Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/SD

**E05: CLINICAL OBSERVATIONS SUMMARY** 

**Test Compound:** D-alpha-Tocopheryl acetate

**CAS Number:** 58-95-7

Date Report Requested: 10/23/2014 Time Report Requested: 16:25:24

First Dose M/F: NA / NA

Lab: MBA

C Number: C61370

Lock Date: Not Entered.

Cage Range: All

Date Range: All

Reasons For Removal:

Removal Date Range: All

Treatment Groups: All

Study Gender: Both

PWG Approval Date NONE

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/SD

## **E05: CLINICAL OBSERVATIONS SUMMARY**

**Test Compound:** D-alpha-Tocopheryl acetate

**CAS Number:** 58-95-7

Date Report Requested: 10/23/2014 Time Report Requested: 16:25:24

First Dose M/F: NA / NA

Lab: MBA

OBSERVATIONS	UNTREAT	CONTROL	VEHICLE (	CONTROL	.125	G/KG	.250 G/KG	
	CURRENT*	TOTAL+	CURRENT*	TOTAL+	CURRENT*	TOTAL+	CURRENT*	TOTAL-
Alopecia Right Eye	0/0	1 / 60 DAY 45	0/0	0 / 60	0/0	0 / 60	0/0	0 / 60
Blood In Urine	0/0	0 / 60	0/0	0 / 60	0/0	0 / 60	0/0	0 / 60
diarrhea	0/0	0 / 60	0/0	2 / 60 DAY 18	0/0	0 / 60	0/0	0 / 60
maciated	0/0	2 / 60 DAY 25	0/0	1 / 60 DAY 18	0/0	1 / 60 DAY 17	0/0	0 / 60
lyperactive	0/0	0 / 60	0/0	0 / 60	0/0	1 / 60 DAY 58	0/0	0 / 60
lypoactivity	0/0	0 / 60	0/0	0 / 60	0/0	1 / 60 DAY 66	0/0	0 / 60
<i>M</i> alocclusion	0/0	2 / 60 DAY 25	0/0	3 / 60 DAY 18	0/0	3 / 60 DAY 17	0/0	7 / 60 DAY 18
Micro-Ophthalmia	0/0	0 / 60	0/0	0 / 60	0/0	0 / 60	0/0	0 / 60

<sup>\*</sup> ANIMALS WITH OBSERVATION IN CURRENT PERIOD / TOTAL ANIMALS OBSERVED IN CURRENT PERIOD (WITHIN 7 DAYS OF RUN DATE)

<sup>+</sup> ROW 1 = CUMULATIVE NO. OF ANIMALS WITH OBSERVATION / TOTAL ANIMALS STARTED ON STUDY ROW 2 = DAY OF ONSET

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/SD

## **E05: CLINICAL OBSERVATIONS SUMMARY**

**Test Compound:** D-alpha-Tocopheryl acetate

**CAS Number:** 58-95-7

Date Report Requested: 10/23/2014 Time Report Requested: 16:25:24

First Dose M/F: NA / NA

Lab: MBA

OBSERVATIONS	UNTREAT	CONTROL	VEHICLE (	CONTROL	.125	G/KG	.250	G/KG
	CURRENT*	TOTAL+	CURRENT*	TOTAL+	CURRENT*	TOTAL+	CURRENT*	TOTAL+
lasal Discharge	0/0	0 / 60	0/0	0 / 60	0/0	0 / 60	0/0	0 / 60
Prolapse Penis	0/0	0 / 60	0/0	1 / 60 DAY 18	0/0	0 / 60	0/0	0 / 60
Reddened Mouth	0/0	0 / 60	0/0	0 / 60	0/0	0 / 60	0/0	0 / 60
Reddened Right Eye	0/0	0 / 60	0/0	0 / 60	0/0	0 / 60	0/0	1 / 60 DAY 67
Reddened Eye	0/0	1 / 60 DAY 25	0/0	1 / 60 DAY 1	0/0	0 / 60	0/0	0 / 60
tuffled Fur	0/0	2 / 60 DAY 25	0/0	1 / 60 DAY 66	0/0	1 / 60 DAY 67	0/0	0 / 60
Sore Body Dorsal	0/0	0 / 60	0/0	1 / 60 DAY 39	0/0	0 / 60	0/0	0 / 60
Sore Head	0/0	1 / 60 DAY 1	0/0	2 / 60 DAY 1	0/0	1 / 60 DAY 1	0/0	1 / 60 DAY 1

<sup>\*</sup> ANIMALS WITH OBSERVATION IN CURRENT PERIOD / TOTAL ANIMALS OBSERVED IN CURRENT PERIOD (WITHIN 7 DAYS OF RUN DATE)

<sup>+</sup> ROW 1 = CUMULATIVE NO. OF ANIMALS WITH OBSERVATION / TOTAL ANIMALS STARTED ON STUDY ROW 2 = DAY OF ONSET

Test Type: 90-DAY Route: GAVAGE

Species/Strain: Rat/SD

## **E05: CLINICAL OBSERVATIONS SUMMARY**

**Test Compound:** D-alpha-Tocopheryl acetate

**CAS Number:** 58-95-7

Date Report Requested: 10/23/2014 Time Report Requested: 16:25:25

First Dose M/F: NA / NA

Lab: MBA

**SEX:MALE** 

**WEEK: 14** 

<b>OBSERVATIONS</b>	UNTREAT	CONTROL	VEHICLE (	CONTROL	.125	G/KG	.250	G/KG
	CURRENT*	TOTAL+	CURRENT*	TOTAL+	CURRENT*	TOTAL+	CURRENT*	TOTAL+
Sore Neck	0/0	0 / 60	0/0	0 / 60	0/0	0 / 60	0/0	2 / 60 DAY 32
Sore Right Eye	0/0	1 / 60 DAY 38	0/0	0 / 60	0/0	0 / 60	0/0	0 / 60
Sore Right Front Foot	0/0	0 / 60	0/0	0 / 60	0/0	0 / 60	0/0	0 / 60
Sore Right Front Leg	0/0	0 / 60	0/0	0 / 60	0/0	0 / 60	0/0	0 / 60
Sore Shoulder	0/0	0 / 60	0/0	0 / 60	0/0	0 / 60	0/0	0 / 60
Swelling Right Rear Foot	0/0	0 / 60	0/0	1 / 60 DAY 52	0/0	0 / 60	0/0	0 / 60
Wound Neck	0/0	0 / 60	0/0	0 / 60	0/0	0 / 60	0/0	1 / 60 DAY 25

<sup>\*</sup> ANIMALS WITH OBSERVATION IN CURRENT PERIOD / TOTAL ANIMALS OBSERVED IN CURRENT PERIOD (WITHIN 7 DAYS OF RUN DATE)

<sup>+</sup> ROW 1 = CUMULATIVE NO. OF ANIMALS WITH OBSERVATION / TOTAL ANIMALS STARTED ON STUDY ROW 2 = DAY OF ONSET

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/SD

## **E05: CLINICAL OBSERVATIONS SUMMARY**

**Test Compound:** D-alpha-Tocopheryl acetate

**CAS Number:** 58-95-7

Date Report Requested: 10/23/2014 Time Report Requested: 16:25:25

First Dose M/F: NA / NA

Lab: MBA

<b>OBSERVATIONS</b>	.500	G/KG	1.0 0	S/KG	2.0 G	i/KG
	CURRENT*	TOTAL+	CURRENT*	TOTAL+	CURRENT*	TOTAL+
Alopecia Right Eye	0/0	0 / 60	0/0	0 / 60	0/0	0 / 60
Blood In Urine	0/0	0 / 60	0/0	1 / 60 DAY 32	0/0	0 / 60
Diarrhea	0/0	0 / 60	0/0	0 / 60	0/0	18 / 60 DAY 18
Emaciated	0/0	0 / 60	0/0	0 / 60	0/0	1 / 60 DAY 18
Hyperactive	0/0	0 / 60	0/0	0 / 60	0/0	1 / 60 DAY 58
Hypoactivity	0/0	0 / 60	0/0	0 / 60	0/0	1 / 60 DAY 66
Malocclusion	0/0	4 / 60 DAY 17	0/0	5 / 60 DAY 18	0/0	4 / 60 DAY 18
Micro-Ophthalmia	0/0	0 / 60	0/0	0 / 60	0/0	1 / 60 DAY 17

<sup>\*</sup> ANIMALS WITH OBSERVATION IN CURRENT PERIOD / TOTAL ANIMALS OBSERVED IN CURRENT PERIOD (WITHIN 7 DAYS OF RUN DATE)

<sup>+</sup> ROW 1 = CUMULATIVE NO. OF ANIMALS WITH OBSERVATION / TOTAL ANIMALS STARTED ON STUDY ROW 2 = DAY OF ONSET

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/SD

# **E05: CLINICAL OBSERVATIONS SUMMARY**

**Test Compound:** D-alpha-Tocopheryl acetate

**CAS Number:** 58-95-7

Date Report Requested: 10/23/2014 Time Report Requested: 16:25:25

First Dose M/F: NA / NA

Lab: MBA

OBSERVATIONS	.500	G/KG	1.0 G	G/KG	2.0 G	/KG
	CURRENT*	TOTAL+	CURRENT*	TOTAL+	CURRENT*	TOTAL+
Nasal Discharge	0/0	1 / 60 DAY 73	0/0	0 / 60	0/0	0 / 60
Prolapse Penis	0/0	0 / 60	0/0	0 / 60	0/0	0 / 60
Reddened Mouth	0/0	0 / 60	0/0	1 / 60 DAY 18	0/0	0 / 60
Reddened Right Eye	0/0	0 / 60	0/0	0 / 60	0/0	0 / 60
Reddened Eye	0/0	0 / 60	0/0	0 / 60	0/0	1 / 60 DAY 26
Ruffled Fur	0/0	0 / 60	0/0	0 / 60	0/0	1 / 60 DAY 26
Sore Body Dorsal	0/0	0 / 60	0/0	0 / 60	0/0	0 / 60
Sore Head	0/0	0 / 60	0/0	1 / 60 DAY 25	0/0	1 / 60 DAY 25

<sup>\*</sup> ANIMALS WITH OBSERVATION IN CURRENT PERIOD / TOTAL ANIMALS OBSERVED IN CURRENT PERIOD (WITHIN 7 DAYS OF RUN DATE)

<sup>+</sup> ROW 1 = CUMULATIVE NO. OF ANIMALS WITH OBSERVATION / TOTAL ANIMALS STARTED ON STUDY ROW 2 = DAY OF ONSET

Test Type: 90-DAY

Route: GAVAGE Species/Strain: Rat/SD

## **E05: CLINICAL OBSERVATIONS SUMMARY**

**Test Compound:** D-alpha-Tocopheryl acetate

**CAS Number:** 58-95-7

Date Report Requested: 10/23/2014 Time Report Requested: 16:25:25

First Dose M/F: NA / NA

Lab: MBA

**SEX:MALE** 

**WEEK: 14** 

<b>OBSERVATIONS</b>	.500	G/KG	1.0 G	s/KG	2.0 G	i/KG
	CURRENT*	TOTAL+	CURRENT*	TOTAL+	CURRENT*	TOTAL+
Sore	0/0	1 / 60	0/0	1 / 60	0/0	1 / 60
Neck		DAY 26		DAY 25		DAY 25
Sore Right Eye	0/0	0 / 60	0/0	0 / 60	0/0	0 / 60
Sore	0/0	0 / 60	0/0	1 / 60	0/0	0 / 60
Right Front Foot				DAY 38		
Sore	0/0	1 / 60	0/0	0 / 60	0/0	0 / 60
Right Front Leg		DAY 39				
Sore	0/0	0 / 60	0/0	0 / 60	0/0	1 / 60
Shoulder						DAY 32
Swelling	0/0	0 / 60	0/0	0 / 60	0/0	0 / 60
Right Rear Foot						
Wound	0/0	0 / 60	0/0	0 / 60	0/0	0 / 60
Neck						

<sup>\*\*\*</sup>END OF MALE DATA\*\*\*

<sup>\*</sup> ANIMALS WITH OBSERVATION IN CURRENT PERIOD / TOTAL ANIMALS OBSERVED IN CURRENT PERIOD (WITHIN 7 DAYS OF RUN DATE)

<sup>+</sup> ROW 1 = CUMULATIVE NO. OF ANIMALS WITH OBSERVATION / TOTAL ANIMALS STARTED ON STUDY ROW 2 = DAY OF ONSET

Test Type: 90-DAY Route: GAVAGE

Species/Strain: Rat/SD

## **E05: CLINICAL OBSERVATIONS SUMMARY**

**Test Compound:** D-alpha-Tocopheryl acetate

**CAS Number:** 58-95-7

Date Report Requested: 10/23/2014 Time Report Requested: 16:25:25

First Dose M/F: NA / NA

Lab: MBA

<b>OBSERVATIONS</b>	UNTREAT	CONTROL	VEHICLE (	CONTROL	.125	G/KG	.250 G/KG	
	CURRENT*	TOTAL+	CURRENT*	TOTAL+	CURRENT*	TOTAL+	CURRENT*	TOTAL+
opecia	0/0	1 / 60	0/0	0 / 60	0/0	0 / 60	0/0	0 / 60
Left Rear Leg		DAY 73						
opecia	0/0	0 / 60	0/0	1 / 60	0/0	0 / 60	0/0	0 / 60
Neck				DAY 32				
opecia	0/0	1 / 60	0/0	0 / 60	0/0	0 / 60	0/0	0 / 60
Right Rear Leg		DAY 73						
Discoloration	0/0	0 / 60	0/0	0 / 60	0/0	0 / 60	0/0	0 / 60
Right Eye								
xophthalmos	0/0	0 / 60	0/0	0 / 60	0/0	0 / 60	0/0	0 / 60
ead Tilted	0/0	0 / 60	0/0	0 / 60	0/0	0 / 60	0/0	0 / 60
acrimation	0/0	2/60	0/0	0 / 60	0/0	0 / 60	0/0	0 / 60
		DAY 65						- · · · ·
alocclusion	0/0	2/60	0/0	3/60	0/0	3/60	0/0	0 / 60
	3,3	DAY 23	0,0	DAY 30	0,0	DAY 15	3, 3	0,00

<sup>\*</sup> ANIMALS WITH OBSERVATION IN CURRENT PERIOD / TOTAL ANIMALS OBSERVED IN CURRENT PERIOD (WITHIN 7 DAYS OF RUN DATE)

<sup>+</sup> ROW 1 = CUMULATIVE NO. OF ANIMALS WITH OBSERVATION / TOTAL ANIMALS STARTED ON STUDY ROW 2 = DAY OF ONSET

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/SD

## **E05: CLINICAL OBSERVATIONS SUMMARY**

**Test Compound:** D-alpha-Tocopheryl acetate

**CAS Number:** 58-95-7

Date Report Requested: 10/23/2014 Time Report Requested: 16:25:26

First Dose M/F: NA / NA

Lab: MBA

<b>OBSERVATIONS</b>	UNTREAT	CONTROL	VEHICLE (	CONTROL	.125	G/KG	.250	G/KG
	CURRENT*	TOTAL+	CURRENT*	TOTAL+	CURRENT*	TOTAL+	CURRENT*	TOTAL+
/licro-Ophthalmia	0/0	1 / 60 DAY 80	0/0	0 / 60	0/0	0 / 60	0/0	0 / 60
lasal Discharge	0/0	0 / 60	0/0	0 / 60	0/0	0 / 60	0/0	0/60
Opacity	0/0	0 / 60	0/0	0 / 60	0/0	0 / 60	0/0	0 / 60
Override	0/0	0 / 60	0/0	0 / 60	0/0	1 / 60 DAY 10	0/0	0 / 60
Ruffled Fur	0/0	0 / 60	0/0	0 / 60	0/0	0 / 60	0/0	0 / 60
Sore Neck	0/0	0 / 60	0/0	1 / 60 DAY 25	0/0	0 / 60	0/0	0 / 60

<sup>\*</sup> ANIMALS WITH OBSERVATION IN CURRENT PERIOD / TOTAL ANIMALS OBSERVED IN CURRENT PERIOD (WITHIN 7 DAYS OF RUN DATE)

<sup>+</sup> ROW 1 = CUMULATIVE NO. OF ANIMALS WITH OBSERVATION / TOTAL ANIMALS STARTED ON STUDY ROW 2 = DAY OF ONSET

## **E05: CLINICAL OBSERVATIONS SUMMARY**

**Test Compound:** D-alpha-Tocopheryl acetate

**CAS Number:** 58-95-7

Date Report Requested: 10/23/2014 Time Report Requested: 16:25:26

First Dose M/F: NA / NA

Lab: MBA

**SEX:FEMALE** 

Test Type: 90-DAY

Species/Strain: Rat/SD

Route: GAVAGE

**WEEK: 14** 

OLX .I LINALL	WLLIX. 14					
OBSERVATIONS	.500	G/KG	1.0	G/KG	2.0	G/KG
	CURRENT*	TOTAL+	CURRENT*	TOTAL+	CURRENT*	TOTAL+
Alopecia Left Rear Leg	0/0	0 / 60	0/0	0 / 60	0/0	0 / 60
Alopecia Neck	0/0	0 / 60	0/0	0 / 60	0/0	1 / 60 DAY 31
olopecia Right Rear Leg	0/0	0 / 60	0/0	0 / 60	0/0	0 / 60
Discoloration Right Eye	0/0	0 / 60	0/0	0 / 60	0/0	1 / 60 DAY 23
xophthalmos	0/0	0 / 60	0/0	0 / 60	0/0	1 / 60 DAY 0
Head Tilted	0/0	0 / 60	0/0	0 / 60	0/0	1 / 60 DAY 65
Lacrimation	0/0	2 / 60 DAY 31	0/0	0 / 60	0/0	2 / 60 DAY 32
Malocclusion	0/0	4 / 60 DAY 25	0/0	2 / 60 DAY 24	0/0	4 / 60 DAY 23

<sup>\*</sup> ANIMALS WITH OBSERVATION IN CURRENT PERIOD / TOTAL ANIMALS OBSERVED IN CURRENT PERIOD (WITHIN 7 DAYS OF RUN DATE)

<sup>+</sup> ROW 1 = CUMULATIVE NO. OF ANIMALS WITH OBSERVATION / TOTAL ANIMALS STARTED ON STUDY ROW 2 = DAY OF ONSET

Test Type: 90-DAY Route: GAVAGE

Species/Strain: Rat/SD

## **E05: CLINICAL OBSERVATIONS SUMMARY**

**Test Compound:** D-alpha-Tocopheryl acetate

**CAS Number:** 58-95-7

Date Report Requested: 10/23/2014 Time Report Requested: 16:25:26

First Dose M/F: NA / NA

Lab: MBA

OBSERVATIONS	.500 G/KG		10	1.0 G/KG		2.0 G/KG		
OBSERVATIONS								
	CURRENT*	TOTAL+	CURRENT*	TOTAL+	CURRENT*	TOTAL+		
Micro-Ophthalmia	0/0	0 / 60	0/0	0 / 60	0/0	0 / 60		
Nasal Discharge	0/0	0 / 60	0/0	0 / 60	0/0	1 / 60 DAY 32		
Opacity	0/0	0 / 60	0/0	0 / 60	0/0	1 / 60 DAY 51		
Override	0/0	0 / 60	0/0	1 / 60 DAY 39	0/0	0 / 60		
Ruffled Fur	0/0	0 / 60	0/0	0 / 60	0/0	1 / 60 DAY 65		
Sore Neck	0/0	0 / 60	0/0	0 / 60	0/0	0 / 60		

<sup>\*</sup> ANIMALS WITH OBSERVATION IN CURRENT PERIOD / TOTAL ANIMALS OBSERVED IN CURRENT PERIOD (WITHIN 7 DAYS OF RUN DATE)

<sup>+</sup> ROW 1 = CUMULATIVE NO. OF ANIMALS WITH OBSERVATION / TOTAL ANIMALS STARTED ON STUDY ROW 2 = DAY OF ONSET

**Test Type:** 90-DAY **Route:** GAVAGE

Species/Strain: Rat/SD

**E05: CLINICAL OBSERVATIONS SUMMARY** 

**Test Compound:** D-alpha-Tocopheryl acetate

**CAS Number:** 58-95-7

\*\* END OF REPORT \*\*

First Dose M/F: NA / NA

Lab: MBA

Date Report Requested: 10/23/2014 Time Report Requested: 16:25:26

<sup>\*</sup> ANIMALS WITH OBSERVATION IN CURRENT PERIOD / TOTAL ANIMALS OBSERVED IN CURRENT PERIOD (WITHIN 7 DAYS OF RUN DATE)

<sup>+</sup> ROW 1 = CUMULATIVE NO. OF ANIMALS WITH OBSERVATION / TOTAL ANIMALS STARTED ON STUDY ROW 2 = DAY OF ONSET