FINAL STUDY REPORT

STUDY TITLE

INTRACUTANEOUS REACTIVITY TEST OF POLAR AND NON-POLAR EXTRACTS OF SPUN MELT PP NONWOVEN FABRIC IN NEW ZEALAND WHITE RABBITS

TEST GUIDELINE: ISO 10993-23:2021

STUDY NO.: LBPL/NG-2642 (TX)

STUDY CODE: IRTNZW

STUDY COMPLETED ON: 09/02/2023

STUDY DIRECTOR

Mrs. Bhagyashree M.

SPONSOR

KTEX NONWOVENS PVT. LTD.
SURVEY NO.241, OPP. KHAMTA VILLAGE BUS STOP
RAJKOT-JAMNAGAR HIGHWAY-360 110,
GUJARAT

TEST FACILITY

LIVEON BIOLABS PRIVATE LIMITED
PLOT NO. 46 & 47, II PHASE, WATER TANK ROAD
KIADB INDUSTRIAL AREA, ANTHARASANAHALLI
TUMAKURU-572106, KARNATAKA,
INDIA.

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1. OBJECTIVE

The objective of this study is to assess the possible irritation likely to arise from Intracutaneous injection of extract of the test item, "Spun Melt PP Nonwoven Fabric" following its single administration in New Zealand White Rabbits. This study will provide a rational basis of risk assessment in humans.

2. STUDY DETAILS

Study Title	:	Intracutaneous Reactivity Test of Polar and Non-Polar Extracts of Spun Melt PP Nonwoven Fabric in New Zealand White Rabbits.
Study Number	:	LBPL/NG-2642 (TX)
Study Code	:	IRTNZW
ULR No	:	TC-679422000001264F
Sponsor	:	KTEX NONWOVENS PVT LTD Survey no.241, opp. Khamta village bus stop Rajkot-jamnagar highway-360 110, Gujarat
Test Facility	:	LIVEON BIOLABS PRIVATE LIMITED Plot No.46 & 47, II Phase Water Tank Road, KIADB Industrial Area Antharasanahalli, Tumakuru – 572106 Karnataka, India.

3. STUDY RESPONSIBILITIES

Study Director	:	Mrs. Bhagyashree M.
Study Personnel I	:	Ms. Chitrashree S. R.
Study Personnel II	:	Ms. Bhavana S. B.
Study Personnel III	:	Mr. Vasantha Kumar B. S.
Study Personnel IV	:	Ms. Supritha G.
Study Personnel V		Ms. Mamatha G.
Study Veterinarian	:	Dr. Sunkad Meghana
Sponsor Representative	:	Mustanshir Vohra

4. STUDY SCHEDULE

Study Initiation Date	:	16/12/2022
Experiment Start Date	:	20/12/2022
Acclimatization Period	:	20/12/2022 to 26/12/2022
Treatment Start Date	:	27/12/2022
Experiment End Date	:	30/12/2022
Draft Report to Sponsor	:	07/01/2023
Study Completion Date	:	09/02/2023

5. ABBREVIATIONS AND SYMBOLS

AAALAC	:	Association for Assessment and Accreditation of Laboratory Animal Care
°C	:	Degree Celsius
CPCSEA	:	Committee for the Purpose of Control and Supervision of Experiments on Animals
dB	:	Decibel
g	:	Gram
h/hr (s)	:	Hour (s)
IAEC	:	Institutional Animal Ethics Committee
IEC	:	International Electrotechnical Commission
IRTNZW	:	Intracutaneous Reactivity Test in New Zealand White Rabbits
ISO	:	International Organization for Standardization
LBPL	:	Liveon Biolabs Private Limited
mL/kg	:	Millilitre per kilogram
mL	:	Millilitre
mins	:	Minutes
SD	:	Study Director
TFM	:	Test Facility Management
TIIS	:	Test Item Information Sheet
QAU	:	Quality Assurance Unit
<	:	Less than
%	:	Percentage
&	:	and

6. STATEMENT OF STUDY COMPLIANCE

Study Number : LBPL/NG-2642 (TX)

Study Title : Intracutaneous Reactivity Test of Polar and Non-Polar Extracts of Spun Melt PP Nonwoven Fabric in New Zealand White Rabbits.

This Study was performed in compliance with ISO/IEC 17025:2017. This study was conducted in accordance with the standard operating procedures and the mutually agreed Study Plan signed by Study Director on 16/12/2022 Sponsor representative agreed through email on 07/12/2022

DECLARATION

The Study Director hereby declares that the work was performed under her 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.

The Study Director accepts overall responsibility for the technical conduct of the study as well as the interpretation, analysis, documentation and reporting of the results.

09/02/2023

Study Director
Sign. and Date

7. STATEMENT OF QUALITY ASSURANCE UNIT

This is to state that the following study was inspected by Quality Assurance Unit of Liveon Biolabs Private Limited in compliance with ISO/IEC 17025:2017.

Study Number : LBPL/NG-2642 (TX)

Study Title : Intracutaneous Reactivity Test of Polar and Non-Polar Extracts of Spun Melt PP Nonwoven Fabric in New Zealand White Rabbits.

The following study phases were inspected and findings were reported to the Management and Study Director on the dates shown below.

Sl. No.	Inspection Phase	Dates		
		Inspected on	Reporting to	
			SD	TFM
1.	Draft Study Plan	01/12/2022	01/12/2022	01/12/2022
2.	Final Study Plan	16/12/2022	16/12/2022	16/12/2022
3.	Draft Study Report	09/01/2023	09/01/2023	09/01/2023
4.	Final Study Report	09/02/2023	09/02/2023	09/02/2023

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

09/02/2023

Quality Assurance Unit
Sign. and Date

8. STATEMENT OF CONFIDENTIALITY

The information and data presented in this Study Report is considered as confidential and proprietary information of the KTEX NONWOVENS PVT. LTD. and will not be disclosed to anyone without the expressed or written approval of sponsor, except to the employees of this test facility wherever necessary and to persons authorized by law or judicial judgement.

03/02/2023

Test Facility Management
Sign. and Date

9. STATEMENT OF TEST FACILITY MANAGEMENT

Study Number	:	LBPL/NG-2642 (TX)
Study Title	:	Intracutaneous Reactivity Test of Polar and Non-Polar Extracts of Spun Melt PP Nonwoven Fabric in New Zealand White Rabbits.

This is to affirm that for the above mentioned study, Test Facility Management has made available all the resources to the study director necessary for conduct of the study in compliance with ISO/IEC 17025:2017 and mutually agreed study plan.

09/02/2023

Test Facility Management
Sign. and Date

10. STUDY SUMMARY

Intracutaneous reactivity test was performed to evaluate irritation following Intracutaneous injection of test item extracts of "Spun Melt PP Nonwoven Fabric" when administered in New Zealand White Rabbits. The study was performed as per the guideline ISO 10993-23:2021.The test item was extracted in polar vehicle control i.e., 0.9% Sodium Chloride injection and non-polar vehicle control i.e., Sesame oil as per the guideline ISO 10993 - Part 12. This study also provides rational basis of risk assessment in humans.

Three Male Rabbits were acclimatized for 7 days. The test item was Irregular shaped device hence; 0.2g/mL was selected for extraction as per ISO 10993-12:2021 (as per Annexure 1).

The Test Item was non-sterile in condition before Extraction it was sterilized by Autoclave 121°C. 2.0010g of test item was weighed and transferred to the Beaker containing 10 mL of 0.9% NaCl Similarly, 2.0004g of test item was weighed and transferred to the beaker containing 10 mL of sesame oil. Similar procedure was followed for polar and non-polar vehicle control without test item and was subjected to extraction at 37.0°C for a period 70 hours 01 minutes orbital shaker incubator at 110 rpm. Test item in respective Polar and non-polar were observed for clarity of extraction and found to be clear without any particles during pre and post-extraction period.

pH of polar and non-polar test item extracts and vehicle control was checked using pH strips and pH was measured between 6 -7.

18 hours prior to the test item administration, the fur of the flank region of the animals were closely clipped on both sides (right and left side) of the spinal columns for injection of the control extract (right side) test item extract (left side) and injection sites were marked with marker pen.

Three Male rabbits were administered with a dose volume of 0.2mL/site of the test item extract and vehicle control by Intracutaneous route into five separate sites. Only polar and non-polar vehicle controls were administered to the right side of the spinal column of each rabbit. Similarly, polar and non-polar test item extract on the left side of the spinal column of each rabbit. The animals were observed after injection for clinical signs of toxicity, erythema and oedema at (about 24hr, 48hr, and 72hr) post-injection. Body weights were measured on the day of dosing and at the end of the experimental period.

No Mortality, Morbidity and clinical signs were observed during course of the experiment. There were no test item extract-related skin reactions at the injection sites. There were no changes in body weights during the study period.

Under the test conditions employed, there was no test item-related skin reaction was observed in all test animals. The difference between the polar test extract mean score and polar vehicle control mean score was '0.000'. The difference between the non-polar test extract mean score and non-polar vehicle control mean score was '0.000'. Hence, the test item, "Spun Melt PP Nonwoven Fabric" meets the requirement of the test guideline ISO

10993 Part-23:2021, since the test item score was less than 1 and considered to be "Non-irritant".

11. STUDY COMPLIANCE

The study was performed with the following:

- ISO/IEC 17025:2017, General Requirements for the Competence of Testing and Calibration Laboratories.
- Standard Operating Procedures of Test Facility and the mutually agreed Study Plan.

12. STUDY GUIDELINES

The design of this study is based on the study objective(s) and procedures as detailed in the study plan, the overall product development strategy for the test item, and the below mentioned guidelines in principles as applicable.

- ISO 10993-23:2021 –Biological Evaluation of Medical Devices part: 23 Tests for Irritation.

13. IAEC APPROVAL

This protocol has been approved by Liveon Biolabs Private Limited Institutional Animal Ethics Committee (IAEC). IAEC approved protocol number: LBPL-IAEC-049-06/2022.

14. ANIMAL WELFARE AND VETERINARY CARE

Liveon Biolabs Private Limited is an AAALAC International accredited facility and registered with CPCSEA, Department of Animal Husbandry and Dairying (DAHD), Ministry of Fisheries, Animal Husbandry and Dairying (MoFAH&D), Government of India. Also, Liveon Biolabs Private Limited ensures that animal experiments are performed in accordance with the recommendation of the regulatory guidelines for laboratory animal facility published in the gazette of India, 2021. AAALAC International Certificate is enclosed as Annexure 8.

During the conduct of study none of the animals were injured, and no moribund animals were observed.

15. AMENDMENT AND DEVIATIONS

There were no amendment and No deviations occurred during the conduct of study.

16. SAFETY PRECAUTIONS

The personnel involved in study conduct wore all necessary personnel protective equipment like gloves, head cap and facemask in addition to protective body garments and slippers/shoes to ensure adequate personnel health and safety and to avoid inhalation and skin contact with the test item.

17. MATERIALS AND METHODS

17.1 Materials

17.1.1 Test Item Information

The test item information provided by the sponsor to Liveon Biolabs Private Limited is furnished below:

Name of Test Item	:	Spun melt PP Nonwoven Fabric
Test Item Code by Test Facility	:	S441/TI-001
Intended use of device in Human / others (to specify)	:	Human Use in Gown, Drapes, CSR Wraps, Diapers or sanitary pads
Site of Contact	:	Skin
Duration of contact with Human body	:	6-12 hours
Material category (As per ISO-10993 Part-1)	:	Surface Medical Device
Weight in g.(without packing)	:	35gm
Storage Condition	:	Ambient (+19 to +25°C)
Test Item Code by Sponsor (if any)	:	KTEXSM001
Batch No/Lot no	:	2220524A
Date of Manufacture		24/05/2022
Date of Expiry		2 years from date of manufacture
Sterility Status	:	Non-Sterile (Autoclave Method)
Test Item Supplied by	:	KTEX NONWOVENS PVT LTD Sdurvey no.241, opp. Khamta village bus stop Rajkot-jamnagar highway-360 110,Gujarat

The Sponsor is responsible for the authenticity of the test item and no further characterization of test item was performed at Liveon Biolabs Private Limited. Test Item information, Certificate of Analysis and Material Safety Data Sheet provided by the Sponsor in Liveon Biolabs Private Limited. TIIS Certificate of Analysis and Material Safety Data Sheet was presented as Annexure 9, Annexure 10 and Annexure 11 respectively.

17.1.2 Test System

Animal Species	:	Rabbit *(Oryctolagus Cuniculus)*
Strain	:	New Zealand White
Justification for Selection of Species	:	Rabbit is one of the recommended species for conducting intracutaneous reactivity test as per guideline ISO-10993-23-2021

Source	:	In-house breed animals
Age (at treatment)	:	03 - 04months
Total Number of Animals	:	Females (Females were Nulliparous & Non-pregnant)
Animal Accession Number	:	NWa6854- NWa6856
Body Weight range (at treatment)	:	2.69124kg - 2.80943kg

17.1.3 Test System Management

17.1.3.1 Animal Room Preparation

Prior to housing the animals, the experimental room was decontaminated by fumigation and microbial load was checked by settle plate method. The experimental room floor was mopped daily once.

17.1.3.2 Husbandry Conditions

Animals were housed in an environment-controlled room temperature of 20.0-22.8°C and relative humidity of 45-69%. The photoperiod was12 hours fluorescent light and 12 hours darkness. Adequate fresh air supply of 12 - 15 air cycles/hour and sound level of <80 dB was maintained in the experimental room.

The relative humidity, maximum and minimum temperature in the experimental room was recorded once daily and temperature and relative humidity included in the raw data file

17.1.3.3 Housing

Animals were housed individually in a standard stainless cage (approximately cage size 1.6 Length × 2 Breadth × 1.6 Height feet) provided with stainless steel wire bottom grill facilitated with polycarbonate resting board, feed hopper and polycarbonate water bottle with stainless steel sipper tube. Additionally, hanging bells were provided as an enrichment device to minimize the animal stress and promote overall wellbeing of animals.

Steam sterilized corn cob was provided as bedding material. The latest analysis and contaminants report of bedding material was included in the Annexure 5 & Annexure 12.

17.1.3.4 Diet and Water

AF- 1000M Rabbit Diet manufactured by Krishna Valley Agrotech was provided *ad libitum* to Rabbits.

Deep bore-well water subjected to filtration by reverse osmosis and UV sterilized, was provided *ad libitum* to Rabbits in polycarbonate bottles with stainless rubber corked steel sipper tubes. There were no known contaminants in the bedding, food and water provided to the animals.

The feed provided were tested for contaminants. The latest analysis reports of feed and contaminants report was included in the Annexure 6 & Annexure 13.The water provided were tested for contaminants. The latest

analysis reports of water and contaminants report was included in the Annexure 7 & Annexure 14.

17.1.4 Test System Preparation

17.1.4.1 Acclimatization

After examination for good health and the suitability for the study, the animals were acclimatized for 7 days prior to treatment. During acclimatization animals were observed daily once. Veterinary examination was performed before selecting the animals for the study.

17.1.4.2 Animal Identification

During acclimatization period (Temporary identification), each animal was identified by ear marking with animal No. written on the ear lobe using marker pen. The cages were identified with cage cards indicating study number, study code, species, strain, sex, acclimatization start and acclimatization end date.

During treatment period (Permanent identification), each animal was identified by ear marking with animal accession number written on the ear lobe using indelible marker pen. The cages were identified with cage cards indicating study number, study code, species, strain, sex, treatment start date and experiment end date.

17.1.4.3 Clipping of Animals

18 hours prior to the test item administration the fur of the flank region of the animals were clipped with a sufficient distance on both sides of the spinal columns for injection of the test item extracts and control extracts.

17.2 Methods

17.2.1 Experimental Procedures

17.2.1.1 Selection and Justification for the Choice of Extraction Medium

The commercially available 0.9% w/v sodium chloride for injection (Normal saline) for polar extraction and sesame oil for non-polar extraction of test item and polar and non-polar vehicle control as per the guideline ISO 10993 "Biological Evaluation of Medical Devices", Part 12 (Sample preparation and reference materials).

Sodium Chloride Injection (NaCl) – Polar Vehicle
(Batch No: 1124208, Manufacture Date: 04-2022, Expiry Date: 08-2025
Mfd by: Aculife Healthcare Private Limited.)

Sesame oil (SO) – Non-Polar Vehicle
(Batch No: G/P1, Manufacture Date: 06/09/2022, Expiry Date: 05/12/2025
Mfd by: KLF Nirmal Industries Private Limited.)

17.2.1.2 Preparation of Test Item Extract

The test item was Irregular shaped device hence, 0.2g/mL was selected for extraction as per ISO 10993-12:2021 (Annexure 1).
The Test Item was non-sterile in condition before extraction it was sterilized under Autoclave 121°C.

2.0010g of test item was weighed and transferred to the beaker containing 10mL of 0.9% w/v NaCl Similarly, 2.0004g of test item was weighed and transferred to the beaker containing 10mL of sesame oil. Similar extraction procedure was followed for polar and non-polar vehicle control without test item for 10 mL and was subjected to extraction at 37.0 for a period 70 hours 01 minutes with continuous agitation in orbital shaker incubator at 110 rpm. Before extraction, beaker was washed with purified water. Test item in respective Polar and non-polar were observed for clarity of extraction and found to be clear without any particles during pre- and post-extraction period. Vehicle Control and test item extract of polar and non-polar Vehicle were observed to be clear, free from any particulates when observed after the incubation period. Extraction procedure was carried out under aseptic condition.

After the completion of the process of extraction, the vehicle control and test item extract were administered to the respective intracutaneous sites of animals.

17.2.1.3 pH

pH value for pre- and post-extraction was checked using pH strips and same was mentioned in the raw data and Report.

Vehicle	Appearance	Pre-Extraction pH	Post Extraction pH
Polar Vehicle Control	Clear	6-7	6-7
Polar Test Item Extract	Clear	6-7	6-7
Non-polar Vehicle Control	Clear	6-7	6-7
Non-polar Test Item Extract	Clear	6-7	6-7

17.3 Test Procedure

Three animals were injected with control on right side, and extract on left side of the spinal column at 5 different sites (0.2 mL per site). The injection sites were examined for evidence of any tissue reaction such as erythema, edema and necrosis. The detailed procedure for injection site and administration are represented in the Annexure 2 and Annexure 3.

18. OBSERVATIONS

18.1 Mortality, Morbidity and Clinical Signs

Animals were observed for mortality and morbidity twice daily i.e., once in the morning and once in the evening except during a weekend wherein the animals were observed for mortality and morbidity only in the morning. Animals were observed for clinical signs daily once. The appearance of each injection site was observed immediately after injection at (about 24hr, 48hr and 72hr).

18.2 Body Weight

Individual animal body weight was measured on the day of receipt, on Day 1 (prior to dose), and on Day 4 (at the end of the experimental period).

18.3 Skin Reaction

The skin reaction for erythema and edema was scored according to the as per Annexure 4.

19. EVALUATION CRITERIA

- After 72hr grading, all erythema grades plus edema grades 24hr, 48hr and 72hr are totaled separately for each test sample or vehicle control for each individual animal.
- The score of a test sample or vehicle control sample on each individual animal was calculated by dividing each of the totals by 15 (3 Scoring time points X 5 test or vehicle control sample injection sites).
- The overall mean score for each test sample and each corresponding control was calculated by adding scores for the three animals and divided by three.
- The final test sample score can be obtained by subtracting the score of the vehicle control from the test sample score. The requirements of the test are met when the final test sample score is 1, 0. When any observation period the average reaction to the test sample is greater than the average reaction to the vehicle control.

20. RESULTS

20.1 Mortality, Morbidity and Clinical Signs

Refer to Table 1 and Appendix 1

There were no mortality/morbidity/no clinical signs observed in any of the tested animals throughout the experimental period.

20.2 Body Weight

Refer to Table 2 and Appendix 2

There were no changes observed in body weight measured during the course of observation period.

20.3 Skin Reaction Scores

Refer to Table 3 and Appendix 3, 4 & 5

There were no test item related erythema and edema reactions scored at the sites of injection of test item and respective control sites on the skin of rabbits. However, few scorings of erythema and no edema reactions observed in both control and test item sites owing to injection procedure and these reactions are consider to be incidental.

The overall score for polar extract of test item:

Animal No. NWa6854, NWa6855 & NWa6856
The difference between the sum scores of polar extracts of test item to that of polar Vehicle = 0.000 - 0.000= 0.000

The overall score for non - polar extract of test item:

Animal No. NWa6854, NWa6855 & NWa6856
The difference between the sum scores of non-polar extracts of test item to that of non-polar Vehicle = 0.000 - 0.000= 0.000

21. DATA COMPILATION

All individual animal data are presented in appendices and summarized and presented in tables. All findings are presented in the report.

22. CONCLUSION

Under the test conditions employed, no test item-related skin reaction was observed in all test animals. The difference between the polar test extract mean score and polar vehicle control mean score was '0.000'. The difference between the non-polar test extract mean score and non-polar vehicle control mean score was '0.000'. Hence, the test item, "Spun Melt PP Nonwoven Fabric" meets the requirement of the test guideline ISO 10993 Part-23:2021 since the test item score was less than 1 and considered to be "Non-irritant".

23. ANIMAL EUTHANASIA AND DISPOSAL

At the end of experiment period all the animals were sacrificed using lethal dose of Sodium thiopental injection. The carcasses were stored in deep freezer until disposed of through Medicare Environmental Management Pvt. Ltd.

Details of Sodium Thiopentone Injection IP: Batch No: 172442, Manufacture Date: Oct-2021, Expiry Date: Sep-2023, Manufactured by: NEON laboratories limited.

24. STUDY REPORT DISTRIBUTION

The Final Study Report will be distributed as follows:

Copy No. 1/2 – Sponsor

Copy No. 2/2 – Archives, Liveon Biolabs Private Limited

25. ARCHIVING

All study-related records, Study Plan, Raw Data, Study Report, and the Test Item sample was maintained in the archives of Liveon Biolabs Private Limited for 5 years from the date of study completion. All the records and test item was handled according to ISO/IEC 17025:2017. After the completion of archiving period, the test facility management will coordinate with the sponsor for further course of action on archived material.

26. REFERENCES

- ISO/IEC 17025:2017, General Requirements for the Competence of Testing and Calibration Laboratories.
- ISO 10993-1-2018: Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process.
- ISO 10993-2:2006: Biological Evaluation of Medical Devices - Part 2: Animal Welfare Requirements.
- ISO 10993-23:2021: Biological Evaluation of Medical Devices – Part 23: Tests for Irritation.
- ISO 10993-12:2021: Biological Evaluation of Medical Devices - Part 12: Sample preparation and reference materials.
- Standard Operating Procedures of Test Facility and the mutually agreed Study Plan.

Table 1. Summary of Clinical Signs Mortality and Morbidity

Refer to Appendix 1

Animal No.	Sex	Clinical Signs observations			Mortality / Morbidity
		24 hr	48 hr	72 hr	
NWa6854	F	1	1	1	0/1
NWa6855	F	1	1	1	0/1
NWa6856	F	1	1	1	0/1

1-Normal, F-Female, 0'-No mortality observed out of '1' animals

Table 2. Summary of Body Weight Gain (%)

Refer to Appendix 2

Animal No.	Sex	Body Weight Gain (%)
		Days (1-4)
NWa6854	F	1.81
NWa6855	F	1.53
NWa6856	F	1.23

Table 3. Calculation for Skin Reactions

Refer to Appendix 3

The individual animal score with respect to the total number of injection sites for 3 observations is as follows:

Animal No.	Polar extract	Polar Vehicle	Non-Polar extract	Non-Polar Vehicle
NWa6854	0	0	0	0
NWa6855	0	0	0	0
NWa6856	0	0	0	0

Table 4. Overall Sum Score of Test Item Extracts and Control Extracts

Refer to Appendix 4 & 5

Animal No.	Vehicle name	Overall sum score of test item extracts - Overall sum score of test control extracts
NWa6854	0.9% NaCl	0.000
NWa6855		
NWa6856		
NWa6854	Sesame oil	0.000
NWa6855		
NWa6856		

Appendix 1. Individual Animal Clinical Signs

Animal No	Sex	Clinical Signs			
		Day 1	Day 2	Day 3	Day 4
NWa6854	F	1	1	1	1
NWa6855	F	1	1	1	1
NWa6856	F	1	1	1	1

1-Normal, F-Female

Appendix 2. Individual Animal Body Weights (Kg.)

Animal No.	Sex	Body Weight (Kg)	
		Day 1	Day 4
NWa6854	F	2.78216	2.83239
NWa6855	F	2.69124	2.73246
NWa6856	F	2.80943	2.84399

F-Female

Appendix 3. Evaluation of Skin Reaction

Animal No.	Observed Time	Type of Vehicle	Skin Reaction	Scores of Skin Reaction											Total Score
				Test Site (Extract)					Total Score	Control Site (Vehicle)					
				1	2	3	4	5		1	2	3	4	5	
NWa6854	24 hr	Polar	Erythema	0	0	0	0	0	**0**	0	0	0	0	0	**0**
			Edema	0	0	0	0	0	**0**	0	0	0	0	0	**0**
		Non-Polar	Erythema	0	0	0	0	0	**0**	0	0	0	0	0	**0**
			Edema	0	0	0	0	0	**0**	0	0	0	0	0	**0**
	48 hr	Polar	Erythema	0	0	0	0	0	**0**	0	0	0	0	0	**0**
			Edema	0	0	0	0	0	**0**	0	0	0	0	0	**0**
		Non-Polar	Erythema	0	0	0	0	0	**0**	0	0	0	0	0	**0**
			Edema	0	0	0	0	0	**0**	0	0	0	0	0	**0**
	72 hr	Polar	Erythema	0	0	0	0	0	**0**	0	0	0	0	0	**0**
			Edema	0	0	0	0	0	**0**	0	0	0	0	0	**0**
		Non-Polar	Erythema	0	0	0	0	0	**0**	0	0	0	0	0	**0**
			Edema	0	0	0	0	0	**0**	0	0	0	0	0	**0**
				Total score for polar extract					0	Total score for polar Vehicle					0
				Total score for non-polar extract					0	Total score for non-polar Vehicle					0

Note: 0-No Erythema / Edema,

Appendix 3. (Contd....) Evaluation of Skin Reaction

Animal No.	Observed Time	Type of Vehicle	Skin Reaction	Scores of Skin Reaction											Total Score
				Test Site (Extract)					Total Score	Control Site (Vehicle)					
				1	2	3	4	5		1	2	3	4	5	
NWa6855	24 hr	Polar	Erythema	0	0	0	0	0	**0**	0	0	0	0	0	**0**
			Edema	0	0	0	0	0	**0**	0	0	0	0	0	**0**
		Non-Polar	Erythema	0	0	0	0	0	**0**	0	0	0	0	0	**0**
			Edema	0	0	0	0	0	**0**	0	0	0	0	0	**0**
	48 hr	Polar	Erythema	0	0	0	0	0	**0**	0	0	0	0	0	**0**
			Edema	0	0	0	0	0	**0**	0	0	0	0	0	**0**
		Non-Polar	Erythema	0	0	0	0	0	**0**	0	0	0	0	0	**0**
			Edema	0	0	0	0	0	**0**	0	0	0	0	0	**0**
	72 hr	Polar	Erythema	0	0	0	0	0	**0**	0	0	0	0	0	**0**
			Edema	0	0	0	0	0	**0**	0	0	0	0	0	**0**
		Non-Polar	Erythema	0	0	0	0	0	**0**	0	0	0	0	0	**0**
			Edema	0	0	0	0	0	**0**	0	0	0	0	0	**0**
				Total score for polar extract					0	Total score for polar Vehicle					0
				Total score for non-polar extract					0	Total score for non-polar Vehicle					0

Note: 0-No Erythema / Edema,

Appendix 3. (Contd....) Evaluation of Skin Reaction

Animal No.	Observed Time	Type of Vehicle	Skin Reaction	Scores of Skin Reaction											Total Score
				Test Site (Extract)					Total Score	Control Site (Vehicle)					
				1	2	3	4	5		1	2	3	4	5	
NWa6856	24 hr	Polar	Erythema	0	0	0	0	0	**0**	0	0	0	0	0	**0**
			Edema	0	0	0	0	0	**0**	0	0	0	0	0	**0**
		Non-Polar	Erythema	0	0	0	0	0	**0**	0	0	0	0	0	**0**
			Edema	0	0	0	0	0	**0**	0	0	0	0	0	**0**
	48 hr	Polar	Erythema	0	0	0	0	0	**0**	0	0	0	0	0	**0**
			Edema	0	0	0	0	0	**0**	0	0	0	0	0	**0**
		Non-Polar	Erythema	0	0	0	0	0	**0**	0	0	0	0	0	**0**
			Edema	0	0	0	0	0	**0**	0	0	0	0	0	**0**
	72 hr	Polar	Erythema	0	0	0	0	0	**0**	0	0	0	0	0	**0**
			Edema	0	0	0	0	0	**0**	0	0	0	0	0	**0**
		Non-Polar	Erythema	0	0	0	0	0	**0**	0	0	0	0	0	**0**
			Edema	0	0	0	0	0	**0**	0	0	0	0	0	**0**
				Total score for polar extract					0	Total score for polar Vehicle					0
				Total score for non-polar extract					0	Total score for non-polar Vehicle					0

Note: 0-No Erythema / Edema,

Appendix 4. The Mean Score for Individual Animal at Each Site for Each Time Point

Animal No.	Polar extract	Polar Vehicle	Non-Polar extract	Non-Polar Vehicle
NWa6854	0.000	0.000	0.000	0.000
NWa6855	0.000	0.000	0.000	0.000
NWa6856	0.000	0.000	0.000	0.000
Mean	**0.000**	**0.000**	**0.000**	**0.000**

Appendix 5. The Overall Score for Individual Animal at Each Site for Each Time Point

The overall score for polar extract of test item:

Animal No. NWa6854, NWa6855 & NWa6856
The difference between the sum scores of polar extracts of test item to that of polar Vehicle = 0.000 - 0.000 = 0.000

The overall score for non - polar extract of test item:

Animal No. NWa6854, NWa6855 & NWa6856
The difference between the sum scores of non-polar extracts of test item to that of non-polar Vehicle = 0.000 - 0.000 = 0.000

Annexure 1. Standard Surface Areas and Extract Liquid Volumes

Thickness[a] mm	Extraction ratio (surface area or mass/volume) ±10 %	Examples of forms of materials
<0,5	6 cm^2/ml	film, sheet, tubing wall
0,5 to 1,0	3 cm^2/ml	tubing wall, slab, small moulded items
>1,0	3 cm^2/ml	larger moulded items
irregularly shaped solid devices	0,2 g/ml	powder, pellets, foam, non-absorbent moulded items, porous high-density materials
irregularly shaped porous devices (low-density materials)	0,1 g/ml	membranes, textiles

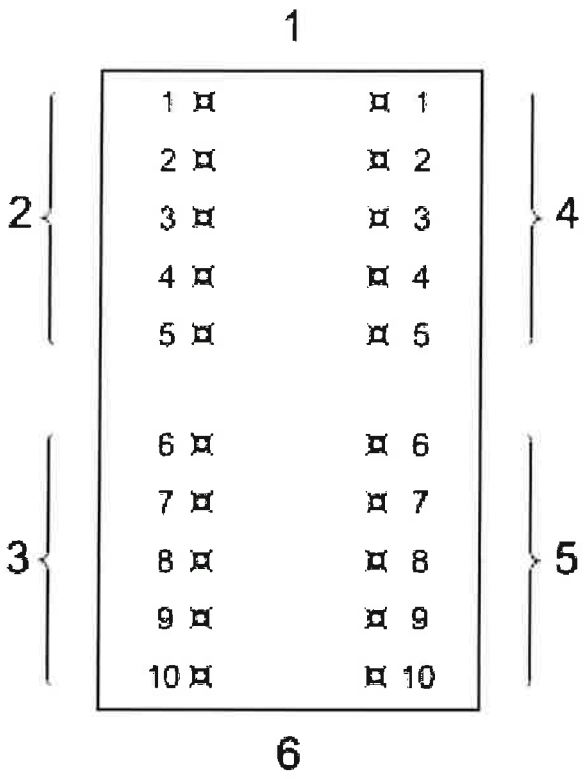
[a] If the medical device includes multiple tissue contacting components with different thicknesses, the extraction ratio should be justified. One way to do this is to base the ratio on the thinnest material layer of that component.

NOTE While there are no standardized methods available at present for testing solvent absorbing polymer materials (e.g. absorbents and hydrocolloids), a suggested protocol is as follows:

— determine the volume of extraction vehicle that each 0,1 g or 1,0 cm^2 of material absorbs;

— then, in performing the material extraction, add this additional volume to each 0,1 g or 1,0 cm^2 in an extraction mixture.

Annexure 2. Arrangement of Injection Sites



INDICATIONS

1. Cranial End
2. 0.2 mL Injection of Polar Extract
3. 0.2 mL Injection of Non-Polar Extract
4. 0.2 mL Injection of Polar vehicle control
5. 0.2 mL Injection of Non-Polar vehicle control
6. Caudal End

Annexure 3. Administration of Test Item

Sl. No.	Treatment	Extract	Incubation	Dose Volume/Site (mL)	Total Volume Injected	Region
1	Polar vehicle control	0.9% Sodium Chloride Injection	37.0 °C for 70 hr 01 min	0.2 mL	1.0 mL	Right
2	Polar Test Item Extract	Test Item + 0.9% Sodium Chloride Injection		0.2 mL	1.0 mL	Left
3	Non-polar vehicle control	Sesame oil		0.2 mL	1.0 mL	Right
4	Non-polar Test Item Extract	Test item + Sesame oil		0.2 mL	1.0 mL	Left

Annexure 4. Evaluation of Skin Reactions

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
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 1mm)	3
Severe oedema (raised more than 1 mm and extending beyond the area of exposure)	4
Maximal possible score for irritation	8
Other adverse changes at the skin sites shall be recorded and reported.	

Annexure 5. Analysis Report for Bedding Material

ANNEXURE 7: RECORD FOR THE RESULTS OF MICROBIAL MONITORING REPORT OF AUTOCLAVED BEDDING MATERIAL

Date of Sampling: 19/09/2022 Date of Reporting: 21/09/2022

Sl. No.	Source	Results
01	Corn Cob Bedding material LBPL-CC-039	No growth of bactia on the Nutrient Agar plates

Analyzed by 22/09/2022
Sign. and Date

Verified by 22/09/2022
Sign. and Date

Annexure 6. Analysis Report for Feed

ANNEXURE 5: RECORD THE RESULTS FOR MICROBIAL MONITORING OF FEED SAMPLES REPORT

Date of Sampling: 01/10/2022 Date of Reporting: 07/10/2022

Sl. No.	Summary of Findings	Results
1	Name / Source	Rabbit feed from Krishna valley
2	Batch No	343
3	Total viable organisms	$< 1 \times 10^4$ cfu/g
4	Fungi	$< 1 \times 10^4$ cfu/g
5	Mesophilic spores	$< 1 \times 10^4$ cfu/g
6	*Salmonella* sp.	
7	*E. coli.*	
8	*Coliforms*	

Remarks: —

Analyzed by: 07/10/2022
Sign. and Date

Verified by: 07/10/2022
Sign. and Date

Annexure 6. (Contd.,) Analysis Report for Feed

kvat
Krishna Valley Agrotech LLP

Krishna Valley Agrotech LLP

An ISO 9001:2015 & GMP Certified Company
Corporate Office: Bungalow No. 5, Acacia Garden 1, Magarpatta City,Pune 411028,
Customer Care No: 120-61096713, Website: www.kvat.co.in

Factory address: E-43 & E3/14, MIDC, Kupwad block, Sangli, Maharashtra-416436

AF-1000M Rabbit Diets (Autoclavable)

CERTIFICATE OF ANALYSIS

Lot No : 343

Date of manufacture: 18.09.2022

Expiry date: 17.03.2023

Report date: 19.09.2022

Authorized signatory

Proximate analysis	
Analysis	Result %
Crude Protein	17.58
Ether extract	4.12
Crude Fiber	11.20
Moisture	8.95
Calcium	0.88
Phosphorus	0.70
Total ash	7.90
Gross Energy	3.0 Kcal/gm

Consolidated results obtained from one or more independent testing laboratories.

Analysis	Result	Units	Established Maximum concentration
Heavy Metals			
Arsenic	0.12	ppm	1.00
Cadmium	0.04	ppm	0.50
Lead	0.08	ppm	1.50
Mercury	0.03	ppm	0.20
Mycotoxins			
Aflatoxin B1,B2, G1, G2	<5.00	ppb	5.00
Chlorinated Hydrocarbons	<0.01	ppm	0.05
Organophosphates	<0.10	ppm	0.5
Phytoestrogen	Complies	µg/g	12
Microbial Examination			
Total Aerobic Count	Complies	CFU/gm	$<1x10^3$ CFU/gm
Mold Count	Absent	CFU/ 10 gm	Absent/10 gm
Escherichia coli	Absent	CFU/ 10 gm	Absent/10 gm
Salmonella	Absent	CFU/ 10 gm	Absent/10 gm
Shigella	Absent	CFU/ 10 gm	Absent/10 gm
Pseudomonas aeruginosa	Absent	CFU/ 10 gm	Absent/10 gm

QC/F/ 05,C0,1.1.2020

Annexure 7. Analysis Report for RO Water

ANNEXURE 2: RECORD FOR THE RESULTS OF MICROBIAL MONITORING OF WATER SAMPLES

Start Date: 05/12/2022 End Date: 07/12/2022

Sl. No.	Source/sample	Results		Remarks
		Coliform counts / 100 mL	*E. coli* count / 100 ml	
(1)	RO water point ground floor (1)	00	N.P	—
(2)	RO water point ground floor (2)	00	N P	—
(3)	RO water point 1st floor (3)	00	N P	—
(4)	RO water point 1st floor (4)	00	N P	—
(5)	RO water point (near RO room) (5)	00	N P	—

Presumptive Test

Quality of Water	*Coliform* count / 100 mL
Excellent	0
Satisfactory	1 – 3
Intermediate	4 – 9
Unsatisfactory	10 *Coliforms* or any *Coliform* organism present in consecutive samples or presence of any *Coliform* organism in more than 5% of routine samples.

Differential test

Quality of water	*Escherichia coli* count / 100 mL
Excellent	0
Unsatisfactory	1 or more *Escherichia coli* or any *Coliforms* organism present in consecutive samples or presence of any *Coliforms* organism in more than 5% of routine samples.

Analyzed by: 07/12/2022 (Sign. and Date)

Verified by: 08/12/2022 (Sign. and Date)

Note : NP (not Performed)

Annexure 8. AAALAC Certificate

5205 Chairman's Court, Suite 300
Frederick, MD USA 21703

October 29, 2019

R. Rajesh, M.Sc.
Scientist In-Charge
Animal Facility
Liveon Biolabs Private Limited
#46 & 47 Water Tank Road
KIADB Industrial Area
Karnataka 572106
India

Dear Mr. Rajesh:

The AAALAC International Council on Accreditation has reviewed the report of the recent site visit to Liveon Biolabs Private Limited, Karnataka, India. The Council commends you and the staff for providing and maintaining an excellent program of laboratory animal care and use. Especially noteworthy were the very involved Institutional Official and all staff members during the entire site visit; the clean and refabricated animal rooms and corridors; the well established traffic flow and personal protective equipment; and the good water and feed quality reports. The Council is pleased to inform you that the program conforms with AAALAC International standards as set forth by the *Guide for the Care and Use of Laboratory Animals*, NRC 2011 and the Guidelines of the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA). Therefore, **FULL ACCREDITATION** shall continue.

Council acknowledges receipt of the correspondence dated September 13 and August 12, 2019 detailing actions taken relative to concerns expressed by the site visitors during the exit briefing. Specifically, the items addressed satisfactorily included: ensuring social housing of mice and rabbits when possible or unless otherwise justified and providing resting boards for rabbits housed on wire-bottom cages.

Council has no further recommendations to offer for improvement of the animal care and use program at this time. We look forward to following your program activities and wish you continued success.

AAALAC International requires an Annual Report detailing changes made during the year in accredited units. In the interim, AAALAC International expects to be apprised in a timely manner of significant programmatic changes or concerns should they occur. Please note that, at your request, AAALAC International will provide your institution with a separate letter simply verifying that your animal care and use program is accredited. Should you also wish to distribute an electronic copy of this letter to program staff, a Portable Document Format (pdf) version will be sent upon request.

Council acknowledges the September 13, 2019 correspondence describing the previous use of poultry and wishes to clarify that per the AAALAC International Rules of Accreditation ... "All animals used or to be used in research, teaching, or testing at accreditable units are to be included and evaluated in accordance with the standards...". If poultry studies are conducted in the future, the AAALAC International Executive Office must be notified and an updated Program Description must be submitted.

Sincerely,

Bart Carter, D.V.M., M.S.
President, Council on Accreditation

BC:cma
001655

tel: 301.696.9626
fax: 301.696.9627

accredit@aaalac.org
www.aaalac.org

Annexure 9. Test Item Information Sheet

MEDICAL DEVICES TEST ITEM / REFERENCE ITEM INFORMATION SHEET

Sl. No.	Particulars	Details
1	**Sponsor Name and Address** **(As in Study Plan and Study Report)**	Ktex Nonwovens Pvt Ltd Survey No.241, Opp. Khamta Village Bus Stop, Rajkot-Jamnagar Highway- 360 110, Gujarat
2	Manufactured by (Name and address) (Specify "same as study sponsor", if applicable. Otherwise provide details)	same as study sponsor
3	Supplied by (Name and address) (Specify "same as study sponsor", if applicable. Otherwise provide details)	same as study sponsor
4	Address for Communication with Email	mustanshir@ktexnonwovens.com, docs@ktexnonwovens.com
5	Address for Invoicing	same as study sponsor
6	Sponsor Representative Name	Mustanshir Vohra
7	Monitoring Scientist Name	
8	**Test Item** / Reference Item information (Mark as applicable) **Name of the Test Item** ■ Reference Item ☐	Spun melt PP Nonwoven Fabric
9	Intended Use of device in Human / Others (to Specify)	Human Use in Gown, Drapes, CSR Wraps, Diapers or sanitary pads.
10	Site of Contact	Skin
11	Duration of Contact with Human Body	6-12 Hours
12	Material Category (As per ISO 10993 Part 1)	Surface Medical Device
13	Weight in g. (without packing) ■	35 gm.
	Surface Area in cm^2 ☐	
	Thickness in mm ☐	
	Others (to Specify) ☐	
14	pH (If applicable)	
15	Material Safety Data Sheet Attached	■ Yes ☐ No
16	Certificate of Analysis Attached	■ Yes ☐ No
17	Storage Condition	■ Ambient (+19 to +25°C) ☐ Cool and Dry (+2 to +8°C) ☐ Frozen (-18 to -20°C) ☐ Hygroscopic ☐ Light Sensitive ☐ Any other (Please specify_____)
18	Test Item Code by Sponsor (If any)	KTEXSM001
19	Batch No. / Lot No.	2220524A
20	Date of Mfg.	24/05/2022

Annexure 9. (Contd.,) Test Item Information Sheet

21	Date of Exp. / Retest date (When stored as detailed below) (fill-up expiry date and/ retest date, whichever is applicable). If not, provide justification	2 Years From Date of Manufacturing
22	Quantity Dispatched and Date of Dispatch	19/09/2022
23	Name of Carrier / Mode of Shipment	Courier
24	Type of Packing and No. of Packs / Bottles	Zipper bag 2 packs of 1 or 2 mtrs Nonwoven fabrics
25	Sterility Status	☐ Sterile ■ Non-sterile* Sterile by _____
	*If Non-sterile, Select method of Sterilization	■ Autoclave Method ☐ Surface Sterillzation ☐ Post Extraction Filtration ☐ Other
26	Material Category	Medical Devices tems

List out the test to be conducted:

Sl. No.	Test / Study Name	Test Guideline
1.	Skin Sensitization Test	ISO 10993-10:2021 & OECD Test Guideline 406
2.	Skin Irritation Test	SO 10993-23:2021

Sponsor's Authorization:

As a Sponsor or Sponsor representative of these studies, I agree with below points:

- The studies requested are to meet the regulatory requirements of test item.
- The animal usage is necessary for requested studies as per guideline requirements. The species chosen is appropriate to the study and as per guidelines requirements.
- The studies requested are not an unnecessary duplication of previous work.

Sponsor or Sponsor Representative:
Mustanshir Vohra

26/09/2022
Sign. and Date

Instructions for filling Test Item / Reference Item Information Sheet:

- Fill the information sheet with available information.
- If the information is not available mentioned as NA and if section or column is not applicable for test item, reference item, mention as NA (Not Applicable).
- Add column or rows as per requirements.

Annexure 10. Certificate of Analysis

KTE Partners in Growth	**Ktex Nonwovens Pvt. Ltd.** POLYPROPYLENE SPUNBONDED NON WOVEN FABRICS **CERTIFICATE OF ANALYSIS**	Doc No: KN/CD/QA/FF/02 Rev No.: 03 Rev Date : 01-02-2022

COA Number :-	KN-DPHP-3172
Cont. No :-	GJ. 23.Y. 6471
Customer Name:-	DPHP

Date :-	05-Sep-22
Invoice No.:-	KTPL/22-23/416

Properties	Units	Test Method	Typical Analysis*	Specification	Remark
Product Code/Type	35.0 Spunmelt				
Treatment	Hydrophobic				
Structure	Oval				
Colour	White				
Lot No.	KTEXSM001				
Slit Width	MM	By Std. Measuring tape	800	±5	Passed
Weight	g/m^2	NWSP 130.1.R0(15)	34.65	±2	Passed
Tensile Strength MD	N/5 cm	NWSP 110.4.R0(15)	85.52	>70	Passed
Tensile Strength CD	N/5 cm	NWSP 110.4.R0(15)	52.12	>34	Passed
Tensile Elongation MD	%	NWSP 110.4.R0(15)	87.43	45-130	Passed
Tensile Elongation CD	%	NWSP 110.4.R0(15)	90.47	45-130	Passed
Water resistance($100cm^2$)	mmWC@ 60mbar	NWSP 080.6.R0(15)	631	>370	Passed

Test Certified: This certifies that the above item and run number have been produced and inspected in Conformance with the Ktex product specification.
The results are presented without any implied warranty. The certificate is strictly and exclusively limited for Customer reference only.

Ktex Nonwovens Pvt. Ltd. Complies with the strictest product and process controls according to the latest international standards.
Ktex Nonwovens Pvt. Ltd., reserves the right to update production data according the process and technological developments.
The above data sheet gives typical figures only and no implied warranty should be assumed.

(This is system generated report hence signature is not required.)

KTEX NONWOVENS PVT. LTD.

QUALITY MANAGEMENT ISO 9001:2015 CERTIFIED COMPANY

MANUFACTURER:-
Ktex Nonwovens Pvt. Ltd.
Survey No 241,Sanosara,
Opp. Khamta Bus Stop, Jamnagar Highway,
Village - Khamta, Tal - Dhrol,
Jamnagar, 360110, Gujarat, India.
Tel #: +91-9727055055

Annexure 11. Material Safety Data Sheet

KTEX
Partners in Growth

MATERIAL SAFETY DATA SHEET (MSDS)

Poly prepylene nonwoven fabric

Rev. Date:20/12/2021 Ver-01
Supersedes: 01/07/2018

SECTION1: PRODUCT IDENTIFICATION AND MANUFACTURER

1.1 Product Identifier

Trade Name: PP Spunbond/Meltblown Nonwoven Fabric

1.2 Relevant identified uses of the substance/mixture and uses advised against

Product Use: Hygiene, medical, industrial use&Filtration.

Uses Advised Against: None known.

1.3 Supplier Details

Address: KTEX Nonwovens Pvt. Ltd.
Survey No 241, Sanosara,
Opp. Khamta Village Bus Stop,
Rajkot - Jamnagar Highway,
Tal. Dhrol,
Dist. Jamnagar 360 110.
Phone: +91-9727055055, +91-9909355055.
E-mail: docs@ktexnonwovens.com
Emergency Phone Number
Info: +91-8758855055

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance/mixture Classification

Classification (Regulation (EC) No. 1272/2008)

Not a Hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.2. Label Elements:

Labelling (Regulation (EC) No. 1272/2008)

Not a Hazardous substance or mixture according to Regulation (EC) No. 1272/2008

2.3. Other Hazards: None known.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Mixture: >95% Polypropylene with max & 5%other additives.

SECTION 4: FIRST AID MEASURES:

4.1 Inhalation: N/A.

4.2 If swallowed: Do not induce vomiting; get immediate medical attention.

4.3 Eye Contact: Rinse eyes with water. If irritation persists, contact a physician. If symptoms, Persist, Obtain medical attention.

SECTION 5: FIRE FIGHTING MEASURES:

5.1 Extinguishing media: Dry Powder.

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire fighting : Exposure to decomposition products may be a hazard to health.

5.3 Advice for fire fighters

Special protective equipment for Fire fighters	: Wear self- contained breathing apparatus for fire Fighting if necessary. Use personal protective Equipment.

SECTION 6: ACCIDENTAL RELEASE MEASURES:

6.1 Personal precautions, protective equipment & emergency procedure

Personal precautions	: Ensure adequate ventilation, especially in confined areas. Avoid inhalation of vapour or mist.

6.2 Environmental precautions

Environmental precautions	: Do not release in water or sanitary sewer system & land openly. If the product contaminates land, river & lakes inform respective authorities.

6.3 Methods and material for containment and Cleaning up

Methods for cleaning up	: Keep in suitable, closed containers for disposal.

SECTION 7: HANDLING AND STORAGE:

7.1 Precaution for safe handling:

Advise on protection against fire & explosion.	: Normal measures for preventive fire protection.
Hygiene measures.	: Handle in accordance with good industrial hygiene and safety practice. : General industrial hygiene practice.

7.2 Condition for safe storage, including any incompatibilities:

Advice on common storage	: Keep away from food, drink and animal feedingstuffs.
Safe Storage	: Store in tightly closed container in cool, dry, well-ventilated area away from heat or Sources of ignition. : Store at ambient temperature out of direct sunlight.
Other data	: No decomposition if stored and applied as directed.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION:

8.1 Control parameters: Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Engineering measures	**:** Non required.
Hand Protection	**:** Non required.
Eye Protection	**:** Safety goggles or glasses.
Respiratory Protection	**:** Respiratory protection is not normally required if good ventilation is maintained and exposure guidlines are not exceeded.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Basic Properties:

Annexure 11. (Contd.,) Material Safety Data Sheet

Physical state	: Solid.
Colour	: As per Customer requirement.
Odor/Odor Threshold	: Characteristic odor/No data available.
pH, @25°C	: 7.0
Density	: 0.855 gm/cc.
Flash point	: Not measured.
Melting Point	: 180 °C
Solidification Point	: 145 °C
Boiling Point	: Not measured.
Solubility in water	: Not soluble.
Oxidizing Properties	: Not Applicable.

SECTION 10: CHEMICAL STABILITY AND REACTIVITY

10.1 Reactivity	:Hazardous polymerization will not occur.
10.2 Chemical stability	:No decomposition if used as directed.
10.3 Possibility of hazardous reactions	
Hazardous reactions	:No decomposition if stored and applied as directed.
10.4 Conditions to avoid	: None known.
10.5 Incompatible materials	
Materials to avoid	: None known.
10.6 Hazardous decomposition products	
Hazardous decomposition products	: Build-up of dangerous/toxic possible in cases of fire/high temperatures.

SECTION 11: TOXOLOGICAL INFORMATION:

11.1 Information on toxicological effects	
Acute toxicity	
Acute oral toxicity	: Not classified.
Skin corrosion/irritation	: Not measured.
Skin Sensitization	: Not measured.

SECTION 12: ECOLOGICAL INFORMATION

12.1 This product has no known eco-toxicological effect.

SECTION 13: DISPOSABLE CONSIDERATIONS

13.1 Waste disposal recommendation Waste materials may be disposed in a sanitary landfill.

SECTION 14: TRANSPORTATION INFORMATION:

14.1 Each and every slit roll and pallet roll are labelled with proper tracebility of process used.
No other specific requirement.

SECTION 15: REGULATORY INFORMATION:

15.1 Classification and labeling Danger symbol	: N/A.
15.2 Danger Label	: N/A.
15.3 Safety phrases	:N/A.

Annexure 11. (Contd.,) Material Safety Data Sheet

SECTION 16: OTHER INFORMATION:

16.1 Applications:-

- Hygiene
- Medical
- Industrial Application
- Dust Collectors
- Filtration

16.2 Physical Properties:-

- Thermo bonded No chemical
- Excellent bi-directional and wear properties
- Soft and Comfortable
- Grammage between 08-150 g/m2

16.3 Possible Additional Nonwoven Features:-

- Printing
- Lamination
- Electrostatic charging

16.4 By using Additives or pigment pastes:-

- Drying in every imaginable Shade
- Fire retardant properties
- Antistatic properties
- Increased UV and Gamma ray protection.
- Hydrophilic Properties.
- Alcohal repellency Properties.

Annexure 12. Contaminant Analysis of Bedding Material

SMSLA

SMS LABS SERVICES PRIVATE LIMITED

TEST REPORT

TC-6118

ULR - TC611822000010596F
Report No : ED22050367-01

Report Date: 02 Jun 2022

Customer Name	: **M/s. Liveon Biolabs Private Limited**		
Customer Address	: #46 & 47, Water Tank Road, KIADB Industrial Area. Phase II, Antharasanahalli, Tumakuru-572106		
Sample Name	: Corn Cob	Sample Sent on	: 27 May 2022
Sample Drawn By	: Customer	Sample Received on	: 28 May 2022
Sample Quantity	: 500gm x 1No	Test Started on	: 28 May 2022
Sample Identification	: LBPL-CC-0029	Test Completed on	: 02 Jun 2022

TEST RESULTS

S.NO	Parameter	Test Method	Unit	Results
Food & Agri- Cereals, Pulses & Cereal Products				
Biological				
1	*Escherichia coli*	IS 5887 (Part 1)	Per g	Absent
2	*Pseudomonas aeruginosa*	SMSLA/MB/SOP/36	Per 10g	Absent
3	*Salmonella spp*	ISO 6579 (Part 1)	Per 25g	Absent
4	*Staphylococcus aureus*	IS 5887 (Part 2)	Per g	Absent
Mycotoxins				
5	Aflatoxin B1	SMSLA/HC/SOP/02	µg/kg	BLQ(LOQ:0.50)
6	Aflatoxin B2	SMSLA/HC/SOP/02	µg/kg	BLQ(LOQ:0.50)
7	Aflatoxin G1	SMSLA/HC/SOP/02	µg/kg	BLQ(LOQ:0.50)
8	Aflatoxin G2	SMSLA/HC/SOP/02	µg/kg	BLQ(LOQ:0.50)
Pesticides				
9	4-Bromo-2-Chlorophenol	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
10	Acephate	SMSLA/LS/SOP/02	mg/kg	BLQ(LOQ:0.01)
11	Aldrin	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
12	Chlordane	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
13	Chlorfenvinphos	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
14	Chlorothalonil	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
15	Chlorpyrifos Ethyl	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
16	Chlorpyrifos Methyl	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
17	Diazinon	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
18	Dichlorvos	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)

Authorized Signatory-Chemical

Authorized Signatory- Biological

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Annexure 12. (Contd.,) Contaminant Analysis of Bedding Material

SMSLA

SMS LABS SERVICES PRIVATE LIMITED

TEST REPORT

TC-6118

ULR - TC611822000010596F
Report No : FD22050367-01

Report Date: 02 Jun 2022

S.NO	Parameter	Test Method	Unit	Results
19	Dieldrin	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
20	Dimethoate	SMSLA/LS/SOP/02	mg/kg	BLQ(LOQ:0.01)
21	Endosulfan Sulfate	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
22	Endosulfan-Alpha	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
23	Endosulfan-Beta	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
24	Endrin	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
25	Ethion	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
26	Etrimphos	SMSLA/LS/SOP/02	mg/kg	BLQ(LOQ:0.01)
27	Fenitrothion	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
28	HCH-Alpha	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
29	HCH-Beta	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
30	HCH-Gamma	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
31	Heptachlor	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
32	Iprobenphos (Kitazin)	SMSLA/LS/SOP/02	mg/kg	BLQ(LOQ:0.01)
33	Malathion	SMSLA/LS/SOP/02	mg/kg	BLQ(LOQ:0.01)
34	Methamidophos	SMSLA/LS/SOP/02	mg/kg	BLQ(LOQ:0.01)
35	Monocrotophos	SMSLA/LS/SOP/02	mg/kg	BLQ(LOQ:0.01)
36	o,p-DDD	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
37	o,p-DDE	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
38	o,p-DDT	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
39	o,p-Dicofol	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
40	Omethoate	SMSLA/LS/SOP/02	mg/kg	BLQ(LOQ:0.01)
41	Oxydemeton methyl	SMSLA/LS/SOP/02	mg/kg	BLQ(LOQ:0.01)
42	p,p-DDD	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
43	p,p-DDE	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
44	p,p-DDT	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
45	p,p-Dicofol	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
46	Parathion ethyl	SMSLA/LS/SOP/02	mg/kg	BLQ(LOQ:0.01)
47	Parathion methyl	SMSLA/LS/SOP/02	mg/kg	BLQ(LOQ:0.01)

A. Kanagavel
Authorized Signatory - Chemical

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Annexure 12. (Contd.,) Contaminant Analysis of Bedding Material

SMSLA

SMS LABS SERVICES PRIVATE LIMITED

TEST REPORT

TC-6118

ULR - TC611822000010596F
Report No : FD22050367-01

Report Date: 02 Jun 2022

S.NO	Parameter	Test Method	Unit	Results
48	Phorate	SMSLA/LS/SOP/02	mg/kg	BLQ(LOQ:0.01)
49	Phosalone	SMSLA/LS/SOP/02	mg/kg	BLQ(LOQ:0.01)
50	Phosphamidon	SMSLA/LS/SOP/02	mg/kg	BLQ(LOQ:0.01)
51	Profenofos	SMSLA/LS/SOP/02	mg/kg	BLQ(LOQ:0.01)
52	Quinalphos	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
53	Triazophos	SMSLA/LS/SOP/02	mg/kg	BLQ(LOQ:0.01)
Trace Metal Elements				
54	Arsenic	SMSLA/IS/SOP/02	mg/kg	BLQ(LOQ:0.1)
55	Cadmium	SMSLA/IS/SOP/02	mg/kg	BLQ(LOQ:0.01)
56	Lead	SMSLA/IS/SOP/02	mg/kg	BLQ(LOQ:0.1)
57	Mercury	SMSLA/IS/SOP/02	mg/kg	BLQ(LOQ:0.1)

Note: BLQ: Below Limit of Quantification; LOQ: Limit of Quantification.
<10Cfu/g can be taken as absent in 1:10 dilution.cfu-colony forming unit.

/********** End of the Report **********/

K. Elakkiyathasan
Authorized Signatory - Chemical

A. Kanagavel
Authorized Signatory - Chemical

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Annexure 13. Contaminant Analysis of Feed

SMSLA

SMS LABS SERVICES PRIVATE LIMITED

TEST REPORT

TC-6118

ULR - TC611822000010599F
Report No : FD22050367-04

Report Date: 02 Jun 2022

Customer Name	: M/s. Liveon Biolabs Private Limited		
Customer Address	: #46 & 47, Water Tank Road, KIADB Industrial Area, Phase-II, Antharasanahalli, Tumakuru-572106		
Sample Name	: Rabbit Feed	Sample Sent on	: 27 May 2022
Sample Quantity	: 500gm x 1No	Sample Received on	: 28 May 2022
Sample Identification	: Batch No: 323, Mfg Date: 22.04.22, Exp Date: 22.10.22	Test Started on	: 30 May 2022
Sample Drawn By	: Customer	Test Completed on	: 02 Jun 2022

TEST RESULTS

S.NO	Parameter	Test Method	Unit	Results
Animal Food & Feeds				
Chemical				
1	Calcium	IS 7874 (Part 2)	g/100g	1.25
2	Carbohydrates	SMSLA/FD/SOP/011	g/100g	61.85
3	Crude Fat	IS 7874 (Part 1)	g/100g	3.14
4	Crude Fibre	IS 7874 (Part 1)	g/100g	12.68
5	Crude Protein	AOAC 2001.11	g/100g	18.00
6	Moisture	IS 7874 (Part 1)	g/100g	9.12
7	Phosphorus	IS 7874 (Part 2)	g/100g	0.63
8	Total Ash	IS 7874 (Part 1)	g/100g	7.89
Mycotoxins				
9	Aflatoxin B1	SMSLA/HC/SOP/02	µg/kg	BLQ(LOQ:0.50)
10	Aflatoxin B2	SMSLA/HC/SOP/02	µg/kg	BLQ(LOQ:0.50)
11	Aflatoxin G1	SMSLA/HC/SOP/02	µg/kg	BLQ(LOQ:0.50)
12	Aflatoxin G2	SMSLA/HC/SOP/02	µg/kg	BLQ(LOQ:0.50)
Pesticides				
13	4-Bromo-2-Chlorophenol	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
14	Aldrin	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
15	Chlordane	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
16	Chlorfenvinphos	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
17	Chlorothalonil	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
18	Chlorpyrifos Ethyl	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)

P. Jayasudha
P. Jayasudha
Authorized Signatory - Chemical

A. Kan[illegible]
Authorized Signatory - Chemical

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Annexure 13. (Contd.,) Contaminant Analysis of Feed

SMSLA

SMS LABS SERVICES PRIVATE LIMITED

TEST REPORT

TC-6118

ULR - TC611822000010599F
Report No : FD22050367-04

Report Date: 02 Jun 2022

S.NO	Parameter	Test Method	Unit	Results
19	Chlorpyrifos Methyl	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
20	Diazinon	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
21	Dichlorvos	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
22	Dieldrin	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
23	Dimethoate	SMSLA/LS/SOP/02	mg/kg	BLQ(LOQ:0.01)
24	Endosulfan Sulfate	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
25	Endosulfan-Alpha	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
26	Endosulfan-Beta	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
27	Endrin	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
28	Ethion	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
29	Fenitrothion	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
30	HCH-Alpha	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
31	HCH-Beta	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
32	HCH-Delta	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
33	HCH-Gamma	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
34	Heptachlor	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
35	Malathion	SMSLA/LS/SOP/02	mg/kg	BLQ(LOQ:0.01)
36	o,p-DDD	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
37	o,p-DDE	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
38	o,p-DDT	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
39	o,p-Dicofol	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
40	Oxyfluorfen	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
41	p,p-DDD	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
42	p,p-DDE	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
43	p,p-DDT	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
44	p,p-Dicofol	SMSLA/GS/SOP/02	mg/kg	BLQ(LOQ:0.01)
45	Paraoxon methyl	SMSLA/LS/SOP/02	mg/kg	BLQ(LOQ:0.01)
46	Parathion ethyl	SMSLA/LS/SOP/02	mg/kg	BLQ(LOQ:0.01)
47	Parathion methyl	SMSLA/LS/SOP/02	mg/kg	BLQ(LOQ:0.01)
48	Phorate	SMSLA/LS/SOP/02	mg/kg	BLQ(LOQ:0.01)
49	Phosalone	SMSLA/LS/SOP/02	mg/kg	BLQ(LOQ:0.01)

A. Kanagavel
Authorized Signatory - Chemical

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Annexure 13. (Contd.,) Contaminant Analysis of Feed

SMSLA

SMS LABS SERVICES PRIVATE LIMITED

TEST REPORT

TC-6118

ULR - TC611822000010599F
Report No : FD22050367-04

Report Date: 02 Jun 2022

S.NO	Parameter	Test Method	Unit	Results
50	Profenofos	SMSLA/LS/SOP/02	mg/kg	BLQ(LOQ:0.01)
Trace Metal Elements				
51	Arsenic	SMSLA/IS/SOP/01	mg/kg	0.99
52	Cadmium	SMSLA/IS/SOP/01	mg/kg	BLQ(LOQ:0.1)
53	Lead	SMSLA/IS/SOP/01	mg/kg	0.33
54	Magnesium	SMSLA/IS/SOP/05	mg/kg	0.23656
55	Mercury	SMSLA/IS/SOP/01	mg/kg	BLQ(LOQ:0.1)
56	Potassium	SMSLA/IS/SOP/05	mg/kg	1.4634
57	Sodium	SMSLA/IS/SOP/05	mg/kg	0.3041
58	Zinc	SMSLA/IS/SOP/01	mg/kg	55.23

Note: BLQ: Below Limit of Quantification; LOQ: Limit of Quantification.

/********** End of the Report **********/

K. Elakkiyathasan
Authorized Signatory - Chemical

A. Kanagavel
Authorized Signatory - Chemical

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Annexure 14. Contaminant Analysis of RO Water

SMSLA

SMS LABS SERVICES PRIVATE LIMITED

TEST REPORT

TC-6118

ULR - TC611822000009912F
Report No : QEN-22050203-01

Report Date : 07 Jun 2022

Customer Name	:	**M/s. Liveon Biolabs Private Limited.**			
Customer Address	:	Plot No. 46 & 47, Water Tank Road, II Phase, KIADB Industrial Area, Antharasanahalli, Tumakuru, Karnataka 572106			
Sample Name	:	Water	Sample Quantity	:	15 Ltr
Sample Description	:	RO Water	Sampling Date	:	26 May 2022
Reference	:	Test Request Form Dated 26.05 2022	Sample Received on	:	28 May 2022
Sample Drawn By	:	Laboratory	Test Started on	:	28 May 2022
Sample Location	:	Liveon Biolab Plant	Test Completed on	:	06 Jun 2022
Sample Procedure	:	SMSLA/EN/SOP/001 & SMSLA/MB/SOP/06			

TEST RESULTS

S.NO	Parameter	Test Method	Unit	Results	Requirements as per IS 10500-2012-Amd:4	
					Acceptable Limit	Permissible Limit in the absence of alternative source
Biological						
1	*Escherichia coli*	IS 15185	Per 100mL	Absent	Absent/100mL	Absent/100mL
2	*Total Coliforms*	IS 15185	Per 100mL	Absent	Absent/100mL	Absent/100mL
Clause 4, Table 1 Organoleptic And Physical parameters						
3	Colour	IS 3025 (Part 04)	Hazen	2.0	5.0 Max	15.0 Max
4	Odour	IS 3025 (Part 05)	--	Agreeable	Agreeable	Agreeable
5	pH Value	IS 3025 (Part 11)	--	7.27	6.5 - 8.5	No Relaxation
6	Taste	IS 3025 (Part 08)	--	Agreeable	Agreeable	Agreeable
7	Total Dissolved Solids	IS 3025 (Part 16)	mg/L	170	500.0 Max	2000.0 Max
8	Turbidity	IS 3025 (Part 10)	NTU	0.4	1.0 Max	5.0 Max
Clause 4, Table 2 General Parameters Concerning Substances Undesirable In Excessive Amounts						
9	Aluminium	IS 3025 (Part 65)	mg/L	BLQ(LOQ:0.001)	0.03 Max	0.2 Max
10	Ammonia (as Total Ammonia-N)	IS 3025 (Part 34)	mg/L	BLQ(LOQ:0.03)	0.5 Max	No Relaxation
11	Anoinic Detergents (as MBAS)	Annex K of IS 13428	mg/L	BLQ(LOQ:0.05)	0.2 Max	1.0 Max
12	Barium	IS 3025 (Part 65)	mg/l	BLQ(LOQ:0.001)	0.7 Max	No Relaxation
13	Boron	IS 3025 (Part 65)	mg/L	BLQ(LOQ:0.025)	0.5 Max	2.4 Max

D. KARTHIK
Microbiologist

R. PRABHU
Senior Chemist

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Annexure 14. (Contd.,) Contaminant Analysis of RO Water

SMSLA

SMS LABS SERVICES PRIVATE LIMITED

TEST REPORT

TC-6118

ULR - TC611822000009912F
Report No : QEN-22050203-01

Report Date : 07 Jun 2022

S.NO	Parameter	Test Method	Unit	Results	Requirements as per IS 10500-2012-Amd:4	
					Acceptable Limit	Permissible Limit in the absence of alternative source
14	Calcium (as Ca)	IS 3025 (Part 40)	mg/L	12	75.0 Max	200.0 Max
15	Chloramines (as Cl2)	APHA 23rd Edition:4500 Cl G 2017	mg/L	BLQ(LOQ:1.0)	4.0 Max	No Relaxation
16	Chloride (as Cl)	IS 3025 (Part 32)	mg/L	40	250.0 Max	1000.0 Max
17	Copper	IS 3025 (Part 65)	mg/L	BLQ(LOQ:0.001)	0.05 Max	1.5 Max
18	Fluoride as F	IS 3025 (Part 60)	mg/L	BLQ(LOQ:0.1)	1.0 Max	1.5 Max
19	Free Residual Chlorine	IS 3025 (Part 26)	mg/L	BLQ(LOQ:0.1)	0.2 Min	1.0 Min
20	Iron (as Fe)	IS 3025 (Part 53)	mg/L	BLQ(LOQ:0.05)	1.0 Max	No Relaxation
21	Magnesium (as Mg)	IS 3025 (Part 46)	mg/L	5.8	30.0 Max	100.0 Max
22	Manganese	IS 3025 (Part 65)	mg/L	BLQ(LOQ:0.001)	0.1 Max	0.3 Max
23	Mineral Oil	IS 3025 (Part 39)	mg/L	BLQ(LOQ:1.0)	1.0 Max	No Relaxation
24	Nitrate (as NO3)	APHA 23rd Edition:4500 NO3 B 2017	mg/L	8.1	45.0 Max	No Relaxation
25	Phenolic Compound (as C6H5OH)	IS 3025 (Part 43)	mg/L	BLQ(LOQ:0.001)	0.001 Max	0.002 Max
26	Selenium	IS 3025 (Part 65)	mg/L	BLQ(LOQ:0.001)	0.01 Max	No Relaxation
27	Silver	IS 3025 (Part 65)	mg/L	BLQ(LOQ:0.001)	0.1 Max	No Relaxation
28	Sulphate (as SO4)	IS 3025 (Part 24)	mg/L	16	200.0 Max	400.0 Max
29	Sulphide (as H2S)	IS 3025 (Part 29)	mg/L	BLQ(LOQ:0.04)	0.05 Max	No Relaxation
30	Total Alkalinity (as CaCO3)	IS 3025 (Part 23)	mg/L	62	200.0 Max	600.0 Max
31	Total Hardness (as CaCO3)	IS 3025 (Part 21)	mg/L	54	200.0 Max	600.0 Max
32	Zinc	IS 3025 (Part 65)	mg/L	BLQ(LOQ:0.001)	5.0 Max	15.0 Max
Clause 4, Table 3 Parameters Concerning Toxic Substances						
33	Arsenic	IS 3025 (Part 65)	mg/L	BLQ(LOQ:0.001)	0.01 Max	No Relaxation
34	Bromo dichloromethane	SMSLA/GEF/SOP/03	mg/L	BLQ (LOQ:0.005)	0.06 Max	No relaxation
35	Bromoform	SMSLA/GEF/SOP/03	mg/L	BLQ (LOQ:0.005)	0.1 Max	No Relaxation
36	Cadmium	IS 3025 (Part 65)	mg/L	BLQ(LOQ:0.001)	0.003 Max	No Relaxation
37	Chloroform	SMSLA/GEF/SOP/03	mg/L	BLQ (LOQ:0.005)	0.2 Max	No Relaxation
38	Chromium	IS 3025 (Part 65)	mg/L	BLQ(LOQ:0.001)	0.05 Max	No Relaxation
39	Cyanide (as CN)	IS 3025 (Part 27)	mg/L	BLQ(LOQ:0.01)	0.05 Max	No Relaxation

R. PRABHU
Senior Chemist

Laboratory Address : 39/6, Thiruvallur High Road, Puduchatram Post, Thirumazhisai Via, Poonamallee Taluk, Chennai - 600124.
Certified By : ISO 9001 & ISO 45001.

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Annexure 14. (Contd.,) Contaminant Analysis of RO Water

SMSLA

SMS LABS SERVICES PRIVATE LIMITED

TEST REPORT

TC-6118

ULR - TC611822000009912F
Report No : QEN-22050203-01

Report Date : 07 Jun 2022

S.NO	Parameter	Test Method	Unit	Results	Requirements as per IS 10500-2012-Amd:4	
					Acceptable Limit	Permissible Limit in the absence of alternative source
40	Dibromochloromethane	SMSLA/GEF/SOP/03	mg/L	BLQ (LOQ:0.005)	0.1 Max	No Relaxation
41	Lead	IS 3025 (Part 65)	mg/L	BLQ(LOQ:0.001)	0.01 Max	No Relaxation
42	Mercury	EPA 200.8	mg/L	BLQ(LOQ:0.0005)	0.001 Max	No Relaxation
43	Molybdenum	IS 3025 (Part 65)	mg/L	BLQ(LOQ:0.001)	0.07 Max	No Relaxation
44	Nickel	IS 3025 (Part 65)	mg/L	BLQ(LOQ:0.001)	0.02 Max	No Relaxation
45	PAHs	SMSLA/GS/SOP/01	mg/L	BLQ(LOQ:0.00001)each	0.0001 Max	No Relaxation
46	PCBs	SMSLA/GS/SOP/01	mg/L	BLQ(LOQ:0.00001)each	0.0005 Max	No Relaxation
47	Uranium	IS 3025 (Part 65)	mg/L	BLQ(LOQ:0.001)	0.03 Max	No relaxation
Clause 4, Table 5 Pesticide Residues						
48	2,4-D	SMSLA/LS/SOP/01	µg/L	BLQ(LOQ:0.01)	30.0 Max	No Relaxation
49	Alachlor	SMSLA/GS/SOP/01	µg/L	BLQ(LOQ:0.01)	20.0 Max	No Relaxation
50	Aldrin	SMSLA/GS/SOP/01	µg/L	BLQ(LOQ:0.01)	0.03 Max	No Relaxation
51	Atrazine	SMSLA/GS/SOP/01	µg/L	BLQ(LOQ:0.01)	2.0 Max	No Relaxation
52	Butachlor	SMSLA/GS/SOP/01	µg/L	BLQ(LOQ:0.01)	125.0 Max	No Relaxation
53	Chlorpyrifos Ethyl	SMSLA/GS/SOP/01	µg/L	BLQ(LOQ:0.01)	30.0 Max	No Relaxation
54	Dieldrin	SMSLA/GS/SOP/01	µg/L	BLQ(LOQ:0.01)	0.03 Max	No relaxation
55	Endosulfan Sulfate	SMSLA/GS/SOP/01	µg/L	BLQ(LOQ:0.01)	0.4 Max	No Relaxation
56	Endosulfan-Alpha	SMSLA/GS/SOP/01	µg/L	BLQ(LOQ:0.01)	0.4 Max	No Relaxation
57	Endosulfan-Beta	SMSLA/GS/SOP/01	µg/L	BLQ(LOQ:0.01)	0.4 Max	No Relaxation
58	Ethion	SMSLA/GS/SOP/01	µg/L	BLQ(LOQ:0.01)	3.0 Max	No Relaxation
59	HCH-Alpha	SMSLA/GS/SOP/01	µg/L	BLQ(LOQ:0.01)	0.01 Max	No Relaxation
60	HCH-Beta	SMSLA/GS/SOP/01	µg/L	BLQ(LOQ:0.01)	0.04 Max	No Relaxation
61	HCH-Delta	SMSLA/GS/SOP/01	µg/L	BLQ(LOQ:0.01)	0.04 Max	No Relaxation
62	HCH-Gamma	SMSLA/GS/SOP/01	µg/L	BLQ(LOQ:0.01)	2.0 Max	No Relaxation
63	Isoproturon	SMSLA/LS/SOP/01	µg/L	BLQ(LOQ:0.01)	9.0 Max	No Relaxation
64	Malathion	SMSLA/LS/SOP/01	µg/L	BLQ(LOQ:0.01)	190.0 Max	No Relaxation
65	Monocrotophos	SMSLA/LS/SOP/01	µg/L	BLQ(LOQ:0.01)	1.0 Max	No Relaxation

K. Prakash

K.PRAKASH
Senior Chemist

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Annexure 14. (Contd.,) Contaminant Analysis of RO Water

SMSLA

SMS LABS SERVICES PRIVATE LIMITED

TEST REPORT

TC-6118

ULR - TC611822000009912F
Report No : QEN-22050203-01

Report Date : 07 Jun 2022

S.NO	Parameter	Test Method	Unit	Results	Requirements as per IS 10500-2012-Amd:4	
					Acceptable Limit	Permissible Limit in the absence of alternative source
66	o,p-DDD	SMSLA/GS/SOP/01	µg/L	BLQ(LOQ:0.01)	1.0 Max	No Relaxation
67	o,p-DDE	SMSLA/GS/SOP/01	µg/L	BLQ(LOQ:0.01)	1.0 Max	No Relaxation
68	o,p-DDT	SMSLA/GS/SOP/01	µg/L	BLQ(LOQ:0.01)	1.0 Max	No Relaxation
69	p,p-DDD	SMSLA/GS/SOP/01	µg/L	BLQ(LOQ:0.01)	1.0 Max	No Relaxation
70	p,p-DDE	SMSLA/GS/SOP/01	µg/L	BLQ(LOQ:0.01)	1.0 Max	No Relaxation
71	p,p-DDT	SMSLA/GS/SOP/01	µg/L	BLQ(LOQ:0.01)	1.0 Max	No Relaxation
72	Parathion methyl	SMSLA/LS/SOP/01	µg/L	BLQ(LOQ:0.01)	0.3 Max	No Relaxation
73	Phorate	SMSLA/LS/SOP/01	µg/L	BLQ(LOQ:0.01)	2.0 Max	No Relaxation

Note : BLQ- Below Limit of Quantification LOQ: Limit of Quantification
Free Residual Chlorine Limit to be applicable only Chlorinated Water

Remarks : The RO Water sample conforms to the requirements of Acceptable Limits as per IS 10500:2012 : Amd 4 for the Parameters tested above.

/********** End of the Report **********/

K. PRAKASH
Senior Chemist

Laboratory Address : 39/6, Thiruvallur High Road, Puduchatram Post, Thirumazhisai Via, Poonamallee Taluk, Chennai - 600124.
Certified By : ISO 9001 & ISO 45001.

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Annexure 14. (Contd.,) Contaminant Analysis of RO Water

SMSLA

SMS LABS SERVICES PRIVATE LIMITED

TEST REPORT

Report No : QEN-22050203-01 **Report Date :** 07 Jun 2022

Customer Name	**M/s. Liveon Biolabs Private Limited.**		
Customer Address	: Plot No. 46 & 47, Water Tank Road, II Phase, KIADB Industrial Area, Antharasanahalli, Tumakuru, Karnataka 572106		
Sample Name	: Water	Sample Quantity	: 15 Ltr
Sample Description	: RO Water	Sampling Date	: 26 May 2022
Reference	: Test Request Form Dated 26.05.2022	Sample Received on	: 28 May 2022
Sample Drawn By	: Laboratory	Test Started on	: 28 May 2022
Sample Location	: Liveon Biolab Plant	Test Completed on	: 06 Jun 2022
Sample Procedure	: SMSLA/EN/SOP/001		

TEST RESULTS

S.NO	Parameter	Test Method	Unit	Results	Requirements as per IS 10500-2012-Amd:4	
					Acceptable Limit	Permissible Limit in the absence of alternative source
Clause 4, Table 4 Parameters Concerning Radioactive Substances						
1	Alpha Emitters*	IS 14194 (Part 02)	Bq/L	BLQ(LOQ:0.1)	0.1 Max	No Relaxation
2	Beta Emitters*	IS 14194 (Part 01)	Bq/L	BLQ(LOQ:1.0)	1.0 Max	No Relaxation

Note : BLQ: Below Limit of Quantification LOQ: Limit of Quantification & Bq: Becquerel *Sub Contracted Parameters.

Remarks : The RO Water sample conforms to the requirements of Acceptable Limits as per IS 10500:2012 : Amd : 4 for the Parameters tested above

/********** End of the Report **********/

R. PRABHU
Senior Chemist

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Annexure 15. Study Plan

Liveon Biolabs

STUDY PLAN

STUDY TITLE

INTRACUTANEOUS REACTIVITY TEST OF POLAR AND NON-POLAR EXTRACTS OF SPUN MELT PP NONWOVEN FABRIC IN NEW ZEALAND WHITE RABBITS

TEST GUIDELINE: ISO 10993-23:2021

STUDY NO.: LBPL/NG-2642 (TX)

STUDY CODE: IRTNZW

STUDY DIRECTOR

Mrs. Bhagyashree M

SPONSOR

KTEX NONWOVENS PVT. LTD.
SURVEY NO.241, OPP. KHAMTA VILLAGE BUS STOP
RAJKOT-JAMNAGAR HIGHWAY-360 110,
GUARAT

TEST FACILITY

LIVEON BIOLABS PRIVATE LIMITED
PLOT NO. 46 & 47, II PHASE, WATER TANK ROAD
KIADB INDUSTRIAL AREA, ANTHARASANAHALLI
TUMAKURU-572106, KARNATAK
INDIA.

Annexure 15. (Contd.,) Study Plan

Liveon Biolabs

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Annexure 15. (Contd.,) Study Plan

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1. OBJECTIVE

The objective of this study is to assess the possible irritation likely to arise from Intracutaneous injection of extract of the test item, "Spun Melt PP Nonwoven Fabric" Following its single administration in New Zealand White Rabbits. This study will provide a rational basis of risk assessment in humans.

2. STUDY DETAILS

Study Title	:	Intracutaneous Reactivity Test of Polar and Non-Polar Extracts Spun Melt PP Nonwoven Fabric in New Zealand White Rabbits.
Study Number	:	LBPL/NG-2642 (TX)
Study Code	:	IRTNZW
ULR No	:	TC-679422000001264F
Sponsor	:	KTEX NONWOVENS PVT LTD Survey no.241, Opp. Khamta Village Bus Stop Rajkot-Jamnagar Highway-360 110, Guarat
Test Facility	:	LIVEON BIOLABS PRIVATE LIMITED Plot No.46 & 47, II Phase Water Tank Road, KIADB Industrial Area Antharasanahalli, Tumakuru – 572106 Karnataka, India.

3. STUDY RESPONSIBILITIES

Study Director	:	Mrs. Bhagyashree M
Study Veterinarian	:	Dr. Sunkad Meghana
Sponsor Representative	:	Mustanshir Vohra

4. STUDY SCHEDULE

Study Initiation Date	:	16/12/2022
Experiment Start Date	:	20/12/2022
Acclimatization Period	:	20/12/2022 to 26/12/2022
Treatment Date	:	27/12/2022
Experiment End Date	:	30/12/2022
Draft Report to Sponsor	:	Latest by 07/01/2023
Study Completion Date	:	Latest by 06/02/2023 or Within a week after receiving comments for draft report from sponsor.

Annexure 15. (Contd.,) Study Plan

5. ABBREVIATIONS AND SYMBOLS

AAALAC	:	Association for Assessment and Accreditation of Laboratory Animal Care
CPCSEA	:	Committee for the Purpose of Control and Supervision of Experiments on Animals
dB	:	decibel
g	:	Gram
h/hr (s)	:	Hour (s)
IAEC	:	Institutional Animal Ethics Committee
IEC	:	International Electrotechnical Commission
IRTNZW	:	Intracutaneous Reactivity Test in New Zealand White Rabbits
ISO	:	International Organization for Standardization
mL/kg	:	Millilitre per kilogram
mL	:	Millilitre
Or	:	Eccetra
rpm	:	Revolutions per minute
SD	:	Standard Deviation
SOP	:	Standard operating procedure
TFM	:	Test Facility Management
TIIS	:	Test Item Information Sheet
QAU	:	Quality Assurance Unit
<	:	Less than

Note: Additional abbreviations and symbols (if any) will be provided in Study Report.

6. QUALITY ASSURANCE UNIT RESPONSIBILITIES

The Quality Assurance Unit Liveon Biolabs Private Limited will inspect at different phases of the study to review the draft study plan, final study plan, raw data, draft study report and final study report to assure the integrity of study in compliance with ISO/IEC 17025:2017. Findings of all the inspections during the study will be recorded and reported to the Study Director and Test Facility Management. A statement of Quality Assurance will be provided in the Study Report.

7. STUDY COMPLIANCE

The study will be performed in compliance with the following:

- ISO/IEC 17025:2017, General Requirements for the Competence of Testing and Calibration Laboratories.
- Standard Operating Procedures of Test Facility and the mutually agreed Study Plan.

8. STUDY GUIDELINES

The design of this study is based on the study objective(s) and procedures as detailed in the Study Plan, the overall product development strategy for the test item, and the below mentioned guidelines in principles as applicable.

- ISO 10993-23:2021 - Biological Evaluation of Medical Devices-Part 23: Tests for Irritation.

9. IAEC APPROVAL

The use of animals for this study has been approved by Liveon Biolabs Private Limited IAEC. IAEC approved Protocol No.: LBPL-IAEC-049-06/2022. Any significant changes to this Study Plan will be intimated to IAEC and approvals will be sought subsequently, if required.

10. ANIMAL WELFARE AND VETERINARY CARE

Liveon Biolabs Private Limited is an AAALAC International accredited facility and registered with CPCSEA, Department of Animal Husbandry and Dairying (DAHD), Ministry of Fisheries, Animal Husbandry and Dairying (MoFAH&D), Government of India. Also, Liveon Biolabs Private Limited ensures that animal experiments are performed in accordance with the recommendation of the regulatory guidelines for laboratory animal facility published in the gazette of India, 2021.

During study if any animal gets injured, ill or moribund, care will be taken as per the current veterinary practices. If required, for humane reasons, animals will be euthanized as per the standard procedures. The objective of the study will be considered before any decision and event of any unlikely situations will be intimated to the sponsor.

11. AMENDMENT AND DEVIATION PROCEDURES

This Study Plan may be amended or subjected to alterations. The amendment to the approved Study Plan will be put in writing and realized only after written consent from the Study Sponsor. If immediate action is necessary, verbal agreement with the Sponsor will be confirmed as soon as possible by Study Plan Amendment.

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Any unintended change(s) to the Study Plan will be documented in the raw data and mentioned in the report as deviation(s).

12. SAFETY PRECAUTIONS

The personnel involved in study conduct will be wearing all necessary personnel protective equipment like gloves, head cap and face mask in addition to protective body garments and slippers/shoes to ensure adequate personnel health and safety and to avoid inhalation and skin contact with the test item.

13. MATERIALS AND METHODS

13.1 Materials

13.1.1 Test Item Information

The Test Item Information provided by the sponsor to Liveon Biolabs Private Limited is furnished below:

Name of Test Item	:	Spun melt PP Nonwoven Fabric
Test Item Code by Test Facility	:	S441/TI-001
Intended use of device in Human / others (to specify)	:	Human Use in Gown, Drapes, CSR Wraps, Diapers or sanitary pads
Site of Contact	:	Skin
Duration of contact with Human body	:	6-12 hours
Material category (As per ISO-10993 Part-1)	:	Surface Medical Device
Weight in g.(without packing)	:	35gm
Storage Condition	:	Ambient (+19 to +25°C)
Test Item Code by Sponsor (if any)	:	KTEXSM001
Batch No/Lot no	:	2220524A
Date of Manufacture	:	24/05/2022
Date of Expiry	:	2 years from date of manufacture
Sterility Status	:	Non-Sterile (Autoclave Method)
Test Item Supplied by	:	KTEX NONWOVENS PVT LTD Survey No.241, Opp. Khamta Village Bus Stop Rajkot-Jamnagar Highway-360 110, Guarat

The Sponsor is responsible for the authenticity of the test item and no further characterization of test item will be performed at Liveon Biolabs Private Limited. Test Item information and Certificate of Analysis provided by the Sponsor in Liveon Biolabs Private Limited. Test Item information and Certificate of Analysis is presented as Annexure 5 and Annexure 6 respectively.

13.1.2 **Test System**

Animal Species	:	Rabbit *(Oryctolagus Cuniculus)*
Strain	:	New Zealand White
Justification for Selection of Species	:	Rabbit is one of the recommended species for conducting intracutaneous reactivity test as per guideline ISO-10993-23
Source	:	In-house breed animals
Age (at treatment)	:	About 03 - 04months (exact age will be provided in the report)
Total Number of Animals	:	03 Males / Females (Females will be Nulliparous & Non-pregnant)
Animal Accession Number	:	NWa6854- NWa6856
Body Weight range (at treatment)	:	Not Less than 2 Kg (exact weight will be provided in the report)

13.1.3 Test System Management

13.1.3.1 Animal Room Preparation

Prior to housing the animals, the experimental room will be decontaminated by fumigation and microbial load will be checked by settle plate method. The experimental room floor will be mopped daily once.

13.1.3.2 Husbandry Conditions

Animals will be housed in an environment-controlled room temperature of 20 ± 3 °C and relative humidity of 30-70%. The photoperiod will be 12 hours fluorescent light and 12 hours darkness. Adequate fresh air supply of 12 - 15 air cycles/hour and sound level of <80 dB will be maintained in the experimental room.

The relative humidity, maximum and minimum temperature in the experimental room will be recorded once daily. The copies of results will be included in Study File.

13.1.3.3 Housing

Animals will be housed individually in a standard stainless cage (approximately cage size: length 1.6 x Breadth 2 x Height 1.6 feet / length 2 x Breadth 1.7 x Height 1.3 feet) provided with stainless steel wire bottom grill facilitated with polycarbonate resting board, feed hopper and polycarbonate water bottle with stainless steel sipper tube and stainless steel litter trays with corn cob bedding material placed below the cage. Additionally, hanging bells will be provided as an enrichment device to minimize the animal stress and promote overall wellbeing of animals. Steam sterilized corn cob will be provided as bedding material.

Annexure 15. (Contd.,) Study Plan

Liveon Biolabs

13.1.3.4 Diet and Water

AF- 1000M Rabbit Diets manufactured by Krishna Valley Agrotech LLP will be provided *ad libitum* to Rabbits or others to specify in the report.
Deep bore-well water subjected to reverse osmosis and UV sterilized, will be provided *ad libitum* to Rabbits in polycarbonate bottles with stainless rubber corked steel sipper tubes.

Based on the latest analytical certificate/s available, there are no known contaminants in the bedding, food and water that are expected to interfere with the results of this study. The analysis reports will be included in the Study Report.

13.1.4 Test System Preparation

13.1.4.1 Acclimatization

After examination for good health and the suitability for the study, the animal will be acclimatized at least for 5 days prior to treatment. During acclimatization animals will be observed at least once daily. Veterinary examination will be performed before selecting the animals for the study.

13.1.4.2 Animal Identification

During acclimatization period (Temporary identification), each animal will be identified by ear marking with animal number written on the ear lobe using indelible marker pen. The cages will be identified with cage cards indicating study number, study code, species, strain, sex, acclimatization start and acclimatization end date etc.

During treatment period (Permanent identification), each animal will be identified by ear marking with animal accession number written on the ear lobe using indelible marker pen. The cages will be identified with cage cards indicating study number, study code, species, strain, sex, treatment start date and experiment end date etc.

13.1.4.3 Clipping of Animals

About 4 to 18 hour prior to the treatment / test item administration, the flank region of animal fur will be removed by clipping. Care will be taken to avoid abrasion to the skin.

13.2 Methods

13.2.1 Experimental Procedures

13.2.1.1 Selection and Justification for the Choice of Extraction Medium

The commercially available 0.9% w/v sodium chloride for injection (Normal saline) for polar test item extraction and sesame oil for non-polar test item extraction and respective polar and non-polar Vehicle Control are selected as per the guideline ISO 10993 "Biological Evaluation of Medical Devices", Part 12 (Sample preparation and reference materials).

The details of Vehicles used will be recorded in the raw data and presented in the study report.

13.2.1.2 Preparation of Test Item Extract

The test item is irregular shaped solid devices hence, 0.2g/mL of test item will be prepared for extraction as per ISO 10993-12:2021 (Annexure 1).

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The contact period of Test Item is limited exposure (60 minutes) hence the extraction condition will be selected (37 ± 1) °C for (72 ± 2) hrs.

The Test Item is in Non-Sterile condition before extraction it will be sterilized under Autoclaved at 121°C.

Example preparation of 10mL: 2g of test item will be taken and transferred to the clean beaker / suitable container containing 10 mL of 0.9% NaCl Similarly, 2g of test item will be taken and transferred to the beaker / suitable container containing 10 mL of sesame oil. Similar procedure will be followed for polar and non-polar Vehicle Control without test item.

All the (polar and non-polar test item and polar and non-polar Vehicle Control) beaker / suitable container will be subjected to extraction at 37 ± 1°C for a period 72 ± 2 hrs with continuous agitation in orbital shaker incubator at 110 ± 2 rpm.

Pre and post extraction condition for the appearance of extracts will be checked. The extract will be filtered if any particulates observed using syringe filters / filter papers. The extracts will be prepared under aseptic conditions.

Note: Before extraction, beakers / suitable container will be sterilized. pH of extracts will be checked using pH strips for pre- and post-extraction and will be mentioned in the raw data file and Study report

13.3 Test Procedure

Three animals will be injected with respective Vehicle Control on one side (1mL), and extract on another side of the spinal column of intracutaneous at 5 different sites (0.2 mL per site). The injection sites will be examined for evidence of any tissue reaction such as erythema, oedema, and necrosis. The detailed procedure for injection site is presented in Annexure 2 and 3 respectively.

14. OBSERVATIONS

14.1 Mortality, Morbidity and Clinical Signs

Animals will be observed twice daily for mortality, morbidity and at least once daily for clinical signs throughout the observation period. Based on clinical signs the animals will be observed once for morbidity and mortality during weekends and holidays.

The appearance of each injection site will be observed immediately after injection and at (24 ± 2h), (48 ± 2h) and (72 ± 2h) after injection.

14.2 Body Weight

Individual animal body weights will be measured on the day of receipt, on Day 1, (prior to test item administration), on Day 4 (at the end of the experimental period).

14.3 Skin Reaction

The tissue reaction for erythema and oedema will be scored according to the system given as per Annexure 4.

Annexure 15. (Contd.,) Study Plan

Liveon Biolabs

15. EVALUATION CRITERIA

- After (72 ± 2h) grading, all erythema grades plus oedema grades (24 ± 2h), (48 ± 2h) and (72 ±.2h) are totaled separately for each test sample or Vehicle Control for each individual animal.
- The score of a test sample or Vehicle Control sample on each individual animal will be calculated by dividing each of the totals by 15 (3 Scoring time points X 5 test or Vehicle Control sample injection sites).
- The overall mean score for each test sample and each corresponding Vehicle Control will be calculated by adding scores for the three animals and divided by three.
- The final test sample score can be obtained by subtracting the score of the Vehicle Control from the test sample score. The requirements of the test are met if the final test sample score is 10 or less. If at any observation period the average reaction to the test sample is questionably greater than the average reaction to the Vehicle Control, repeat the test using three additional rabbits. The requirements of the test are met if the final test sample score is 1, 0 or less.

16. ANIMAL EUTHANASIA AND DISPOSAL

At the end of experimental period (day 4), all the animals will be sacrificed by using lethal dose of sodium thiopental injection. The carcasses will be stored in deep freezer and will be disposal through Medicare Environmental Management Pvt. Ltd or others to be specify in the study report.

Note: Sodium Thiopentone injection details will be included in study report and raw data.

17. DATA COMPILATION

All individual animal data will be presented in appendices and / or summarized and presented in tables. All findings will be presented in the report as per the standard reporting format.

Annexure 15. (Contd.,) Study Plan

Liveon Biolabs

18. STUDY REPORT

The Final Study Report will include but not limited to the following information, as appropriate:

- The descriptive title.
- The name and address of the Sponsor and the Test Facility along with the study schedule.
- List of Scientists/Professionals.
- The test item and its code, composition and other appropriate characteristics and vehicle with identification by name.
- Vehicle:
  - Justification for the choice of vehicle.
- A description of the test rabbit, including species, strain, source, number, sex, age at start of the treatment, body weight range, housing conditions, and method of identification.
- Test conditions:
  - Details of food , bedding and RO water quality and analysis reports
- A description of the dose volume, dose regimen, route of administration, extract preparations and duration of the treatment period.
- Observation and Results:
  - Tabulation of response data and dose level for each animal (i.e., tables of clinical signs and mortality, rabbit showing signs of toxicity (if any) including nature, severity, and duration of effects)
- Individual weights of rabbit.
- Pathology data (if done).
- Conclusion.
- A description of all circumstances if any, that may have affected the quality or integrity of the study.
- Study plan deviations, if any.
- The Quality Assurance Statement signed by Quality Assurance Unit.
- The storage location of all raw data, the report, a sample of test item and the archiving period.
- Statement of confidentiality
- Statement of study compliance.
- Statement of Test Facility Management.
- AAALAC Certificate.
- A copy of the final signed study plan and any amendments if any as an annexure

Note: If response from sponsor for finalization of draft report is not received within six months after sending draft report in spite of repeated reminders, management could approve termination of study, or finalization of report and archiving. In such an event, any subsequent requests from sponsor for modification, correction or addition to the final report will be subject to report amendment at additional cost.

Annexure 15. (Contd.,) Study Plan

Liveon Biolabs

19. STUDY PLAN DISTRIBUTION

The Final Study Plan will be distributed as follows:

a) Copy No. 1/2 – Archives, Liveon Biolabs Private Limited.
b) Copy No. 2/2 – Sponsor.

20. STUDY REPORT DISTRIBUTION

The Final Study Report will be distributed as follows:

a) Copy No. 1/2 – Sponsor
b) Copy No. 2/2 – Archives, Liveon Biolabs Private Limited.

21. ARCHIVING

All study-related records, study plan, raw data Amendments and Deviations (if any) , final report, and the test item samples will be maintained in the archives of LBPL for 5 years from the date of study completion. All the records and test item will be handled according to ISO/IEC 17025:2017. After the completion of archiving period, the TFM will coordinate with the sponsor for further course of action on archived material.

Annexure 15. (Contd.,) Study Plan

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22. REFERENCES

- ISO 10993-1:2018: Biological evaluation of medical devices-Part-1: Evaluation and testing within a risk management process.
- ISO 10993-2:2006: Biological evaluation of medical devices-Part 2: Animal welfare requirements.
- ISO 10993-23:2021: Biological evaluation of medical devices-Part 23: Tests for Irritation.
- ISO 10993-12:2021: Biological evaluation of medical devices-Part 12: Sample preparation and reference materials.
- ISO/IEC 17025:2017, General Requirements for the Competence of Testing and Calibration Laboratories.
- Standard Operating Procedures of Test Facility and the mutually agreed Study Plan.

Annexure 15. (Contd.,) Study Plan

Liveon Biolabs

23. STUDY PLAN APPROVAL

The Study Plan for the Study No LBPL/NG-2642 (TX) has been agreed by the Sponsor through E-mail on 07/12/2022 and approved by the Study Director

For LIVEON BIOLABS PRIVATE LIMITED (Test Facility):

Mrs Bhagyashree M
Study Director
(Sign & Date)

Quality Assurance Unit
(Sign & Date)

Test Facility Management
16/12/2022
(Sign & Date)

For KTEX NONWOVENS PVT LTD. (Sponsor):

Mustanshir Vohra
Sponsor Representative
24/12/22
(Sign & Date)

Annexure 15. (Contd.,) Study Plan

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Annexure 1. Standard Surface Areas and Extract Liquid Volumes

Thickness[a] mm	Extraction ratio (surface area or mass/volume) ±10 %	Examples of forms of materials
≤ 0.5	6 cm^2/ml	film, sheet, tubing wall
0.5 to 1.0	3 cm^2/ml	tubing wall, slab, small moulded items
>1.0	3 cm^2/ml	larger moulded items
irregularly shaped solid devices	0.2 g/ml	powder, pellets, foam, non-absorbent moulded items, porous high-density materials
irregularly shaped porous devices (low-density materials)	0.1 g/ml	membranes, textiles

[a] If the medical device includes multiple tissue contacting components with different thicknesses, the extraction ratio should be justified. One way to do this is to base the ratio on the thinnest material layer of that component.

NOTE While there are no standardized methods available at present for testing solvent absorbing polymer materials (e.g. absorbents and hydrocolloids), a suggested protocol is as follows:

— determine the volume of extraction vehicle that each 0.1 g or 1.0 cm^2 of material absorbs;

— then, in performing the material extraction, add this additional volume to each 0.1 g or 1.0 cm^2 in an extraction mixture.

Annexure 15. (Contd.,) Study Plan

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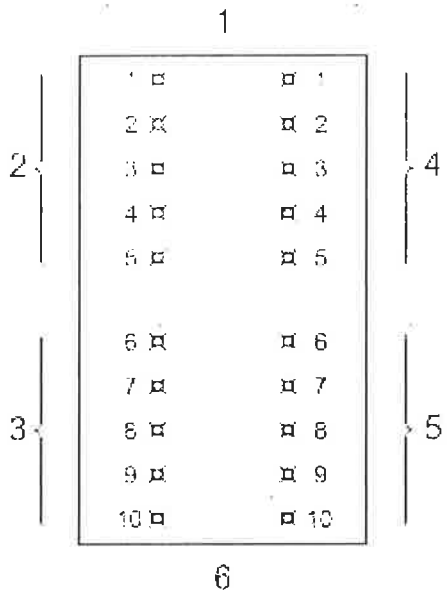
Annexure 2. Arrangement of Injection Sites



INDICATIONS

1. Cranial End
2. 0.2 mL Injection of Polar Test Item Extract
3. 0.2 mL Injection of Non-Polar Test Item Extract
4. 0.2 mL Injection of Polar Vehicle Control
5. 0.2 mL Injection of Non-Polar Vehicle Control
6. Caudal End

Annexure 15. (Contd.,) Study Plan

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Annexure 3. Administration of Test Item

Sl. No.	Treatment	Extract	Incubation	Dose Volume/Site (ml)	Total Volume Injected	Region
1	Polar Vehicle control	0.9% Sodium Chloride Injection	37±1°C for 72±2 hr.	0.2 mL	1.0 mL	Right
2	Polar Test Item Extract	Test Item + 0.9% Sodium Chloride Injection		0.2 mL	1.0 mL	Left
3	Non-polar Vehicle control	Sesame oil		0.2 mL	1.0 mL	Right
4	Non-Polar Test Item Extract	Test item + Sesame oil		0.2 mL	1.0 mL	Left

Annexure 15. (Contd.,) Study Plan

Liveon Biolabs

Annexure 4. Evaluation of Skin Reactions

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
Edema Formation	**Score**
No edema	0
Very slight edema (Barely perceptible)	1
Slight edema (edges of area well defined by definite raising)	2
Moderate edema (raised approximately 1mm)	3
Severe edema (raised more than 1 mm and extending beyond the area of exposure)	4
Maximal possible score for irritation	8
Other adverse changes at the skin sites shall be recorded and reported.	

Annexure 15. (Contd.,) Study Plan

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Annexure 5. Test Item Information Sheet

MEDICAL DEVICES TEST ITEM / REFERENCE ITEM INFORMATION SHEET

Sl. No.	Particulars	Details
1	Sponsor Name and Address (As in Study Plan and Study Report)	Klex Nonwovens Pvt Ltd Survey No.241, Opp. Khamta Village Bus Stop, Rajkot-Jamnagar Highway- 360 110, Gujarat
2	Manufactured by (Name and address) (Specify "same as study sponsor", if applicable. Otherwise provide details)	same as study sponsor
3	Supplied by (Name and address) (Specify "same as study sponsor", if applicable. Otherwise provide details)	same as study sponsor
4	Address for Communication with Email	mustanshir@ktexnonwovens.com, docs@ktexnonwovens.com
5	Address for Invoicing	same as study sponsor
6	Sponsor Representative Name	Mustanshir Vohra
7	Monitoring Scientist Name	
8	Test Item / Reference Item information (Mark as applicable) Name of the Test Item ☒ Reference Item ☐	Spun melt PP Nonwoven Fabric
9	Intended Use of device in Human / Others (to Specify)	Human Use in Gown, Drapes, CSR Wraps, Diapers or sanitary pads
10	Site of Contact	Skin
11	Duration of Contact with Human Body	6-12 Hours
12	Material Category (As per ISO 10993 Part 1)	Surface Medical Device
13	Weight in g. (without packing) ☒	35 gm.
	Surface Area in cm² ☐	
	Thickness in mm ☐	
	Others (to Specify) ☐	
14	pH (If applicable)	
15	Material Safety Data Sheet Attached	☒ Yes ☐ No
16	Certificate of Analysis Attached	☒ Yes ☐ No
17	Storage Condition	☒ Ambient (+19 to +25°C) ☐ Cool and Dry (+2 to +8°C) ☐ Frozen (-16 to -20°C) ☐ Hygroscopic ☐ Light Sensitive ☐ Any other (Please specify_____)
18	Test Item Code by Sponsor (If any)	KTEXSM001
19	Batch No. / Lot No.	2220524A
20	Date of Mfg.	24/05/2022

Annexure 15. (Contd.,) Study Plan

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Annexure 5. (Contd.,) Test Item Information Sheet

21	Date of Exp. / Retest date (When stored as detailed below) (fill-up expiry date and/ retest date, whichever is applicable). If not, provide justification	2 Years From Date of Manufacturing
22	Quantity Dispatched and Date of Dispatch	19/09/2022
23	Name of Carrier / Mode of Shipment	Courier
24	Type of Packing and No. of Packs / Bottles	Zipper bag 2 packs of 1 or 2 mix Nonwoven fabrics
25	Sterility Status	☐ Sterile ☒ Non-sterile*
		Sterile by _____
	*If Non sterile, Select method of Sterilization	☒ Autoclave Method ☐ Surface Sterilization ☐ Post Extraction Filtration ☐ Other
26	Material Category	Medical Devices Items

List out the test to be conducted:

Sl. No.	Test / Study Name	Test Guideline
1.	Skin Sensitization Test	ISO 10993-10:2021 & OECD Test Guideline 406
2.	Skin Irritation Test	SO 10993-23:2021

Sponsor's Authorization:

As a Sponsor or Sponsor representative of these studies, I agree with below points:

- The studies requested are to meet the regulatory requirements of test item.
- The animal usage is necessary for requested studies as per guideline requirements. The species chosen is appropriate to the study and as per guidelines requirements.
- The studies requested are not an unnecessary duplication of previous work.

Sponsor or Sponsor Representative:
Mustanshir Vohra

23/09/2022
Sign. and Date

Instructions for filling Test Item / Reference Item Information Sheet:

- Fill the information sheet with available information.
- If the information is not available mentioned as NA and if section or column is not applicable for test item, reference item, mention as NA (Not Applicable).
- Add column or rows as per requirements.

Annexure 15. (Contd.,) Study Plan

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Annexure 6: Certificate of Analysis

Ktex Nonwovens Pvt. Ltd.

POLYPROPYLENE SPUNBONDED NON WOVEN FABRICS

CERTIFICATE OF ANALYSIS

Doc No.: FM/QD/QA/01/00
Rev No. 01
Rev Date : 01-02-2022

COA Number :-	KN-DPHP-3172	Date :-	05-Sep-22
Cont. No :-	GJ. 23.Y. 6471	Invoice No.:-	KTPL/22-23/416
Customer Name:-	DPHP		

Properties	Units	Test Method	Typical Analysis	Specification	Remark
Product Code/Type	35.0 Spunmelt				
Treatment	Hydrophobic				
Structure	Oval				
Colour	White				
Lot No.	KTEXSM001				
Slit Width	MM	By Std. Measuring tape	800	±5	Passed
Weight	g/m²	NWSP 130.1.R0(15)	34.65	±2	Passed
Tensile Strength MD	N/5 cm	NWSP 110.4.R0(15)	85.52	>70	Passed
Tensile Strength CD	N/5 cm	NWSP 110.4.R0(15)	52.12	>34	Passed
Tensile Elongation MD	%	NWSP 110.4.R0(15)	87.43	45-130	Passed
Tensile Elongation CD	%	NWSP 110.4.R0(15)	90.47	45-130	Passed
Water resistance(100cm²)	mmWC@ 69mbar	NWSP 080.6.R0(15)	631	>370	Passed

Test Certified: This certifies that the above item and run number have been produced and inspected in Conformance with the Ktex product specification.
The results are presented without any implied warranty. The certificate is strictly and exclusively limited for Customer reference only.

Ktex Nonwovens Pvt. Ltd. Complies with the strictest product and process controls according to the latest international standards.
Ktex Nonwovens Pvt. Ltd., reserves the right to update production data according the process and technological developments.
The above data sheet gives typical figures only and no implied warranty should be assumed.

(This is system generated report hence signature is not required.)

KTEX NONWOVENS PVT. LTD. JAMNAGAR

ISO 9001:2015

MANUFACTURER:-
Ktex Nonwovens Pvt. Ltd.
Survey No 241,Sanosara,
Opp. Khamta Bus Stop, Jamnagar Highway,
Village - Khamta, Tal - Dhrol,
Jamnagar, 360110, Gujarat, India.
Tel #: +91-9727055055