SDS SAFETY DATA SHEET

According to directive 1907/2006/EC, Article 31 Date of issue: 2015.11.03 Supersedes version of: 2011.02.07 *n.a.= not applicable; n.k.= unknown*

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Dentatus Classic / Surtex Titanium Posts

Manufacturer: Dentatus AB Finspångsgatan 42, SE-163 53 Spånga, Sweden Tel: +46 8 564 50900; Fax: +46 8 564 50901

2. HAZARDS IDENTIFICATION

Classification of the substance or mixture Classification according to Regulation (EC) 1272/2008 : not applicable Classification according to Directive 67/548/EEC or Directive 1999/45/EC: not applicable Information concerning particular hazards for human and environment:Risk Identification: The product does not have to be labeled due to the calculation procedure of the "General classification guideline for preparations of the EU" in the latest valid version.

Label elements:

Labeling according to EU guidelines: Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of dangerous substance Directive 1999/45/EWG.

Other hazards

Results of PBT and vPvB assessment PBT: not applicable **vPvB:** not applicable

3. COMPOSITION / INFORMATION ON INGREDIENTS

Common chemical / generic name: Titanium, Grade 1

CAS # (titanium): 7440-32-6

Chemical characteristics: Solid metal

Hazardous components: None

4. FIRST-AID MEASURE	<u>S</u>	
General Information:	No special measures required	
After skin contact:	No special measures required	
After eye contact:	n.a. (or as for any solid object)	
After swallowing:	Contact physician	

5. FIRE-FIGHTING MEASURES

Extinguishing media:

Protective equipment:

6. ACCIDENTAL RELEASE MEASURES

Personal precautions:

Environmental precautions:

Methods for cleaning up: Pick up mechanically

Additional information: None

7. HANDLING AND STORAGE

Handling: For dental use only. No special measures required.

Handling procedures: Avoid touching posts with bare hands as body fats can compromise bonding

n.a.

Recommendation for fire and explosion protection: No special measures required.

n.a.

Storage: No special requirements

Requirements at store rooms and containers: No special requirements

Additional storage conditions: No special requirements

Storage classifications: n.a

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Additional information for technical plants: n.a.

Components with limits of values to be supervised at the workplace: The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace

Additional information: The lists valid during the making were used as basis.

Personal protective equipment: n.a.

Respiration:	n.a.
Hands:	n.a.
Eyes:	Use safety goggles when cutting or grinding material
Clothes:	n.a.

9. PHYSICAL AND CHEMICAL PROPERTIES

Color: Grey metal Appe	arance:	Solid	<u>Odor</u> :	None	
Information on change in the physical state:					
Melting point (°C)	1670				
Decomposition temp. (°C)	n.a.				
Flash point (°C)	n.a.				
Explosive properties	n.a.				
Flammable limits	n.a.				
Oxidizing properties	n.a.				
Density (g/cm ³)	4.51				
Relative density	n.a.				
Solubility (% by weight)	n.a.				
Octanol/water partition	n.a.				
coefficient					

10. STABILITY AND REACTIVITY n.a.

11. TOXICOLOGICAL INFORMATION Acute toxicity:

Primary irritation:

skin: no irritating effect eye: no irritating effect

Additional toxicological information: When used and handled according to instructions, the product does, to our experience and the information provided to us, not have any harmful effects.

12. ECOLOGICAL INFORMATION n.a.

<u>13. DISPOSAL CONSIDERATIONS</u> Dispose of according to Federal, State and Local regulations. Small, not used quantities can be disposed of as household waste. If used, dispose of as contaminated goods.

14. TRANSPORT INFORMATIONn.a.Land transport ADR, RID: --Maritime transport: IMDG-Code: --Air transport ICAO-TI/IATA-DGR: --

15. REGULATORY INFORMATION Product is CE marked.

Classification according to EC-guidelines: The product is a medical device according to EC-directive 93/42 EEC.

Chemical safety assessment:

A Chemical Safety Assessment has not been carried out.

<u>16. OTHER INFORMATION</u> This product shall be handled and used according to manufacturer's instructions. Adaptation according to 1907/2006/EG, Article 31

Approved by:	Jaan Roosaar
Approval date:	2015-11-03