

According to Regulation (EC) No 1907/2006

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Zirkon BioStar Ultra, Zirkon BioStar Ultra Colour, Zirkon BioStar Ultra Multilayer**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1 Product identifier:****Commercial product name:** Zirkon BioStar Ultra, Zirkon BioStar Ultra Colour, Zirkon BioStar Ultra Multilayer**1.2 Relevant identified uses of the substance or mixture and uses advised against****Use of the substance/mixture:** Zirkon BioStar Ultra, Zirkon BioStar Ultra Colour, Zirkon BioStar Ultra 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****Manufacturer:****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
Internet: www.dentaldirekt.de
Responsible Department: info@dentaldirekt.de**Supplier:****Street / mailbox:** SILADENT Dr. Böhme & Schöps GmbH
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 / www.siladent.de**1.4 Emergency telephone number****Further Information:** +49 (0) 761 19240 (VIZ Freiburg)

Medical device.

SECTION 2: Hazards identification**2.1 Classification of the substance or mixture****Regulation (EC) No. 1272/2008:** This mixture is not classified as hazardous according to Regulation (EC) No. 1272/2008.**2.2 Label Elements****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: Zirconium oxide (ZrO₂), erbium-doped; Zirconium dioxide**Hazardous components:** none (according to Regulation (EC) No 1907/2006 (REACH))**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

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	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. Get medical help if you feel unwell.
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
5.2 Special hazards arising from the substance or mixture:	In case of fire may be liberated: Carbon dioxide (CO ₂), 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.

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. Avoid contact with skin, eyes and clothes. In case of inadequate ventilation wear respiratory protection.
For non-emergency personnel:	Remove persons to safety.
For emergency responders:	No information available.

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- 6.2 Environmental precautions:** Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.
Knock down dust with water spray jet.
- 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.
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.
- Advice on general occupational hygiene:** Minimum standard for preventive measures while handling with working materials are specified in the TRGS 500.
Wash hands before breaks and after work.
Apply skin care products after work.
Wash contaminated clothing prior to re-use.
When using do not eat, drink, smoke, sniff.
Work in well-ventilated zones or use proper respiratory protection.
- 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.
- 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.

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SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limits

CAS No	Substance	ppm	mg/m ³	fib/cm ³	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.

Skin protection:

Protective clothing.

Respiratory protection:

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) (P1, FFP1)

Thermal hazards:

No information available.

Environmental exposure controls:

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: various

Odour: odourless

Changes in the physical state

Melting point/freezing point: >2300 °C

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

Flammability

Solid/liquid:

No data available

Gas:

No data available

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Explosive properties:	No data available
Lower explosion limits:	No data available
Upper explosion limits:	No data available
Self-ignition temperature	
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
Solubility in other solvents:	No information available.
Partition coefficient n-octanol/water:	No data available
Vapour pressure:	No data available
Density:	No data available
Bulk density:	1000 kg/m ³
Relative vapour density:	No data available

9.2 Other information
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:	The product is: hygroscopic

SECTION 10: Stability and reactivity

10.1 Reactivity:	No further relevant information available.
10.2 Chemical stability:	The product is chemically stable under recommended conditions of storage, use and temperature.
10.3 Possibility of hazardous reactions:	Reaction with: Acid
10.4 Conditions to avoid:	No information available.
10.5 Incompatible materials:	No information available.
10.6 Hazardous decomposition products:	No known hazardous decomposition products.
Further information:	No further relevant information available.

SECTION 11: Toxicological information

11.1 Information on toxicological effects	
Toxicokinetics, metabolism and distribution:	No information available.
Acute toxicity:	Based on available data, the classification criteria are not met.
Irritation and corrosivity:	Based on available data, the classification criteria are not met. slightly irritant but not relevant for classification.
Sensitising effects:	Based on available data, the classification criteria are not met.
Carcinogenic/mutagenic/toxic effects for reproduction:	Based on available data, the classification criteria are not met.

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

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) Non hazardous waste according to Directive 2008/98/EC (waste framework directive).

List of Wastes Code - residues/unused products

060316 WASTES FROM INORGANIC CHEMICAL PROCESSES; wastes from the MFSU of salts and their solutions and metallic oxides; metallic oxides other than those mentioned in 06 03 15

Contaminated packaging:	Dispose of waste according to applicable legislation. Non-contaminated packages may be recycled.
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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)	
14.1 UN number or ID number:	No dangerous good in sense of this transport regulation.

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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):

1 - slightly hazardous to water

Additional information:

Germany
 Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen (AwSV)
 TRGS 220, TRGS 400, TRGS 420, TRGS 500, TRGS 555, TRGS 600, TRGS 900
 DGUV Information 213-850
 DGUV Information 213-730

15.2 Chemical safety assessment:

Chemical safety assessments for substances in this mixture were not carried out.

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

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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

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.)