

# Safety Data Sheet (SDS)

according to Regulation (EC) No 1907/2006, article 31\*



## 1. \* Identification of the substance/mixture and of the company/undertaking

### 1.1 Product identifier

Trade name: **Plurasil dublitec**

Product type: duplication silicone

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

**Use of the substance or mixture:** Addition-vulcanising duplication silicone for the dental duplication technique.

**Uses advised against:** The product is intended solely for the above application and should only be used by qualified and instructed persons, do nothing on clothes, not cleanable.

### 1.3\* Details of the supplier of the safety data sheet

**Company name:** Pluradent AG & Co KG  
**Street/Mailbox:** Kaiserleistr. 3  
**Place:** D-63067 Offenbach a.M.  
**Contact for technical information:** Pluradent Vertrieb  
**Phone / Telefax / E-Mail:** +49 (0) 69-82983-0 / +49 (0) 69-82983-271 / regulatory.affairs@pluradent.de

### 1.4\* Emergency telephone number

Germany: Giftnotruf Mainz - 24 Hour Service - Tel.: +49 (0) 6131/19240

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## 2. Hazards identification

### 2.1 Classification of the substance or mixture

#### Classification according to Regulation (EC) No 1272/2008:

This mixture is not classified as hazardous according to Regulation (EC) No. 1272/2008.

#### Classification according to Directive 67/548/EEC or 1999/45/EC:

This mixture is not classified as hazardous according to Directive 1999/45/EC. The product does not have to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.

Observe the general safety regulations when handling chemicals.

### 2.2 Label elements

#### Labelling according to EU guidelines:

Observe the general safety regulations when handling chemicals. The product is not subject to identification regulations under EU Directives and the Ordinance on Hazardous Materials (German GefStoffV).

#### Special labelling of certain mixtures

Safety data sheet available for professional user on request.

#### Hazard pictograms:

none

F-530-QMS-27.01.16

# Safety Data Sheet (SDS)

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## Hazard statements

No further relevant information available.

## 2.3 Other hazards

Results of PBT and vPvB assessment:

PBT: Not applicable.

vPvB: Not applicable.

## 3. Composition/information on ingredients

### 3.2 Mixtures

Description: room temperature vulcanising 2-component silicone.

#### Dangerous components:

EC-No. :	Chemical Name:	Quantity
CAS-No. :	Classification according Directive 67/548/EEC	
Index-No.	Classification according to Regulation (EC) No. 1272/2008 [CLP]	
REACH-No.		
	Isoparaffin-mixture C12, C16 and C20	2,5 - 10 %
14464-46-1	X <sub>n</sub> – Harmful – R65, R66	
	Asp. Tox. 1 - H304	

**Additional information:** For the wording of the listed risk phrases refer to section 16.

## 4. First aid measures



### 4.1 Description of first aid measures

#### General information

No special measures required.

#### After inhalation

Supply fresh air; consult doctor in case of complaints.

#### After skin contact

Generally the product does not irritate the skin.

#### 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.

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## 5. Firefighting measures

### 5.1 Extinguishing media

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.

#### **Additional information**

No further relevant information available.

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## 6. Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

Avoid contact with skin and eyes.

### 6.2 Environmental precautions

Do not allow product to reach ground water, water course or sewage system.

### 6.3 Methods and material for containment and cleaning up

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

### 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.

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## 7. Handling and storage

### 7.1 Precautions for safe handling

When using do not eat, drink or smoke.

**Information about fire- and explosion-protection:** No special measures required.

### 7.2 Conditions for safe storage, including any incompatibilities

**Storage:** -

**Requirements for storage rooms and vessels:** Keep container tightly closed.

**Advice on storage compatibility:** Not required.

**Further information about storage conditions:** None

### 7.3 Specific end use(s)

No further relevant information available.

F-530-QMS-27.01.16

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## 8. Exposure controls/personal protection

### 8.1 Control parameters

#### 8.1.1 Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

**Additional information:** The lists that were valid during the making were used as basis.

#### 8.1.2. DNEL/PNEC-values

No further relevant information available.

#### 8.1.3. Control-Banding

No further relevant information available.

### 8.2 Exposure controls

#### 8.2.1 Appropriate engineering controls

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

#### 8.2.2 Individual protection measures - Personal protective equipment

##### General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

##### Respiratory protection:

Not required.

##### Protection of hands



##### Protective gloves

Not required.

##### Eye protection



Goggles recommended during refilling.

#### 8.2.3 Environmental exposure controls:

##### General notes:

Do not allow product to reach ground water, water course or sewage system.

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Trade name: **Plurasil dublitec**



## 9. Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Appearance: - Form : - Colour : Odour : Odour threshold :	Fluid pinkish characteristic Not determined
pH-value at 20 °C :	Not determined
Change in condition Melting point/ freezing point : Boiling point/Boiling range :	undetermined 301°C
Flash point : Flammability (solid, gaseous) : Evaporation rate : Ignition temperature : Auto-ignition temperature : - Solid : - Gas : Decomposition temperature : Oxidizing properties Danger of explosion : Explosion limits - lower : - upper :	131°C Not applicable Not determined 400°C Product is not self igniting. Not applicable Not applicable > 180°C Not oxidizing. Product does not present an explosion hazard. Not determined Not determined
Vapour pressure at 20°C : Vapour density :	100 hPa. Not determined
Density at 20 °C :	1,4 g/cm <sup>3</sup>
Relative density :	Not determined
Solubility in / Miscibility with water :	Not miscible or difficult to mix.
Partition coefficient (n-octanol/water) :	Not determined
Viscosity Dynamic at 23°C : cinematic :	5300 mPas Not determined
Solvent content: Organic solvents:	0,0%

### 9.2 Other information

No further relevant information available.

## 10. Stability and reactivity

### 10.1 Reactivity

No hazardous reaction when handled and stored according to provisions.

### 10.2 Chemical Stability

Stable under normal handling and storage conditions.

#### Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

### 10.3 Possibility of hazardous reactions

No dangerous reactions known.

### 10.4 Conditions to avoid

No further relevant information available.

F-530-QMS-27.01.16

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## 10.5 Incompatible materials

No further relevant information available.

## 10.6 Hazardous decomposition products

No dangerous decomposition products known.

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## 11. Toxicological information

### 11.1 Information on toxicological effects

#### Acute toxicity

#### Primary irritant effect:

**On the skin:** Based on available data, the classification criteria are not met.  
No irritant effect.

**On the eye:** Based on available data, the classification criteria are not met.  
No irritant effect.

**Sensitization:** Based on available data, the classification criteria are not met.  
No sensitizing effects known.

#### 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.

#### Specific target organ toxicity - single exposure

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

#### Specific target organ toxicity - repeated exposure

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

#### Severe effects after repeated or prolonged exposure

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

#### Aspiration hazard

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

#### Additional toxicological information

No further relevant information available.

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## 12. Ecological information

### 12.1 Toxicity

**Aquatic toxicity:** No further relevant information available.

### 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.

This substance does not meet the PBT/vPvB criteria of REACH, annex XIII.

### 12.6 Other adverse effects

No further relevant information available.

**Further information:**

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.

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## 13. Disposal considerations

### 13.1 Waste treatment methods

**Advise on disposal:**

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

**Contaminated packaging:**

Disposal must be made according to official regulations.

**Waste codes / waste designations according to EWC / AVV:**

No further relevant information available.

**Packaging:**

Disposal must be made according to official regulations.

F-530-QMS-27.01.16

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## 14. Transport information

### 14.1 UN-Number

ADR, ADN, IMDG, IATA No dangerous good in sense of this transport regulation.

### 14.2 UN proper shipping name

ADR/RID, ADN, IMDG, IATA No dangerous good in sense of this transport regulation.

### 14.3 Transport hazard class(es)

No dangerous good in sense of this transport regulation..

### 14.4 Packing group

ADR/RID, ADN, IMDG, IATA No dangerous good in sense of this transport regulation.

### 14.5 Transport/Additional information:

No dangerous good in sense of this transport regulation..

### 14.6 Environmental hazards:

Marine Pollutant:  yes /  no

### 14.7 Special precautions for user

No dangerous good in sense of this transport regulation.

### 14.8 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

No dangerous good in sense of this transport regulation.

### 14.9 UN "Model Regulation"

No dangerous good in sense of this transport regulation.

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## 15. Regulatory information

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

#### EU regulations:

#### National regulations:

Water hazard class : 1 - slightly water contaminating  
(German Regulation) (Self-assessment)

### 15.2 Chemical safety assessment:

A Chemical Safety Assessment has not been carried out.

F-530-QMS-27.01.16



## 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. The receiver of our product is solely responsible for adhering to existing laws and regulations.

### Changes compared to the previous version

\* Data changed compared to the previous version are marked with \*.

### Abbreviations and acronyms:

ADR	Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
RID	Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
IATA-DGR	Dangerous Goods Regulations by the "International Air Transport Association" (IATA)
ICAO	International Civil Aviation Organization
ICAO-TI	Technical Instructions by the "International Civil Aviation Organization" (ICAO)
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 (division of the American Chemical Society)
GefStoffV	Gefahrstoffverordnung (Ordinance on Hazardous Substances, Germany)
LC <sub>50</sub>	Lethal concentration, 50 percent
LD <sub>50</sub>	Lethal dose, 50 percent
ErC <sub>50</sub>	EC <sub>50</sub> in terms of reduction of growth rate.
EC <sub>50</sub>	The effective concentration of a substance that causes 50% of the maximum response.
NOEC	No Observed Effect Concentration

Asp. Tox.                      Aspiration toxicity

### Relevant phrases

H304                      May be fatal if swallowed and enters airways.

R65                      Harmful: may cause lung damage if swallowed.

R66                      Repeated exposure may cause skin dryness or cracking.

### Further information

Department issuing MSDS: Regulatory Affairs

The information contained in this security data sheet is based on our best knowledge and conscience on topically available information about the correct use of the product under normal conditions. The user is solely responsible for any other usage of this product in connection with other processes / procedures which is not described in this data sheet. This document does not show any explicit or implicit guarantee with regard to product quality or suitability for a certain purpose.