

**Safety Data Sheet in accordance with Regulation (EU) 2020/878**

Product Name: Puran HC / Sinomer HC Paste	Version:	2026-05-01
	Replaces Version:	2024-09-22

1 Section 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product Identifier**

Substance name, trade name: Puran HC / Sinomer HC Paste
Identification number: F02<>, A71<>, 763029670002P, 763029670102P

1.2 Relevant identified uses of the substance or mixture and uses advised against

Relevant identified use: Mixture for the manufacture of prosthetic devices

Uses advised against: Any uses other than those identified

1.3 Details of the supplier providing the safety data sheet

Manufacturer / Supplier	NOVODENT Ets. Industriestrasse 32 9487 Bendern Liechtenstein
Contact point for technical information	See manufacturer / supplier
Telephone	+423 377 1500
Fax	+423 355 1509
E-mail	frontoffice@novodent.com

1.4 Emergency telephone number

Contact point	Number
NOVODENT Ets.	+423 377 1500
Tox-Zentrum (Schweiz)	+41 44 251 51 51

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2 Section 2: Hazards identification

2.1 Classification of the substance or mixture - Classification according to Regulation (EC) No. 1272/2008

Skin.sens. H317, Skin irrit. H315

2.2 Labelling elements according to Regulation (EC) No. 1272/2008

Hazard-determining components

Oligomer, Polyurethandimethacrylat

Pictogram



Signal word: Warning

CODE	HAZARD STATEMENTS
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.

CODE	PRECAUTIONARY STATEMENTS
P101	If medical advice is needed, have product container or label at hand.
P280	Schutzhandschuhe/Schutzkleidung/Augenschutz/Gesichtsschutz tragen.
P302+P352	IF ON SKIN: Wash with plenty of water and soap.
P273	Avoid release to the environment.

Additional labelling elements

None

2.3 Other hazards

PBT or vPvB: Not determined, mixture. May polymerise if overheated.

3 Section 3: Composition / information on ingredients

3.1 Substances

This product is a mixture as defined in Section 3.2.

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Field	Value
Substance name	Oligomer
EG-Nr.	Not applicable
CAS-Nr.	82339-26-2
Concentration	< 25 %

Classification according to Regulation (EC) No. 1272/2008:
Skin.sens. H317, Eye.irrit.H319

Feld	Value
Substance name	Polyurethandimethacrylat
EG-Nr.	Not applicable
CAS-Nr.	72869-86-4
Concentration	< 2,5 %

Classification according to Regulation (EC) No. 1272/2008:
Eye.irrit.H319, Skin.sens.H315, respiratory.sens.H335

Feld	Wert
Substance name	Polymethylmethacrylat (PMMA)
EG-Nr.	Nicht anwendbar
CAS-Nr.	9011-14-7
Concentration	>70 %

Classification according to Regulation (EC) No. 1272/2008:
Eye.irrit.H319, Skin.sens.H315, respiratory.sens.H335

For the full text of the hazard statements, see Section 16.

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4 Section 4: First aid measures

4.1 Description of first aid measures

After inhalation:

Provide fresh air. Consult a physician if symptoms persist.

After skin contact:

Wash with soap and water and rinse thoroughly. If skin irritation persists, seek medical advice.

After ingestion:

Rinse mouth and drink plenty of water. Do not induce vomiting. Consult a physician if symptoms persist.

4.2 Most important symptoms and effects, both acute and delayed

None known.

4.3 Indication of any immediate medical attention and special treatment needed

No special measures required.

5 Section 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media:

Carbon dioxide (CO₂), dry chemical powder or water spray.

Unsuitable extinguishing media:

Water jet.

5.2 Special hazards arising from the substance or mixture

None known.

5.3 Advice for firefighters

Wear self-contained breathing apparatus.

Cool containers exposed to fire with water spray.

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6 Section 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Schutzausrüstung gemäß Abschnitt 8 verwenden. Ungeschützte Personen fernhalten. Für ausreichende Lüftung sorgen.

6.2 Use personal protective equipment as described in Section 8. Keep unprotected persons away. Ensure adequate ventilation.

Do not allow to enter drains/surface water/groundwater.

6.3 Methods and material for containment and cleaning up

No information available.

6.4 Reference to other sections

See Sections 7 and 8 for protective measures.

7 Section 7: Handling and storage

7.1 Precautions for safe handling

Measures to prevent fire and explosion:

Keep away from ignition sources – no smoking. Take measures against electrostatic discharge.

Measures to prevent the formation of dust and aerosols:

Keep containers tightly closed.
Avoid generating dust and wear a protective mask.

Measures to protect the environment:

Prevent the product and larger quantities of contaminated washing water from entering water bodies and soil. Cover drains to prevent product entry.

General hygiene measures:

Do not eat, drink or smoke in working areas.
Wash hands thoroughly after use.
Remove contaminated clothing and protective equipment before entering areas where food is consumed.

7.2 Conditions for safe storage, including any incompatibilities

Information on storage conditions:

Store between 2 °C and 30 °C (for quality reasons).

Requirements for storage rooms and containers:

Store only in the original container in a cool place protected from light.

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Information on storage conditions:

Store between 2 °C and 30 °C (for quality reasons).

Avoid exposure to sunlight and keep away from heat sources.

Storage class:

LGK 10

7.3 Specific end uses

For further information, please refer to our instructions for use. Use is restricted to trained professionals (e.g. dentists, dental technicians).

8 Section 8: Exposure controls / personal protection

8.1 Control parameters

None.

8.2 Exposure controls

Appropriate engineering controls:

Ensure good ventilation/extraction at the workplace. See Section 7.

Individual protection measures – personal protective equipment:**Eye / face protection:**

Use safety glasses with side protection in accordance with EN 166. Eye wash facilities must be provided in areas with risk of exposure.

Skin protection:**Hand protection:**

Latex gloves are not suitable.

Prolonged exposure:

Glove material: Nitrile rubber (NBR)

Layer thickness: approx. 0.5 mm

Breakthrough time: > 480 minutes

Short-term exposure:

Glove material: Nitrile rubber (NBR)

Layer thickness: approx. 0.1 mm

Breakthrough time: > 30 minutes

Other skin protection:

Wear suitable protective clothing. Skin protection creams can protect exposed areas of skin but must not be applied after exposure has already occurred.

Respiratory protection:

Not required.

Thermal hazards (heat/cold protection):

Not required.

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Appropriate engineering controls:

Ensure good ventilation/extraction at the workplace. See Section 7.

Environmental exposure controls:

Avoid release into the environment. See Section 6.

9 Section 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Field	Value
Appearance	
Physical state	Solid
Colour	Whitish / clear / pink (depending on formulation)
Odour	Characteristic, slightly ester-like
Odour threshold	No data available
pH value	Not determined
Melting/freezing point	150 °C (typical PMMA)
Initial boiling point and boiling range	Not determined (decomposition before boiling)
Flash point	Not applicable (solid; no defined flash point)
Evaporation rate	Not determined
Flammability	Not readily flammable
Lower and upper explosion limits	The product is not explosive; dust explosion possible in finely divided form
Vapour pressure	Not applicable
Vapour density	Not applicable
Relative density	1.2 g/cm ³ at 20 °C
Solubility	Insoluble in water
Partition coefficient (n-octanol/water)	Not determined
Auto-ignition temperature	No self-ignition under normal conditions
Decomposition temperature	> 250 °C
Viscosity	Not applicable
Explosive properties	Dust explosion hazard possible in fine particulate form

9.2 Other information



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No further relevant information available.

10 Section 10: Stability and reactivity

10.1 Reactivity

Under normal intended use, no decomposition occurs. Thermal decomposition > 250 °C. At elevated temperatures, decomposition may occur with the formation of potentially irritating vapours (methyl methacrylate).

10.2 Chemical stability

The product is chemically stable under normal ambient conditions (room temperature).

10.3 Possibility of hazardous reactions

Polymerisation may occur with heat development.

10.4 Conditions to avoid

Avoid exposure to strong UV radiation. Avoid temperature increase due to friction. Avoid direct contact with heat sources. Avoid temperatures above 60 °C. Avoid direct sunlight. Loss of dissolved air. Loss of polymerisation inhibitor.

10.5 Incompatible materials

Avoid initiators that produce free radicals and avoid contact with peroxides..

10.6 Hazardous decomposition products

None known under normal storage and handling conditions.



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11 Section 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity:

Not classified; based on available data, the classification criteria are not met.

Skin corrosion/irritation:

Not classified; based on available data, the classification criteria are not met.

Serious eye damage/irritation:

Not classified; based on available data, the classification criteria are not met.

Respiratory or skin sensitisation:

Respiratory tract: Not classified, based on the available data the classification criteria are not met.

Skin: May cause allergic skin reactions (due to contained dibenzoyl peroxide).

Germ cell mutagenicity:

Not classified; based on available data, the classification criteria are not met.

Carcinogenicity:

Not classified; based on available data, the classification criteria are not met.

Reproductive toxicity:

Not classified; based on available data, the classification criteria are not met.

Specific target organ toxicity – single exposure (STOT SE):

Not classified; based on available data, the classification criteria are not met.

Specific target organ toxicity – repeated exposure (STOT RE):

Not classified; based on available data, the classification criteria are not met.

Aspiration hazard:

Not classified; based on available data, the classification criteria are not met.

Toxicological data:

Field	Value
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Acute toxicity:

Oral (rat):	No data available.
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Dermal (rabbit):	No data available.
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Irritation:

Skin:	No data available.
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Eyes:	No data available.
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Sensitisation:

Skin:	No data available.
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Additional information:

The information is based on data of the individual components as well as literature data. Repeated or prolonged contact with the powder may cause irritation of the skin and mucous membranes. Sensitising effects are possible due to the contained dibenzoyl peroxide.

Symptoms and effects (delayed and chronic):

Inhalation of dust may cause irritation of the respiratory tract. Skin contact may cause irritation and allergic reactions.

12 Section 12: Ecological information

12.1 Toxicity

Harmful to aquatic life with long lasting effects.

Water hazard class (WGK): not hazardous to water (nwg)

Do not allow to enter water bodies or drains.

12.2 Persistence and degradability

No data available.

12.3 Bioaccumulative potential

No data available.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

Not determined.

12.6 Other adverse effects

No further relevant information available.

13 Section 13: Disposal considerations

13.1 Waste treatment methods

Product:

Dispose of in accordance with local official regulations.



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Product:

Dispose of in accordance with local official regulations.

Contaminated packaging:

Dispose of in accordance with local official regulations (landfill or incineration plant).

Waste code according to the European Waste Catalogue (EWC):

20 01 39 Acrylic

Special precautions:

Do not allow to enter drains.

Relevant EU or other regulations:

No further relevant information available.

14 Section 14: Transport information

14.1 UN-Number

Not applicable and therefore not subject to labelling requirements.

14.2 UN proper shipping name

ADR/RID: Not applicable and therefore not subject to labelling requirements.

IMDG: Not applicable and therefore not subject to labelling requirements.

IATA: Not applicable and therefore not subject to labelling requirements.

14.3 Packing group

III

14.4 Environmental hazards

ADR/RID:

Not environmentally hazardous.

IMDG:

Not classified as a marine pollutant.

IATA:

Not environmentally hazardous.

14.5 Special precautions for user

Strictly observe the instructions for use.

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14.6 Transport in bulk according to Annex II of MARPOL and the IBC Code

Not applicable.

15 Section 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulations:

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer:

Not applicable.

Regulation (EU) 2019/1021 on persistent organic pollutants (POP):

Not applicable.

Regulation (EU) No. 649/2012 (PIC Regulation):

Not applicable.

Regulation (EC) No. 648/2004 (Detergents Regulation):

Not applicable.

Restrictions according to Annex XVII of Regulation (EC) No. 1907/2006 (REACH):

Not applicable.

National regulations:

Water hazard class (WGK):

not hazardous to water (nwg)

Seveso III Directive (2012/18/EU):

This product is not subject to the Seveso III Directive.

15.2 Other information

No chemical safety assessment has been carried out for this mixture.

16 Section 16: Other information

Changes compared to the previous version:

Transfer to new software. Toxicological data have been taken from literature sources.

Abbreviations:

ADR

European Agreement concerning the International Carriage of Dangerous Goods by Road

CAS

Chemical Abstracts Service

EG

European Community

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Abbreviations:

EN	European Standard
IATA-DGR	International Air Transport Association – Dangerous Goods Regulations
ICAO-TI	International Civil Aviation Organization – Technical Instructions
IMDG-Code	International Maritime Dangerous Goods Code
LC	Lethal concentration
LD	Lethal dose
MARPOL	International Convention for the Prevention of Pollution from Ships
PBT	Persistent, bioaccumulative and toxic
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
UN	United Nations
VOC	Volatile organic compounds
vPvB	Very persistent and very bioaccumulative
WGK	Water hazard class

References and data sources:

Regulations:

REACH Regulation (EC) No. 1907/2006, as last amended by Regulation (EU) 2018/675
CLP Regulation (EC) No. 1272/2008, as last amended by Regulation (EU) 2018/669

Internet:

<https://www.llv.li>
<https://publikationen.dguv.de>
<https://dguv.de/ifa/stoffdatenbank>
<https://www.gischem.de>
<https://echa.europa.eu>
<https://www.ncbi.nlm.nih.gov>

Methods according to Article 9 of Regulation (EC) No. 1272/2008:

Physical hazards: Assessment based on test data

Health and environmental hazards: Calculation method

H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H412 Harmful to aquatic life with long lasting effects.

Training advice:

Use is carried out by trained professionals (e.g. dentists, dental technicians). No additional specific training is required.

Further information:

This product is part of a multi-component system.
The information in this safety data sheet is based on the current state of knowledge at the time of preparation. It is intended to describe the product with regard to safety requirements and does not constitute a guarantee of properties.



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Safety data sheet prepared by:
NOVODENT Ets. (see Section 1.3)

Annex:
Exposure scenarios: Not applicable (not required for mixtures).