Ruthinium WE TAKE CARE OF YOUR SMILE

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

Printing date 13.03.2018 *Version number 6* *Revision: 13.03.2018*

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

· **1.1 Product identifier**

· **Trade name: DILUENTE PER 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)
Centro Antiveleni di Milano 02 66101029 (CAV Ospedale Niguarda Ca' Granda -Milano)
Centro Antiveleni di Pavia 0382 24444 (CAV IRCCS Fondazione Maugeri - Pavia)
Centro Antiveleni di Bergamo 800 883300 (CAV Ospedali Riuniti - Bergamo)
Centro Antiveleni di Firenze 055 7947819 (CAV Ospedale Careggi - Firenze)
Centro Antiveleni di Roma 06 3054343 (CAV Policlinico Gemelli - Roma)
Centro Antiveleni di Roma 06 49978000 (CAV Policlinico Umberto I - Roma)
Centro Antiveleni di Napoli 081 7472870 (CAV Ospedale Cardarelli - Napoli)
Centro Antiveleni di Foggia 0881 732326 (CAV Ospedale Univ. - Foggia)
Centro Antiveleni di Roma 06 68593726 (CAV Osp. Pediatrico Bambino Gesù - Roma)

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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

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· **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.
P264	Wash thoroughly after handling.
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.
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 characterisation: Mixtures**
· **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

CAS: 80-62-6 EINECS: 201-297-1 Reg.nr.: 01-2119452498-28-xxxx	methyl methacrylate Flam. Liq. 2, H225; Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	70 - 100%

· **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:**
Rescue workers must wear the protective equipment described in section 8.2 of this safety data sheet.
· **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:**
If skin irritation continues, consult a doctor.
Immediately wash with water and soap and rinse thoroughly.
· **After eye contact:** Rinse opened eye for several minutes under running water.
· **After swallowing:** Rinse your mouth well
· **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.

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 with full jet

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· **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.

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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.
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.

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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.
Store in a cool location.
· **Information about storage in one common storage facility:** Store away from oxidising agents.
· **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/m³, 100 ppm Long-term value: 208 mg/m³, 50 ppm

· **DNELs**		
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)

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Inhalative	Long term, systemic effect	8.2 mg/kg bw/day (general population)
	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**

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**
· **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 skin.
Avoid contact with the eyes and skin.
· **Respiratory protection:**
Short term filter device:
Filter AX
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

Only use EN 374-3 certified protective gloves against chemical agents.
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**
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.
Recommended thickness of the material: $\geq$ 0.2 mm
· **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.
Value for the permeation: Level 2/3

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· ***Eye protection:***

Tightly sealed goggles

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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 determined.
· **Change in condition**	
Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	101 °C
· **Flash point:**	10 °C
· **Flammability (solid, gas):**	Not applicable.
· **Ignition temperature:**	430 °C
· **Auto-ignition temperature:**	Product is not selfigniting.
· **Explosive properties:**	Product is not explosive. However, formation of explosive air/vapour mixtures are possible.
· **Explosion limits:**	
Lower:	2.1 Vol %
Upper:	12.5 Vol %
· **Vapour pressure at 20 °C:**	47 hPa
· **Density at 20 °C:**	0.95 g/cm³
· **Relative density**	Not determined.
· **Vapour density**	Not determined.
· **Evaporation rate**	Not determined.
· **Solubility in / Miscibility with**	
water at 20 °C:	15.9 g/l Soluble.
· **Partition coefficient: n-octanol/water:**	1.38 log POW
· **Viscosity:**	
Dynamic:	Not determined.
Kinematic:	Not determined.
· **Solvent content:**	
Water:	13.5 %
· **9.2 Other information**	No further relevant information available.

SECTION 10: Stability and reactivity

· **10.1 Reactivity** No further relevant information available.

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· **10.2 Chemical stability**
· **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
· **10.3 Possibility of hazardous reactions** Reacts with catalysts, oxidising agents and strong alkali.
· **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.

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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 relevant for classification:**		
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)

· **Primary irritant effect:**
· **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.
· **CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)**
· **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.

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SECTION 12: Ecological information

· **12.1 Toxicity**

· **Aquatic toxicity:**	
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)

· **12.2 Persistence and degradability** Easily biodegradable
· **12.3 Bioaccumulative potential** Non significant accumulation 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

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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
· **14.4 Packing group**	
· **ADR, IMDG, IATA**	II
· **14.5 Environmental hazards:**	
· **Marine pollutant:**	No
· **14.6 Special precautions for user**	Warning: Flammable liquids.
· **Danger code (Kemler):**	339
· **EMS Number:**	F-E,S-D
· **Stowage Category**	B
· **Stowage Code**	SW2 Clear of living quarters.
· **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code**	Not applicable.
· **Transport/Additional information:**	
· **ADR**	
· **Limited quantities (LQ)**	1L

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· **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
· **UN "Model Regulation":**	UN 1247 METHYL METHACRYLATE MONOMER, STABILIZED SOLUTION, 3, II

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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
· **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3
· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

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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.
· **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
· **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 Harmonised System of Classification and Labelling of Chemicals

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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
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Skin Sens. 1: Skin sensitisation – Category 1
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
· **** Data compared to the previous version altered.***