

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

**Product designation:** NOVOtray 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: NOVOtray Powder Article number starting: F10 / UDI 763029670010P

## 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 - < 2.5 %

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/m³ Long-term value: 5 e mg/m³
MAK (Austria)	Short-term value: 10 E mg/m³ Long-term value: 5 E mg/m³
AGW (Germany)	Long-term value: 5 E mg/m³ 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.

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## 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

Characteristic ester-like Smell: Smell threshold: No data available pH value: Undetermined 150°C | 302 °F Melting point/freezing point: Initial boiling point and boiling Not determined

range:

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

Network: 07 - Produkte\07-2 Sicherheitsdatenblätter\07-02-02 NOVODENT Produkte Dokument Art: Safety Data Sheet Formular: Nr. SDB-05-2 / Responsible QM / Edition DOK9000 / File: SDB-05-2\_NOVOtray\_Pulver-EN



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Not determined

Evaporation rate: Not determined Flammability (solid, gas): No data available

Upper/lower flammability or The product is not explosive

explosion limits:

Vapour pressure: Not applicable Vapour density: Not applicable

relative density: On 20°C (68°F) 1,2g/cm<sup>3</sup> Solubility(s): Insoluble in water Partition coefficient: Not determined

n-octanol/water: The product is not self-igniting Auto-ignition temperature:

Decomposition temperature : Not determined Viscosity: Not applicable

explosive properties: None

#### Other details 9.2

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

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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
 Skin
 Not classified, Based on available data, the classification criteria are not met.
 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:  $\square$  Yes /  $\boxtimes$  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.