

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

1.1. Product identifier

DD Prefab
DD Ti-Base 2CUT
DD Ti-Base 2CUT noLock
DD Scanbody 2.0
DD Implant Screw

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

Use of the substance/mixture

DD Solid Connect® implant components are used to support prosthetic restorations in combination with endosseous dental implants in the upper and/or lower jaw.

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 number:

+49 (0) 761 19240 (VIZ Freiburg), Poisons information Centre of Ireland +353 1 809 21 66; <http://www.poisons.ie/Public>

Further Information

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 in accordance with 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.

Dust can form an explosive mixture with air.

Comb. Dust (Combustible Dust)

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Titanium and titanium alloys

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Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (Regulation (EC) No 1272/2008)			
7429-90-5	aluminium powder (stabilised)			>=5,5-6,5 %
	231-072-3	013-002-00-1		
	Flam. Sol. 1, Water-react. 2; H228 H261			

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	
7429-90-5	231-072-3	aluminium powder (stabilised)	>=5,5-6,5 %
		oral: LD50 = > 15900 mg/kg	

Further Information

No information available.

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

In case of allergic symptoms, especially in the breathing area, seek medical advice immediately.

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

Rinse immediately carefully and thoroughly with eye-bath or water. 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

Sand,

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Unsuitable extinguishing media

, Foam, Carbon dioxide, Dry extinguishing powder

5.2. Special hazards arising from the substance or mixture

Water reacts with burning titanium to release hydrogen.

5.3. Advice for firefighters

In case of fire: Wear self-contained breathing apparatus.

Solid metal will not ignite.

Forms such as foil, fine wire, turnings, millings, grindings, powder and dust et cetera are flammable. Once ignited titanium burns fiercely giving off intense heat and is difficult to extinguish

Titanium will burn in an atmosphere of carbon dioxide or nitrogen.

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

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Provide adequate ventilation.

Avoid dust formation. In case of inadequate ventilation wear respiratory protection.

Fire extinguishing agent

Avoid contact with skin, eyes and clothes.

For non-emergency personnel

Remove persons to safety.

For emergency responders

Reference to other sections: 5

Keep away from clothing and other combustible materials.

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

Cleaning agent: Water

Metal powder /-Dust

Do not use a brush or compressed air for cleaning surfaces or clothing. Do not use a dry brush as dust clouds or static can be created.

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

- Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
- Forms such as foil, fine wire, turnings, millings, grindings, powder and dust et cetera are flammable. Once ignited titanium burns fiercely giving off intense heat and is difficult to extinguish
- Use only antistatically equipped (spark-free) tools.

Advice on general occupational hygiene

- Work in well-ventilated zones or use proper respiratory protection.
- Only wear fitting, comfortable and clean protective clothing.
- Wash hands before breaks and after work.
- Separate storage of work clothes.
- Make available sufficient washing facilities

Further information on handling

- Observe instructions for use.
- Avoid dust formation. Working places should be designed to allow cleaning at any time.
- Materials soiled with product such as cleaning rags, tissues and protective clothing, may ignite spontaneously a few hours later.
- 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.
- Only allow access to authorised staff.
- 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.
- Keep away from: Acid, Oxidizing agent
- Keep away from combustible material.

Powder Residues, Grindings, Dust Extractor Sludges: Do not store. Dispose of as soon after arising as possible.

Further information on storage conditions

- Keep away from: Frost, Heat
- Protect from moisture.

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/m ³	fib/cm ³	Category	Origin
7429-90-5	Aluminium metal (Respirable Fraction)	-	1		TWA (8 h)	
-	Dust non-specific, respirable	-	4		TWA (8 h)	
-	Dust non-specific, total inhalable	-	10		TWA (8 h)	
13463-67-7	Titanium dioxide, respirable dust	-	4		TWA (8 h)	

DNEL/DMEL values

CAS No	Substance	Exposure route	Effect	Value
7440-32-6	Titanium			
	Consumer DNEL, long-term	oral	systemic	350 mg/kg bw/day
7429-90-5	aluminium powder (stabilised)			
	Worker DNEL, long-term	inhalation	systemic	3,72 mg/m ³
	Worker DNEL, long-term	inhalation	local	3,72 mg/m ³
	Consumer DNEL, long-term	oral	systemic	7,9 mg/kg bw/day

PNEC values

CAS No	Substance	Value
	Environmental compartment	
7440-32-6	Titanium	
	Freshwater	0,076 mg/l
	Freshwater (intermittent releases)	0,37 mg/l
	Marine water	0,6 mg/l
	Freshwater sediment	600 mg/kg
	Marine sediment	60 mg/kg
	Micro-organisms in sewage treatment plants (STP)	60 mg/l
	Soil	60 mg/kg
7429-90-5	aluminium powder (stabilised)	
	Micro-organisms in sewage treatment plants (STP)	20 mg/l

8.2. Exposure controls

Appropriate engineering controls

- Provide adequate ventilation as well as local exhaust at critical locations.
- dust formation: Provide earthing of containers, equipment, pumps and ventilation facilities.
- Wet scrubber for dust elimination of waste gases

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
- Suitable material: NBR (Nitrile rubber), Butyl caoutchouc (butyl rubber).

Thickness of the glove material: For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

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Breakthrough time: >480 min

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. Breakthrough times and swelling properties of the material must be taken into consideration.

Observe the wear time limits as specified by the manufacturer. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

Check leak tightness/impermeability prior to use.

Do not wear gloves near rotary machines and tools.

Skin protection

Protective clothing. (Germany To follow: DGUV-Information 209-002 "Schleifen")

Personnel handling dry titanium powder should wear non sparking shoes, non combustible or flame retardant clothing and goggles or face shields

Respiratory protection

If fine dust or metal fumes are generated during processing, it is recommended to provide adequate ventilation to keep the metal and alloying element content in the air within the limits.

If technical exhaust or ventilation measures are not possible or insufficient, respiratory protection must be worn.

The filter class must be suitable for the maximum contaminant concentration (gas/vapour/aerosol/particulates) that may arise when handling the product. If the concentration is exceeded, self-contained breathing apparatus must be used.

Particle filter device (EN 143)

Thermal hazards

No data available

Environmental exposure controls

Devices with local exhaust

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state:	solid
Colour:	white
Odour:	odourless

Changes in the physical state

Melting point/freezing point:	>1630 °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

Explosive properties

Metal powder: Dust can form an explosive mixture with air.

Lower explosion limits:	No data available
Upper explosion limits:	No data available
Auto-ignition temperature:	No data available

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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.

Dissolution rate: No data available

Partition coefficient n-octanol/water: No data available

Vapour pressure: No data available

Vapour pressure: No data available

Density: ~4,4 g/cm³

Relative density: No data available

Bulk density: No data available

Relative vapour density: No data available

Particle characteristics: No data available

9.2. Other information**Information with regard to physical hazard classes**

Sustaining combustion: No data available

Oxidizing properties
Not oxidising.

Other safety characteristics

Solvent separation test: No data available

Solvent content: 0%

Solid content: 100%

Evaporation rate: No data available

Further Information

Forms such as foil, fine wire, turnings, millings, grindings, powder and dust et cetera are flammable. Once ignited titanium burns fiercely giving off intense heat and is difficult to extinguish

SECTION 10: Stability and reactivity**10.1. Reactivity**

Metal powder: Dust can form an explosive mixture with air.

10.2. Chemical stability

No information available.

10.3. Possibility of hazardous reactions

Metal powder:
Dust can form an explosive mixture with air.
Formation of explosive mixtures with: Chlorine (Cl₂)

10.4. Conditions to avoid

No information available.

10.5. Incompatible materials

Oxidizing agent,
Acids (Titanium metal is rapidly dissolved by hydrofluoric acid or hydrofluoric-nitric acid mixtures. Titanium

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enters into thermite type reactions with iron oxides. Explosive reactions have been reported whilst attempting to use titanium metal or powder in red fuming nitric acid.)

10.6. Hazardous decomposition products

No information available.

Further information

There are no data available on the mixture itself.

SECTION 11: Toxicological information

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

Toxicokinetics, metabolism and distribution

No information available.

Acute toxicity

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

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
7429-90-5	aluminium powder (stabilised)				
	oral	LD50 > 15900 mg/kg	Rat	Study report (1969)	OECD Guideline 401

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.

11.2. Information on other hazards

Endocrine disrupting properties

No data available

SECTION 12: Ecological information

12.1. Toxicity

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CAS No	Chemical name						
	Aquatic toxicity	Dose	[h] [d]	Species	Source	Method	
7429-90-5	aluminium powder (stabilised)						
	Acute fish toxicity	LC50	6,17 mg/l	96 h	Oncorhynchus mykiss	Canadian Journal of Fisheries and Aquati	Juvenile rainbow trout were exposed to f
	Acute algae toxicity	ErC50 mg/l	0,0169	72 h	Pseudokirchneriella subcapitata	Study report (2009)	OECD Guideline 201
	Acute crustacea toxicity	EC50	0,72 mg/l	48 h	Ceriodaphnia dubia	Study report (1992)	other: USEPA 1985. Methods for measuring
	Fish toxicity	NOEC	0,4 mg/l	7 d	Pimephales promelas	Study report (1992)	other: USEPA 1989. Short-term Methods fo
	Crustacea toxicity	NOEC	1,02 mg/l	6 d	Ceriodaphnia dubia	Study report (1992)	other: US EPA

12.2. Persistence and degradability

Not applicable for inorganic substances.

Poorly watersoluble, inorganic product. Can be mechanically precipitated to a large extent in biological sewage plants.

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

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

List of Wastes Code - residues/unused products

170407 CONSTRUCTION AND DEMOLITION WASTES (INCLUDING EXCAVATED SOIL FROM CONTAMINATED SITES); metals (including their alloys); mixed metals

Contaminated packaging

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

SECTION 14: Transport information
Land transport (ADR/RID)

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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.
14.2. UN proper shipping name:	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****EU regulatory information**

Restrictions on use (REACH, annex XVII):

Entry 40

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): - - non-hazardous to water

Additional information

Germany

Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen (AwSV)

TRGS 220, TRGS 400ff., TRGS 500, TRGS 555, TRGS 722-724, TRGS 800, TRGS 900

DGUV-Information 209-002 "Schleifen"

15.2. Chemical safety assessment

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

aluminium powder (stabilised)

SECTION 16: Other information**Changes**

This data sheet contains changes from the previous version in section(s):

1,2,4,5,6,7,8,9,10,11,12,13,14,15,16.

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)
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: Effect concentration, 50 percent
DNEL: Derived No Effect Level
PNEC: Predicted No Effect Concentration
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative

Key literature references and sources for data

GESTIS

Relevant H and EUH statements (number and full text)

H228 Flammable solid.
H261 In contact with water releases flammable gases.

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.)