

## 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**
- **Application of the substance / the preparation** Material for dental use
- **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.

- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**



Xi; Irritant

R37/38: Irritating to respiratory system and skin.



Xi; Sensitising

R43: May cause sensitisation by skin contact.



F; Highly flammable

R11: Highly flammable.

- **Information concerning particular hazards for human and environment:**

The product has to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.

- **Classification system:**

The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

- **2.2 Label elements**

- **Labelling according to Regulation (EC) No 1272/2008**

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

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**· 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/sparks/open flames/hot surfaces. - No smoking.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P264 Wash thoroughly after handling.

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

P403+P235 Store in a well-ventilated place. Keep cool.

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 Chemical characterization: Mixtures****· Description:** Mixture of substances listed below with nonhazardous additions.**· Dangerous components:**

CAS: 80-62-6	methyl methacrylate	50-100%
EINECS: 201-297-1	Xi R37/38;  Xi R43;  F R11 Flam. Liq. 2, H225;  Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	

**· Additional information:** For the wording of the listed risk phrases refer to section 16.

### SECTION 4: First aid measures

**· 4.1 Description of first aid measures****· After inhalation:**

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.**· After eye contact:** Rinse opened eye for several minutes under running water.**· After swallowing:** If symptoms persist consult doctor.**· 4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.**· 4.3 Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

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### SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:** CO<sub>2</sub>, sand, extinguishing powder. Do not use water.
- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

### SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**  
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.  
Do not flush with water or aqueous cleansing agents
- **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.
- **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 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

- **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:**

#### 80-62-6 methyl methacrylate

WEL	Short-term value: 416 mg/m <sup>3</sup> , 100 ppm
	Long-term value: 208 mg/m <sup>3</sup> , 50 ppm

- **DNELs**

Methyl Methacrylate - Inhalation 210 mg/m<sup>3</sup>Methyl Methacrylate - Dermal 74.3 mg/m<sup>3</sup>

- **PNECs** Methyl Methacrylate - Water 0.94 mg / l

- **Additional information:** The lists valid during the making were used as basis.

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· **8.2 Exposure controls**· **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.**Avoid contact with the skin.**Avoid contact with the eyes and skin.*· **Respiratory protection:***In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.*· **Protection of hands:***Protective gloves**The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.**Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.**Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation*· **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*

## SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**· **General Information**· **Appearance:****Form:** *Fluid***Colour:** *Colourless*· **Odour:** *Characteristic*· **Odour threshold:** *Not determined.*· **pH-value:** *Not applicable*· **Change in condition****Melting point/Melting range:** *Undetermined.***Boiling point/Boiling range:** *100°C*· **Flash point:** *10°C*· **Flammability (solid, gaseous):** *Not applicable.*· **Ignition temperature:** *430°C*· **Decomposition temperature:** *Not determined.*

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· <b>Self-igniting:</b>	Product is not selfigniting.
· <b>Danger of explosion:</b>	Product is not explosive. However, formation of explosive air/vapour mixtures are possible.
· <b>Explosion limits:</b>	
<b>Lower:</b>	2.1 Vol %
<b>Upper:</b>	12.5 Vol %
· <b>Vapour pressure at 20°C:</b>	47 hPa
· <b>Density at 20°C:</b>	0.94 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with water at 20°C:</b>	1.6 g/l
· <b>Partition coefficient (n-octanol/water):</b>	Not determined.
· <b>Viscosity:</b>	
<b>Dynamic:</b>	Not determined.
<b>Kinematic:</b>	Not determined.
· <b>9.2 Other information</b>	No further relevant information available.

### SECTION 10: Stability and reactivity

- **10.1 Reactivity**
- **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**  
The product is normally supplied in a stabilized form. Avoid excessive heat for long periods of time, the product can polymerize. Avoid heat, flames and other sources of ignition
- **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 toxicological effects**
- **Acute toxicity:**

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

**80-62-6 methyl methacrylate**

Oral	LD50	7872 mg/kg (rat)
Dermal	LD50	> 5000 mg/kg (rabbit)
Inhalative	LC50/4 h	33 mg/l (mouse)
		29.8 mg/l (rat)

- **Primary irritant effect:**
- **on the skin:**  
Irritant to skin and mucous membranes.  
No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** Sensitization possible through skin contact.
- **Additional toxicological information:**

The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:

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Irritant

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## SECTION 12: Ecological information

### · 12.1 Toxicity

#### · Aquatic toxicity:

**80-62-6 methyl methacrylate**

EC50 69 mg/kg (daphnia)

### · 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

Not worth-mentioning accumulating in organisms

### · 12.4 Mobility in soil

No further relevant information available.

### · 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.

### · 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.

#### · Uncleaned packaging:

#### · Recommendation:

Disposal must be made according to official regulations.

#### · Recommended cleansing agents:

Water.

## SECTION 14: Transport information

### · 14.1 UN-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

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· <b>14.4 Packing group</b>	
· <b>ADR, IMDG, IATA</b>	II
· <b>14.5 Environmental hazards:</b>	
· <b>Marine pollutant:</b>	No
· <b>14.6 Special precautions for user</b>	Warning: Flammable liquids.
· <b>Danger code (Kemler):</b>	339
· <b>EMS Number:</b>	F-E,S-D
· <b>14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable.
· <b>Transport/Additional information:</b>	
· <b>ADR</b>	
· <b>Tunnel restriction code</b>	D/E
· <b>UN "Model Regulation":</b>	UN1247, METHYL METHACRYLATE MONOMER, STABILIZED, solution, 3, II

### SECTION 15: Regulatory information

- **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.

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

· **Relevant phrases**

H225 Highly flammable liquid and vapour.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H335 May cause respiratory irritation.

R11 Highly flammable.

R37/38 Irritating to respiratory system and skin.

R43 May cause sensitisation by skin contact.

· **Contact:** ---

· **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 Harmonized System of Classification and Labelling of Chemicals

DNEL: Derived No-Effect Level (REACH)

PNEC: Predicted No-Effect Concentration (REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent