Service life of dental alloys	
Systematic title based on use descriptor	SU21, AC7, ERC 10a, 11a (Service life of substances in articles) SU14, SU20 (downstream use leading to inclusion in article)
Processes, tasks activities covered	Service life of dental alloys in the patient's mouth. Accidental swallowing
2. Operational conditions and risk management measures	
Compliance with the essential requirements of the Medical Devices Directive 93/42/EEC as amended by MDD 2007/47/EC – Metallic materials for fixed and removable restorations and appliances.	
2.1 Control of consumers exposure	
Product (article) characteristic	
Product Description	Cobalt chromium based metal casting alloys are used for "removable dental applications?such as crowns, bridges and partial dentures. They are classified according to ISO 22674:2006 as type 3, 4 and 5. The alloy is casted into a plate or the shape of a tooth and may then be covered with ceramic (covered/uncovered)
Amount of substance in article	Up to 65% Cobalt in the dental alloys.
Density of dental alloy	8.4 g/cm³
Release rate (R)	Artificial plaque solution acc. to ISO 10271:2001: Typical: <2 µg Co/cm/7 days (measured data) = 0.29 µg Co/cm/d or 0.012 µg Co/cm/h
Surface area (S)	Surface area (S) of dental appliance in the mouth 1 - 40 cm^2 depending on the kind of application (estimate) Typical: 20 cm^2(estimate)
Amounts used	
Up to 65% Cobalt in the dental alloys and up to 90g may be used for a dental appliance.	
Frequency and duration of use/exposure from service life	
Service life of dental appliance: 24h/7days/week	
Human factors not influenced by risk management	
Service life of dental appliance: Adult/adolescent; Body weight: 60 kg; exposed body parts: Finger tips (4)	
Other given operational conditions affecting consumers exposure from article service life	
Secretion of saliva : 0.6 – 1.5 L/day ; Typical: 1L	
Conditions and measures at level of article production to prevent release during service life	
Assure that the dental alloy complies with Medical Devices Directive 93/42/EEC as amended by MDD 2007/47/EC. Furthermore, dental alloy shall only be used by properly qualified and experienced personnel and should not be used outside of the scope of its intended use as defined herein, and as per established acceptable practice in the dental profession.	
Conditions and measures related to information and behavioural advice to consumers	
Not applicable.	
Conditions and measures related to personal protective equipment and hygiene	
Not applicable.	
2.2 Control of environmental exposure	
Product (article) characteristic	
Cobalt can be in any form in an article.	
Amounts used	
Not applicable.	
Frequency and duration of use/exposure from service life	
Continuous use/release: 365 days/year.	
Environment factors not influenced by risk management	
Flow rate of receiving surface should be sufficiently high to dilute the effluent concentration of the STP below the PNEC (Water/ Sedimentation).	
Other given operational conditions affecting environmental exposure	
Indoor or outdoor use of products containing cobalt is possible. There are no intended Co releases due to wide dispersive use and the non-intended releases are negligible and pose no threat to the environment.	
Conditions and measures related to municipal sewage treatment plant	
Presence of municipal sewage treatment plant.	

Conditions and measures related to disposal of articles at end of service life

Fraction of daily/annual use expected in waste: 60% of all articles, 40% is recycled. (EC, 2010)
Appropriate waste codes: 20 01 34; 20 01 33; 20 01 40; 20 03 01; 20 03 07
Suitable Disposal: Waste from end-of-life articles can be disposed of as municipal waste, except when they are separately regulated, like electronic devices, batteries, vehicles, etc. Disposal of wastes is possible via incineration (Directive 2000/76/EC) or landfilling (BAT Reference Document 2006, Council Directive 1999/31/EC and Council Decision 19/12/2002).

Conditions and measures related to recovery of articles at the end of service life

Shredders pre-treating metal wastes maximum release factors to air of 0.0015 after RMM and no releases to water and soil.

3. Exposure estimation and reference to its source

The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective Derived No Effect Level (DNEL) and is given in brackets below. For oral exposure, the RCR is based on the chronic, systemic DNEL for cobalt of 9.5 µg Co/kg bw/day. Due to the sensitising properties of cobalt, dermal exposure has to be avoided.

Human exposure prediction

Service life of dental alloys after installation

Exposure route	Exposure assessment instrument/tool/method
Oral	Typical: 0.097 µg/kg bw/d (0.01); Release rate (R) * Surface area (S) / body weight adult
Dermal/ Mucous membranes	Negligible. Qualitative assessment: The dermal contact to the dental appliance will be short during the removal of the appliance; the predominant skin contact is with the saliva film on the appliance. Furthermore, mucous membranes are constantly in contact with saliva. Note: Co concentration in salvia expected to be low (an appliance w surface area of up to 20cm^2 release rate of 0.012 µg/cm/h typical salvia production of 1L per day, permanent swallowing).
Inhalation	Not to be expected. Qualitative assessment: Vapour pressure of cobalt is low, no processes at high temperatures or dust generating tasks are expected.

Accidental ingestion of dental alloys

The dental appliances are made from a cobalt based alloy which conforms to the Medical Devices Directive 93/42/EEC as amended by MDD 2007/47/EC (MDD). This directive invokes compliance to the essential requirements which ensure the safe use of the dental appliances. The standard ISO 22674:2006 classifies metallic materials that are suitable for the fabrication of dental appliances and restorations and adherence to this standard will ensure compliance to the MDD.
Accidental swallowing of pieces does not need to be considered.

Environmental exposure prediction

Note: The measures reported in this section have not been taken into account in the exposure estimates related to the exposure scenario above. They are not subject to obligation laid down in Article 37 (4) of REACH. Thus, the downstream user is not obliged to i) carry out an own CSA and ii) to notify the use to the Agency, if he does not implement these measures.

4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

Consumer exposure

The DU complies with the conditions set in this exposure scenario, if the dental alloy has a declaration of compliance to the Medical Devices Directive 93/42/EEC as amended by MDD 2007/47/EC by the OEM and the values for release rate as well as the surface area of the dental appliance are not exceeded. Optional an own assessment can be performed using the release rate from the EN ISO 22674 testing and the equation given above. The exposure estimate needs to be below the DNEL oral, systemic of 9.5 µg/kg/d.

Environmental emissions

Note: The measures reported in this section have not been taken into account in the exposure estimates related to the exposure scenario above. They are not subject to obligation laid down in Article 37 (4) of REACH. Thus, the downstream user is not obliged to i) carry out an own CSA and ii) to notify the use to the Agency, if he does not implement these measures.