

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

- **1.1 Product identifier**
- **Trade name:** PANAVIA 21 ; OXYGUARD II
- **Article number:** 050-O
- **Registration number** Not applicable
- **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** Dental materials
- **1.3 Details of the supplier of the safety data sheet**
- **Supplier :**  
Kuraray Europe GmbH  
Philipp-Reis-Str. 4,  
65795 Hattersheim am Main  
Germany  
Phone: +49 (0)69 305 35 835  
E-mail: dental.eu@kuraray.com
- **Further information obtainable from:** Supplier
- **1.4 Emergency telephone number:**  
[United Kingdom] Only for NHS and other healthcare professionals; UK National Poisons Information Service (NPIS): +44 (0)344 892 0111 Ireland NPIC: +353 (0)1 809 2566  
For members of Public; NHS 111 in England: 111, NHS 24 in Scotland: 111, NHS Direct in Wales: 111 or 0845 4647, Ireland NPIC: +353 (0)1 809 2166(8 am to 10 pm)  
[3E Company] (Great Britain (London))+44 20 351 47487, (United Kingdom - Domestic)+44 800 680 0425, (United Kingdom - International)+44 808 189 0979 (Europe Non-Specific)+1 760 476 3962 \*Kuraray  
Access Code: 334674

**SECTION 2: Hazards identification**

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
The product is not classified, according to the GB CLP regulation.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable
- **vPvB:** Not applicable

**SECTION 3: Composition/information on ingredients**

- **3.2 Mixtures**
- **Description:**  
This mixture does not contain any substances to be mentioned according to the criteria of Regulation (EC) No 1272/2008.
- **Dangerous components:** Void

**SECTION 4: First aid measures**

- **4.1 Description of first aid measures**
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Generally the product does not irritate the skin.

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- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult doctor.
- **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**  
No further relevant information available.

## SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**  
CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.  
Use fire extinguishing methods suitable to surrounding conditions.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

## SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** See Section 8.
- **6.2 Environmental precautions:**  
Before cleaning, pre-clean the equipment under running water with a damp cloth.
- **6.3 Methods and material for containment and cleaning up:**  
Dispose contaminated material as waste according to section 13.  
Absorb liquid components with liquid-binding material.  
Vacuum or sweep material and place in a disposal container. Provide ventilation.  
Use appropriate Personal Protective Equipment (PPE).
- **6.4 Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

## SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**  
Ensure good ventilation/exhaustion at the workplace.  
Avoid contact with skin and eyes. Do not swallow. Avoid generating dust. Do not breathe dust/fume/gas/mist/vapors/spray.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store in a refrigerator (2-8°C).
- **Information about storage in one common storage facility:** Not required
- **Further information about storage conditions:**  
Keep container tightly sealed.  
Store in cool, dry conditions in well sealed receptacles.  
Protect from heat and direct sunlight.
- **7.3 Specific end use(s)** No further relevant information available.

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**SECTION 8: Exposure controls/personal protection**· **8.1 Control parameters**· **Ingredients with limit values that require monitoring at the workplace:****56-81-5 Glycerol**WEL (Great Britain) Long-term value: 10 mg/m<sup>3</sup>· **Additional information:** The lists valid during the making were used as basis.· **8.2 Exposure controls**· **Appropriate engineering controls** No further data; see section 7.· **Personal protective equipment:**· **Respiratory protection:** Suitable respiratory protective device recommended.· **Hand protection**

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· **Penetration time of glove material**

The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye/face protection** Safety glasses**SECTION 9: Physical and chemical properties**· **9.1 Information on basic physical and chemical properties**· **General Information**· **Physical state**

Liquid

· **Colour:**

Green

· **Odour:**

Odourless

· **Melting point/freezing point:**

Not determined.

· **Boiling point or initial boiling point and boiling range**

290 °C (56-81-5 Glycerol)

· **Flammability**

Not determined

· **Lower and upper explosion limit**· **Lower:**

2.6 Vol % (56-81-5 Glycerol)

· **Upper:**

11.3 Vol % (56-81-5 Glycerol)

· **Flash point:**

177 °C (56-81-5 Glycerol)

· **Auto-ignition temperature:**

393 °C (56-81-5 Glycerol)

· **Decomposition temperature:**

Not applicable.

· **pH at 20 °C**

5.8-6.2

· **Kinematic viscosity**

Not determined

· **Solubility**· **water:**

Fully miscible.

· **Partition coefficient n-octanol/water (log value)**

Not applicable.

· **Vapour pressure at 25 °C:**

0 hPa (56-81-5 Glycerol)

· **Density:**

Not determined

· **Relative vapour density**

Not determined

· **Particle characteristics**

Not applicable.

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**· 9.2 Other information****· Information with regard to physical hazard classes**

· Explosives	Product does not present an explosion hazard.
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void
· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void
· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void
· Desensitised explosives	Void

**SECTION 10: Stability and reactivity**

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability** No hazardous reaction when handled and stored according to provisions.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** Carbon monoxide and carbon dioxide

**SECTION 11: Toxicological information**

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **LD/LC50 values relevant for classification:**
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** 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.
- **11.2 Information on other hazards**

**· Endocrine disrupting properties**

None of the ingredients is listed.

**SECTION 12: Ecological information**

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.

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- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable
- **vPvB:** Not applicable
- **12.6 Endocrine disrupting properties**  
The product does not contain substances with endocrine disrupting properties.
- **12.7 Other adverse effects**
- **Additional ecological information:**
- **General notes:**  
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water  
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

**SECTION 13: Disposal considerations**

- **13.1 Waste treatment methods**
- **Recommendation**  
Dispose of this product as medical waste.  
Mix residues on disposable materials (e.g. paper, tray) and dispose of them as solid waste.
- **Uncleaned packaging:**
- **Recommendation:**  
Dispose of packaging according to regulations on the disposal of packagings.  
Non contaminated packagings may be recycled.  
Do not rinse product containers before disposal.

**SECTION 14: Transport information**

- |   |                |
|---|----------------|
| · <b>14.1 UN number or ID number</b>                                  |                |
| · <b>ADR, ADN, IMDG, IATA</b>   | Void           |
| · <b>14.2 UN proper shipping name</b>                                 |                |
| · <b>ADR, ADN, IMDG, IATA</b>   | Void           |
| · <b>14.3 Transport hazard class(es)</b>                              |                |
| · <b>ADR, IMDG, IATA</b>  |                |
| · <b>Class</b>  | Void           |
| · <b>14.4 Packing group</b>   |                |
| · <b>ADR, ADN, IMDG, IATA</b>   | Void           |
| · <b>14.5 Environmental hazards:</b>                                  | Not applicable |
| · <b>14.6 Special precautions for user</b>                            | Not applicable |
| · <b>14.7 Maritime transport in bulk according to IMO instruments</b> | Not applicable |
| · <b>UN "Model Regulation":</b>                                       | Void           |

**SECTION 15: Regulatory information**

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

· <b>Regulated explosives precursors</b>
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None of the ingredients is listed.
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· **Regulated poisons**

None of the ingredients is listed.

· **Reportable explosives precursors**

None of the ingredients is listed.

· **Reportable poisons**

None of the ingredients is listed.

· **Directive 94/33/EC:** Care should be taken when people under 18 handle this product.

· **Directive 94/85/EEC:** No further relevant information available.

· **Named dangerous substances - ANNEX I** None of the ingredient is listed.

· **REGULATION (EU) 2019/1021 on persistent organic pollutants (POP)**

None of the ingredients is listed.

· **Regulation (EU) No 649/2012**

None of the ingredients is listed.

· **REGULATION (EU) 2019/1148**

· **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**

None of the ingredients is listed.

· **Regulation (EC) No 273/2004 on drug precursors**

None of the ingredients is listed.

· **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**

None of the ingredients is listed.

· **REGULATION (EU) 2024/590 on substances that deplete the ozone layer**

None of the ingredients is listed.

· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

**SECTION 16: Other information**

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Medical devices as defined in Regulation (EU) 2017/745 and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Regulation (EC) No 1272/2008 (GB CLP/ GHS) usually if they are in the finished state and intended for the final user.

This Safety Data Sheets is in compliance with Regulation (EC) No 1907/2006, Article 31 as amended by Regulation (EU) 2020/878.

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

The classification of the mixture is generally based on the calculation method using substance data according to Regulation (EC) No 1272/2008.

· **Abbreviations and acronyms:** ELINCS: European List of Notified Chemical Substances

· **\* Data compared to the previous version altered.**