

# DERMACYN® WOUND CARE

## TOXICITY AND STABILITY TEST RESULTS

STUDY	GUIDELINE	RESULTS
Skin Irritation	ISO 10993-10	Irritation response category: negligible
Ocular Irritation	ISO 10993-10	No positive irritation response
Acute Oral Toxicity	US EPA OPPTS 870.1100	No observable abnormalities LD <sub>50</sub> > 5000 mg/kg
Acute Dermal Toxicity	US EPA OPPTS 870.1200	No observable abnormalities LD <sub>50</sub> > 5000 mg/kg
Acute Inhalation Toxicity	US EPA OPPTS 870.1300	No observable abnormalities LD <sub>50</sub> > 5000 mg/kg
Dermal Sensitization	US EPA OPPTS 870.2600	No sensitizing reaction
Cytotoxicity (in-vitro)	ISO 10993-5	Non-toxic, grade 0 - in the MEM elution, and Agar overlay methods
Systemic Toxicity	ISO 10993-5	No indication of systemic toxicity, performed the same as negative control
Stability	Real-time and accelerated aging	Shelf life of one year from date of manufacture

Dermacyn® Wound Care is manufactured under Good Manufacturing (cGMP) requirements set forth by the US Food and Drug Administration (FDA) and ISO 13485:2003 standards.

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