

According to Regulation (EC) No 1907/2006

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**Zirkon BioStar HT Smile, Zirkon BioStar HT Smile Colour, Zirkon BioStar HT Smile Multilayer****SECTION 1: Identification of the substance/mixture and of the company/undertaking**

- 1.1 Product identifier:**  
**Commercial product name:** Zirkon BioStar HT Smile, Zirkon BioStar HT Smile Colour, Zirkon BioStar HT Smile Multilayer
- 1.2 Relevant identified uses of the substance or mixture and uses advised against**  
**Use of the substance/mixture:** Zirkon BioStar HT Smile, Zirkon BioStar HT Smile Colour, Zirkon BioStar HT Smile Multilayer milling blanks are intended for the production of fixed dentures for long-term use.
- Uses advised against:** No information available.
- 1.3 Details of the supplier of the safety data sheet**  
**Company name:** Dental Direkt GmbH  
**Street:** Industriezentrum 106-108  
**Place:** DE-32139 Spenge  
**Telephone:** +49-(0)5225 - 8 63 19-0  
**Telefax:** +49-(0)5225 - 8 63 19-99  
**e-mail:** [info@dentaldirekt.de](mailto:info@dentaldirekt.de)  
**Internet:** [www.dentaldirekt.de](http://www.dentaldirekt.de)  
**Responsible Department:** [info@dentaldirekt.de](mailto:info@dentaldirekt.de)
- Supplier:** SILADENT Dr. Böhme & Schöps GmbH  
**Street / mailbox:** Im Klei 26  
**Country code. / postal code / city:** DE - 38644 Goslar  
**Phone:** +49 (0) 53 21 / 37 79 - 0  
**Fax:** +49 (0) 53 21 / 38 96 32  
**E-mail / Website:** [info@siladent.de](mailto:info@siladent.de) / [www.siladent.de](http://www.siladent.de)
- 1.4 Emergency telephone number** +49 (0) 761 19240 (VIZ Freiburg)  
**Further Information:** Medical device

**SECTION 2: Hazards identification**

- 2.1 Classification of the substance or mixture**  
**Regulation (EC) No. 1272/2008:** Aquatic Chronic 3; H412
- Full text of hazard statements: see SECTION 16.
- 2.2 Label Elements**  
**Hazard statements**  
**H412** Harmful to aquatic life with long lasting effects.
- Precautionary statements**  
**P273** Avoid release to the environment.  
**P501** Dispose of contents/container to an appropriate recycling or disposal facility.
- 2.3 Other hazards:** The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

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

- 3.2 Mixtures**  
**Chemical characterization:** The product contains: Yttrium zirconium oxide

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CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (Regulation (EC) No 1272/2008)			
12061-16-4	Dierbium trioxide			< 1 %
	235-045-7			
	Aquatic Acute 1, Aquatic Chronic 1; H400 H410			

Full text of H and EUH statements: see section 16.

**Specific Conc. Limits, M-factors and ATE**

CAS No	EC No	Chemical name	Quantity
	Specific Conc. Limits, M-factors and ATE		
12061-16-4	235-045-7	Dierbium trioxide	< 1 %
	M chron.; H410: M=1		

Further Information:

No information available.

**SECTION 4: First aid measures**
**4.1 Description of first aid measures**
**General information**

Take off contaminated clothing and wash it before reuse. In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

**After inhalation:**

Remove person to fresh air and keep comfortable for breathing. In case of respiratory tract irritation, consult a physician.

**After contact with skin:**

After contact with skin, wash immediately with plenty of water and soap. If skin irritation occurs: Get medical advice/attention.

**After contact with eyes:**

Protect uninjured eye. Rinse immediately carefully and thoroughly with eye-bath or water. Remove contact lenses, if present and easy to do. Continue rinsing. In case of eye irritation consult an ophthalmologist.

**After ingestion:**

Rinse mouth immediately and drink plenty of water. Never give anything by mouth to an unconscious person or a person with cramps. Do NOT induce vomiting. Call a physician immediately.

**4.2 Most important symptoms and effects, both acute and delayed:**

No information available.

**4.3 Indication of any immediate medical attention and special treatment needed:**

First Aid, decontamination, treatment of symptoms.

**SECTION 5: Firefighting measures**
**5.1 Extinguishing media**
**Suitable extinguishing agent:**

The product itself does not burn. Co-ordinate fire-fighting measures to the fire surroundings.

**Unsuitable extinguishing media:**

No data available

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- 5.2 Special hazards arising from the substance or mixture:** In case of fire may be liberated: Carbon dioxide (CO<sub>2</sub>), Carbon monoxide, MetalOx
- 5.3 Advice for firefighters:** Co-ordinate fire-fighting measures to the fire surroundings. The product itself does not burn. In case of fire: Wear self-contained breathing apparatus.
- Additional information:** Do not allow run-off from fire-fighting to enter drains or water courses. Residues of fire and contaminated water have to be disposed according to the local regulations.

### SECTION 6: Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures**
- General advice:** See protective measures under point 7 and 8.  
Personal protection equipment: see section 8  
Provide adequate ventilation.  
Avoid dust formation. In case of inadequate ventilation wear respiratory protection.  
Avoid contact with skin, eyes and clothes.
- For non-emergency personnel:** Remove persons to safety.
- For emergency responders:** No information available.
- 6.2 Environmental precautions:** Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.
- 6.3 Methods and material for containment and cleaning up**
- For containment:** Take up mechanically. Avoid dust formation. Collect in closed and suitable containers for disposal. Dispose of waste according to applicable legislation.
- For cleaning up:** Clean with detergents. Avoid solvent cleaners.
- Other information:** Provide fresh air.
- 6.4 Reference to other sections:** Safe handling: see section 7  
Personal protection equipment: see section 8  
Disposal: see section 13

### SECTION 7: Handling and storage

- 7.1 Precautions for safe handling**
- Advice on safe handling:** Wear personal protection equipment (refer to section 8).  
Keep container tightly closed.  
Avoid contact with skin, eyes and clothes.  
Avoid release to the environment. Clear spills immediately.  
Avoid dust formation. Avoid: Dust deposits  
Do not breathe dust. In case of inadequate ventilation wear respiratory protection.
- Advice on protection against fire and explosion:** No special fire protection measures are necessary.

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**Advice on general occupational hygiene:** Minimum standard for preventive measures while handling with working materials are specified in the TRGS 500.  
 Wash contaminated clothing prior to re-use.  
 When using do not eat, drink, smoke, sniff.  
 Wash hands before breaks and after work.  
 Apply skin care products after work.

**Further information on handling:** Avoid dust formation. Protect from moisture. Provide adequate ventilation as well as local exhaust at critical locations.  
 To follow: Occupational exposure limit values.

**7.2 Conditions for safe storage, including any incompatibilities Requirements for storage rooms and vessels:** Keep/Store only in original container.  
 Keep the packing dry and well sealed to prevent contamination and absorption of humidity.

**Hints on joint storage:** Keep away from food, drink and animal feedingstuffs.

**Advice on storage compatibility:** Keep the packing dry and well-sealed to prevent contamination and absorption of humidity.

**Further information on storage conditions:** Keep away from: Frost, Heat Protect from moisture.  
 Handle with care - avoid bumps, friction and impact.

**7.3 Specific end use(s):** No data available

**SECTION 8: Exposure controls/personal protection**

**8.1 Control parameters**

CAS No	Substance	ppm	mg/m <sup>3</sup>	fib/cm <sup>3</sup>	Category	Origin
-	Dust non-specific, respirable	-	4		TWA (8 h)	
-	Dust non-specific, total inhalable	-	10		TWA (8 h)	

**8.2 Exposure controls**

**Appropriate engineering controls:** Technical ventilation of workplace.

**Individual protection measures, such as personal protective equipment**

**Eye/face protection:** Suitable eye protection: EN 166  
 Eye glasses with side protection goggles

**Hand protection:** Tested protective gloves must be worn: EN ISO 374  
 The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances.

Suitable material: NBR (Nitrile rubber), Butyl caoutchouc (butyl rubber)  
 Breakthrough times and swelling properties of the material must be taken into consideration. Observe the wear time limits as specified by the manufacturer.

Replace when worn out.

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<b>Skin protection:</b>	Protective clothing.
<b>Respiratory protection:</b>	Usually no personal respirative protection necessary. Respiratory protection necessary at: exceeding exposure limit values, dust formation Use appropriate respiratory protection. Particle filter device (EN 143)
<b>Thermal hazards:</b>	No information available.
<b>Environmental exposure controls:</b>	See section 7. No additional measures necessary.

### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic physical and chemical properties

Physical state:	solid, Powder
Colour:	white
Odour:	odourless
<b>Changes in the physical state</b>	
Melting point/freezing point:	No data available
Boiling point or initial boiling point and boiling range:	No data available
Sublimation point:	No data available
Softening point:	No data available
Pour point:	No data available
Flash point:	No data available
<b>Flammability</b>	
Solid/liquid:	No data available
Gas:	No data available
<b>Explosive properties:</b>	
Lower explosion limits:	No data available
Upper explosion limits:	No data available
<b>Self-ignition temperature</b>	
Solid:	No data available
Gas:	No data available
Decomposition temperature:	No data available
pH-Value:	No data available
Viscosity / dynamic:	No data available
Water solubility:	practically insoluble
<b>Solubility in other solvents:</b>	
Partition coefficient n-octanol/water:	No information available.
Vapour pressure:	No data available
Density:	No data available
Bulk density:	1.000-1.500 kg/m <sup>3</sup>
Relative vapour density:	No data available

9.2 Other information: No information available.

#### Information with regard to physical hazard classes

Sustaining combustion:	No data available
Oxidizing properties:	No data available

#### Other safety characteristics

Solid content:	100,00 %
Evaporation rate:	No data available
Further Information	

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**Zirkon BioStar HT Smile, Zirkon BioStar HT Smile Colour, Zirkon BioStar HT Smile Multilayer****SECTION 10: Stability and reactivity**

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<b>10.1 Reactivity:</b>	No hazardous reaction when handled and stored according to provisions.
<b>10.2 Chemical stability:</b>	The product is chemically stable under recommended conditions of storage, use and temperature.
<b>10.3 Possibility of hazardous reactions:</b>	No information available.
<b>10.4 Conditions to avoid:</b>	No information available.
<b>10.5 Incompatible materials:</b>	MetalOx
<b>10.6 Hazardous decomposition products:</b>	Not applicable.
<b>Further information:</b>	No further relevant information available.

**SECTION 11: Toxicological information**

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<b>11.1 Information on toxicological effects Toxicocinetics, metabolism and distribution:</b>	No information available.
<b>Acute toxicity:</b>	Based on available data, the classification criteria are not met.
<b>Irritation and corrosivity:</b>	Based on available data, the classification criteria are not met.
<b>Sensitising effects:</b>	Based on available data, the classification criteria are not met.
<b>Carcinogenic/mutagenic/toxic effects for reproduction:</b>	Based on available data, the classification criteria are not met.
<b>STOT-single exposure:</b>	Based on available data, the classification criteria are not met.
<b>STOT-repeated exposure:</b>	Based on available data, the classification criteria are not met.
<b>Aspiration hazard:</b>	Based on available data, the classification criteria are not met.
<b>Practical experience:</b>	After eye contact: Dust may cause mechanical irritation. Following inhalation: dust/mist May cause respiratory irritation.

**SECTION 12: Ecological information**

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<b>12.1 Toxicity:</b>	No information available.
<b>12.2 Persistence and degradability:</b>	Product/Substance is inorganic.
<b>12.3 Bioaccumulative potential:</b>	No information available.
<b>12.4 Mobility in soil:</b>	No information available.
<b>12.5 Results of PBT and vPvB assessment:</b>	The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.
<b>12.6 Endocrine disrupting properties:</b>	This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

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**12.7 Other adverse effects:** No information available.

### SECTION 13: Disposal considerations

#### 13.1 Waste treatment methods

##### Disposal recommendations:

Dispose of waste according to applicable legislation. The allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process. (AVV 200130)  
Hazardous waste according to Directive 2008/98/EC (waste framework directive).

##### Contaminated packaging:

Dispose of waste according to applicable legislation. Non-contaminated packages may be recycled.

### SECTION 14: Transport information

#### Land transport (ADR/RID)

##### 14.1 UN number or ID number:

No dangerous good in sense of this transport regulation.

#### Inland waterways transport (ADN)

##### 14.1 UN number or ID number:

No dangerous good in sense of this transport regulation.

#### Marine transport (IMDG)

##### 14.1 UN number or ID number:

No dangerous good in sense of this transport regulation.

#### Air transport (ICAO-TI/IATA-DGR)

##### 14.1 UN number or ID number:

No dangerous good in sense of this transport regulation.

#### 14.5 Environmental hazards

##### ENVIRONMENTALLY HAZARDOUS:

No

#### 14.6 Special precautions for user:

No dangerous good in sense of this transport regulation.

#### 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code:

No dangerous good in sense of this transport regulation.

### SECTION 15: Regulatory information

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

##### EU regulatory information

Information according to 2012/18/EU (SEVESO III):

Not subject to 2012/18/EU (SEVESO III)

##### Additional information:

Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH)  
Classification according to Regulation (EC) No 1272/2008 [CLP]  
Directive (EU) 2018/851 of the European Parliament and of the Council of 30 May 2018 amending Directive 2008/98/EC on waste  
Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives

##### National regulatory information

Water hazard class (D):

2 - obviously hazardous to water

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### Additional information:

Germany:

Hazardous Substances Ordinance (GefStoffV)

Verordnung über Anlagen zum Umgang mit

wassergefährdenden Stoffen (AwSV)

TRGS 201, TRGS 220, TRGS 400, TRGS 420, TRGS 500,

TRGS 509, TRGS 510, TRGS 555, TRGS 600,

TRGS 900

DGUV Information 213-850

DGUV Information 213-730

### 15.2 Chemical safety assessment:

For the following substances of this mixture a chemical safety assessment has been carried out: Dierbium trioxide

### SECTION 16: Other information

#### 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 conernat le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
IMDG:	International Maritime Code for Dangerous Goods
IATA:	International Air Transport Association
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)
CAS:	Chemical Abstracts Service (division of the American Chemical Society)
GHS:	Globally Harmonized System of Classification and Labelling of Chemicals
CLP:	Regulation on Classification, Labelling and Packaging of Substances and Mixtures,
LC50:	Lethal concentration, 50 percent
LD50:	Lethal dose, 50 percent
EC50:	Effective concentration, 50 percent
DNEL:	Derived No Effect Level
PNEC:	Predicted No Effect Concentration
PBT:	Persistent, Bioaccumulative and Toxic
vPvB:	very Persistent and very Bioaccumulative

#### Classification for mixtures and used evaluation method according to Regulation (EC) No 1272/2008 [CLP]

Classification	Classification procedure
Aquatic Chronic 3; H412	Calculation method

#### Relevant H and EUH statements (number and full text)

H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

#### Further Information

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)