water treatment plants.
· **12.3 Bioaccumulative potential** Non significant accumulation in organisms
· **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 substance/mixture does not contain components considered to have endocrine disrupting properties according to Article 57(f) of REACH or Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or more;
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**
Do not discard the product or its packaging. Do not empty into drains. Recycle the product. When recycling is not possible, dispose through an authorized company in compliance with the local or national regulations. The assignment of the waste code is the user's responsibility, after determining the properties of the waste and the process generating it and after discussing it with the authorities

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responsible for disposal.

· ***Uncleaned packaging:***
· ***Recommendation:***
Empty the containers before disposal. Do not reuse the emptied containers. Send the empty containers to recycling or to an authorized company in compliance with local and national regulations.
· ***Recommended cleansing agents:*** *Water.*

SECTION 14: Transport information

· ***14.1 UN number or ID number***	
· ***ADR, IMDG, IATA***	*UN1247*
· ***14.2 UN proper shipping name***	
· ***ADR***	*1247 METHYL METHACRYLATE MONOMER, STABILIZED solution*
· ***IMDG, IATA***	*METHYL METHACRYLATE MONOMER, STABILIZED solution*
· ***14.3 Transport hazard class(es)***	
· ***ADR, IMDG, IATA***	

· ***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):***	*339*
· ***EMS Number:***	*F-E,S-D*
· ***Stowage Category***	*B*
· ***Stowage Code***	*SW2 Clear of living quarters.*
· ***14.7 Maritime transport in bulk according to IMO instruments***	*Not applicable.*
· ***Transport/Additional information:***	
· ***ADR***	
· ***Limited quantities (LQ)***	*1L*
· ***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***	*D/E*
· ***IMDG***	
· ***Limited quantities (LQ)***	*1L*
· ***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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· **UN "Model Regulation":** UN 1247 METHYL METHACRYLATE MONOMER, STABILIZED SOLUTION, 3, II

SECTION 15: Regulatory information

· **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
Safety data sheet prepared in accordance with Regulation 1907/2006/EC Article 31, Regulation (EU) No 878/2020 as subsequent amendments.

· **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
· **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.

· **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**
H225 Highly flammable liquid and vapour.
H241 Heating may cause a fire or explosion.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.
EUH208 Contains . **May produce an allergic reaction.**
· **Classification according to Regulation (EC) No 1272/2008**
As required by Regulation 1272/2008/CE art. 9, the classification of this compound is based on the calculation method taken from the data of the single substances therein and from the experimental data of this compound where available (viewable in sections 9, 11 and 12 in this document).
Procedure used for the classification of the mixture
Flam. Liq. 2, H225 - According to experimental data
Skin Irrit. 2, H315 - Calculation method
Skin Sens 1 / 1A / 1B, H317 -Calculation method
STOT SE 3, H335 - Calculation method
· **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

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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)
DNEL: Derived No-Effect Level (REACH)
PNEC: Predicted No-Effect Concentration (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
Self-react. B: Self-reactive substances and mixtures – Type B
Org. Perox. B: Organic peroxides – Type B
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
Skin Sens. 1B: Skin sensitisation – Category 1B
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1
Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1