

International Research and Development Corporation

SPONSOR: 3M Company
COMPOUND: Fluorad® Fluorochemical Surfactant FC-95
SUBJECT: Ninety Day Subacute Rat Toxicity Study.



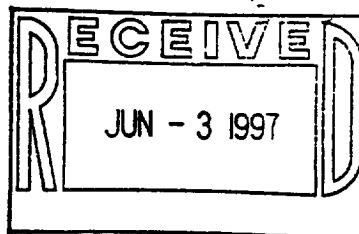
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I. SYNOPSIS

Fluorochemical Surfactant was fed in the diet at levels of 30, 100, 300, 1,000 and 3,000-ppm to Charles River CD rats for 3 months. Five male and 5 female rats were initiated at each dosage level and in the control group. The rats were observed twice daily for overt signs of toxicity and mortality. Individual body weights and sex group food consumptions were recorded weekly. Hematological, biochemical and urinalysis studies were conducted during the pretest period and at 1 and 3 months of study.

At dosage levels of 300, 1,000 and 3,000 ppm, all rats died prior to scheduled termination of the study. Overt signs of toxicity including: emaciation, convulsions, altered posture, red material (right eye and/or mouth), yellow material (anogenital region), increased sensitivity to external stimuli and reduced motor activity were evident prior to most deaths. Time of death was directly related to the dosage level with the earliest deaths seen in the 3,000-ppm treatment group.

At the 30-ppm dosage level, neither male nor female rats showed any compound related changes in appearance or behavior. Mean body weights were slightly lower for the rats at the 30-ppm dosage level when compared to the controls. At the 30-ppm dosage level, one female rat showed a slightly elevated glucose level and one male rat showed a slightly elevated alkaline phosphatase value at 1 month of study. At 3 months of study, one male rat at the 30-ppm dosage level showed slight to moderate elevations in glucose, blood urea nitrogen and γ -glutamyl transpeptidase activity.

At the 100-ppm dosage level at 3 months, body weight means when compared to the controls were lower for males and for females. Food consumption means when compared to the controls were lower (statistically significant) for males and females. At the 100-ppm

dosage level, slight increases in creatinine phosphokinase (CPK) and alkaline phosphatase activity, slight to moderate increases in glucose and blood urea nitrogen, and slight to marked increases in plasma glutamic oxalacetic and pyruvic transaminase activities (PGOT and PGPT) were seen at 1 month of study. At 3 months of study, slight to moderate decreases in hemoglobin, hematocrit and erythrocyte counts were seen for male and female rats and slight to moderate increases in PGOT and PGPT activities were seen for two of the three surviving female rats at the 100-ppm dosage level.

Compound-related gross changes such as emaciation, areas of discoloration involving the stomach and liver were observed among treated rats that died prior to sacrifice. Similar changes were also observed in the liver of a few rats sacrificed at termination of study from the 30- and 100-ppm groups.

Microscopically, compound-related lesions were observed among all test groups. Morphological changes consisting of centrilobular to midzonal cytoplasmic enlargement (hypertrophy) of hepatocytes were observed in the livers. Necrosis of liver cells was also present among these rats. The incidence and relative severity of the above lesions were more evident among male test rats.

In addition, especially among rats from the 300-, 1,000-, and 3,000-ppm dosage level that died prior to sacrifice, changes involving the primary (thymus, bone marrow) and secondary (spleen, mesenteric lymph nodes) lymphoid organs, stomach, intestines, muscle and skin, were observed and were all considered as compound related.

The other changes described in the tissues of these rats were lesions of naturally occurring diseases.

II. COMPOUND

The compound was received from 3M Company, Saint Paul, Minnesota on October 24, 1977 as indicated below:

<u>Label</u>	<u>Description</u>
Fluorochemical Surfactant	white powder 6 x 5 lb tins

III. CLINICAL STUDIES

A. METHOD:

1. General Procedure:

Thirty male (196 to 232 g each) and 30 female (165 to 206 g each) Charles River CD rats purchased as weanlings from The Charles River Breeding Laboratories, Inc., Portage, Michigan were used in this study. The rats were distributed among the groups, based upon a computer-generated table of random numbers. The rats were housed individually in suspended wire-mesh cages and maintained in a temperature-, humidity- and light-controlled room. During the pretest period, rats were provided ground Purina® Laboratory Chow® and water ad libitum. During the actual study, the rats were provided the appropriate test diet and water ad libitum.

This study was initiated November 2, 1977 and terminated by sacrifice of all remaining rats on January 31, 1978.

2. Compound Administration:

The compound was mixed weekly with ground Purina® Laboratory Chow® (i.e., ground basal diet) on a weight/weight basis to provide dosage levels of 30, 100, 300, 1,000 and 3,000 ppm for feeding. Five male and five female rats were used at each dosage level and in a control group. Control rats received the ground basal diet. Diet samples (100 each) were taken immediately after preparation of each diet and after 7 days standing in weeks 1, 4 and 12. The samples were frozen and subsequently shipped to the sponsor. Diets were prepared in the following manner: before weighing, the compound was ground using a mortar with pestle. The appropriate quantity of Fluorochemical Surfactant as mixed with 500 g of the ground basal diet in a Hobart blender to provide the premix. The proper quantity of premix was subsequently blended in a twin-shell blender, equipped with an intensifier bar, with the amount of ground Purina® Laboratory Chow® necessary to

provide the appropriate quantity by group of prepared diet. Control rats received the ground basal diet.

3. Observations:

The rats were observed twice daily for overt signs of toxicity and for mortality. Detailed observations were recorded weekly or daily when a specific condition existed. Individual body weights and food consumption were recorded weekly during the pretest and treatment periods.

4. Laboratory Tests:

Once during the pretest period and at 1 month and 3 months of the study, blood (orbital sinus puncture technique) and overnight urine samples were obtained from all surviving rats for analysis. Food and water were withheld prior to the collection of samples.

a. Hematology:

Hematological studies included: hemoglobin¹, hematocrit², total erythrocytes³, reticulocytes⁴, and total³ and differential leucocyte counts.

b. Biochemistry:

Biochemical studies included: fasting glucose⁵, blood urea nitrogen⁵ (BUN), plasma glutamic pyruvic (PGPT) and plasma glutamic oxalacetic (PGOT) transaminase activities⁵, plasma alkaline phosphatase activity⁵, γ -glutamyl transpeptidase⁶ (γ -GTP), creatinine phosphokinase (CPK)⁷ and calcium⁸. Plasma alkaline phosphatase values were not obtained for the pretest (baseline) period because of interference from the anticoagulant.

c. Urinalysis:

Urinalysis included: measurement of volume, pH⁹, and specific gravity; description of color and appearance; qualitative tests for protein⁹, glucose⁹, ketones⁹, bilirubin⁹, and occult blood⁹; and microscopic examination of sediment.

d. Serum Samples:

Serum samples were obtained for all surviving rats at 13 weeks of study. The samples were pooled by sex and group, frozen, and subsequently shipped to the sponsor.

5. Statistical Analysis:

All statistical analyses compared the treatment groups with the control group, by sex. Body weights (week 13), food consumption (1-13 weeks), hematological, biochemical and urinalysis parameters (1 and 3 months) and absolute and relative organ weights (terminal) were compared by analysis of variance (one-way classification) Bartlett's test for homogeneity of variances and the appropriate t-test (for equal or unequal variances) as described by Steel and Torrie¹⁰ using Dunnett's¹¹ multiple comparison tables to judge the significance of differences.

B. RESULTS:

1. General Behavior, Appearance and Survival:

Control rats exhibited no behavioral anomalies related to the testing procedure. Rats given the compound at 30 ppm of the diet exhibited no specific behavioral signs of toxicity and there was no mortality. Changes in general behavior and appearance for male rats at the 100-ppm dosage level included the following: increased sensitivity to external stimuli and red material around the mouth were observed for one rat; increased sensitivity to external stimuli, leans to left and convulsions following handling were noted for a second rat; and one rat was cold to the touch (one day after collection of blood) and died. No compound-related signs of overt toxicity were noted for any of the females at 100-ppm dosage level.

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All rats in the 300-, 1,000- and 3,000-ppm dosage levels died prior to the scheduled sacrifice. Most exhibited one or more of the following signs of overt toxicity: emaciation, convulsions following handling, altered posture (hunched back), red material around right eye, yellow material around the anogenital region, increased sensitivity to external stimuli, reduced motor activity and moist red material around the mouth or nose. At 300 ppm, death for males occurred from day 13 through day 25 and for females from day 18 through day 28. At 1,000 ppm, death for males and females occurred from day 8 through day 14. At 3,000 ppm, death for males and females occurred from day 7 through day 8.

Observation	Number of Rats/Observation/Dosage Level			
	100 ppm	300 ppm	1,000 ppm	3,000 ppm
Emaciation		5	10	6
Convulsion	1	10	3	1
Altered position (hunched back)	1	1	7	6
Red material (right eye)	2	1		
Yellow material (anogenital region)		2		3
Increased sensitivity	2	2		
Reduced motor activity				4
Moist red material (mouth)	1	1	1	

Survival (prior to sacrifice) after 3 months of compound administration was as follows:

Dosage Level	No. Surviving/No. Initiated	
	Male	Female
Control	5/5	5/5
30 ppm <i>2 mg/kg</i>	5/5	5/5
100 ppm	2/5	3/5
300 ppm	0/5	0/5
1,000 ppm	0/5	0/5
3,000 ppm	0/5	0/5

2. Body Weights (Tables 1-2):

Comparison of mean body weights of the 30-ppm and 100-ppm groups indicate a lower body weight gain at both dosage levels when compared to the controls. Moderate to marked losses of body weight were seen prior to death for rats at the 300-, 1,000- and 3,000-ppm dosage level.

Group mean body weights after 90 days of compound administration were as follows:

<u>Dosage Level</u>	<u>Group Mean Body Weights, g</u>	
	<u>Male</u>	<u>Female</u>
Control	472	264
30 ppm	431 (- 8.7)	243 (- 8.0)
100 ppm	393 (-16.7)	221 (-16.3)

3. Food Consumption (Tables 3-4):

Group mean averages for food consumption declined consistently as the dosage level was increased.

<u>Dosage Level</u>	<u>Average Food Consumption (grams/rat/day)</u>	
	<u>Male</u>	<u>Female</u>
Control	27.4	19.7
30 ppm	26.0	19.0
100 ppm	23.9	15.8
300 ppm	12.8	9.3
1,000 ppm*	7.5	6.6
3,000 ppm*	5.0	4.2

*values for 1 week only

4. Laboratory Tests (Tables 5-8):

a. Hematology:

At the 30-ppm dosage level (1 and 3 months) and at the 100-ppm dosage level (1 month) hematologic values were within the expected range.

For the 100-ppm dosage level at 3 months, the two surviving male rats had lower erythrocyte, hemoglobin, hematocrit and leucocyte counts (differences when compared to controls were statistically significant, $p < 0.01$). The three surviving female rats had slightly

lower hemoglobin and reticulocyte counts (statistically significant, $p < 0.05$) as well as slightly lower erythrocyte, hematocrit and leucocyte counts. All other hematologic values of male and female rats at this dosage level were within the expected range.

b. Biochemistry:

One control rat showed moderately elevated PGOT and PGPT activity at 3 months of study.

At the 30-ppm dosage level, one female rat showed a slightly elevated glucose level and one male rat showed a slightly elevated alkaline phosphatase value at 1 month of study. At 3 months of study, one male rat at the 30-ppm dosage level showed slight to moderate elevations in glucose, blood urea nitrogen and γ -glutamyl transpeptidase activity.

At the 100-ppm dosage level, slight to moderate increases in glucose (3 males, 1 female) and blood urea nitrogen (5 males, 4 females) were seen at 1 month of study. Also noted at 1 month of study, for 3 males and 2 females at the 100-ppm dosage level, were slight to marked increases in PGOT and PGPT. The creatinine phosphokinase (CPK) levels generally were slightly increased for rats at the 100-ppm dosage level at 1 month of study. Alkaline phosphatase activity also was slightly elevated for a few rats at the 100-ppm dosage level at 1 month of study. The group mean glucose values for males, blood urea nitrogen values for males and females, and CPK and alkaline phosphatase values for females at the 100-ppm dosage level were significantly higher ($p < 0.05$) than the control means at 1 month of study.

At 3 months of study, 2 of the 3 surviving female rats at the 100-ppm dosage level showed slight to moderate increases in PGOT and PGPT activity. One of these females also showed a slight elevation in CPK activity.

c. Urinalysis:

No changes considered to be related to compound were seen in the urinalysis studies.

IV. PATHOLOGICAL STUDIES

A. METHODS:

1. Gross Pathology:

After 90 days of compound administration, five rats/sex in the control and 30-ppm groups, and two and three female rats in the 100-ppm groups were sacrificed with carbon dioxide and necropsied. At necropsy, organs and tissues were examined for gross abnormalities and collected in 10% neutral buffered formalin (eyes in Russell's fixative). Liver samples, obtained from all of the rats at terminal sacrifice, were frozen and subsequently shipped to the sponsor.

All rats that died prior to termination, were also necropsied, and tissues were collected as above.

2. Histopathology:

Microscopic examination of formalin-fixed, hematoxylin and eosin stained, paraffin sections was performed for all rats in the control, 30-, 100-, 300-, 1,000- and 3,000-ppm dosage levels. The following tissues were examined histologically:

brain with cervical cord	aorta	pancreas
lumbar spinal cord	spleen	liver
peripheral nerve	mesenteric lymph nodes	kidneys
eyes	thymus	urinary bladder
pituitary	bone with marrow	testes
thyroid	(sternum)	ovaries
parathyriod	salivary gland	prostate
adrenals	stomach	uterus
lung	small intestine	skin (mammary gland)
heart with	(3 levels)	and all tissues
coronary vessels	colon	with gross lesions

B. RESULTS:

1. Gross Pathology (Table 17) and Organ Weights (Tables 18-19):

Compound-related gross necropsy lesions and/or observations were present among rats in all experimental groups. The livers of these rats showed varying degrees of discoloration and/or enlargement, while in the stomach, foci of discoloration in glandular mucosa,

presumably hemorrhages were also observed. In addition to the above gross observation, emaciation was evident especially among rats that died prior to sacrifice (300-, 1,000- and 3,000-ppm levels).

2. Histopathology (Table 20):

Compound-related lesions were observed histologically in the following organs and tissues.

a. Liver: Slight to marked, focal necrosis of liver cells with no lobular distribution was seen among rats at the 100-ppm and higher treatment levels. The above lesion was accompanied by focal to multifocal, very slight to slight, cytoplasmic enlargement (hypertrophy) of hepatocytes in the centrilobular to midzonal regions of the affected liver lobules in all test groups, especially among male rats. There was a slight increase in cytoplasmic vacuolation of hepatocytes in 30-ppm treated rats, but this finding was not evident at the higher dose levels; therefore, this lesion was considered insignificant.

b. Stomach: Mucosal hyperkeratosis and/or acanthosis was observed in the forestomach (nonglandular portion) while mucosal hemorrhages and/or erosions were observed in the glandular portion.

c. Bone Marrow: Hypocellularity was noted.

d. Thymus: Depletion in number and size of lymphoid follicles was noted.

e. Spleen: Decrease in size of the organ (atrophy) with a corresponding decrease in size and number of lymphoid follicles and cells was observed.

f. Mesenteric Lymph Nodes: Depletion in size and number of lymphoid follicles was noted.

g. Small Intestine (duodenum, jejunum, ileum): Decreased atrophy in the height and thickness of the villi were noted.

h. Skeletal Muscle: Atrophy was evident.

i. Skin: Epidermal hyperkeratosis and/or acanthosis was noted.

The findings in the stomach, lymphoid organs, intestine, muscle and skin, were prominent among all rats (300-, 1,000- and 3,000-ppm levels) that died prior to sacrifice.

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Ninety Day Subacute Rat Toxicity Study.

TABLE I.

Group Mean Body Weights, Grams; Weight Ranges; and Survival.

Week of Study	Control			30 ppm			100 ppm			300 ppm			1,000 ppm			3,000 ppm		
	Mean Body Wt.	Weight Ranges	Survival	Mean Body Wt.	Weight Ranges	Survival	Mean Body Wt.	Weight Ranges	Survival	Mean Body Wt.	Weight Ranges	Survival	Mean Body Wt.	Weight Ranges	Survival	Mean Body Wt.	Weight Ranges	Survival
MALES:																		
-1	220	212-228	5/5	215	206-227	5/5	217	212-224	5/5	202	196-214	5/5	217	207-232	5/5	219	216-223	5/5
0	245	233-259	5/5	239	227-265	5/5	226	200-252	5/5	223	210-250	5/5	231	212-251	5/5	245	237-252	5/5
1	301	276-330	5/5	294	272-328	5/5	276	246-306	5/5	217	200-244	5/5	186	164-204	5/5	159	156-164	3/5
2	323	302-358	5/5	303	274-332	5/5	291	244-330	5/5	207	200-224	4/5			0/5			0/5
3	342	308-376	5/5	330	303-360	5/5	301	258-350	5/5	192	183-200	3/5						
4	368	346-405	5/5	351	311-387	5/5	307	262-359	5/5			0/5						
5	380	352-406	5/5	356	328-392	5/5	308	278-362	3/5									
6	416	380-444	5/5	389	360-420	5/5	324	275-363	3/5									
7	434	400-466	5/5	404	370-440	5/5	351	280-390	3/5									
8	444	414-483	5/5	411	376-448	5/5	373	284-420	3/5									
9	451	418-487	5/5	422	386-455	5/5	388	282-442	3/5									
10	463	437-495	5/5	429	399-458	5/5	391	292-457	3/5									
11	475	448-518	5/5	440	410-476	5/5	398	320-476	2/5									
12	486	458-526	5/5	444	418-466	5/5	412	344-480	2/5									
13	472	438-523	5/5	431	408-464	5/5	393	320-466	2/5									
FEMALES:																		
-1	186	168-197	5/5	186	172-199	5/5	188	170-206	5/5	187	165-202	5/5	178	172-188	5/5	179	169-192	5/5
0	193	168-207	5/5	192	180-208	5/5	198	182-222	5/5	197	175-215	5/5	180	179-181	5/5	187	177-198	5/5
1	219	190-236	5/5	220	206-240	5/5	212	190-234	5/5	176	164-188	5/5	142	120-150	5/5	135	126-140	3/5
2	219	186-236	5/5	224	204-244	5/5	204	182-226	5/5	166	150-182	5/5			0/5			0/5
3	233	207-244	5/5	231	213-255	5/5	202	192-214	5/5	166	152-178	4/5						
4	241	212-264	5/5	235	216-262	5/5	210	195-235	5/5			0/5						
5	252	222-278	5/5	246	232-264	5/5	217	208-222	3/5									
6	262	224-286	5/5	256	238-276	5/5	222	212-234	3/5									
7	266	230-290	5/5	256	238-280	5/5	221	212-234	3/5									
8	271	236-297	5/5	254	234-285	5/5	224	217-235	3/5									
9	267	233-298	5/5	254	236-278	5/5	227	217-245	3/5									
10	275	234-310	5/5	252	238-274	5/5	225	216-241	3/5									
11	281	242-310	5/5	264	244-290	5/5	236	230-244	3/5									
12	306	243-394	5/5	260	240-284	5/5	234	225-250	3/5									
13	264	224-298	5/5	243	228-262	5/5	221	206-238	3/5									

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Ninety Day Subacute Rat Toxicity Study.

TABLE 2.

Individual Weekly Body Weights, Grams.

Group, Rat No.	Sex	Pretest		Week of Study												
		-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13
Control:																
73886	M	222	249	314	330	354	372	396	424	438	452	453	464	484	482	466
73887	M	225	248	286	302	328	346	352	380	400	414	418	437	448	464	456
73888	M	228	259	330	358	376	405	406	444	466	483	487	495	518	526	523
73889	M	212	233	300	322	342	367	372	404	424	422	442	441	448	458	438
73890	M	212	235	276	302	308	352	374	428	440	451	456	476	476	498	477
73891	F	194	200	230	230	240	251	262	278	280	285	270	279	294	394	268
73892	F	179	184	208	210	230	227	238	248	252	246	248	256	260	262	243
73893	F	194	207	232	236	244	264	278	286	290	297	298	310	310	320	298
73894	F	168	168	190	186	207	212	222	224	230	236	233	234	242	243	224
73895	F	197	205	236	234	242	252	260	274	280	293	286	296	300	310	285
30 ppm:																
73896	M	216	232	282	300	325	343	344	382	394	408	425	424	434	444	417
73897	M	227	265	328	332	360	387	392	420	440	448	455	458	476	466	464
73898	M	217	240	306	316	344	366	368	410	420	420	431	444	446	454	438
73899	M	208	229	280	292	318	346	350	372	394	401	413	420	434	436	428
73900	M	206	227	272	274	303	311	328	360	370	376	386	399	410	418	408
73901	F	172	180	208	204	213	220	232	238	238	234	236	238	248	241	228
73902	F	199	208	240	242	254	262	264	274	280	285	278	274	290	284	262
73903	F	195	191	210	216	216	216	236	250	244	245	244	243	260	253	235
73904	F	193	201	238	244	255	255	264	276	276	273	272	265	276	280	259
73905	F	172	181	206	212	215	221	232	244	240	235	240	240	244	240	231
100 ppm:																
73906	M	213	200	270	292	292	309	Died								
73907	M	224	252	306	330	350	359	362	363	390	415	439	424	Died		
73908	M	212	224	272	300	319	305	284	335	382	420	442	457	476	480	466
73910	M	221	245	284	290	284	302	Died								
73946	M	213	208	246	244	258	262	278	275	280	284	282	292	320	344	320
73911	F	206	217	232	224	210	211	222	234	234	235	245	241	244	250	238
73912	F	205	222	234	226	214	235	Died								
73913	F	170	182	190	188	196	195	208	212	212	217	218	217	230	228	206
73914	F	181	195	204	200	192	204	Died								
73915	F	178	186	198	182	200	206	220	220	216	221	217	216	234	225	219

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TABLE 2. Cont. Individual Weekly Body Weights, Grams.

Group, Rat No.	Sex	Pretest		Week of Study												
		-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13
<u>300 ppm:</u>																
73916	M	198	210	212	200	183	Died									
73917	M	200	213	200	Died											
73918	M	196	212	210	204	192	Died									
73919	M	203	230	220	200	200	Died									
73920	M	214	250	244	224	Died										
73921	F	190	200	188	174	165	Died									
73922	F	183	192	168	162	168	Died									
73923	F	202	215	178	182	178	Died									
73924	F	194	202	184	164	152	Died									
73925	F	165	175	164	150	Died										
<u>1,000 ppm:</u>																
73926	M	207	212	164	Died											
73927	M	207	212	170	Died											
73928	M	220	230	190	Died											
73929	M	232	251	202	Died											
73930	M	217	248	204	Died											
73931	F	188	180	150	Died											
73932	F	175	180	120	Died											
73933	F	176	181	148	Died											
73934	F	180	180	150	Died											
73935	F	172	179	142	Died											
<u>3,000 ppm:</u>																
73936	M	218	242	164	Died											
73937	M	217	237	158	Died											
73938	M	223	252	Died												
73939	M	216	245	Died												
23940	M	223	248	156	Died											
73941	F	187	197	140	Died											
73942	F	169	178	Died												
73943	F	192	198	140	Died											
73944	F	177	183	126	Died											
73945	F	170	177	Died												

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TABLE 3. **T-test Comparison Between Average Food Consumption
of Control and Treated Groups.**

Week of Study	Sex	Control	30 ppm	100 ppm
1-13	M	27.4	26.0*	23.9**
	F	19.7	19.0	15.8**

*Significantly different than Control group mean, $p < 0.05$.

**Significantly different than Control group mean, $p < 0.01$.

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TABLE 4.

Mean Food Consumption.

Week of Study	Control		30 ppm		100 ppm		300 ppm		1,000 ppm		1,000 ppm	
	g/ rat/ day	kg/ kg/ day	g/ rat/ day	kg/ kg/ day	g/ rat/ day	kg/ kg/ day	g/ rat/ day	kg/ kg/ day	g/ rat/ day	kg/ kg/ day	g/ rat/ day	kg/ kg/ day
MALES:												
1	27.0	89.6	27.6	93.9	25.5	92.3	18.2	84.0	7.5	40.6	5.0	31.1
2	24.9	77.0	23.0	75.8	21.2	72.9	7.9	38.0				
3	26.7	78.1	25.6	77.7	21.0	69.7	12.2	63.7				
4	24.7	67.0	23.9	68.1	16.9	54.9						
5	28.7	75.6	25.2	70.8	19.2	62.5						
6	28.5	68.5	27.5	70.7	21.1	65.1						
7	29.5	67.9	27.6	68.3	26.0	74.1						
8	26.9	60.6	26.0	63.3	27.5	73.7						
9	28.0	62.0	27.9	66.1	26.2	67.5						
10	28.5	61.5	26.1	60.9	26.1	66.9						
11	28.3	59.5	25.5	58.1	28.1	70.7						
12	26.5	54.6	23.8	53.6	25.9	62.8						
13	28.2	59.7	27.8	64.4	26.5	67.4						
FEMALES:												
1	19.9	90.8	21.2	96.4	18.9	88.9	11.0	62.7	6.6	46.3	4.2	31.0
2	16.9	77.2	16.9	75.5	13.9	68.3	7.0	42.3				
3	20.3	87.3	19.1	82.9	15.7	77.9	9.8	59.2				
4	18.7	77.5	16.9	71.7	13.2	62.9						
5	20.3	80.7	17.9	72.9	14.9	68.5						
6	20.5	78.1	19.4	75.7	17.1	77.2						
7	21.0	79.1	20.5	80.1	16.9	76.3						
8	20.3	74.7	19.9	78.5	15.9	71.0						
9	21.1	78.9	20.0	78.9	15.9	70.1						
10	21.1	76.7	18.4	73.0	16.3	72.4						
11	20.1	71.7	19.8	75.1	16.0	67.8						
12	17.2	56.1	17.1	65.8	14.7	62.9						
13	18.3	69.2	20.3	83.5	15.6	70.6						

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TABLE 3.

MALES: Means and Significance^a of Hematological Values.

Hematology	Study Month	Control	30 ppm	100 ppm
Erythrocytes, 10 ⁶ /cmm	Pretest	5.96	6.42	6.40
	1	6.50	6.28	6.30
	3	7.57	7.43	5.52**
Hematocrit, %	Pretest	43	47	48
	1	45	48	45
	3	50	46**	39**
Hemoglobin, g/100 ml	Pretest	15.5	15.5	15.9
	1	16.0	14.9	15.3
	3	16.6	15.6	12.1**
Leucocytes, 10 ⁶ /cmm	Pretest	11.32	10.60	10.76
	1	13.14	12.69	9.87
	3	12.50	9.63	6.21**
Neutrophils, %	Pretest	7	11	17
	1	11	12	17
	3	14	15	30
Lymphocytes, %	Pretest	93	88	82
	1	88	86	81
	3	84	83	69*
Eosinophils, %	Pretest	0	1	1
	1	1	2	1
	3	1	2	0
Monocytes, %	Pretest	0	0	0
	1	0	0	1
	3	1	0	0
Basophils, %	Pretest	0	0	0
	1	0	0	0
	3	0	0	0
Reticulocytes, %	Pretest	5.3	5.2	5.4
	1	3.9	3.2	2.7
	3	2.8	2.9	3.2

*Significantly different than Control group mean, p<0.05.

**Significantly different than Control group mean, p<0.01.

^aStatistical analyses were not concluded on the pretest values.

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TABLE 5.

FEMALES: Means and Significance^a of Hematological Values.

Hematology	Study Month	Control	30 ppm	100 ppm
Erythrocytes, 10 ⁶ /cmm	Pretest	6.74	6.69	6.36
	1	6.54	6.58	6.69
	3	6.59	7.28**	6.03
Hematocrit, %	Pretest	48	48	45
	1	47	47	48
	3	45	47	41
Hemoglobin, g/100 ml	Pretest	16.2	16.0	15.0
	1	15.9	15.7	16.1
	3	15.4	16.0	13.8*
Leucocytes, 10 ³ /cmm	Pretest	9.23	9.77	9.39
	1	7.23	7.07	10.25
	3	7.29	5.68	6.26
Neutrophils, %	Pretest	17	8	11
	1	15	8*	8*
	3	21	19	25
Lymphocytes, %	Pretest	82	91	88
	1	81	91**	91**
	3	76	80	75
Eosinophils, %	Pretest	1	1	1
	1	3	1**	1**
	3	2	1	0
Monocytes, %	Pretest	0	0	0
	1	1	0	0
	3	1	0	0
Basophils, %	Pretest	0	0	0
	1	0	0	0
	3	0	0	0
Reticulocytes, %	Pretest	4.4	4.1	4.4
	1	3.1	2.3*	2.4
	3	3.2	2.8	1.8*

*Significantly different than Control group mean, $p < 0.05$.**Significantly different than Control group mean, $p < 0.01$.^aStatistical analyses were not performed on the pretest value.

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Ninety Day Subacute Rat Toxicity Study.

TABLE 6.

Individual Hematological Values - Pretest.

Group, Rat Number	Sex	Erythro- cytes 10 ⁶ /cmm	Hemato- crit %	Hemo- globin g/100 ml	Leuco- cytes 10 ³ /cmm	Neutrophils		Lympho- cytes %	Eosino- phils %	Mono- cytes %	Baso- phils %	Reticulo- cytes %
						Seg. %	Non-Seg. %					
Control:												
73886	M	6.25	47	16.5	10.20	8	0	92	0	0	0	4.6
73887	M	5.95	44	15.2	12.38	9	0	91	0	0	0	3.4
73888	M	5.77	43	14.9	11.55	6	0	94	0	0	0	7.3
73889	M	5.58	45	15.4	11.01	6	0	94	0	0	0	4.6
73890	M	6.26	48	15.7	11.45	6	0	94	0	0	0	6.7
Mean		5.96	45	15.5	11.32	7	0	93	0	0	0	5.3
73891	F	6.42	50	16.4	8.65	9	0	91	0	0	0	2.5
73892	F	6.36	41	15.5	7.83	11	0	89	0	0	0	4.4
73893	F	6.67	48	15.5	10.05	12	0	86	2	0	0	6.2
73894	F	7.36	51	17.4	9.52	34	0	66	0	0	0	3.5
73895	F	6.89	49	16.3	10.08	17	0	82	1	0	0	5.4
Mean		6.74	48	16.2	9.23	17	0	82	1	0	0	4.4
30 ppm:												
73896	M	6.77	49	16.4	10.15	12	0	87	1	0	0	6.9
73897	M	5.89	44	14.7	9.05	10	0	89	1	0	0	10.3
73898	M	6.57	47	15.1	12.52	17	0	82	1	0	0	5.8
73899	M	6.41	48	15.4	12.68	6	0	94	0	0	0	2.7
73900	M	6.48	48	15.7	8.61	8	0	91	1	0	0	0.3
Mean		6.42	47	15.5	10.60	11	0	88	1	0	0	5.2
73901	F	7.16	50	16.9	9.49	6	0	93	1	0	0	3.8
73902	F	6.28	44	15.5	9.17	11	0	89	0	0	0	5.8
73903	F	7.05	50	16.2	9.57	11	0	89	0	0	0	2.0
73904	F	6.23	47	15.4	6.81	6	0	94	0	0	0	5.9
73905	F	6.73	48	16.1	13.80	5	0	93	2	0	0	3.1
Mean		6.69	48	16.0	9.77	8	0	91	1	0	0	4.1
100 ppm:												
73906	M	6.68	49	15.9	10.19	15	0	83	2	0	0	6.4
73907	M	5.99	45	15.2	14.31	10	0	89	1	0	0	6.8
73908	M	6.25	47	15.6	8.00	18	0	81	1	0	0	6.4
73910	M	6.57	50	16.4	13.42	13	0	87	0	0	0	3.5
73946	M	6.52*	49	16.2	7.88	30	1	69	0	0	0	4.1
Mean		6.40	48	15.9	10.76	17	0	82	1	0	0	5.4
73911	F	6.08	42	14.8	11.85	13	0	87	0	0	0	2.3
73912	F	6.51	46	15.3	10.73	11	0	87	2	0	0	5.1
73913	F	6.41	45	14.8	5.67	11	0	87	2	0	0	2.6
73914	F	6.19	43	14.2	10.34	9	0	91	0	0	0	5.9
73915	F	6.61	47	15.9	8.36	12	0	88	0	0	0	6.0
Mean		6.36	45	15.0	9.39	11	0	88	1	0	0	4.4

All Polychromatals

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TABLE 6.

Individual Hematological Values - Pretest.

Group, Rat Number	Sex	Erythro- cytes 10 ⁶ /mm	Hemato- crit %	Hemo- globin g/100 ml	Leuco- cytes 10 ³ /mm	Neutrophils		Lympho- cytes %	Eosino- phils %	Mono- cytes %	Baso- phils %	Reticulo- cytes %
						Seg. %	Non-Seg. %					
300 ppm:												
73916	M	7.30	50	15.8	10.11	16	0	83	1	0	0	4.5
73917	M	6.18	42	14.5	8.85	6	0	93	1	0	0	3.9
73918	M	6.61	49	16.1	11.93	10	0	90	0	0	0	4.3
73919	M	5.96	43	14.9	10.32	7	0	92	1	0	0	8.3
73920	M	6.31	47	15.1	13.36	10	0	90	0	0	0	6.4
Mean		6.47	46	15.3	10.91	10	0	89	1	0	0	5.5
73921	F	6.69	49	15.8	7.76	14	0	85	1	0	0	1.6
73922	F	7.12	49	17.0	11.18	7	0	93	0	0	0	2.3
73923	F	6.66	48	15.9	9.30	10	0	90	0	0	0	2.7
73924	F	6.48	48	16.5	11.49	12	0	88	0	0	0	3.0
73925	F	6.45	48	16.2	10.78	5	0	95	0	0	0	3.7
Mean		6.68	48	16.3	10.10	10	0	90	0	0	0	2.7
1,000 ppm:												
73926	M	7.08	49	16.5	12.76	9	0	91	0	0	0	2.0
73927	M	6.14	48	16.1	13.67	12	0	88	0	0	0	6.7
73928	M	6.09	49	16.0	9.75	17	0	83	0	0	0	6.7
73929	M	6.84	49	16.4	13.02	8	0	91	1	0	0	8.0
73930	M	6.53	47	15.1	15.59	8	0	91	1	0	0	5.4
Mean		6.54	48	16.0	12.96	11	0	89	0	0	0	5.8
73931	F	6.66	50	16.7	10.50	17	0	82	1	0	0	2.0
73932	F	7.60	51	17.8	12.79	15	0	84	1	0	0	3.1
73933	F	7.33	49	17.6	14.12	17	0	83	0	0	0	4.0
73934	F	7.12	47	16.8	11.74	15	0	83	2	0	0	3.5
73935	F	6.36	46	15.4	17.48	7	0	92	1	0	0	1.8
Mean		7.01	49	16.9	13.33	14	0	85	1	0	0	2.9
3,000 ppm:												
73936	M	7.12	49	16.4	13.52	9	0	91	0	0	0	5.8
73937	M	7.11	47	15.5	17.97	8	0	92	0	0	0	6.9
73938	M	6.35	44	15.0	14.79	9	0	91	0	0	0	6.0
73939	M	6.32	46	15.1	17.28	6	0	94	0	0	0	5.7
73940	M	6.48	49	16.4	15.29	14	0	86	0	0	0	5.3
Mean		6.68	47	15.7	15.77	9	0	91	0	0	0	5.9
73941	F	6.00	44	15.5	13.11	13	0	85	2	0	0	4.8
73942	F	7.15	49	17.3	12.25	14	0	85	1	0	0	5.0
73943	F	6.51	49	17.4	9.49	14	0	85	1	0	0	2.4
73944	F	6.59	48	16.2	11.87	16	0	81	3	0	0	2.5
73945	F	6.53	46	15.6	11.72	10	0	90	0	0	0	3.6
Mean		6.56	47	16.4	11.69	13	0	86	1	0	0	3.7

TABLE 1.

Individual Hematological Values - 1 Month.

Group, Rat Number	Sex	Erythro- cytes 10 ⁶ /mm ³	Hemato- crit %	Hemo- globin g/100 ml	Leuco- cytes 10 ³ /mm ³	Neutrophils		Lympho- cytes %	Eosino- phils %	Mono- cytes %	Baso- phils %	Reticu- cytes %
						Seg. %	Non-Seg. %					
Control:												
73886	M	6.76	47	16.9	13.63	6	0	93	1	0	0	3.8
73887	M	6.35	-	14.8	9.95	9	0	89	2	0	0	3.5
73888	M	6.45	42	15.9	16.14	11	0	88	0	1	0	3.0
73889	M	6.48	46	16.2	12.44	12	0	87	1	0	0	3.3
73890	M	6.46	45	16.2	13.52	17	0	81	1	1	0	5.9
Mean		6.50	45	16.0	13.14	11	0	88	1	0	0	3.9
73891	F	6.51	44	16.2	7.89	23	0	73	3	1	0	3.0
73892	F	6.68	50	16.6	7.37	17	0	81	2	0	0	3.4
73893	F	6.66	46	16.0	9.50	8	0	89	3	0	0	2.8
73894	F	6.68	47	15.8	6.15	11	0	83	3	3	0	3.3
73895	F	6.19	46	15.1	5.22	15	0	79	3	3	0	3.1
Mean		6.54	47	15.9	7.23	15	0	81	3	1	0	3.1
30 ppm:												
73896	M	6.87	51	16.5	9.11	16	0	83	1	0	0	2.6
73897	M	6.46	46	15.3	11.15	12	0	84	4	0	0	3.5
73898	M	6.59	49	15.4	12.12	16	0	82	2	0	0	3.1
73899	M	6.44	46	15.0	15.74	8	0	90	2	0	0	2.0
73900	M	5.04*	49	12.5	15.31	6	0	94	0	0	0	4.8
Mean		6.28	48	14.9	12.69	12	0	86	2	0	0	3.2
73901	F	6.64	49	16.2	5.22	7	0	92	1	0	0	3.1
73902	F	6.50	51	17.0	6.36	8	0	92	0	0	0	1.8
73903	F	6.58	48	15.2	7.30	13	0	86	1	0	0	2.4
73904	F	6.55	45	16.3	7.92	9	0	90	1	0	0	2.2
73905	F	6.61	44	13.9	8.56	5	0	93	1	1	0	1.9
Mean		6.58	47	15.7	7.07	8	0	91	1	0	0	2.3
100 ppm:												
73906	M	7.08	50	16.7	10.42	21	0	77	1	1	0	2.8
73907	M	6.38	48	16.1	8.96	13	0	85	2	0	0	1.9
73908	M	5.71	43	13.7	9.05	29	0	70	1	0	0	3.5
73910	M	5.96	38	14.6	13.32	8	0	92	0	0	0	1.0
73946	M	6.39	46	15.4	7.60	16	0	79	2	3	0	2.4
Mean		6.30	45	15.3	9.87	17	0	81	1	1	0	2.7
73911	F	6.68	48	15.7	12.65	10	0	88	2	0	0	2.6
73912	F	7.08	48	16.4	13.08	8	0	92	0	0	0	3.7
73913	F	6.71	47	16.1	7.26	5	0	95	0	0	0	1.1
73914	F	6.50	47	15.9	9.82	8	0	90	1	1	0	2.9
73915	F	6.48	48	16.5	8.45	8	0	92	0	0	0	1.7
Mean		6.69	48	16.1	10.25	8	0	91	1	0	0	2.4

*11 Polychromasia

- Data not available

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TABLE 7. Cont.

Individual Hematological Values - 1 Month.

Table 7. Cont.												
Group, Rat Number	Sex	Erythro- cytes 10 ⁶ /cmm	Hemato- crit %	Hemo- globin g/100 ml	Leuco- cytes 10 ³ /cmm	Neutrophils		Lympho- cytes %	Eosino- phils %	Mono- cytes %	Baso- phils %	Reticulo- cytes %
						Seg. %	Non-Seg. %					
<u>300 ppm:</u>												
73916	M	Died										
73917	M	Died										
73918	M	Died										
73919	M	Died										
73920	M	Died										
73921	F	Died										
73922	F	Died										
73923	F	Died										
73924	F	Died										
73925	F	Died										
<u>1,000 ppm:</u>												
73926	M	Died										
73927	M	Died										
73928	M	Died										
73929	M	Died										
73930	M	Died										
73931	F	Died										
73932	F	Died										
73933	F	Died										
73934	F	Died										
73935	F	Died										
<u>3,000 ppm:</u>												
73936	M	Died										
73937	M	Died										
73938	M	Died										
73939	M	Died										
73940	M	Died										
73941	F	Died										
73942	F	Died										
73943	F	Died										
73944	F	Died										
73945	F	Died										

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TABLE B.

Individual Hematological Values - 3 Months.

Group, Rat Number	Sex	Erythro- cytes 10 ⁶ /cmm	Hemato- crit %	Hemo- globin g/100 ml	Leuco- cytes 10 ³ /cmm	Neutrophils		Lympho- cytes %	Eosino- phils %	Mono- cytes %	Baso- phils %	Reticulo- cytes %
						Seg. %	Non-Seg. %					
Control:												
73886	M	8.10	52	17.3	10.35	14	0	82	2	2	0	2.3
73887	M	7.39	50	16.4	13.89	17	0	81	1	1	0	3.0
73888	M	7.16	47	15.7	16.20	8	0	91	1	0	0	3.0
73889	M	7.62	50	17.0	10.25	12	0	85	2	1	0	2.7
73890	M	7.59	50	16.4	11.80	20	1	77	0	2	0	3.1
Mean		7.57	50	16.6	12.50	14	0	84	1	1	0	2.8
73891	F	6.88	48	16.3	7.02	17	0	81	2	0	0	3.3
73892	F	6.85	47	15.5	4.95	12	0	86	1	1	0	2.9
73893	F	6.77	47	15.5	8.71	15	0	83	1	1	0	2.7
73894	F	5.96	44	16.0	9.68	36	0	56	6	2	0	3.4
73895	F	6.47	40	13.6	6.07	23	0	75	2	0	0	3.5
Mean		6.59	45	15.4	7.29	21	0	76	2	1	0	3.2
30 ppm:												
73896	M	7.58	46	16.1	8.60	11	0	88	1	0	0	2.5
73897	M	7.18	48	15.2	10.65	13	0	85	2	0	0	2.6
73898	M	8.21	46	15.7	9.90	22	0	77	1	0	0	3.3
73899	M	7.00	46	15.2	10.35	8	0	90	1	1	0	3.0
73900	M	7.18	45	15.7	8.66	20	0	77	3	0	0	3.1
Mean		7.43	46	15.6	9.63	15	0	83	2	0	0	2.9
73901	F	7.70	49	16.5	4.80	23	0	75	1	1	0	3.2
73902	F	7.15	44	15.6	6.31	11	0	87	1	1	0	3.6
73903	F	7.36	48	15.8	5.37	22	0	78	0	0	0	2.5
73904	F	7.30	48	16.3	5.16	27	1	70	2	0	0	2.5
73905	F	6.91	47	16.0	6.77	11	0	86	3	0	0	2.3
Mean		7.28	47	16.0	5.68	19	0	80	1	0	0	2.8
100 ppm:												
73906	M	Died										
73907	M	Died										
73908	M	5.04	38	11.0	5.70	24	0	76	0	0	0	3.5
73910	M	Died										
73946	M	6.00	39	13.2	6.71	37	0	62	1	0	0	2.9
Mean		5.52	39	12.1	6.21	31	0	68	1	0	0	3.2
73911	F	6.14	40	14.1	7.58	28	1	71	0	0	0	2.4
73912	F	Died										
73913	F	5.91	43	13.8	6.37	26	0	74	0	0	0	2.1
73914	F	Died										
73915	F	6.04	39	13.6	4.84	21	0	79	0	0	0	3.0
Mean		6.03	41	13.8	6.26	25	0	75	0	0	0	3.8

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Ninety Day Subacute Rat Toxicity Study.

TABLE 8. Cont.

Individual Hematological Values - 3 Months.

TABLE 6. CONT.												
Group, Rat Number	Sex	Erythro- cytes 10 ⁶ /cmm	Hemato- crit %	Hemo- globin g/100 ml	Leuco- cytes 10 ³ /cmm	Neutrophils		Lympho- cytes %	Eosino- phils %	Mono- cytes %	Baso- phils %	Reticulo- cytes %
						Seg. %	Non-Seg. %					
<u>300 ppm:</u>												
73916	M	Died										
73917	M	Died										
73918	M	Died										
73919	M	Died										
73920	M	Died										
73921	F	Died										
73922	F	Died										
73923	F	Died										
73924	F	Died										
73925	F	Died										
<u>1,000 ppm:</u>												
73926	M	Died										
73927	M	Died										
73928	M	Died										
73929	M	Died										
73930	M	Died										
73931	F	Died										
73932	F	Died										
73933	F	Died										
73934	F	Died										
73935	F	Died										
<u>3,000 ppm:</u>												
73936	M	Died										
73937	M	Died										
73938	M	Died										
73939	M	Died										
73940	M	Died										
73941	F	Died										
73942	F	Died										
73943	F	Died										
73944	F	Died										
73945	F	Died										

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Ninety Day Subacute Rat Toxicity Study.

TABLE 9.

MALES: Means and Significance^a of Biochemical Values.

Biochemistry	Study Month	Control	30 ppm	100 ppm
Glucose, mg/100 ml	Pretest	84	120	112
	1	120	111	158*
	3	112	110	112
B.U.N., mg/100 ml	Pretest	11.2	15.4	15.3
	1	15.4	15.2	29.5*
	3	15.3	28.9	23.9
Y-G.T.P., Sigma units/ml	Pretest	2	1	1
	1	1	1	1
	3	1	3	2
Creatinine Phosphokinase, Sigma units/ml	Pretest	13	15	12
	1	15	10	44
	3	12	11	10
P.G.O.T., int'l units/l	Pretest	95	112	101
	1	112	106	539
	3	101	88*	90
P.G.P.T., int'l units/l	Pretest	93	47	33
	1	47	54	485
	3	33	43	37
Calcium, meq/l	Pretest	9.5	8.4	10.4
	1	8.4	8.5	7.6
	3	10.4	10.2	10.1
Alkaline Phosphatase, int'l units/l	Pretest ^b			
	1	166	190	229
	3	89	127	103

^aSignificantly different than Control group mean, p 0<05.^aSignificantly different than Control group mean, p 0<01.^aStatistical analyses were not conducted on the pretest values.^bNot determined in pretest period because of anticoagulant interference.

Fluorochemical
Surfactant

Ninety Day Subacute Rat Toxicity Study.

TABLE 9. ----- FEMALES: Means and Significance^a of Biochemical Values.

Biochemistry	Study Month	Control	30 ppm	100 ppm
Glucose, mg/100 ml	Pretest	103	119	112
	1	119	125	149
	3	112	110	107
B.U.N., mg/100 ml	Pretest	11.3	17.0	14.6
	1	17.0	20.0	40.0*
	3	14.6	20.2	20.6*
γ -G.T.P., Sigma units/ml	Pretest	2	2	0
	1	2	1	1
	3	0	1	1
Creatinine Phosphokinase, Sigma units/ml	Pretest	10	8	9
	1	8	11	32*
	3	9	9	25
P.G.O.T., int'l units/l	Pretest	82	103	205
	1	103	107	290
	3	205	91	397
P.G.P.T., int'l units/l	Pretest	79	56	136
	1	56	61	179
	3	136	34	504
Calcium, mg/l	Pretest	10.3	10.1	10.2
	1	10.1	8.1	8.7
	3	10.2	10.4	10.4
Alkaline Phosphatase, int'l units/l	Pretest ^b			
	1			
	3	99	125	182**
		47	75	142

*Significantly different than Control group mean, $p < 0.05$.*Significantly different than Control group mean, $p < 0.01$.^aStatistical analyses were not conducted on the pretest values.^bNot determined in pretest period because of anticoagulant interference.

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Ninety Day Subacute Rat Toxicity Study.

TABLE 10.

Individual Biochemical Values - Pretest.

Group, Rat Number	Sex	Glucose mg/100 ml	B.U.N. mg/100 ml	γ -G.T.P. Sigma units/ml	C.P.K.* Sigma units/ml	P.G.O.T. int'l units/l	P.G.P.T. int'l units/l	Calcium meq/l
<u>Control:</u>								
73886	M	96	11.7	1	12	96	102	9.5
73887	M	93	9.9	2	13	108	105	9.6
73888	M	69	10.5	2	15	87	84	9.0
73889	M	81	11.7	2	12	96	84	9.4
73890	M	81	12.0	2	14	90	90	9.9
Mean		84	11.2	2	13	95	93	9.5
73891	F	75	11.1	2	14	87	96	9.5
73892	F	87	12.0	2	13	93	66	9.8
73893	F	132	11.7	2	12	66	72	9.4
73894	F	111	10.2	2	8	78	69	10.2
73895	F	111	11.7	2	5	87	90	12.8
Mean		103	11.3	2	10	82	79	10.3
<u>30 ppm:</u>								
73896	M	84	12.9	2	23	84	84	9.7
73897	M	93	8.7	2	42	96	81	9.5
73898	M	87	11.4	1	38	93	78	8.5
73899	M	75	10.8	1	15	90	78	8.9
73900	M	66	9.0	1	12	93	69	9.0
Mean		81	10.6	1	26	91	78	9.1
73901	F	99	15.3	1	13	81	99	9.7
73902	F	90	9.0	1	5	81	93	9.8
73903	F	102	12.0	1	12	102	117	9.2
73904	F	81	11.7	1	24	87	96	9.5
73905	F	93	6.6	1	9	78	90	9.1
Mean		93	10.9	1	13	86	99	9.5
<u>100 ppm:</u>								
73906	M	96	9.0	1	9	1128	1104	9.1
73907	M	93	12.3	1	10	114	120	9.7
73908	M	81	9.0	1	11	90	111	9.9
73910	M	93	9.9	1	10	81	87	10.1
73946	M	54	12.0	1	37	96	150	9.8
Mean		83	10.4	1	15	302	314	9.7
73911	F	90	10.5	1	11	75	81	10.4
73912	F	81	11.7	1	20	114	96	10.5
73913	F	87	6.6	1	10	78	72	10.6
73914	F	72	6.9	2	23	132	90	10.8
73915	F	78	9.3	1	24	66	66	10.8
Mean		82	9.0	1	18	93	81	10.6

*Creatinine phosphokinase.

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Ninety Day Subacute Rat Toxicity Study.

TABLE 10. Cont.

Individual Biochemical Values - Pretest.

Group, Rat Number	Sex	Glucose mg/100 ml	B.U.N. mg/100 ml	γ -G.T.P. Sigma units/ml	C.P.K.* Sigma units/ml	P.G.O.T. int'l units/l	P.G.P.T int'l units/l	Calcium meq/l
<u>300 ppm:</u>								
73916	M	84	8.7	2	19	87	102	11.3
73917	M	102	7.5	2	21	84	87	11.8
73918	M	105	9.3	1	10	84	93	11.5
73919	M	87	9.0	1	27	72	84	11.1
73920	M	93	9.3	2	11	69	87	11.7
Mean		94	8.8	2	18	79	91	11.5
73921	F	111	11.7	1	6	60	78	11.4
73922	F	90	9.6	1	10	87	90	11.4
73923	F	108	9.0	1	13	72	84	12.1
73924	F	93	12.0	2	11	63	96	11.0
73925	F	108	12.0	1	10	60	87	10.3
Mean		102	10.9	1	10	68	87	11.2
<u>1,000 ppm:</u>								
73926	M	108	14.1	1	14	84	84	11.7
73927	M	108	11.4	2	8	60	90	11.6
73928	M	96	9.3	2	18	87	66	11.3
73929	M	105	11.1	2	9	75	66	10.2
73930	M	90	8.7	2	41	129	90	11.6
Mean		101	10.9	2	18	87	79	11.3
73931	F	111	12.6	1	16	117	129	10.7
73932	F	90	10.8	1	13	87	75	10.9
73933	F	81	8.7	2	12	72	60	11.3
73934	F	96	9.3	2	12	90	96	12.0
73935	F	99	10.8	2	12	93	90	11.4
Mean		95	10.4	2	13	92	90	11.3
<u>3,000 ppm:</u>								
73936	M	87	9.3	2	11	84	108	11.2
73937	M	93	14.4	2	14	84	132	11.6
73938	M	78	11.7	2	12	81	99	11.1
73939	M	75	12.6	2	10	108	126	11.5
73940	M	81	23.7	22	14	105	93	11.6
Mean		83	14.3	6	12	92	112	11.4
73941	F	102	11.4	2	32	93	99	10.9
73942	F	87	11.4	2	16	78	108	11.1
73943	F	102	11.7	1	9	72	117	10.8
73944	F	96	17.7	2	21	90	102	11.3
73945	F	96	12.3	1	11	90	126	9.2
Mean		97	12.9	2	18	85	110	10.7

*Creatinine phosphokinase.

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Ninety Day Subacute Rat Toxicity Study.

TABLE II.

Individual Biochemical Values - 1 Month.

Group, Rat Number	Sex	Glucose mg/100 ml	B.U.N. mg/100 ml	γ-G.T.P. Sigma units/ml	C.P.K.* Sigma units/ml	P.G.O.T. int'l units/l	P.G.P.T. int'l units/l	Calcium mg/l	Alk. Phos. int'l units/l
<u>Control:</u>									
73886	M	138	17.4	3	16	108	54	8.1	201
73887	M	108	14.4	1	8	93	39	8.0	147
73888	M	117	14.7	1	8	90	33	7.7	147
73889	M	120	15.3	1	30	150	66	9.3	138
73890	M	117	15.0	0	11	117	45	8.7	198
Mean		120	15.4	1	15	112	47	8.4	166
73891	F	120	18.0	2	6	117	60	8.3	93
73892	F	126	16.5	2	10	108	60	8.8	120
73893	F	123	15.3	2	6	93	51	9.3	105
73894	F	117	15.3	1	8	105	54	10.8	87
73895	F	108	19.8	1	12	93	54	13.4	90
Mean		119	17.0	2	8	103	56	10.1	99
<u>30 ppm:</u>									
73896	M	108	13.5	1	9	93	54	7.7	207
73897	M	117	15.0	1	10	90	42	8.4	267
73898	M	108	18.6	1	15	123	75	8.7	162
73899	M	111	15.3	1	6	99	48	8.8	168
73900	M	111	13.5	0	8	123	51	8.9	147
Mean		111	15.2	1	10	106	54	8.5	190
73901	F	120	22.2	0	6	102	45	7.5	132
73902	F	147	16.8	2	9	111	72	8.0	144
73903	F	120	22.5	1	8	93	51	8.2	90
73904	F	123	17.7	1	9	120	66	8.1	120
73905	F	114	21.0	1	23	108	72	8.8	138
Mean		125	20.0	1	11	107	61	8.1	125
<u>100 ppm:</u>									
73906	M	135	29.7	1	36	363	345	8.0	219
73907	M	171	30.0	1	29	243	180	8.0	198
73908	M	183	30.0	2	96	1527	1248	7.0	180
73910	M	171	34.5	2	44	396	480	7.2	258
73946	M	129	23.4	1	16	168	171	7.6	288
Mean		158	29.5	1	44	539	485	7.6	229
73911	F	153	29.7	0	42	432	282	8.3	162
73912	F	225	42.0	2	56	657	393	8.2	132
73913	F	120	38.4	1	24	123	75	9.0	180
73914	F	123	60.3	1	19	120	78	8.8	231
73915	F	126	29.7	1	17	117	69	9.2	204
Mean		149	40.0	1	32	290	179	8.7	182

*Creatinine phosphokinase.

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Ninety Day Subacute Rat Toxicity Study.

TABLE 11. C

Individual Biochemical Values - 1 Month.

Group, Rat Number	Sex	Glucose mg/100 ml	B.U.N. mg/100 ml	γ -G.T.P. Sigma units/ml	C.P.K.* Sigma units/ml	P.G.O.T. int'l units/l	P.G.P.T. int'l units/l	Calcium mg/l	Alk. Phos. int'l units/l
<u>300 ppm:</u>									
73916	M	Died							
73917	M	Died							
73918	M	Died							
73919	M	Died							
73920	M	Died							
73921	F	Died							
73922	F	Died							
73923	F	Died							
73924	F	Died							
73925	F	Died							
<u>1,000 ppm:</u>									
73926	M	Died							
73927	M	Died							
73928	M	Died							
73929	M	Died							
73930	M	Died							
73931	F	Died							
73932	F	Died							
73933	F	Died							
73934	F	Died							
73935	F	Died							
<u>3,000 ppm:</u>									
73936	M	Died							
73937	M	Died							
73938	M	Died							
73939	M	Died							
73940	M	Died							
73941	F	Died							
73942	F	Died							
73943	F	Died							
73944	F	Died							
74945	F	Died							

*Creatinine phosphokinase.

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Surfactant

Ninety Day Subacute Rat Toxicity Study.

TABLE 12.

Individual Biochemical Values - 3 Months.

Group, Rat Number	Sex	Glucose mg/100 ml	B.U.N. mg/100 ml	γ -G.T.P. Sigma units/ml	C.P.K.* Sigma units/ml	P.G.O.T. int'l units/l	P.G.P.T. int'l units/l	Calcium mg/l	Alk. Phos. int'l units/l
<u>Control:</u>									
73886	M	116	14.1	0	11	109	42	10.4	120
73887	M	105	14.2	1	13	97	31	10.0	79
73888	M	110	15.7	1	12	95	30	10.8	99
73889	M	111	17.6	1	8	102	32	10.3	59
73890	M	118	14.9	0	14	102	30	10.3	86
Mean		112	15.3	1	12	101	33	10.4	89
73891	F	105	16.0	1	8	87	29	11.0	46
73892	F	102	14.0	1	9	86	27	10.3	43
73893	F	128	13.9	0	9	88	24	9.7	47
73894	F	111	12.0	0	9	663	560	9.8	47
73895	F	112	17.0	0	11	100	41	10.2	53
Mean		112	14.6	0	9	205	136	10.2	47
<u>30 ppm:</u>									
73896	M	145	74.4	13	11	86	39	10.5	175
73897	M	91	16.5	1	10	86	48	10.1	139
73898	M	116	19.1	0	12	100	38	9.9	107
73899	M	94	18.3	1	13	79	42	9.8	105
73900	M	105	16.1	0	8	90	49	10.5	111
Mean		110	28.9	3	11	88	43	10.2	127
73901	F	105	23.6	0	6	71	19	10.5	70
73902	F	125	17.6	0	9	90	23	10.5	95
73903	F	121	22.1	1	8	90	38	10.3	49
73904	F	103	17.4	1	9	106	53	10.4	60
73905	F	95	20.1	1	11	96	35	10.5	99
Mean		110	20.2	1	9	91	34	10.4	75
<u>100 ppm:</u>									
73906	M	Died							
73907	M	Died							
73908	M	100	21.4	1	7	87	46	10.3	79
73910	M	Died							
73946	M	123	26.3	2	13	93	27	9.9	127
Mean		112	23.9	2	10	90	37	10.1	103
73911	F	117	19.0	0	7	95	60	10.8	95
73912	F	Died							
73913	F	121	19.0	1	42	786	1344	10.0	176
73914	F	Died							
73915	F	84	23.8	1	27	309	108	10.4	154
Mean		107	20.6	1	25	397	504	10.4	142

*Creatinine phosphokinase.

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Ninety Day Subacute Rat Toxicity Study.

TABLE 12.

Individual Biochemical Values - 3 Months.

Group, Rat Number	Sex	Glucose mg/100 ml	B.U.N. mg/100 ml	γ -G.T.P. Sigma units/ml	C.P.K.* Sigma units/ml	P.G.O.T. int'l units/l	P.G.P.T. int'l units/l	Calcium meq/l	Alk. Phos. int'l units/l
<u>300 ppm:</u>									
73916	M	Died							
73917	M	Died							
73918	M	Died							
73919	M	Died							
73920	M	Died							
73921	F	Died							
73922	F	Died							
73923	F	Died							
73924	F	Died							
73925	F	Died							
<u>1,000 ppm:</u>									
73926	M	Died							
73927	M	Died							
73928	M	Died							
73929	M	Died							
73930	M	Died							
73931	F	Died							
73932	F	Died							
73933	F	Died							
73934	F	Died							
73935	F	Died							
<u>3,000 ppm:</u>									
73936	M	Died							
73937	M	Died							
73938	M	Died							
73939	M	Died							
73940	M	Died							
73941	F	Died							
73942	F	Died							
73943	F	Died							
73944	F	Died							
73945	F	Died							

*Creatinine phosphokinase.

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Ninety Day Subacute Rat Toxicity Study.

TABLE 13.

Means and Significance^a of Urinalysis Values.

Urinalysis	Study Month	Control	30 ppm	100 ppm
MALES:				
Volume, ml	Pretest	2.1	3.5	3.2
	1	2.8	3.1	3.3
	3	3.1	2.3	3.5
pH,	Pretest	7.6	7.0	7.0
	1	7.4	6.5	6.8
	3	7.2	6.3	7.4
Specific Gravity,	Pretest	1.050	1.054	1.047
	1	1.067	1.057	1.042
	3	1.068	1.067	1.042
FEMALES:				
Volume,	Pretest	1.3	1.7	1.6
	1	1.8	2.1	2.9
	3	0.8	2.1	0.0
pH,	Pretest	6.8	7.0	6.8
	1	7.0	7.3	6.7
	3	6.7	7.2	QNS
Specific Gravity,	Pretest	1.079	1.063	1.069
	1	1.038	1.048	1.054
	3	1.071	1.055	QNS

QNS - Quantity not sufficient

^aStatistical analyses were not conducted on pretest values.

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Ninety Day Subacute Rat Toxicity Study.

TABLE 14.

Individual Urinalysis Values - Pretest.

Group, Rat Number	Sex	Volume ml	Color and Appear.	pH	Spec. Grav.	Albu- min	Glucose	Bili- rubin	Occlt Blood	Ke- tones	Erythro- cytes	Epi. Cells	Amor. Urates	Triple Phos- phates	Calc. Ox.	Bacteria
Control:																
73886	H	2.5	DS-cl	7.5	1.070	2+	N	N	1+	2+	occ		F	M		M
73887	H	0.5	DS-cl	7.6	1.010	1+	N	N	2+	tr	1-3		occ	occ		M
73888	H	3.5	DS-cl	8.2	1.035	N	N	N	1+	N			F	F		M
73889	H	2.5	DS-C	6.9	1.065	N	N	N	1+	N	occ		occ	occ		M
73890	H	1.5	DS-cl	7.9	1.070	N	N	N	3+	N	1-3	occ	F	M		M
73891	F	0.5	DS-C	7.9	1.075	N	N	N	4+	1+	1-3	occ	F	occ		M
73892	F	1.0	S-C	6.3	1.080	N	N	N	1+	N		occ	occ	M		M
73893	F	1.0	S-C	6.0	1.095	N	N	N	N	N			occ	F		F
73894	F	0.5	S-C	6.0	1.090	tr	N	N	N	N			occ	M		M
73895	F	2.0	S-cl	8.0	1.055	N	N	N	3+	tr			occ	M		M
30 ppm:																
73896	H	2.5	S-C	6.8	1.065	tr	N	N	N	1+			occ	F		M
73897	H	5.5	DS-cl	6.9	1.050	N	N	N	1+	tr			M	F		M
73898	H	5.0	DS-C	7.2	1.040	N	N	N	tr	N			occ	M		M
73899	H	3.5	S-C	6.9	1.050	N	N	N	N	2+		occ	occ	F		M
73900	H	1.0	DS-cl	7.1	1.065	tr	N	N	3+	N	occ		occ	occ		M
73901	F	4.0	S-C	7.0	1.037	N	N	N	N	N			occ	occ		M
73902	F	1.0	DS-C	6.1	1.090	tr	N	N	tr	1+	occ		F	F		M
73903	F	1.5	DS-cl	8.4	1.039	N	N	N	2+	tr	occ		occ	F		M
73904	F	1.5	S-C	6.0	1.080	tr	N	N	N	N		occ	occ	F		F
73905	F	0.5	DS-cl	7.5	1.070	tr	N	N	4+	2+			occ	M		M
100 ppm:																
73906	H	3.5	S-C	7.0	1.045	N	N	N	1+	tr			occ	F		M
73907	H	4.0	S-C	6.9	1.050	N	N	N	N	N			occ	F		M
73908	H	2.5	S-C	6.0	1.065	N	N	N	N	tr	1-3		occ	F		M
73910	H	4.0	DS-cl	8.3	1.038	N	N	N	3+	N		occ	F	F		M
73946	H	2.0	LS-C	6.9	1.036	N	N	N	N	N			F	F		F
73911	F	2.0	S-C	5.9	1.065	N	N	N	N	N			occ	F		F
73912	F	2.5	DS-cl	7.8	1.070	N	N	N	4+	N			F	M	occ	M
73913	F	1.0	LS-C	6.0	1.075	N	N	N	N	N			occ	occ		F
73914	F	1.0	DS-cl	6.2	1.085	tr	N	N	2+	N	occ		F	F		M
73915	F	1.5	S-cl	7.9	1.050	N	N	N	tr	N			occ	M		M

137-085

Code: tr - Trace
1+ - Trace to slight
2+ - Slight to moderate
3+ - Moderate
4+ - Marked
S - Straw
LS - Light Straw
DS - Dark Straw
LAM - Light Amber
DAM - Dark Amber
cl - Cloudy
C - Clear
N - Negative
F - Few
L - Loaded
M - Many
R - Rare
occ - Occasional

TABLE 14. cont.

Individual Urinalysis Values - Pretest.

Group, Rat Number	Sex	Volume ml	Color and Appear.	pH	Spec. Grav.	Albu- min	Glu- cose	Bill- rubin	Occult Blood	Ke- tones	Erythro- cytes	Epi. Cells	Amor. Urates	Triple Phos- phates	Calc. Ox.	Bacteria
300 ppm:																
73916	H	QNS														
73917	H	1.5	DS-cl	8.0	1.045	N	N	N	4+	N			occ	occ		M
73918	H	<0.5	S-C	8.2	1.070	tr	N	N	N	N			occ	F		M
73919	H	4.0	DS-cl	5.3	1.042	N	N	N	1+	N			F	M		M
73920	M	7.0	DS-cl	8.0	1.036	N	N	N	tr	N		occ	F	M		M
73921	F	2.0	S-C	7.9	1.085	N	N	N	N	N	occ	occ	occ	F		M
73922	F	3.5	DS-cl	5.9	1.040	N	N	N	4+	N			occ	M		M
73923	F	4.0	S-C	7.8	1.045	N	N	N	N	N			F	F		M
73924	F	2.0	S-C	6.9	1.065	N	N	N	N	N	occ		occ	F		M
73925	F	2.0	S-C	6.1	1.070	N	N	N	N	N			occ	F		M
1,000 ppm:																
73926	M	8.0	S-cl	8.9	1.032	N	N	N	tr	N	occ		occ	F		M
73927	M	4.5	LS-cl	8.0	1.036	N	N	N	N	N			occ	M		M
73928	M	5.5	LS-cl	7.9	1.036	N	N	N	N	N		occ	occ	occ		M
73929	M	5.0	S-C	6.3	1.042	N	N	N	N	N			occ	M		M
73930	M	4.0	S-cl	8.1	1.040	N	N	N	N	N			occ	F		M
73931	F	<0.5	DS-cl	6.5	1.090	tr	N	N	1+	N			occ	F		F
73932	F	1.5	DS-C	7.0	1.080	N	N	N	2+	tr	1-3		F	M		M
73933	F	<0.5	DS-C	8.9	1.070	tr	N	N	4+	N	occ		occ	F		M
73934	F	5.0	LS-C	7.1	1.036	N	N	N	N	N		occ	occ	M		M
73935	F	QNS														
3,000 ppm:																
73936	M	2.5	DS-cl	8.2	1.050	tr	N	N	1+	tr	1-3	occ	M	M		M
73937	M	4.5	S-cl	8.4	1.038	N	N	N	1+	N	occ		F	M		M
73938	M	5.0	S-cl	8.4	1.037	N	N	N	tr	N			occ	occ		M
73939	M	3.5	S-C	6.1	1.045	N	N	N	N	N			occ	M		M
73940	M	6.0	S-cl	6.4	1.048	N	N	N	N	N			occ	M		M
73941	F	4.0	DS-cl	8.1	1.035	N	N	N	4+	N	occ	occ	F	M		M
73942	F	4.0	DS-C	8.4	1.036	tr	N	N	4+	N			occ	F		M
73943	F	2.5	DS-cl	8.6	1.042	1+	N	N	4+	N	1-3		F	F		M
73944	F	1.0	DS-cl	6.7	1.070	N	N	N	4+	N		occ	occ	F		M
73945	F	3.5	DS-cl	7.0	1.038	N	N	N	3+	N			occ	F		M

137-085

Code: tr - Trace S - Straw N - Negative QNS - Quantity not sufficient
 1+ - Trace to slight LS - Light Straw F - Few
 2+ - Slight to moderate DS - Dark Straw L - Loaded
 3+ - Moderate LAw - Light Amber M - Many
 4+ - Marked DAw - Dark Amber R - Rare
 cl - Cloudy occ - Occasional
 C - Clear

TABLE 15.

Individual Urinalysis Values - 1 Month.

Group, Rat Number	Sex	Volume ml	Color and Appear.	pH	Spec. Grav.	Albu- min	Glucose	Billi- rubin	Occult Blood	Ke- tonen	Erythro- cytes	Epi. Cells	Amor. Urates	Triple Phos- phates	Calc. Ox.	Bacteria
<u>Control:</u>																
73886	M	3.5	S-cl	6.9	1.040	N	N	N	tr	N	occ	occ	F	occ	F	M
73887	M	0.5	S-C	6.8	1.045	N	N	N	tr	N		occ	F	M		M
73888	M	5.0	S-cl	6.8	1.080	N	N	N	N	N			occ	F		M
73889	M	4.5	DS-cl	8.3	1.080	N	N	N	1+	tr	1-3	occ	occ	M		M
73890	M	0.5	DS-cl	8.2	1.090	N	N	N	1+	tr			occ	occ		F
73891	F	2.0	DS-cl	8.0	1.045	N	N	N	2+	N	occ	occ	F	M	F	M
73892	F	QNS														
73893	F	1.0	DS-cl	7.6	1.045	N	N	N	1+	N			F	M	occ	M
73894	F	1.0	S-C	6.2	1.040	N	N	N	tr	N	1-3	occ	F	F	F	M
73895	F	3.0	LS-C	6.0	1.020	N	N	N	N	N		1-3	occ	M		M
<u>30 ppm:</u>																
73896	M	5.5	LS-C	6.3	1.040	N	N	N	N	N	1-3	occ	occ	M	occ	M
73897	M	5.0	DS-cl	6.2	1.045	N	N	N	N	N	1-3	occ	F	occ		M
73898	M	1.5	DS-cl	8.0	1.040	N	N	N	tr	N		occ	F	F	occ	M
73899	M	1.5	S-C	6.2	1.070	N	N	N	N	N	occ	occ	F	M	occ	M
73900	M	2.0	S-C	5.8	1.090	N	N	N	N	N	occ	occ	F	F		M
73901	F	2.5	S-cl	6.9	1.050	N	N	N	N	N		occ	occ	F		M
73902	F	1.0	S-cl	7.0	1.040	N	N	N	N	N	1-3		F	M		M
73903	F	3.5	S-cl	6.8	1.055	N	N	N	N	N	1-3	occ	occ	F	occ	M
73904	F	2.5	DS-cl	8.0	1.045	N	N	N	1+	N	occ	occ	F	F	F	M
73905	F	1.0	DS-cl	8.0	1.050	N	N	N	1+	N		occ	F	M		M
<u>100 ppm:</u>																
73906	M	2.5	S-C	6.8	1.045	N	N	N	N	1+	1-3	occ	occ	M		M
73907	M	2.5	S-C	7.0	1.045	N	N	N	N	1+			occ	F		M
73908	M	7.5	S-C	7.0	1.035	N	N	N	N	tr		occ	F	M		M
73910	M	2.0	S-C	6.5	1.050	N	N	N	N	1+		occ	occ	F		M
73946	M	2.0	S-cl	6.5	1.077	N	N	N	N	1+	occ		occ	F		M
73911	F	3.5	S-C	5.9	1.040	N	N	N	N	N		occ	F	F		M
73912	F	3.5	DS-cl	7.9	1.050	N	N	N	1+	N			F	occ	M	M
73913	F	QNS														
73914	F	3.5	S-cl	6.5	1.045	N	N	N	tr	N		occ	F	F	M	M
73915	F	1.0	S-cl	6.3	1.080	N	N	N	N	N		occ	F	M	occ	M

137-085

Code: tr - Trace
1+ - Trace to slight
2+ - Slight to moderate
1+ - Moderate
4+ - Marked

S - Straw
LS - Light Straw
DS - Dark Straw
LAM - Light Amber
DAM - Dark Amber
cl - Cloudy
C - Clear

N - Negative
P - Few
L - Loaded
M - Many
R - Rare
occ - Occasional

QNS - Quantity not sufficient

TABLE 15.

Individual Urinalysis Values - 1 Month.

Group, Rat Number	Sex	Volume ml	Color and Appear.	pH	Spec. Grav.	Albu- min	Glu- cose	Billi- rubin	Occult Blood	Ke- tones	Erythro- cytes	Epi. Cells	Amor. Urates	Triple Phos- phates	Calc. Ox.	Bacteria
<u>300 ppm:</u>																
73916	H	Died														
73917	H	Died														
73918	H	Died														
73919	H	Died														
73920	H	Died														
73921	F	Died														
73922	F	Died														
73923	F	Died														
73924	F	Died														
73925	F	Died														
<u>1,000 ppm:</u>																
73926	H	Died														
73927	H	Died														
73928	H	Died														
73929	H	Died														
73930	H	Died														
73931	F	Died														
73932	F	Died														
73933	F	Died														
73934	F	Died														
73935	F	Died														
<u>3,000 ppm:</u>																
73936	H	Died														
73937	H	Died														
73938	H	Died														
73939	H	Died														
73940	H	Died														
73941	F	Died														
73942	F	Died														
73943	F	Died														
73944	F	Died														
73945	F	Died														

137-085

Code:

tr - Trace
14 - Trace to slight
24 - Slight to moderate
30 - Moderate
44 - Marked

S - Straw
LS - Light Straw
DS - Dark Straw
LAm - Light Amber
DAm - Dark Amber
cl - Cloudy
C - Clear

N - Negative
F - Few
L - Loaded
M - Many
R - Rare
occ - Occasional

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Ninety Day Subacute Rat Toxicity Study.

TABLE 16.

Individual Urinalysis Values - 3 Months.

Group, Rat Number	Sex	Volume ml	Color and Appear.	pH	Spec. Grav.	Albu- min	Glucose	Billi- rubin	Occult Blood	Ke- tonen	Erythro- cytes	Epi. Cells	Amor. Urates	Triple Phos- phates	Calc. Ox.	Bacteria
Control:																
73886	M	0.5	S-cl	7.0	1.110	tr	N	N	2+	N			H	F	occ	H
73887	M	1.5	DS-cl	8.0	1.070	N	N	N	3+	N	1-3		F	H		H
73888	M	4.0	S-cl	7.2	1.059	N	N	N	1+	N	occ	occ	F	F		H
73889	M	4.0	S-cl	6.8	1.045	N	N	N	N	N		occ	F	F		H
73890	M	3.0	S-cl	7.0	1.057	N	N	N	2+	N		occ	F	F		H
73891	F	2.5	LS-C	6.2	1.042	N	N	N	N	N			F	F		F
73892	F	<0.5	DS-cl	8.0	1.060	N	N	N	4+	N	1-3		H	F	occ	H
73893	F	QNS														
73894	F	0.7	LS-cl	6.0	1.110	N	N	N	N	N	1-3		H	F		F
73895	F	QNS														
10 ppm:																
73896	M	1.0	LS-cl	6.0	1.080	N	N	N	N	N		occ	occ	F	occ	F
73897	M	5.0	LS-cl	6.2	1.042	N	N	N	N	N			occ	occ		F
73898	M	3.5	S-cl	6.0	1.062	N	N	N	N	N	1-3		F	F		F
73899	M	2.5	S-cl	6.3	1.080	N	N	N	N	1+	1-3		F	F		H
73900	M	2.0	S-cl	7.2	1.070	N	N	N	N	N		occ	F	F	occ	H
73901	F	2.0	S-cl	7.8	1.022	tr	N	N	3+	N	occ		H	F	F	H
73902	F	0.7	S-cl	5.0	1.120	tr	N	N	N	N			F	H		H
73903	F	2.0	S-cl	8.2	1.030	N	N	N	3+	N			F	H		H
73904	F	5.0	LS-cl	6.8	1.040	N	N	N	N	N	occ	occ	H	F		H
73905	F	0.8	DS-cl	8.0	1.062	N	N	N	3+	N	1-3		F	H	occ	H
100 ppm:																
73906	M	Died														
73907	M	Died														
73908	M	5.0	LS-C	6.0	1.042	N	N	N	N	N			F	occ		F
73910	M	Died														
73946	M	2.0	DS-cl	8.8	1.042	N	N	N	3+	N			H	H	occ	H
73911	F	QNS														
73912	F	Died														
73913	F	QNS														
73914	F	Died														
73915	F	QNS														

137-085

Code: tr - Trace
1+ - Trace to slight
2+ - Slight to moderate
3+ - Moderate
4+ - Marked

S - Straw
LS - Light Straw
DS - Dark Straw
LAM - Light Amber
DAM - Dark Amber
cl - Cloudy
C - Clear

N - Negative
F - Few
L - Loaded
H - Many
R - Rare
occ - Occasional

QNS - Quantity not sufficient

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Ninety Day Subacute Rat Toxicity Study.

TABLE 16. cont.

Individual Urinalysis Values - 3 Months.

Group, Rat Number	Sex	Volume ml	Color and Appear.	pH	Spec. Grav.	Albu- min	Glu- cose	Billi- rubin	Occult Blood	Ke- tones	Erythro- cytes	Epi. Cells	Amor. Urates	Triple Phos- phates	Calc. Ox.	Bacterin
<u>300 ppm:</u>																
73916	M	Died														
73917	M	Died														
73918	M	Died														
73919	M	Died														
73920	M	Died														
73921	F	Died														
73922	F	Died														
73923	F	Died														
73924	F	Died														
73925	F	Died														
<u>1,000 ppm:</u>																
73926	M	Died														
73927	M	Died														
73928	M	Died														
73929	M	Died														
73930	M	Died														
73931	F	Died														
73932	F	Died														
73933	F	Died														
73934	F	Died														
73935	F	Died														
<u>3,000 ppm:</u>																
73936	M	Died														
73937	M	Died														
73938	M	Died														
73939	M	Died														
73940	M	Died														
73941	F	Died														
73942	F	Died														
73943	F	Died														
73944	F	Died														
73945	F	Died														

137-085

Code: tr - Trace S - Straw N - Negative
 1+ - Trace to slight LS - Light Straw F - Few
 2+ - Slight to moderate DS - Dark Straw L - Loaded
 3+ - Moderate LAm - Light Amber M - Many
 4+ - Marked DAm - Dark Amber R - Rare
 cl - Cloudy occ - Occasional
 C - Clear

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Ninety Day Subacute Rat Toxicity Study.

TABLE 17.

Summary of Gross Necropsy Observations.

	Terminal Sacrifice												Deaths, Unscheduled Sacrifice											
	Control		30 ppm		100 ppm		300 ppm		1,000 ppm		3,000 ppm		Control		30 ppm		100 ppm		300 ppm		1,000 ppm		3,000 ppm	
	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F
Number necropsied	5	5	5	5	2	3											3	2	5	5	5	5	5	5
No gross lesions	4	3	2														1	2					1	
External																								
emaciation																								
hair loss, forelimb			1	1															2		1			
reddish material around mouth/nose/ forelimb																	1		1		1			
yellowish/red material, anogenital region																			1		1	1		1
Eyes																								
corneal opacity		1																						
Lungs																								
congestion																	1		2		1	1		
white/dark brown/red/yellow foci			2														1		1					
atelectasis																							1	
Lymph Nodes																								
red discoloration - cervical																	1							
red/dark black discoloration - mesenteric																							1	2
Stomach																								
hyperemia/congestion																								
dark brown/red foci - glandular mucosa						1											2		1		1		2	
linear hemorrhage - glandular mucosa																		3	4		3	4	2	5
Small Intestine																								
dark red - greenish contents																			1				2	
semisolid, dark brown, tan contents																					3			
black, mucoid material																							1	
Liver																								
enlarged					2	2											1							
congestion																					1			
accentuated lobulation						2	2										2							
yellowish/brown/white foci			2	1	1	1																	2	
irregular areas																		2			3			
greenish - yellow exudate																		1						
adhesion to right kidney																					1			
brown in color					2	2	3																	
Kidneys																								
hydronephrosis						1																	1	
congestion																								

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Ninety Day Subacute Rat Toxicity Study.

TABLE 17. Cont.

Summary of Gross Necropsy Observations.

	Terminal Sacrifice												Deaths, Unscheduled Sacrifice											
	Control		30 ppm		100 ppm		300 ppm		1,000 ppm		3,000 ppm		Control		30 ppm		100 ppm		300 ppm		1,000 ppm		3,000 ppm	
	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F
Uterus																								
enlarged/hydrometra			1		2																			
Miscellaneous																								
scanty abdominal fat																					1		1	

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Ninety Day Subacute Rat Toxicity Study.

TABLE 18.

Absolute (Grams) and Relative (% Body Weight) Organ Weights.

Group, Sex	Body Wt. g	Spleen		Liver		Kidneys		Brain		Adrenals		Thyroid/ Parathyroid ₂		Pituitary ₂	
		g	%	g	%	g	%	g	%	g	x10 ⁻²	g	x10 ⁻²	g	x10 ⁻²
Control:															
M	454	0.77	0.17	13.80	3.05	4.01	0.89	2.27	0.50	74	1.64	41	0.90	22	0.49
F	253	0.48	0.19	7.74	3.07	2.21	0.88	2.06	0.82	76	2.99	36	1.46	20	0.79
70 ppm:															
M	414	0.61	0.15	17.19	4.16	3.60	0.87	2.30	0.56	55**	1.34*	32*	0.78	15*	0.36
F	233	0.45	0.19	9.69*	4.17**	2.05	0.88	2.13	0.92	82	3.56	35	1.50	20	0.89
100 ppm:															
M	373	0.56	0.14	29.51	7.88*	3.73	1.00*	2.28	0.64	70	1.96	36	0.98	14	0.40
F	206	0.38	0.18	13.54**	6.57**	2.09	1.01*	1.98	0.96	79	3.82	26	1.25	19	0.92

Group mean relative organ weights shown in this table were calculated by averaging the individually calculated relative organ weights.

*Significantly different from control group mean, $p < 0.05$.
**Significantly different from control group mean, $p < 0.01$.

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Ninety Day Subacute Rat Toxicity Study.

TABLE 19.

Individual Organ Weights - Terminal Sacrifice.

Group Rat No.	Sex	Body Wt. g	Spleen g	Liver g	Kidneys g	Brain g	Adrenals mg	Thyroid/ Parathyroid mg	Pituitary mg
<u>Control:</u>									
73886	M	450	0.77	13.44	3.95	2.31	73	42	30
73887	M	439	0.63	15.24	4.10	2.19	74	40	19
73888	M	500	0.76	13.92	4.14	2.47	89	48	22
73889	M	423	0.84	12.83	3.74	2.23	66	40	20
73890	M	457	0.85	13.58	4.12	2.13	70	34	19
73891	F	262	0.40	7.02	2.28	2.19	88	32	22
73892	F	232	0.42	7.05	1.92	1.87	31	30	16
73893	F	284	0.54	7.97	2.32	1.87	79	30	20
73894	F	213	0.60	7.05	2.10	2.11	72	52	21
73895	F	273	0.45	9.59	2.44	2.27	112	35	20
<u>30 ppm:</u>									
73896	M	404	0.58	18.48	3.70	2.35	62	29	12
73897	M	442	0.77	19.75	4.75	2.34	54	28	17
73898	M	423	0.59	19.63	3.96	2.01	55	38	18
73899	M	416	0.40	9.46	1.80	1.89	49	33	13
73900	M	387	0.69	18.65	3.80	2.90	56	33	14
73901	F	216	0.40	9.46	1.80	1.89	64	23	18
73902	F	251	0.51	10.55	2.22	2.19	70	36	14
73903	F	224	0.45	8.98	2.13	2.30	96	38	32
73904	F	251	0.48	9.98	2.16	2.13	63	34	18
73905	F	221	0.39	9.50	1.93	2.14	116	43	20
<u>100 ppm:</u>									
73908	M	446	0.77	35.75	4.50	2.10	65	40	12
73946	M	300	0.35	23.26	2.96	2.45	74	32	16
73911	F	221	0.38	13.83	2.38	2.15	70	36	24
73913	F	192	0.35	12.45	1.78	1.75	70	20	17
73915	F	206	0.40	14.34	2.10	2.04	96	22	16

TABLE 20.

Histomorphologic Observations.

Tissue Lesion	Group, Rat No., Sex	Control					30 ppm					100 ppm				
		M	F	M	F	M	M	F	M	F	M	M	F	M	F	F
Brain (With Cervical Cord)		1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Spinal Cord (Lumbar)		1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Peripheral Nerve		1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Pituitary focal cytoplasmic vacuolation of basophils parenchymal cyst		2	2	2	2	3	1	1	1	1	1	1	1	1	1	1
Thyroid remnant of ultimobranchial rest focal interstitial lymphoid infiltrates		1	1	1	1	1	x	x	x	x	x	1	1	1	1	1
Parathyroid		1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Adrenal focal cytoplasmic vacuolation of cortical cells diffuse congestion		2	1	1	1	1	2	2	2	3	4	2	2	3	2	2
Lung focal peribronchial lymphoid hyperplasia focal perivascular lymphoid infiltrates focal aggregates of alveolar macrophages congestion (agonal) focal interstitial inflammatory cell infiltrates alveolar edema		2	2	2	2	2	2	2	3	3	2	3	2	2	2	2
Eye		1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Heart focal myocardial degeneration/mineralization focal interstitial lymphoid infiltrates in myocardium focal myocardial fibrosis focal necrosis with mononuclear cell infiltrates in myocardium		1	1	2	1	1	1	1	1	1	1	1	1	1	1	1
Aorta		1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Spleen atrophy depletion in number and size of lymphoid follicles increased hemosiderin pigment in red pulp		1	1	1	1	1	1	1	1	1	1	1	1	1	1	1

Code: x - condition present 4 - moderate
1 - not remarkable 5 - marked

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Ninety Day Subacute Rat Toxicity Study.

TABLE 20.

Histomorphologic Observations.

Tissue Lesion	Group, Rat No.	Sex	300 ppm					1,000 ppm					3,000 ppm				
			M*	M*	M*	M*	F*	M*	M*	M*	M*	F*	M*	M*	M*	F*	F*
Brain (With Cervical Cord)			1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Spinal Cord (Lumbar)			1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Peripheral Nerve			1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Pituitary			1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
focal cytoplasmic vacuolation of basophilic chromophils							x										x
Thyroid			1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
remnant of ultimobranchial rest					x			x	x		x		x	x			x
focal interstitial lymphoid infiltrates																	
Parathyroid			1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Adrenal			1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
focal cytoplasmic vacuolation of cortical cells							2				2						
diffuse congestion			2			2	2	2	2	2	3	2	2	3	2	2	2
Lung								1									
focal peribronchial lymphoid hyperplasia			2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
focal perivascular lymphoid infiltrates																	
focal aggregates of alveolar macrophages			2	2	2	2	3	2	2	2	2	2	2	2	2	2	2
congestion (agonal)			3	2	2	3	2	2	2	3	2	3	3	2	2	2	3
focal interstitial inflammatory cell infiltrates					2												
alveolar edema																	
Eye			1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Heart			1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
focal myocardial degeneration/mineralization						2											
focal interstitial lymphoid infiltrates in myocardium																	
focal myocardial fibrosis												2		2			
focal necrosis with mononuclear cell infiltrates in myocardium													3				
Aorta			1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Spleen																	
atrophy			x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
depletion in number and size of lymphoid follicles			4	3	5	4	4	3	4	4	3	5	4	5	4	5	5
increased hemosiderin pigment in red pulp																	

Code: x - condition present 4 - moderate
 1 - not remarkable 5 - marked
 2 - very slight 6 - extreme
 3 - absent * - died

TABLE 20. Cont.

Ninety Day Subacute Rat Toxicity Study.

Histomorphologic Observations.

[illegible]

Code: x - condition present 4 - moderate
 1 - not remarkable 5 - marked
 2 - very slight 6 - extreme

TABLE 20. Cont.

Histomorphologic Observations.

Tissue Lesion	Group, Rat No.	Sex	300 ppm										1,000 ppm										3,000 ppm									
			M*	M*	M*	M*	M*	F*	F*	F*	F*	F*	M*	M*	M*	M*	M*	F*	F*	F*	F*	F*	M*	M*	M*	M*	M*	F*	F*	F*	F*	F*
Mesenteric Lymph Node depletion in size and number of follicles			2	3	3	4	4	4	3	4	4	4	3	3	3	5	4	4	4	3	4		4	3	4	4	4	4	4	3	4	3
Thymus depletion in size and number of lymphoid follicles			-	2	3	4	-	4	4	4	3	3	4	-	4	5	5	4	4	4	-	4	5	5	5	4	4	-	4	4	3	5
Bone Marrow (Sternum) hypocellular osteoclastic resorption of bone			1	2	1	2	3	3	2	3	4	3	3	4	3	4	3	4	3	3	3	3	4	3	3	3	4	3	3	4	4	3
Salivary Gland			1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Stomach focal mucosal erosion in glandular portion focal mucosal hemorrhage in glandular portion mucosal hyperkeratosis in forestomach (nonglandular)			2	1	2	1	2		2	2	1		3	1		3		3		3	2	3	1	1	1	A			2	3	3	
								3	2				2		2		2	2		3						2					4	
							2						2			3	2	2		3	2						3	3			2	
Small Intestine (Duodenum, Jejunum, Ileum) atrophy (decrease in size of mucosal villi)			3	1	3	3	2	3	2	3	3	3	3	2	2	3	3	3	4	4	3	3	2	3	3	4	A	3	3	4	3	3
Large Intestine (Colon)			1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	A	1	1	1	1	1
Pancreas focal interstitial lymphoid infiltrates focal cytoplasmic vacuolation of acinar cells focal atrophy of acinar cells				1	1		1	1	1	1			1	1	1	1	1	1	1	1	1	1	1	1	1	1	A	1	A	1	1	1
			2			3	2				2		2												2							
Liver focal periportal/sinusoidal lymphoid infiltrates capsular fibrosis diffuse, sinusoidal congestion focal portal/sinusoidal extramedullary hematopoiesis focal hepatocellular necrosis focal cytoplasmic vacuolation of hepatocytes focal hepatocellular hypertrophy multifocal, hepatocellular hypertrophy increased yellowish-brown pigment in cytoplasm of hepatocytes																																
			3		2	3	3	2		2		3	4		2	3		2	3		3	3	4	3	2		2	2		3		
			4	4		3	4	5		3	2	3			5	5					4		3	4		3	3		3	2		
			2		2	2				2											2	2								2		
									3						2	2									2	2						

Code: x - condition present 4 - moderate
1 - not remarkable 5 - marked
2 - very slight 6 - extreme
3 - slight A - died

TABLE 20. cont.

Histomorphologic Observations.

Tissue Lesion	Group, Rat No.	Sex	Control										30 ppm										100 ppm									
			M	M	M	M	M	F	F	F	F	F	M	M	M	M	M	F	F	F	F	F	M*	M*	M	M*	M	F	F*	F	F*	F
			73886	73887	73888	73889	73890	73891	73892	73893	73894	73895	73896	73897	73898	73899	73900	73901	73902	73903	73904	73905	73906	73907	73908	73910	73916	73911	73912	73913	73914	73915
Kidney																																
hydronephrosis			2										3	2					2							2				1		
focal interstitial lymphoid infiltrates			2	2	2	3	3	2	2	2	2	2	3	3	2	2	2	2	2	2	2	2	2	2	4	2	2	2	2		2	2
tubular nephrosis			2			2								2											3							
hyaline droplets in cytoplasm of proximal convoluted tubules							4																									
tubular necrosis with mineralization																									4							
parenchymal cyst																																
proteinaceous tubular casts												2							2						2							
atrophy (decrease in size)											2																					
Urinary Bladder			1	-	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Testes			1	1	1	1	1						1	1	1	1	1						1	1	1	1	1					
Ovaries								1	1	1	1	1						1	1	1	1	1					1	1	1	1	1	1
Prostate				1	1	1								1	1	1	1						1	1	1		1					
focal interstitial lymphoid infiltrates			2				3						2												3							
Uterus									1	1	1								1	1		1						1	1	1	1	1
hydrometra							4				2							4			4											
Skeletal Muscle			1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
atrophy																																
Skin			1	1	1	1	1	1	1	1	1		1	1	1	1	1	1	1	1	1	1	1			1	1	1	1	1	1	1
focal epidermal acanthosis												2											1									
diffuse epidermal hyperkeratosis																								2	2							

Code: x - condition present 4 - moderate
 1 - not remarkable 5 - marked
 2 - very slight 6 - extreme
 3 - slight * - died

TABLE 20. cont.

Histomorphologic Observations.

			300 ppm										1,000 ppm										3,000 ppm									
Tissue Lesion	Group, Rat No.	Sex	M*	M*	M*	M*	M*	F*	F*	F*	F*	F*	M*	M*	M*	M*	M*	F*	F*	F*	F*	F*	M*	M*	M*	M*	M*	F*	F*	F*	F*	F*
			73916	73917	73918	73919	73920	73921	73922	73923	73924	73925	73926	73927	73928	73929	73930	73931	73932	73933	73934	73935	73936	73937	73938	73939	73940	73941	73942	73943	73944	73945
Kidney																																
hydronephrosis				4				2					2	2		2				2				3		2	2				2	
focal interstitial lymphoid infiltrates					2																											
tubular nephrosis																																
hyaline droplets in cytoplasm of proximal convoluted tubules																																
tubular necrosis with mineralization																																
parenchymal cyst																																x
proteinaceous tubular casts																																
atrophy (decrease in size)			x			x	x		x	x	x		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Urinary Bladder			1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Testes			1	1	1	1	1						1	1	1	1	1						1	1	1	1	1					
Ovaries								1	1	1	1	1					1	1	1	1	1							1	1	1	1	1
Prostate			1	1		1							1	1	1	1	1						1	1	1	1	1					
focal interstitial lymphoid infiltrates					2		2																									
Uterus								1	1	1	1	1					1	1	1	1	1	-					1	1	1	1	1	
hydrometra																																
Skeletal Muscle			1	1		1			1																							
atrophy					2		2	3		3	3	3	3	2	3	4	4	3	3	3	3	3	4	4	3	2	4	2	3	3	3	4
Skin				1									1				1	1									1		1			
focal epidermal acanthosis			2		3	3	3	2								2						2		2		2						
diffuse epidermal hyperkeratosis			3		3	3	4	3	2	2		2	2		3	3	3	2			2	2	4	2	2	2	3		2		2	2

Codes: x - condition present 4 - moderate
 1 - not remarkable 5 - marked
 2 - very slight 6 - extreme