

# Material Information HeraeniumSun Lot 1

(according to EN ISO 9333)

## Chemical Composition (Content in mass %):

HeraeniumSun Lot 1	Co	Fe	Cr	Si	Mo	B	Mn
	27,1	41,6	21,8	5,4	2,7	1,0	0,4

This solder is free of Beryllium, Cadmium and Lead.

**Manufacturer:** Kulzer GmbH

**Bio-compatibility:** We certify that this product has been evaluated according to the internationally valid directives EN ISO 7405, "Dentistry – Evaluation of biocompatibility of medical devices used in dentistry" – and EN ISO 10993 series, "Biological evaluation of medical devices". The evaluation covers, among other things, possible risk of cytotoxicity, allergisation, irritation, and genotoxicity. The studies conducted were carried out in independent testing facilities according to OECD directives and fulfil the requirements of GLP (Good Laboratory Practice). The evaluation proves the biological compatibility of this dental solder.

**Corrosion:** Corrosion testing was carried out at Kulzer's testing facility according to the EN ISO 9333 : "Dentistry – Hard solders", test of corrosion-resistance, test media: 0,1 molar lactic acid / common salt solution, 7 days at 37°C." The dental solder showed no signs of chemical corrosion.

**Evaluation:** Based on the above test and evaluation, this solder is classified as biocompatible (biologically compatible) when used as intended. A clinical evaluation proved that specified characteristics and performance related requirements are fulfilled.

**The conformity of HeraeniumSun Lot 1 with internationally valid directives is proven and certified by the Technical Control Board of Rheinland (CE 0197). This document is subject to an internal approval process. It was created electronically and is valid without signature.**

### Contact in Germany

Kulzer GmbH  
Leipziger Straße 2  
63450 Hanau, Germany  
info.lab@kulzer-dental.com  
kulzer.com

Giving a hand to oral health.



**KULZER**  
MITSUI CHEMICALS GROUP