





## N-Fill

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H411 Toxic to aquatic life with long lasting effects.

**Precautionary statements**

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.  
 P280 Wear protective gloves/protective clothing/eye protection/face protection.  
 P302+P352 IF ON SKIN: Wash with plenty of water.  
 P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
 P310 Immediately call a POISON CENTER/doctor.  
 P333+P313 If skin irritation or rash occurs: Get medical advice/attention.  
 P362+P364 Take off contaminated clothing and wash it before reuse.

**Additional advice on labelling**

Medical devices (93/42/EWG) which are invasive or used in direct phys. contact with the human body, are exempted from provisions of Reg. (EC) No 1272/2008 (CLP/GHS) if they are in finished state and intended for the final user.

**2.3. Other hazards**

The non-polymerized material could irritate skin due to longer contact.

**SECTION 3: Composition/information on ingredients****3.2. Mixtures****Chemical characterization**

Material contains dimethacrylates, dental glass, photochemical Initiators, Nanoparticles, Stabilisators, iron pigments.

**Hazardous components**

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification according to Regulation (EC) No. 1272/2008 [CLP]			
	suspension of nanoparticles			15 - < 20 %
	Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1, STOT SE 3; H315 H319 H317 H335			
72869-86-4	7,7,9-(resp. 7,9,9-)Trimethyl-4,13-dioxo-3,14-dioxo-5,12-diaza-hexadecane-1,16-dioldimethacrylate			5 - < 10 %
	276-957-5			
	Aquatic Chronic 3; H412			
1565-94-2	Bisphenol-A-bis-(2-hydroxypropyl)methacrylate			5 - < 10 %
	Acute Tox. 4, Eye Dam. 1, Skin Sens. 1, Aquatic Chronic 1; H302 H318 H317 H410			

Full text of H and EUH statements: see section 16.

**SECTION 4: First aid measures****4.1. Description of first aid measures****General information**

Polymerized material is non-hazardous.

**After inhalation**

Not applicable as all components have got a boiling point above 250°C.

**After contact with skin**

After contact with skin, wash immediately with polyethylene glycol, followed by plenty of water. Take off immediately all contaminated clothing and wash it before reuse. Medical treatment necessary.

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**After contact with eyes**

In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart and consult an ophthalmologist.

**After ingestion**

Rinse mouth immediately and drink plenty of water. Cause vomiting with larger quantities, consult a doctor if symptoms persist.

**4.2. Most important symptoms and effects, both acute and delayed**

No information available.

**4.3. Indication of any immediate medical attention and special treatment needed**

Treat symptomatically.

**SECTION 5: Firefighting measures****5.1. Extinguishing media****Suitable extinguishing media**

Co-ordinate fire-fighting measures to the fire surroundings.

**5.2. Special hazards arising from the substance or mixture**

Non-flammable.

**5.3. Advice for firefighters**

Wear a self-contained breathing apparatus and chemical protective clothing. Full protection suit.

**Additional information**

Suppress gases/vapours/mists with water spray jet. Collect contaminated fire extinguishing water separately.

Do not allow entering drains or surface water.

**SECTION 6: Accidental release measures****6.1. Personal precautions, protective equipment and emergency procedures**

Provide adequate ventilation. Do not breathe gas/fumes/vapour/spray. Avoid contact with skin, eyes and clothes. Use personal protection equipment.

**6.2. Environmental precautions**

Do not allow to enter into surface water or drains.

**6.3. Methods and material for containment and cleaning up**

Take up mechanically. Treat the recovered material as prescribed in the section on waste disposal.

**6.4. Reference to other sections**

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

**SECTION 7: Handling and storage****7.1. Precautions for safe handling****Advice on safe handling**

If handled uncovered, arrangements with local exhaust ventilation have to be used. Avoid generation of dust.

Do not breathe dust. Only adequately trained personnel should handle this product. For use in dentistry only.

**Advice on protection against fire and explosion**

No special fire protection measures are necessary.

**7.2. Conditions for safe storage, including any incompatibilities****Requirements for storage rooms and vessels**

Keep container tightly closed. Keep locked up. Store in a place accessible by authorized persons only. Provide adequate ventilation as well as local exhaust at critical locations. Protect from exposure to the light. Store not above 25°C.

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**Advice on storage compatibility**

No special measures are necessary.

**7.3. Specific end use(s)**

For filling of cavities in the anterior and posterior region, comply with professional industrial hygiene.

**SECTION 8: Exposure controls/personal protection****8.1. Control parameters****8.2. Exposure controls****Appropriate engineering controls**

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

**Protective and hygiene measures**

Remove contaminated, saturated clothing immediately. Draw up and observe skin protection programme.

Wash hands and face before breaks and after work and take a shower if necessary. When using do not eat or drink.

**Eye/face protection**

Suitable eye protection: goggles.

**Hand protection**

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

**Skin protection**

Wear suitable protective clothing.

**Respiratory protection**

In case of inadequate ventilation wear respiratory protection.

**SECTION 9: Physical and chemical properties****9.1. Information on basic physical and chemical properties**

Physical state:	very solid paste
Colour:	tooth colored yellowish
Odour:	practically odorless

pH-Value: not determined

**Test method****Changes in the physical state**

Melting point: not determined

Initial boiling point and boiling range: not determined

Flash point: 110 °C ASTM D 3278

**Flammability**

Solid: not determined

Gas: not applicable

Lower explosion limits: not determined

Upper explosion limits: not determined

**Auto-ignition temperature**

Solid: not determined



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Gas: not applicable

Decomposition temperature: not determined

#### **Oxidizing properties**

Not oxidizing.

Vapour pressure: <1 hPa DIN 51640  
(at 20 °C)

Density: not determined

Water solubility: insoluble

#### **Solubility in other solvents**

not determined

Partition coefficient: not determined

Vapour density: not determined

Evaporation rate: not determined

#### **9.2. Other information**

Solid content: not determined

### SECTION 10: Stability and reactivity

#### **10.1. Reactivity**

Material will polymerize when exposed to daylight.

#### **10.2. Chemical stability**

The product is stable under storage at normal ambient temperatures.

#### **10.3. Possibility of hazardous reactions**

No known hazardous reactions.

#### **10.4. Conditions to avoid**

Direct light.

#### **10.5. Incompatible materials**

No information available.

#### **10.6. Hazardous decomposition products**

No known hazardous decomposition products.

#### **Further information**

With incomplete combustion toxic gases such as carbon monoxide may be generated.

### SECTION 11: Toxicological information

#### **11.1. Information on toxicological effects**

##### **Acute toxicity**

Based on available data, the classification criteria are not met.

##### **ATEmix tested**

	Dose	Species	Source
LD50, oral	5000 mg/kg	Rat	Literature



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CAS No	Chemical name			
	Exposure route	Dose	Species	Source
72869-86-4	7,7,9-(resp. 7,9,9-)Trimethyl-4,13-dioxo-3,14-dioxa-5,12-diaza-hexadecane-1,16-dioldimethacrylate			
	oral	LD50 >2000 mg/kg	Rat	OECD 401, limit test
1565-94-2	Bisphenol-A-bis-(2-hydroxypropyl)methacrylate			
	oral	LD50 >5000 mg/kg	Rat	Manufacturer

#### Irritation and corrosivity

Causes skin irritation.

Causes serious eye damage.

#### Sensitising effects

May cause an allergic skin reaction. (suspension of nanoparticles), (Bisphenol-A-bis-(2-hydroxypropyl)methacrylate)

#### Carcinogenic/mutagenic/toxic effects for reproduction

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.

#### Additional information on tests

This mixture is classified as hazardous according to regulation (EC) No. 1272/2008 [CLP].

#### Practical experience

#### Observations relevant to classification

When used and handled according to specifications, the product gives to the present knowledge and experience no adverse health effects .

## SECTION 12: Ecological information

### 12.1. Toxicity

Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

CAS No	Chemical name				
	Aquatic toxicity	Dose	[h]   [d]	Species	Source
72869-86-4	7,7,9-(resp. 7,9,9-)Trimethyl-4,13-dioxo-3,14-dioxa-5,12-diaza-hexadecane-1,16-dioldimethacrylate				
	Acute fish toxicity	LC50 10,1 mg/l	96 h	Brachydanio rerio	OECD 203
1565-94-2	Bisphenol-A-bis-(2-hydroxypropyl)methacrylate				
	Acute fish toxicity	LC50 >100 mg/l	96 h	Poecilia reticulata (Guppy)	Manufacturer

### 12.2. Persistence and degradability

The product has not been tested.

### 12.3. Bioaccumulative potential

The product has not been tested.

#### Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
72869-86-4	7,7,9-(resp. 7,9,9-)Trimethyl-4,13-dioxo-3,14-dioxa-5,12-diaza-hexadecane-1,16-dioldimethacrylate	3,39
1565-94-2	Bisphenol-A-bis-(2-hydroxypropyl)methacrylate	4,63



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**12.4. Mobility in soil**

The product has not been tested.

**12.5. Results of PBT and vPvB assessment**

The product has not been tested.

**12.6. Other adverse effects**

No information available.

**Further information**

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

**SECTION 13: Disposal considerations****13.1. Waste treatment methods****Advice on disposal**

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil. Dispose of waste according to applicable legislation.

**Waste disposal number of waste from residues/unused products**

200139 MUNICIPAL WASTES (HOUSEHOLD WASTE AND SIMILAR COMMERCIAL, INDUSTRIAL AND INSTITUTIONAL WASTES) INCLUDING SEPARATELY COLLECTED FRACTIONS; separately collected fractions (except 15 01); plastics

**Contaminated packaging**

Non-contaminated packages may be recycled. Handle contaminated packages in the same way as the substance itself.

**SECTION 14: Transport information****14.6. Special precautions for user**

No information available.

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

not applicable

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

2010/75/EU (VOC): 5,958 %

2004/42/EC (VOC): 16,106 %

**National regulatory information**

Employment restrictions: Observe restrictions to employment for juvenils according to the 'juvenile work protection guideline' (94/33/EC).

Water contaminating class (D): 3 - highly water contaminating

Skin resorption/Sensitization: Causes allergic hypersensitivity reactions.

**15.2. Chemical safety assessment**

Chemical safety assessments for substances in this mixture were not carried out.

**SECTION 16: Other information****Changes**

This data sheet contains changes from the previous version in section(s): 2,3,4,6,7,10,11,13,15,16.

**Abbreviations and acronyms**

ADR: Accord européen sur le transport des marchandises dangereuses par Route



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(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

LC50: Lethal concentration, 50%

LD50: Lethal dose, 50%

#### Relevant H and EUH statements (number and full text)

H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

#### Further Information

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

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*(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)*