

Certificate of Biocompatibility

Product: COJÍN MIMOS
Batch N°: 17-P043
Company: THINK PIPE LINE S.L.
Result: BIOCOMPATIBLE
 (no cytotoxic, no irritant, no sensitizer)

Study / Parameter	Method / Directive	Acceptance criteria	Results
92617 / In vitro cytotoxicity	Cell viability in vitro by MTT and NRU / ISO-10993-5, ISO-10993-12	Viability >90% (negative control) y ≤10% (positive control)	NO CYTOTOXIC Viability (%) in Balb/c 3T3 clon A31 mouse cells in presence of 8 concentrations (0.59–10%) of extract, for 24 hours: No cellular morphological changes <i>Viability MTT: 96.76 – 115.22%</i> <i>Viability NRU: 84.70 – 97.48%</i>
92717 / In vitro dermical irritation	Cell viability by MTT and IL-1 α measurement / OECD TG 439, ISO-10993-12	Mean OD >0.6% and deviation < 18 (negative control), mean viability <40% and deviation <18 (positive control) and IL-1 α <60 pg/mL	NO IRRITANT Viability (%) in reconstructed skin epidermis in presence of the extract at concentrations of 25, 50 y 100%: <i>Viability MTT: 98.50 – 100.26%</i> <i>IL-1α: <BLOQ – 30.72 pg/mL</i>
92817 / In vitro sensibilization	Cell viability and mean of CD86 y CD54 expression / OECD TG 442E, ISO-10993-12	Viability >90% (negative control), RFI (solvent) <150 (CD86) and <200 (CD54), RFI (positive) ≥150 (CD86) and ≥200 (CD54), extract viability >50% in 4 concentrations, MFI ratio CD86 and CD54 >105% of medium and solvent and ≤10% of positive control	NO SENSITIZER Cytotoxicity (%) THP-1 human monocytic leukemia cells in presence of 8 concentrations (2.8–10%) of extract: <i>Viability: 96.4–97.5%</i> <i>RFI CD86: 84–111%</i> <i>RFI CD54: 82–96%</i>

Date: 3rd July 2018



Javier González (Study director)

* The information contained in this certificate is part of reports 92617, 92717 and 92817 carried out by UTOX-PCB / CERETOX under good laboratory practices."