

SECTION 1: Identification of the substance/mixture and of the company/undertaking ***1.1 Product identifier**

- Trade name: RESPAL NF | RESPAL NF AUTOPOLIMERIZZANTE | REPORT/N | RESTRAY NF (Liquid)

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:** Manufacture of dental prosthesis

1.3 Details of the supplier of the safety data sheet**Manufacturer/Supplier:**

SPD SALMOIRAGHI PRODUZIONE DENTARIA S.R.L.

Via Roncomarzo, 10 - 26837 Mulazzano (LO) Italia

www.spd-dental.com | Tel. +39 02 989231 | Fax +39 02 989340

- E-mail address of the person responsible for SDS:** info@spd-dental.com

1.4 Emergency telephone number:

Centro Antiveneni Ospedale Niguarda Cà Granda

Piazza Ospedale Maggiore, 3 - 20162 Milano (MI) Italia

Tel. +39 02 66101029

Always contact the nearest hospital or medical center

SECTION 2: Hazards identification ***2.1 Classification of the substance or mixture**

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

Flam. Liq. 2 H225 Highly flammable liquid and vapour

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.

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.

P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.

P370+P378 In case of fire: Use for extinction: CO₂, sand, extinguishing powder.

P403+P233 Store in a well-ventilated place. Keep container tightly closed.

2.3 Other hazards

- (- Data not available)

- **Results of PBT and vPvB assessment:** (- Not applicable)

SECTION 3: Composition/information on ingredients *

3.1 Substances (- Section does not apply)

3.2 Mixtures

- **Dangerous components:**

		RESPAL NF	RESPAL NF AUTOP.	REPORT/N	RESTRAY NF
CAS: 80-62-6 EINECS: 201-297-1	Methyl Methacrylate Flam. Liq. 2, HS225; Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	> 95%	> 95%	> 95%	> 92%
CAS: 97-90-5 EINECS: 202-617-2	Etylen Glycol Dimethacrylate Skin Sens. 1, H317; STOT SE 3, H335	< 5%	< 3%	< 3%	-
CAS: 99-97-8 EINECS: 202-805-4	N,N-Dimetil-p-toluidine Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331; STOT RE 2, H373; Aquatic Chronic 3, H412	-	< 1 %	< 1 %	< 1 %
CAS: 131-57-7 EINECS: 205-031-5	Benzophenone-3 Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	-	< 1 %	< 2 %	< 1 %

For the wording of the listed risk phrases refer to section 16.

SECTION 4: First aid measures *

4.1 Description of first aid measures

- **Inhalation:** Bring to fresh air and, in case of symptoms, consult a doctor.
- **Skin contact:** Remove contaminated clothing. Rinse with water. If symptoms persist, consult a doctor.
- **Eye contact:** Flush eyes with running water and the inside of the eyelids for at least 15 minutes. If irritation persists, consult a doctor.
- **Ingestion:** Rinse mouth with water. Do not induce vomiting and seek medical advice 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:

Medical advice is necessary in case of symptoms that are clearly related to the effect of the product on the skin and / or eyes, ingestion or inhalation of the vapors of the same. Show the product label and the present Safety Data Sheet.

SECTION 5: Firefighting measures *

5.1 Extinguishing media

- **Suitable extinguishing agents:** CO₂, sand, extinguishing powder.
- **For safety reasons unsuitable extinguishing agents:** Water.

5.2 Special hazards arising from the substance or mixture:

Product heated above the flash point generates flammable vapours, that can explode or burn in contact with air. Vapours could reach an ignition source and start burning. In case of fire, to avoid explosion risk, keep containers cool using water and approach fire from sheltered positions.

5.3 Advice for firefighters

- **Protective equipment:** No special equipments required.

SECTION 6: Accidental release measures *

6.1 Personal precautions, protective equipment and emergency procedures:

Switch off engines, lights or any electrical apparatus nearby. Remove any ignition source. Do not smoke. Ensure adequate ventilation of the premises. Wear protective equipment and keep away unprotected persons.

6.2 Environmental precautions:

Avoid discharge of the material into the drains, surface water and / or groundwater.

6.3 Methods and material for containment and cleaning up:

Dry released material using inert absorbents such as sand or sawdust. Collect and dispose into appropriate containers; provide appropriate containers labelling and set for final disposal. Wash and ventilate contaminated areas.

6.4 Reference to other sections:

See Section 13 for information on disposal. See Section 8 for information on personal protection equipment.

SECTION 7: Handling and storage *

7.1 Precautions for safe handling:

Check the integrity of the containers prior to their handling and use. Handling only by

trained personnel. Close containers immediately after collection of the desired quantities. Avoid formation of vapors. Do not inhale the vapors. Provide adequate ventilation of the working area. Wash hands after handling if protective gloves are not used. Do not eat, drink or smoke during use. Take precautions against the formation of electrostatic charges and against the possibility of fire. Keep away from heat sources. Consider the use of personal protective equipment.

7.2 Conditions for safe storage, including any incompatibilities: Store in a cool (max 23°C), dry, well-ventilated place, away from light and away from sources of ignition and heat. Keep containers tightly sealed. Do not contaminate the material and heat it: it could become unstable and begin a progressive unwanted polymerization. Take precautions to avoid accumulation of static charge.

7.3 Specific end use(s): No further relevant information available.

SECTION 8: Exposure controls/personal protection *

8.1 Control parameters

This evaluation is intended for Dental Laboratories.

Components with critical values that require monitoring at the workplace:

CAS 80-62-6 Methyl methacrylate

TWA () Short-term value: 410 mg/m³, 100 ppm
Long-term value: 205 mg/m³, 50 ppm
A4

DNEL

CAS 80-62-6 Methyl methacrylate

Dermal	Worker, l.te, syst.	74,3 mg/Kg/d (human)
Inhalative	Worker, l.te, syst.	210 mg/m ³ (human)

PNEC

CAS 80-62-6 Methyl methacrylate

Freshwater 0,94 mg/l (water)

The lists that were valid during the compilation were used as basis.

8.2 Exposure controls

▪ **Appropriate engineering controls:** Work in well-ventilated areas; If possible, use mechanical aspirations to reduce the spread of vapors. Under normal conditions of Dental Laboratory, adopting general precautions shown below, it is unlikely to reach high concentrations of vapor. Evaluate the possibility of adopting protective equipment at least for the hands (gloves).

▪ **Personal protective equipment**

Eyes / face protection

Not necessary with sufficient ventilation; otherwise, it is recommended the use of generic goggles. In case of high quantities to be manipulated, use protective mask (filter A).

Skin protection

It is recommended the use of protective gloves solvent-resistant to prevent possible skin sensitization. The glove material has to be impermeable and resistant to the product. The selection of glove material must be made in consideration of the penetration times, rates of diffusion and the degradation. As the product is a preparation of several substances, the resistance of glove materials can not be calculated in advance and has therefore to be checked prior the use. For permanent contact in work areas without great risk of injury (Dental Laboratory), use gloves PVA. For the permanent contact of a maximum of 15 minutes are suitable gloves made of butyl rubber, fluoro, nitrile, chloroprene.

The use of light protective clothing (gowns) is considered sufficient for normal Laboratory activity. For larger amounts, use Splash aprons, complete gowns, shoe covers or rubber boots resistant to chemicals.

Respiratory protection

In premises with little ventilation or in the presence of high concentrations, wear a respirator filter type A for vapors. Always provide proper ventilation of rooms.

SECTION 9: Physical and chemical properties *

9.1 Information on basic physical and chemical properties

Appearance

- | | |
|----------|------------|
| • Form | Liquid |
| • Colour | Colourless |

Odour	Characteristic
Odour threshold	1 ppm
pH	Not applicable
Melting point / freezing point	Melting point: - 48°C
Boiling point / Boiling range:	100°C at atmospheric pressure
Flash point:	8°C
Evaporation rate	3,1 (butyl acetate = 1)
Flammability (solid, gas)	Altamente infiammabile
Explosion / Flash limit in % volume of air	Lower limit: 2,1 Upper limit: 12,5
Steam pressure at 20 °C:	47 hPa
Vapor Density (Air = 1)	3,45
Density at 20 °C	0,950 g/cm ³
Solubility / Miscibility in water Little and / or immiscible	Little and / or immiscible
Solubility in fat and / or in organic solvents	Miscible in common organic solvents
n-Octanol/water ripartition coefficient	1,38
Auto-ignition temperature	430°C
Decomposition temperature	Not applicable
Viscosity at 20°C	0,6 mPas
Explosive properties	Mixture is not explosive, however, formation of explosive mixtures of air / vapor
Oxidizing properties	Not applicable

9.2 Other information: No further relevant information available.

SECTION 10: Stability and reactivity *

10.1 Reactivity: No further relevant information available.

10.2 Chemical stability: Material is stabilized with Topanol-A, however, it remains highly unstable and flammable.

10.3 Possibility of hazardous reactions: Formation of explosive vapor / air mixtures.

10.4 Conditions to avoid: Avoid exposure to light and air. Heating, open flames and sparks. Humidity.

10.5 Incompatible materials: Strong acids and bases, iron oxide and oxidizers, peroxides, reducing agents, amines.

10.6 Hazardous decomposition products: None under normal conditions of storage and use.

SECTION 11: Toxicological information *

11.1 Information on toxicological effects

Based on the available literature, the methyl methacrylate is essentially non-toxic when absorbed through the digestive system, inhalation and / or skin. For some individuals, the methyl methacrylate shows a strong dermal sensitizer power.

▪ Acute toxicity

Rat DL50 (oral): > 5000 mg/kg

Rab DL50 (dermal): > 5000 mg/kg

Rat CL50-4 hours (Inhalative): > 24 mg/l

▪ **Skin corrosion/irritation:** Causes skin irritation. May cause an allergic skin reaction.

▪ **Corrosion to respiratory:** Data not available.

▪ **Serious eye damage / irritation:** Has irritancy.

▪ **Respiratory sensitization:** Has sensitizing power.

▪ **Germ cell mutagenicity:** Based on available data, the classification criteria are not met.

▪ **Carcinogenicity:** Currently available studies on humans do not allow firm conclusions about a possible carcinogenic powder of the substance (EU, 2002; SCOEL, 2006). Carcinogenicity studies of two years in rats and mice exposed by inhalation to methyl methacrylate showed no evidence of carcinogenicity (NTP, 1986).

The International Agency for Research on Cancer (IARC) allocates the methyl methacrylate in the group 3 (not classifiable as to carcinogenic to humans), based on inadequate evidence of carcinogenicity in humans and evidence indicating lack of carcinogenicity in experimental animals (IARC, 1994).

US Environmental Protection Agency (EPA) shows that the methyl methacrylate is considered a "not likely a human carcinogen" by all routes of exposure since it has been investigated in four well conducted chronic studies by

inhalation ben condotti in three relevant animal species in the absence of proven carcinogenic effects (Assessment of 1998, confirmed in 2006, of the USEPA film online 2014).

- **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:** Data not available.
- **Likely routes of exposure:** The main routes of potential exposure are expected to be skin contact and inhalation in workers exposed to the use of methyl methacrylate.
- **Immediate, delayed and chronic effects from short- and long-term exposure:** Symptoms may be burning and irritation of the skin; burning and watery eyes; cough, laryngitis and difficulty breathing, headache, nausea, vomiting. It may cause allergic reactions of the upper respiratory tract and skin, however cases of diseases related to the material are of low probability, in the amounts and exposures expected in a dental laboratory. The effects of exposure to the vapors of the material does not appear to be cumulative, but high concentrations can be irritating to some individuals. In susceptible individuals, the material can have a sensitizing effect on the skin.
- **Interactive effects:** Data not available.

SECTION 12: Ecological information *

12.1 Toxicity

▪ Short-term effects

Fish (*Onchorynchus mykiss*) CL50-96 hours: > 79 mg/l; NOEC-96 hours: 40 mg/l [method: U.S. EPA Guideline] (EU, 2002; OECD, 2004).

Crustaceans (*Daphnia magna*) CE50-48 hours: 69 mg/l (effect: immobilization) (EU, 2002; OECD, 2004).

Algae (*Selenastrum capricornutum*) CE50-72 hours: > 110 mg/l; NOEC-72 hours: 49 (biomass) and 110 mg/l (growth rate) [method: OECD 201] (EU, 2002; OECD, 2004).

▪ Long-term effects

Crustaceans (*Daphnia magna*) NOEC-21 days: 37 mg/l (EU, 2002; OECD, 2004).

12.2 Persistence and degradability: It is expected that bio degrades easily to the ground and in water. The vapor phase degrades photochemically in the atmosphere.

12.3 Bioaccumulative potential: It is not expected to bio concentrate in aquatic organisms.

12.4 Mobility in soil: High mobility in the soil. It evaporates from water, wet and dry surfaces. In the atmosphere exists only in steam. In water, it adsorbs to sediment and suspended solids. The substance shows a small but biologically significant effect on the carbon cycle in the soil.

12.5 Results of PBT and vPvB assessment: Not applicable.

12.6 Other adverse effects: No further relevant information available.

SECTION 13: Disposal considerations *

The product, in the case of disposal as is, according to Directive 2008/98 / EC, should be classified as hazardous waste:

- H3A "Highly flammable" liquid substance whose flash point below 21 ° C (including extremely flammable liquids).
- H4 "Irritant": non-corrosive substance which, through immediate, prolonged or repeated contact with the skin or mucous membrane, can cause inflammation.
- H13 "Sensitizing": substance which, through inhalation or skin penetration may lead to a reaction of hypersensitization such that on further exposure to the substance produces characteristic adverse effects.

13.1 Waste treatment methods

The methods of waste management must be evaluated case by case, in relation to the composition of the waste itself, in light of the provisions of Community and national legislation in force. Small amounts may be hardened with the other components of the system and disposed of with household waste. Larger quantities must be disposed of as hazardous waste in compliance with local government. It is not allowed for disposal through the discharge wastewater.

- **Waste code:** 55512
- **European waste catalogue:** 18 01 06 Sostanze chimiche pericolose o contenenti sostanze pericolose

- **Uncleaned packagings:** Disposal in accordance with local authority requirements.

SECTION 14: Transport information *

Transport in original closed containers, at a temperature below 30 °C, protected from light and direct heat. Keep away from sources of ignition and excessive heat. Take precautionary measures against static discharge.

14.1 UN Number

- **ADR, IMDG, IATA** 1247

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**



Class 3 (F1) Flammable liquids
Label 3
Exemption Limited quantity: LQ 4
 Compound Packing: max 3 L inner packages / max 30 Kg outer packages;
 Shrink-Wrapped Trays: 1 L inner packages / 20 Kg outer packages

- **IMDG, IATA**



Class 3 (F1) Flammable liquids
Label 3

14.4 Packing group

- **ADR, IMDG, IATA** II

14.5 Environmental hazards:

- **ADR and RID:** the product is not hazardous to the environment.
- **IMDG Code:** the product is not a marine pollutant.
- **ADN:** the product is hazardous to the environment only in tanks.

14.6 Special precautions for user

The transport of dangerous goods, including loading and unloading must be carried out by persons who have received the necessary training required by the modal regulations.

- **Kemler Number:** 339
- **EMS Number:** F-E, S-D

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

- **Product name:** METHYL METHACRYLATE
- **Ship Type:** 2
- **Pollution category:** Y

SECTION 15: Regulatory information ***15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

No further relevant information available.

15.2 Chemical safety assessment

A chemical safety assessment has not been carried out.

SECTION 16: Other information *

These data are based on our present knowledge. However, they 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.
H319 Causes serious eye irritation.
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.
H413 May cause long lasting harmful effects to aquatic life.

- **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, Hazard Category 2
Acute Tox. 3: Acute toxicity, Hazard Category 3
Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2
Eye Irrit. 2: Serious eye damage/eye 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
Aquatic Chronic 4: Hazardous to the aquatic environment - Chronic Hazard, Category 4

- * - **Section compared to the previous version altered.**