

# Material Safety Data Sheet

according to (EC) No. 1907/2006/EC Article 31

Revision:05

Revision Date: 30.04.2024

Print Date : 30.04.2024



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

### 1.1. Product identifier

Stark – Bulk Fill Composite

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

*Medical device, please follow the instructions for use*

· **Application of the substance / the mixture** Dental filling material

### 1.3. Details of the supplier of the safety data sheet

Manufacturer Name: President Dental GmbH

Street: Kesselbodenstrasse 5

Zip-Code / Town/ Country: 85391 , Allershausen, Germany

Contact for technical information: +49 (0) 230 39228772

Phone / Fax / E-Mail: +49 (0) 8166 389 9 820 / +49 (0) 8166 389 9 821 / [info@presidentdental.com](mailto:info@presidentdental.com)

[www.presidentdental.com](http://www.presidentdental.com)

**Further information obtainable from:** R&D, PRESIDENT DENTAL GmbH,

### 1.4. Emergency Telephone Number

+49 (0) 8166 389 9 820 (8.00 am – 4.30 pm Mon-Fri)

## SECTION 2: Hazards identification


### 2.1. Classification of the substance or mixture

According to Regulation (EC) No. 1272/2008

*Skin Sens. 1 H317 May cause an allergic skin reaction.*

*Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects*

### 2.2 Label Elements

By regulation of (EG) No 1272/2008	
The product is classified and labelled according to the CLP regulation.	
Hazard Pictograms	 GHS07

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Signal word	Warning
Hazard-determining components of labelling:	<i>di-urethane dimethacrylate</i> <i>tetramethylene dimethacrylate</i>
Hazard statements	H317 May cause an allergic skin reaction. H412 Harmful to aquatic life with long lasting effects.
Precautionary statements	P261 Avoid breathing dust/fume/gas/mist/vapours/spray. P280 Wear protective gloves. P333+P313 If skin irritation or rash occurs: Get medical advice/attention. P321 Specific treatment (see on this label). P501 Dispose of contents/ container in accordance with local/regional/national/international regulations.
Other Hazards	
Results of PBT and vPvB ASSESSMENT	
PBT	Not applicable
vPvB	Not applicable




## SECTION 3: Composition/information on ingredients

### 3.1. Mixtures:

Urethandimethacrylate

1,4-Butandiol dimethacrylate

### 3.2 Dangerous components:

Dangerous components		
CAS: 41137-60-4	di-urethane dimethacrylate	10-25%
	 Aquatic Chronic 2, H411;  Skin Sens. 1B, H317	
CAS: 2082-81-7 EINECS: 218-218-1	tetramethylene dimethacrylate	2.5-10%
	 Skin Sens. 1B, H317	

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

## SECTION 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.

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After skin contact	Immediately wash with water and soap and rinse thoroughly. If skin irritation continues, consult a doctor.
After eye contact	Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
After swallowing	Rinse out mouth and then drink plenty of water. Call a doctor immediately

## 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: Fire Fighting Measures

### 5.1 Extinguishing media

#### Suitable extinguishing agents

*CO2, powder or water spray. Fight larger fire with 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:** Adapt to environment.

## SECTION 6: Accidental release measures

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

*Avoid eye and skin contact with the substance.*

### 6.2 Environmental precautions:

*No special measures required.*

*Do not allow to enter sewers/ surface or ground water.*

### 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

*No dangerous substances are released.*

*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

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**7.1. Precautions for safe handling:** *Store in cool, dry place in tightly closed receptacles.*

**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:**

*Close container immediately after use and protect product from light incidence.*

*Storage between 10 °C and 25 °C.*

**Information about storage in one common storage facility:** *Store away from foodstuffs.*

**Further information about storage conditions:** *None*

**7.3 Specific end use(s):** *No further relevant information available.*

## SECTION 8: Exposure controls/personal protection

**8.1 Control parameters**

**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 valid during the making were used as basis.*

**8.2 Exposure controls**

- **Appropriate engineering controls** *No further data; see section 7.*
- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures**  
*The usual precautionary measures are to be adhered to when handling chemicals.*
- **Respiratory protection:** *Not necessary if room is well-ventilated*
- **Hand protection** *Protective gloves.*
- **Material of gloves**  
*Butyl rubber, BR*  
*Nitrile rubber, NBR*
- **Penetration time of glove material**  
*0,3 mm*  
*Penetration time 60 min.*  
*0,11 mm*  
*Penetration time 10 min.*
- **Eye/face protection** *Goggles recommended during refilling.*
- **Body protection:** *Protective work clothing.*

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## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

#### General Information

<b>Colour</b>	Different according to colouring
<b>Odour</b>	Characteristic
<b>Odour threshold:</b>	Not determined
<b>Melting point/freezing point:</b>	<-20 °C
	Undetermined
<b>Boiling point or initial boiling point and boiling range</b>	Undetermined
<b>Flammability</b>	Not applicable.
<b>Lower and upper explosion limit</b>	
<b>Lower:</b>	Not determined.
<b>Upper:</b>	Not determined.
<b>Flash point:</b>	113 °C
<b>Auto-ignition temperature:</b>	400 °C
<b>Decomposition temperature:</b>	Not determined.
<b>pH</b>	Not determined.
<b>Viscosity:</b>	
<b>Kinematic viscosity</b>	Not determined.
<b>Dynamic viscosity</b>	Not determined.
<b>Solubility</b>	
<b>Water:</b>	Not miscible or difficult to mix
<b>Partition coefficient n-octanol/water (log value)</b>	Not determined.
<b>Vapour pressure:</b>	1,3 mbar (110 °C) Not determined.
<b>Density and/or relative density</b>	
<b>Density:</b>	Not determined.
<b>Relative density</b>	Not determined.
<b>Vapour density</b>	Not determined.

### 9.2 Other information

<b>Appearance:</b>	
<b>Form</b>	Pasty
<b>Important information on protection of health and environment, and on safety.</b>	

## SECTION 10: Stability and reactivity

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**10.1 Reactivity** No further relevant information available.

**10.2 Chemical stability**

**Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.

**10.3 Possibility of hazardous reactions** Exothermic polymerization

**10.4 Conditions to avoid** No further relevant information available.

**10.5 Incompatible materials:**

In presence of radical formers (e. g. peroxides), deoxidizing substances, and/or heavy metal ions, polymerization with heat release is possible.

**10.6 Hazardous decomposition products:** No dangerous decomposition products known

## SECTION 11: Toxicological information

**11.1 Information on toxicological effects**

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

**LD/LC50 values relevant for classification:**

**tetramethylene dimethacrylate** LD-50 oral > 5000 mg/kg (rat)

**Primary irritant effect:**

**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**

May cause an allergic skin reaction.

**CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**

**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.

## SECTION 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.

**Additional ecological information:**

**General notes:** Not known to be hazardous to water.

**12.5 Results of PBT and vPvB assessment**

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**PBT:** Not applicable.

**vPvB:** Not applicable.

**12.6 Other adverse effects** No further relevant information available.

## SECTION 13: Disposal considerations Substance / Preparation:

### 13.1 Waste treatment methods

#### Recommendation

Must be specially treated adhering to official regulations.

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

#### European waste catalogue

08 04 10	Waste adhesive and sealants other than mentioned in 08 04 09
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#### Uncleaned packaging:

##### Recommendation:

Empty contaminated packagings thoroughly. They may be recycled after thorough and proper cleaning.

Packagings that may not be cleansed are to be disposed of in the same manner as the product.

**Recommended cleansing agents:** Ethyl acetate

## SECTION 14: Transport information

#### European waste catalogue

14.1 UN-Number ADR, ADN, IMDG, IATA	Void
14.2 UN proper shipping name ADR, ADN, IMDG, IATA	Void
14.3 Transport hazard class(es) ADR, ADN, IMDG, IATA Class	Void
14.4 Packing group ADR, IMDG, IATA	Void
14.5 Environmental hazards: Marine pollutant	Void
14.6 Special precautions for user	Not applicable
14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable
UN "Model Regulation"	Void

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## SECTION 15: Regulatory information

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

Directive 2012/18/EU

Named dangerous substances - ANNEX I None of the ingredients is listed.

National regulations

Technical instructions (air):

Class	Share in %
III	2,5-10

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.

### Relevant phrases

H317 May cause an allergic skin reaction.

### Abbreviations and acronyms:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the

International Transport of Dangerous Goods by Rail)

ICAO: International Civil Aviation Organisation

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised 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)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

Skin Sens. 1B: Sensitisation - Skin, Hazard Category 1B

\* Data compared to the previous version altered.