

STUDY REPORT**Original: 1/2****STUDY TITLE****ACUTE DERMAL TOXICITY STUDY OF BIO-X KLEANZE EC IN SPRAGUE
DAWLEY RATS****(As per OECD Guideline No. 402: Acute Dermal Toxicity - Fixed Dose Procedure)****STUDY No.: BIO-ATX 2993****Study Completion Date: 24 March 2021****SPONSOR****OKADA ECOTECH PTE LTD
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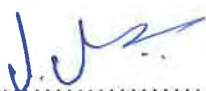
QUALITY ASSURANCE STATEMENT

The Study No.: BIO-ATX 2993, entitled “Acute Dermal Toxicity Study of Bio-X Kleanze EC in Sprague Dawley Rats” has been inspected according to the OECD Principles of Good Laboratory Practice [C(97)186/Final].

The dates of inspections and dates of reporting to the Study Director and the Management have been listed below:

Inspection Dates	Inspection Phases	Reporting Dates	
		Study Director	Management
Initiation Phase			
29 January 2021	Study plan verification	29 January 2021	29 January 2021
In-Life Phase			
25 February 2021	Test item application - Main study	25 February 2021	25 February 2021
Reporting Phase			
19 March 2021	Draft report inspection	19 March 2021	19 March 2021
23 March 2021	Final report inspection	23 March 2021	23 March 2021

Inspections were performed according to the Standard Operating Procedures of the test facility’s Quality Assurance Unit. The study report was inspected against the approved study plan and pertinent raw data and accurately reflects the raw data.



(Signature)
Mr. PRAVEEN B.
 Quality Assurance Unit

24 March 2021

(Date)

STATEMENT OF GLP COMPLIANCE

The Study No.: BIO-ATX 2993, entitled “Acute Dermal Toxicity Study of Bio-X Kleanze EC in Sprague Dawley Rats” was performed in compliance with the OECD Principles of Good Laboratory Practice [C(97)186/Final].

DECLARATION

I hereby declare that the work was performed under my supervision and in accordance with the described procedures. It is assured that the reported results faithfully represent the raw data obtained during the experimental work. No circumstances have been left unreported which may have affected the quality or integrity of the data or which might have a potential bearing on the validity and reproducibility of this study.

I accept overall responsibility for the technical conduct of the study as well as the interpretation, analysis, documentation and reporting of the results.

D. Jhansi

(Signature)

Ms. D. JHANSI
Study Director

24 March 2021

(Date)

STATEMENT OF CONFIDENTIALITY

This report contains **CONFIDENTIAL** and **PROPRIETARY** information of **OKADA ECOTECH PTE LTD, SINGAPORE** and will not be disclosed to anyone without the expressed or written approval of sponsor, except to the employees of test facility wherever necessary and to persons authorized by law or judicial judgement.



.....
(Signature)

Ms. D. JHANSI
Study Director



.....
(Date)



.....
(Signature)

Dr. NITIN M. SHETTY
Deputy Test Facility Management



.....
(Date)

ABBREVIATIONS OF COMMONLY USED UNITS AND SYMBOLS

AAALAC	-	Association for Assessment and Accreditation of Laboratory Animal Care
AM	-	Ante Meridiem
B	-	Breadth
CPCSEA	-	Committee for the Purpose of Control and Supervision of Experiments on Animals
cm	-	Centimeter
F	-	Female
g	-	Gram
GLP	-	Good Laboratory Practice
GHS	-	Globally Harmonized System of Classification and Labelling of Chemicals
H	-	Height
h/hr	-	Hour
hrs	-	Hours
IAEC	-	Institutional Animal Ethics Committee
kg	-	Kilogram
L	-	Length
mg	-	Milligram
min	-	Minute
mL	-	Milliliter
mm	-	Millimeter
n	-	Number of Animals
N	-	Normal
NAD	-	No Abnormality Detected
No.	-	Number
OECD	-	Organization for Economic Co-operation and Development
SD	-	Standard Deviation
TS	-	Terminal Sacrifice
°C	-	Degree Celsius
%	-	Percentage

1. STUDY DETAILS

- 1.1 Study Title** : Acute Dermal Toxicity Study of Bio-X Kleanze EC in Sprague Dawley Rats
- 1.2 Study Number** : BIO-ATX 2993
- 1.3 Study Code** : ADR
- 1.4 Sponsor Details**
- Sponsor : Okada Ecotech Pte Ltd
24 Pioneer Crescent #04-08
628557 Singapore
- Sponsor's Representative : K. E. Tan
Okada Ecotech Pte Ltd
24 Pioneer Crescent #04-08
628557 Singapore
- Monitoring Scientist : A. Z. Tan
Okada Ecotech Pte Ltd
24 Pioneer Crescent #04-08
628557 Singapore
- 1.5 Test Facility** : Bionees India Private Limited
Devarahosahally,
Sompura Hobli, Nelamangala Taluk,
Bangalore Rural District, PIN - 562 111,
Karnataka, India
- 1.6 Study Responsibilities**
- Study Director : Ms. D. Jhansi., M.Sc
Bionees India Private Limited,
Devarahosahally,
Sompura Hobli, Nelamangala Taluk,
Bangalore Rural District, PIN - 562 111,
Karnataka, India
E-mail: bionees@bionees.in
- Study Co-ordinator : Ms. Amulya T. S., B.E., (Biotech)
- Study Personnel : Ms. Kowstubha G.D., M.Sc.
- Study Veterinarian : Dr. K. R. Sneha., M.V.Sc.
- Study Pathologists : Dr. Sowmya Bharath, M.V.Sc, DABT, DIBTP
Dr. Prajapati Ramdatt Khemabhai., M.V.Sc.
- 1.7 Study Schedule**
- Study Initiation Date : 10 February 2021
- Experimental Starting Date : 11 February 2021
- Acclimatization Date : Start: 11 February 2021 End: 24 February 2021
- Treatment Date : Range Finding Study 200 mg/kg : 16 February 2021
Range Finding Study 1000 mg/kg : 19 February 2021
Range Finding Study 2000 mg/kg : 22 February 2021
Main Study 2000 mg/kg : 25 February 2021

Necropsy Date : Range Finding Study 200 mg/kg : 02 March 2021
Range Finding Study 1000 mg/kg : 05 March 2021
Range Finding Study 2000 mg/kg : 08 March 2021
Main Study 2000 mg/kg : 11 March 2021

Experimental Completion Date : 11 March 2021

Draft Report Submission Date : 20 March 2021

Study Completion Date : 24 March 2021

2. SUMMARY

The test item, Bio-X Kleanze EC was evaluated for Acute Dermal Toxicity in Sprague Dawley Rats.

The study was performed in two phases that is range finding study and main study. The animals were dosed in a stepwise procedure with one female in range finding study. The range finding study was performed with three female rats (one rat per dose) and the main study was performed with two female rats. On the day before the application of the test item, fur on the dorso-lateral area of the trunk of the animals was removed by clipping closely with an electric hair clipper and care was taken to avoid abrading the skin.

Required volume of the test item was calculated based on individual animal body weight and then undiluted test item was applied on the clipped area (approximately 10% of the total body surface area) and was covered with cotton gauze and held in place with non-irritating adhesive tape. The whole area was wrapped with a suitable semi-occlusive dressing using crepe bandage. The contact period of test item was 24 hours. At the end of the contact period, the residual test item was washed using distilled water and dried with absorbent cotton.

As there was no information available on the test item, a starting dose of 200 mg/kg body weight was selected from the fixed dose levels of 50, 200, 1000 and 2000 mg/kg body weight. No clinical signs and mortality was observed at the dose level of 200 mg/kg body weight in range finding study. Further, one animal was dosed at 1000 mg/kg body weight. No clinical signs and mortality was observed at the dose level of 1000 mg/kg body weight in range finding study. Next one animal was dosed at 2000 mg/kg body weight. No clinical signs and mortality was observed at the dose level of 2000 mg/kg body weight in range finding study. Hence, during main study, two animals were administered with the same dose level of 2000 mg/kg body weight. No clinical signs and mortalities were observed at the dose level of 2000 mg/kg body weight. No mortality was observed at any of the dosed steps. Hence, no further testing was carried out.

All the animals were observed for clinical signs of toxicity and mortality at 20 to 30 mins, 1 hr (± 10 mins), 2 hrs (± 10 mins), 4 hrs (± 10 mins) and 6 hrs (± 10 mins) on treatment day 1 and thereafter once daily for clinical signs of toxicity and twice daily for mortality during the 14 days observation period. The treatment sites were scored at 24, 48 and 72 hours after removal of test item using draize method. The body weight was recorded at receipt, on day 1 before test item application and on days 8 and 15. At the end of observation period, all the animals were humanely sacrificed by carbon dioxide asphyxiation and subjected to necropsy and detailed gross pathological examination.

No treatment related mortality and clinical signs were noted

No skin reactions were observed at 24, 48 and 72 hours at the treatment site after removal of test item.

No treatment related changes in body weights and percent change in body weights with respect to day 1 were noted. Normal increase in body weights were noted during the observation period.

No treatment related gross pathological changes were noted in range finding study and main study animals during necropsy.

Conclusion

Under the experimental conditions employed and based on the above results, it is concluded that the acute dermal median lethal dose (LD₅₀) of test item Bio-X Kleanze EC in Sprague Dawley rats is > 2000 mg/kg body weight and classified as “Category 5 / Unclassified” (2000 < ATE ≤ 5000 mg/kg body weight) according to the Globally Harmonized System (GHS) of Classification.

3. STUDY COMPLIANCE

3.1 GLP Compliance

The study was performed:

- a. In compliance with the OECD Principles of Good Laboratory Practice [C(97)186/Final].
- b. In accordance with the Standard Operating Procedures at Bionees India Private Limited and as per the mutually agreed study plan with the sponsor.

3.2 Regulatory Guideline

The study was performed in accordance with the OECD Guideline for Testing of Chemicals No. 402 (Section 4: Health Effects) “Acute Dermal Toxicity: Fixed Dose Procedure” adopted on 09 October 2017.

3.3 Animal Welfare

The study was performed in an AAALAC accredited facility:

- a. In accordance with the recommendation of the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) guidelines for laboratory animal facility published in the Gazette of India, 2018.
- b. In accordance with the protocol approved by Institutional Animal Ethics Committee (IAEC) (IAEC Protocol No. BIO-IAEC-4099 and Approval Date: 01/12/2020).

4. SAFETY PRECAUTIONS

Gloves, head cap, face mask and goggles were used in addition to protective body garments and slippers/shoes to ensure adequate personnel health and safety and to avoid ingestion, inhalation, skin and eye contact with the test item.

5. OBJECTIVE

The objective of this study was to assess the toxic potential of the test item Bio-X Kleanze EC when applied by dermal route to female Sprague Dawley rats at one or more defined dose.

This also gives details on classification and labelling of chemical for safety and risk assessment and LD₅₀ cut-off value.

6. MATERIALS AND METHODS

6.1 Test Item Information

The test item information provided by the sponsor as per Test Item Data Sheet and Certificate of Analysis is presented below:

Name of Test Item	: Bio-X Kleanze EC
CAS No.	: Not applicable
Physical appearance (with color)	: Clear Brown liquid
Batch No.	: 2020061201
Date of Manufacture	: 12 June 2020
Date of Expiry	: 12 June 2023

Storage Conditions : Ambient (21 to 29°C)
 Batch Produced by : Okada Ecotech Pte Ltd, Singapore
 (Name and address)
 Test Item Code by Test Facility : D1155-001

The responsibility for the correct identity and stability of the test item rests with the sponsor. The Certificate of Analysis of test item provided by the sponsor is presented as Annexure 2.

6.2 Test System

Animal species : Rat (*Rattus norvegicus*)
Strain : Sprague Dawley
Justification for Selection of Species : Rat is one of the recommended species by regulatory agencies for conducting pre-clinical toxicological studies among rodents.
Source of Supply : In-house bred animals
Body Weight Range at Receipt : 200.72 g to 206.44 g
Age at Treatment : 10 weeks
No. of Animals and Sex : Range finding study : 3 Females
 Main study : 2 Females
 Total of 5 females were received.
 (Females used were nulliparous and non-pregnant)
 Randomization was done during acclimatization period.
Animal Identification : Acclimatization period: All the animals were identified by tail marking using a black marker pen. Additionally, a cage card was displayed which included study no., cage no., sex, animal no. (temporary), start date and end date of acclimatization period.
 Treatment period: The animals were identified by writing last 4 digits of the animal number on tail using a red permanent marker pen. Additionally, a cage card was displayed which included study no., cage no., sex, animal no. (Permanent), treatment date and date of necropsy.
 Animal Numbers : Rf2846 to Rf2850

6.3 Husbandry

a. Environmental conditions : Animals were housed under standard laboratory conditions, in an environmentally monitored air-conditioned room with adequate fresh air supply (12 to 15 air changes per hour), room temperature 19.4°C to 22.9°C and relative humidity 47% to 64% with 12 hours fluorescent light and 12 hours dark cycle. The temperature and relative humidity were recorded once daily.

- b. Housing** : Maximum of three animals were housed in a standard polypropylene cage (size: L 430 x B 285 x H 150 mm) with stainless steel mesh top grill having facilities for holding pelleted feed and drinking water in water bottle fitted with stainless steel sipper tube. For range finding study animals were housed individually after treatment. For main study, during treatment, the animals were housed individually; and after patch removal, animals were housed together. Clean sterilized paddy husk was provided as bedding material. Paper shredding was provided as enrichment.
- c. Feed** : Altromin maintenance diet for rats and mice (manufactured by Altromin Spezialfutter GmbH & Co. KG) was provided *ad libitum* to the animals throughout the experimental period. The contaminant analysis test report of the feed is presented as Annexure 3.
- d. Water** : Water was provided *ad libitum* throughout the acclimatization and experimental period. Deep bore-well water passed through Reverse osmosis unit was provided in plastic water bottles with stainless steel sipper tubes.

The contaminant analysis test reports for the water and bedding material nearest to the experimental period are presented as Annexures 4 and 5 respectively.

6.4 Acclimatization

Healthy and young adult animals were acclimatized for a period of five (200 mg/kg body weight), eight (1000 mg/kg body weight) and eleven days (2000 mg/kg body weight) for range finding study and fourteen days for the main study animals to laboratory conditions prior to dosing and were observed for clinical signs once daily. Veterinary examination of all the animals was performed on the day of receipt.

6.5 Preparation of Animals

On the day, before the application of the test item, fur on the dorso-lateral area of the trunk of the animals was removed by clipping closely with an electric hair clipper (approximately 10% of surface area of body). Care was taken to avoid abrading the skin.

6.6 Study Design

The study was performed in two phases that is range finding study and main study. Range finding study was performed with one animal and main study was performed with two animals.

The animals were dosed in a stepwise procedure with one female in range finding study. Since the LD₅₀ of the test item is not available, hence, a starting dose of 200 mg/kg body weight was selected from the fixed dose levels of 50, 200, 1000 and 2000 mg/kg body weight. No clinical signs and mortality was observed at the dose level of 200 mg/kg body weight in range finding study. Further, one animal was dosed at 1000 mg/kg body weight after approximately 72 hours. No clinical signs and mortality was observed at the dose level of 1000 mg/kg body weight in range finding study. Next one animal was dosed at 2000 mg/kg body weight approximately after 72 hours. No clinical signs and mortality was observed at the dose level of 2000 mg/kg

body weight in range finding study. Hence, during main study, two animals were administered with the same dose level of 2000 mg/kg body weight after approximately 72 hours. No clinical signs and mortalities were observed at the dose level of 2000 mg/kg body weight. No mortality was observed at any of the dosed steps. Hence, no further testing was carried out.

Details of the step wise test procedure according to the OECD 402 guideline is presented as Annexure 1.

6.7 Route of Application and Justification for Selection

The test item was applied topically (dermal exposure). The dermal route was selected as it is one of the probable route of exposure to humans and indicates a concern for human health.

6.8 Preparation of Test item

As per sponsor communication, test item was prepared for 80 dilutions.

80 dilutions: 0.13 mL of test item was taken and 10 mL of distilled water was added.

6.9 Method of Test Item Application

Required volume of the formulated test item was calculated based on individual animal body weight and then diluted test item was applied on the clipped area (approximately 10% of the total body surface area) and was covered with cotton gauze and held in place with non-irritating adhesive tape. The whole area was wrapped with a suitable semi-occlusive dressing using crepe bandage. The contact period of test item was 24 hours. At the end of the contact period, the residual test item was washed using distilled water and dried with absorbent cotton.

For example:

$$\text{Volume applied (mL)} = \frac{\text{Dose (mg/kg)} / 1000 \times \text{Body weight (g)}}{\text{Density (mg/mL)}}$$

The density of test item was measured by taking 1 mL of (formulated 80 dilutions) test item in a syringe followed by dispensing the same into a beaker for measurement (mg/mL). The same procedure was repeated thrice and the mean density of test item was found to be 981.20 mg/mL.

The detail of distilled water used is as follows:

Batch No.	:	393 & 423
Manufactured Date	:	04/02/2021 & 16/02/2021
Expiry Date	:	03/02/2022 & 15/02/2022
Manufactured by	:	Mysore Research Chemical Laboratories

6.10 Observations

The following observations were made during the experimental period.

6.10.1 Clinical Signs of Toxicity and Mortality

All the animals were observed for clinical signs of toxicity and mortality at 20 to 30 mins, 1 hr (± 10 mins), 2 hrs (± 10 mins), 4 hrs (± 10 mins) and 6 hrs (± 10 mins) post dosing on day 1 and thereafter once daily for clinical signs of toxicity and twice daily for mortality during the 14 days observation period.

Observations included changes in skin, fur, eyes and mucous membranes along with changes in respiratory, circulatory, autonomic and central nervous system, somatomotor activity and behaviour pattern. The treatment site was observed at 24, 48 and 72 hours after removal of test item using draize method.

Table: Grading of Skin Reactions

1. Erythema and Eschar Formation	Score
No erythema.....	0
Very slight erythema (barely perceptible).....	1
Well defined erythema.....	2
Moderate to severe erythema.....	3
Severe erythema (beet redness) to eschar formation preventing grading of erythema.....	4

Maximum possible score: 4

2. Oedema Formation	Score
No oedema	0
Very slight oedema (barely perceptible).....	1
Slight oedema (edges of area well defined by definite rising).....	2
Moderate oedema (raised approximately 1 millimetre)	3
Severe oedema (raised more than 1 millimetre and extending beyond area of exposure)	4

Maximum possible score: 4

6.10.2 Body Weight

Individual animal body weights were recorded at receipt, on day 1 before test item application and on days 8 and 15 during the experimental period.

6.10.3 Pathology

a) Necropsy

On day 15, all the animals were humanely sacrificed by carbon dioxide asphyxiation and subjected to necropsy and a complete gross pathological examination.

b) Histopathology

Histopathological examination was not carried out as there were no gross pathological findings in any of the animals.

7. INTERPRETATION OF RESULTS

The test item was classified according to the Globally Harmonized System of Classification and Labelling of Chemicals (Refer Annexure 6).

8. STUDY REPORT PREPARATION

Individual animal data is summarized and presented as tables. All findings are presented in the study report as per the standard reporting procedure of the test facility.

9. AMENDMENTS AND DEVIATIONS

No amendments were raised and no deviations occurred during the conduct of the study.

10. STUDY REPORT DISTRIBUTION

Original: 1/2 - Sponsor

Original: 2/2 - Archives, Bioneeeds India Private Limited

11. ARCHIVING

All materials and data generated in the study will be stored in the archives of the test facility. The study plan, raw data and study report will be maintained in the archives of Bioneeeds India Private Limited for 9 years from the date of completion of the study. At the end of archiving period, the sponsor's instructions will be sought either to extend the archiving period or to return the archived material to the sponsor or for the disposal.

12. REFERENCE

The Globally Harmonized System of Classification and Labelling of Chemicals (GHS), 8th edition, 2019 (ST/SG/AC.10/30/REV.8).

13. RESULTS AND DISCUSSION

13.1 Clinical Signs of Toxicity and Mortality

No treatment related clinical signs of toxicity and mortality were observed in both range finding study and main study animals.

Refer Table 1

13.2 Skin Reactions

No skin reactions were observed in the treatment sites at 24, 48 and 72 hours after removal of test item.

Refer Table 2

13.3 Body Weight

No treatment related changes were observed in mean body weights and percent change in body weights with respect to day 1 in both range finding study and main study animals. All animals revealed physiologically normal increase in the body weight in both range finding study and main study.

Refer Table 3

13.4 Pathology

No treatment related gross pathological changes were in both range finding study and main study animals.

Refer Table 4

14. CONCLUSION

Under the experimental conditions employed and based on the above results, it is concluded that the acute dermal median lethal dose (LD₅₀) of test item Bio-X Kleanze EC in Sprague Dawley rats is > 2000 mg/kg body weight and classified as “Category 5 / Unclassified” (2000 < ATE ≤ 5000 mg/kg body weight) according to the Globally Harmonized System (GHS) of Classification.

15. TABLES

TABLE 2. INDIVIDUAL ANIMAL LOCAL SKIN REACTIONS

Phase of the Experiment	Animal No	Sex	Dose (mg/kg body weight)	Days					
				3 (24 hours)		4 (48 hours)		5 (72 hours)	
				ER	ED	ER	ED	ER	ED
Range finding Study	Rf2846	Female	200	0	0	0	0	0	0
	Rf2847	Female	1000	0	0	0	0	0	0
	Rf2848	Female	2000	0	0	0	0	0	0
Main Study	Rf2849	Female	2000	0	0	0	0	0	0
	Rf2850	Female	2000	0	0	0	0	0	0

ER: Erythema; ED: Edema; 0: No erythema/edema

TABLE 3. BODY WEIGHT (g) AND PERCENT CHANGE IN BODY WEIGHT WITH RESPECT TO DAY 1

Phase of the Experiment	Dose (mg/kg body weight)	Animal No.	Sex	Volume applied (ml)	Body Weight (g) on Days			Percent Change in Body Weight with Respect to Day	
					1	8	15	1 to 8	1 to 15
Range Finding Study	200	Rf2846	F	0.04	217.68	231.59	247.18	6.39	13.55
	1000	Rf2847	F	0.22	218.42	233.41	248.69	6.86	13.86
	2000	Rf2848	F	0.46	227.46	241.16	256.67	6.02	12.84
Main Study	2000	Rf2849	F	0.47	228.46	240.36	256.19	5.21	12.14
		Rf2850	F	0.48	235.51	247.82	259.07	5.23	10.00
			Mean		231.99	244.09	257.63	5.22	11.07
			±SD		4.99	5.28	2.04	0.01	1.51
			n		2	2	2	2	2

F: Female; SD: Standard Deviation; n: number of animals.

TABLE 4. GROSS PATHOLOGY FINDINGS

Phase of the Experiment	Dose (mg/kg body weight)	Animal No.	Sex	Fate	Gross Pathology Findings	
					External	Internal
Range finding Study	200	Rf2846	F	TS	NAD	NAD
	1000	Rf2847	F	TS	NAD	NAD
	2000	Rf2848	F	TS	NAD	NAD
Main Study	2000	Rf2849	F	TS	NAD	NAD
		Rf2850	F	TS	NAD	NAD

NAD: No Abnormality Detected; F: Female; TS: Terminal Sacrifice

16. ANNEXURES

ANNEXURE 1. FLOW CHART FOR THE TESTING PROCEDURE

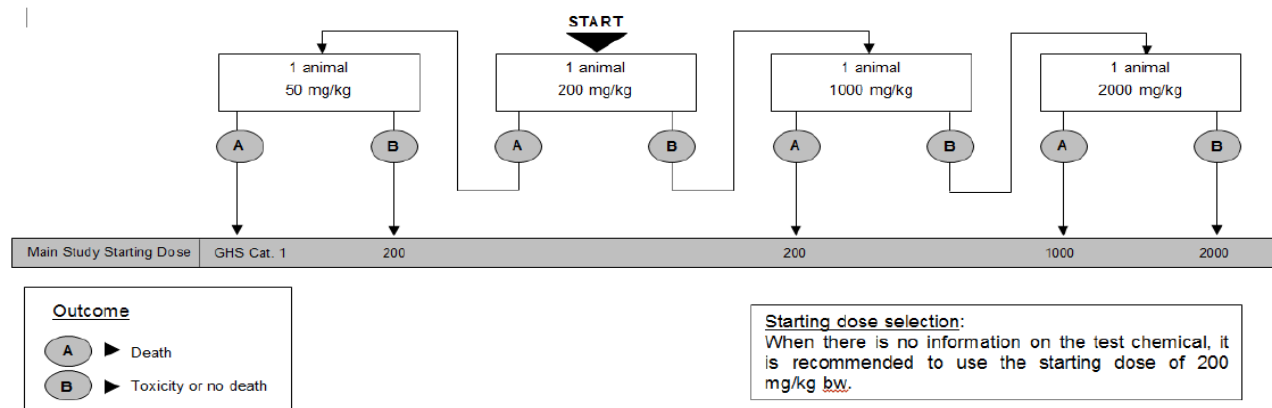
402

OECD/OCDE

ANNEX 2

FLOWCHART FOR THE TESTING PROCEDURE

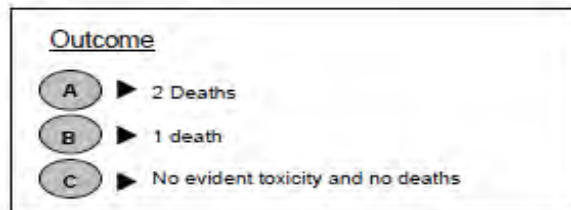
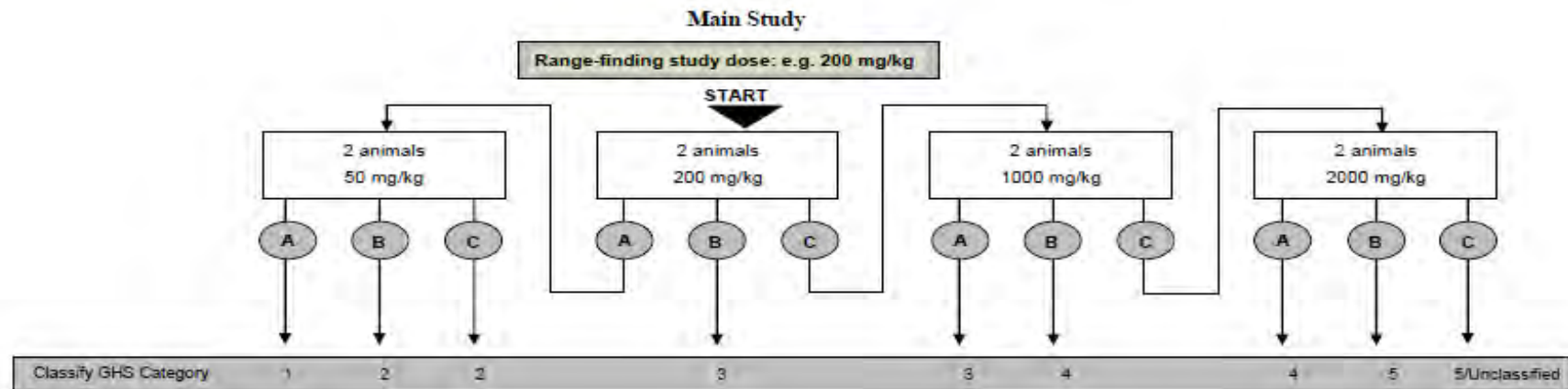
Range-Finding Study



© OECD, (2017)

ANNEXURE 1 (Contd...). FLOW CHART FOR THE TESTING PROCEDURE

ENV/JM/WRPR(2017)36



ANNEXURE 2. CERTIFICATE OF ANALYSIS OF BIO-X KLEANZE EC



OKADA ECOTECH PTE LTD (REG NO 199805584M)

24 Pioneer Crescent, #04-08, West Park Bizcentral, Singapore 628557
 Tel: (65) 6872 3515 Fax: (65) 6872 6558
 Website: www.okada-ecotech.com

CERTIFICATE OF ANALYSIS

Attention : **To whom it may concern**
 Product Name : **Bio-X® Kleanze EC**
 Batch Number : 2020061201
 Date of Test : 1 December 2020

TEST	SPECIFICATIONS	RESULT
Appearance	Clear brown	OK
Odor	Pleasant	OK
Viscosity (cP) (BF DVII #1/100RPM/30Deg C)	20 ± 5 cps	20.0
Specific Gravity	0.95 ± 0.10	0.96
Dispersibility in Water	All proportion dispersible	OK


 Tan Aik Zen
 (Chemical Engineer)

ANNEXURE 3. CONTAMINANT ANALYSIS TEST REPORT OF FEED

Nr.: QA - 72 Aufbewahrungsdauer 15 Jahre nach Erstellen			
Altromin Spezialfutter GmbH & Co. KG Im Seelenkamp 20 D-32791 Lage Tel.: +49 (0)5232 / 6088-0 Fax: +49 (0)5232 / 6088-20 E-Mail: analysen@altromin.de			
Producer Certificate			
Description	Maintenance diet for rats and mice		
Type	1324		
	Isoflavone Genistein <350 ppm		
	10mm pellets, 12.5 kg double plasticbags		
Customer	ATNT Laboratories, India		
Batch no. / Lot no.	202010200420		
Order no.	Altromin Doc. No. 49280		
Production date	20.10.2020		
Expiry date	20.10.2021		
Guaranteed nutritional values			
% in air-dry substance	Value*	Tolerance**	
Crude protein	19,2	16,8 – 21,6	
Crude fat	4,1	3,1 – 6,1	
Crude fibre	6,1	4,4 – 7,8	
Crude ash	6,9	4,9 – 7,9	
Moisture	11,3	< 12,4	
NfE - Nitrogen free extracts	52,4		
Calcium	0,7	0,4 – 1,3	
Phosphorus	0,5	0,2 – 0,8	
<small>* The producer guarantees that nutritional values of this batch are within the declared tolerance values. ** Tolerances according to Annex IV of Regulation (EU) Nr 767/2009</small>			
Physical analysis			
Pellet hardness kg/cm ² - Kahl			22
Sensory evaluation			
Olfactory			ok
Visual			ok
This product is compliant with the specifications and quality requirements of Altromin and therefore has been approved for delivery.			
Date: November 05th 2020		Accepted and released for use <i>25/11/2020</i> Hans-Leopold Altrogge QA-Manager	
<small>This is a computer printed and has therefore not been signed and dated by hand</small>			

ANNEXURE 3 (Contd...). CONTAMINANT ANALYSIS TEST REPORT OF FEED

Nr.: QA - 72-1 Aufbewahrungsdauer: 15 Jahre nach Erstellen	
Altromin Spezialfutter GmbH & Co. KG Im Seelenkamp 20 D-32791 Lage Tel. +49 (0)5232 / 6088-0 Fax: +49 (0)5232 / 6088-20	
	
<h3>Producer Certificate</h3>	
Description	1324 Maintenance diet for rats and mice
Customer	ATNT Laboratories, India
Batch no. / Lot no.	202010200420
Production date	20.10.2020
Expiry date	20.10.2021
Guaranteed diet status:	
Aflatoxins	
Aflatoxin B1	< 2.5 µg/kg
Aflatoxin B2	< 0.6 µg/kg
Aflatoxin G1	< 2.5 µg/kg
Aflatoxin G2	< 0.6 µg/kg
Sum B1, B2, G1, G2	below detection limit
Heavy metals	
Lead (Pb)	< 1.00 mg/kg
Cadmium (Cd)	< 0.20 mg/kg
Mercury (Hg)	< 0.05 mg/kg
Arsenic (As)	< 1.00 mg/kg
Polychlorinated Biphenyls	
PCB	below detection limit
Pesticides and residuals	
Chlorpyriphos-methyl	< 0.100 mg/kg
Ethoxyquin	< 5.000 mg/kg
Piperonylbutoxid	< 0.500 mg/kg
Pirimiphos-methyl	< 0.500 mg/kg
all screened substances not mentioned are usually below detection limit (see attached list)	
Microbiological status	
Total aerobic count	< 10 ⁵ cfu/g
Yeasts	< 10 ² cfu/g
Moulds	< 10 ² cfu/g
E. coli	< 10 ¹ cfu/g
Salmonella in 25 g	not detectable
Accepted and released for use Date: November 05th 2020	
Hans-Leopold Altrogge 05/11/2020 (Quality Manager)	
<small>This is a computer printout and has therefore not been signed and dated by hand.</small>	

ANNEXURE 4. CONTAMINANT ANALYSIS TEST REPORT OF WATER



INSTITUTE FOR ANALYSIS OF DAIRY, FOOD & CULTURES.
 #8, Siddhi Vinayaka Complex, Nagarabhavi 2nd Stage, 2nd Block
 Near BDA Complex, 80 Feet Ring Road, Bangalore-560 072
 Ph: +91-80-2318 6906 to 10, Cell : +91 8152881444/8152881222
 Mail: accounts@iadfac.com/vd@iadfac.com/qa@iadfac.com

CERTIFICATE OF ANALYSIS

BOOKING NO. : 0010

CERTIFICATE NO. : 0010/2020-2021

NAME OF MANUFACTURER/PARTY :		BIONEEDS INDIA PRIVATE LIMITED Devarahasahalli, Sompura Hobali, Nelamangla Taluk, Bangalore Rural Dist, BANGALORE - 562111 KARNATAKA	
1. MFG. LIC. NO.	: NM	3. DATE	: 06/05/2020
2. REFERENCE NO.	: NM	5. NAME OF SAMPLE	: Drinking Water (R O Water)
4. DATE OF RECEIPT	: 06/05/2020	6. DETAILS OF RAW MATERIAL / FINAL PRODUCTS (In Bulk/Finished Pack)	
(A) MANUFACTURER NAME	: NM	(B) BATCH NO.	: NM
(C) BATCH SIZE	: NM	(D) DATE OF MFG.	: NM
(E) SAMPLE QUANTITY	: 5Lx1 Can	(F) DATE OF EXPIRY	: NM
(G) PACKING	: Plastic Bottle	(H) STARTING DATE	: 08/05/2020
(I) SEALED	: Sealed	(J) ENDING DATE :	: 19/05/2020
(K) BRAND NAME	: NM	(L) SAMPLING PROTOCOL	: NA
(M) DATE OF SAMPLING/SAMPLE COLLECTION	: 06/05/2020	(N) REPORT GEN. DATE	: 19/05/2020

Specification as per IS 10500:2012

SR	TEST NAME	UNIT	RESULT	ACCEPTABLE LIMIT	PERMISSIBLE LIMIT	METHOD OF TEST
1	CHEMICAL TESTING					
	Water, Residues in Water					
1	Colour	CU	<1	5 Max	15 Max	IS 3025 (Part-4) : 1983
2	Odour	-	Agreeable	Agreeable	Agreeable	IS 3025 (Part-5) : 2018
3	pH Value	-	6.6	6.5-8.5	No Relaxation	IS 3025 (Part-11) : 1983
4	Taste	-	Agreeable	Agreeable	Agreeable	IS 3025 (Part-7&Part-8) : 2017
5	Turbidity (as NTU)	-	<1	1 Max	5 Max	IS 3025 (Part-10) : 1984
6	Total Dissolved Solids	mg/l	23	500 Max	2000 Max	IS 3025 (Part-16) : 1984
7	Aluminium (as Al)	mg/l	<0.02	0.03 Max	0.2 Max	IS 3025 (Part-55) : 2003
8	Boron (as B)	mg/l	<0.1	0.5 Max	2.4 Max	IS 3025 (Part-57) : 2005
9	Calcium (as Ca)	mg/l	1	75 Max	200 Max	IS 3025 (Part-40) : 1991
10	Chloride (as Cl)	mg/l	2	250 Max	1000 Max	IS 3025 (Part-32) : 1988
11	Copper (as Cu)	mg/l	<0.05	0.05 Max	1.5 Max	IS 3025 (Part-42) : 1992
12	Fluoride (as F)	mg/l	<0.1	1.0 Max	1.5 Max	IS 3025 (Part-60) : 2013
13	Free residual Chlorine	mg/l	<0.1	0.2 Min	1.0 Max	IS 3025 (Part-26) : 1986
14	Iron (as Fe)	mg/l	<0.05	1.0 Max	No Relaxation	IS 3025 (Part-53) : 2003
15	Magnesium (as Mg)	mg/l	<1	30 Max	100 Max	IS 3025 (Part-46) : 1994
16	Manganese (as Mn)	mg/l	<0.1	0.1 Max	0.3 Max	IS 3025 (Part-59) : 2006

<p>Remarks :</p> <p><i>Accepted and released for use on 06/05/2020</i></p>	<p>For IADFAC Laboratories Pvt. Ltd.</p> <p><i>Karan</i></p> <p>Authorised Signatory Karunakara A.C. (ID No-132) Senior Manager-Chemical</p>	<p>CONTD. ON NEXT PAGE.....</p> <p style="text-align: center;">AUTHORISED SIGNATORY</p>
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Note :

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3. The report cannot be reproduced, completely or in part, in any form of media (including print) without an explicit written permission from IADFAC Lab.
4. Sample drawn and submitted by the party for Analysis unless otherwise stated.
5. Analysed Food samples are destroyed within one month. Analysed Packaged Drinking Water samples destroyed after 3 months.

ANNEXURE 4 (Contd...). CONTAMINANT ANALYSIS TEST REPORT OF WATER



INSTITUTE FOR ANALYSIS OF DAIRY, FOOD & CULTURES.
 #8, Siddhi Vinayaka Complex, Nagarabhavi 2nd Stage, 2nd Block
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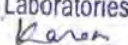
CERTIFICATE OF ANALYSIS

BOOKING NO. : 0010
 CERTIFICATE NO. : 0010/2020-2021

NAME OF MANUFACTURER/PARTY :		BIONEEDS INDIA PRIVATE LIMITED Devarahosahalli, Sompura Hobali, Nelamangla Taluk, Bangalore Rural Dist, BANGALORE - 562111 KARNATAKA	
1. MFG. LIC. NO.	: NM	3. DATE	: 06/05/2020
2. REFERENCE NO.	: NM	5. NAME OF SAMPLE	: Drinking Water (R O Water)
4. DATE OF RECEIPT	: 06/05/2020		
6. DETAILS OF RAW MATERIAL / FINAL PRODUCTS (In Bulk/Finished Pack)			
(A) MANUFACTURER NAME	: NM	(B) BATCH NO.	: NM
(C) BATCH SIZE	: NM	(D) DATE OF MFG.	: NM
(E) SAMPLE QUANTITY	: 5Lx1 Can	(F) DATE OF EXPIRY	: NM
(G) PACKING	: Plastic Bottle	(H) STARTING DATE	: 08/05/2020
(I) SEALED	: Sealed	(J) ENDING DATE	: 19/05/2020
(K) BRAND NAME	: NM	(L) SAMPLING PROTOCOL	: NA
(M) DATE OF SAMPLING /SAMPLE COLLECTION	: 06/05/2020	(N) REPORT GEN. DATE	: 19/05/2020

Specification as per IS 10500:2012

SR	TEST NAME	UNIT	RESULT	ACCEPTABLE LIMIT	PERMISSIBLE LIMIT	METHOD OF TEST
17	Nitrate (as NO ₃)	mg/l	1.16	45 Max	No Relaxation	IS 3025 (Part-34) : 1988
18	Selenium (as Se)	mg/l	<0.01	0.01 Max	No Relaxation	IS 3025 (Part-56) : 2003
19	Sulphate (as SO ₄)	mg/l	<1	200 Max	400 Max	IS 3025 (Part-24) : 1986
20	Total Alkalinity as calcium carbonate	mg/l	8.0	200 Max	600 Max	IS 3025 (Part-23) : 1986
21	Total Hardness (as CaCO ₃)	mg/l	4	200 Max	600 Max	IS 3025 (Part-21) : 2009
22	Cadmium (as Cd)	mg/l	<0.003	0.003 Max	No Relaxation	IS 3025 (Part-41) : 1992
23	Lead (as Pb)	mg/l	<0.01	0.01 Max	No Relaxation	IS 3025 (Part-47) : 1994
24	Mercury (as Hg)	mg/l	<0.001	0.001 Max	No Relaxation	IS 3025 (Part-48) : 1994
25	Total Arsenic (as As)	mg/l	<0.01	0.01 Max	No Relaxation	IS 3025 (Part-37) : 1988
26	Total Chromium (as Cr)	mg/l	<0.05	0.05 Max	No Relaxation	Annexure- J of IS 13428 : 2005
Pesticide residues						
1	Endosulfan					
a	Alpha Endosulfan	µg/l	<0.01	0.4 Max	No Relaxation	FSSAI Manual of water 2016
b	Beta Endosulfan	µg/l	<0.01	0.4 Max	No Relaxation	FSSAI Manual of water 2016
c	Endosulfan sulphate	µg/l	<0.01	0.4 Max	No Relaxation	FSSAI Manual of water 2016
2	Ethion	µg/l	<0.01	3 Max	No Relaxation	FSSAI Manual of water 2016

<p>Remarks : <i>Accepted and released for use @ 21/05/2020</i></p> <p style="text-align: center;">For IADFAC Laboratories Pvt. Ltd.  Authorised Signatory Karunakara A.C. (ID No-132) Senior Manager-Chemical</p>	<p>CONTD. ON NEXT PAGE.....</p> <p>AUTHORISED SIGNATORY</p>
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- Analysed Food samples are destroyed within one month, Analysed Packaged Drinking Water samples destroyed after 3 months.

ANNEXURE 4 (Contd...). CONTAMINANT ANALYSIS TEST REPORT OF WATER



INSTITUTE FOR ANALYSIS OF DAIRY, FOOD & CULTURES.
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 Mail: accounts@iadfac.com/bd@iadfac.com/qa@iadfac.com

CERTIFICATE OF ANALYSIS

BOOKING NO. : 0010
 CERTIFICATE NO. : 0010/2020-2021

NAME OF MANUFACTURER/PARTY :		BIONEEDS INDIA PRIVATE LIMITED	
		Devarahosahalli, Sompura Hobali, Nelamangla Taluk, Bangalore Rural Dist, BANGALORE - 562111 KARNATAKA	
1. MFG. LIC. NO.	: NM	3. DATE	: 06/05/2020
2. REFERENCE NO.	: NM	5. NAME OF SAMPLE	: Drinking Water (R O Water)
4. DATE OF RECEIPT	: 06/05/2020		
6. DETAILS OF RAW MATERIAL / FINAL PRODUCTS (In Bulk/Finished Pack)			
(A) MANUFACTURER NAME	: NM	(B) BATCH NO.	: NM
(C) BATCH SIZE	: NM	(D) DATE OF MFG.	: NM
(E) SAMPLE QUANTITY	: 5Lx1 Can	(F) DATE OF EXPIRY	: NM
(G) PACKING	: Plastic Bottle	(H) STARTING DATE	: 08/05/2020
(I) SEALED	: Sealed	(J) ENDING DATE	: 19/05/2020
(K) BRAND NAME	: NM	(L) SAMPLING PROTOCOL	: NA
(M) DATE OF SAMPLING / SAMPLE COLLECTION	: 06/05/2020	(N) REPORT GEN. DATE	: 19/05/2020

Specification as per IS 10500:2012

SR	TEST NAME	UNIT	RESULT	ACCEPTABLE LIMIT	PERMISSIBLE LIMIT	METHOD OF TEST
3	Monocrotophos	µg/l	<0.01	1 Max	No Relaxation	FSSAI Manual of water 2016
--	--	--	-- End of Report --	--	--	--

Remarks :

Accepted & released for For IADFAC Laboratories Pvt. Ltd.
 19/05/2020
 Karunakara A.C. (ID No-132)
 Senior Manager-Chemical

AUTHORISED SIGNATORY

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ANNEXURE 5. CONTAMINANT ANALYSIS TEST REPORT OF BEDDING MATERIAL



INSTITUTE FOR ANALYSIS OF DAIRY, FOOD & CULTURES.
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CERTIFICATE OF ANALYSIS

BOOKING NO. 0011
 CERTIFICATE NO. : 0011/2020-2021

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		Devarahosahalli ,Sompura Hobali, Nelamangla Taluk, Bangalore Rural Dist, BANGALORE - 562111 KARNATAKA	
1.MFG. LIC. NO.	NM	4. OTHER REFERENCE NO	NM
2. REFERENCE NO.	NM	5. DATE OF RECEIPT	06/05/2020
3. DATE	06/05/2020	6. NAME OF SAMPLE	Paddy husk
7. DETAILS OF RAW MATERIAL / FINAL PRODUCTS (In Bulk/Finished Pack)			
(A) BATCH NO.	NM	(H) SEALED	Sealed
(B) BATCH SIZE	NM	(I) STARTING DATE	08/05/2020
(C) DATE OF MFG.	NM	(J) ENDING DATE :	19/05/2020
(D) DATE OF EXPIRY	NM	(K) BRAND NAME	NM
(E) SAMPLE QUANTITY	1 kg	(L) SAMPLING PROTOCOL	NA
(F) MFG NAME	NM	(M) DATE OF SAMPLING	06/05/2020
(G) PACKING	Zip lock cover	(N) REPORT GEN. DATE	19/05/2020

SR	TEST NAME	UNIT	RESULT	SPECIFICATIONS	METHOD OF TEST
	CHEMICAL TESTING				
	Animal Food & Feed				
	Heavy Metals				
1	Arsenic	mg/kg	<0.1	-	AOAC 20th Edition 2016
2	Lead	mg/kg	<0.1	-	AOAC 20th Edition 2016
3	Cadmium	mg/kg	<0.1	-	AOAC 20th Edition 2016
4	Mercury	mg/kg	<0.1	-	AOAC 20th Edition 2016
	Chlorinated Hydrocarbons				
1	Hexachlorobenzene (HCB)	mg/kg	Not detected	-	AOAC 20th Edition 2016
2	Hexachlorocyclohexane (HCH)	mg/kg	Not detected	-	AOAC 20th Edition 2016
3	HCH (Lindane)	mg/kg	Not detected	-	AOAC 20th Edition 2016
4	Heptachlor & epoxide	mg/kg	Not detected	-	AOAC 20th Edition 2016
5	Chlordane	mg/kg	Not detected	-	AOAC 20th Edition 2016
6	Aldrin	mg/kg	Not detected	-	AOAC 20th Edition 2016
7	Dieldrin	mg/kg	Not detected	-	AOAC 20th Edition 2016
8	Endrin	mg/kg	Not detected	-	AOAC 20th Edition 2016
9	DDE	mg/kg	Not detected	-	AOAC 20th Edition 2016
10	DDD	mg/kg	Not detected	-	AOAC 20th Edition 2016

Remarks : *Accepted and released for use*
07/05/2020
 For IADFAC Laboratories Pvt. Ltd.
Karan
 Authorised Signatory
 Karunakara A.C. (ID No-132)
 Senior Manager-Chemical
 CONTD. ON NEXT PAGE.....
AUTHORISED SIGNATORY

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 3. The report cannot be reproduced, completely or in part, in any form of media (including print) without an explicit written permission from IADFAC Lab. P. Ltd
 4. Sample drawn and submitted by the party for Analysis unless otherwise stated.
 5. Analysed Food sample destroyed within one month. Analysed Packaged Drinking Water sample destroyed after 3 months.

ANNEXURE 5 (Contd...). CONTAMINANT ANALYSIS TEST REPORT OF BEDDING MATERIAL



INSTITUTE FOR ANALYSIS OF DAIRY, FOOD & CULTURES.
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CERTIFICATE OF ANALYSIS

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		Devarahosahalli, Sompura Hoballi, Nelamangla Taluk, Bangalore Rural Dist, BANGALORE - 562111 KARNATAKA	
1. MFG. LIC. NO.	NM	4. OTHER REFERENCE NO	NM
2. REFERENCE NO.	NM	5. DATE OF RECEIPT	06/05/2020
3. DATE	06/05/2020	6. NAME OF SAMPLE	Paddy husk
7. DETAILS OF RAW MATERIAL / FINAL PRODUCTS (In Bulk/Finished Pack)			
(A) BATCH NO.	NM	(H) SEALED	Sealed
(B) BATCH SIZE	NM	(I) STARTING DATE	06/05/2020
(C) DATE OF MFG.	NM	(J) ENDING DATE :	19/05/2020
(D) DATE OF EXPIRY	NM	(K) BRAND NAME	NM
(E) SAMPLE QUANTITY	1 kg	(L) SAMPLING PROTOCOL	NA
(F) MFG NAME	NM	(M) DATE OF SAMPLING /SAMPLE COLLECTION	06/05/2020
(G) PACKING	Zip lock cover	(N) REPORT GEN. DATE	19/05/2020

SR	TEST NAME	UNIT	RESULT	SPECIFICATIONS	METHOD OF TEST
11	DDT	mg/kg	Not detected	-	AOAC 20th Edition 2016
12	Endosulfan	mg/kg	Not detected	-	AOAC 20th Edition 2016
13	Endosulfan Sulphate	mg/kg	Not detected	-	AOAC 20th Edition 2016
14	Phosphoric Acid Esters	mg/kg	Not detected	-	AOAC 20th Edition 2016
15	Malathion	mg/kg	Not detected	-	AOAC 20th Edition 2016
16	Fenitrothion	mg/kg	Not detected	-	AOAC 20th Edition 2016
17	Pirimiphos(-methyl)	mg/kg	Not detected	-	AOAC 20th Edition 2016
18	Chlorpyrifos (-methyl)	mg/kg	Not detected	-	AOAC 20th Edition 2016
19	All other Phosphates	mg/kg	Not detected	-	AOAC 20th Edition 2016
20	Polychlorinated Biphenyls (PCB)	mg/kg	Not detected	-	AOAC 20th Edition 2016
Mycotoxins					
1	Aflatoxin B1	µg/kg	Not detected	-	AOAC 20th Edition 2016
2	Aflatoxin B2	µg/kg	Not detected	-	AOAC 20th Edition 2016
3	Aflatoxin G1	µg/kg	Not detected	-	AOAC 20th Edition 2016
4	Aflatoxin G2	µg/kg	Not detected	-	AOAC 20th Edition 2016
5	Zearalenone	µg/kg	Not detected	-	AOAC 20th Edition 2016
6	Ochratoxin A	µg/kg	Not detected	-	AOAC 20th Edition 2016
Nitrosamines					
1	Nitrosodiethylamine	µg/kg	Not detected	-	AOAC 20th Edition 2016

Remarks : *Accepted and released for use on 21/05/2020*

For IADFAC Laboratories Pvt. Ltd.
Karunakara
 Authorised Signatory
 Karunakara A.C. (ID No-132)
 Senior Manager Chemical
 AUTHORIZED SIGNATORY

CONTD. ON NEXT PAGE.....

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- Analysed Food sample destroyed within one month. Analysed Packaged Drinking Water sample destroyed after 3 months.

ANNEXURE 5 (Contd...). CONTAMINANT ANALYSIS TEST REPORT OF BEDDING MATERIAL

INSTITUTE FOR ANALYSIS OF DAIRY, FOOD & CULTURES.
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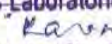
CERTIFICATE OF ANALYSIS

BOOKING NO. 0011
 CERTIFICATE NO. : 0011/2020-2021

NAME OF MANUFACTURER/PARTY :		BIONEEDS INDIA PRIVATE LIMITED Devarahosahalli, Sompura Hobali, Nelamangla Taluk, Bangalore Rural Dist, BANGALORE - 562111 KARNATAKA	
1.MFG. LIC. NO.	NM	4. OTHER REFERENCE NO	NM
2. REFERENCE NO.	NM	5. DATE OF RECEIPT	06/05/2020
3. DATE	06/05/2020	6. NAME OF SAMPLE	Paddy husk
7. DETAILS OF RAW MATERIAL / FINAL PRODUCTS (In Bulk/Finished Pack)			
(A) BATCH NO.	NM	(H) SEALED	Sealed
(B) BATCH SIZE	NM	(I) STARTING DATE	08/05/2020
(C) DATE OF MFG.	NM	(J) ENDING DATE :	19/05/2020
(D) DATE OF EXPIRY	NM	(K) BRAND NAME	NM
(E) SAMPLE QUANTITY	1 kg	(L) SAMPLING PROTOCOL	NA
(F) MFG NAME	NM	(M) DATE OF SAMPLING /SAMPLE COLLECTION	06/05/2020
(G) PACKING	Zip lock cover	(N) REPORT GEN. DATE	19/05/2020

SR	TEST NAME	UNIT	RESULT	SPECIFICATIONS	METHOD OF TEST
2	Nitrosodimethylamine	µg/kg	Not detected	-	AOAC 20th Edition 2016
--	--	--	-- End of Report --	--	--

Remarks : For IADFAC Laboratories Pvt. Ltd.
Accepted and released for use


 Authorised Signatory
 Karunakara A.C. (ID No-132)
 Senior Manager-Chemical
AUTHORISED SIGNATORY

21/05/2020

Note :

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4. Sample drawn and submitted by the party for Analysis unless otherwise stated.
5. Analysed Food sample destroyed within one month. Analysed Packaged Drinking Water sample destroyed after 3 months.

ANNEXURE 6. GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELLING OF CHEMICALS (GHS)

Acute Dermal Toxicity Classifications

Route	Category 1	Category 2	Category 3	Category 4	Category 5
Dermal (mg/kg body weight)	ATE \leq 50	50 < ATE \leq 200	200 < ATE \leq 1000	1000 < ATE \leq 2000	2000 < ATE \leq 5000

ATE: Acute Toxicity Estimate

Note:

- Criteria for Category 5 are intended to enable the identification of test item which are of relatively low acute toxicity hazard but which under certain circumstances may present a danger to vulnerable populations. These test items are anticipated to have on oral or dermal LD₅₀ in the range of 2000 to 5000 mg/kg bodyweight and equivalent doses for inhalation. The specific criteria for Category 5 are:
 - i) The test item is classified in this category if reliable evidence is already available that indicates the LD₅₀ to be in the range of Category 5 values or other animal studies or toxic effects in humans indicate a concern for human health of an acute nature.
 - ii) The test item is classified in this category, through extrapolation, estimation or measurement of data, if assignment to a more hazardous category is not warranted, and
 - Reliable information is available indicating significant toxic effects in humans; or
 - Any mortality is observed when tested up to Category 4 values by the oral, inhalation or dermal routes; or
 - Where expert judgment confirms significant clinical signs of toxicity, when tested up to Category 4 values, except for diarrhoea, piloerection or an ungroomed appearance; or
 - Where expert judgment confirms reliable information indicating the potential for significant acute effects from other animal studies.

ANNEXURE 7. GLP CERTIFICATE



**National Good Laboratory Practice (GLP) Compliance Monitoring Authority (NGCMA)
Department of Science and Technology
GOVERNMENT OF INDIA**

Certificate of GLP Compliance

This is to certify that

**Bionees India Private Limited
Devarahosahally, Sompura Hobli, Nelamangala Taluk
Bengaluru Rural District - 562111, Karnataka (India)**

is a GLP certified test facility in compliance with the NGCMA's Document No. GLP-101 "Terms & Conditions of NGCMA for obtaining and maintaining GLP certification by a test facility" and OECD Principles of GLP.

The test facility conducts the below-mentioned tests/ studies:

- **Physical-chemical Testing (Including Five Batch Analysis)**
- **Toxicity Studies**
- **Mutagenicity Studies**
- **Environmental Toxicity Studies on Aquatic and Terrestrial Organisms**
- **Studies on Behaviour in Water, Soil and Air; Bioaccumulation**
- **Residue Studies**
- **Analytical and Clinical Chemistry Testing**
- **Others**

The specific areas of expertise, test items and test systems are listed in the annexure overleaf.

Validity: September 23, 2020 – September 22, 2023

Certificate No. : GLP/C-153/2020
Issue Date : 13-10-2020



(Signature)
(Dr. Neeraj Sharma)
Head, NGCMA

ANNEXURE 7 (Contd...). GLP CERTIFICATE

National GLP Compliance Monitoring Authority (NGCMA)

Annexure to Certificate of GLP Compliance No. GLP/C-153/2020

Areas of Expertise:

- **Physical-chemical Testing (Including Five Batch Analysis)**

- **Toxicity Studies**

- o Acute Toxicity
- o Developmental and Reproductive Toxicity
- o Eye Irritation/ Corrosion (*in vitro* and *in vivo*)
- o Guinea Pig Maximization
- o Immunogenicity
- o Inhalation Toxicity
- o Local Lymph Node Assay (LLNA)
- o Local Tolerance
- o Neurotoxicity
- o Phototoxicity
- o Pyrogen Test
- o Repeated Dose Toxicity
- o Skin Irritation/ Corrosion (*in vitro* and *in vivo*)
- o Skin Sensitization (*in vitro* and *in vivo*)

- **Mutagenicity Studies**

- o 3T3 NRU Assay (*in vitro*)
- o Bacterial Reverse Mutation (AMES) Test
- o Cell Gene Mutation Test (*in vitro* and *in vivo*)
- o Chromosomal Aberration Test (*in vitro* and *in vivo*)
- o Comet Assay
- o Cytotoxicity (*in vitro*)
- o Micronucleus Test (*in vitro* and *in vivo*)
- o Mouse Lymphoma Assay (MLA)
- o MTT Assay

- **Environmental Toxicity Studies on Aquatic and Terrestrial Organisms**

- **Studies on Behaviour in Water, Soil and Air; bioaccumulation**

- **Residue Studies**

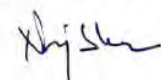
- **Analytical and Clinical Chemistry Testing**

- **Others**

- o ADME Studies
- o Bioanalysis
- o Biocompatibility Studies
- o Drug Metabolism & Pharmacokinetic (DMPK)
- o Hemocompatibility Studies
- o Implantation Studies
- o In chemico Skin Sensitization: Direct Peptide Reactivity Assay
- o Maximum Tolerated Dose (MTD) Studies
- o Method Development
- o Method Validation
- o Skin Absorption (*in vitro*)

Test Item(s): Agrochemicals, Cosmetics Products, Feed Additives, Food Additives, Industrial chemicals, Medical Devices (*Applicable only for Bio-compatibility, not applicable for Batch Release parameters required as per MDR, 2017*) and Pharmaceuticals (Human and Veterinary)

Test System(s): Algae, Bovine, Cell lines, Chicken, Collembolan, Crop plant seeds, Cyanobacteria, Daphnia, Diatoms, Earthworm, *E-Coli*, Fish, Guinea Pigs, Hamsters, Honeybees, Human Cavader Skin, Human Lymphocytes, Japanese quail, Lemna, Mallard duck, Mice, Pigeon, Predatory Mites, Rabbit, Rat, *Salmonella typhimurium*, Silkworm and Tissue Culture.

(Dr. Neeraj Sharma)
Head, NGCMA