

Telomer Research Program

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Report Title: Purified 8-2 Alcohol: *Salmonella* – *Escherichia coli*/Mammalian – Microsome Reverse Mutation Assay with a Confirmatory Assay

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Study Dates:

Initiation: October 23, 2001

In Life: October 29, 2001 – December 10, 2001

Completion: February 11, 2002

Study Objective: To evaluate the test article for the ability to induce reverse mutations at the histidine locus in several strains of *Salmonella typhimurium* (TA98, TA100, TA1535, and TA1537), and at the tryptophan locus in *Escherichia coli* tester strain WP2uvrA in the presence or absence of an exogenous metabolic activation system (S9 microsomes).

Materials and Methods: The tester strains were exposed to the test article via plate incorporation both with and without the S9 mix. All doses (including a vehicle and positive control) were plated in triplicate. The plates were incubated for 52±4 hr at 37±2°C prior to counting using an automated colony counter. Criteria were in place to assure assay validity. To be considered positive, the test article needed to produce at least a 2-fold increase in the mean number of revertants per plate over the appropriate vehicle control.

Findings: No increase in revertants was seen in any of the tester strains. Data table follows.

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Mean Revertants Per Plate with Standard Deviation

Dose/Plate	TA98		TA100		TA1535		TA1537		WPV _{uvrA}	
	Mean	S.D	Mean	S.D.	Mean	S.D.	Mean	S.D.	Mean	S.D.
Microsome: Rat Liver Vehicle Control (DMSO)	30	3	117	7	13	5	8	2	15	11
Test Article 33.3 µg	29	4	102	11	16	1	10	5	15	4
100 µg	24	4	109	8	10	1	8	3	19	0
333 µg	29	10	103	14	12	3	10	1	14	6
1000 µg	31	4	117	2	15	5	9	3	16	9
3330 µg	32	12	106	8	16	3	11	3	20	2
5000 µg	34	9	116	5	13	4	11	2	20	1
Positive Control ^a	543	31	1041	53	148	15	169	18	256	33
Microsomes: None Vehicle Control (DMSO)	15	9	97	16	13	4	5	2	16	2
Test Article 33.3 µg	14	4	82	10	12	6	6	3	16	3
100 µg	15	3	79	8	11	5	6	4	16	1
333 µg	16	7	90	6	12	2	7	4	10	3
1000 µg	18	2	94	4	9	2	8	2	11	2
3330 µg	21	9	92	18	14	4	7	5	17	6
5000 µg	16	5	95	2	14	3	6	3	21	4
Positive Control ^b	205	12	999	44	633	47	943	106	125	35
^a TA98	benzo[a]pyrene		2.5 µg/plate		^b TA98	2-nitrofluorene		1.0 µg/plate		
TA100	2-aminoanthracene		2.5 µg/plate		TA100	sodium azide		2.0 µg/plate		
TA1535	2-aminoanthracene		2.5 µg/plate		TA1535	sodium azide		2.0 µg/plate		
TA1537	2-aminoanthracene		2.5 µg/plate		TA1537	ICR-191		2.0 µg/plate		
WP2 _{uvrA}	2-aminoanthracene		25.0 µg/plate		WP2 _{uvrA}	4-nitroquinolone-N-oxide		1.0 µg/plate		

Conclusion: Purified 8-2 Alcohol was not mutagenic in this test system.

Publications / Presentations:

A) Covance Study 22900-0-409 OECD, Dated 2/11/02.

B) Results cited in: Kennedy, G. L., Jung, R., Iwai, H., Shin-Ya, S., Murphy, S., Drouot, N., Finlay, C., Donner, M., Erexson, G., and Stankowski, L., Jr., "Genetic Toxicology of 8-2 Telomer B Alcohol", Toxicol. Sci. 72(S-1):209:2003.