

R. J. REYNOLDS TOBACCO COMPANY  
BIOCHEMICAL/BIOBEHAVIORAL R & D  
WINSTON-SALEM, NORTH CAROLINA 27106

\*\*\* PATH/TOX SYSTEM CUIRUT \*\*\*  
SUB-CHRONIC (90-DAY) INHALATION STUDY IN RATS.

\*DRAFT\* KOLMOGOROV-SMIRNOV STATISTIC SUMMARY, \*DRAFT\*

PRINTED: 23-MAR-87  
PAGE: 1

STUDY NUMBER: R10001

# TABLE INCLUDES:

SEX=ALL; GROUP=ALL; SCREEN=ALL; WEEKS=ALL  
DEATH=1, 2, 3, 4; FIND=ALL; SUBSET=ALL

## ORGAN/TISSUE EXAMINED

\*\* TOP OF LIST \*\*

TRACHEA (TR)

--LYMPHO CYTIC INFILTRATION

NUMBER EXAMINED:

20

4

7

8

13

20

20

20

20

20

20

20

20

20

20

20

20

20

20

20

20

20

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20

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20

20

20

20

20

20

20

20

20

20

20

20

20

20

20

20

20

LARYNX (LA)

--LYMPHO CYTIC INFILTRATION

NUMBER EXAMINED:

20

4

7

8

13

20

20

20

20

20

20

20

20

20

20

20

20

20

20

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20

20

20

20

20

20

20

20

20

20

LUNGS (LU)

--MACROPHAGES, NONPIGMENTED

NUMBER EXAMINED:

20

5

5

5

8

20

20

20

20

20

20

20

20

20

20

20

20

20

20

20

20

20

20

20

20

20

20

20

20

20

20

--VASCULAR MINERALIZATION

--CONGESTION

--MACROPHAGES, BROWN/GOLD, INDIVIDUAL

7252 18905

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\*\*\* PATH/TOX SYSTEM CODE \*\*\*  
SUB-CHRONIC (90-DAY) INHALATION STUDY IN RATS.

EXPOSED: 23-MAR-67  
PAGE: 2

\*TRAFFIC\* KOLMOGOROV-SMIRNOV STATISTIC SUMMARY \*DATA\*

STUDY NUMBER: R8001

# TABLE INCLUDES:

SEX=ALL; GROUP=ALL; SCREEN=ALL; WEEKS=ALL  
DEATH=1, 2, 3; FIND=ALL; SUBSET=ALL

## --- NUMBER OF ANIMALS --- AFFECTED ---

TABLE INCLUDES: SEX=ALL; GROUP=ALL; SCREEN=ALL; WEEKS=ALL DEPTH=1, 2, 3, T; FIND=ALL; SUBSET=ALL												
SEX:	SIZE											
GROUP:	-1-	-2-	-3-	-4-	-5-	-6-	-7-	-8-	-9-			
NUMBER:	20	10	29	29	25	20	30	25	20			
ORGAN/TISSUE EXAMINED												
THYMIC L.N. (TN) ---HYPERPLASIA, LYMPHOID	NUMBER EXAMINED: -> -> -> -> TI>	19 5 3 11 190	10 6 2 2 10	29 11 12 16 0	29 16 7 0 29	24 3 3 19 24	18 1 6 11 0	23 0 1 10 28	23 0 1 22 23	19 0 1 18 19		
PERIBRONCH. L.N. (PL) ---HYPERPLASIA, LYMPHOID	NUMBER EXAMINED: -> -> -> -> TI>	19 6 1 10 190	9 8 0 1 9	29 10 4 15 29	29 24 3 0 29	22 7 1 14 22	18 1 0 17 18	27 0 1 5 27	23 0 1 21 23	19 1 2 16 19		
TRACHEA PAS/AB (TR1) ---GOBLET CELLS, NEGATIVE	NUMBER EXAMINED: -> P> TI>	20 8 12 200	10 8 2 10	29 16 13 29	29 16 13 29	25 15 10 25	20 14 6 20	30 20 3 30	25 22 3 25	20 18 2 20		
---GOBLET CELLS, FEW	-> P> TI>	14 6 200	2 8 10	13 16 29	13 16 29	10 15 25	6 14 20	10 20 30	7 18 25	5 15 20		
LARYNX PAS/AB (LA1) ---GOBLET CELLS, NEGATIVE	NUMBER EXAMINED: -> P> TI>	20 5 15 200	10 0 10 10	29 11 18 29	29 12 17 29	25 5 20 25	20 4 16 20	30 11 19 30	25 17 8 25	20 12 8 20		
---GOBLET CELLS, FEW	-> P> TI>	15 5 200	10 0 10	18 11 29	17 12 29	20 5 25	16 4 20	19 11 30	8 17 25	8 12 20		
LUNG PAS/AB (LU1) ---ALVEOLAR GOBLET CELLS, FEW	NUMBER EXAMINED: -> P> TI>	20 3 17 200	10 0 10 10	29 4 25 29	29 3 26 29	25 0 25 25	20 1 19 20	30 10 20 30	25 20 5 25	20 18 2 20		

\*\* CONTINUED ON NEXT PAGE \*\*

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SUB-CHRONIC (90-DAY) INHALATION STUDY IN RATS

PRINTED: 23-MAR-87  
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\*DRAFT\* KOIMOGOROV-SMIRNOV STATISTIC SUMMARY \*DRAFT\*

STUDY NUMBER: R1001

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; SCREEN=ALL; WEEKS=ALL  
DEATH=1, 2, 3, 4; FIND=ALL; SUBSET=ALL

ORGAN/TISSUE EXAMINED

\*\* FROM PREVIOUS PAGE \*\*

LUNG PAS/AB (111) .....  
--- BRONCHIOAL COBLET CELLS, MANY

NASAL 1, HEE (NP1) .....  
--- HYPERPLASIA, EPITHELIAL

--- HYPERHYPH, COBLET CELL

--- METAPLASIA, SQUAMOUS

--- INFLAMMATION, CHRONIC ACTIVE

NASAL 2, HEE (NP2) .....  
--- HYPERHYPH, COBLET CELL

1

— NUMBER OF ANIMALS AFFECTED —											
SEX:	MALE										
GROUP:	-1-	-2-	-3-	-4-	-5-	-6-	-7-	-8-	-9-		
NUMBER:	20	10	29	29	25	20	30	25	20		
EXAMINED:	20	10	29	29	25	20	30	25	20		
P>	20	10	29	29	25	20	30	25	20		
TI>	20	10	29	29	25	20	30	25	20		
EXAMINED:	19	10	29	28	25	19	28	25	19		
P>	19	10	29	28	25	19	28	25	19		
TI>	19	10	29	28	25	19	28	25	19		
EXAMINED:	1	5	0	2	2	1	3	0	0		
P>	1	5	0	2	2	1	3	0	0		
TI>	1	5	0	2	2	1	3	0	0		
EXAMINED:	18	8	29	28	25	19	28	14	4		
P>	18	8	29	28	25	19	28	14	4		
TI>	18	8	29	28	25	19	28	14	4		
EXAMINED:	14	4	15	18	19	13	11	9	3		
P>	14	4	15	18	19	13	11	9	3		
TI>	14	4	15	18	19	13	11	9	3		
EXAMINED:	19	10	29	28	25	19	28	25	19		
P>	19	10	29	28	25	19	28	25	19		
TI>	19	10	29	28	25	19	28	25	19		

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\*\*\* PAH/TOX SYSTEM OUTPUT \*\*\*  
SUB-CHRONIC (90-DAY) INHALATION STUDY IN RATS.

PRINTED: 23-MAR-87  
PAGE: 4

\*DRAFT\* KOINDGOROV-SMIRNOV STATISTIC SUMMARY \*DRAFT\* STUDY NUMBER: R18001

TABLE INCLUDES:  
SEX=ALL; GROUP=ALL; SCREEN=ALL; WEEKS=ALL  
DEATH=1, 2, 3; FIND=ALL; SUBSET=ALL

--- NUMBER OF ANIMALS AFFECTED ---

ORGAN/TISSUE EXAMINED	SEX	NUMBER OF ANIMALS AFFECTED									
		GROUP:	-1-	-2-	-3-	-4-	-5-	-6-	-7-	-8-	-9-
		NUMBER:	20	10	29	29	25	20	30	25	20
THYMUS GLAND (TM) --- CONGESTION		NUMBER EXAMINED:	20	9	29	29	25	20	29	25	20
		>	7	9	3	13	10	6	11	9	17
		1>	4	0	6	6	5	5	11	3	1
		2>	5	0	9	9	8	8	14	11	7
		3>	4	0	1	1	2	1	3	3	0
		4>	0	0	0	0	3	0	6	0	0
		T1>	200	9*	29	29	25	20	29	25	20
SPLEEN (SP) --- HEMOSIDERIN PIGMENT		NUMBER EXAMINED:	19	9	28	0	0	18	10	0	20
		>	3	6	22	0	0	13	10	0	15
		1>	14	3	25	0	0	3	10	0	7
		2>	2	0	1	0	0	3	1	0	0
		3>	0	0	0	0	0	0	0	0	0
		T1>	190	9*	28	0	0	18	10	0	20

\*\* END OF LIST \*\*

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\*\*\* PATH/TOX SYSTEM OUTPUT \*\*\*  
SUB-CHRONIC (90-DAY) INHALATION STUDY IN RATS.

PRINTED: 23-MAR-67  
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\*DRAFT\* KOIMOGOROV-SMIRNOV STATISTIC SUMMARY \*DRAFT\*

STUDY NUMBER: R0001

# TABLE INCLUDES:

SEX=ALL; GROUP=ALL; SCREEN=ALL; WEEKS=ALL  
DEATH=1, 2, 3, T; FIND=ALL; SUBSET=ALL

## --- NUMBER OF ANIMALS --- AFFECTED ---

SEX:	FEMALES									
	GROUP:	-1-	-2-	-3-	-4-	-5-	-6-	-7-	-8-	-9-
NUMBER:	20	10	30	30	30	30	19	29	30	19
ORGAN/TISSUE EXAMINED										
** TOP OF LIST **										
LARVAX (IA)										
--- LYMPHO CYTIC INFILTRATION										
NUMBER EXAMINED:	20	10	30	30	30	30	19	29	30	19
TI>	2	6	4	9	3	3	3	7	4	6
TI>	15	3	5	15	4	23	6	3	10	4
TI>	3	1	19	2	15	1	10	0	15	7
TI>	200	100	30	30	30	30	19	29	30	19
LUNGS (IU)										
--- VASCULAR MINERALIZATION										
NUMBER EXAMINED:	20	10	30	30	30	30	19	29	30	19
TI>	7	10	12	18	16	5	9	10	13	7
TI>	2	0	8	6	5	4	6	11	13	6
TI>	11	0	10	6	9	3	13	29	30	19
TI>	200	100	30	30	30	30	19	29	30	19
THYMIC L.N. (TN)										
--- HYPERPLASIA, LYMPHOID										
NUMBER EXAMINED:	17	6	28	28	28	28	15	22	27	19
TI>	0	4	7	5	2	0	7	2	0	0
TI>	3	2	17	20	14	28	14	11	24	17
TI>	14	0	0	1	0	0	0	0	0	0
TI>	170	60	28	28	28	28	15	22	27	19
PERITONEAL L.N. (PL)										
--- HYPERPLASIA, LYMPHOID										
NUMBER EXAMINED:	20	9	27	27	27	27	18	24	30	16
TI>	1	1	6	2	2	2	2	10	2	0
TI>	18	2	19	18	18	25	14	12	25	15
TI>	0	0	0	0	0	0	0	0	1	0
TI>	200	90	27	27	27	27	18	24	30	16
TRACHEA PAS/AB (TRU)										
--- COBLET CELLS, NEGATIVE										
NUMBER EXAMINED:	20	9	30	30	30	30	19	29	30	19
TI>	4	5	10	16	14	14	9	11	23	18
TI>	16	4	20	14	16	16	10	16	27	11
TI>	200	90	30	30	30	30	19	29	30	19
--- COBLET CELLS, FEW										
NUMBER EXAMINED:	16	4	20	14	16	16	10	16	7	1
TI>	4	5	10	16	14	14	9	11	23	18
TI>	200	90	30	30	30	30	19	29	30	19

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\*\*\* PATH/TOX SYSTEM OUTPUT \*\*\*  
SUB-CHRONIC (90-DAY) INHALATION STUDY IN RATS

REVISED: 23-MAR-87  
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\*DRAFT\* KOIMOGOROV-SMIRNOV STATISTIC SUMMARY \*DRAFT\*

STUDY NUMBER: R0001

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; SCREEN=ALL; WEEKS=ALL  
DEATH=1, 2, 3; T=FIND=ALL; SUBSET=ALL

--- NUMBER OF ANIMALS --- AFFECTED ---

ORGAN/TISSUE EXAMINED	SEX:	FEMALE									
		GROUP:	-1-	-2-	-3-	-4-	-5-	-6-	-7-	-8-	-9-
		NUMBER:	20	10	30	30	30	19	29	30	19
LUNG PAS/AB (LUL)											
--- BRONCHIOLAR COBLET CELLS, FEW		NUMBER EXAMINED:	20	9	30	30	30	19	29	30	19
		>	0	1	1	3	2	4	9	24	15
		P>	20	8	29	27	28	15	20	6	4
		TL>	200	9	30	30	30	19	29	30	19
--- BRONCHIOLAR COBLET CELLS, MANY											
		>	20	9	30	30	30	18	29	15	11
		P>	0	0	0	0	0	1	0	15	8
		TL>	200	9	30	30	30	19	29	30	19
NASAL L H&E (NPI)											
--- HYPERPLASIA, EPITHELIAL		NUMBER EXAMINED:	20	10	29	29	30	19	29	30	19
		>	11	3	17	11	17	13	29	2	0
		1>	9	4	8	14	10	4	8	0	0
		2>	0	3	3	4	3	2	1	21	10
		3>	0	0	0	0	0	0	0	7	0
		4>	0	0	1	0	0	0	1	0	0
		TL>	200	10	29	29	30	19	29	30	19
--- HYPERROPHY, COBLET CELL											
		>	4	6	9	7	10	6	6	2	0
		1>	8	3	10	17	9	7	7	5	3
		2>	8	1	9	4	2	6	14	19	9
		3>	0	1	1	1	3	0	2	4	7
		TL>	200	10	29	29	30	19	29	30	19
--- METAPLASIA, SQUAMOUS											
		>	20	10	28	28	30	19	29	27	3
		1>	0	0	0	0	0	0	0	7	7
		2>	0	0	1	1	0	0	0	1	8
		3>	0	0	0	0	0	0	0	0	1
		TL>	200	10	29	29	30	19	29	30	19
--- INFLAMMATION, CHRONIC ACTIVE											
		>	15	4	18	13	25	15	12	11	6
		1>	5	4	7	14	5	4	13	9	9
		2>	0	2	4	0	0	0	4	10	4
		3>	0	0	0	0	0	0	0	0	0
		TL>	200	10	29	29	30	19	29	30	19

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WINSTON-SALEM, NORTH CAROLINA 27106

\*\*\* PATH/TOX SYSTEM CUPUT \*\*\*  
SUB-CHRONIC (90-DAY) INHALATION STUDY IN RATS.

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\*DRAFT\* KOIMDCCOV-SMIRNOV STATISTIC SUMMARY \*DRAFT\* STUDY NUMBER: RFR001

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; SCREEN=ALL; WEEKS=ALL  
DEATH=1, 2, 3, 4; FIND=ALL; SUBSET=ALL

— NUMBER OF — ANIMALS — AFFECTED —

ORGAN/TISSUE EXAMINED	SEX:	FEMALE									
		GROUP: -1-	-2-	-3-	-4-	-5-	-6-	-7-	-8-	-9-	-10-
NUMBER:		20	10	30	30	30	19	29	30	30	19
NASAL 2, H&E (NP2) —HYPERKROPH, GOBLET CELL	NUMBER EXAMINED:	20	10	29	29	30	19	29	30	30	19
	->	12	7	14	15	12	11	8	13	13	6
	1>	8	3	11	14	17	7	22	15	10	3
	2>	0	0	4	0	1	1	1	2	3	1
	TL>	200	10	29	29	30	19	29*	30	30	19
SPLEEN (SP) —EXTRAMEDULLARY HEMATOPOIESIS	NUMBER EXAMINED:	20	8	27	0	0	17	0	0	0	19
	->	0	0	2	0	0	1	0	0	0	15
	1>	16	0	24	0	0	13	0	0	0	3
	2>	2	8	1	0	0	3	0	0	0	2
	3>	2	0	0	0	0	0	0	0	0	19
	TL>	200	8*	27	0	0	17	0	0	0	19
KIDNEYS (KD) —ONCOSTIOM	NUMBER EXAMINED:	20	8	27	0	0	17	0	0	0	19
	->	20	3	26	0	0	14	0	0	0	19
	2>	0	5	0	0	0	3	0	0	0	0
	3>	0	0	0	0	0	0	0	0	0	0
	TL>	200	8*	26	0	0	17	0	0	0	19

\*\* END OF LIST \*\*

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DESCRIPTION OF THE "TABLE INCLUDES:" PORTION OF THE OUTPUT TABLE HEADING

"SD" - THIS IS THE SEX/DOSAGE GROUP NUMBER. THE FIRST DIGIT INDICATES THE SEX OF THE GROUP. MALES ARE "1" AND FEMALES ARE "2". THE SECOND DIGIT IS THE DOSAGE GROUP WITHIN THE SEX. THE "SEX" AND "DOSAGE-GROUP" DESCRIPTIONS ARE THE EXPANDED FORMS OF THE "SD" NUMBER.

"SEX" - INDICATES WHICH SEXES WERE SELECTED FOR THIS OUTPUT TABLE. IF BOTH MALE AND FEMALE WERE SELECTED OR THE SEX WAS NOT USED AS A SELECTION CRITERION, THE SEX WILL BE "B" - BOTH. IF ONLY MALE OR ONLY FEMALE ANIMALS WERE SELECTED, THE SEX WILL BE "M" OR "F", RESPECTIVELY (EG. "SEX=F").

"GROUP" - INDICATES THE DOSAGE GROUP OR GROUPS SELECTED FOR THIS OUTPUT TABLE. IF ALL GROUPS WERE SELECTED OR THE DOSAGE GROUP WAS NOT USED AS A SELECTION CRITERION, THE GROUP WILL BE "ALL". IF INDIVIDUAL GROUPS WERE SPECIFIED, THE GROUPS WILL BE DISPLAYED WITH COMMAS SEPARATING THEM (EG. "GROUP=1,3,4").

"SCREEN" - INDICATES THE SCREEN NUMBER (SDS - SEX/DOSAGE/SCREEN GROUP OF 15) ANIMALS SELECTED WITHIN EACH QUALIFYING SEX AND DOSAGE GROUP. IF THE SCREEN NUMBER WAS NOT USED AS A SELECTION CRITERION, THE SCREEN WILL BE "ALL". IF A SCREEN NUMBER WAS INDICATED, ONLY ONE MAY BE SPECIFIED, THAT SCREEN NUMBER WILL BE DISPLAYED (EG. "SCREEN=2").

"WEEKS" - INDICATES THE NUMBER OF WEEKS AN ANIMAL WAS ON THE STUDY AT THE TIME OF DEATH. IF ALL WEEKS WERE SPECIFIED OR THE NUMBER OF WEEKS WAS NOT USED AS A SELECTION CRITERION, THE WEEKS WILL BE "ALL". IF WEEKS ON STUDY WERE SPECIFIED, EITHER A SINGLE WEEK OR THE LOWER AND UPPER BOUNDS OF A RANGE OF WEEKS ARE DISPLAYED (EG. "WEEKS=14", "WEEKS=4-15").

"DEATH" - INDICATES THE DEATH CODES OF THE ANIMALS SELECTED FOR THE OUTPUT TABLE. IF ALL DEATH CODES WERE SUPPLIED OR THE DEATH CODE WAS NOT USED AS A SELECTION CRITERION, THE DEATH CODE WILL BE "ALL". IF INDIVIDUAL DEATH CODES WERE SUPPLIED, THE DEATH CODES WILL BE DISPLAYED WITH COMMAS SEPARATING THEM (EG. "DEATH=1,2,3,D,T").

"FINDING" - INDICATES THE CLASSES OF FINDINGS SELECTED FOR THE OUTPUT TABLE. IF ALL FINDINGS TYPES WERE SPECIFIED OR THE FINDING TYPE WAS NOT USED AS A SELECTION CRITERION, THE FINDING TYPE WILL BE "ALL". IF INDIVIDUAL CLASSES OF FINDINGS WERE SELECTED, THE FINDINGS CLASS WILL BE DISPLAYED WITH COMMAS SEPARATING THEM (EG. "FINDING=M,B,I,X").

"INTERIM" - INDICATES THAT THE OUTPUT TABLE HAS BEEN GENERATED BEFORE THE STUDY WAS SIGNED OFF. NORMALLY, "DRAFT" WILL BE DISPLAYED ON EITHER SIDE OF THE REPORT HEADING IF THE OUTPUT TABLE IS GENERATED BEFORE THE STUDY IS SIGNED OFF. THE "DRAFT" NOTATION MAY BE CHANGED TO "INTERIM" BY ENTERING THE "INTERIM" KEYWORD.

"SUBSET" - INDICATES WHETHER ALL OF THE TISSUES APPEAR ON THE REPORT OR JUST SOME TARGET TISSUES WERE SELECTED. IF ALL OF THE TISSUES WERE SELECTED OR TISSUES WERE NOT USED AS A SELECTION CRITERION, THE SUBSET WILL BE "ALL". IF A SUBSET OF THE TISSUE LIST WAS USED, THE SUBSET INDICATOR WILL BE "T". THE USE OF BODY SYSTEM SUBSETS IS INDICATED BY A "B".