ISOCLAST™ ACTIVE MAMMALIAN TOXICOLOGY

Isoclast™ active demonstrates low acute mammalian toxicity

Isoclast™ active exhibits low acute mammalian toxicity, and is non-genotoxic. Results from subchronic and chronic toxicity studies revealed the liver to be the primary target organ with effects of limited concern or no relevance to humans. Rat-specific neonatal effects occurred, but they did not occur in rabbits and are not relevant to humans. Chronic studies in rats and mice resulted in liver tumors after a lifetime of exposure to Isoclast. However, the underlying mechanism is well understood and Isoclast is considered to be non-carcinogenic to humans. Based on available data, use of Isoclast in the manner consistent with label directions represents low risk to humans.

Study	Animal or Test System	Results
Acute oral LD(50)	Rat	1,000 mg/kg
Acute dermal LD(50)	Rat	>5,000 mg/kg
Acute inhalation LC(50)	Rat	>2.09 mg/L
Dermal irritation	Rabbit	Minimal
Eye irritation	Rabbit	Slight
Skin sensitization	Mouse	None
4-week dietary exposure	Rat	NOAEL = 24.8 mg/kg bw/d
13-week dietary exposure	Rat	NOAEL = 6.36 mg/kg bw/d
4-week dermal exposure	Rat	NOAEL = 1,000 mg/kg bw/d
Developmental toxicity	Rat	NOAEL = 11.5 mg/kg bw/d
Genotoxicity	Ames test Chromosomal aberration Mouse micronucleus (in vivo)	Negative Negative Negative
Acute neurotoxicity	Rat	NOAEL = 25 mg/kg bw/d

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