

対照群の生存率と腫瘍発生状況 : B6.129-Trp53tm1Brdマウス (TACONIC) を用いた26週～45週間試験
(米国NTP2005～2013年)

NTP report	Route	Survival rate								Total tumor incidence								Remarks
		26-30 week				40-45 week				26-30 week				40-45 week				
		♂		♀		♂		♀		♂		♀		♂		♀		
No.of mice	%	No.of mice	%	No.of mice	%	No.of mice	%	No.of mice	%	No.of mice	%	No.of mice	%	No.of mice	%	No.of mice	%	
1	feed	-	-	-	-	14/15	93	14/15	93	-	-	-	-	0/15	0	4/15	0.267	STUDY RATIONALE The vast majority of studies utilizing genetically modified mice for cancer hazard identification have employed a dosing duration of 6 months, after which mice are examined for tumor development. Although this may be adequate to identify relatively potent carcinogens, there is uncertainty over the adequacy of this dosing duration to produce a tumor response with weaker carcinogens. To partially address this question, the current studies were carried out for 9 months rather than 6 months.
2	feed	-	-	-	-	14/15	93	14/15	93	-	-	-	-	0/15	0	1/15	6.7	
5	drinking	15/15	100	15/15	100	9/10	90	9/10	90	2/15	13.3	1/15	6.7	1/10	10	3/10	20	
	gavage	15/15	100	15/15	100	10/10	100	9/10	90	0/15	0	0/15	6.7	3/10	30	1/10	10	
6	drinking	14/15	93	14/15	93	9/10	90	9/10	90	1/15	6.7	2/15	6.7	1/10	10	3/10	30	
7	gavage	-	-	-	-	15/15	100	13/15	87	-	-	-	-	0/15	0	4/15	26.7	
9	dermal	-	-	15/15	100	-	-	-	-	-	-	0/15	0	-	-	-	-	
10	dermal	-	-	15/15	100	-	-	-	-	-	-	0/15	6.7	-	-	-	-	Skin (application site) : hyperplasia, epidermis ** Vehicle control group; 0/15 High dose group; 8/15
11	drinking	15/15	100	15/15	100	9/10	90	10/10	100	0/15	0	1/15	6.7	1/10	10	0/10	0	
14	gavage*	27/27	100	24/27	89	24/27	89	23/26	88	1/27	3.704	4/26	15.4	8/27	0.3	4/26	15.4	30 week study Male: Equivocal evidence carcinogenicity Female: No evidence carcinogenicity 45 week study Male: Clear evidence carcinogenicity Female: Equivocal evidence carcinogenicity
15	feed	-	-	-	-	25/25	100	23/25	92	-	-	-	-	3/25	12	6/25	24	
16	gavage*	-	-	-	-	20/25	80	25/25	100	-	-	-	-	7/25	28	4/25	16	Male: Clear evidence carcinogenicity Female: Equivocal evidence carcinogenicity
Mean			98.6		97.4		92.5		92.3		4.7		7.0		10.0		14.9	

*: In utero and postnatal gavage study

** : SUMMARY OF TECHNICAL REPORTS REVIEW SUBCOMMITTEE COMMENTS (excerpt from technical report)

Dr. Sikka inquired why the study durations were shorter than in some other GMM studies reported. Dr. Chhabra replied that the ideal study duration was being developed at the time the studies started; often papillomas were seen as early as 9 weeks for positive controls. Dr. J.R. Bucher, NIEHS, added that subsequent information has indicated that 9 months was closer to the optimum duration for maximizing study sensitivity.