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REPORT TO

JOHNSON & JOHNSON RESEARCH FOUNDATION

90-DAY SUBACUTE DUST INHALATION TOXICITY STUDY WITH
CORNSTARCH POWDER BASE - BPC #4030-106
IN GOLDEN SYRIAN HAMSTERS

APRIL 19, 1977

IBT NO. 8562-09039

I. Introduction

A white powder identified as Cornstarch Powder Base, was received from the Johnson & Johnson Research Foundation for the purpose of conducting a 90-day subacute dust inhalation toxicity study using golden Syrian hamsters as experimental animals.

II. Summary

A subacute dust inhalation toxicity study was conducted wherein 2 groups of 60 golden Syrian hamsters (30 males and 30 females) each were exposed to the dust of Cornstarch Powder Base 7 days per week for a total of 88 consecutive exposures. The low test (T-I) and the high test (T-II) groups received exposures of 43 minutes and 133 minutes per day, respectively. An additional group of 60 hamsters (30 males and 30 females) served as untreated control animals for comparison purposes and received exposures to clean dry air (-40°C dewpoint) only.

Below is an outline of the target and actual dust concentrations.

Group	Exposure Length	Target Analytical Respirable Dust Concentrations (mg/M ³)	Actual Analytical Respirable Dust Concentrations (mg/M ³)
T-I	43 minutes	1.50	1.53
T-II	133 minutes	1.50	1.56

Observations were made with respect to incidence of mortality, reactions displayed and body weight effects. Hematologic studies were conducted on 10 males and 10 females from each group prior to inhalation exposure and again at 44 and 86 days. At the conclusion of testing all surviving animals were sacrificed and complete necropsy examinations were performed. A complete set of representative tissues and organs was obtained from each animal and preserved in 10% neutral buffered formalin.

Histopathologic studies were conducted on lung, liver, lymph nodes and both kidneys from each untreated control animal and T-II test animal that died or was sacrificed.

Below is a summary of the mortality data.

Group	Sex	Mortality
Untreated Control	M	2*/30
	F	0/30
T-I	M	3/30
	F	3*/30
T-II	M	2/30
	F	1/30

There were no untoward behavior reactions noted during the 90-day period. Mean body weight gains for T-I and T-II hamsters compared favorably with those of the controls.

* Includes an animal sacrificed in extremis.

The hematologic studies conducted prior to exposure and after 44 and 86 days of testing revealed no consistent differences between test and control animals.

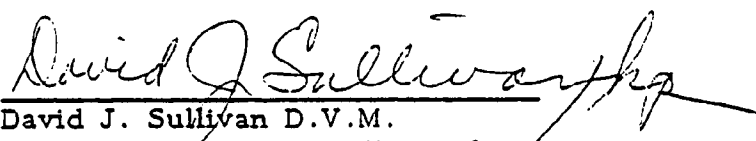
No treatment-related gross or histopathologic changes were observed.

Respectfully submitted,

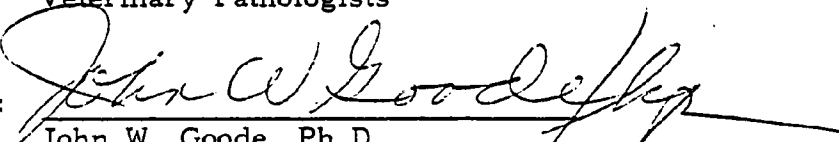
INDUSTRIAL BIO-TEST LABORATORIES, INC.

Report prepared by:

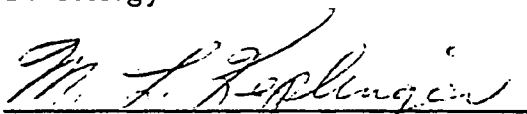

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III. Procedure

A. Experimental Animals

Young adult golden Syrian hamsters* were used as test animals. One hundred eighty were selected after having been under observation for at least 5 days to insure their general health and suitability for the study. The animals were individually housed in stainless steel cages and permitted a standard laboratory diet** plus water ad libitum, except during inhalation exposure. The animals were separated into 3 groups, each consisting of 60 animals (30 males and 30 females). These groups were designated as untreated control, T-I (low dose) and T-II (high dose).

B. Exposure Apparatus and Method of Exposure

The study was designed so that T-I animals were exposed for 43 minutes and T-II animals for 133 minutes per day, 7 days per week, for 13 weeks. To facilitate the scheduling of the necropsies the animals received 88 rather than 90 exposures. Test group animals were exposed in a specially constructed stainless steel and glass inhalation chamber having a capacity of 5m³. Each animal was caged separately during exposure to minimize filtration of inspired air by animal fur, which often occurs when cage mates huddle together during exposures. Untreated control animals were exposed to clean, dry air (-40°C dewpoint) only.

* Engle Laboratory Animals, Inc. Farmersburg, Indiana.

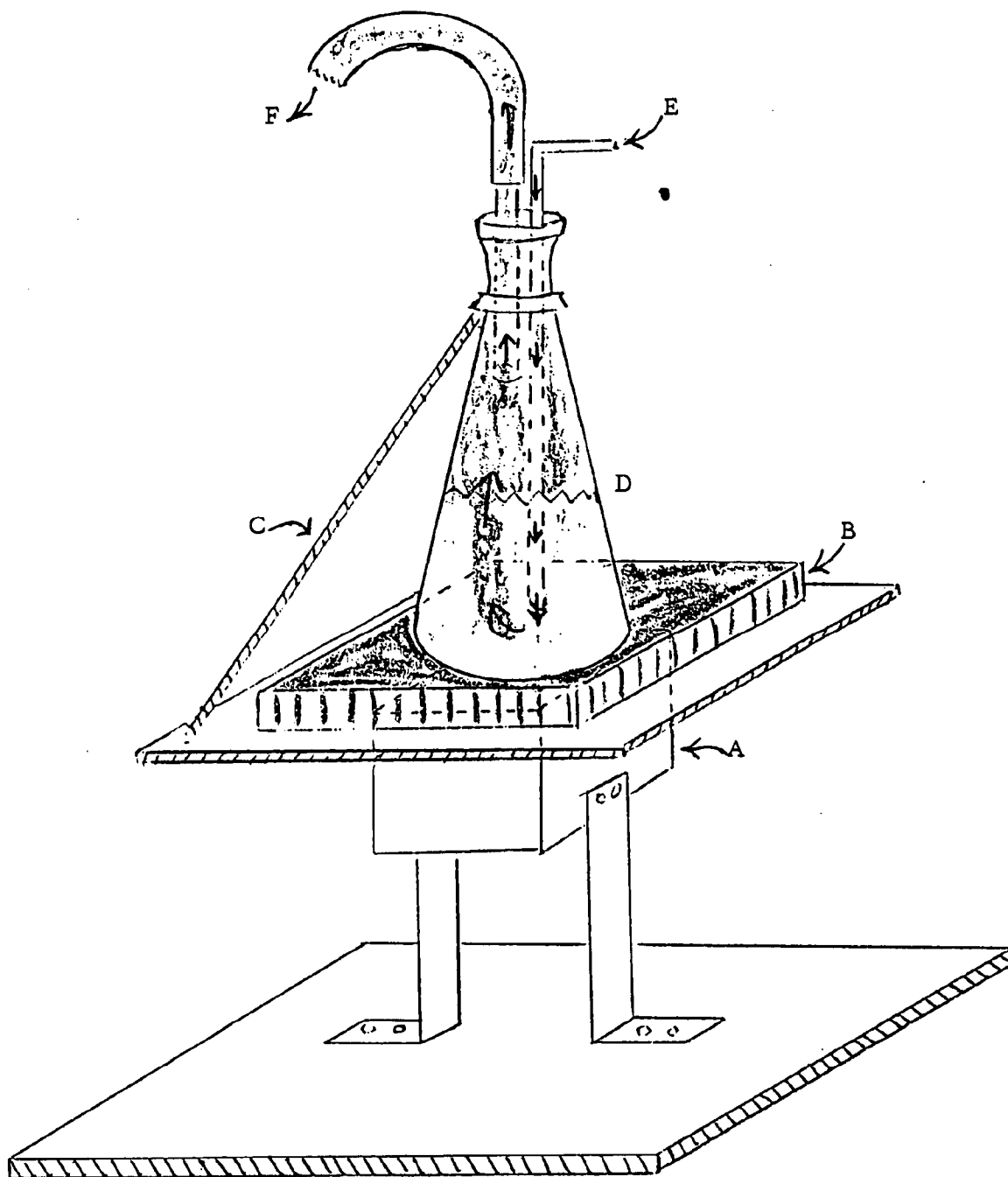
** Wayne Lab-Blox, Allied Mills, Inc., Chicago, Illinois.

The test material was generated with a specially designed dust generating shaker mechanism (see diagram). A stream of clean, dry air (-40°C dewpoint) was passed through the generator and the resulting air/dust mixture then introduced into the exposure chamber. An additional stream of clean, dry air (40°C dewpoint) was added to the test material prior to introduction into the exposure chamber at a rate of 320 l/min. The test atmosphere was then exhausted at the bottom of the chamber. Air flow rates through the system were measured with rotameters connected upstream of duct contamination.

The concentration of respirable test material dust (2.0 to 10.0 microns) present in the exposure chamber during each exposure period was determined by sampling the test atmosphere in the breathing zone of the animals. Test atmosphere dust concentrations were continuously monitored by means of a Thermo-Systems Model 10316 Cyclone respirable mass separator.* During each exposure period, 60 second samples were taken every 10 minutes at a rate of 1.7 l/min. At the end of each exposure average analytical concentrations were determined. The average daily respirable dust concentrations are presented in Table I.

* Thermo-Systems, Inc., St. Paul, Minnesota.

DUST SHAKER MECHANISM



- A. Electric Vibrating Motor
- B. Foam Rubber Cushion
- C. Support Springs (only one shown)
- D. Test Material Level
- E. Incoming Air (glass tubing)
- F. Resulting Air/Dust Mixture to Exposure Chamber (rubber tubing)

TABLE I

TEST MATERIAL: Cornstarch Powder Base

90-Day Subacute Dust Inhalation Toxicity Study - Golden Syrian Hamsters

Outline of Test Conditions

Exposure Number	Test Atmosphere Temperature (°C)	Test Atmosphere Pressure (inches Hg)	Average Analytical Respirable Dust Concentrations	
			T-I	T-II
1	27	30.01	2.06	2.22
2	26	29.96	1.87	1.42
3	27	29.97	1.20	1.38
4	27	30.10	1.24	1.56
5	25	30.15	1.60	1.60
6	26	30.06	1.62	1.67
7	27	29.97	1.11	1.40
Weekly Mean			1.53	1.61
8	26	30.08	0.98	1.30
9	27	30.02	1.45	1.28
10	26	29.95	*	*
11	25	30.00	1.42	1.28
12	27	30.03	1.61	1.35
13	27	30.05	1.47	1.82
14	27	30.04	1.04	1.37
Weekly Mean			1.33	1.40

* Data not available: Equipment malfunction

TABLE I continued

TEST MATERIAL: Cornstarch Powder Base

90-Day Subacute Dust Inhalation Toxicity Study - Golden Syrian Hamsters

Outline of Test Conditions

Exposure Number	Test Atmosphere Temperature (°C)	Test Atmosphere Pressure (inches Hg)	Average Analytical Respirable Dust Concentrations (mg/M ³)	
			T-I	T-II
15	26	30.05	1.63	1.43
16	27	30.13	1.39	1.65
17	26	30.05	1.50**	1.50**
18	27	30.06	2.30**	2.30**
19	27	30.07	2.30**	2.30**
20	27	30.06	1.61	1.32
21	26	30.05	1.65	1.77
Weekly Mean			1.77	1.75
22	25	30.09	1.45	1.55
23	27	30.06	1.01	1.24
24	26	30.09	1.38	1.11
25	27	30.02	1.60	1.12
26	26	29.91	1.65	1.33
27	27	29.96	1.41	1.67
28	25	29.96	1.54	1.77
Weekly Mean			1.43	1.40

* Data not available: Equipment malfunction

** Gravimetric filter samples

TABLE I continued

TEST MATERIAL: Cornstarch Powder Base

90-Day Subacute Dust Inhalation Toxicity Study - Golden Syrian Hamsters

Outline of Test Conditions

Exposure Number	Test Atmosphere Temperature (°C)	Test Atmosphere Pressure (inches Hg)	Average Analytical Respirable Dust Concentrations (mg/M ³)	
			T-I	T-II
29	26	29.98	1.66	1.54
30	25	30.10	1.66	1.81
31	25	30.07	*	1.44
32	27	29.88	*	1.04
33	24	30.04	1.14	1.36
34	25	30.02	1.19	1.31
35	25	29.96	0.99	1.08
Weekly Mean			1.33	1.37
36	26	29.96	1.54	1.62
37	25	29.98	1.39	1.26
38	27	29.95	2.48	1.96
39	25	29.93	1.42	1.44
40	27	29.94	1.74	1.62
41	27	29.94	1.26	1.51
42	27	29.96	1.40	1.62
Weekly Mean			1.60	1.58

* Data not available: Equipment malfunction

TABLE I continued

TEST MATERIAL: Cornstarch Powder Base

90-Day Subacute Dust Inhalation Toxicity Study - Golden Syrian Hamsters

Outline of Test Conditions

Exposure Number	Test Atmosphere Temperature (°C)	Test Atmosphere Pressure (inches Hg)	Average Analytical Respirable Dust Concentrations (mg/M ³)	
			T-I	T-II
43	26	30.07	1.30	1.60
44	26	30.06	1.34	1.56
45	27	29.98	1.28	2.01
46	28	30.00	1.32	1.58
47	27	30.05	1.64	1.60
48	27	30.00	1.31	1.32
49	26	30.01	1.21	1.55
Weekly Mean			1.34	1.60
50	26	30.00	1.62	1.83
51	27	29.00	1.29	1.52
52	27	30.06	2.14	1.81
53	25	30.13	1.50	1.40
54	26	30.16	1.68	1.90
55	26	30.10	1.70	1.80
56	25	30.09	1.08	1.32
Weekly Mean			1.57	1.65

TABLE I continued

TEST MATERIAL: Cornstarch Powder Base

90-Day Subacute Dust Inhalation Toxicity Study - Golden Syrian Hamsters

Outline of Test Conditions

Exposure Number	Test Atmosphere Temperature (°C)	Test Atmosphere Pressure (inches Hg)	Average Analytical Respirable Dust Concentrations (mg/M ³)	
			T-I	T-II
57	25	30.07	1.90	1.54
58	26	30.15	1.85	1.65
59	25	30.10	2.55	2.34
60	26	29.96	1.05	1.84
61	26	29.96	1.22	1.23
62	26	30.08	1.26	1.68
63	26	30.22	1.90	1.85
Weekly Mean			1.68	1.73
64	25	30.23	0.97	1.25
65	26	30.17	1.45	1.29
66	26	30.00	1.60	1.74
67	25	29.96	1.73	1.54
68	27	30.36	0.89	1.28
69	26	30.22	1.89	1.81
70	27	30.06	1.61	1.35
Weekly Mean			1.45	1.47

TABLE I continued

TEST MATERIAL: Cornstarch Powder Base

90-Day Subacute Dust Inhalation Toxicity Study - Golden Syrian Hamsters

Outline of Test Conditions

Exposure Number	Test Atmosphere Temperature (°C)	Test Atmosphere Pressure (inches Hg)	Average Analytical Respirable Dust Concentrations	
			T-I	T-II
71	26	30.03	1.76	1.55
72	26	30.08	1.84	1.55
73	27	30.09	1.38	1.35
74	27	30.13	1.53	1.63
75	26	30.21	1.39	1.42
76	26	29.97	1.82	1.55
77	27	29.98	1.16	1.28
Weekly Mean			1.55	1.48
78	27	30.09	2.53	1.86
79	26	30.25	2.28	1.58
80	27	30.28	1.81	1.64
81	27	30.22	1.35	1.56
82	27	30.14	1.25	1.44
83	26	30.04	1.31	1.70
84	27	30.04	1.31	1.53
Weekly Mean			1.69	1.62

TABLE I continued

TEST MATERIAL: Cornstarch Powder Base

90-Day Subacute Dust Inhalation Toxicity Study - Golden Syrian Hamsters

Outline of Test Conditions

Exposure Number	Test Atmosphere Temperature (°C)	Test Atmosphere Pressure (inches Hg)	Average Analytical Respirable Dust Concentrations (mg/M ³)	
			T-I	T-II
85	25	29.90	1.26	1.61
86	26	29.84	1.52	1.67
87	27	29.85	1.45	1.86
88	26	29.84	***	***
Weekly Mean			1.41	1.71
Study Mean			1.53	1.56

* Data not available: Equipment malfunction

** Gravimetric filter samples

*** Data not available: Sampling machine ran out of chart paper.

C. Mortality and Reactions

Inspections of all animals for mortality and abnormal behavioral reactions were made daily during the investigational period.

D. Individual Body Weight Data

Individual body weights were determined before the first inhalation exposure and weekly thereafter. The data were recorded as an index to growth.

E. Hematologic Studies

Hematologic studies included determination of total leukocyte and erythrocyte counts, differential leukocyte counts and hematocrit. These studies were conducted prior to inhalation exposure and again at 44 and 86 days on 10 males and 10 females from each group.

F. Pathology

Arrangements were made to subject any animal which might die during the test to a thorough necropsy and sections of representative tissues and organs were placed in fixative for histopathologic study unless precluded by advanced postmortem autolysis.

At the conclusion of a 88-day investigational period, the animals were sacrificed for pathologic study by exsanguination after they were rendered unconscious with CO₂ in a closed chamber. A complete necropsy was conducted on all animals and representative sections of the following tissues and organs were obtained from each animal and preserved in 10%

neutral buffered formalin: adrenals, aorta, bladder, bone, brain, caecum, colon, duodenum, esophagus, eye, gall bladder, gonads, heart, ileum, jejunum, kidneys, liver, lungs, lymph node, mesentery nodes, muscle, optic nerve, pancreas, parathyroid, peripheral nerve, pituitary, prostate, salivary glands, seminal vessel, skin, spinal cord, spleen, sternum, stomach, trachea, thymus, thyroid, tongue and uterus.

Histopathologic studies were conducted on selected tissues and organs obtained from each group T-II and untreated control hamster which included the following: lung, liver, both kidneys and lymph nodes (cervical tracheobronchial, mesenteric).

IV. Results

A. Mortality and Reactions

There were no untoward behavioral reactions noted during the exposure period. Nine animals died and 2 were sacrificed in extremis during the study. On day 57, animal number 66 died and was noted to have broken teeth and to be emaciated. This condition was also noted in 5 of the 6 animals which died or were sacrificed in extremis after day 57. All animals which died or were sacrificed in extremis prior to day 57 were emaciated. Mortality data including time of death and moribund sacrifices are presented in Table II.

TABLE II

TEST MATERIAL: Cornstarch Powder Base

90-Day Subacute Dust Inhalation Toxicity Study - Golden Syrian Hamsters

Mortality

Group	Animal Number and Sex	Time of Death (Test Day)
UC	27-M	61
	3-M*	62
T-I	71-M	48
	66-M	57
	67-M	89
	92-F	23
	94-F	44
	110-F*	85
T-II	126-M	63
	140-M	90
	157-F	40

* Sacrificed in extremis

B. Body Weight Data

Body weight means for the T-I and T-II animals compared favorably with those of the untreated control animals. A summary of mean values is presented in Table III. Individual body weights and weight gain data are presented in Tables IV and V.

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TABLE III

TEST MATERIAL: CORNSTARCH POWDER BASE
 90-DAY SUBCUTE INHALATION TOXICITY STUDY - GOLDEN SYRIAN HAMSTERS
 BODY WEIGHT AND WEIGHT CHANGE DATA
 SUMMARY OF MEAN VALUES

GROUP	SEX	BODY WEIGHT (GRAMS)													13-WEEK BODY WEIGHT CHANGE (G.)	
		0	1	2	3	4	5	6	7	8	9	10	11	12		13
UC	M	67	78	85	94	99	103	104	108	110	117	117	119	117	120	53
T-I	M	72	81	87	93	99	102	104	109	115	117	116	118	110	118	47
T-II	M	72	80	85	92	95	99	102	105	109	112	111	114	115	117	45
UC	F	68	79	84	93	97	100	103	108	112	114	113	117	117	118	50
T-I	F	66	74	81	90	94	98	99	107	111	114	113	114	110	117	50
T-II	F	68	76	82	91	95	99	103	110	113	116	118	120	119	121	53

TABLE IV

TEST MATERIAL: CORNSTARCH POWDER BASE
 90-DAY SUBACUTE INHALATION TOXICITY STUDY - GOLDEN SYRIAN HAMSTERS
 INDIVIDUAL BODY WEIGHT AND WEIGHT CHANGE DATA - MALE

UC

BODY WEIGHTS (GRAMS)

ANIMAL NUMBER	0	1	2	3	4	5	6	7	8	9	10	11	12	13	BODY WEIGHT CHANGE (G.)
1	61	74	86	99	100	109	112	117	122	124	124	125	125	127	66
2	70	87	95	93	100	105	106	110	113	114	112	116	115	118	48
3	59	71	79	82	81	72	58	51	47	***	***	***	***	***	***
4	57	71	79	94	95	98	97	103	107	109	110	112	110	115	58
5	58	69	78	89	96	90	97	104	110	112	115	119	116	121	63
6	63	71	81	94	100	104	102	108	114	117	119	118	116	120	57
7	75	89	98	103	113	117	116	124	128	136	137	134	132	136	61
8	69	84	91	100	105	109	109	115	118	118	114	114	110	113	44
9	72	86	93	99	102	106	109	116	120	118	120	125	118	124	52
10	64	79	81	101	103	112	113	118	121	127	125	127	120	127	63
11	67	75	82	95	103	104	105	113	119	127	125	127	122	128	61
12	68	76	84	97	96	99	99	102	104	106	106	104	105	108	40
13	63	74	79	87	93	96	97	100	101	102	105	110	109	111	48
14	71	82	86	97	102	108	110	113	117	114	117	118	118	122	51
15	72	83	91	102	109	115	117	123	125	126	124	132	127	132	60
16	64	78	83	91	96	100	102	109	113	115	115	116	114	119	55
17	63	75	82	84	94	99	97	105	107	110	111	116	111	115	52
18	73	80	89	101	107	112	111	115	120	119	121	118	119	120	47
19	66	75	83	91	95	99	101	103	100	105	104	108	105	107	41
20	67	76	73	82	86	92	94	96	99	105	102	107	104	109	42
21	71	84	89	102	112	114	114	116	118	119	119	124	121	125	54
22	67	75	82	90	97	101	101	103	107	108	109	113	107	112	45
23	72	84	88	101	102	106	114	114	121	123	119	122	120	121	49
24	68	78	87	94	99	105	108	109	114	116	114	118	113	116	48
25	66	76	82	88	92	95	99	106	106	107	109	107	113	109	43
26	77	89	95	102	110	115	121	124	127	129	130	133	136	134	57
27	67	74	81	89	94	97	97	89	70	***	***	***	***	***	***
28	54	69	77	87	94	94	101	102	106	111	112	116	117	114	60
29	68	77	87	92	85	96	103	111	112	120	116	119	122	119	51
30	75	83	90	96	106	110	116	121	127	127	129	128	132	129	54
MEAN	67	78	85	94	99	103	104	108	110	117	117	119	117	120	53
SD	5.6	5.8	6.0	6.3	7.7	9.4	11.4	13.7	16.6	8.6	8.4	8.1	8.3	8.0	7.4

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TABLE IV CONTINUED
 TEST MATERIAL: CORNSTARCH POWDER BASE
 90-DAY SUBACUTE INHALATION TOXICITY STUDY - GOLDEN SYRIAN HAMSTERS
 INDIVIDUAL BODY WEIGHT AND WEIGHT CHANGE DATA - MALE

ANIMAL NUMBER	BODY WEIGHTS (GRAMS)														BODY WEIGHT CHANGE (G.)
	0	1	2	3	4	5	6	7	8	9	10	11	12	13	
61	69	86	95	103	107	115	120	125	130	133	134	136	133	136	67
62	62	73	80	82	90	90	92	99	102	105	105	107	101	107	45
63	68	81	87	95	97	100	104	111	116	118	117	115	110	115	47
64	66	86	92	101	108	110	109	118	122	122	125	128	119	119	53
65	74	85	93	105	109	115	116	119	119	115	111	118	109	114	40
66	72	84	78	64	66	67	69	57	***	***	***	***	***	***	****
67	80	94	101	97	106	109	112	124	129	111	97	74	54	***	****
68	73	85	93	97	107	108	109	112	114	114	111	112	104	109	36
69	66	77	86	92	101	106	103	109	111	120	119	120	112	121	55
70	69	74	78	74	84	86	89	94	97	95	85	96	90	97	28
71	81	89	89	90	93	96	68	***	***	***	***	***	***	***	****
72	61	70	73	80	89	95	97	102	108	110	108	110	109	116	55
73	88	99	104	112	122	126	131	132	139	143	145	148	141	152	64
74	72	83	91	100	110	115	122	128	131	134	134	137	132	142	70
75	80	87	95	104	111	114	119	125	130	135	134	140	132	141	61
76	62	68	73	82	87	92	95	97	97	100	101	102	95	100	38
77	82	94	99	103	111	115	107	91	106	111	112	115	110	115	33
78	66	78	83	91	92	96	101	107	113	117	117	123	116	121	55
79	66	73	78	86	93	98	104	107	112	115	115	116	113	118	52
80	70	76	73	80	77	73	77	79	86	91	91	92	71	73	3
81	76	82	93	96	102	106	108	110	113	111	108	109	103	108	32
82	83	92	102	112	120	127	134	138	144	149	148	150	143	151	68
83	74	80	83	77	85	92	96	100	102	105	105	110	103	107	33
84	74	81	88	96	103	105	111	115	120	120	121	125	116	121	47
85	76	81	90	95	102	107	110	114	114	112	110	106	94	100	24
86	66	67	72	80	86	90	91	97	98	103	105	106	97	106	40
87	68	75	82	91	96	96	102	110	106	109	114	116	109	118	50
88	73	77	86	96	103	105	110	117	120	124	126	128	118	127	54
89	74	81	89	93	103	104	107	114	113	120	121	122	116	124	50
90	76	84	90	103	106	115	116	123	125	126	129	131	126	134	58
MEAN	72	81	87	93	99	102	104	109	115	117	116	118	110	118	47
SD	6.7	7.8	9.1	11.2	12.4	13.7	15.5	16.6	13.5	13.5	14.9	16.8	19.2	17.3	15.2

Industrial BIO-TEST Laboratories, Inc.

TABLE IV CONTINUED
 TEST MATERIAL: CORNSTARCH POWDER BASE
 90-DAY SUBACUTE INHALATION TOXICITY STUDY - GOLDEN SYRIAN HAMSTERS
 INDIVIDUAL BODY WEIGHT AND WEIGHT CHANGE DATA - MALE

T-II

BODY WEIGHTS (GRAMS)

ANIMAL NUMBER	0	1	2	3	4	5	6	WEEK	7	8	9	10	11	12	13	BODY WEIGHT CHANGE (G.)
121	64	70	75	79	76	80	87	92	92	96	103	104	106	106	107	43
122	66	72	81	97	98	101	110	114	114	116	125	123	131	131	130	64
123	80	95	89	95	102	110	112	111	111	113	121	122	127	129	130	50
124	76	81	87	89	93	87	93	104	104	106	105	103	103	107	104	28
125	66	71	75	83	86	90	92	98	98	94	102	104	106	104	105	39
126	83	93	97	110	114	113	112	109	94	****	****	****	****	****	****	****
127	67	66	72	79	85	93	91	100	100	106	110	109	112	113	115	48
128	82	84	88	96	99	103	100	107	110	110	113	113	117	118	117	35
129	82	84	80	93	95	102	101	108	109	112	112	112	112	114	112	30
130	77	86	91	97	102	109	108	115	118	118	116	114	116	118	116	39
131	80	90	93	100	108	112	116	122	128	128	132	134	139	140	140	60
132	78	84	85	85	93	101	100	104	107	107	107	105	106	110	108	30
133	70	84	89	101	106	116	121	123	130	130	133	133	135	130	133	63
134	69	81	82	84	88	95	96	97	101	101	101	101	101	106	105	36
135	60	69	70	79	82	66	74	80	86	86	92	89	90	92	91	31
136	71	79	88	93	96	103	104	107	110	110	110	109	117	117	114	43
137	73	86	91	101	103	110	114	117	123	123	125	127	133	138	136	63
138	65	75	79	87	84	88	90	94	94	94	94	90	95	98	96	31
139	76	84	89	100	106	113	113	120	126	126	130	130	132	138	138	62
140	73	81	86	83	90	96	97	100	101	101	99	91	75	55	****	****
141	74	83	89	98	105	108	112	115	119	119	122	121	125	128	128	54
142	78	88	92	106	109	115	119	125	128	128	128	127	130	131	132	54
143	68	74	77	86	91	93	95	97	101	101	102	102	107	109	107	39
144	68	77	83	90	93	96	99	101	107	107	109	106	107	111	109	41
145	61	69	71	73	79	79	88	87	92	92	95	99	101	103	103	42
146	71	83	92	100	102	103	110	111	116	116	120	124	125	126	127	56
147	68	75	83	90	91	93	98	96	97	97	108	106	113	112	112	44
148	70	80	85	88	84	89	94	97	102	102	100	100	103	103	105	35
149	72	78	82	86	87	92	96	95	98	98	102	102	106	109	107	35
150	70	87	98	102	102	106	113	114	124	124	126	127	131	134	135	65
MEAN	72	80	85	92	95	99	102	105	105	109	112	111	114	115	117	45
SD	6.2	6.9	7.4	3.9	9.7	11.9	11.1	11.1	11.1	12.1	12.2	13.1	15.1	17.4	13.8	12.0

TABLE V
TEST MATERIAL: CORNSTARCH POWDER BASE
90-DAY SUBACUTE INHALATION TOXICITY STUDY - GOLDEN SYRIAN HAMSTERS
INDIVIDUAL BODY WEIGHT AND WEIGHT CHANGE DATA - FEMALE

UC

ANIMAL NUMBER	BODY WEIGHTS (GRAMS)													BODY WEIGHT CHANGE (G.)	
	0	1	2	3	4	5	6	7	8	9	10	11	12		13
31	69	81	86	96	101	106	106	110	113	114	112	116	115	112	43
32	65	75	81	84	89	92	95	100	103	100	102	102	104	100	35
33	62	77	81	90	94	96	96	102	102	104	103	107	106	106	44
34	80	93	105	115	118	127	132	140	144	148	151	155	155	157	77
35	62	72	79	85	90	91	93	103	105	107	106	109	110	113	51
36	62	69	78	87	93	98	92	96	102	97	100	102	97	100	38
37	72	87	96	105	109	114	118	127	134	137	135	135	134	133	61
38	73	81	87	98	104	100	100	104	107	105	104	111	111	107	34
39	73	85	92	98	97	92	94	108	113	113	107	114	114	117	44
40	62	75	83	92	100	105	107	113	117	119	115	121	119	120	58
41	71	77	82	89	93	99	103	107	110	105	105	111	114	115	44
42	65	79	85	95	101	107	116	115	123	132	131	134	141	137	72
43	67	74	81	86	93	99	102	105	111	116	113	115	113	114	47
44	62	76	76	84	92	99	92	98	99	106	107	107	108	106	44
45	66	79	83	92	95	96	94	97	104	111	109	117	118	115	49
46	69	83	85	91	94	95	96	103	107	107	104	104	109	106	37
47	67	73	83	89	96	94	97	101	109	107	108	117	114	115	48
48	65	77	79	83	84	89	102	110	116	117	115	121	123	122	57
49	66	77	77	82	84	87	90	94	100	104	106	108	107	111	45
50	71	74	70	87	87	92	93	97	99	100	98	100	101	111	40
51	67	80	86	94	98	99	107	108	115	117	115	118	117	117	50
52	67	78	86	94	97	96	100	101	106	108	108	109	108	115	48
53	71	82	81	91	93	95	98	101	109	100	103	107	107	107	36
54	71	83	90	97	101	100	102	102	110	112	103	113	108	112	41
55	75	90	98	104	110	118	123	128	134	139	135	146	146	149	74
56	68	84	86	94	91	96	105	111	108	115	112	122	117	121	53
57	65	80	85	98	108	112	119	118	114	114	115	113	108	112	47
58	71	84	86	100	104	107	110	116	120	127	126	132	126	129	58
59	60	70	77	86	90	97	100	102	110	117	117	119	117	120	60
60	69	82	88	97	97	108	111	118	122	133	133	139	139	142	73
MEAN	68	79	84	93	97	100	103	108	112	114	113	117	117	118	50
SD	4.5	5.6	7.0	7.4	7.3	9.0	10.3	10.5	10.7	12.8	12.6	13.4	13.7	13.7	11.9

Industrial BIO-TEST Laboratories, Inc.

TABLE V CONTINUED
 TEST MATERIAL: CORNSTARCH POWDER BASE
 90-DAY SUBACUTE INHALATION TOXICITY STUDY - GOLDEN SYRIAN HAMSTERS
 INDIVIDUAL BODY WEIGHT AND WEIGHT CHANGE DATA - FEMALE

ANIMAL NUMBER	BODY WEIGHTS (GRAMS)													BODY WEIGHT CHANGE (G.)
	0	1	2	3	4	5	6	7	8	9	10	11	12	13
91	66	73	81	83	87	93	98	98	98	101	100	101	94	107
92	67	75	81	83	87	93	98	98	98	101	100	101	94	107
93	64	71	76	81	82	88	91	94	95	99	102	104	92	102
94	64	69	78	82	85	90	95	98	98	101	100	101	94	106
95	80	89	96	102	105	104	106	107	107	110	104	102	94	106
96	66	77	82	83	88	93	98	103	103	110	112	115	105	118
97	73	80	85	89	91	93	98	103	103	112	124	121	112	125
98	59	71	76	78	88	96	87	92	95	99	100	100	89	101
99	62	68	78	83	91	99	99	103	107	110	108	113	99	114
100	64	68	75	83	91	94	95	99	102	105	105	112	96	110
101	70	84	95	99	111	114	116	126	136	135	130	132	113	130
102	64	70	77	89	93	94	100	111	115	116	118	124	111	124
103	70	87	91	98	104	105	106	111	114	119	121	126	110	125
104	79	92	104	120	124	135	137	140	141	145	141	137	124	136
105	71	90	87	99	106	107	107	112	121	128	128	126	116	128
106	68	77	82	91	93	98	100	102	108	112	113	114	102	113
107	58	61	65	72	79	84	90	99	97	99	100	101	86	99
108	57	63	72	78	86	87	88	91	96	99	99	104	92	100
109	69	83	97	111	119	129	135	147	152	155	157	164	166	163
110	67	71	80	80	77	87	84	88	96	94	81	64	64	94
111	66	71	81	97	103	107	112	117	121	124	126	125	129	135
112	64	69	82	95	98	102	102	104	113	123	123	134	133	139
113	69	78	87	87	81	83	70	68	73	70	71	69	68	64
114	68	74	88	96	103	109	109	117	125	131	134	134	136	137
115	73	85	93	103	109	111	115	126	126	127	123	126	130	131
116	55	70	81	88	87	96	96	106	108	111	112	116	123	117
117	62	73	84	95	95	107	111	120	123	133	135	133	135	122
118	57	61	67	73	78	80	80	91	93	95	91	96	98	95
119	69	69	77	83	89	90	93	107	108	106	105	108	109	109
120	64	71	79	83	92	91	91	99	101	106	100	104	104	101
MEAN	66	74	81	90	94	98	99	107	111	114	113	114	110	117
SD	6.0	7.7	9.9	11.5	12.7	15.3	18.3	16.1	16.5	17.6	18.5	20.3	20.3	19.0
														17.9

TABLE V CONTINUED
 TEST MATERIAL: CORNSTARCH POWDER BASE
 90-DAY SUBACUTE INHALATION TOXICITY STUDY - GOLDEN SYRIAN HAMSTERS
 INDIVIDUAL BODY WEIGHT AND WEIGHT CHANGE DATA - FEMALE

T-11

BODY WEIGHTS (GRAMS)

ANIMAL NUMBER	0	2	3	4	5	6	WEEK	7	8	9	10	11	12	13	BODY WEIGHT CHANGE (G.)
151	70	79	91	106	112	114	109	119	123	131	133	141	140	135	65
152	61	72	76	77	84	89	94	96	96	99	101	105	104	103	42
153	62	69	70	75	77	81	86	91	91	93	96	96	93	96	34
154	63	66	78	86	92	99	103	106	115	118	118	122	118	125	62
155	74	83	92	100	103	107	110	105	116	117	118	125	122	128	54
156	61	75	82	97	106	112	119	130	131	139	138	140	137	136	75
157	63	69	69	66	58	50	****	****	****	****	****	****	****	****	****
158	59	63	68	73	78	73	77	89	94	96	99	106	106	109	50
159	70	82	89	99	101	106	107	113	117	120	123	123	119	125	55
160	72	83	91	90	93	95	98	104	103	107	109	109	109	112	40
161	71	74	82	91	99	102	108	114	119	124	121	125	125	131	60
162	71	82	86	91	93	94	98	100	102	105	103	105	105	107	36
163	68	81	82	90	93	102	98	104	106	109	113	115	112	115	47
164	62	58	66	73	79	87	91	95	100	104	108	105	103	107	45
165	69	73	82	95	102	110	115	122	121	133	130	136	135	139	70
166	68	80	87	95	96	96	93	104	105	106	106	107	105	104	36
167	69	70	68	78	82	90	94	103	108	113	116	120	118	127	58
168	77	81	85	94	93	99	100	106	107	113	115	117	116	117	40
169	71	81	89	100	113	121	126	141	146	148	152	156	157	159	88
170	64	61	68	74	76	77	79	86	87	90	90	90	94	95	31
171	70	77	83	97	103	107	113	122	123	126	128	128	127	127	57
172	72	84	91	102	108	114	118	124	129	133	136	136	138	139	67
173	75	89	95	103	109	113	118	119	127	129	131	135	131	139	64
174	84	100	108	120	122	122	125	138	137	135	133	140	136	137	53
175	67	77	78	80	83	87	89	96	99	97	98	100	97	101	34
176	71	80	89	100	109	112	116	121	123	123	121	126	129	125	54
177	65	78	85	93	99	106	108	113	113	109	106	101	94	102	37
178	57	50	70	76	79	89	90	96	98	98	136	101	101	103	46
179	67	81	87	96	100	110	113	120	127	131	129	138	136	143	76
180	74	90	98	100	102	109	115	120	126	127	127	131	130	129	55
MEAN	68	76	82	91	95	99	103	110	113	116	118	120	119	121	53
SD	5.8	9.1	9.7	12.3	14.3	15.9	13.7	14.5	14.7	15.4	15.1	16.6	16.7	16.4	14.4

C. Hematology

The results of hematologic studies done on male and female hamsters from the control group and from treatment groups T-I and T-II are presented in Tables VI through XI.

Mean values for total leukocyte and erythrocyte count, differential leukocyte count, hemoglobin concentration, hematocrit and erythrocyte indices (MCV, MCH and MCHC) of treated hamsters were not different than those values obtained from control (untreated) hamsters prior to and after 44 and 86 days of treatment.

TABLE VI
 TEST MATERIAL: Cornstarch Powder Base
 90-Day Subacute Inhalation Toxicity Study - Golden Syrian Hamsters
 Hematologic Data - Males

Group	Animal Number	Total Leukocyte Count (thousands/mm ³)			Erythrocyte Count (millions/mm ³)			Hemoglobin Concentration (g/100 ml)			Hematocrit Value (%)		
		-1	44	86	-1	44	86	-1	44	86	-1	44	86
UC	1	4.5	8.7	11.4	7.26	8.06	8.33	16.6	18.6	19.4	44.9	46.9	47.3
	2	8.5	6.1	8.8	6.63	8.76	9.24	15.3	18.8	20.7	41.4	49.2	49.5
	3	8.5	20.6	-	7.59	8.74	-	16.9	18.7	-	46.6	49.1	-
	4	8.8	8.0	10.1	7.39	9.14	9.18	16.3	19.5	20.1	44.7	51.4	46.3
	5	9.6	8.9	9.0	7.66	8.01	8.81	16.7	18.1	19.1	46.0	44.9	43.5
	6	8.1	11.7	11.4	7.19	8.16	9.16	16.0	19.9	20.6	43.1	46.0	50.6
	7	13.2	8.0	11.9	6.99	8.10	8.53	15.7	18.0	19.4	43.1	46.9	48.4
	8	7.8	8.8	12.3	6.98	8.66	8.72	15.8	19.0	20.5	42.7	49.1	46.1
	9	8.2	10.9	9.2	6.95	8.31	9.15	15.9	19.3	19.8	42.8	45.0	50.5
	10	6.3	11.9	6.4	7.34	8.68	8.65	16.1	20.0	19.9	43.4	46.9	47.6
Mean		8.4	10.4	10.1	7.20	8.46	8.86	14.5	19.0	19.9	43.9	47.5	47.8

- = Animal died

TABLE VI continued
 TEST MATERIAL: Cornstarch Powder Base
 90-Day Subacute Inhalation Toxicity Study - Golden Syrian Hamsters

Hematologic Data - Males

Group	Animal Number	Total Leukocyte Count (thousands/mm ³)			Erythrocyte Count (millions/mm ³)			Hemoglobin Concentration (g/100 ml)			Hematocrit Value (%)		
		-1	44	86	-1	44	86	-1	44	86	-1	44	86
T-1	61	8.7	15.3	10.5	6.88	8.42	8.03	16.0	20.4	20.2	43.7	50.0	47.4
	62	8.8	10.6	11.7	7.10	9.48	8.40	15.5	20.1	19.3	42.9	51.8	48.7
	63	19.8	9.8	9.5	7.24	8.67	8.24	16.2	18.7	19.4	44.6	48.8	44.5
	64	18.0	9.4	10.4	6.94	8.58	8.88	15.4	18.5	19.9	42.6	48.3	47.8
	65	8.5	9.0	10.5	7.01	9.41	8.75	15.1	19.5	19.3	42.1	52.3	45.4
	66	10.9	10.2	-	7.15	8.94	-	16.0	18.3	-	45.1	50.7	-
	67	10.5	9.5	-	7.16	8.50	-	16.5	18.6	-	45.4	45.4	-
	68	7.8	10.0	10.6	6.91	9.35	8.26	15.3	19.4	19.8	42.2	51.6	47.7
	69	17.7	12.1	7.9	6.94	8.98	8.03	15.6	19.2	18.8	42.8	50.0	43.4
	70	11.5	10.0	7.5	7.20	8.64	8.22	15.9	18.3	19.0	44.3	47.8	46.0
	Mean	15.2	10.6	9.8	7.10	8.90	8.40	15.8	19.1	19.5	43.6	49.7	46.4

- = Animal died

TABLE VI continued

TEST MATERIAL: Cornsarch Powder Base

90-Day Subacute Inhalation Toxicity Study - Golden Syrian Hamsters

Hematologic Data - Males

Group	Animal Number	Total Leukocyte Count (thousands/mm ³)			Erythrocyte Count (millions/mm ³)			Hemoglobin Concentration (g/100 ml)			Hematocrit Value (%)		
		-1	44	86	-1	44	86	-1	44	86	-1	44	86
T-II	121	8.4	8.8	9.6	6.98	8.69	8.36	16.1	18.8	19.2	42.4	49.1	45.5
	122	9.3	7.5	8.5	6.84	8.53	8.67	16.2	18.7	19.5	41.9	46.0	47.3
	123	7.9	7.3	10.7	6.85	8.66	8.19	16.3	18.4	19.2	43.4	49.1	43.9
	124	9.8	8.5	7.9	7.13	9.06	8.20	14.9	19.1	19.0	43.9	47.0	43.9
	125	9.1	10.4	7.6	6.39	8.41	7.68	15.4	18.5	18.5	40.9	47.0	40.9
	126	7.8	11.7	-	7.02	9.17	-	16.1	19.2	-	43.3	47.8	-
	127	7.3	8.2	6.2	7.35	8.71	8.17	16.5	18.1	18.8	43.9	45.8	43.3
	128	9.6	8.8	6.9	6.97	8.96	8.33	16.1	18.8	18.5	43.6	51.6	44.0
	129	10.3	16.9	10.5	6.49	9.68	8.27	15.3	21.6	19.4	39.9	53.6	44.8
	130	6.2	9.7	8.0	6.45	9.07	7.96	15.3	19.0	19.3	39.5	51.2	42.5
Mean		8.6	9.8	8.4	6.85	8.89	8.20	15.8	19.0	19.0	42.3	48.8	44.2

TABLE VII
 TEST MATERIAL: Cornstarch Powder Base
 90-Day Subacute Inhalation Toxicity Study - Golden Syrian Hamsters
 Hematologic Data - Females

Group	Animal Number	Total Leukocyte Count (thousands/mm ³)			Erythrocyte Count (millions/mm ³)			Hemoglobin Concentration (g/100 ml)			Hematocrit Value (%)		
		-1	44	86	-1	44	86	-1	44	86	-1	44	86
UC	31	6.6	8.4	8.3	6.58	8.21	7.49	15.4	17.9	17.9	40.7	47.3	42.7
	32	5.5	6.3	9.9	6.80	7.56	7.92	15.4	16.2	19.2	42.3	42.9	44.1
	33	7.6	8.4	9.6	6.97	7.87	7.73	16.2	17.6	18.3	44.1	46.0	43.0
	34	8.1	9.2	8.4	6.87	8.15	7.78	16.0	18.2	17.8	43.4	47.6	43.8
	35	6.8	10.5	12.1	6.78	8.12	7.77	15.7	18.0	19.2	42.1	47.1	46.1
	36	6.3	8.7	10.6	6.66	7.81	7.58	15.7	18.2	18.7	41.3	46.3	43.0
	37	6.6	7.9	8.9	6.36	7.86	7.89	15.1	17.9	18.3	40.5	46.7	44.3
	38	9.7	8.3	10.0	6.96	8.79	8.30	16.0	18.5	19.0	43.0	48.7	43.7
	39	5.7	9.0	*	6.59	8.32	8.17	15.7	18.5	19.4	41.0	46.0	46.0
	40	4.8	10.7	11.8	7.26	8.35	8.33	16.5	18.5	19.3	44.4	48.1	47.0
Mean		6.8	8.7	9.9	6.78	8.10	7.90	15.8	18.0	18.7	42.3	46.7	44.4

* WBC lost due to malfunctioning equipment.

TABLE VII continued
 TEST MATERIAL: Cornstarch Powder Base
 90-Day Subacute Inhalation Toxicity Study - Golden Syrian Hamsters
 Hematologic Data - Females

Group	Animal Number	Total Leukocyte Count (thousands/mm ³)			Erythrocyte Count (millions/mm ³)			Hemoglobin Concentration (g/100 ml)			Hematocrit Value (%)		
		-1	44	86	-1	44	86	-1	44	86	-1	44	86
T-I	91	4.9	7.5	12.2	7.09	8.45	7.80	15.6	18.1	19.7	42.4	48.4	44.1
	92	7.7	-	-	6.95	-	-	15.3	-	-	41.9	-	-
	93	6.6	7.5	9.5	6.91	8.01	7.66	16.2	17.9	19.0	43.4	46.5	44.2
	94	6.7	21.2	-	6.98	9.00	-	16.2	19.6	-	42.9	46.3	-
	95	8.6	10.8	10.3	6.48	8.58	7.71	15.9	19.8	19.1	42.3	47.6	43.3
	96	4.3	9.8	10.5	6.69	8.66	7.50	15.2	18.2	18.0	41.9	49.4	41.9
	97	7.5	8.1	10.2	6.35	8.15	8.19	16.1	18.0	19.8	46.0	46.5	45.5
	98	6.1	9.9	8.1	7.03	8.67	8.14	15.7	18.0	18.2	42.6	48.9	43.6
	99	7.1	9.1	8.9	6.80	8.23	7.95	15.3	18.0	18.9	42.7	48.5	44.8
	100	7.3	10.6	10.3	6.45	8.01	7.79	15.2	17.4	17.9	39.3	46.3	42.4
Mean		6.7	10.5	10.0	6.77	8.42	7.84	15.7	18.3	18.8	42.5	47.6	43.7

- = Animal died

TABLE VII continued
 TEST MATERIAL: Cornstarch Powder Base
 90-Day Subacute Inhalation Toxicity Study - Golden Syrian Hamsters
 Hematologic Data - Females

Group	Animal Number	Total Leukocyte Count (thousands/mm ³)			Erythrocyte Count (millions/mm ³)			Hemoglobin Concentration (g/100 ml)			Hematocrit Value (%)		
		-1	44	86	-1	44	86	-1	44	86	-1	44	86
T-II	151	8.5	17.8	9.9	6.61	8.65	7.38	15.0	20.9	17.5	42.0	50.2	43.1
	152	7.8	10.5	6.6	6.83	8.27	7.67	15.7	17.9	17.6	43.0	47.7	43.7
	153	8.0	9.5	7.6	6.56	8.25	7.44	15.6	17.9	18.1	42.4	47.1	43.1
	154	5.8	9.1	6.4	7.01	8.32	8.18	16.5	18.2	18.2	43.8	47.8	46.0
	155	8.6	11.4	12.5	6.75	8.50	8.35	15.0	18.3	20.8	41.6	45.8	48.2
	156	6.2	9.5	6.4	7.05	8.22	7.82	15.7	17.5	18.1	43.9	47.6	44.1
	157	7.6	-	-	6.66	-	-	15.4	-	-	42.7	-	-
	158	7.0	6.5	8.8	6.87	8.27	7.88	16.0	17.3	18.6	43.1	47.2	46.4
	159	5.5	9.5	9.6	6.71	7.98	7.68	15.3	17.2	18.4	41.9	46.7	42.9
	160	6.4	8.4	9.7	6.52	8.22	7.61	15.1	17.7	17.5	41.3	46.7	43.1
Mean		7.1	10.2	8.6	6.76	8.30	7.78	15.5	18.1	18.3	42.6	47.4	44.5

- = Animal died

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TABLE VIII
 TEST MATERIAL: Cornstarch Powder Base
 90-Day Subacute Inhalation Toxicity Study - Golden Syrian Hamsters
 Hematologic Data - Males

Group	Animal Number	Neutrophils*			Lymphocytes			Monocytes			Eosinophils			Basophils		
		-1	44	86	-1	44	86	-1	44	86	-1	44	86	-1	44	86
UC	1	14	8	15	86	92	84	0	0	1	0	0	0	0	0	0
	2	14	13	14	84	87	85	0	0	0	2	0	1	0	0	0
	3	14	80	-	86	19	-	0	1	-	0	0	-	0	0	-
	4	14	14	26	84	86	68	0	0	0	2	0	6	0	0	0
	5	24	7	22	76	93	74	0	0	2	0	0	2	0	0	0
	6	12	11	13	83	87	86	0	0	0	5	2	1	0	0	0
	7	29	10	24	69	88	72	0	1	1	2	1	3	0	0	0
	8	9	19	18	91	78	81	0	0	0	0	3	1	0	0	0
	9	16	10	8	83	90	92	0	0	0	1	0	0	0	0	0
	10	13	16	16	86	82	82	0	0	0	1	2	2	0	0	0
Mean		15.9	18.8	17.3	82.8	80.2	80.4	0	0.2	0.4	1.3	0.8	1.8	0	0	0

* Bands have been totaled in with the neutrophils.

- = Animal died

Industrial BIO-TEST Laboratories, Inc.

TABLE VIII continued
 TEST MATERIAL: Cornstarch Powder Base
 90-Day Subacute Inhalation Toxicity Study - Golden Syrian Hamsters
 Hematologic Data - Males

Group	Animal Number	Neutrophils*			Differential Leukocyte Count (Number of Cells per Hundred)						Eosinophils			Basophils		
		-1	44	86	-1	44	86	-1	44	86	-1	44	86	-1	44	86
T-1	61	18	24	12	82	76	87	0	0	0	0	0	1	0	0	0
	62	17	16	23	80	83	76	0	0	0	3	1	1	0	0	0
63	65	18	17	17	34	79	80	0	0	2	1	3	1	0	0	0
	64	56	10	24	43	89	74	0	1	1	1	0	1	0	0	0
65	21	13	15	15	79	86	81	0	0	0	0	1	4	0	0	0
	66	32	29	-	68	67	-	0	2	-	1	2	-	0	0	-
67	14	15	-	-	85	85	-	0	0	-	1	0	-	0	0	-
	68	12	19	8	86	80	89	0	0	0	2	1	3	0	0	0
69	37	30	24	24	62	68	74	0	1	0	1	1	2	0	0	0
	70	18	18	14	80	82	86	0	0	0	2	0	0	0	0	0
Mean		28.9	19.1	17.3	69.9	79.5	80.9	0	0.4	0.4	1.2	0.9	1.6	0	0	0

* Bands have been totaled in with the neutrophils.

- = Animal died

Industrial BIO-TEST Laboratories, Inc.

TABLE VIII continued
 TEST MATERIAL: Cornstarch Powder Base
 90-Day Subacute Inhalation Toxicity Study - Golden Syrian Hamsters
 Hematologic Data - Males

Group	Animal Number	Neutrophils*			Lymphocytes			Monocytes			Eosinophils			Basophils		
		Test Day:	Test Day:	Test Day:	Test Day:	Test Day:	Test Day:	Test Day:	Test Day:	Test Day:	Test Day:	Test Day:	Test Day:	Test Day:	Test Day:	Test Day:
		-1	44	86	-1	44	86	-1	44	86	-1	44	86	-1	44	86
T-II	121	22	10	13	77	90	83	0	0	0	1	0	4	0	0	0
	122	22	20	20	78	80	76	0	0	1	0	0	3	0	0	0
	123	15	13	17	83	87	76	1	0	1	1	0	6	0	0	0
	124	13	13	13	87	86	83	0	0	1	0	1	3	0	0	0
	125	15	19	32	84	81	67	0	0	0	1	0	1	0	0	0
	126	17	37	-	79	63	-	0	0	-	4	0	-	0	0	0
	127	12	16	27	87	84	71	0	0	1	1	0	1	0	0	0
	128	17	9	10	81	91	90	0	0	0	2	0	0	0	0	0
	129	27	12	6	73	87	75	0	1	0	0	0	3	0	0	0
130	14	16	14	14	86	84	85	0	0	0	0	0	1	0	0	0
Mean	17.4	16.5	16.9	16.9	81.5	83.3	78.4	0.1	0.1	0.4	1.0	0.1	2.4	0	0	0

* Bands have been totaled in with the neutrophils.

- = Animal died

Industrial BIO-TEST Laboratories, Inc.

TABLE IX
 TEST MATERIAL: Cornstarch Powder Base
 90-Day Subacute Inhalation Toxicity Study - Golden Syrian Hamsters

Hematologic Data - Females																	
Group	Animal Number	Neutrophils*			Differential Leukocyte Count (Number of Cells per Hundred)												
		-1	44	86	Lymphocytes			Monocytes			Eosinophils			Basophils			
					Test Day:				Test Day:				Test Day:			Test Day:	
					-1	44	86	-1	44	86	-1	44	86	-1	44	86	
UC	31	27	25	18	69	73	76	3	1	0	1	1	6	0	0	0	
	32	23	16	22	74	80	77	1	1	0	2	3	1	0	0	0	
	33	45	22	22	53	77	78	0	0	0	2	1	0	0	0	0	
	34	16	14	10	80	79	86	1	0	0	3	7	4	0	0	0	
	35	24	12	34	72	87	64	2	0	0	2	1	2	0	0	0	
	36	23	6	10	73	89	87	2	0	0	2	5	3	0	0	0	
	37	25	16	22	75	84	77	0	0	0	0	0	1	0	0	0	
	38	30	8	19	70	89	73	0	0	0	0	3	8	0	0	0	
	39	28	17	17	70	81	80	-	0	0	0	2	2	3	0	0	0
	40	12	36	28	86	63	71	1	0	0	1	1	1	0	0	0	0
Mean	22.8	17.2	20.2	72.2	80.2	76.9	1.0	0.2	0	1.5	2.4	2.9	0	0	0	0	

* Bands have been totalled in with the neutrophils.

Industrial BIO-TEST Laboratories, Inc.

TABLE IX continued
 TEST MATERIAL: Cornstarch Powder Base
 90-Day Subacute Inhalation Toxicity Study - Golden Syrian Hamsters
 Hematologic Data - Females

Group	Animal Number	Neutrophils*			Lymphocytes			Monocytes			Eosinophils			Basophils		
		-1	44	86	-1	44	86	-1	44	86	-1	44	86	-1	44	86
T-1	91	18	15	15	82	84	85	0	0	0	0	1	0	0	0	0
	92	28	-	-	71	-	-	0	-	-	1	-	-	0	-	-
	93	20	19	7	78	80	91	1	1	0	1	0	2	0	0	0
	94	14	90	-	82	10	-	0	0	-	4	0	-	0	0	-
	95	30	16	14	64	84	85	1	0	0	5	0	1	0	0	0
	96	15	25	25	85	73	74	0	0	0	0	2	1	0	0	0
	97	18	25	18	78	72	78	1	0	1	3	3	3	0	0	0
	98	24	23	28	76	77	71	0	0	0	0	0	1	0	0	0
	99	43	17	21	55	79	78	2	0	0	0	4	1	0	0	0
	100	17	16	19	81	83	80	0	0	0	2	1	1	0	0	0
Mean		21.3	27.3	18.4	75.2	71.3	80.3	0.5	0.1	0.1	1.6	1.2	1.2	0	0	0

* Bands have been totaled in with the neutrophils.

- = Animal died

Industrial BIO-TEST Laboratories, Inc.

TABLE IX continued
 TEST MATERIAL: Cornstarch Powder Base
 90-Day Subacute Inhalation Toxicity Study - Golden Syrian Hamsters
 Hematologic Data - Females

Group	Animal Number	Neutrophils*		Differential Leukocyte Count (Number of Cells per Hundred)						Eosinophils		Basophils	
		-1	44	86	-1	44	86	-1	44	86	-1	44	86
T-II	151	16	21	33	83	78	64	1	0	0	0	1	3
	152	15	16	16	84	82	81	0	0	0	1	2	3
153	10	13	6	88	87	91	91	0	0	0	2	0	3
	23	18	14	74	81	84	84	0	0	0	3	1	2
155	15	16	11	82	83	85	85	0	0	0	3	1	4
	15	29	19	84	70	78	78	0	0	0	3	1	3
157	27	-	-	66	-	-	-	0	-	-	7	-	-
	29	13	27	70	84	71	71	1	0	0	0	3	2
159	29	15	11	71	82	83	83	0	0	0	0	3	6
	17	18	25	82	81	75	75	0	0	0	1	1	0
Mean	18.4	17.7	18.0	78.4	80.8	79.1	79.1	0.2	0	0	2.0	1.4	2.8

* Bands have been totaled in with the neutrophils.

- = Animal died

TABLE X

TEST MATERIAL: Cornstarch Powder Base
90-Day Subacute Inhalation Toxicity Study - Golden Syrian Hamsters

Hematologic Data - Males

Group	Animal Number	MCV (μ 3)			Erythrocyte Indices			MCHC (%)		
		Test Day:			Test Day:			Test Day:		
		-1	44	86	-1	44	86	-1	44	86
UC	1	63	58	59	22.5	22.3	22.7	36.9	38.8	41.7
	2	63	57	56	22.9	20.8	21.2	37.1	37.4	41.2
	3	62	57	-	21.9	20.7	-	36.1	37.4	-
	4	61	57	56	21.8	20.6	21.2	36.5	37.1	44.0
	5	61	56	55	21.7	21.9	21.0	36.4	39.5	44.7
	6	61	57	57	22.0	23.5	21.9	37.1	42.4	41.2
	7	62	58	59	22.3	21.5	22.2	36.6	37.7	49.6
	8	62	57	56	22.4	21.1	22.8	37.0	37.9	45.3
	9	62	57	57	22.6	22.4	21.1	37.1	42.1	39.8
	10	60	58	57	21.7	22.0	22.4	37.1	41.7	42.4
Mean		62	57	57	22.2	20.7	21.8	36.8	39.2	43.3

- = Animal died

TABLE X continued

TEST MATERIAL: Cornstarch Powder Base

90-Day Subacute Inhalation Toxicity Study - Golden Syrian Hamsters

Hematologic Data - Males

Group	Animal Number	MCV (μ^3)			Erythrocyte Indices			MCHC (%)		
		-1	44	86	-1	44	86	-1	44	86
T-I	61	63	60	61	23.1	23.3	24.5	37.1	39.9	43.3
	62	61	55	60	21.7	20.6	22.5	36.4	38.0	40.3
	63	62	57	56	22.1	20.7	22.9	36.3	37.4	44.2
	64	62	57	56	21.9	20.9	21.8	36.2	37.5	42.2
	65	61	56	57	21.5	20.1	21.4	36.1	36.5	43.6
	66	64	57	-	22.2	19.7	-	35.5	35.3	-
	67	60	56	-	21.5	20.9	-	36.4	40.2	-
	68	62	56	60	21.4	20.0	23.3	36.4	36.8	42.1
	69	62	56	56	22.2	20.6	22.8	36.5	37.5	44.2
	70	62	56	58	21.8	20.3	22.5	35.8	37.4	41.9
Mean		62	57	58	21.9	20.7	22.7	36.3	37.6	42.7

- = Animal died

TABLE X continued

TEST MATERIAL: Cornstarch Powder Base

90-Day Subacute Inhalation Toxicity Study - Golden Syrian Hamsters

Hematologic Data - Males

Group	Animal Number	Erythrocyte Indices						MCHC (%)		
		MCV (μ^3)		MCH (μg)		MCHC (%)		Test Day:		
		-1	44	86	-1	44	86	-1	44	86
T-II	121	61	57	56	22.7	20.9	22.4	37.9	37.4	42.8
	122	62	57	57	23.5	21.1	21.8	38.8	40.1	41.8
	123	64	57	58	23.5	20.6	22.9	37.7	36.7	42.8
	124	62	56	55	20.9	20.2	22.5	33.9	39.8	43.9
	125	64	58	58	23.9	21.1	22.9	37.9	38.5	45.7
	126	62	56	-	22.7	20.0	-	37.2	39.3	-
	127	61	56	55	22.2	20.0	22.5	37.7	38.9	44.1
	128	63	58	55	22.8	20.3	21.5	36.8	35.6	42.7
	129	62	56	56	23.4	21.6	22.9	38.5	39.4	44.0
	130	62	57	55	23.4	20.2	23.5	36.7	36.3	46.0
Mean		62	57	56	22.9	20.6	22.5	37.5	38.2	43.8

TABLE XI

TEST MATERIAL: Cornstarch Powder Base

90-Day Subacute Inhalation Toxicity Study - Golden Syrian Hamsters

Hematologic Data - Females

Group	Animal Number	Erythrocyte Indices								
		MCV (μ^3)			MCH (μg)			MCHC (%)		
		Test Day:			Test Day:			Test Day:		
		-1	44	86	-1	44	86	-1	44	86
UC	31	62	58	59	23.1	21.1	23.2	37.9	37.0	43.1
	32	63	57	58	22.4	20.8	23.7	36.4	37.2	44.2
	33	64	59	57	23.0	21.6	23.1	36.7	37.5	43.4
	34	64	59	58	23.0	21.5	22.4	36.9	37.5	41.5
	35	63	58	61	22.8	21.4	24.1	37.4	37.4	42.4
	36	63	59	59	23.2	22.5	24.0	38.1	38.6	44.1
	37	64	60	58	23.6	22.0	22.6	37.5	37.5	42.1
	38	63	56	55	22.8	20.4	22.4	37.1	37.2	44.2
	39	63	58	58	23.5	21.4	23.1	38.4	39.5	42.8
	40	62	58	59	22.5	21.4	22.5	37.1	37.7	41.8
	Mean	63	58	58	23.0	21.4	23.1	37.4	37.7	43.0

TABLE XI continued

TEST MATERIAL: Cornstarch Powder Base

90-Day Subacute Inhalation Toxicity Study - Golden Syrian Hamsters

Hematologic Data - Females

Group	Animal Number	MCV (μ^3)			Erythrocyte Indices			MCHC (%)		
		-1	44	86	-1	44	86	-1	44	86
T-I	91	61	58	58	22.1	20.7	24.5	36.9	36.4	45.5
	92	61	-	-	21.7	-	-	36.5	-	-
	93	63	58	60	23.2	21.6	24.2	37.4	37.7	43.7
	94	62	55	-	22.9	20.8	-	37.9	41.6	-
	95	66	58	58	24.2	22.1	24.1	37.6	40.8	44.7
	96	62	57	58	22.5	20.3	23.4	37.2	36.0	43.7
	97	73	59	57	25.0	21.3	23.6	35.9	37.8	44.3
	98	61	57	55	22.2	20.1	21.8	36.9	36.0	42.5
	99	63	59	58	22.3	21.1	23.1	36.9	36.3	42.7
	100	62	58	56	23.3	21.1	22.4	38.8	36.9	42.9
	Mean	63	58	58	22.9	21.0	23.4	37.2	37.7	43.8

- = Animal died

TABLE XI continued

TEST MATERIAL: Cornstarch Powder Base

90-Day Subacute Inhalation Toxicity Study - Golden Syrian Hamsters

Hematologic Data - Females

Group	Animal Number	Erythrocyte Indices						MCHC (%)		
		MCV (μ^3)		MCH (μg)		MCHC (%)		Test Day:		
		-1	44	86	-1	44	86	-1	44	86
T-II	151	64	58	60	22.4	23.2	23.1	35.7	40.6	41.2
	152	64	58	59	22.7	20.8	22.5	36.4	36.7	41.2
	153	65	58	60	23.4	21.0	23.8	36.9	37.4	42.7
	154	63	59	58	23.3	21.2	21.8	37.7	37.6	40.2
	155	62	58	60	22.1	20.7	24.2	36.2	39.2	43.8
	156	62	58	58	22.2	20.6	22.6	36.7	35.9	41.9
	157	65	-	-	22.9	-	-	36.2	-	-
	158	63	57	61	23.1	20.2	22.9	37.2	35.8	40.7
	159	63	59	58	22.6	20.9	23.4	36.6	36.2	43.7
	160	64	57	58	22.9	20.7	22.4	36.6	37.1	41.4
	Mean	64	58	59	22.8	21.0	23.0	36.6	37.4	41.9

- = Animal died

D. Gross Pathologic Observations

No treatment-related gross alterations were observed in any of the tissues and organs examined. They consisted of the following:

Group	Animal Number and Sex	Disposition	Observation
Control	3-M	Moribund Sacrifice	Carcass - Emaciated Right Ear - Inner ear infection
T-I	66-M	Died	Lung - Emphysematous Carcass - Emaciated
T-I	67-M	Died	Carcass - Emaciated
T-I	92-F	Died	Lung - Diffuse red discoloration
T-I	94-F	Died	Lung - Consolidated foci
T-I	110-F	Moribund Sacrifice	Carcass - Emaciated
T-II	140-M	Died	Lung - Diffuse red discoloration Carcass - Emaciated

E. Histopathologic Findings

The results of the histopathologic studies are presented in Tables XII and XIII. The grading system and abbreviations used in these tables are as follows:

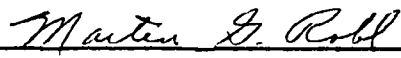
- x = Tissue present on slide and examined
- = Tissue not present on slides
- 1 = Trace or minimal in severity
- 2 = Mild in severity
- 3 = Moderate in severity
- 4 = Marked in severity
- 5 = Extreme in severity
- p = Lesion present, not graded

The pathologist's statement follows on the next page.

IBT No. 8562-09039
Johnson & Johnson

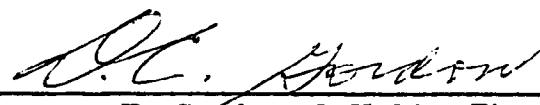
I have completed a histopathological evaluation of a series of selected tissues (lung, kidneys, liver and lymph nodes) from hamsters of the control and T-II test groups of Study No. 8562-09039.

No treatment-related changes were observed. The lesions described were those of naturally occurring diseases or related to the method of sacrifice. With regard to the latter, there were varying degrees of capillary congestion and intra-alveolar hemorrhage which occurred just prior to sacrifice in some animals. In most instances, these lesions were present among both the control and test animals. The lesions are summarized in Table XII and individual data are presented in Table XIII. All tissues present on the slides and examined by light microscopy are also accounted for, by sex and experimental group, in Table XIII. Those tissues which were absent were random in occurrence with regard to experimental group and did not interfere with the above conclusions.



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Reviewed and Approved:



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TABLE XII

TEST MATERIAL: Cornstarch Powder Base

90-Day Subacute Inhalation Toxicity Study - Golden Syrian Hamsters

Final Sacrifice

Summary of Histopathological Findings - Males

Organ or Tissue	Histologic Findings	Group and Exposure Level: Number Examined:		T-II 30	
		Control 29	Average Grade	Incidence	Average Grade
Lung	Focal mineralized debris in alveoli	1	1.0	2	1.0
	Focal aggregates of alveolar macrophages	1	1.0	1	1.0
	Focal intraalveolar hemorrhage (agonal)	3	P	0	-
	Multifocal intraalveolar hemorrhage (agonal)	1	P	0	-
	Focal congestion (agonal)	11	P	17	P
	Diffuse congestion (agonal)	4	P	5	P
	Subacute focal bronchopneumonia	1	2.5	0	-
	Terminally inhaled blood (agonal)	3	P	0	-
	Focal pigment - laden macrophages	2	1.0	0	-
	Focal amyloidosis	0	-	1	1.5
	Focal bronchiolar epithelial hyperplasia	0	-	1	1.0
Lymph node (cervical)	Lymphoid hyperplasia	4	1.6	3	1.0
	Subacute lymphadenitis	1	1.0	0	-
Lymph node (mesenteric)	Lymphoid hyperplasia	8	1.3	14	1.0
	Subacute lymphadenitis	1	1.5	0	-
Liver	Focal extramedullary hematopoiesis	11	1.3	9	1.1
	Subacute cholangitis	1	2.0	0	-
	Focal pigment - laden sinusoidal macrophages	0	-	2	1.0
	Multifocal pigment - laden sinusoidal macrophages	1	1.5	0	-
	Focal necrotic hepatitis	0	-	1	1.0
	Multifocal necrotic hepatitis	0	-	1	1.5
Kidneys	Focal tubular nephrosis - unilateral	5	1.0	3	1.0
	Focal tubular nephrosis - bilateral	19	1.0	17	1.3
	Focal mineralized microconcretions in tubules-unilateral	7	1.0	4	1.0
	Focal mineralized microconcretions in tubules-bilateral	1	1.0	2	1.0

TABLE XII continued

TEST MATERIAL: Cornstarch Powder Base

90-Day Subacute Inhalation Toxicity Study - Golden Syrian Hamsters

Final Sacrifice

Summary of Histopathological Findings - Females

Organ or Tissue	Histologic Findings	Control 30		T-II 30	
		Incidence	Average Grade	Incidence	Average Grade
Lung	Focal mineralized debris in alveoli	2	1.0	3	1.0
	Focal aggregates of alveolar macrophages	3	1.0	1	1.0
	Focal intraalveolar hemorrhage (agonal)	1	P	0	-
	Focal congestion (agonal)	12	P	7	P
	Diffuse congestion (agonal)	10	P	3	P
	Subacute focal bronchopneumonia	1	1.0	0	-
	Subacute focal bronchiolitis	0	-	1	1.5
	Terminally inhaled blood (agonal)	0	-	1	P
	Focal debris in bronchiolar lumen	0	-	4	1.0
	Focal bronchiolar epithelial hyperplasia	1	1.0	0	-
	Focal pigment - laden macrophages	2	1.5	0	-
	Lymphoid hyperplasia	2	1.0	7	1.0
	Lymphoid hyperplasia	15	1.0	9	1.0
Liver	Focal extramedullary hematopoiesis	8	1.3	13	1.2
	Focal bile duct proliferation	1	1.0	2	1.3
	Multifocal bile duct proliferation	0	-	1	2.5
	Focal pigment - laden sinusoidal macrophages	0	-	1	1.5
	Subacute multifocal cholangitis	0	-	1	3.0
	Focal necrotic hepatitis	1	1.0	1	2.0
	Multifocal cytoplasmic vacuolation hydrophic	1	2.0	0	-
	Amyloidosis	1	2.0	0	-

TABLE XII continued
 TEST MATERIAL: Cornstarch Powder Base
 90-Day Subacute Inhalation Toxicity Study - Golden Syrian Hamsters

Organ or Tissue	Histologic Findings	Summary of Histopathological Findings - Females			
		Control		T-II	
		Number Examined:	Average Grade	Incidence	Average Grade
Kidneys	Focal tubular nephrosis - unilateral	3	1.0	6	1.0
	Focal tubular nephrosis - bilateral	7	1.1	4	1.0
	Focal mineralized microconcretions in tubules - unilateral	4	1.0	2	1.0
	Focal mineralized microconcretions in tubules - bilateral	2	1.0	0	-
	Focal proteinaceous tubular casts - unilateral	1	2.0	0	-

Grading System

- 1 = minimal in severity
 2 = mild in severity
 3 = moderate in severity
 4 = marked in severity
 5 = extreme in severity
 p = present, no grade

TABLE XIII

TEST MATERIAL: Cornstarch Powder Base
90-Day Subacute Inhalation Toxicity Study - Golden Syrian Hamsters
Final Sacrifice

Individual Histopathological Findings - Males																																
Organ	Exposure Level: Animal Number:	Control																														
		1	2	3*	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	28	29	30		
Lung	Histologic Findings	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	X	X	X	X	
	Focal mineralized debris in alveoli	1																														
	Focal aggregates of alveolar macrophages																															
	Focal intraalveolar hemorrhage (agonal)																															
	Multifocal intraalveolar hemorrhage (agonal)																															
	Focal congestion (agonal)																															
	Diffuse congestion (agonal)																															
	Subacute focal bronchopneumonia																															
	Terminally inhaled blood (agonal)																															
	Focal pigment-laden macrophages																															
	Lymph node (cervical)																															
																	</															

* Sacrificed in extremis.

TABLE XIII continued
 TEST MATERIAL: Cornstarch Powder Base
 90-Day Subacute Inhalation Toxicity Study - Golden Syrian Hamsters
 Final Sacrifice

Individual Histopathological Findings - Males																															
Organ	Group and Exposure Level: Animal Number: Histologic Findings	Control																													
		1	2	3*	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	28	29	30	
Lymph node (mesenteric)	Subacute lymphadenitis	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	X	X	X
	Lymphoid hyperplasia									1-2	1					1					1-2	1	1	1	1	1	1	1	2	2	
Lymph node (tracheo- bronchial)		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		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	X	X	X	X
Liver	Focal extramedullary hematopoiesis																														
	Subacute cholangitis																														
	Multifocal pigment - laden macrophages										1				1-2				1	1	1-2	1-2	2	1					1		2
																						1-2									
Kidneys	Focal tubular nephrosis unilateral	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	X	X	X	X
	Focal tubular nephrosis bilateral											1	1																		1
	Focal mineralized microconcretions in tubules - unilateral	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1-2	1-2	1-2						1	1	1
	Focal mineralized microconcretions in tubules in - bilateral																														

* Sacrificed in extremis.

TABLE XIII continued

TEST MATERIAL: Cornstarch Powder Base

90-Day Subacute Inhalation Toxicity Study - Golden Syrian Hamsters

Final Sacrifice

Individual Histopathological Findings - Males

Organ	Group and Exposure Level: Animal Number:	T-II																												
		Histologic Findings																												
		121	122	123	124	125	126**	127	128	129	130	131	132	133	134	135	136	137	138	139	140**	141	142	143	144	145	146	147	148	149
Lung	Focal congestion (agonal)	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	X	X	X
	Diffuse congestion (agonal)	p	p		p																									
	Focal amyloidosis																													
	Focal mineralized debris alveoli																													
	Focal bronchiolar epithelial hyperplasia																													
	Focal aggregates of alveolar macrophages																													
Lymph node (cervical)		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	X	X	X
	Lymphoid hyperplasia																													
Lymph node (mesenteric)		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	X	X	X
	Lymphoid hyperplasia	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

** Animal found dead.

TABLE XIII continued

TEST MATERIAL: Cornstarch Powder Base

90-Day Subacute Inhalation Toxicity Study - Golden Syrian Hamsters

Group and Exposure Level:		Individual Histopathological Findings - Males																													
Organ	Animal Number:	121	122	123	124	125	126**	127	128	129	130	131	132	133	134	135	136	137	138	139	140**	141	142	143	144	145	146	147	148	149	150
	Histologic Findings	T-II																													
Lymph node (tracheobronchial)		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Liver		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	X	X	X	
	Focal extramedullary hematopoiesis	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1-2	1	1	1	1	1	1	1	1	1	
	Focal necrotic hepatitis	1																													
	Multifocal necrotic hepatitis																														
	Focal pigment - laden macrophages																														
Kidneys		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	X	X	X	
	Focal tubular nephrosis unilateral																														
	Focal tubular nephrosis bilateral	1-2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	
	Focal mineralized microconcretions in tubules - unilateral																														
	Focal mineralized microconcretions in tubules - bilateral																														

** Animal found dead.

**** Animal found dead.**

TABLE XIII continued
 TEST MATERIAL: Cornstarch Powder Base
 90-Day Subacute Inhalation Toxicity Study - Golden Syrian Hamsters

Group and Exposure Level: Animal Number:		Individual Histopathological Findings - Females																													
		Final Sacrifice																													
		Control																													
Organ	Histologic Findings	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60
Liver	Focal extramedullary hematopoiesis	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	X	X	X	X
	Focal necrotic hepatitis	1	1				1	1	1	1	3																				
	Multifocal cytoplasmic vacuolation - hydropic																														
	Focal bile duct proliferation																														
	Amyloidosis													1																	
Kidneys	Focal tubular nephrosis unilateral	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	X	X	X	X
	Focal tubular nephrosis bilateral	1					1-2	1-2	1	1																1	1				
	Focal mineralized microconcretions in tubules - unilateral																														
	Focal mineralized microconcretions in tubules - bilateral																														
	Focal proteinaceous tubular casts - unilateral																														

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TABLE XIII continued
 TEST MATERIAL: Cornstarch Powder Base
 90-Day Subacute Inhalation Toxicity Study - Golden Syrian Hamsters

Organ	Group and Exposure Level: Animal Number: Histologic Findings	Individual Histopathological Findings - Females																															
		Final Sacrifice																															
		31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60		
Lung	Focal aggregates of alveolar macrophages	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	X	X	X	X	X	
	Focal intraalveolar hemorrhage (agonal)																																
	Focal congestion (agonal)																																
	Diffuse congestion (agonal)	P						P																									
	Subacute focal bronchopneumonia																																
	Focal pigment - laden macrophages																																
	Focal mineralized debris in alveoli																																
	Focal bronchiolar epithelial hyperplasia																																
Lymph node (cervical)	Lymphoid hyperplasia	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	X	X	X	X	X	
Lymph node (mesenteric)	Lymphoid hyperplasia	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	X	X	X	X	X	

TABLE XIII continued
 TEST MATERIAL: Cornstarch Powder Base
 90-Day Subacute Inhalation Toxicity Study - Golden Syrian Hamsters
 Final Sacrifice

Individual Histopathological Findings - Females																																
Group and		T-II																														
Exposure Level:																																
Animal Number:		151	152	153	154	155	156	157**	158	159	160	161	162	163	164	165	166	167	168	169	170	171	172	173	174	175	176	177	178	179	180	
Organ	Histologic Findings																															
Lung	Focal congestio.a (agonal)	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	X	X	X	X	
	Diffuse congestion (agonal)	P											P						P	P	P									P	P	
	Focal debris in bronchiolar lumen																															
	Focal aggregates of alveolar macrophages																															
	Terminally inhaled blood (agonal)																															
	Subacute focal bronchiolitis																															
	Focal mineralized debris in alveoli																															
	Lymph node (cervical)																															
	Lymphoid hyper-plasia																															

** Animal found dead.

TABLE XIII continued

TEST MATERIAL: Cornstarch Powder Base

[illegible]

†† Animal found dead.