Revision: 07.10.2023



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

Printing date 07.10.2023

Version number 10 (replaces version 9)

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

- · 1.1 Product identifier
- · Trade name: ACRY ORT SC LIQUIDO
- 1.2 Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.
- · 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.

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· Precautionary statements

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition

sources. No smoking. Avoid breathing vapours.

P280 Wear protective gloves / eye protection / face protection.

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

with water [or shower].

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

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



P261



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.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves.

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

with water [or 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 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 Stanton Flam. Liq. 2, H225; Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	80-100%
CAS: 99-97-8 EINECS: 202-805-4 Index number: 612-056-00-9	N,N-dimethyl-p-toluidine → Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331; → STOT RE 2, H373; Aquatic Chronic 3, H412	0.1-<1%

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

__ IF

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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.

· 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.
- · After eye contact: Rinse opened eye for several minutes under running water.
- · After swallowing:

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: May cause slight skin irritation by prolonged or repeated contact

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
- · 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:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Ensure adequate ventilation.

Dispose of the material collected according to regulations.

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.

Avoid contact with eyes and skin.

· Information about fire - and explosion protection:

Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.

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- · 7.2 Conditions for safe storage, including any incompatibilities
- Storage:
- · Requirements to be met by storerooms and receptacles:

Store in a cool location.

Store only in the original receptacle.

- 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 (80-100%)

OEL Short-term value: 100 ppm Long-term value: 50 ppm

IOELV, Sens

· DNELs

CAS: 80-62-6 methyl methacrylate

A3. 00-0	2-0 metryr metriacryrate	
ermal	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)
halative	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)
	ermal	Long term, systemic effect Long term, systemic effect halative Long term, local effect

· 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.

Avoid contact with the skin.

Avoid contact with the eyes and skin.

- · Respiratory protection: Use suitable respiratory protective device in case of insufficient ventilation.
- Hand protection



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

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.

Rubber gloves Nitrile rubber, NBR

· 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
Colour:
Odour:
Odour threshold:

Liquid
Colourless

Characteristic
Not determined.

• Melting point/freezing point: -48 °C

· Boiling point or initial boiling point and

boiling range 101 °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 determined.

· Viscosity:

Kinematic viscosityDynamic:Not determined.Not determined.

· Solubility

• water at 20 °C: 1.6 g/l Soluble.

· Partition coefficient n-octanol/water (log

value) Not determined.

· Vapour pressure at 20 °C: 47 hPa

· Density and/or relative density

Density at 20 °C: 0.95 g/cm³
 Relative density Not determined.
 Vapour density Not determined.

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· 9.2 Other information

· Appearance:

· Form: Liquid

· 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
 Self-reactive substances and mixtures
 Pyrophoric liquids
 Pyrophoric solids
 Self-heating substances and mixtures

· Substances and mixtures, which emit

flammable gases in contact with water

Oxidising liquids
Oxidising solids
Organic peroxides
Corrosive to metals
Oesensitised 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:

ATE (Acute Toxicity Estimates)

Oral	LD50	12,500 mg/kg (rat)
		37,500 mg/kg (rat)
Inhalative	LC50/4 h	175 mg/l (rat)

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Trade name: ACRY ORT SC LIQUIDO

			(Contd. of page 6)
CAS: 80-6	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: 99-9	97-8 N,N-d	imethyl-p-toluidine	
Oral	LD50	100 mg/kg (rat)	
Dermal	LD50	300 mg/kg (rat)	
Inhalative	LC50/4 h	1.4 mg/l (rat)	

- · 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 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 i	methyl	methacry	late
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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.
- · 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:

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.

IE

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Trade name: ACRY ORT SC LIQUIDO

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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.

· 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): EMS Number:	339 F-E,S-D
Stowage Category	В
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 m Maximum net quantity per outer packaging: 500 l
Transport category	2

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Trade name: ACRY ORT SC LIQUIDO

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· Tunnel restriction code	D/E
· IMDG · Limited quantities (LQ) · Excepted quantities (EQ)	1L 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

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.

H301 Toxic if swallowed.

H311 Toxic in contact with skin.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H331 Toxic if inhaled.

H335 May cause respiratory irritation.

H373 May cause damage to organs through prolonged or repeated exposure.

H412 Harmful to aquatic life with long lasting effects.

· 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

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Skin Sens 1 / 1A / 1B, H317 -Calculation method

STOT SE 3, H335 - Calculation method

· Date of previous version: 28.09.2023

· Version number of previous version: 9

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

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 Acute Tox. 3: Acute toxicity – Category 3 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

STOT RE 2: Specific target organ toxicity (repeated exposure) - Category 2

Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard - Category 3

* Data compared to the previous version altered.