

STUDY REPORT

Original: 1/2

STUDY TITLE

**SKIN SENSITISATION STUDY OF BIO-X KLEANZE EC IN GUINEA PIGS BY
BUEHLER TEST METHOD**

(As per "OECD Guideline No. 406: Skin Sensitisation")

STUDY No.: BIO-ATX 2831

Study Completion Date: 23 February 2021

SPONSOR

OKADA ECOTECH PTE LTD
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628557 SINGAPORE

TEST FACILITY

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CONFIDENTIAL

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QUALITY ASSURANCE STATEMENT

The Study No.: BIO-ATX 2831, entitled “Skin Sensitisation Study of Bio-X Kleanze EC in Guinea Pigs by Buehler Test Method” 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 | | | |
| 14 December 2020 | Study plan verification | 14 December 2020 | 14 December 2020 |
| 08 January 2021 | Study plan amendment no. 1 verification | 08 January 2021 | 08 January 2021 |
| In-Life Phase | | | |
| 29 December 2020 | Test item application - Induction I | 29 December 2020 | 29 December 2020 |
| Reporting Phase | | | |
| 11 February 2021 | Draft report inspection | 11 February 2021 | 11 February 2021 |
| 19 February 2021 | Final report inspection | 19 February 2021 | 19 February 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

23 February 2021
(Date)

STATEMENT OF GLP COMPLIANCE

The Study No.: BIO-ATX 2831, entitled “Skin Sensitisation Study of Bio-X Kleanze EC in Guinea Pigs by Buehler Test Method” 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

23 February 2021

(Date)

STATEMENT OF CONFIDENTIALITY

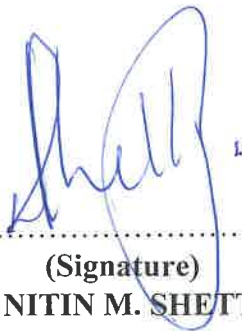
This report contains **CONFIDENTIAL** and **PROPRIETARY** information of **OKADA ECOTECH PTE LTD, SINGAPORE** and will not be disclosed to anyone without the expressed or written approval of sponsor, except to the employees of test facility wherever necessary and to persons authorized by law or judicial 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 |
| B | - Breadth |
| CPCSEA | - Committee for the Purpose of Control and Supervision of Experiments on Animals |
| cm | - Centimeter |
| Ery | - Erythema |
| GLP | - Good Laboratory Practice |
| GHS | - Globally Harmonized System of Classification and Labelling of Chemicals |
| Ede | - Oedema |
| g | - Gram |
| H | - Height |
| h/hr | - Hour |
| IAEC | - Institutional Animal Ethics Committee |
| kg | - Kilogram |
| LF | - Left Flank |
| L | - Length |
| min | - Minute |
| mg | - Milligram |
| mL | - Milliliter |
| n | - Number of Animals |
| NAD | - No Abnormality Detected |
| N | - Normal |
| OECD | - Organization for Economic Co-operation and Development |
| RF | - Right Flank |
| SD | - Standard Deviation |
| sq cm | - Square centimeter |
| TS | - Terminal Sacrifice |
| v/v | - Volume by volume |
| °C | - Degree Celsius |
| % | - Percentage |

1. STUDY DETAILS

- 1.1 Study Title** : Skin Sensitisation Study of Bio-X Kleanze EC in Guinea Pigs by Buehler Test Method
- 1.2 Study Number** : BIO-ATX 2831
- 1.3 Study Code** : SSG
- 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.

1.7 Study Schedule

| | | | |
|------------------------------|-----------------|---|--|
| Study Initiation Date | | : | 16 December 2020 |
| Experimental Starting Date | | : | 17 December 2020 |
| Pre Study | Acclimatization | : | Start: 17 December 2020 End: 21 December 2020 |
| | Treatment Date | : | 22 December 2020 |
| Main Study | Acclimatization | : | Start: 17 December 2020 End: 28 December 2020 |
| | Induction - I | : | 29 December 2020 |
| | Induction - II | : | 05 January 2021 |
| | Induction - III | : | 12 January 2021 |
| | Challenge | : | 26 January 2021 |
| Experimental Completion Date | | : | 29 January 2021 |
| Draft Report Submission Date | | : | 12 February 2021 |
| Study Completion Date | | : | 23 February 2021 |

2. SUMMARY

The study was conducted to evaluate the Skin Sensitisation potential of the test item Bio-X Kleanze EC in Guinea Pigs by Buehler Test Method.

The study was conducted in two phases viz., pre study and main study. For pre study, approximately 24 hours before treatment, fur from the right and left flank region was clipped closely using an electric hair clipper exposing an area of approximately 80 sq. cm. Care was taken to avoid abrasion on the skin. The dose of 25% v/v and 50% v/v of 80 dilutions of test item were applied topically to the anterior left flank (site 1) and posterior left flank (site 2), respectively, whereas 75% v/v and 100% v/v of 80 dilutions test item were applied topically to the anterior right flank (site 3) and posterior right flank (site 4) respectively to each pre study animals. No skin reactions and clinical signs were observed in any of the tested doses approximately at 24 and 48 hours observation period after patch removal.

In pre study (G1), no skin reactions were observed at the highest dose i.e. undiluted (80 dilutions) test item. Hence, both 80 dilutions (highest concentration) and 160 dilutions (lowest concentration) of test item was selected for induction and challenge phase of main study.

The main study comprised of three groups, G2 (Vehicle control), G3 (Treatment) and G4 (Treatment). The main study included three inductions on day 1, 8 and 15 and challenge on day 29. Approximately 24 hours prior to initiation of the treatment, fur from the left and right flank was clipped closely using an electric hair clipper exposing an area of approximately 80 sq. cm. for induction and challenge phase of the experiment, respectively.

On induction days 1, 8 and 15, 0.5 mL of distilled water, 0.5 mL of undiluted concentration of 80 dilutions and 0.5 mL of undiluted concentration of 160 dilutions test item were applied topically on the left flank of the G2, G3 and G4 group animals, respectively. On challenge day 29. In all animals 0.5 mL of distilled water applied to anterior part of right flank. Only in G2 group animals out of 10 animals 5 animals were treated with 0.5 mL undiluted test item of 80 dilutions and 5 animals treated with 0.5 mL of undiluted test item of 160 dilutions applied on posterior part of right flank and 0.5 mL of distilled water applied to anterior part of right flank. In G3 and G4 group 0.5 mL of undiluted test item of 80 dilutions and 160 dilutions were applied to posterior part of right flank respectively. The test patches were covered by approximately 4×6 cm² cotton gauze and held in place with non-irritating adhesive tape and wrapped with occlusive dressing using crepe bandage. After 6 hours of contact period, the test patches were removed, and the application sites were cleaned with normal saline swabs and dried. During induction phase, the test item application sites were observed for skin reactions approximately at 1 and 24 hours post removal of the test patches according to Draize method (1959), and during the challenge phase the skin reactions were observed approximately at 24 and 48 hours, post removal of the test patch, according to Magnusson and Kligman grading scale.

All the animals were observed once daily for clinical signs of toxicity and twice daily for mortality/morbidity during the experimental period. Individual animal body weight was recorded at receipt, on day 1 (before start of the treatment) and at termination for the pre study and main study.

In induction phase, no skin reactions were observed in vehicle control and treatment group animals approximately at 1 and 24 hours of observation period of post patch removal.

In challenge phase, the animals did not reveal any skin reactions at anterior and posterior part of right flank of vehicle control and treatment group animals approximately at 24 and 48 hours of post patch removal.

No clinical signs of toxicity and mortality were observed till termination. All the treated animals revealed physiologically normal increase in body weights during the observation period. All the surviving animals were sent back to Animal Facility after experiment completion.

Conclusion

Under the experimental conditions employed and based on the results of the experiment, it is concluded that Bio-X Kleanze EC did not show any Skin Sensitisation or allergic potential in Guinea pigs. Hence, the test item does not meet classification criteria according to the Globally Harmonized System (GHS) of Classification and Labelling of Chemicals.

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 OECD Guideline for Testing of Chemicals, Section 4, Number 406, “Skin Sensitisation”, adopted on 17 July 1992.

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) (Protocol No.: BIO-IAEC-4079 and Approval Date: 20/10/2020).

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 to produce Skin Sensitisation by Buehler Test Method in Dunkin Hartley Guinea pigs.

This also gives the details of classification and labelling of chemical for safety and risk assessment.

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 (Name and address) : Okada Ecotech Pte Ltd, Singapore
 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 sponsor is presented as Annexure 2.

6.2 Selection of Vehicle and Justification for Selection

The test item was miscible in distilled water. Hence, as per test guideline (OECD guideline No. 406) distilled water was used as a vehicle for both topical induction and challenge phase.

The details of distilled water used is given below:

Batch No. : 188B, D16, 258D, 198D, 251B
 Date of Manufacture : 10/12/2020, 29/12/2020, 18/01/2021, 10/12/2020, 21/11/2020
 Date of Expiry : 09/12/2021, 28/12/2021, 18/01/2022, 09/12/2021, 20/11/2021
 Manufactured by : Mysore Research Chemical Laboratories

6.3 Test System

Animal Species : Guinea Pig (*Cavia porcellus*)
Strain : Dunkin Hartley
Justification for Selection of Species : The Guinea pig has been the animal of choice for predictive sensitisation tests for several decades.
Source of Supply : Procured from approved breeder, Adita Biosys Private Limited
 Plot No.: SPL-26, 2nd Phase, KSSIDC Industrial Estate, Madhugiri Road, Antharasanahalli, Tumakuru-572106, Karnataka, India
No. of Groups : Pre Study : 1
 Main Study: 3
No. of Animals / Group and Sex : Pre-Study:
 G1 - 2 Females
 Main Study:
 G2 - 10 Females (Vehicle Control)
 G3, G4 -20 Females/group (Test Item)
 (Females used were nulliparous and non-pregnant)
Age at Receipt : 9 weeks
Body Weight Range at Receipt : 303.44 g to 328.79 g
Animal Identification : Acclimatization period: Cage cards
 Treatment period: Animal identification was done by writing last two digits of animal number on ear of guinea pig using black marker pen and cage cards.

6.4 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 19.5°C to 22.9°C, relative humidity 48% to 65%, with 12 hours light and 12 hours dark cycle. The temperature and relative humidity were recorded once daily.
- b. Housing** : Single animal was housed in a standard polypropylene cage (size: L 430 x B 280 x H 190 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. Clean sterilized paddy husk was provided as bedding material.
- c. Feed** : Altromin Diet for Guinea Pigs (manufactured by Altromin Spezialfutter GmbH & Co. KG) was provided *ad libitum* to the Guinea Pigs. 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 bottle with stainless steel sipper tubes.

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

6.5 Acclimatization

Healthy young adult animals were acclimatized for five days and twelve days to experimental room conditions prior to treatment for pre study and main study respectively, and were observed for clinical signs once daily. Veterinary examination of all the animals was performed on the day of receipt.

6.6 Grouping

The animals for the main study were weighed and arranged in an ascending order according to their body weights. These body weight stratified Guinea pigs were distributed to both the experimental groups using Microsoft excel spreadsheet such that body weight variation of animals selected for the experiment did not exceed $\pm 20\%$ (-3.96% to +3.93%) of the mean body weight. The animals are randomized and assigned to the treatment groups. The grouping was done one day prior to the initiation of treatments. Body weights of the animals were analyzed statistically for differences in mean body weights, in order to rule out any statistically significant differences between groups.

6.7 Study Design

6.7.1 Pre Study

The objective of the pre-study was to determine the appropriate concentrations of test item that was to be employed in the main study.

No skin reactions were observed at any of the test doses, hence the highest dose of the test item was selected for the induction and challenge phase of the main study.

| Group | Treatment | No. of Animals | Animal No. | Site of Exposure | Dose |
|-------|---------------------------------|----------------|-----------------|-------------------------------|--|
| G1 | Bio-X Kleanze EC (80 dilutions) | 2 | Gd4965 & Gd4966 | Anterior Part of Left Flank | 25 % v/v 80 dilutions Test Item in Distilled Water |
| | | | | Posterior Part of Left Flank | 50 % v/v 80 dilutions Test Item in Distilled Water |
| | | | | Anterior Part of Right Flank | 75 % v/v 80 dilutions Test Item in Distilled Water |
| | | | | Posterior Part of Right Flank | 100% v/v 80 dilutions test item |

6.7.2 Main Study

| Group | Treatment | No. of Animals | Animal No. | Day | Type of Treatment | Dose |
|-------------------------------|--|----------------|------------------|-----|-------------------|--|
| G2 | Vehicle Control | 5 | Gd4967 to Gc4971 | 1 | Induction - I | 0.5 mL of distilled water |
| | | | | 8 | Induction - II | 0.5 mL of distilled water |
| | | | | 15 | Induction - III | 0.5 mL of distilled water |
| | | | | 29 | Challenge | Anterior Part of Right Flank |
| Posterior Part of Right Flank | 0.5 mL of 100% v/v 80 dilutions test item | | | | | |
| G2 | Vehicle Control | 5 | Gd4972 to Gc4976 | 1 | Induction - I | 0.5 mL of distilled water |
| | | | | 8 | Induction - II | 0.5 mL of distilled water |
| | | | | 15 | Induction - III | 0.5 mL of distilled water |
| | | | | 29 | Challenge | Anterior Part of Right Flank |
| Posterior Part of Right Flank | 0.5 mL of 100% v/v 160 dilutions test item | | | | | |
| G3 | Bio-X Kleanze EC (80 dilutions) | 20 | Gd4977 to Gd4996 | 1 | Induction - I | 0.5 mL of 100% v/v 80 dilutions test item |
| | | | | 8 | Induction - II | 0.5 mL of 100% v/v 80 dilutions test item |
| | | | | 15 | Induction - III | 0.5 mL of 100% v/v 80 dilutions test item |
| | | | | 29 | Challenge | Anterior Part of Right Flank |
| Posterior Part of Right Flank | 0.5 mL of 100% v/v 80 dilutions test item | | | | | |
| G4 | Bio-X Kleanze EC (160 dilutions) | 20 | Gd4997 to Gd5016 | 1 | Induction - I | 0.5 mL of 100% v/v 160 dilutions test item |
| | | | | 8 | Induction - II | 0.5 mL of 100% v/v 160 dilutions test item |
| | | | | 15 | Induction - III | 0.5 mL of 100% v/v 160 dilutions test item |
| | | | | 29 | Challenge | Anterior Part of Right Flank |
| Posterior Part of Right Flank | 0.5 mL of 100% v/v 160 dilutions test item | | | | | |

The quantity of test item and volume prepared may vary depending on different intervals of the study. The preparation details were recorded in the raw data.

6.8 Positive Control Response Validation

The positive control was not included in this study as the reliability of the skin sensitisation was tested using 2-Mercaptobenzothiazole as a part of separate study. The positive control result is presented as Annexure 1.

6.9 Dose Selection and Justification for Selection

The animals did not revealed any skin reactions after application of undiluted (80 dilutions) test item at 24 hours and 48 hours after patch removal in the pre-study. Hence, undiluted (80 and 160 dilutions) test item was selected for induction and challenge phase of the main study.

6.10 Route of Application and Justification for Selection

The test item and vehicle were applied topically. The topical route was selected as it is one of the probable routes of exposure to humans.

6.11 Dose Formulation

Required quantity of test item was taken and made up with vehicle as per the doses of the pre study.

Dose concentrations prepared for pre study is indicated in the following table:

| Treatment | Test Concentration* (v/v) 80 dilutions | Quantity of Test Item(mL) | Volume of Vehicle Added (mL) |
|---------------------|---|---------------------------|------------------------------|
| Topical Application | 25% | 0.5 | 1.5 |
| | 50% | 1.0 | 1.0 |
| | 75% | 1.5 | 0.5 |
| | Undiluted test item | 2.0 | - |

*: Test concentration means the concentration of test item in the prepared formulations.

6.12 Preparation of Animals

Approximately 24 hours before treatment, for induction and challenge phase, the fur from the left flank region and right flank region of the Guinea pigs was closely clipped using an electric hair clipper respectively, exposing an area of approximately 80 sq. cm. Care was taken to avoid abrasion to the skin.

6.13 Application of Test Item

The undiluted test item was applied on to the pre-clipped area of the skin. Approximately 4×6 cm² of cotton gauze was covered on the applied area of the skin and held in place with non-irritating adhesive tape. The whole area was wrapped with a suitable occlusive dressing (crepe bandage) for the duration of the exposure period in order to avoid the animal accessing the patch and their ingestion or inhalation of the test item. The test patch was held in its position for 6 hours, after which the test patches were removed, and the area was cleaned with normal saline swabs and dried with cotton.

The details of normal saline used is given below:

Batch No. : 1G03401
 Date of Manufacture : 07/2020
 Date of Expiry : 06/2023
 Manufactured by : Aculife Healthcare Private Ltd.

6.14 Treatment

6.14.1 Pre Study

The test item was made up with the required quantity of distilled water and applied topically to the pre-clipped area of the pre study animals, at four different sites as per section 6.7.1. The test item application, patch removal and cleaning procedure were done as per the 6.13.

6.14.2 Main Study

The main study comprised of two phases, viz,

- i) Induction
- ii) Challenge

i) Induction

In the induction phase, 0.5 mL of 80 dilutions test item was applied topically on days 1, 8 and 15 on the left flank region for G3 group animals.

In the induction phase, 0.5 mL of 160 dilutions test item was applied topically on days 1, 8 and 15 on the left flank region for G4 group animals

Approximately, 24 hours before at each treatment, fur from the application site (left flank) was closely clipped as per the section 6.12 in both vehicle control and treatment group animals. For vehicle control and treatment group (G2 and G3) animals, 0.5 mL of distilled water and 0.5 mL of undiluted test item were applied respectively on to the pre-clipped area (left flank) and covered by approximately 4×6 cm² cotton gauze patch. The test item application, patch removal and cleaning procedure were done as per the section 6.13.

ii) Challenge

Approximately 24 hours before the application of the test item, the untreated right flank of the Guinea pigs was clipped closely as per section 6.12. Both vehicle control and treatment group (G2, G3 & G4) animals were challenged on Day 29. The highest non-irritable concentration, undiluted test item, was selected from the pre study results. 0.5 mL of 80 and 160 dilutions test item and 0.5 mL of distilled water was applied to the posterior and anterior part of the right flank region, respectively. The test patch was covered by approximately 4×6 cm² cotton gauze and held in place with non-irritating adhesive tape and crepe bandage. The test patch was kept in contact with the skin for a period of 6 hours, after completion of the exposure period, the patches were removed, and the area was cleaned with normal saline swabs and dried.

The application sites of the skin were examined approximately at 3 hours (i.e., 30 hours after challenge application) for skin reactions and were scored using Magnusson and Kligman grading scale.

The application sites of the skin were observed again at 48 hours (54 hours after the challenge application) in order to confirm the previous days observations. All the observations were recorded.

Magnusson and Kligman Grading Scale for the Evaluation of Challenge Patch Test Reactions are as follows:

- 0 = no visible changes
- 1 = discrete or patchy erythema
- 2 = moderate and confluent erythema
- 3 = intense erythema and swelling

iii) Re-challenge: Topical Application

Re-challenge was not performed as there were no ambiguous scores obtained from the challenge phase treatment.

6.15 Observations

The following observations were made during experimental period.

6.15.1 Clinical Signs of Toxicity and Mortality

All the animals were observed once daily for clinical signs of toxicity and twice daily for mortality/morbidity during the experimental period.

6.15.2 Skin Reactions Scoring

a) Pre Study

The skin reactions were observed approximately at 24 and 48 hours post removal of the test patch. The skin reactions were scored and recorded according to Draize method (1959).

Evaluation of Skin Reactions - Draize method

| | |
|--|--------------|
| 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 slight eschar formation (injuries in depth)..... | 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 raising)..... | 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 |

b) Main Study

I) Induction

The skin reactions were scored approximately at 1 and 24 hours post removal of the test patch after induction (topical application). The skin reactions were observed and recorded according to Draize method (1959).

II) Challenge

The skin reactions were scored approximately at 24 and 48 hours post removal of the test patch after challenge application. The skin reactions were observed and recorded according to Magnusson and Kligman grading scale.

Note: After completion of the experiment, all the surviving animals were sent back to Animal Facility.

6.15.3 Body Weight

Individual animal body weight was recorded at receipt, on day 1 (before start of the treatment) and at termination (day 32) for the pre study and main study animals.

7. STUDY REPORT PREPARATION AND RESULTS

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

8. INTERPRETATION OF RESULTS

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

9. AMENDMENTS AND DEVIATIONS

One Amendment was raised to correct the name of Monitoring Scientist as per revised Test Item Data Sheet.

No deviations occurred during the conduct of the study.

10. STUDY REPORT DISTRIBUTION

Original: 1/2 - Sponsor

Original: 2/2 - Archives, Bionees 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 Bionees 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. REFERENCES

- Draize J H, Dermal toxicity. Assoc. Food and Drug Officials, U.S. Appraisal of the Safety of Chemicals in Food, Drugs and Cosmetics, Texas State Dept. of Health, Austin, Texas 1959: 46–59.
- 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 clinical signs of toxicity and mortality were observed in both the pre study and main study animals.

Refer to Tables 1 and 2

13.2 Skin Reactions Scoring

No erythema and oedema were observed in G1 group animals in any of the applied test concentrations approximately at 24 and 48 hours after patch removal in pre study.

No erythema and oedema were observed in both the vehicle control (G2) and treatment group (G3 and G4) animals in induction phase approximately at 1 and 24 hours observations after patch removal in main study.

No skin reactions were observed in both the vehicle control (G2) and treatment group (G3 and G4) approximately at 24 hours and 48 hours observations after patch removal of challenge application in main study.

Refer to Tables 3 and 4

13.3 Body Weight

The animals did not reveal any treatment related changes in body weight and percent body weight change with respect to day 1. All animals showed physiologically normal increase in body weights.

Refer to Tables 5 and 6

14. CONCLUSION

Under the experimental conditions employed and based on the results of the experiment, it is concluded that Bio-X Kleanze EC did not show any Skin Sensitisation or allergic potential in Guinea pigs. Hence, the test item does not meet classification criteria according to the Globally Harmonized System (GHS) of Classification and Labelling of Chemicals.

15. TABLES

TABLE 1. CLINICAL SIGNS OF TOXICITY AND MORTALITY RECORD DURING PRE STUDY

| Group, Sex & Treatment | Animal No. | Clinical Signs of Toxicity and Mortality on Days | | | |
|-------------------------------|------------|--|---|---|---|
| | | 1 | 2 | 3 | 4 |
| G1, Female & Bio-X Kleanze EC | Gd4965 | N | N | N | N |
| | Gd4966 | N | N | N | N |

N: Normal

TABLE 2. CLINICAL SIGNS OF TOXICITY AND MORTALITY RECORD DURING MAIN STUDY

| Group, Sex & Treatment | Animal No. | Clinical Signs of Toxicity and Mortality on Day | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|------------|---|---|---|---|---|---|---|---|---|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|---|
| | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 | 32 | |
| G2, Female & Vehicle Control | Gb4967 | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N |
| | Gb4968 | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N |
| | Gb4969 | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N |
| | Gb4970 | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N |
| | Gb4971 | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N |
| | Gb4972 | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N |
| | Gb4973 | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N |
| | Gb4974 | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N |
| | Gb4975 | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N |
| | Gb4976 | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N |

N: Normal

TABLE 2 (Contd...). CLINICAL SIGNS OF TOXICITY AND MORTALITY RECORD DURING MAIN STUDY

| Group, Sex & Treatment | Animal No. | Clinical Signs of Toxicity and Mortality on Day | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|------------|---|---|---|---|---|---|---|---|---|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|---|---|---|---|---|---|
| | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 | 32 | | | | | | |
| G3, Female & Bio-X Kleanze EC (80 dilutions) | Gd4977 | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | | | | | |
| | Gd4978 | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | | | | |
| | Gd4979 | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | | | | |
| | Gd4980 | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | | | |
| | Gd4981 | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | | | |
| | Gd4982 | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | | | |
| | Gd4983 | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | | | |
| | Gd4984 | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | | |
| | Gd4985 | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | | |
| | Gd4986 | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | | |
| | Gd4987 | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | |
| | Gd4988 | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | |
| | Gd4989 | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | |
| | Gd4990 | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | |
| | Gd4991 | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | |
| | Gd4992 | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | |
| | Gd4993 | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | |
| | Gd4994 | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N |
| | Gd4995 | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N |
| | Gd4996 | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N |

N: Normal

TABLE 2 (Contd...). CLINICAL SIGNS OF TOXICITY AND MORTALITY RECORD DURING MAIN STUDY

| Group, Sex & Treatment | Animal No. | Clinical Signs of Toxicity and Mortality on Day | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|------------|---|---|---|---|---|---|---|---|---|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|---|
| | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 | 32 | |
| G4, Female & Bio-X Kleanze EC (160 dilutions) | Gd4997 | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | |
| | Gd4998 | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N |
| | Gd4999 | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N |
| | Gd5000 | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N |
| | Gd5001 | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N |
| | Gd5002 | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N |
| | Gd5003 | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N |
| | Gd5004 | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N |
| | Gd5005 | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N |
| | Gd5006 | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N |
| | Gd5007 | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N |
| | Gd5008 | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N |
| | Gd5009 | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N |
| | Gd5010 | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N |
| | Gd5011 | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N |
| | Gd5012 | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N |
| | Gd5013 | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N |
| | Gd5014 | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N |
| Gd5015 | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | |
| Gd5016 | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | |

N: Normal

TABLE 3. SKIN REACTIONS SCORING RECORD DURING PRE STUDY

| Group, Sex & Treatment | Animal No. | Site | Dose (%v/v) | 24 hours* | | 48 hours* | |
|-------------------------------|------------|------|-------------|-----------|-----|-----------|-----|
| | | | | Ery | Ede | Ery | Ede |
| G1, Female & Bio-X Kleanze EC | Gd4965 | ALF | 25 | 0 | 0 | 0 | 0 |
| | | PLF | 50 | 0 | 0 | 0 | 0 |
| | | ARF | 75 | 0 | 0 | 0 | 0 |
| | | PRF | 100 | 0 | 0 | 0 | 0 |
| | Gd4966 | ALF | 25 | 0 | 0 | 0 | 0 |
| | | PLF | 50 | 0 | 0 | 0 | 0 |
| | | ARF | 75 | 0 | 0 | 0 | 0 |
| | | PRF | 100 | 0 | 0 | 0 | 0 |

Ery: Erythema; Ede: Oedema; ALF: Anterior Left Flank; PLF: Posterior Left Flank; ARF: Anterior Right Flank; PRF: Posterior Right Flank; 0: No erythema/No oedema

*: Observation time points after removal of the test patch

TABLE 4. SKIN REACTIONS SCORING RECORD DURING MAIN STUDY

| Group, Sex & Treatment | Animal No. | Induction Phase | | | | | | | | | | | | Challenge Phase | | | | Sensitisation Rate (%) | |
|------------------------------|------------|----------------------------------|-----|---------|-----|----------------------------------|-----|---------|-----|----------------------------------|-----|---------|-----|-----------------------------------|----------------|----------------|----------------|------------------------|---|
| | | Induction I - Day 1 | | | | Induction II - Day 8 | | | | Induction III - Day 15 | | | | Day 29 | | | | | |
| | | Skin Reaction Score (Left Flank) | | | | Skin Reaction Score (Left Flank) | | | | Skin Reaction Score (Left Flank) | | | | Skin Reaction Score (Right Flank) | | | | | |
| | | 1 hr* | | 24 hrs* | | 1 hr* | | 24 hrs* | | 1 hr* | | 24 hrs* | | 24 hrs* | | 48 hrs* | | | |
| Ery | Ede | Ery | Ede | Ery | Ede | Ery | Ede | Ery | Ede | Ery | Ede | Ery | Ede | Post | Ant | Post | Ant | | |
| G2, Female & Vehicle Control | Gd4967 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 [#] | 0 | 0 [#] | 0 | 0 |
| | Gd4968 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 [#] | 0 | 0 [#] | 0 | |
| | Gd4969 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 [#] | 0 | 0 [#] | 0 | |
| | Gd4970 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 [#] | 0 | 0 [#] | 0 | |
| | Gd4971 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 [#] | 0 | 0 [#] | 0 | |
| G2, Female & Vehicle Control | Gd4972 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 [@] | 0 | 0 [@] | 0 | | |
| | Gd4973 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 [@] | 0 | 0 [@] | 0 | | |
| | Gd4974 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 [@] | 0 | 0 [@] | 0 | | |
| | Gd4975 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 [@] | 0 | 0 [@] | 0 | | |
| | Gd4976 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 [@] | 0 | 0 [@] | 0 | | |

Ery: Erythema; Ede: Oedema; hr(s): Hour(s); 0: No Erythema/Oedema; Post: Posterior part (test item); Ant: Anterior part (vehicle control); 0: No visible change for challenge scoring

*: Observation time points after removal of the test patch.

#: 80 dilutions

@: 160 dilutions

TABLE 4 (Contd...). SKIN REACTIONS SCORING RECORD DURING MAIN STUDY

| Group, Sex & Treatment | Animal No. | Induction Phase | | | | | | | | | | | | Challenge Phase | | | | Sensitisation Rate (%) | |
|--|------------|----------------------------------|---|----------------------------------|---|----------------------------------|---|-----------------------------------|---|-----------------------------------|---|-----------------------------------|---|-----------------------------------|---|---------|---|------------------------|---|
| | | Induction I - Day 1 | | | | Induction II - Day 8 | | | | Induction III - Day 15 | | | | Day 29 | | | | | |
| | | Skin Reaction Score (Left Flank) | | Skin Reaction Score (Left Flank) | | Skin Reaction Score (Left Flank) | | Skin Reaction Score (Right Flank) | | Skin Reaction Score (Right Flank) | | Skin Reaction Score (Right Flank) | | Skin Reaction Score (Right Flank) | | | | | |
| | | 1 hr* | | 24 hrs* | | 1 hr* | | 24 hrs* | | 1 hr* | | 24 hrs* | | 24 hrs* | | 48 hrs* | | | |
| Ery | | Ede | | Ery | | Ede | | Ery | | Ede | | Ery | | Ede | | Post | | Ant | |
| | Gd4977 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Gd4978 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Gd4979 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Gd4980 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Gd4981 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Gd4982 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Gd4983 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Gd4984 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Gd4985 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| G3, Female & Bio-X Kleanze EC (80 dilutions) | Gd4986 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Gd4987 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Gd4988 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Gd4989 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Gd4990 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Gd4991 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Gd4992 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Gd4993 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Gd4994 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Gd4995 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Gd4996 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

Ery: Erythema; Ede: Oedema; hr(s): Hour(s); 0: No Erythema/Edema; Post: Posterior part (test item); Ant: Anterior part (vehicle control); 0: No visible change for challenge scoring

*: Observation time points after removal of the test patch.

TABLE 4 (Contd...). SKIN REACTIONS SCORING RECORD DURING MAIN STUDY

| Group, Sex & Treatment | Animal No. | Induction Phase | | | | | | | | | | | | Challenge Phase | | | | Sensitisation Rate (%) | |
|---|------------|----------------------------------|---|----------------------------------|---|----------------------------------|---|-----------------------------------|---|-----------------------------------|---|-----------------------------------|---|-----------------------------------|---|---------|---|------------------------|---|
| | | Induction I - Day 1 | | | | Induction II - Day 8 | | | | Induction III - Day 15 | | | | Day 29 | | | | | |
| | | Skin Reaction Score (Left Flank) | | Skin Reaction Score (Left Flank) | | Skin Reaction Score (Left Flank) | | Skin Reaction Score (Right Flank) | | Skin Reaction Score (Right Flank) | | Skin Reaction Score (Right Flank) | | Skin Reaction Score (Right Flank) | | | | | |
| | | 1 hr* | | 24 hrs* | | 1 hr* | | 24 hrs* | | 1 hr* | | 24 hrs* | | 24 hrs* | | 48 hrs* | | | |
| Ery | | Ede | | Ery | | Ede | | Ery | | Ede | | Ery | | Ede | | Post | | Ant | |
| G4, Female & Bio-X Kleanze EC (160 dilutions) | Gd4997 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Gd4998 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Gd4999 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Gd5000 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Gd5001 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Gd5002 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Gd5003 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Gd5004 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Gd5005 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Gd5006 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Gd5007 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Gd5008 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Gd5009 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Gd5010 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Gd5011 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Gd5012 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Gd5013 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Gd5014 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Gd5015 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Gd5016 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |

Ery: Erythema; Ede: Oedema; hr(s): Hour(s); 0: No Erythema/Edema; Post: Posterior part (test item); Ant: Anterior part (vehicle control); 0: No visible change for challenge scoring

*: Observation time points after removal of the test patch.

TABLE 5. BODY WEIGHT (g) AND PERCENT CHANGE IN BODY WEIGHT WITH RESPECT TO DAY 1 DURING PRE STUDY

| Group, Sex & Treatment | Animal No. | Body Weight (g) on Day | | Percent Change in Body Weight with Respect to Day 1 to 4 |
|-------------------------------|-------------|------------------------|---------------|--|
| | | 1 | 4 | |
| G1, Female & Bio-X Kleanze EC | Gd4965 | 315.31 | 328.91 | 4.31 |
| | Gd4966 | 316.09 | 330.42 | 4.53 |
| | Mean | 315.70 | 329.67 | 4.42 |
| | ±SD | 0.55 | 1.07 | 0.16 |

SD: Standard Deviation

TABLE 6. BODY WEIGHT (g) AND PERCENT CHANGE IN BODY WEIGHT WITH RESPECT TO DAY 1 DURING MAIN STUDY

| Group, Sex & Treatment | Animal No. | Body Weight (g) on Day | | Percent Change in Body Weight with Respect to Day |
|--|---------------|------------------------|---------------|---|
| | | 1 | 32 | 1 to 32 |
| G2, Female & Vehicle Control (80 dilutions) | Gd4967 | 315.81 | 392.78 | 24.37 |
| | Gd4968 | 321.62 | 405.91 | 26.21 |
| | Gd4969 | 325.11 | 411.54 | 26.58 |
| | Gd4970 | 327.01 | 415.82 | 27.16 |
| | Gd4971 | 327.48 | 417.47 | 27.48 |
| | Mean | 323.41 | 408.70 | 26.36 |
| ±SD | 4.83 | 9.96 | 1.22 | |
| G2, Female & Vehicle Control (160 dilutions) | Gd4972 | 329.48 | 422.69 | 28.29 |
| | Gd4973 | 330.32 | 426.10 | 29.00 |
| | Gd4974 | 331.15 | 428.76 | 29.48 |
| | Gd4975 | 334.19 | 430.82 | 28.91 |
| | Gd4976 | 336.64 | 432.94 | 28.61 |
| | Mean | 332.36 | 428.26 | 28.86 |
| ±SD | 2.98 | 4.01 | 0.44 | |
| G3, Female & Bio-X Kleanze EC (80 dilutions) | Gd4977 | 318.42 | 400.48 | 25.77 |
| | Gd4978 | 320.92 | 410.51 | 27.92 |
| | Gd4979 | 321.84 | 412.64 | 28.21 |
| | Gd4980 | 322.13 | 411.19 | 27.65 |
| | Gd4981 | 325.96 | 414.37 | 27.12 |
| | Gd4982 | 326.84 | 418.56 | 28.06 |
| | Gd4983 | 327.42 | 420.88 | 28.54 |
| | Gd4984 | 328.19 | 422.91 | 28.86 |
| | Gd4985 | 329.81 | 424.57 | 28.73 |
| | Gd4986 | 328.36 | 426.18 | 29.79 |
| | Gd4987 | 329.15 | 430.93 | 30.92 |
| | Gd4988 | 330.19 | 428.47 | 29.76 |
| | Gd4989 | 330.54 | 429.83 | 30.04 |
| | Gd4990 | 331.72 | 430.49 | 29.78 |
| | Gd4991 | 332.86 | 427.86 | 28.54 |
| | Gd4992 | 334.19 | 428.37 | 28.18 |
| Gd4993 | 335.03 | 430.19 | 28.40 | |
| Gd4994 | 334.98 | 426.88 | 27.43 | |
| Gd4995 | 339.56 | 428.57 | 26.21 | |
| Gd4996 | 340.13 | 431.16 | 26.76 | |
| Mean | 329.41 | 422.75 | 28.33 | |
| ±SD | 5.85 | 8.68 | 1.32 | |

SD: Standard Deviation

TABLE 6 (Contd...). BODY WEIGHT (g) AND PERCENT CHANGE IN BODY WEIGHT WITH RESPECT TO DAY 1 DURING MAIN STUDY

| Group, Sex & Treatment | Animal No. | Body Weight (g) on Day | | Percent Change in Body Weight with Respect to Day |
|---|-------------|------------------------|---------------|---|
| | | 1 | 32 | 1 to 32 |
| G4, Female & Bio-X Kleanze EC (160 dilutions) | Gd4997 | 319.18 | 396.59 | 24.25 |
| | Gd4998 | 320.91 | 400.64 | 24.84 |
| | Gd4999 | 321.48 | 402.87 | 25.32 |
| | Gd5000 | 323.16 | 408.91 | 26.53 |
| | Gd5001 | 324.64 | 411.11 | 26.64 |
| | Gd5002 | 326.32 | 412.47 | 26.40 |
| | Gd5003 | 326.98 | 414.86 | 26.88 |
| | Gd5004 | 327.11 | 416.91 | 27.45 |
| | Gd5005 | 328.28 | 418.38 | 27.45 |
| | Gd5006 | 329.36 | 418.57 | 27.09 |
| | Gd5007 | 330.14 | 423.89 | 28.40 |
| | Gd5008 | 329.29 | 420.19 | 27.60 |
| | Gd5009 | 331.53 | 424.82 | 28.14 |
| | Gd5010 | 332.61 | 423.67 | 27.38 |
| | Gd5011 | 331.83 | 425.59 | 28.26 |
| | Gd5012 | 333.19 | 421.37 | 26.47 |
| Gd5013 | 334.86 | 422.92 | 26.30 | |
| Gd5014 | 335.19 | 424.66 | 26.69 | |
| Gd5015 | 336.82 | 427.17 | 26.82 | |
| Gd5016 | 341.43 | 430.58 | 26.11 | |
| | Mean | 329.22 | 417.31 | 26.75 |
| | ±SD | 5.72 | 9.32 | 1.07 |

SD: Standard Deviation

16. ANNEXURES

ANNEXURE 1. SUMMARY REPORT OF POSITIVE CONTROL



ANNEXURE 1. SUMMARY REPORT

The positive control was tested according to Buehler Test Method in Dunkin Hartley Guinea pigs under Study No.: BIO-ATX 2408, to evaluate the sensitivity and reliability of the experimental technique used for the study by using a known sensitizer, 2-Mercaptobenzothiazole 97% as suggested by OECD Guideline No. 406. The study was conducted during 16 October 2020 to 28 November 2020.

In induction phase, 100% of 2-Mercaptobenzothiazole 97% (2-MBT) was applied since it was the minimal irritant concentration and in challenge phase, 75% of 2-MBT was applied as it was the highest non-irritant concentration in pre-study.

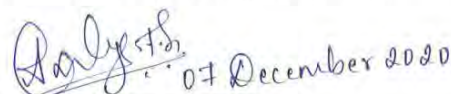
In induction phase, skin reactions like very slight erythema (barely perceptible) to no erythema was observed at the treated site of treatment group (G3) animals on day 1, 8 and 15 approximately at 1 and 24 hours of observation period of post patch removal. However, vehicle control group (G2) animals did not show any skin reaction on day 1, 8 and 15 approximately at 1 and 24 hours of observation period of post patch removal. The skin reactions were scored as per Draize Method (1959).

At challenge phase, the skin reactions like discrete or patchy erythema to no erythema was observed at posterior part of right flank of 2-MBT application site in 15/20 animals (i.e. 75%) approximately at 24 hours and 12/20 animals (i.e. 60%) approximately at 48 hours post patch removal, the mean sensitization rate was 67.5%. However, no skin reactions were observed in all the animals at anterior part of right flank of vehicle control application site. The skin reactions were scored according to Magnusson and Kligman grading scale.

| | | Scoring Details | | | | | | | | | | |
|-----------------------------|--------|---|------|-------|------|-------|------|--|------------------------|--------------|--------|--------|
| Species: Guinea pig | | Strain: Dunkin Hartley | | | | | | Sex: Female | | | | |
| | | Induction Phase | | | | | | Challenge Phase | | | | |
| | | Dose: 100 mg test item moistened with 0.1 mL of 80% ethanol/water | | | | | | Dose: 75 mg test item moistened with 0.1 mL of acetone | | | | |
| Group | Days | 1 | | 8 | | 15 | | 29 | Sensitization Rate (%) | | | |
| | Obsn* | ERY | EDE | ERY | EDE | ERY | EDE | | Post. Rt. FL. | Ant. Rt. FL. | 24 hrs | 48 hrs |
| Vehicle Control (n=10) | 1 hr | 0/10 | 0/10 | 0/10 | 0/10 | 0/10 | 0/10 | - | - | | | |
| | 24 hrs | 0/10 | 0/10 | 0/10 | 0/10 | 0/10 | 0/10 | 0/10 | 0/10 | | | |
| | 48 hrs | - | - | - | - | - | - | 0/10 | 0/10 | 75 | 60 | |
| Treatment (n=20) | 1 hr | 16/20 | 0/20 | 15/20 | 0/20 | 16/20 | 0/20 | - | - | | | |
| | 24 hrs | 11/20 | 0/20 | 10/20 | 0/20 | 12/20 | 0/20 | 15/20 | 0/20 | | | |
| | 48 hrs | - | - | - | - | - | - | 12/20 | 0/20 | | | |
| Mean Sensitization Rate (%) | | | | | | | | | | 67.5 | | |

n: Number of animals; Obsn: Observation; hr/hrs: Hour/Hours; ERY: Erythema; EDE: Oedema; Post: Posterior (treatment), Ant: Anterior (Control); Rt.: Right; FL.: Flank; *: Observation after patch removal
 Note: Vehicle: 80% ethanol/water for induction phase and acetone for challenge phase
 Treatment: 2-Mercaptobenzothiazole 97%

Conclusion: Based on the above results of the experiment and under experimental conditions employed, it is concluded that “2-Mercaptobenzothiazole - 97%” showed a mean skin sensitisation rate of 67.5% in challenge phase. Hence, the test item is classified as a “Sensitizer (Sub-category 1A)” according to the Globally Harmonized System (GHS) of classification and labelling of chemicals.



Ms. AMULYA T. S.
Study Director


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 - 72-1 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 | |
|  | |
| <h2>Producer Certificate</h2> | |
| Description | 3023 Maintenance diet for guineapigs |
| Customer | ATNT Laboratories, India |
| Batch no. / Lot no. | 202003040700 |
| Production date | 04.03.2020 |
| Expiry date | 04.03.2021 |
| 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 | |
| Chlorpyrifos-methyl | < 0.100 mg/kg |
| 2-Phenylphenol | < 0.100 mg/kg |
| Diphenylamin | < 0.050 mg/kg |
| Ethoxyquin | < 5.000 mg/kg |
| Folpet | < 1.000 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 |
| <i>Accepted and released for use 04.08.20</i> Date: April 08th 2020 | |
| Hans-Leopold Altrogge (Quality Manager) | |
| <small>This is a computer printed and has (possibly not been signed) and dated by hand</small> | |

ANNEXURE 3 (Contd...). 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 Guinea pigs |
| Type | 3023 4mm-pellets, 12,5kg double plastic bags |
| Customer | ATNT Laboratories, India |
| Batch no. / Lot no. | 202003040700 |
| Order no. | Altromin Doc. No. 47764 |
| Production date | 04.03.2020 |
| Expiry date | 04.03.2021 |

Guaranteed nutritional values

| % in air-dry substance | Value* | Tolerance** |
|------------------------------|--------|-------------|
| Crude protein | 18,0 | 15,8 – 20,3 |
| Crude fat | 4,4 | 3,4 – 6,4 |
| Crude fibre | 14,5 | 12,0 – 17,0 |
| Crude ash | 8,8 | 6,6 – 9,9 |
| Moisture | 11,6 | < 12,7 |
| NfE - Nitrogen free extracts | 42,7 | |
| Calcium | 0,9 | 0,6 – 1,5 |
| Phosphorus | 0,5 | 0,2 – 0,8 |

* 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

Physical analysis

| | |
|---|----|
| Pellet hardness kg/cm ² - Kahl | 12 |
|---|----|

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.

Accepted and released for use 05/05/20
Date: April 08th 2020

Hans-Leopold Altrogge
QA-Manager

This is a computer printout and has therefore not been signed and dated by hand

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/bd@iadfac.com/qa@iadfac.com

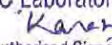
CERTIFICATE OF ANALYSIS

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 |
|----|--|------|-----------|------------------|-------------------|--------------------------------|
| 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 | - | 8.6 | 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-28) : 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 |

| | | |
|---|--|---|
| Remarks : <i>Accepted and released for use on 21/05/2020</i> | For IADFAC Laboratories Pvt. Ltd,  Authorised Signatory Karunakara A.C. (ID No-132) Senior Manager-Chemical | CONTD. ON NEXT PAGE..... _____ AUTHORISED SIGNATORY |
|---|--|---|

Note :

1. The results listed, refer only to the samples analysed & applicable parameters, Endorsement products is neither inferred nor implied.
2. Total liability of our institute is limited to the invoiced amount.
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
 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/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 Hoballi, 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 |

| | | |
|--|--|---|
| Remarks : <i>Accepted and released for use @ 21/05/2020</i> | For IADFAC Laboratories Pvt. Ltd.  Authorised Signatory Karunakara A.C. (ID No-132) Senior Manager-Chemical | CONTD. ON NEXT PAGE..... _____ AUTHORISED SIGNATORY |
|--|--|---|

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- Sample drawn and submitted by the party for Analysis unless otherwise stated.
- 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
 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/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 use @ 21/05/2020 For IADFAC Laboratories Pvt. Ltd.
 Karunakara A.C. (ID No-132)
 Senior Manager-Chemical

AUTHORISED SIGNATORY

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

ANNEXURE 5. CONTAMINANT ANALYSIS TEST REPORT OF BEDDING MATERIAL



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

| | | | |
|--|----------------|--|------------|
| NAME OF MANUFACTURER/PARTY : | | BIONEEDS INDIA PRIVATE LIMITED | |
| | | 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 | 06/05/2020 |
| (G) PACKING | Zip lock cover | (N) REPORT GEN. DATE | 19/05/2020 |

| SR | TEST NAME | UNIT | RESULT | SPECIFICATIONS | METHOD OF TEST |
|----|-----------------------------|-------|--------------|----------------|------------------------|
| 1 | 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*

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

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- Sample drawn and submitted by the party for Analysis unless otherwise stated.
- 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.
 #8, Siddhi Vinayaka Complex, Nagarabhavi 2nd Stage, 2nd Block
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| | | Devarahasahalli, 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 | 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 | Chlorpyiphos (-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 : For IADFAC Laboratories Pvt. Ltd.
Kare
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Authorised Signatory
 Karunakara A.C. (ID No-132)
 Senior Manager, Chemical
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 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



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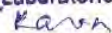
| | | | |
|--|----------------|---|------------|
| NAME OF MANUFACTURER/PARTY : | | BIONEEDS INDIA PRIVATE LIMITED | |
| | | Devarahosahalli, Sompura Hobali, Nelamangla Taluk, Bangalore Rural Dist, BANGALORE - 562111 KARNATAKA | |
| 1. MFG. LIC. NO. | NM | 4. OTHER REFERENCE NO | NM |
| 2. REFERENCE 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 | 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 :

Accepted and released for use
 21/05/2020

For IADFAC Laboratories Pvt. Ltd.


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

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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)**

Skin Sensitisation (Buehler Assay)

| Categories | Skin Sensitiser |
|------------------------|--|
| Category 1 | A response of at least 15 % of the animals is considered positive |
| Sub-category 1A | $\geq 15\%$ responding at $\leq 0.2\%$ topical induction dose or $\geq 60\%$ responding at $>0.2\%$ to $\leq 20\%$ topical induction dose |
| Sub-category 1B | $\geq 15\%$ to $<60\%$ responding $>0.2\%$ to $\leq 20\%$ topical induction dose or $\geq 15\%$ responding at $>20\%$ topical induction dose |

Note:

Sub-category 1A: Substances showing a high frequency of occurrence in humans and/or a high potency in animals can be presumed to have the potential to produce significant Sensitisation in humans. Severity of reaction may also be considered.

Sub-category 1B: Substances showing a low to moderate frequency of occurrence in humans and/or a low to moderate potency in animals can be presumed to have the potential to produce Sensitisation in humans. Severity of reaction may also be considered.

ANNEXURE 7. GLP CERTIFICATE



सत्यमेव जयते

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





(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**

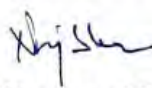
- **Others**

- 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