

Diphotérine® : Safety Tests

Test	Results	References
Ocular irritation	Non irritant	test n°133/4, in the rabbit, Safepharm Laboratories Limited, UK, 1987
<i>In vitro</i> Evaluation of the eye irritation potential of a medical device	No cytotoxic or irritant potential to the eye after a short (10 minutes) or prolonged (24 hours) time of contact	Test n°REL/032/05/IRRO/ELB, on human fibroblast cultures, test Integra, Italy, 2005
Cutaneous irritation	Non irritant	test n°2005-024, <i>in vitro</i> , Dermal Irritection® test method, Integra, Italy, 2005
Ocular irritation of a residue of a rinsing of an acid with Diphotérine®	Non irritant	Test n°6463 TAL, in the rabbit, hydrochloric acid, Centre International de Toxicologie, France, 1990
Ocular irritation of a residue of a rinsing of a base with Diphotérine®	Non irritant	Test n°6462 TAL, in the rabbit, sodium hydroxide, Centre International de Toxicologie, France, 1990
Oral toxicity	Oral LD ₅₀ > 2000 mg/kg ; non toxic, no death, normal evolution of weight, no abnormality at necropsy	test n°6564 TAR, in the rat, Centre International de Toxicologie, France, 1990
Acute dermal Toxicity	Acute dermal LD ₅₀ > 2000 mg/kg; non toxic, no death, no sign of systemic toxicity or dermal irritation, normal evolution of weight, no abnormality at necropsy	test n°133/9, in the rat, Safepharm Laboratories Limited, UK, 1988
Sensitisation	Non sensitising	test n°20030418ST, Magnusson and Kligman method, in the Guinea pig, OECD 406, CERB, France, 2003 (15)
Mutagenesis	Non mutagenic ; negative Ames test	test n°29023 MMT, Bacterial reverse mutation Test on <i>Salmonella typhimurium</i> TA 1535, TA 1537, TA98, TA 100et TA 102, <i>Escherichia Coli</i> WP2 uvrA, Centre International de Toxicologie, France, 2005
Cytotoxicity	Non cytotoxic	test n°REL/003/06/IRRC/ELB, ISO 10993-5 standard, Integra, Italy, 2006
Anti-inflammatory potential	Non anti-inflammatory ; no cytotoxic or irritant effect observed on a 3D human epidermidis model	test n°REL/011/06/FUNZ/ELB, MTT <i>in vitro</i> tests + pro-irritation potential IL-1 α , Integra, Italy, 2006