

**SHRIRAM INSTITUTE FOR INDUSTRIAL RESEARCH**



**PROJECT NO. : TOX-355B**  
**PRODUCT : NHH 44 Bt-COTTON SEEDS**  
**STUDY : SUB CHRONIC ORAL TOXICITY STUDY IN RATS**  
**REPORT NO. : 000046990**  
**DATE : 18.5.2007**

Confidential

**TABLE - 6.01**  
**INTENSITY OF GROSS PATHOLOGICAL LESIONS IN CONTROL**  
**GROUP OF MALE RATS AT TERMINAL SACRIFICE**

<b>ANIMAL NO.</b>	<b>SEX</b>	<b>LUNG</b>	<b>LIVER</b>	<b>HEART</b>	<b>GONADS</b>	<b>SPLEEN</b>	<b>KIDNEY</b>	<b>BRAIN</b>	<b>ADRENAL</b>	<b>GASTRO- INTESTINAL - TRACT</b>
<b>1</b>	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
<b>2</b>	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
<b>3</b>	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
<b>4</b>	MALE	Congestion	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
<b>5</b>	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
<b>6</b>	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
<b>7</b>	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
<b>8</b>	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
<b>9</b>	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
<b>10</b>	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

NAD: No Abnormal Development

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**TABLE - 6.02**  
**INTENSITY OF GROSS PATHOLOGICAL LESIONS IN CONTROL**  
**GROUP OF FEMALE RATS AT TERMINAL SACRIFICE**

ANIMAL NO.	SEX	LUNG	LIVER	HEART	GONADS	SPLEEN	KIDNEY	BRAIN	ADRENAL	GASTRO- INTESTINAL - TRACT
1	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
2	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
3	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
4	FEMALE	NAD	Mild Hepatomegaly	NAD	NAD	NAD	NAD	NAD	NAD	NAD
5	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
6	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
7	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
8	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
9	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
10	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

NAD: No Abnormal Development



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**TABLE - 6.03**  
**INTENSITY OF GROSS PATHOLOGICAL LESIONS IN NHH 44 Bt-COTTON SEEDS**  
**(1000 mg/kg.B.wt.) OF MALE RATS AT TERMINAL SACRIFICE**

ANIMAL NO.	SEX	LUNG	LIVER	HEART	GONADS	SPLEEN	KIDNEY	BRAIN	ADRENAL	GASTRO- INTESTINAL - TRACT
1	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
2	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
3	MALE	NAD	Focal fatty changes	NAD	NAD	NAD	NAD	NAD	NAD	NAD
4	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
5	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
6	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
7	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
8	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
9	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
10	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

NAD: No Abnormal Development

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**TABLE - 6.04**  
**INTENSITY OF GROSS PATHOLOGICAL LESIONS IN NHH 44 Bt-COTTON SEEDS**  
**(1000 mg/kg.B.wt.) OF FEMALE RATS AT TERMINAL SACRIFICE**

ANIMAL NO.	SEX	LUNG	LIVER	HEART	GONADS	SPLEEN	KIDNEY	BRAIN	ADRENAL	GASTRO-INTESTINAL-TRACT
1	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
2	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
3	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
4	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
5	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
6	FEMALE	NAD	Mild focal discolouration	NAD	NAD	NAD	NAD	NAD	NAD	NAD
7	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
8	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
9	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
10	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

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**TABLE - 6.05**  
**INTENSITY OF GROSS PATHOLOGICAL LESIONS IN NHH 44 NON Bt-COTTON SEEDS**  
**(1000 mg/kg.B.wt.) OF MALE RATS AT TERMINAL SACRIFICE**

ANIMAL NO.	SEX	LUNG	LIVER	HEART	GONADS	SPLEEN	KIDNEY	BRAIN	ADRENAL	GASTRO-INTESTINAL-TRACT
1	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
2	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
3	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
4	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
5	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
6	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	Mild thickening
7	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
8	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
9	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
10	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

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**TABLE - 6.06**  
**INTENSITY OF GROSS PATHOLOGICAL LESIONS IN NHH 44 NON Bt-COTTON SEEDS**  
**(1000 mg/kg.B.wt.) OF FEMALE RATS AT TERMINAL SACRIFICE**

ANIMAL NO.	SEX	LUNG	LIVER	HEART	GONADS	SPLEEN	KIDNEY	BRAIN	ADRENAL	GASTRO- INTESTINAL- TRACT
1	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
2	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
3	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
4	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
5	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
6	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
7	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
8	FEMALE	Mild Congestion	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
9	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
10	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

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**TABLE - 7.01**  
**INTENSITY OF HISTO PATHOLOGICAL LESIONS IN CONTROL GROUP**  
**OF MALE RATS AT TERMINAL SACRIFICE**

ANIMAL NO.	SEX	LUNG	LIVER	HEART	GONADS	SPLEEN	KIDNEY	BRAIN	ADRENAL	GASTRO- INTESTINAL - TRACT
1	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
2	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
3	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
4	MALE	Infiltration of MN cells	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
5	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
6	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
7	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
8	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
9	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
10	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

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**TABLE - 7.02**  
**INTENSITY OF HISTO PATHOLOGICAL LESIONS IN CONTROL GROUP**  
**OF FEMALE RATS AT TERMINAL SACRIFICE**

ANIMAL NO.	SEX	LUNG	LIVER	HEART	GONADS	SPLEEN	KIDNEY	BRAIN	ADRENAL	GASTRO- INTESTINAL- TRACT
1	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
2	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
3	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
4	FEMALE	NAD	Fatty infiltration, regeneration	NAD	NAD	NAD	NAD	NAD	NAD	NAD
5	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
6	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
7	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
8	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
9	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
10	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

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**TABLE - 7.03**  
**INTENSITY OF HISTOPATHOLOGICAL LESIONS IN NHH 44 Bt-COTTON SEEDS**  
**(1000 mg/kg.B.wt.) OF MALE RATS AT TERMINAL SACRIFICE**

ANIMAL NO.	SEX	LUNG	LIVER	HEART	GONADS	SPLEEN	KIDNEY	BRAIN	ADRENAL	GASTRO-INTESTINAL - TRACT
1	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
2	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
3	MALE	NAD	Vacuolation of hepatocytes	NAD	NAD	NAD	NAD	NAD	NAD	NAD
4	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
5	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
6	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
7	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
8	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
9	MALE		NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
10	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

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**INTENSITY OF HISTOPATHOLOGICAL LESIONS IN NHH 44 Bt-COTTON SEEDS**  
**(1000 mg/kg.B.wt.) OF FEMALE RATS AT TERMINAL SACRIFICE**

ANIMAL NO.	SEX	LUNG	LIVER	HEART	GONADS	SPLEEN	KIDNEY	BRAIN	ADRENAL	GASTRO- INTESTINAL- TRACT
1	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
2	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
3	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
4	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
5	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
6	FEMALE	NAD	Hepatocentric de generation with infiltration of MN cells	NAD	NAD	NAD	NAD	NAD	NAD	NAD
7	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
8	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
9	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
10	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

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**(1000 mg/kg.B.wt.) OF MALE RATS AT TERMINAL SACRIFICE**

ANIMAL NO.	SEX	LUNG	LIVER	HEART	GONADS	SPLEEN	KIDNEY	BRAIN	ADRENAL	GASTRO-INTESTINAL - TRACT
1	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
2	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
3	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
4	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
5	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
6	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	Mucinous enteritis with regeneration of villi
7	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
8	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
9	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
10	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

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**INTENSITY OF HISTOPATHOLOGICAL LESIONS IN NHH 44 NON Bt-COTTON SEEDS**  
**(1000 mg/kg.B.wt.) OF FEMALE RATS AT TERMINAL SACRIFICE**

ANIMAL NO.	SEX	LUNG	LIVER	HEART	GONADS	SPLEEN	KIDNEY	BRAIN	ADRENAL	GASTRO- INTESTINAL- TRACT
1	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
2	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
3	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
4	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
5	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
6	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
7	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
8	FEMALE	Blood vessels engorged with erythrocytes	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
9	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
10	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

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