

IRRISEPT® Wound Debridement and Cleansing System

FDA-Required Safety Studies

STUDY TITLE	PURPOSE	SUMMARY	CONCLUSION
Cytotoxicity Assay in L-929 Mouse Fibroblast Cells for Liquids	Evaluate IRRISEPT cytotoxicity in a mammalian cell line.	Cultures of L-929 cells (mouse fibroblast) were plated with IRRISEPT and positive and negative controls for a period of 72 hours. Cultures were evaluated for cytotoxic effects by microscopic evaluation after 24, 48 and 72± hour incubation period. At all evaluations, IRRISEPT was rated as “mildly reactive” with no signs of extensive cell lysis. Positive and negative controls displayed complete and no cell lysis, respectively.	IRRISEPT 450mL is considered non-cytotoxic under the conditions of this test.
ISO Intracutaneous Reactivity Test (Albino rabbits, New Zealand White strain, female)	To determine if IRRISEPT causes local irritation in the dermal tissue of rabbits.	Each rabbit received intracutaneous injections of IRRISEPT and control. The animals were observed daily for abnormal clinical signs. The appearance of each injection site was noted at 24 ±2, 48 ±2, and 72±2 hours post injection. The tissue reactions were rated for gross evidence of erythema and edema. None of the animals on study showed abnormal clinical signs during the 72 hour test period.	IRRISEPT 450mL would be considered a non-irritant under the conditions of this test.
Rat Wound Model to Determine Wound Irritation Resulting from a Wound Irrigation Solution	To compare wound irritation that might develop in response to irrigation with IRRISEPT and Saline (control)	Two full dermal thickness wounds were surgically created on either side of the spine. Each wound was immediately irrigated for ten seconds with either test (IRRISEPT) or control (Saline). The test article sites were rinsed with saline for ten seconds following irrigation. At 24, 48, and 72 ±2 hours, wounds were evaluated and scored for erythema and edema. Other adverse changes at the wound sites were recorded and reported. None of the animals on study showed abnormal clinical signs during the 72 hour test period.	IRRISEPT 450mL would be considered a non-irritant under the conditions of this test.
ISO Guinea Pig Maximization Sensitization Test Method for Liquid Test Articles	To evaluate the allergenic potential or sensitizing capacity of IRRISEPT.	Test animals were injected with IRRISEPT™ and saline control. One week later, the animals were topically patched with IRRISEPT and controls for a period of 48±2 hours. Following a two-week rest period, the animals were topically patched again for 24 ± 2hours. The dermal patch sites were observed for erythema and edema 24 ± 2 and 48 ±2 hours after patch removal. None of the animals in the study showed abnormal clinical signs during the test period	IRRISEPT 450mL did not elicit a sensitization response under the conditions of this test.