

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

- **1.1 Product identifier**
- **Trade name: MONOMERO SELF CURING**
- **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*
- **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
ethylene dimethacrylate

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.
P260 Do not breathe dust/fume/gas/mist/vapours/spray.
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 EINECS: 201-297-1	methyl methacrylate ☒ Xi R37/38; ☒ Xi R43; ☒ F R11 ☒ Flam. Liq. 2, H225; ☒ Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	70 - 100%
CAS: 97-90-5 EINECS: 202-617-2	ethylene dimethacrylate ☒ Xi R37; ☒ Xi R43 ☒ Skin Sens. 1, H317; STOT SE 3, H335	2 - 5%
CAS: 99-97-8 EINECS: 202-805-4	N,N-dimethyl-p-toluidine ☒ T R23/24/25 R33-52/53 ☒ Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331; ☒ STOT RE 2, H373; Aquatic Chronic 3, H412	0.1 - 1%

Regulation (EC) No 648/2004 on detergents / Labelling for contents

preservation agents (3,3'-Bis (1-hydroxymethyl-2,5-dioxoimidazolidin-4-yl)-1,1'-methylenediurea, 2-bromo-2-nitropropane-1,3-diol)

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· **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.

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **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.
- **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** No special precautions are necessary if used correctly.
- **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.

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- 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 ³ , 100 ppm
	Long-term value: 208 mg/m ³ , 50 ppm

· **DNELs**

80-62-6 methyl methacrylate

Dermal	Long term, local effect	1.5 mg/kg (consumer) 1.5 mg/kg (worker professional)
	Long term, systemic effect	8.2 mg/kg bw/day (consumer) 13.67 mg/kg (worker professional)
Inhalative	Long term, local effect	105 mg/m ³ (consumer) 210 mg/m ³ (worker professional)
	Long term, systemic effect	74.3 mg/m ³ (consumer) 210 mg/m ³ (worker professional)

· **PNECs**

80-62-6 methyl methacrylate

PNEC	0.94 mg/l (freshwater)
	5.74 mg/kg (freshwater sediments)
	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.

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

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- **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 trough 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 determined.

- **Change in condition**

Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	101 °C

- **Flash point:** 10 °C

- **Flammability (solid, gaseous):** Not applicable.

- **Ignition temperature:** 430 °C

- **Decomposition temperature:** Not determined.

- **Self-igniting:** Product is not selfigniting.

- **Danger of explosion:** 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/cm ³
Relative density	Not determined.
Vapour density	Not determined.
Evaporation rate	Not determined.

- **Solubility in / Miscibility with water:** Soluble.

- **Partition coefficient (n-octanol/water):** Not determined.

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|--------------------------------|--|
| · Viscosity: | |
| Dynamic: | Not determined. |
| Kinematic: | Not determined. |
| · Solvent content: | |
| Organic solvents: | 0.0 % |
| Water: | 0.4 % |
| · 9.2 Other information | 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)

97-90-5 ethylene dimethacrylate

Oral	LD50	3300 mg/kg (rat)
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- **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:
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** Easily biodegradable

· **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

· **14.4 Packing group**

· **ADR, IMDG, IATA**

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· 14.5 Environmental hazards:	
· Marine pollutant:	No
· 14.6 Special precautions for user	
· Danger code (Kemler):	Warning: Flammable liquids. 339
· EMS Number:	F-E,S-D
· 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	
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
· UN "Model Regulation":	UN1247, 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**
This product is to be considered as a preparation according to EU-legislation.
This surfactant complies with the biodegradability criteria as laid down in Regulation (EC) No.648/2004 on detergents. Data to support this assertion are held at the disposal of the competent authorities of the Member States and will be made available to them at their direct request or at the request of a detergent manufacturer.
- 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.
- H301 Toxic if swallowed.
- H311 Toxic in contact with skin.
- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.

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- 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.
-
- R11 Highly flammable.
 R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
 R33 Danger of cumulative effects.
 R37 Irritating to respiratory system.
 R37/38 Irritating to respiratory system and skin.
 R43 May cause sensitisation by skin contact.
 R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

· **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
 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
 Flam. Liq. 2: Flammable liquids, Hazard Category 2
 Acute Tox. 3: Acute toxicity, Hazard Category 3
 Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2
 Skin Sens. 1: Sensitisation - Skin, Hazard Category 1
 STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3
 STOT RE 2: Specific target organ toxicity - Repeated exposure, Hazard Category 2
 Aquatic Chronic 3: Hazardous to the aquatic environment - Chronic Hazard, Category 3

· *** Data compared to the previous version altered.**

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