

Table 29 Blood Chemistry - Summary

Test Substance Dose(mg/kg)	Female																		
	ASAT(GOT)		ALAT(GPT)		γGT		ALP		Total Bilirubin mg/dL		Urea Nitrogen mg/dL		Creatinine mg/dL		Glucose mg/dL		Total Cholesterol mg/dL		
	U/L		U/L		U/L		U/L		mg/dL		mg/dL		mg/dL		mg/dL		mg/dL		
		Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57
1, 3-BAC 0	Mean	143.8	126.2	45.2	21.2	1.2	1.2	260.8	151.4	0.10	0.10	17.76	17.00	0.34	0.42	122.8	123.4	60.4	73.0
	S.D.	25.1	18.0	8.1	3.7	0.8	1.3	81.8	19.4	0.00	0.00	2.47	4.43	0.05	0.04	11.9	19.7	5.0	4.6
	n	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
1, 3-BAC 10	Mean	151.2		52.6		2.0		221.4		0.06		20.66		0.36		116.8		69.8	
	S.D.	10.8		11.9		0.7		34.4		0.05		0.61		0.05		6.5		19.2	
	n	5		5		5		5		5		5		5		5		5	
1, 3-BAC 60	Mean	107.0*		44.6		2.0		240.6		0.10		18.84		0.40		139.2		53.8	
	S.D.	6.4		9.2		0.0		49.1		0.00		2.97		0.00		14.9		8.1	
	n	5		5		5		5		5		5		5		5		5	
1, 3-BAC 300	Mean	140.6	119.2	63.6*	29.8	1.8	1.0	358.6	197.0*	0.06	0.10	18.12	16.66	0.32	0.42	111.8	109.0	62.8	74.8
	S.D.	25.7	19.5	12.1	19.3	1.1	0.0	146.9	30.6	0.05	0.00	2.64	3.05	0.04	0.04	9.4	11.3	7.5	17.0
	n	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5

Significantly different from control : *, P<0.05; **, P<0.01.

Table 29 Blood Chemistry - Summary

Female

Test Substance Dose (mg/kg)		Triglyceride		Total Protein		Albumin		A/G Ratio		Calcium		Inorganic Phosphorus		Na		K		Cl	
		mg/dL		g/dL		g/dL				mg/dL		mg/dL		mmol/L		mmol/L		mmol/L	
		Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57
1, 3-BAC 0	Mean	62.2	13.0	6.80	7.26	3.14	3.50	0.862	0.936	11.04	10.08	10.02	6.54	145.8	145.4	4.56	4.30	102.2	104.0
	S.D.	39.7	4.1	0.39	0.60	0.21	0.37	0.063	0.052	0.13	0.61	0.70	0.87	0.8	1.5	0.30	0.37	0.4	2.0
	n	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
1, 3-BAC 10	Mean	49.4		6.98		3.18		0.836		11.22		10.00		145.0		4.70		101.6	
	S.D.	13.0		0.54		0.23		0.043		0.35		0.46		0.7		0.29		1.5	
	n	5		5		5		5		5		5		5		5		5	
1, 3-BAC 60	Mean	67.0		6.80		3.26		0.926		10.94		9.72		146.4		4.46		102.4	
	S.D.	8.0		0.10		0.11		0.027		0.38		0.48		0.5		0.09		0.9	
	n	5		5		5		5		5		5		5		5		5	
1, 3-BAC 300	Mean	54.4	10.8	6.34	7.34	2.98	3.66	0.882	0.994	10.84	9.94	10.18	6.28	145.2	145.6	4.90	4.04	102.4	105.0
	S.D.	24.8	5.5	0.38	0.62	0.22	0.45	0.054	0.097	0.42	0.34	1.24	0.83	1.5	1.5	0.14	0.38	2.1	1.2
	n	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5

Significantly different from control

: *, P<0.05; **, P<0.01.

Table 30 Urinalysis - Summary Male

Test Substance Dose (mg/kg)	pH										Protein					Glucose					Ketones					Bilirubin				Occult Blood				
	5.0	5.5	6.0	6.5	7.0	7.5	8.0	8.5	>=9		-	+/-	1+	2+	3+	-	+/-	1+	2+	3+	-	+/-	1+	2+	3+	-	1+	2+	3+	-	+/-	1+	2+	3+
Day 38											Day 38					Day 38					Day 38					Day 38								
1, 3-BAC 0																																		
n	0	0	0	0	0	0	0	1	4	0	0	3	2	0	5	0	0	0	0	0	0	5	0	0	5	0	0	0	5	0	0	0	0	
1, 3-BAC 10																																		
n	0	0	0	0	0	0	0	1	4	0	0	4	1	0	5	0	0	0	0	0	3	2	0	0	5	0	0	0	5	0	0	0	0	
1, 3-BAC 60																																		
n	0	0	0	0	0	0	0	1	4	0	0	4	1	0	5	0	0	0	0	0	0	4	1	0	5	0	0	0	5	0	0	0	0	
1, 3-BAC 300																																		
n	0	0	0	0	0	0	0	3	2	1	3	1	0	0	5	0	0	0	0	0	4	1	0	0	5	0	0	0	5	0	0	0	0	

Significantly different from control : *, P<0.05; **, P<0.01.

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Table 30 Urinalysis - Summary

Male

Test Substance Dose(mg/kg)	Urobilinogen				
	EU/dl				
	0.1	1.0	2.0	4.0	>=8
Day 38					
1, 3-BAC 0					
n	5	0	0	0	0
1, 3-BAC 10					
n	5	0	0	0	0
1, 3-BAC 60					
n	5	0	0	0	0
1, 3-BAC 300					
n	5	0	0	0	0

Significantly different from control : *, P<0.05; **, P<0.01.

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Table 31 Organ Weight - Summary

Male

Test Substance Dose(mg/kg)		Final Body Weight		Brain		Thymus		Heart		Liver		Spleen		Kidneys		Adrenals		Testes	
		g		g		mg		g		g		g		mg		g			
		Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57
1, 3-BAC 0	Mean	446.0	489.6	2.084	2.054	340.0	261.4	1.572	1.542	10.672	12.154	0.732	0.808	2.854	2.960	56.60	61.88	3.343	3.326
	S.D.	38.8	42.5	0.052	0.079	46.1	32.5	0.156	0.160	1.098	1.589	0.096	0.178	0.364	0.279	4.90	6.23	0.152	0.374
	n	7	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	7	5
1, 3-BAC 10	Mean	445.0		2.040		368.8		1.542		11.244		0.716		2.772		57.40		3.309	
	S.D.	43.5		0.092		108.2		0.228		1.242		0.121		0.217		6.98		0.317	
	n	12		5		5		5		5		5		5		5		12	
1, 3-BAC 60	Mean	444.8		2.010		334.2		1.580		11.138		0.698		2.874		61.10		3.168	
	S.D.	46.1		0.071		78.5		0.243		1.958		0.121		0.387		6.81		0.228	
	n	12		5		5		5		5		5		5		5		12	
1, 3-BAC 300	Mean	397.5	456.0	2.024	2.078	281.4	317.2	1.350	1.542	9.832	11.702	0.738	0.820	2.762	2.844	70.88*	72.00	2.732	3.122
	S.D.	35.0	29.7	0.074	0.028	35.9	65.8	0.230	0.239	1.026	0.789	0.086	0.159	0.347	0.134	11.76	8.97	1.007	0.513
	n	6	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	6	5

Significantly different from control : *, P<0.05; **, P<0.01.

Table 31 Organ Weight - Summary

Male

Test Substance Dose (mg/kg)		Epididymides	
		g Day 43	Day 57
1, 3-BAC 0	Mean	1.247	1.352
	S. D.	0.051	0.075
	n	7	5
1, 3-BAC 10	Mean	1.248	
	S. D.	0.072	
	n	12	
1, 3-BAC 60	Mean	1.195	
	S. D.	0.081	
	n	12	
1, 3-BAC 300	Mean	1.058	1.256
	S. D.	0.250	0.116
	n	6	5

Significantly different from control

: *, P<0.05; **, P<0.01.

Table 32

Study No. B041798

Organ Weight - Summary (F0 Delivered-on Weaning)
Sex : Female

Test Substance Dose (mg/kg)		F. B. W. (g)	Brain (g)	Thymus (mg)	Heart (g)	Liver (g)	Spleen (g)	Kidneys (g)	Adrenals (mg)
1, 3-BAC 0	Mean	316.2	1.974	276.8	1.146	11.020	0.796	2.082	73.88
	S. D.	16.0	0.101	101.2	0.125	0.610	0.102	0.213	6.81
	n	5	5	5	5	5	5	5	5
1, 3-BAC 10	Mean	299.4	2.002	294.4	1.062	10.902	0.854	2.088	75.70
	S. D.	17.1	0.102	64.9	0.029	0.821	0.154	0.223	6.55
	n	5	5	5	5	5	5	5	5
1, 3-BAC 60	Mean	309.0	1.964	295.2	1.014	10.564	0.764	2.020	78.46
	S. D.	17.3	0.080	96.8	0.097	0.480	0.093	0.047	12.29
	n	5	5	5	5	5	5	5	5
1, 3-BAC 300	Mean	292.8	1.962	221.6	1.044	10.772	0.704	2.174	92.66
	S. D.	18.7	0.070	85.2	0.096	0.750	0.187	0.125	15.91
	n	5	5	5	5	5	5	5	5

Significantly different from control

: *, P<0.05; **, P<0.01.

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Table 33 Organ Weight - Summary

Female #

Test Substance Dose (mg/kg)		Final Body Weight	Brain	Thymus	Heart	Liver	Spleen	Kidneys	Adrenals
		g Day 57	g Day 57	mg Day 57	g Day 57	g Day 57	g Day 57	g Day 57	mg Day 57
1, 3-BAC 0	Mean	296.0	1.908	301.8	1.012	7.824	0.578	1.920	74.58
	S.D.	16.0	0.103	54.2	0.094	0.525	0.042	0.129	3.52
	n	5	5	5	5	5	5	5	5
1, 3-BAC 300	Mean	293.0	2.000	341.4	0.990	8.202	0.538	1.956	79.64
	S.D.	23.6	0.096	90.1	0.072	0.490	0.043	0.205	10.97
	n	5	5	5	5	5	5	5	5

Significantly different from control : *, P<0.05; **, P<0.01.
#:Satellite animal

Table 34 Relative Organ Weight - Summary

Male

Test Substance Dose (mg/kg)		Final Body Weight g		Brain		Thymus		Heart		Liver		Spleen		Kidneys		Adrenals		Testes				
		Day 43	Day 57	%	Day 57	$\times 10^{-3}$ %	Day 57	%	Day 43	Day 57	%	Day 43	Day 57	%	Day 43	Day 57	$\times 10^{-3}$ %	Day 43	Day 57	%	Day 43	Day 57
		Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	
1, 3-BAC 0	Mean	446.0	489.6	0.486	0.422	79.44	53.34	0.366	0.318	2.464	2.478	0.170	0.164	0.660	0.604	13.10	12.66	0.754	0.682			
	S.D.	38.8	42.5	0.023	0.047	15.19	3.84	0.037	0.042	0.107	0.186	0.031	0.026	0.069	0.038	1.07	0.68	0.046	0.067			
	n	7	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	7	5			
1, 3-BAC 10	Mean	445.0		0.474		87.40		0.354		2.596		0.164		0.638		13.28		0.746				
	S.D.	43.5		0.033		31.98		0.017		0.167		0.015		0.029		1.86		0.061				
	n	12		5		5		5		5		5		5		5		12				
1, 3-BAC 60	Mean	444.8		0.460		74.80		0.360		2.500		0.156		0.652		13.82		0.718				
	S.D.	46.1		0.065		11.53		0.052		0.157		0.005		0.086		1.23		0.085				
	n	12		5		5		5		5		5		5		5		12				
1, 3-BAC 300	Mean	397.5	456.0	0.514	0.456	71.76	69.98	0.342	0.338	2.480	2.568	0.188	0.178	0.696	0.626	17.84**	15.74**	0.705	0.686			
	S.D.	35.0	29.7	0.053	0.030	13.14	16.68	0.045	0.029	0.080	0.116	0.019	0.028	0.038	0.042	2.03	1.28	0.275	0.113			
	n	6	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	6	5			

Significantly different from control

: *, P<0.05; **, P<0.01.

Table 34 Relative Organ Weight - Summary

Male

Test Substance Dose(mg/kg)		Epididymides	
		%	
		Day 43	Day 57
1, 3-BAC 0	Mean	0.281	0.278
	S. D.	0.027	0.015
	n	7	5
1, 3-BAC 10	Mean	0.281	
	S. D.	0.020	
	n	12	
1, 3-BAC 60	Mean	0.272	
	S. D.	0.031	
	n	12	
1, 3-BAC 300	Mean	0.270	0.278
	S. D.	0.079	0.028
	n	6	5

Significantly different from control

: *, P<0.05; **, P<0.01.

Table 35

Study No. B041798

Relative Organ Weight - Summary (F0 Delivered-on Weaning)
Sex : Female

Unit : g/100gBW

Test Substance Dose (mg/kg)		F. B. W. (g)	Brain	Thymus ($\times 10^{-3}$)	Heart	Liver	Spleen	Kidneys	Adrenals ($\times 10^{-3}$)
1, 3-BAC 0	Mean	316.2	0.624	88.14	0.360	3.488	0.252	0.658	23.36
	S. D.	16.0	0.017	33.20	0.027	0.188	0.033	0.054	1.84
	n	5	5	5	5	5	5	5	5
1, 3-BAC 10	Mean	299.4	0.666	98.26	0.354	3.640	0.286	0.696	25.40
	S. D.	17.1	0.028	19.48	0.017	0.149	0.054	0.059	3.30
	n	5	5	5	5	5	5	5	5
1, 3-BAC 60	Mean	309.0	0.640	95.02	0.330	3.428	0.248	0.656	25.40
	S. D.	17.3	0.049	27.30	0.033	0.263	0.030	0.041	3.77
	n	5	5	5	5	5	5	5	5
1, 3-BAC 300	Mean	292.8	0.674	75.48	0.356	3.678	0.240	0.744*	31.98*
	S. D.	18.7	0.046	27.74	0.018	0.116	0.066	0.021	7.52
	n	5	5	5	5	5	5	5	5

Significantly different from control

: *, $P < 0.05$; **, $P < 0.01$.

Table 36 Relative Organ Weight - Summary

Female #

Test Substance Dose(mg/kg)		Final Body	Brain	Thymus	Heart	Liver	Spleen	Kidneys	Adrenals
		Weight g Day 57	% Day 57	$\times 10^{-3}$ % Day 57	% Day 57	% Day 57	% Day 57	% Day 57	$\times 10^{-3}$ % Day 57
1, 3-BAC 0	Mean	296.0	0.646	101.44	0.342	2.642	0.196	0.650	25.24
	S.D.	16.0	0.034	13.09	0.019	0.085	0.022	0.032	1.37
	n	5	5	5	5	5	5	5	5
1, 3-BAC 300	Mean	293.0	0.686	115.42	0.338	2.804**	0.184	0.670	27.48
	S.D.	23.6	0.042	23.14	0.019	0.065	0.029	0.071	5.29
	n	5	5	5	5	5	5	5	5

Significantly different from control : *, P<0.05; **, P<0.01.
#: Satellite animal

Table 37 Necropsy Findings - Summary

Scheduled Sacrifice

Organ	Sex	Male				Female				
		1, 3-BAC	1, 3-BAC	1, 3-BAC	1, 3-BAC	1, 3-BAC	1, 3-BAC	1, 3-BAC	1, 3-BAC	
Findings	Test Substance	0	10	60	300	0	10	60	300	
	Dose	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	
	Dose Unit									
	Number of Animals	7	12	12	6	12	12	12	11	
	Number of Animals Examined	<7>	<12>	<12>	<6>	<12>	<12>	<12>	<11>	
Stomach										
	Adhesion, forestomach	0	0	0	0	0	0	0	1	
	Thickening, forestomach, wall	0	0	0	6	0	0	0	11	
	Ulcer, forestomach, mucosa	0	0	0	0	0	0	0	1	
Liver										
	Whitish patch	0	0	0	0	0	0	0	1	
Testis										
	Small	0	0	0	2					
Epididymis										
	Small	0	0	0	2					

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Table 37 Necropsy Findings - Summary Scheduled Sacrifice (Recovery)

Organ	Sex	Male		Female	
		Test Substance	1, 3-BAC	1, 3-BAC	1, 3-BAC
	Dose	0	300	0	300
	Dose Unit	mg/kg	mg/kg	mg/kg	mg/kg
Findings	Number of Animals	5	5	5	5
	Number of Animals Examined	<5>	<5>	<5>	<5>
Uterus					
Distention				1	0

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Table 37 Necropsy Findings - Summary

Death

Organ Findings	Sex Test Substance Dose Dose Unit Number of Animals Number of Animals Examined	Male 1, 3-BAC 300 mg/kg 1 <1>
Thymus		
Dark reddish change		1
Spleen		
Small		1
Lung (and bronchus)		
Dark reddish change		1
Stomach		
Dark reddish change, glandular stomach, mucosa		1
Small intestine, duodenum		
Abnormal contents		1
Small intestine, jejunum		
Abnormal contents		1
Small intestine, ileum		
Abnormal contents		1
Dilatation		1
Large intestine, cecum		
Dilatation		1

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Table 37 Necropsy Findings - Summary

Not pregnant

	Sex	Female
	Test Substance	1, 3-BAC
	Dose	300
Organ	Dose Unit	mg/kg
Findings	Number of Animals	1
	Number of Animals Examined	<1>
<hr/>		
Stomach		
Thickening, forestomach, wall		1

Table 38 Histological Findings - Summary

Scheduled Sacrifice

Organ Findings	Sex Test Substance Dose Dose Unit Number of Animals	Male				Female			
		1, 3-BAC 0 mg/kg 7	1, 3-BAC 10 mg/kg 12	1, 3-BAC 60 mg/kg 12	1, 3-BAC 300 mg/kg 6	1, 3-BAC 0 mg/kg 12	1, 3-BAC 10 mg/kg 12	1, 3-BAC 60 mg/kg 12	1, 3-BAC 300 mg/kg 11
Heart		<5>	<0>	<0>	<5>	<5>	<0>	<0>	<5>
Degeneration, myocardial fiber	Grade	1 2 3 4	2 0 0 0		2 0 0 0	0 0 0 0			1 0 0 0
Lymph node, mandibular		<5>	<0>	<0>	<5>	<5>	<0>	<0>	<5>
Lymph node, mesenteric		<5>	<0>	<0>	<5>	<5>	<0>	<0>	<5>
Thymus		<5>	<0>	<0>	<5>	<5>	<0>	<0>	<5>
Spleen		<5>	<0>	<0>	<5>	<5>	<0>	<0>	<5>
Extramedullary hematopoiesis, erythrocytic	Grade	1 2 3 4	0 0 0 0		0 0 0 0	5 0 0 0			5 0 0 0
Bone marrow, femur		<5>	<0>	<0>	<5>	<5>	<0>	<0>	<5>
Trachea		<5>	<0>	<0>	<5>	<5>	<0>	<0>	<5>
Lung (and bronchus)		<5>	<0>	<0>	<5>	<5>	<0>	<0>	<5>
Accumulation, macrophage	Grade	1 2 3 4	2 0 0 0		3 0 0 0	1 0 0 0			1 0 0 0

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◇, Number of animals examined
1, Minimal; 2, Mild; 3, Moderate; 4, Severe

Table 38 Histological Findings - Summary

Scheduled Sacrifice

Organ Findings	Sex Test Substance Dose Dose Unit Number of Animals	Male				Female			
		1, 3-BAC 0 mg/kg 7	1, 3-BAC 10 mg/kg 12	1, 3-BAC 60 mg/kg 12	1, 3-BAC 300 mg/kg 6	1, 3-BAC 0 mg/kg 12	1, 3-BAC 10 mg/kg 12	1, 3-BAC 60 mg/kg 12	1, 3-BAC 300 mg/kg 11
Lung (and bronchus)	Grade	<5>	<0>	<0>	<5>	<5>	<0>	<0>	<5>
Hemorrhage	1	3			2	3			2
	2	0			0	0			0
	3	0			0	0			0
	4	0			0	0			0
Metaplasia, osseous	1	2			0	2			1
	2	0			0	0			0
	3	0			0	0			0
	4	0			0	0			0
Mineralization, arterial wall	1	1			0	0			0
	2	0			0	0			0
	3	0			0	0			0
	4	0			0	0			0
Stomach		<5>	<5>	<5>	<6>	<5>	<5>	<5>	<12>
Cell infiltration, inflammatory, forestomach, focal	1	0	0	0	0	0	0	0	1
	2	0	0	0	6	0	0	0	9
	3	0	0	0	0	0	0	0	1
	4	0	0	0	0	0	0	0	0
Erosion, glandular stomach	1	0	1	0	0	1	0	0	0
	2	0	0	0	0	0	0	0	0
	3	0	0	0	0	0	0	0	0
	4	0	0	0	0	0	0	0	0

◇, Number of animals examined
 1, Minimal; 2, Mild; 3, Moderate; 4, Severe
 Significantly different from control : **, P<0.01.

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Table 38 Histological Findings - Summary

Scheduled Sacrifice

Organ Findings	Sex Test Substance Dose Dose Unit Number of Animals	Male				Female					
		1, 3-BAC 0 mg/kg 7	1, 3-BAC 10 mg/kg 12	1, 3-BAC 60 mg/kg 12	1, 3-BAC 300 mg/kg 6	1, 3-BAC 0 mg/kg 12	1, 3-BAC 10 mg/kg 12	1, 3-BAC 60 mg/kg 12	1, 3-BAC 300 mg/kg 11		
Stomach	Grade	<5>	<5>	<5>	<6>	<5>	<5>	<5>	<11>		
Hyperkeratosis, forestomach, focal	1	0	0	0	6	**	0	0	0	11	**
	2	0	0	0	0		0	0	0	0	
	3	0	0	0	0		0	0	0	0	
	4	0	0	0	0		0	0	0	0	
Hyperplasia, squamous, forestomach, focal	1	0	0	0	0	**	0	0	0	0	**
	2	0	0	0	0		0	0	0	0	
	3	0	0	0	6		0	0	0	10	
	4	0	0	0	0		0	0	0	1	
Ulcer, forestomach	1	0	0	0	2	*	0	0	0	2	**
	2	0	0	0	3		0	0	0	6	
	3	0	0	0	0		0	0	0	0	
	4	0	0	0	0		0	0	0	1	
Small intestine, duodenum		<5>	<5>	<5>	<5>		<5>	<5>	<5>	<5>	
Small intestine, jejunum		<5>	<5>	<5>	<5>		<5>	<5>	<5>	<5>	
Small intestine, ileum		<5>	<5>	<5>	<5>		<5>	<5>	<5>	<5>	
Large intestine, cecum		<5>	<0>	<0>	<5>		<5>	<0>	<0>	<5>	
Large intestine, colon		<5>	<0>	<0>	<5>		<5>	<0>	<0>	<5>	
Large intestine, rectum		<5>	<0>	<0>	<5>		<5>	<0>	<0>	<5>	

◇, Number of animals examined

1, Minimal; 2, Mild; 3, Moderate; 4, Severe

Significantly different from control : *, P<0.05; **, P<0.01.

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Table 38 Histological Findings - Summary

Scheduled Sacrifice

Organ Findings	Sex Test Substance Dose Dose Unit Number of Animals	Male				Female			
		1, 3-BAC 0 mg/kg 7	1, 3-BAC 10 mg/kg 12	1, 3-BAC 60 mg/kg 12	1, 3-BAC 300 mg/kg 6	1, 3-BAC 0 mg/kg 12	1, 3-BAC 10 mg/kg 12	1, 3-BAC 60 mg/kg 12	1, 3-BAC 300 mg/kg 11
	Grade								
Liver		<5>	<0>	<0>	<5>	<5>	<0>	<0>	<6>
Cell infiltration, inflammatory, focal	1	2			3	1			2
	2	0			0	0			0
	3	0			0	0			0
	4	0			0	0			0
Granulomatous inflammation, focal	1	0			0	0			0
	2	0			0	0			1
	3	0			0	0			0
	4	0			0	0			0
Necrosis, hepatocyte, focal	1	1			0	0			0
	2	0			0	0			0
	3	0			0	0			0
	4	0			0	0			0
Kidney		<5>	<0>	<0>	<5>	<5>	<0>	<0>	<5>
Basophilic tubule, proximal tubule	1	1			0	2			0
	2	0			0	0			0
	3	0			0	0			0
	4	0			0	0			0
Cast, hyaline	1	2			0	0			0
	2	0			0	0			0
	3	0			0	0			0
	4	0			0	0			0

◇ , Number of animals examined
 1 , Minimal; 2 , Mild; 3 , Moderate; 4 , Severe

Table 38 Histological Findings - Summary

Scheduled Sacrifice

Organ Findings	Sex Test Substance Dose Dose Unit Number of Animals	Male				Female			
		1, 3-BAC 0 mg/kg 7	1, 3-BAC 10 mg/kg 12	1, 3-BAC 60 mg/kg 12	1, 3-BAC 300 mg/kg 6	1, 3-BAC 0 mg/kg 12	1, 3-BAC 10 mg/kg 12	1, 3-BAC 60 mg/kg 12	1, 3-BAC 300 mg/kg 11
	Grade								
Kidney		<5>	<0>	<0>	<5>	<5>	<0>	<0>	<5>
Cell infiltration, lymphocyte, interstitium	1	1			2	1			0
	2	0			0	0			0
	3	0			0	0			0
	4	0			0	0			0
Mineralization, medulla	1	2			1	2			1
	2	0			0	0			0
	3	0			0	0			0
	4	0			0	0			0
Urinary bladder		<5>	<0>	<0>	<5>	<5>	<0>	<0>	<5>
Testis		<5>	<5>	<5>	<5>				
Atrophy, seminiferous tubule	1	0	2	0	2	*			
	2	0	0	0	0				
	3	0	0	0	1				
	4	0	0	0	1				
Hyperplasia, interstitial cell, diffuse	1	0	0	0	1				
	2	0	0	0	0				
	3	0	0	0	0				
	4	0	0	0	0				

◇, Number of animals examined
 1, Minimal; 2, Mild; 3, Moderate; 4, Severe
 Significantly different from control : *, P<0.05.

Table 38 Histological Findings - Summary

Scheduled Sacrifice

Organ Findings	Sex Test Substance Dose Dose Unit Number of Animals	Male				Female				
		1, 3-BAC 0 mg/kg 7	1, 3-BAC 10 mg/kg 12	1, 3-BAC 60 mg/kg 12	1, 3-BAC 300 mg/kg 6	1, 3-BAC 0 mg/kg 12	1, 3-BAC 10 mg/kg 12	1, 3-BAC 60 mg/kg 12	1, 3-BAC 300 mg/kg 11	
		Grade								
Epididymis			<5>	<5>	<5>	<5>				
Atrophy, duct		1	0	0	0	0				
		2	0	0	0	1				
		3	0	0	0	0				
		4	0	0	0	0				
Cell debris, duct		1	0	0	0	2				
		2	0	0	0	0				
		3	0	0	0	0				
		4	0	0	0	0				
Decrease, sperm, duct		1	0	0	0	0				
		2	0	0	0	0				
		3	0	0	0	0				
		4	0	0	0	2				
Seminal vesicle			<5>	<0>	<0>	<5>				
Prostate			<5>	<0>	<0>	<5>				
Cell infiltration, lymphocyte, interstitium		1	3			1				
		2	0			0				
		3	0			0				
		4	0			0				
Coagulating gland			<5>	<0>	<0>	<5>				
Ovary							<5>	<0>	<0>	<5>

◇, Number of animals examined
 1, Minimal; 2, Mild; 3, Moderate; 4, Severe

Table 38 Histological Findings - Summary

Scheduled Sacrifice

Organ Findings	Sex Test Substance Dose Dose Unit Number of Animals	Male				Female				
		1, 3-BAC 0 mg/kg 7	1, 3-BAC 10 mg/kg 12	1, 3-BAC 60 mg/kg 12	1, 3-BAC 300 mg/kg 6	1, 3-BAC 0 mg/kg 12	1, 3-BAC 10 mg/kg 12	1, 3-BAC 60 mg/kg 12	1, 3-BAC 300 mg/kg 11	
		Grade								
Uterus						<5>	<0>	<0>	<5>	
Vagina						<5>	<0>	<0>	<5>	
Pituitary			<5>	<0>	<0>	<5>	<5>	<0>	<0>	<5>
Aberrant craniopharyngeal tissue	1	0				1	0		0	
	2	0				0	0		0	
	3	0				0	0		0	
	4	0				0	0		0	
Thyroid			<5>	<0>	<0>	<5>	<5>	<0>	<0>	<5>
Ectopic thymic tissue	1	0				1	0		0	
	2	0				0	0		0	
	3	0				0	0		0	
	4	0				0	0		0	
Ultimobranchial remnant	1	4				4	5		3	
	2	0				0	0		0	
	3	0				0	0		0	
	4	0				0	0		0	
Parathyroid			<5>	<0>	<0>	<5>	<5>	<0>	<0>	<5>
Adrenal			<5>	<5>	<5>	<5>	<5>	<5>	<5>	<5>
Necrosis, fascicular zone, focal	1	0	0	0	0	0	0	0	0	
	2	0	0	0	0	0	0	0	1	
	3	0	0	0	0	0	0	0	0	
	4	0	0	0	0	0	0	0	0	

◇, Number of animals examined
1, Minimal; 2, Mild; 3, Moderate; 4, Severe

Table 38 Histological Findings - Summary

Scheduled Sacrifice

Organ Findings	Sex Test Substance Dose Dose Unit Number of Animals	Male				Female			
		1, 3-BAC 0 mg/kg 7	1, 3-BAC 10 mg/kg 12	1, 3-BAC 60 mg/kg 12	1, 3-BAC 300 mg/kg 6	1, 3-BAC 0 mg/kg 12	1, 3-BAC 10 mg/kg 12	1, 3-BAC 60 mg/kg 12	1, 3-BAC 300 mg/kg 11
Brain	Grade	<5>	<0>	<0>	<5>	<5>	<0>	<0>	<5>
Spinal cord		<5>	<0>	<0>	<5>	<5>	<0>	<0>	<5>
Sciatic nerve		<5>	<0>	<0>	<5>	<5>	<0>	<0>	<5>

◇, Number of animals examined

385

Table 38 Histological Findings - Summary

Scheduled Sacrifice (Recovery)

Organ Findings	Sex Test Substance Dose Dose Unit Number of Animals	Male		Female	
		1, 3-BAC 0 mg/kg 5	1, 3-BAC 300 mg/kg 5	1, 3-BAC 0 mg/kg 5	1, 3-BAC 300 mg/kg 5
	Grade				
Stomach		<5>	<5>	<5>	<5>
Cell infiltration, inflammatory, forestomach, focal	1	0	3	0	2
	2	0	0	0	0
	3	0	0	0	0
	4	0	0	0	0
Cyst, glandular stomach	1	1	0	0	0
	2	0	0	0	0
	3	0	0	0	0
	4	0	0	0	0
Hyperplasia, squamous, forestomach, focal	1	0	5	0	5
	2	0	0	0	0
	3	0	0	0	0
	4	0	0	0	0
Small intestine, duodenum		<5>	<5>	<5>	<5>
Small intestine, jejunum		<5>	<5>	<5>	<5>
Small intestine, ileum		<5>	<5>	<5>	<5>
Testis		<5>	<5>		
Atrophy, seminiferous tubule	1	0	0		
	2	0	0		
	3	0	1		
	4	0	0		

◇, Number of animals examined
 1, Minimal; 2, Mild; 3, Moderate; 4, Severe

986

Table 38 Histological Findings - Summary

Scheduled Sacrifice (Recovery)

Organ Findings	Sex Test Substance Dose Dose Unit Number of Animals	Male		Female	
		1, 3-BAC 0 mg/kg 5	1, 3-BAC 300 mg/kg 5	1, 3-BAC 0 mg/kg 5	1, 3-BAC 300 mg/kg 5
	Grade				
Epididymis		<5>	<5>		
Uterus Dilatation, lumen	1 2 3 4			<1> 1 0 0 0	<0>
Adrenal		<5>	<5>	<5>	<5>

◇, Number of animals examined
1, Minimal; 2, Mild; 3, Moderate; 4, Severe

387

Table 38 Histological Findings - Summary

Death

Organ Findings	Sex	Male
	Test Substance	1, 3-BAC
	Dose	300
	Dose Unit	mg/kg
	Number of Animals	1
	Grade	
Heart		<1>
Lymph node, mandibular		<1>
Thymus		<1>
Atrophy	1	0
	2	1
	3	0
	4	0
Spleen		<1>
Atrophy	1	1
	2	0
	3	0
	4	0
Bone marrow, femur		<1>
Lung (and bronchus)		<1>
Congestion	1	1
	2	0
	3	0
	4	0
Edema	1	1
	2	0
	3	0
	4	0

◇ , Number of animals examined
 1 , Minimal; 2 , Mild; 3 , Moderate; 4 , Severe

Table 38 Histological Findings - Summary

Death

Organ Findings	Sex	Male
	Test Substance	1, 3-BAC
	Dose	300
	Dose Unit	mg/kg
	Number of Animals	1
	Grade	
Stomach		<1>
Cell infiltration, inflammatory, forestomach, focal	1	0
	2	1
	3	0
	4	0
Hemorrhage, glandular stomach	1	1
	2	0
	3	0
	4	0
Hyperplasia, squamous, forestomach, focal	1	0
	2	1
	3	0
	4	0
Liver		<1>
Kidney Cyst		<1>
	1	1
	2	0
	3	0
	4	0
Urinary bladder		<1>
Testis		<1>

◇, Number of animals examined
 1, Minimal; 2, Mild; 3, Moderate; 4, Severe

688

Table 38 Histological Findings - Summary

Death

Organ Findings	Sex Test Substance Dose Dose Unit Number of Animals	Male 1, 3-BAC 300 mg/kg 1	Grade
Epididymis			<1>
Seminal vesicle			<1>
Prostate			<1>
Coagulating gland			<1>
Pituitary			<1>
Parathyroid			<1>
Adrenal			<1>
Brain			<1>
Spinal cord			<1>
Sciatic nerve			<1>

◇, Number of animals examined

390

Table 38 Histological Findings - Summary

Not pregnant

Organ Findings	Sex Test Substance Dose Dose Unit Number of Animals	Female 1, 3-BAC 300 mg/kg 1	Grade
Stomach			<1>
Cell infiltration, inflammatory, forestomach, focal			1 0 2 1 3 0 4 0
Hyperkeratosis, forestomach, focal			1 1 2 0 3 0 4 0
Hyperplasia, squamous, forestomach, focal			1 0 2 0 3 1 4 0
Ulcer, forestomach			1 1 2 0 3 0 4 0
Ovary			<1>

◇, Number of animals examined
1, Minimal; 2, Mild; 3, Moderate; 4, Severe

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Table 39

Study No. B041798

 Reproductive Performance (F0) - Summary
 Mating Stage : 1st

Test Substance Dose (mg/kg)	Number of Pairs	Mean Estrus Cycle	Incidence of Females with Irregular Estrus Cycle	Mating Period		Copulation Index (%)	Fertility Index (%)	
				Number of Estrus	Day of Conceiving			
1, 3-BAC M F	0 0	Mean S. D. n	4.00 0.00 12	0/12	0.0 0.0 12	2.3 1.4 12	100.0 100.0 a) (12/12)	100.0 100.0 b) (12/12)
1, 3-BAC M F	10 10	Mean S. D. n	4.17 0.39 12	0/12	0.0 0.0 12	3.5 2.6 12	100.0 100.0 (12/12)	100.0 100.0 (12/12)
1, 3-BAC M F	60 60	Mean S. D. n	4.00 0.00 12	0/12	0.0 0.0 12	2.3 1.1 12	100.0 100.0 (12/12)	100.0 100.0 (12/12)
1, 3-BAC M F	300 300	Mean S. D. n	4.09 0.20 11	1/12	0.1 0.3 12	3.8 3.4 12	100.0 100.0 (12/12)	91.7 91.7 (11/12)

a): Number of copulated females / Number of pairs
 b): Number of pregnant females / Number of copulated females
 Significantly different from control : *, P<0.05; **, P<0.01.