

according to Regulation (EC) No 1907/2006

DD cubeX²

Revision date: 25.07.2022 Page 1 of 9

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

1.1. Product identifier

DD cubeX²

Further trade names

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

Use of the substance/mixture

DD cubeX² 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: D-32139 Spenge

Telephone: 05225 - 8 63 19-0 Telefax: 05225 - 8 63 19-99

e-mail: info@dentaldirekt.de
Internet: www.dentaldirekt.de
Responsible Department: info@dentaldirekt.de

1.4. Emergency telephone +49 (0) 761 19240 (VIZ Freiburg)

number:

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

Regulation (EC) No 1272/2008

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



according to Regulation (EC) No 1907/2006

DD cubeX²

Revision date: 25.07.2022 Page 2 of 9

Hazardous components

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 media

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



according to Regulation (EC) No 1907/2006

DD cubeX²

Revision date: 25.07.2022 Page 3 of 9

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 (CO2), 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.



according to Regulation (EC) No 1907/2006

DD cubeX²

Revision date: 25.07.2022 Page 4 of 9

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. Observe instructions for use.

Provide adequate ventilation as well as local exhaustion 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 absorbtion 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

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

CAS No	Substance	ppm	mg/m³	fib/cm³	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.



according to Regulation (EC) No 1907/2006

DD cubeX²

Revision date: 25.07.2022 Page 5 of 9

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)

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: white Odour: odourless

Changes in the physical state

Melting point/freezing point:

Boiling point or initial boiling point and

No data available

No data available

boiling range:

Sublimation point:

Softening point:

No data available

No data available

Pour point:

No data available

Flash point:

No data available

Flammability

Solid/liquid: No data available
Gas: No data available

Explosive properties

No data available

Lower explosion limits:

Upper explosion limits:

No data available

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:

Vapour pressure:

No data available

No data available

Density:

No data available

Bulk density:

1.000-1.500 kg/m³

Relative vapour density:

No data available

9.2. Other information



according to Regulation (EC) No 1907/2006

DD cubeX²

Revision date: 25.07.2022 Page 6 of 9

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

No information available.

SECTION 10: Stability and reactivity

10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

10.2. Chemical stability

The product is chemically stable under recommended conditions of storage, use and temperature.

10.3. Possibility of hazardous reactions

No information available.

10.4. Conditions to avoid

No information available.

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

MetalOx

Further information

No further relevant information available.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Toxicocinetics, 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.

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.

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.

Practical experience

After eye contact: Is féidir le deannach a bheith ina chúis le greannú meicniúil.

Following inhalation: dust/mist May cause respiratory irritation.



according to Regulation (EC) No 1907/2006

DD cubeX²

Revision date: 25.07.2022 Page 7 of 9

SECTION 12: Ecological information

12.1. Toxicity

No information available.

12.2. Persistence and degradability

Product/Substance is inorganic.

12.3. Bioaccumulative potential

No information available.

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

Water hazard class 2

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. Maritime transport in bulk according to IMO instruments

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

 Revision No: 05
 IRL - EN
 Print date: 18.07.2022



according to Regulation (EC) No 1907/2006

DD cubeX²

Revision date: 25.07.2022 Page 8 of 9

EU regulatory information

Information according to 2012/18/EU

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

(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

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 Refulations 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: Effectice 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



according to Regulation (EC) No 1907/2006

DD cubeX²

Revision date: 25.07.2022 Page 9 of 9

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.)