Ruthinium WE TAKE CARE OF YOUR SMILE

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

*Printing date 10.12.2020* *Version number 8* *Revision: 10.12.2020*

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

· **1.1 Product identifier**

· **Trade name: ACRY ORT SC POLVERE**
· **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

· **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**
The product is not classified, according to the CLP regulation.

· **2.2 Label elements**
· **Labelling according to Regulation (EC) No 1272/2008** Void
· **Hazard pictograms** Void
· **Signal word** Void
· **Hazard statements** Void
· **Precautionary statements**
P260 Do not breathe dust.
P302+P352 IF ON SKIN: Wash with plenty of water.
· **Additional information:**
EUH208 Contains methyl methacrylate, dibenzoyl peroxide. May produce an allergic reaction.
· **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 based on polymethyl methacrylate

· **Dangerous components:**
absence of hazardous ingredients in accordance with the applicable regulations

| | | |
|---|---|---|
| CAS: 80-62-6<br>EINECS: 201-297-1<br>Reg.nr.: 01-2119452498-28-xxxx | methyl methacrylate<br>Flam. Liq. 2, H225; Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335 | 0.1-1% |
| CAS: 94-36-0<br>EINECS: 202-327-6<br>Reg.nr.: 01-2119511472-50- | dibenzoyl peroxide<br>Org. Perox. B, H241; Aquatic Acute 1, H400 (M=10); Eye Irrit. 2, H319; Skin Sens. 1B, H317, EUH208 | 0.1-1% |

· **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; consult doctor in case of complaints.*
· ***After skin contact:*** *Immediately rinse with water.*
· ***After eye contact:*** *Rinse opened eye for several minutes under running water.*
· ***After swallowing:***
*Rinse out mouth and then drink plenty of water.*
*Do not induce vomiting; call for medical help immediately.*
· ***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:***
*Use fire extinguishing methods suitable to surrounding conditions.*
*CO2, powder or water spray. Fight larger fires with water spray.*
· ***For safety reasons unsuitable extinguishing agents:*** *None in particular*
· ***5.2 Special hazards arising from the substance or mixture***
*No further relevant information available.*
· ***5.3 Advice for firefighters***
· ***Protective equipment:***
*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***
*Wear protective equipment. Keep unprotected persons away.*
*See Section 8 for information on personal protection equipment.*
· ***6.2 Environmental precautions:*** *Do not allow to enter sewers/ surface or ground water.*
· ***6.3 Methods and material for containment and cleaning up:*** *Pick up mechanically.*
· ***6.4 Reference to other sections***
*No dangerous substances are released.*
*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***
*No special precautions are necessary if used correctly.*
*Prevent formation of dust.*
· ***Information about fire - and explosion protection:*** *No special measures required.*

· ***7.2 Conditions for safe storage, including any incompatibilities***
· ***Storage:***
· ***Requirements to be met by storerooms and receptacles:*** *No special requirements.*
· ***Information about storage in one common storage facility:*** *Not required.*
· ***Further information about storage conditions:*** *None.*

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· **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 (0.1-1%)** | |
| WEL | Short-term value: 416 mg/m³, 100 ppm<br>Long-term value: 208 mg/m³, 50 ppm |

| · **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 item 7.
· **Individual protection measures, such as personal protective equipment**
· **General protective and hygienic measures:** Wash hands before breaks and at the end of work.
· **Respiratory protection:** Not required.
· **Hand protection**

Protective gloves

The use of gloves is recommended as a preventive measure
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.
Nitrile rubber, NBR
Neoprene gloves
Recommended thickness of the material: ≥ 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/face protection** Not required.

## SECTION 9: Physical and chemical properties

| | |
|---|---|
| · **9.1 Information on basic physical and chemical properties** | |
| · **General Information** | |
| · **Physical state** | Solid |
| · **Colour:** | Various colours |
| · **Odour:** | Characteristic |
| · **Odour threshold:** | Not determined. |
| · **Melting point/freezing point:** | > 150 °C |
| · **Boiling point or initial boiling point and boiling range** | Undetermined. |
| · **Lower and upper explosion limit** | |
| · **Lower:** | Not determined. |
| · **Upper:** | Not determined. |
| · **Flash point:** | > 250 °C (ASTM D 1929-68) |
| · **Auto-ignition temperature:** | Product is not selfigniting. |
| · **pH** | Not applicable. |
| · **Viscosity:** | |
| · **Kinematic viscosity** | Not applicable. |
| · **Dynamic at 20 °C:** | 0.6 mPas |
| · **Solubility** | |
| · **water:** | Insoluble. |
| · **Partition coefficient n-octanol/water (log value)** | Not determined. |
| · **Vapour pressure:** | Not applicable. |
| · **Density and/or relative density** | |
| · **Density at 20 °C:** | 1.18 g/cm³ |
| · **Relative density at 20 °C** | 0.7 |
| | Not determined. |
| · **Vapour density** | Not applicable. |

| | |
|---|---|
| · **9.2 Other information** | |
| · **Appearance:** | |
| · **Form:** | Powder |
| · **Important information on protection of health and environment, and on safety.** | |
| · **Ignition temperature:** | > 400 °C (ASTM D 1929-68) |
| · **Explosive properties:** | Product does not present an explosion hazard. |
| · **Change in condition** | |
| · **Evaporation rate** | Not applicable. |

| | |
|---|---|
| · **Information with regard to physical hazard classes** | |
| · **Explosives** | Void |
| · **Flammable gases** | Void |
| · **Aerosols** | Void |
| · **Oxidising gases** | Void |
| · **Gases under pressure** | Void |
| · **Flammable liquids** | Void |
| · **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 |

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| | |
|---|---|
| · **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**
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 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 | >5,000 mg/kg (rat) |
| Inhalative | LC50/4 h | 24.3 mg/l (rat) |

· **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
· **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
· **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
· **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** Based on available data, the classification criteria are not met.
· **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) |

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| | |
|---|---|
| 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.
· **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:** Not hazardous for water.

## 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 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.

## SECTION 14: Transport information

| | |
|---|---|
| · **14.1 UN number or ID number** | |
| · **ADR, ADN, IMDG, IATA** | Void |
| · **14.2 UN proper shipping name** | |
| · **ADR, ADN, IMDG, IATA** | Void |
| · **14.3 Transport hazard class(es)** | |
| · **ADR, ADN, IMDG, IATA** | |
| · **Class** | Void |
| · **14.4 Packing group** | |
| · **ADR, IMDG, IATA** | Void |
| · **14.5 Environmental hazards:** | |
| · **Marine pollutant:** | No |
| · **14.6 Special precautions for user** | Not applicable. |
| · **14.7 Maritime transport in bulk according to IMO instruments** | Not applicable. |
| · **Transport/Additional information:** | Not dangerous according to the above specifications. |

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· ***UN "Model Regulation":*** *Void*

## 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.*

· ***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.*

· ***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.*
*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.*
*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*
· ***Version number of previous version:*** *7*
· ***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*
*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*
*Org. Perox. B: Organic peroxides – Type B*
*Skin Irrit. 2: Skin corrosion/irritation – Category 2*

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*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*