15. ES 15: Service life (consumers); dental alloys

15.1. Title section

Article category: Metal articles (AC 7)

Environment	
1: Service life of dental alloys	ERC 10a, ERC 11a
Consumer	
2: Service life of dental alloys after installation	AC 7
Exposure scenario of the uses leading to the inclusion of the substance into the article	
ES 7: Use at industrial sites; Various products; Various sectors; Production and industrial use of cobalt containing alloys, steels and tools	

15.2. Conditions of use affecting exposure

15.2.1. Control of environmental exposure: Service life of dental alloys (ERC 10a, ERC 11a)

Conditions and measures related to external treatment of waste (including article waste)
Dispose of waste product or used containers according to local regulations.
Other conditions affecting environmental exposure
Municipal sewage treatment plant is assumed.

15.2.2. Control of consumer exposure: Service life of dental alloys after installation (AC 7)

Product (article) characteristics
Covers a release rate in artificial plaque solution acc. to ISO 10271:2001 of up to 2 µg Co/cm²/7 days.
Physical form covered in this ES: massive object
Inhalation exposure is considered to be not relevant.
Amount used (or contained in articles), frequency and duration of use/exposure
Duration of contact = 24 hr
Use frequency = 365 events/year
Other conditions affecting consumers exposure
Covers adult use
Covers a surface area of a dental appliance of up to 20 cm².

15.3. Exposure estimation and reference to its source

15.3.1. Environmental release and exposure: Service life of dental alloys (ERC 10a)

Release route	Release rate	Release estimation method
Water	0 kg/day	Estimated release factor
Air	0 kg/day	Estimated release factor
Soil	0 kg/day	Estimated release factor

15.3.2. Consumer exposure: Service life of dental alloys after installation (AC 7)

Route of exposure and type of effects	Exposure estimate	RCR
Inhalation, local, long term	0 mg/m³ (Qualitative assessment)	< 0.01
Oral, systemic, long term	0.097 µg/kg bw/day (Quantitative assessment)	< 0.01

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

Guidance: 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.