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ATTENTION OF: Dr. J. Knaak

FROM: Raymond E. Schroeder

COMPANY: Occidental Chemical
Corporation
Dallas, TX 75244

DATE: 22 April 1997

CC: Dr. Hasmukh Shah
Ms. Wendy Sherman
Chemical Manufacturers
Association
Arlington, VA 22209

MESSAGE: Study No. 96-4080 - Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

This facsimile includes the following summary data for the above referenced study
for your review (Study Weeks -1 through 14):

Tables

1. Summary of Clinical Observations
2. Mean Body Weights - Premating Period
3. Mean Body Weight Change during Premating Period (Weeks 0-10)
4. Mean Food Consumption - Premating Period
5. Mean Body Weights - Mating and Post-mating Periods (Males)
6. Mean Food Consumption - Post-mating Period (Males)

Appendix

- A. Methodology and References

Please contact me with any questions.

Best Regards,

Joanna Brunk
Study Monitor for
Raymond E. Schroeder
Study Director

CMA 118725

STUDY NO. 96-4080
VINYL CHLORIDE COMBINED INHALATION TWO-GENERATION REPRODUCTION
AND DEVELOPMENTAL TOXICITY STUDY IN CD RATS

Status Report

Submitted to: Chemical Manufacturers Association
Chemstar Department
1300 Wilson Blvd.
Arlington, Virginia 22209

Attn: Hasmukh C. Shah, Ph.D.

Date: 22 April 1997

CMA 118726

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TABLE 1
VINYL CHLORIDE COMBINED INHALATION TWO-GENERATION REPRODUCTION
AND DEVELOPMENTAL TOXICITY STUDY IN CD RATS

96-4080

SUMMARY OF CLINICAL OBSERVATIONS - MALES

WEEK: -1		1	2	3	4	5	6	7	8	9	10	11	12	13	14
# OF ANIMALS EXAMINED	I 30	30	30	30	30	30	30	30	30	30	30	30	30	30	30
	II 30	30	30	30	30	30	30	30	30	30	30	30	30	30	30
	III 30	30	30	30	30	30	30	30	30	30	30	30	30	30	30
	IV 30	30	30	30	30	30	30	30	30	30	30	30	30	30	30
<u>NORMAL</u>															
WITHIN NORMAL LIMITS	I 30	29	29	29	29	27	27	25	25	23	23	23	23	23	23
	II 30	30	29	28	26	26	27	26	26	26	26	26	26	26	25
	III 30	30	29	28	28	26	24	23	26	24	23	24	24	24	23
	IV 30	30	30	29	28	27	27	27	29	28	23	26	26	26	26
<u>GENL APPEARANCE</u>															
EARS SWOLLEN/RED - BILATERAL	I 0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	II 0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	III 0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	IV 0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
<u>DERMAL-GENERAL</u>															
ULCERATION - CERVICAL	I 0	0	1	1	1	1	1	1	1	1	1	1	1	1	1
	II 0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	III 0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	IV 0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ALOPECIA - EXTREMITIES/SNOUT	I 0	0	0	0	0	0	0	1	1	0	0	0	0	0	0
	II 0	0	1	1	2	2	1	1	1	1	1	1	1	1	2
	III 0	0	0	0	0	0	0	0	1	1	1	0	1	1	1
	IV 0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ALOPECIA - GENERAL	I 0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	II 0	0	0	1	1	1	1	1	1	1	1	0	0	0	1
	III 0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	IV 0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
YELLOW AND-GENITAL STAINING	I 0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	II 0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	III 0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	IV 0	0	0	0	0	0	0	0	0	0	1	0	0	0	0

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TABLE 1 (cont.)
VINYL CHLORIDE COMBINED INHALATION TWO-GENERATION REPRODUCTION
AND DEVELOPMENTAL TOXICITY STUDY IN CD RATS

96-4080

SUMMARY OF CLINICAL OBSERVATIONS - MALES

WEEK:	-1	1	2	3	4	5	6	7	8	9	10	11	12	13	14
# OF ANIMALS EXAMINED	I 30	30	30	30	30	30	30	30	30	30	30	30	30	30	30
	II 30	30	30	30	30	30	30	30	30	30	30	30	30	30	30
	III 30	30	30	30	30	30	30	30	30	30	30	30	30	30	30
	IV 30	30	30	30	30	30	30	30	30	30	30	30	30	30	30

OCULAR

LACRIMATION - UNILATERAL	I 0	1	0	0	0	0	1	0	0	0	1	1	0	0	0
	II 0	0	0	0	0	0	0	1	1	0	0	0	1	1	1
	III 0	0	0	0	0	0	0	0	0	0	1	0	0	0	0
	IV 0	0	0	0	1	0	0	1	1	0	0	0	0	0	1

CHROMODACRYORRHEA - UNILATERAL	I 0	1	0	0	0	0	1	0	1	2	0	0	0	0	1
	II 0	0	0	0	0	1	1	1	1	3	3	2	2	2	2
	III 0	0	0	0	0	0	2	0	0	0	0	0	0	0	0
	IV 0	0	0	1	2	1	1	1	1	1	1	2	1	1	2

CHROMODACRYORRHEA - BILATERAL	I 0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	II 0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
	III 0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
	IV 0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

LACRIMATION - BILATERAL	I 0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	II 0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	III 0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	IV 0	0	0	0	0	0	0	0	0	0	0	0	0	0	1

ORAL/BUCCAL

INCISORS MALOCCLUDED	I 0	0	0	0	0	0	2	2	3	3	5	5	5	4	4
	II 0	0	0	0	1	1	1	0	1	1	1	3	3	3	2
	III 0	0	1	2	2	2	4	3	3	1	2	3	3	3	3
	IV 0	0	0	1	2	3	3	3	3	0	0	2	2	2	2

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TABLE 1 (cont.)

VINYL CHLORIDE COMBINED INHALATION TWO-GENERATION REPRODUCTION
AND DEVELOPMENTAL TOXICITY STUDY IN CD RATS

96-4080

SUMMARY OF CLINICAL OBSERVATIONS - MALES

WEEK:	-1	1	2	3	4	5	6	7	8	9	10	11	12	13	14
# OF ANIMALS EXAMINED	I 30	30	30	30	30	30	30	30	30	30	30	30	30	30	30
	II 30	30	30	30	30	30	30	30	30	30	30	30	30	30	30
	III 30	30	30	30	30	30	30	30	30	30	30	30	30	30	30
	IV 30	30	30	30	30	30	30	30	30	30	30	30	30	30	30
INCISORS BROKEN/MISSING	I 0	0	0	0	0	0	0	1	1	1	2	2	2	3	3
	II 0	0	0	0	0	0	0	0	0	0	1	0	0	0	0
	III 0	0	0	0	0	0	0	3	3	2	3	2	2	3	3
	IV 0	0	0	0	0	0	0	0	0	1	2	2	2	2	2

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TABLE 1 (cont.)

VINYL CHLORIDE COMBINED INHALATION TWO-GENERATION REPRODUCTION
AND DEVELOPMENTAL TOXICITY STUDY IN CD RATS

96-4080

SUMMARY OF CLINICAL OBSERVATIONS - FEMALES

WEEK:	-1	1	2	3	4	5	6	7	8	9	10	11	12	13	14
# OF ANIMALS EXAMINED	I 30	30	30	30	30	30	30	30	30	30	30	30	30	30	30
	II 30	30	30	30	30	30	30	30	30	30	30	30	30	30	30
	III 30	30	30	30	30	30	30	30	30	30	30	30	30	30	30
	IV 30	30	30	30	30	30	30	30	30	30	30	30	30	30	30
<u>NORMAL</u>															
WITHIN NORMAL LIMITS	I 30	30	30	30	29	29	28	28	28	26	26	26	27	26	26
	II 30	30	30	30	30	30	30	30	30	30	28	28	28	27	25
	III 30	30	30	30	29	29	28	28	28	28	27	28	28	26	27
	IV 30	30	29	29	28	27	25	26	25	25	25	24	23	22	21
<u>GENL APPEARANCE</u>															
EARS SWOLLEN/RED -	I 0	0	0	0	0	0	0	1	1	1	1	1	1	1	1
BILATERAL	II 0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	III 0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	IV 0	0	0	0	0	0	1	1	1	1	1	2	2	2	2
<u>DERMAL-GENERAL</u>															
ALOPECIA -	I 0	0	0	0	0	0	0	0	0	1	1	1	0	0	1
EXTREMITIES/SNOUT	II 0	0	0	0	0	0	0	0	0	0	2	2	2	3	5
	III 0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	IV 0	0	0	0	0	0	0	0	1	1	1	1	1	2	3
ALOPECIA - GENERAL	I 0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	II 0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	III 0	0	0	0	0	0	0	0	0	0	0	0	0	1	1
	IV 0	0	0	0	0	0	0	0	0	0	0	0	2	2	2
<u>OCULAR</u>															
LACRIMATION - UNILATERAL	I 0	0	0	0	0	0	0	0	0	1	1	1	0	0	0
	II 0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	III 0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
	IV 0	0	1	1	1	2	1	1	1	1	2	2	2	2	1
CHROMODACRYORRHEA -	I 0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
UNILATERAL	II 0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	III 0	0	0	0	1	0	0	1	1	1	0	1	1	0	0
	IV 0	0	1	1	1	2	2	1	1	1	1	1	2	1	1

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TABLE 1 (cont.)
VINYL CHLORIDE COMBINED INHALATION TWO-GENERATION REPRODUCTION
AND DEVELOPMENTAL TOXICITY STUDY IN CD RATS

96-4080

SUMMARY OF CLINICAL OBSERVATIONS - FEMALES

WEEK: -1		1	2	3	4	5	6	7	8	9	10	11	12	13	14
# OF ANIMALS EXAMINED	I 30	30	30	30	30	30	30	30	30	30	30	30	30	30	30
	II 30	30	30	30	30	30	30	30	30	30	30	30	30	30	30
	III 30	30	30	30	30	30	30	30	30	30	30	30	30	30	30
	IV 30	30	30	30	30	30	30	30	30	30	30	30	30	30	30
CHROMODACRYORRHEA - BILATERAL	I 0	0	0	0	0	0	1	1	1	1	1	1	1	1	1
	II 0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	III 0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	IV 0	0	0	0	0	0	0	0	0	0	0	1	1	1	1
LACRIMATION - BILATERAL	I 0	0	0	0	0	0	0	0	0	0	0	0	1	1	0
	II 0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	III 0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	IV 0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
<u>ORAL/BUCCAL</u>															
INCISORS MALOCCLUDED	I 0	0	0	0	1	1	1	1	1	1	2	2	2	2	1
	II 0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	III 0	0	0	0	1	1	2	2	2	2	3	2	2	3	2
	IV 0	0	0	0	2	3	4	3	3	1	1	1	1	3	3
ORAL SORE	I 0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	II 0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	III 0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	IV 0	0	1	1	0	0	0	0	0	0	0	0	0	0	0
INCISORS BROKEN/MISSING	I 0	0	0	0	0	1	0	0	1	0	0	0	1	1	1
	II 0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	III 0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	IV 0	0	0	0	0	0	0	0	1	1	1	1	0	0	0
MASS(ES)	I 0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	II 0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	III 0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	IV 0	0	0	0	0	0	0	0	0	0	0	0	0	0	1

CMA 118731

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TABLE 2
VINYL CHLORIDE COMBINED INHALATION TWO-GENERATION REPRODUCTION
AND DEVELOPMENTAL TOXICITY STUDY IN CD RATS

BODY WEIGHT IN GRAMS
MALES
DOSE LEVEL: PPM

STAT SYMBOL:	WEEK		0.0000	10.0000	100.0000	1100.0000
A-L-	-1	MEAN	161.0	161.0	161.1	160.9
		S.D.	9.3	9.3	9.4	9.4
		N	30	30	30	30
A-L-	0	MEAN	233.3	237.7	236.6	234.3
		S.D.	11.6	15.3	12.6	14.0
		N	30	30	30	30
A-L-	1	MEAN	274.5	279.6	277.8	272.4
		S.D.	13.4	19.0	14.5	16.6
		N	30	30	30	30
A-L-	2	MEAN	314.2	322.1	321.7	318.3
		S.D.	16.5	23.5	17.9	20.5
		N	30	30	30	30
A-L-	3	MEAN	348.8	357.7	357.2	348.0
		S.D.	18.0	27.2	20.4	25.3
		N	30	30	30	30
A-L-	4	MEAN	375.3	384.2	382.3	374.7
		S.D.	22.4	32.8	25.5	27.8
		N	30	30	30	30
A-L-	5	MEAN	401.8	412.1	409.2	405.5
		S.D.	25.1	36.2	28.0	30.1
		N	30	30	30	30
A-L-	6	MEAN	417.1	432.4	426.1	424.5
		S.D.	32.7	38.8	29.2	33.3
		N	30	30	30	30

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TABLE 2 (CONT.)
VINYL CHLORIDE COMBINED INHALATION TWO-GENERATION REPRODUCTION
AND DEVELOPMENTAL TOXICITY STUDY IN CD RATS

BODY WEIGHT IN GRAMS
MALES
DOSE LEVEL: PPM

STAT SYMBOL:	WEEK		0.0000	10.0000	100.0000	1100.0000
A-L-	7	MEAN	435.9	452.3	447.3	447.6
		S.D.	31.6	41.1	31.0	37.0
		N	30	30	30	30
A-L-	8	MEAN	447.4	465.9	460.8	463.5
		S.D.	32.4	42.1	32.9	37.0
		N	30	30	30	30
A-L-	9	MEAN	462.6	482.0	477.6	477.8
		S.D.	36.6	46.6	34.8	38.9
		N	30	30	30	30
A-L-	10	MEAN	478.9	498.8	492.5	490.6
		S.D.	35.6	46.7	35.7	39.2
		N	30	30	30	30

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T 2-3
TABLE 2 (cont.)
VINYL CHLORIDE COMBINED INHALATION TWO-GENERATION REPRODUCTION
AND DEVELOPMENTAL TOXICITY STUDY IN CD RATS

BODY WEIGHT IN GRAMS
FEMALES
DOSE LEVEL: PPM

STAT SYMBOL:	WEEK		0.0000	10.0000	100.0000	1100.0000
A-L-	-1	MEAN	116.5	116.2	116.5	116.7
		S.D.	6.0	6.1	5.7	5.8
		N	30	30	30	30
A-L-	0	MEAN	158.0	158.5	156.3	157.0
		S.D.	7.5	9.1	9.3	7.7
		N	30	30	30	30
A-L-	1	MEAN	177.1	173.8	178.1	175.8
		S.D.	9.7	9.5	12.1	9.3
		N	30	30	30	30
A-L-	2	MEAN	196.4	197.3	199.1	197.1
		S.D.	11.9	10.4	14.1	11.7
		N	30	30	30	30
A-L-	3	MEAN	213.2	209.8	214.4	212.2
		S.D.	12.3	10.5	16.6	12.7
		N	30	30	30	30
A-L-	4	MEAN	225.6	222.0	226.7	225.0
		S.D.	15.3	10.7	17.4	13.1
		N	30	30	30	30
K-J-	5	MEAN	241.6	236.6	241.5	236.4
		S.D.	14.7	10.5	19.4	13.0
		N	30	30	30	30
A-L-	6	MEAN	250.7	247.8	252.1	247.5
		S.D.	15.5	13.8	20.7	13.8
		N	30	30	30	30

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T 2-4
TABLE 2 (cont.)
VINYL CHLORIDE COMBINED INHALATION TWO-GENERATION REPRODUCTION
AND DEVELOPMENTAL TOXICITY STUDY IN CD RATS

BODY WEIGHT IN GRAMS
FEMALES
DOSE LEVEL: PPM

STAT SYMBOL:	WEEK		0.0000	10.0000	100.0000	1100.0000
A-L*	7	MEAN	258.5	253.4	259.6	253.1
		S.D.	15.8	14.3	20.7	14.2
		N	30	30	30	30
A-L-	8	MEAN	264.8	259.5	265.4	258.2
		S.D.	16.4	14.0	21.4	15.9
		N	30	30	30	30
A-L-	9	MEAN	274.3	266.5	272.8	265.4
		S.D.	15.4	16.5	22.2	15.5
		N	30	30	30	30
A-L-	10	MEAN	280.6	271.6	279.7	271.0
		S.D.	17.9	16.4	23.6	16.9
		N	30	30	30	30

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TABLE 3

96-4080

UNAUDITED
DRAFTVINYL CHLORIDE COMBINED INHALATION TWO-GENERATION REPRODUCTION
AND DEVELOPMENTAL TOXICITY STUDY IN CD RATS

BODY WEIGHT CHANGE FROM WEEK 0

MALES

DOSE LEVEL: PPM

STAT

SYMBOL:

WEEK

0.0000

10.0000

100.0000

1100.0000

A-L-

10

MEAN

245.6

261.1

255.9

256.3

S.D.

34.4

37.5

31.2

31.6

N

30

30

30

30

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TABLE 3 (CONT.)

VINYL CHLORIDE COMBINED INHALATION TWO-GENERATION REPRODUCTION
AND DEVELOPMENTAL TOXICITY STUDY IN CD RATS

BODY WEIGHT CHANGE FROM WEEK 0

FEMALES

DOSE LEVEL: PPM

STAT	WEEK	0.0000	10.0000	100.0000	1100.0000
------	------	--------	---------	----------	-----------

AL-Q	10	MEAN	122.6	113.1	123.4	114.0
		S.D.	16.2	13.8	21.0	14.6
		N	30	30	30	30

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TABLE 4

96-4080

UNAUDITED
DRAFTVINYL CHLORIDE COMBINED INHALATION TWO-GENERATION REPRODUCTION
AND DEVELOPMENTAL TOXICITY STUDY IN CD RATSFOOD CONSUMPTION G/KG/DAY
MALES
DOSE LEVEL: PPM

STAT SYMBOL:	WEEK		0.0000	10.0000	100.0000	1100.0000
AL-Q	0	MEAN	122.6	125.1	127.1	124.8
		S.D.	6.2	4.4	5.1	6.6
		N	29	30	30	30
A-L-	1	MEAN	98.3	98.8	99.5	97.0
		S.D.	4.8	4.0	4.9	4.8
		N	30	30	30	30
A+L-Q+	2	MEAN	86.7	89.3	91.2	89.1
		S.D.	6.3	3.9	4.3	4.7
		N	30	30	30	30
A+L-Q+	3	MEAN	78.5	79.1	82.1	80.3
		S.D.	3.2	3.5	3.8	3.8
		N	30	30	30	30
A-L-	4	MEAN	72.7	72.5	73.3	73.2
		S.D.	3.1	3.9	3.2	3.5
		N	30	30	30	30
AL-	5	MEAN	68.6	69.5	70.3	71.4
		S.D.	2.7	3.5	3.5	3.8
		N	30	29	30	30
AL+Q	6	MEAN	62.6	66.0	65.0	65.6
		S.D.	4.6	3.4	6.0	3.9
		N	30	29	30	30
AL	7	MEAN	60.2	61.0	62.4	62.3
		S.D.	3.7	2.3	3.5	3.5
		N	30	30	30	30

T 4-2

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TABLE 4 (cont.)

VINYL CHLORIDE COMBINED INHALATION TWO-GENERATION REPRODUCTION
AND DEVELOPMENTAL TOXICITY STUDY IN CD RATSUNAUDITED
DRAFTFOOD CONSUMPTION G/KG/DAY
MALES
DOSE LEVEL: PPM

STAT SYMBOL:	WEEK		0.0000	10.0000	100.0000	1100.0000
A-L-	8	MEAN	57.3	58.1	59.1	58.4
		S.D.	3.3	3.4	2.4	3.0
		N	30	30	30	30
K-J+	9	MEAN	56.0	56.1	57.4	**
		S.D.	3.8	2.7	6.2	59.4
		N	30	30	29	4.0
A-L-Q	10	MEAN	54.4	55.6	56.6	55.2
		S.D.	2.3	2.9	3.1	3.9
		N	30	29	29	30

T 4-3

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TABLE 4 (CONT.)

VINYL CHLORIDE COMBINED INHALATION TWO-GENERATION REPRODUCTION
AND DEVELOPMENTAL TOXICITY STUDY IN CD RATSUNAUDITED
DRAFT

FOOD CONSUMPTION G/KG/DAY

FEMALES

DOSE LEVEL: PPM

STAT SYMBOL:	WEEK		0.0000	10.0000	100.0000	1100.0000
A-L-	0	MEAN	131.8	133.5	134.9	134.9
		S.D.	5.9	9.4	7.8	8.0
		N	29	29	28	26
A-L-Q	1	MEAN	107.4	104.3	109.2	105.4
		S.D.	5.2	5.4	8.7	6.7
		N	30	28	29	27
K-L	2	MEAN	103.6	103.9	105.9	103.9
		S.D.	10.3	5.5	9.5	8.6
		N	30	30	30	30
A-L-	3	MEAN	94.3	94.7	96.9	96.9
		S.D.	5.2	6.2	5.8	6.5
		N	30	30	30	29
A-L-	4	MEAN	90.3	89.0	92.2	90.6
		S.D.	5.6	4.9	5.9	5.9
		N	30	30	30	30
K-L	5	MEAN	85.8	87.6	87.6	87.1
		S.D.	4.3	5.6	7.0	7.8
		N	30	30	30	30
A-L-Q+	6	MEAN	79.4	84.9	84.7	85.0
		S.D.	8.4	5.7	6.0	5.6
		N	29	30	30	30
A-L-	7	MEAN	77.6	76.5	76.5	77.7
		S.D.	5.9	5.7	5.0	6.1
		N	30	30	30	30

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TABLE 4 (cont.)

VINYL CHLORIDE COMBINED INHALATION TWO-GENERATION REPRODUCTION
AND DEVELOPMENTAL TOXICITY STUDY IN CD RATSUNAUDITED
DRAFTFOOD CONSUMPTION G/KG/DAY
FEMALES
DOSE LEVEL: PPM

STAT SYMBOL:	WEEK		0.0000	10.0000	100.0000	1100.0000
A-L+	8	MEAN	74.9	74.3	75.3	76.5
		S.D.	5.8	5.0	5.3	5.9
		N	30	30	30	30
A-L-	9	MEAN	71.9	70.9	73.1	74.4
		S.D.	5.7	5.8	7.0	6.1
		N	30	30	30	28
A-L+	10	MEAN	67.1	68.5	70.1	**
		S.D.	6.2	6.5	5.0	72.2
		N	29	30	30	5.1 29

T 3-1

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TABLE 3

VINYL CHLORIDE COMBINED INHALATION TWO-GENERATION REPRODUCTION
AND DEVELOPMENTAL TOXICITY STUDY IN CD RATSUNAUDITED
DRAFTBODY WEIGHT IN GRAMS
MALES
DOSE LEVEL: PPM

STAT SYMBOL:	WEEK		0.0000	10.0000	100.0000	1100.0000
A-L-	11	MEAN	479.3	499.7	493.6	493.7
		S.D.	36.6	49.8	34.4	38.1
		N	30	30	30	30
A-L-	12	MEAN	488.2	512.0	502.1	505.8
		S.D.	37.2	51.0	36.8	38.7
		N	30	30	30	30
A-L-	13	MEAN	500.6	523.7	511.5	518.2
		S.D.	39.6	51.3	45.6	39.4
		N	30	30	30	30
A-L-	14	MEAN	508.0	523.1	520.3	520.3
		S.D.	43.0	53.7	41.9	42.9
		N	30	30	30	30

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TABLE 6
VINYL CHLORIDE COMBINED INHALATION TWO-GENERATION REPRODUCTION
AND DEVELOPMENTAL TOXICITY STUDY IN CD RATS

FOOD CONSUMPTION g/KG/DAY
MALES
DOSE LEVEL: PPM

STAT SYMBOL:	WEEK		0.0000	10.0000	100.0000	1100.0000
K-1-	13	MEAN	48.4	50.2	51.1	51.0
		S.D.	9.5	7.5	8.8	3.6
		N	30	30	30	30
A+L-Q+	14	MEAN	50.8	49.9	53.0	51.2
		S.D.	3.1	3.8	3.9	3.0
		N	29	30	29	30

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Appendix A

Vinyl Chloride Combined Inhalation Two-Generation Reproduction
and Developmental Toxicity Study in CD Rats

Methodology and References - Statistical Analysis

Parameters analyzed statistically for this status report: body weights
and food consumptionMULTIPLE GROUP ANALYSIS
STAT SYMBOL

STATISTICAL STATEMENT

No Sig p≤0.05 p≤0.01Parametric

A-

No statistical differences among the
means (parametric ANOVA).

A

A+

The means differ significantly
(parametric ANOVA).

L-

The response is not linearly related to
the dose levels.

L

L+

The response is linearly related to the
dose levels.

Q

Q+

The response shows a lack of fit.

*

**

Significantly different from control
(Dunnett's).

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Appendix A (cont.)

Vinyl Chloride Combined Inhalation Two-Generation Reproduction
and Developmental Toxicity Study in CD Rats

Methodology and References - Statistical Analysis

MULTIPLE GROUP ANALYSIS STAT SYMBOL			STATISTICAL STATEMENT
No Sig	$p \leq 0.05$	$p \leq 0.01$	
<u>Nonparametric</u>			
K-			No statistical differences among the means (Kruskal-Wallis, nonparametric).
	K	K+	The means differ significantly (Kruskal-Wallis nonparametric).
J-			There is not an ordered response to dosage.
	J	J+	There is an ordered response to dosage.
	*	**	Significantly different from control (Dunn's Rank Sum).
NT			Not tested due to lack of variance.

Statistical evaluation of equality of means was made by the appropriate one way analysis of variance technique, followed by a multiple comparison procedure if needed. First, Bartlett's test was performed to determine if groups had equal variance. If the variances were equal, parametric procedures were used; if not, nonparametric procedures were used. The parametric procedures were the standard one way ANOVA using the F distribution to assess significance. If significant differences among the means were indicated, Dunnett's test was used to determine which means were significantly different from the control. If a nonparametric procedure for testing equality of means was needed, the Kruskal-Wallis test was used, and if differences were indicated a summed rank test (Dunn) was used to determine which treatments differed from control.

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Appendix A (cont.)

Vinyl Chloride Combined Inhalation Two-Generation Reproduction
and Developmental Toxicity Study in CD Rats

Methodology and References - Statistical Analysis

A statistical test for trend in the dose levels was also performed. In the parametric case (i.e., equal variance) standard regression techniques with a test for trend and lack of fit were used. In the nonparametric case Jonckheere's test for monotonic trend was used.

The test for equal variance (Bartlett's) was conducted at the 1%, two-sided risk level. All other statistical tests were conducted at the 5% and 1%, two-sided risk level.

References for these techniques are Snedecor, G.W., and Cochran, W.G., *Statistical Methods*. 6th edition, Iowa State University Press (1967); Hollander, M. and Wolfe, D.A., *Nonparametric Statistical Methods*. John Wiley and Sons, New York (1973); Dunnett, C.W., *J. Am. Sta. Assn.* Vol. 50 (1955) and *Biometrics*. Vol. 20 (1964).

Bartlett's Test	pp. 296-298	S&C
ANOVA	pp. 277-279	S&C
Dunnett's	pp. 1096-1121	D
	pp. 482-491	Bio
Kruskal-Wallis	pp. 114-116	H&W
Summed Rank Test (Dunn)	p. 131	H&W
Regression Analysis		
Trend	pp. 135-153	S&C
Lack of Fit	pp. 456-459	S&C
Jonckheere's Statistic	pp. 120-123	H&W

CMA 118746