

In-life Observations at the Application Site in Mice in the Two-year Dermal Study of Triclosan

Observation	Sex	Dose group	Incidence	Comment
Cuts	Male	Untreated control	2/48	Cuts were characterized as “slight”, with some being “moderate”. In all instances the cuts were resolved before study termination. The cuts were not attributed to triclosan or vehicle administration.
		Vehicle control	8/48	
		1.25 mg/kg/day	2/48	
		2.7 mg/kg/day	15/48	
		5.8 mg/kg/day	1/48	
		12.5 mg/kg/day	3/48	
	Female	Untreated control	2/48	
		Vehicle control	3/48	
		1.25 mg/kg/day	3/48	
		2.7 mg/kg/day	3/48	
		5.8 mg/kg/day	3/48	
		12.5 mg/kg/day	3/48	
Dark pigmentation	Male	Untreated control	4/48	This lesion was considered to be related to the vehicle. The lesion occurred early (~study day 30) and was resolved by ~study day 60.
		Vehicle control	48/48	
		1.25 mg/kg/day	46/48	
		2.7 mg/kg/day	24/48	
		5.8 mg/kg/day	18/48	
		12.5 mg/kg/day	33/48	
	Female	Untreated control	4/48	
		Vehicle control	15/48	
		1.25 mg/kg/day	36/48	
		2.7 mg/kg/day	29/48	
		5.8 mg/kg/day	11/48	
		12.5 mg/kg/day	9/48	
Dry skin	Male	Untreated control	1/48	This condition either did not occur or occurred at a low incidence except in the 12.5 mg/kg/day dose groups. In male mice, the condition tended to occur late (>300 days) and either resolved or was present at study termination. In female mice, the condition occurred earlier than in males, and tended to resolve before study termination.
		Vehicle control	1/48	
		1.25 mg/kg/day	1/48	
		2.7 mg/kg/day	3/48	
		5.8 mg/kg/day	3/48	
		12.5 mg/kg/day	12/48	
	Female	Untreated control	0/48	
		Vehicle control	0/48	
		1.25 mg/kg/day	0/48	
		2.7 mg/kg/day	0/48	

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		5.8 mg/kg/day	4/48	
		12.5 mg/kg/day	14/48	
Flaking	Male	Untreated control	0/48	This condition either did not occur or was present at a low incidence except for in 12.5 mg/kg/day female mice. The condition tended to be resolved before study termination.
		Vehicle control	1/48	
		1.25 mg/kg/day	0/48	
		2.7 mg/kg/day	4/48	
		5.8 mg/kg/day	2/48	
		12.5 mg/kg/day	5/48	
	Female	Untreated control	0/48	
		Vehicle control	0/48	
		1.25 mg/kg/day	0/48	
		2.7 mg/kg/day	0/48	
		5.8 mg/kg/day	4/48	
		12.5 mg/kg/day	12/48	
Scratches	Male	Untreated control	2/48	This condition appeared to be dose-related in both sexes. In most instances it was resolved before study termination.
		Vehicle control	4/48	
		1.25 mg/kg/day	3/48	
		2.7 mg/kg/day	19/48	
		5.8 mg/kg/day	15/48	
		12.5 mg/kg/day	15/48	
	Female	Untreated control	0/48	
		Vehicle control	1/48	
		1.25 mg/kg/day	2/48	
		2.7 mg/kg/day	4/48	
		5.8 mg/kg/day	10/48	
		12.5 mg/kg/day	15/48	
Sore	Male	Untreated control	2/48	This condition occurred at a low incidence and was not attributed to triclosan or vehicle administration.
		Vehicle control	2/48	
		1.25 mg/kg/day	3/48	
		2.7 mg/kg/day	5/48	
		5.8 mg/kg/day	4/48	
		12.5 mg/kg/day	6/48	
	Female	Untreated	0/48	
		Vehicle	3/48	
		1.25 mg/kg/day	2/48	
		2.7 mg/kg/day	0/48	

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		5.8 mg/kg/day	0/48	
		12.5 mg/kg/day	1/48	
Tissue mass	Male	Untreated control	2/48	The size of the mass typically did not change with time. The lesion resolved before study termination.
		Vehicle control	34/48	
		1.25 mg/kg/day	14/48	
		2.7 mg/kg/day	10/48	
		5.8 mg/kg/day	8/48	
		12.5 mg/kg/day	5/48	
	Female	Untreated control	1/48	
		Vehicle control	4/48	
		1.25 mg/kg/day	0/48	
		2.7 mg/kg/day	0/48	
		5.8 mg/kg/day	0/48	
		12.5 mg/kg/day	0/48	