

# SAFETY DATA SHEET (EC 1907/2006)

## BiOcclus Inlay

Version: 1.8 / GB  
Revision date: 27.09.2017  
Issue date: 03.09.2001  
replaces version: 1.7  
Page: 1 / 8

Material no. 5312060002  
Specification 102679  
VA-Nr 01774669



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

#### 1.1. Product identifier

Trade name BiOcclus Inlay  
REACH Registration No.: if available listed in Chapter. 3

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

Relevant applications identified For dental use only.

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

Company DeguDent GmbH  
Postfach 1364  
D-63403 Hanau

Telephone +49 (0)6181/59-5767  
Telefax +49 (0)6181/59-5879  
Email address SDB.Degudent-DE@dentsplysirona.com

#### 1.4. Emergency telephone number

Emergency information +49 (0)6181/59-50 (This telephone number is available during office hours only.)

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not a hazardous mixture according to Regulation (EC) No 1272/2008.

#### 2.2. Label elements

##### Labelling as per (EU) 1272/2008

Statutory basis Labelling not required according to EU-CLP Ordinance (1272/2008).

#### 2.3. Other hazards

Zinc oxide fumes is released during processing  
A PBT/vPvB evaluation is not available, since a chemical safety evaluation is not required / has not been carried out.

### SECTION 3: Composition/information on ingredients

#### 3.1. Substances

-

#### 3.2. Mixtures

##### Information on ingredients / Hazardous components as per EU-CLP Regulation (EC) No. 1272/2008

• Gold	83.3%		
CAS-No.	7440-57-5	EC-No.	231-165-9
• platinum	4.8%		

# SAFETY DATA SHEET (EC 1907/2006)

## BiOcclus Inlay

Version: **1.8 / GB** Material no. **5312060002**  
Revision date: **27.09.2017** Specification **102679**  
Issue date: **03.09.2001** VA-Nr **01774669**  
replaces version: **1.7**  
Page: **2 / 8**



CAS-No.	7440-06-4	EC-No.	231-116-1
• Iridium	0.1%		
CAS-No.	7439-88-5	EC-No.	231-095-9
• silver	10.0%		
CAS-No.	7440-22-4	EC-No.	231-131-3
• zinc	1.8%		
CAS-No.	7440-66-6	EC-No.	231-175-3

Texts of H phrases, see in Chapter 16

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

##### Inhalation

Dusts and vapours:

Remove to fresh air.

##### Eye contact

Dusts and vapours:

Rinse thoroughly with plenty of water keeping eyelid open.

Consult an eye doctor (ophthalmologist).

#### 4.2. Most important symptoms and effects, both acute and delayed

##### Symptoms

None known

##### Hazards

None known

#### 4.3. Indication of any immediate medical attention and special treatment needed

None known

### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

Suitable extinguishing media: Special powder against metal fire  
quenching powder  
dry sand  
common salt

Unsuitable extinguishing media: Water  
Carbon dioxide (CO<sub>2</sub>)

#### 5.2. Special hazards arising from the substance or mixture

None known.

#### 5.3. Advice for firefighters

Extinction measures are to be adjusted to the specific location.

The product itself does not burn.

Employ protective equipment commonly used in the event of fire.

### SECTION 6: Accidental release measures

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

No special measures are required.

#### 6.2. Environmental precautions

No special environmental precautions required.

# SAFETY DATA SHEET (EC 1907/2006)

## BiOcclus Inlay

Version: **1.8 / GB** Material no. **5312060002**  
Revision date: **27.09.2017** Specification **102679**  
Issue date: **03.09.2001** VA-Nr **01774669**  
replaces version: **1.7**  
Page: **3 / 8**



### 6.3. Methods and material for containment and cleaning up

Use mechanical handling equipment.

### 6.4. Reference to other sections

Wear personal protective equipment; see section 8.

Disposal considerations; see section 13.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

In case of melting, soldering or grinding:

Dusts and vapors: Do not inhale.

Local ventilation.

No special measures are necessary if properly handled.

In case of dust or vapor: Wear personal safety equipment

### 7.2. Conditions for safe storage, including any incompatibilities

#### Storage

No special storage conditions required.

#### German storage class

13 - Non Combustible Solids

### 7.3. Specific end use(s)

We are unaware of any specific end uses which go beyond the data reported in Section 1.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

• platinum			
CAS-No.	7440-06-4	EC-No.	231-116-1
Control parameters	5 mg/m <sup>3</sup>		Time Weighted Average (TWA):(EH40 WEL)
Control parameters	1 mg/m <sup>3</sup>		Time Weighted Average (TWA):(EU ELV)
	Indicative		
• silver			
CAS-No.	7440-22-4	EC-No.	231-131-3
Control parameters	0.1 mg/m <sup>3</sup>		Time Weighted Average (TWA):(EH40 WEL)
Control parameters	0.1 mg/m <sup>3</sup>		Time Weighted Average (TWA):(EU ELV)
	Indicative		

### 8.2. Exposure controls

#### Engineering measures

Zinc oxide fumes is released during processing, In case of melting, soldering or grinding; Adequate exhaustion / ventilation of the work site or machinery must be assured. Vacuuming of objects.

#### Personal protective equipment

##### Respiratory protection

If workplace exposure limit is exceeded apply Dust mask with P2 particle filter.

##### Hand protection

No special protective equipment required.

##### Eye/face protection

Safety glasses with side-shields

##### Skin and body protection

No particular measures required.

# SAFETY DATA SHEET (EC 1907/2006)

## BiOclus Inlay

Version:	1.8 / GB	Material no.	5312060002
Revision date:	27.09.2017	Specification	102679
Issue date:	03.09.2001	VA-Nr	01774669
replaces version:	1.7		
Page:	4 / 8		



### Hygiene measures

Handle in accordance with good industrial hygiene and safety practice., Do not eat, drink, smoke, or sniff while at work. Wash your hands and/or face before breaks and before termination of work., Do not inhale smoke, dust, vapor.

## SECTION 9: Physical and chemical properties

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

Appearance	
Form	solid
Colour	yellow
Odour	odourless
Odour threshold:	not applicable
pH	not applicable (solid)
Melting point/range	980 - 1060 °C
Boiling point/range	not applicable (solid)
Flash point	not applicable
Evaporation rate	not applicable
Flammability (solid, gas)	not flammable
Lower explosion limit	not applicable
Upper explosion limit	not applicable
Vapour pressure	not applicable
Density	17.4 g/cm <sup>3</sup>
Water solubility	insoluble
Partition coefficient: n-octanol/water	not applicable
Autoinflammability	Not capable of spontaneous combustion or heating.
Thermal decomposition	not applicable
Viscosity, dynamic	not applicable
Explosiveness	not applicable
Oxidizing properties	not oxidizing

### 9.2. Other information

Other information No further physicochemical data were determined.

## SECTION 10: Stability and reactivity

# SAFETY DATA SHEET (EC 1907/2006)

## BiOclus Inlay

Version:	1.8 / GB	Material no.	5312060002
Revision date:	27.09.2017	Specification	102679
Issue date:	03.09.2001	VA-Nr	01774669
replaces version:	1.7		
Page:	5 / 8		



### 10.1. Reactivity

no data available

### 10.2. Chemical stability

The product is chemically stable.

### 10.3. Possibility of hazardous reactions

Possibility of hazardous reactions      No dangerous reactions known.

### 10.4. Conditions to avoid

No limitations

### 10.5. Incompatible materials

None known

### 10.6. Hazardous decomposition products

Decomposition products occurring when heated above melting temperature  
metallic vapors

---

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute oral toxicity	no data available
Acute inhalation toxicity	no data available
Acute dermal toxicity	no data available
Skin irritation	no data available
Eye irritation	no data available
Sensitization	no data available
Repeated dose toxicity	no data available
Mutagenicity assessment	no data available
Carcinogenicity	No data available
Toxicity to reproduction	No data available
Further information	No hazardous reactions are known if properly handled and stored.

---

## SECTION 12: Ecological information

### 12.1. Toxicity

*No ecotoxicological data is available for this product.*

### 12.2. Persistence and degradability

Biodegradability      no data available

### 12.3. Bioaccumulative potential

Bioaccumulation      no data available

# SAFETY DATA SHEET (EC 1907/2006)

## BiOcclus Inlay

Version:	1.8 / GB	Material no.	5312060002
Revision date:	27.09.2017	Specification	102679
Issue date:	03.09.2001	VA-Nr	01774669
replaces version:	1.7		
Page:	6 / 8		



### 12.4. Mobility in soil

Mobility The product is insoluble in water.  
No further information available

### 12.5. Results of PBT and vPvB assessment

A PBT/vPvB evaluation is not available, since a chemical safety evaluation is not required / has not been carried out.

### 12.6. Other adverse effects

Further Information Dusts and water-soluble forms of the alloy:, Introduction into soil, natural water bodies or sewerage must be prevented.

---

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

#### Product

Can be used after re-conditioning.

---

## SECTION 14: Transport information

**Not dangerous according to transport regulations.**

14.1. UN number:	--
14.2. UN proper shipping name:	--
14.3. Transport hazard class(es):	--
14.4. Packing group:	--
14.5. Environmental hazards:	--
14.6. Special precautions for user:	No

---

## SECTION 15: Regulatory information

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

#### National legislation

### 15.2. Chemical safety assessment

Chemical safety assessment No Chemical Safety Report as per Articles 2(8), 2(9) or 14 of the REACH Regulation is required for this product.

---

## SECTION 16: Other information

**Classification and applied procedure to derive the classification of mixtures according to EU Regulation (EC) No. 1272/2008 (CLP)**

#### Further information

Changes since the last version are highlighted in the margin. This version replaces all previous versions.

**SAFETY DATA SHEET (EC 1907/2006)****BiOclus Inlay**

Version:	<b>1.8 / GB</b>	Material no.	<b>5312060002</b>
Revision date:	<b>27.09.2017</b>	Specification	<b>102679</b>
Issue date:	03.09.2001	VA-Nr	<b>01774669</b>
replaces version:	1.7		
Page:	<b>7 / 8</b>		



This information and all further technical advice is based on our present knowledge and experience. However, it implies no liability or other legal responsibility on our part, including with regard to existing third party intellectual property rights, especially patent rights. In particular, no warranty, whether express or implied, or guarantee of product properties in the legal sense is intended or implied. We reserve the right to make any changes according to technological progress or further developments. The customer is not released from the obligation to conduct careful inspection and testing of incoming goods. Performance of the product described herein should be verified by testing, which should be carried out only by qualified experts in the sole responsibility of a customer. Reference to trade names used by other companies is neither a recommendation, nor does it imply that similar products could not be used.

**Legend**

<b>ADR</b>	European Agreement concerning the International Carriage of Dangerous Goods by Road
<b>ADN</b>	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
<b>ASTM</b>	American Society for Testing and Materials
<b>ATP</b>	Adaptation to Technical Progress
<b>BCF</b>	Bioconcentration factor
<b>BetrSichV</b>	German Ordinance on Industrial Safety and Health
<b>c.c.</b>	closed cup
<b>CAS</b>	Chemical Abstract Services
<b>CESIO</b>	European Committee of Organic Surfactants and their Intermediates
<b>ChemG</b>	German Chemicals Act
<b>CMR</b>	carcinogenic-mutagenic-toxic for reproduction
<b>DIN</b>	German Institute for Standardization
<b>DMEL</b>	Derived minimum effect level
<b>DNEL</b>	Derived no effect level
<b>EINECS</b>	European Inventory of Existing Commercial Chemical Substances
<b>EC50</b>	half maximal effective concentration
<b>GefStoffV</b>	German Ordinance on Hazardous Substances
<b>GGVSEB</b>	German ordinance for road, rail and inland waterway transportation of dangerous goods
<b>GGVSee</b>	German ordinance for sea transportation of dangerous goods
<b>GLP</b>	Good Laboratory Practice
<b>GMO</b>	Genetic Modified Organism
<b>IATA</b>	International Air Transport Association
<b>ICAO</b>	International Civil Aviation Organization
<b>IMDG</b>	International Maritime Dangerous Goods
<b>ISO</b>	International Organization For Standardization
<b>LOAEL</b>	Lowest observed adverse effect level
<b>LOEL</b>	Lowest observed effect level
<b>NOAEL</b>	No observed adverse effect level
<b>NOEC</b>	no observed effect concentration
<b>NOEL</b>	no observed effect level
<b>o. c.</b>	open cup
<b>OECD</b>	Organisation for Economic Cooperation and Development
<b>OEL</b>	Occupational Exposure Limit
<b>PBT</b>	Persistent, bioaccumulative, toxic
<b>PEC</b>	Predicted effect concentration
<b>PNEC</b>	Predicted no effect concentration
<b>REACH</b>	REACH registration
<b>RID</b>	Convention concerning International Carriage by Rail
<b>STOT</b>	Specific Target Organ Toxicity
<b>SVHC</b>	Substances of Very High Concern
<b>TA</b>	Technical Instructions
<b>TPR</b>	Third Party Representative (Art. 4)
<b>TRGS</b>	Technical Rules for Hazardous Substances
<b>VCI</b>	German chemical industry association

# SAFETY DATA SHEET (EC 1907/2006)

## BiOclus Inlay

Version:	<b>1.8 / GB</b>	Material no.	<b>5312060002</b>
Revision date:	<b>27.09.2017</b>	Specification	<b>102679</b>
Issue date:	03.09.2001	VA-Nr	<b>01774669</b>
replaces version:	1.7		
Page:	<b>8 / 8</b>		



<b>vPvB</b>	very persistent, very bioaccumulative
<b>VOC</b>	volatile organic compounds
<b>VwVwS</b>	German Administrative Regulation on the Classification of Substances Hazardous to Waters into Water Hazard Classes
<b>WGK</b>	Water Hazard Class
<b>WHO</b>	World Health Organization