



Safety data sheet according to Regulation (EU) 2020/878

Product designation: Puran CC, Sinomer Kalt N Powder

Version: 2024-09-22

Replayed Version: 2021-11-08

Section 1: Identification of the substance/mixture and of the company

1.1 Product identifier

Substance name Trade name: Puran CC, Sinomer Kalt N Powder

Article number starting: F04 / UDI 763029670004P | A04 / UDI 763029670101P

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

Relevant identified uses:

Mixture for the fabrication of prosthetic restorations

Uses advised against:

All applications that deviate from the identified use

1.3 Details of the supplier providing the safety data sheet

Manufacturer / Supplier

NOVODENT Ets.

Street/PO Box

Industriestrasse 32

Nat. no./Postal code/City

Liechtenstein - 9487 - Bendern

Contact point for technical information

NOVODENT Ets.

Phone / Fax / E-Mail

+423 377 1500 / -09 / E-Mail: msds@novodent.com

1.4 Emergency phone number

+423 377 1500 (Novodent Ets.)

+41 44 251 51 51 oder 145 (Tox-Zentrum)

Section 2: Potential hazards

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

Skin.sens.H317

2.2 Labelling elements

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

Pictogram:



Signal word: Caution

Hazard-determining components for labelling

contains: Polymethylmethacrylat

Hazard information:



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H317 May cause skin irritation

Safety information:

P101 Keep out of the reach of children.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P302 In case of contact with skin:
P352 *Wash with plenty of soap and water.*
P273 Avoid release into the environment

Further labelling elements

No

2.3 Other dangers

PBT or vPvB. Indeterminate, mixture.
May polymerise on excessive heating.

Section 3: Composition/information on ingredients

3.1 Substances

This product is a mixture as listed under 3.2.

3.2 Mixtures

Substance Name: Polymethylmethacrylat
EC No.: CAS No. 9011-14-7 Index No.: REACH Registration No.:
Anteil : > 95 %
Classification according to Regulation (EC) No 1272/2008:
Skin.sens. H317

Substance Name: Dibenzoylperoxid
EC No.: CAS No. : 94-26-0 Index No.: REACH Registration No.:
Anteil : < 1%
Classification according to Regulation (EC) No 1272/2008:
Org.Perox.B.H241, Eye.irrit.2.H319, Skin.Sens.1.H317

(For the wording of the listed hazard statements see section 16 and 2.2)

Section 4: First aid measures

4.1 Description of the first aid measure

After inhalation

The material is not expected to be harmful by inhalation. Remove to fresh air

After skin contact

Wash off with soap and water and rinse well.

Nach Augenkontakt

Remove contact lenses. Rinse immediately under running water for several minutes with the eyelids open.
Consult a doctor if symptoms persist.

After swallowing

Avoid vomiting and seek immediate medical attention.



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4.2 Most important symptoms and effects, both acute and delayed

None known.

4.3 Indications for immediate medical help or special treatment

Not applicable.

Section 5: Fire-fighting measures

5.1 Extinguishing agent

Suitable: Use water, chlorine dioxide or dry extinguishing agent

Unsuitable: Full water jet, high-pressure water jet

5.2 Special hazards arising from the substance or mixture

None known.

5.3 Advice for firefighters

In case of fire, cool the container with water spray.

Section 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Use protective equipment according to section 8.

6.2 Environmental protection measures

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

6.3 Methods and material for retention and cleaning

No information available.

6.4 Reference to other sections

Protective measures under point 7 and 8.

Section 7: Handling and storage

7.1 Protective measures for safe handling



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Measures to protect against fire and explosions

Avoid skin contact by keeping a safe distance or wearing suitable protective clothing.
Avoid wearing suitable protective clothing.

Measures to prevent dusts and aerosols

Not applicable, as it is a liquid that does not evaporate.

Measures to protect the environment

Prevent product and large quantities of contaminated wash water from entering water and soil.
avoid. Cover sewage systems to prevent product from entering the sewage system.

General hygiene measures

Do not eat, drink or smoke in areas where work is being done.

- Wash hands after use.
- Remove contaminated clothing and protective equipment before entering areas where food is being where food is consumed

7.2 Conditions for safe storage taking into account incompatibilities

Information on storage conditions

2 °C - 30 °C | 35.6 °F - 86 °F (because of quality)

Requirements for storage rooms and containers

No special requirements.

Storage class: 10

7.3 Specific end uses

Industry and sector-specific guidelines

For further information, please refer to our instructions for use.

Section 8: Exposure controls / Personal protective equipment

8.1 Parameters to be monitored

Occupational exposure limit values and/or biological limit values

Occupational exposure limit values (OELs) Germany

Dibenzoylperoxid CAS 94-36-0	
MAK (Swiss)	Short-term value: 5 e mg/m ³ Long-term value: 5 e mg/m ³
MAK (Austria)	Short-term value: 10 E mg/m ³ Long-term value: 5 E mg/m ³
AGW (Germany)	Long-term value: 5 E mg/m ³ 1(I);DFG

8.2 Exposure controls and monitoring

Suitable technical control devices



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No further information, see point 7.

Individual protective measures - personal protective equipment

Eye / face protection

Use safety goggles with side shields according to EN 166:2001. In areas of possible exposure risk, provide eye wash facilities and safety showers be provided.

Skin protection

Gloves

Latex gloves are not suitable

Prolonged exposure:

Glove material: Nitrile rubber (NBR)

Layer thickness (mm): Layer thickness 0.56 mm

Penetration time (min.): >480

Short-term exposure:

Glove material: Nitrile rubber (NBR)

Layer thickness (mm): Layer thickness 0.10 mm

Penetration time (min.): >30

Other skin protection

Wear protective gloves. Recommendations are listed below. Other protective materials may be used depending on the user's risk assessment. Skin protection creams can help protect exposed skin, but should not be applied after exposure has occurred.

Respiratory protection

Not required

Heat / cold protection

Observe storage conditions according to GBA.

Limitation and monitoring of environmental exposure

No information available.

Section 9: Physical and chemical properties

9.1 Information on the basic physical and chemical properties

Appearance

- State of aggregation: Fix (Powder)

- Colour : Rose

Smell : Characteristic ester-like

Smell threshold : No data available

pH value : Undetermined

Melting point/freezing point : 150°C | 302 °F

Initial boiling point and boiling range : Not determined

Flash point : 250°C (482°F) Cleveland open crucible



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Evaporation rate :	Not determined
Flammability (solid, gas) :	No data available
Upper/lower flammability or explosion limits :	The product is not explosive
Vapour pressure :	Not applicable
Vapour density :	Not applicable
relative density :	On 20°C (68°F) 1,2g/cm ³
Solubility(s) :	Insoluble in water
Partition coefficient:	Not determined
n-octanol/water :	Not determined
Auto-ignition temperature :	The product is not self-igniting
Decomposition temperature :	Not determined
Viscosity :	Not applicable
explosive properties :	None

9.2 Other details

% Volatile substances (wt.%):	Not determined
Volatile organic compounds:	Not determined
Solvent content organic:	Not determined
Solids content	Not determined

Section 10: Stability and reactivity

10.1 Reactivity

There is no decomposition when used as directed. Thermal decomposition >250°C (>482°F). May decompose at elevated temperature to form possibly 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.

10.4 Conditions to be avoided

Avoid exposure to strong UV rays. Avoid temperature rise due to friction. Avoid direct contact with heat sources. Avoid temperatures above 60 °C | 140 °F. 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

Section 11: Toxicological information

11.1 Data on toxicological effects

acute	Oral	Not classified, Based on available data, the classification criteria are not met.
toxicity	Dermal	Not classified, Based on available data, the classification criteria are not met.



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

Corrosive/irritant effect on the skin

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

Serious eye damage/irritation

Causes severe eye damage

Sensitisation of the

- Respiratory tract

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

- Skin

May cause allergic skin reactions.

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 after a single exposure

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

Specific target organ toxicity in case of repeated exposure

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

Aspiration risk

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

TOXICITY DATA

Acute toxicity

Oral

No data available

Dermal

No data available

Inhalation

No data available

Local effect on skin and eyes

Acute irritation Dermal

No data available

Acute irritation Eye

No data available

Allergic sensitisation

Sensitisation Skin

No data available

Sensitisation Respiration

No data available

Other information

None

Symptoms and effects (delayed and chronic) with information on routes of exposure. also: information on toxicokinetics, metabolism and distribution

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

Section 12: Environmental information

12.1 Toxicity

Water hazard class 2 (list classification):

Harmful to water

Do not allow to enter waters or drains.

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Soil mobility



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No data available

12.5 Result of the PBT and vPvB assessment

unspecified

12.6 Other harmful effects

No data available

Section 13: Notes on disposal

13.1 Waste treatment process

Treatment of contaminated packaging

Can be deposited in household waste. Do not allow to enter sewers or bodies of water.

Waste code according to the List of Wastes Ordinance (AVV)

20 01 39 plastics

Special precautionary measures

None

Relevant EU or other regulations

No data available

Section 14: Transport information

14.1 UN-Number

Not applicable and therefore not subject to labelling requirements

14.2 Proper UN shipping name

ADR/RID

Not applicable and therefore not subject to labelling requirements

IMDG-Code / ICAO-TI / IATA-DGR

Not applicable and therefore not subject to labelling requirements

14.3 Transport hazard classes

Not applicable

14.4 Packaging group

III (substances with low hazard)

14.5 Environmental hazards

Indicator for environmentally hazardous substances

ADR/RID / IMDG-Code / ICAO-TI / IATA-DGR: ☐ Yes / ☒ No

Marine Pollutant: ☐ Yes / ☒ No

14.6 Special precautions for the user

Always follow the instructions for use.

14.7 Carriage in bulk in accordance with Annex II of the MARPOL Convention and the IBC Code



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Not applicable

Section 15: Legislation

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

Regulation (EC) No 2037/2000 (substances that deplete the ozone layer):

Not applicable

Regulation (EC) No 850/2004 (persistent organic pollutants):

Not applicable

Regulation (EC) No 689/2008 (export and import of dangerous chemicals):

Not applicable

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

Not applicable

Restrictions under Title VIII of Regulation (EC) No 1907/2006:

Not applicable

National regulations

Water hazard class

Water quality class 2 (list classification)

15.2 Chemical Safety Assessment

The mixture has not been subjected to a safety assessment.

Section 16: Other information

Changes compared to the last version

Transfer to new software, toxicological values taken from literature.

Abkürzungen

ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
AwSV	Ordinance on Installations for the Handling of Substances Hazardous to Water
BImSchV	Ordinance on the Implementation of the Federal Immission Control Act
CAS	Chemical Abstracts Service
DIN	Standard of the German Institute for Standardisation
EC	Effective concentration
EG	European Community
EN	European Standard
IATA-DGR	International Air Transport Association-Dangerous Goods Regulations
IBC Code	International Code for the Construction and Equipment of Ships Carrying Dangerous Chemicals in Bulk
ICATO-TI	International Civil Aviation Organization-Technical Instructions
IMDG-Code	International Maritime Code for Dangerous Goods
ISO	Standard of the International Standards Organization
IUCLID	International Uniform Chemical Information Database
LC	Lethal concentration
LD	Lethal dose
Log Kow	Partition coefficient between octanol and water
MARPOL	Maritime Pollution Convention = Convention for the Prevention of Pollution from Ships
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent, bioaccumulative, toxic
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail



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TRGS	Technical regulations for hazardous substances
UN	United Nations
VOC	Volatile Organic Compounds (VOCs)
vPvB	Very persistent and very bioaccumulative
VwVwS	Administrative regulation on substances hazardous to water
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

<http://www.llv.li/kontakt/3408/amt-fur-umwelt>

<http://publikationen.dguv.de>

<http://dguv.de/ifa/stoffdatenbank>

<http://www.gischem.de>

<http://echa.europa.eu/en/candidate-list-table>

<http://www.ncbi.nlm.nih.gov/pubmed/>

Methods according to Article 9 of Regulation (EC) No 1272/2008 have been used to assess the information for the purpose of classification

Physical hazards: Evaluation of test data

Health and environmental hazards: Calculation methods

Wording of the hazard statements and/or precautionary statements referred to in section 2 to 15

All.irrit H317	May cause allergic skin reactions
Eye.irrit H319	May cause serious eye damage
Skin.irrit H315	May cause skin irritation
Respiratory irrit. H335	May cause respiratory tract irritation

Training for employees

No special training is required for activities with the above-mentioned product because they are used by dental technicians.

Further information

This product is part of a 2-component system.

This information is without guarantee or warranty. We do not accept any legal responsibility for it.

SDS Manufactured by: NOVODENT Ets., address and contact see point 1.3

Approach with exposure scenarios

Not applicable as no exposure scenarios need to be developed for mixtures.