Republic of the Philippines
Department of Science and Technology

INDUSTRIAL TECHNOLOGY DEVELOPMENT INSTITUTE
(Formerly National Institute of Science and Technology)
STANDARDS AND TESTING DIVISION
Gen. Santos Ave., Bicutan, Taguig, Metro Manila 1631

Fax No.: (632) 837-31-67 / 837-00-32

Tel. Nos. 837-20-71 to 82
local 2188, 2189

TEST REPORT
No. 0906PTOX0091

Customer's Name : BN Nutraceutical Corp.
Address : 25th F, Burgundy Corp. Tower, Makati City

Sample: Beige powder about
Description : 400 g in aluminum pack marked as
Identification : *BN – 11 (Bionormalizer)*
Date Received : September 13,. 2006
Date(s) Tested : October 25 – November 09, 2006

The median lethal dose (LD50) of the sample, administered orally to female ICR mice is 48.8341 ± 2.4854 g/kg. Toxidrome ranged from decreased motor activity and respiratory rate, piloerection, diarrhea, urination followed by loss of muscle coordination and righting reflex, abdominal respiration, ptosis, tonic convulsion and death of mice.

Details of Acute Oral Toxicity Test enclosed.

Test Method: Modified Acute Oral Toxicity in Mice; OECD, # 401, 1993

VALIDITY OF THE REPORT: The test results are those obtained at the time of the test and pertain only to the sample(s) received by this Laboratory. *Codes and words in italics* are quoted solely for the customer's reference; significance of these codes and words are not verified by this Laboratory. This report is not to be used for advertising purposes or sales promotion.

FE M. SISON
Head, Pharmacology and
Toxicology Laboratory

Issued under the Authority of:

HERMELINA H. BION
Division Chief

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Data:

Concentration of sample suspension – 1 g/mL suspended in distilled water

pH of sample: 4.1

Control: distilled water

Animals used: female ICR mice (26-32 g)

Procedure:

Preliminary dosing was done to determine the expected dose that will cause 50% death of the experimental animals. Three (3) increasing log doses of the test substance were given orally, to the animals in three (3) groups of 10. Another group of 10 animals was given the control, distilled water , equivalent to the volume used for the highest dose of the test substance. The number of deaths and other adverse/abnormal signs and manifestations were closely observed and noted for the first two (2) hours after administration of the test sample. This was continued in the next 24 to 48 hours, daily up to 14 days.

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Results:

Table 1. Behavioral Observation/Toxidrome after Oral Administration of Sample to female ICR Mice

Dose, g/kg	No. of Animals	Observation
0 [a]	10	No effect
41.6667	10	Fifteen (15) to twenty (20) minutes after dosing, the mice manifested decreased motor activity and respiratory rate, piloerection, diarrhea, urination followed by loss of muscle coordination and righting reflex, abdominal respiration, ptosis, tonic convulsion and death of two (2) mice within 35 minutes to one (1) hour. The remaining eight (8) mice recovered within 22 hours.
50	10	Five (5) minutes after the last serial dosing, the mice manifested decreased motor activity and respiratory rate, piloerection, diarrhea, urination followed by loss of muscle coordination and righting reflex, abdominal respiration, ptosis, tonic convulsion and death of five (5) mice within 20 minutes to one (1) hour. The remaining five (5) mice recovered within 22 hours.
60	10	Immediately after the last serial dosing, the mice manifested decreased motor activity and respiratory rate, piloerection, diarrhea, urination followed by loss of muscle coordination and righting reflex, abdominal respiration, ptosis, tonic convulsion and death of nine (9) mice within 15 to 35 minutes. The remaining mouse recovered within 22 hours.

a – control group, the same volume as in the highest dose

Table 2. Summary of Mortality Ratio of Mice Administered Orally with the Sample

$$\text{Mortality Ratio} = \frac{\text{Number of mice with positive sign (death)}}{\text{Total number of animals tested}}$$

Group No.	Dose g/kg	No. of Animals	Mortality Ratio				
			Day 1	Day 2	Day 3	Day 7	Day 14
I	0 [a]	10	0/10	0/10	0/10	0/10	0/10
II	41.6667	10	2/10	2/10	2/10	2/10	2/10
III	50	10	5/10	5/10	5/10	5/10	5/10
IV	60	10	9/10	9/10	9/10	9/10	9/10

a – control group, the same volume as in highest dose

The mice, sacrificed after 14 days showed grossly normal findings on the vital organs. Moreover, an increase in the body weight of mice was also observed.