Liveon Biolabs

FINAL STUDY REPORT

STUDY TITLE

SKIN SENSITIZATION STUDY OF POLAR AND NON-POLAR EXTRACTS OF SPUN MELT PP NONWOVEN FABRIC USING GUINEA PIGS MAXIMIZATION TEST (GPMT)

TEST GUIDELINE: ISO 10993-10:2021

STUDY NO.: LBPL/NG-2641 (TX)

STUDY CODE: GPMT

STUDY COMPLETION DATE: 09/02/2023

STUDY DIRECTOR

Ms. Rangalakshmi G.R.

SPONSOR

KTEX NONWOVENS PVT. LTD.
SDURVEY 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.

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1. OBJECTIVE

The objective of this toxicity study was to assess the potential skin sensitization and biocompatibility of a polar extract (physiological saline) and non-polar extract (sesame oil) "Spun melt PP Nonwoven Fabric" by injecting both polar extract and non-polar extract as a single intradermal injection to evaluate the possibility of hyperreactive skin (visible reactions i.e. erythema/oedema) followed by topical induction (erythema/oedema) and challenge phase for skin reaction(erythema) in guinea pigs. This test also provides information on health hazards likely to be arise from acute exposure by the intended clinical route in humans.

2. STUDY DETAILS

Study Title	:	Skin Sensitization Study of Polar and Non-Polar Extracts of Spun melt PP Nonwoven Fabric using Guinea Pigs Maximization Test (GPMT).
Study Number	:	LBPL/NG-2641 (TX)
Study Code	:	GPMT
ULR No.	:	TC-679422000001263F
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	:	Ms. Rangalakshmi G.R
Study Personnel I	:	Ms. Supritha G
Study Personnel II	:	Ms .Bhavana S.B
Study Personnel III	:	Mr. Ravikumara. K C
Study Personnel IV	:	Mr. Vasanthakumar B S
Study Personnel V	:	Mr. Udayakumar. V G
Study Personnel VI	:	Mrs. Bhagyashree M
Study Personnel VII	:	Ms. Chithrashree S R
Study Personnel VIII	:	Ms. Navya. N
Study Veterinarian	:	Dr. Sunkad Meghana
Sponsor Representative	:	Mr.Mustanshir vohra

4. STUDY SCHEDULE

Study Initiation Date	: 22/12/2022
Experiment Start Date	: 26/12/2022
Acclimatization Period	: 26/12/2022 to 30/12/2022
Treatment Dates	: Intradermal induction phase: 31/12/2022 Topical induction phase : 07/01/2023 Challenge phase: 21/01/2023
Experiment End Date	: 24/01/2023
Draft Report to Sponsor	: 01/02/2023
Study Completion Date	: 09/02/2023

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
°C	:	Degree Celsius
cm	:	Centimeter
dB	:	Decibel
FCA	:	Freund's Complete Adjuvant
g	:	Gram
GPMT	:	Guinea Pigs Maximization Test
h/hr	:	Hour (s)
IAEC	:	Institutional Animal Ethics Committee
IEC	:	International Electrotechnical Commission
ISO	:	International Organization for Standardization
mL	:	Millilitre
No.	:	Number
rpm	:	Revolution Per Minute
RO	:	Reverse Osmosis
SD	:	Standard Deviation
SDS	:	Sodium Dodecyl Sulphate
TS	:	Terminal Sacrifice
TFM	:	Test Facility Management
%	:	Percent
UV	:	Ultraviolet
<	:	Less than
&	:	and

6. STATEMENT OF STUDY COMPLIANCE

Study Number : LBPL/NG-2641 (TX)

Study Title : Skin Sensitization Study of Polar and Non-Polar Extracts of "Spun melt PP Nonwoven Fabric" using Guinea Pigs Maximization Test (GPMT).

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 22/12/2022 and Sponsor Representative on 24/12/2022.

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-2641 (TX)

Study Title : Skin Sensitization Study of Polar and Non-Polar Extracts of Spun melt PP Nonwoven Fabric using Guinea Pigs Maximization Test (GPMT)

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	22/12/2022	22/12/2022	22/12/2022
3	Draft Study Report	01/02/2023	01/02/2023	01/02/2023
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.

08/02/2023

Test Facility Management
Sign. and Date

9. STATEMENT OF TEST FACILITY MANAGEMENT

Study Number : LBPL/NG-2641 (TX)

Study Title : Skin Sensitization Study of Polar and Non-Polar Extracts of Spun melt PP Nonwoven Fabric using Guinea Pigs Maximization Test (GPMT)

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 present 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

Skin sensitization study was performed to evaluate the sensitization following application of test item extracts of "Spun melt PP Nonwoven Fabric" using Guinea Pigs Maximization Test (GPMT) Method as per Biological evaluation of medical devices - Part 10: Tests for Skin Sensitization ISO 10993-10: 2021. The test item was extracted in polar Vehicle i.e., 0.9% Sodium Chloride injection and Non-Polar Vehicle i.e., Sesame Oil as per the guideline ISO 10993 - Part 12.This study also provides rational basis of risk assessment in humans.

Thirty three animals were acclimatized and thirty animals were selected and grouped into four groups, G1a-Polar Vehicle Control, G2a-Polar Test Item Extract, G1b-Non-Polar Vehicle Control and G2b-Non-Polar Test Item Extract.

Fur of all animals was closely clipped about 24 hrs prior to induction phase (induction and topical application) and challenge application phase. In both the case, care was taken to avoid abrasion on the skin.

The Test Item was non-sterile in condition before Extraction it was sterilized by Autoclave 121°C.

On Day 1 intradermal induction phase with one each part of FCA and extract was used for intradermal administration. The animals from control group (G1a and G1b) polar and non-polar vehicle control for respective group whereas test groups (G2a and G2b) were injected with polar and non-polar test item extracts. The animals were injected at the shoulder region with 0.1 mL per injection of 3 pairs of intradermal injections. Injections 1 and 2 were given near the head region about 1 cm apart and injection 3 was given 2 cm apart towards caudal part of the body. On Day 2 (24 hours post intradermal administration) and Day 3 (48 hours post intradermal administration) skin reactions for erythema and oedema were scored and recorded as per Draize method. Skin Irritation was observed (erythema/oedema) at this phase and hence SDS was not applied.

Topical induction was carried out on Day 8 using patches of filter paper (2 cm x 4 cm) impregnated with 0.5 mL of respective vehicle control and test item extracts were applied over the dorsal clipped region of the animals and secured with semi occlusive dressing by hypoallergic tape for 48 hrs. On Day 10 (1-hour post patch removal) and Day 11 (24 hrs post patch removal) skin reactions for erythema and oedema were scored as per Draize method.

Challenge exposure was carried out on Day 22 i.e., after 14 Days completion of the topical induction phase, Patches of filter paper (2 cm x 4 cm) impregnated with 0.5 mL of Polar and Non-polar control extracts. The respective vehicle control (G1a and G1b) were applied to the anterior right flank. Similarly, the patches of filter papers impregnated with 0.5 mL of Polar and Non-polar Test extracts were applied to the anterior left flank of respective test group (G2a and G2b) of animals. Patches were held in contact for 24 hours with semi occlusive dressing by hypoallergic tape. The Re-challenge phase was not performed as there were no skin reactions during Challenge exposure phase.

All animals were observed for skin reactions erythema at 24h and 48h post removal of the dressings in the challenge phase. The skin reactions were scored as per Magnusson and Kligman grading scale. In addition, all the animals of all the phase were observed once daily for clinical signs and twice daily for mortality and morbidity till the end of observation period (Day 25). Body

weights were on Day of receipt, Day 1 and at the end of the observation period (Day 25).

Summary of Study Results: No clinical signs and mortality/morbidity were observed. On Day 2 (24 hours) all animals are normal and Day 3 (48 hours) post intradermal injections, all the animals of vehicle control and test item extracts groups elicits very slight erythema and this owing to FCA in the extracts and conforms the hyperreactive skin prior to topical and challenge phase. On Day 10 and Day 11 Post topical application, all the animals of vehicle control and test item extracts group revealed no erythema/oedema. In challenge phase, all animals of vehicle control and test item extracts group revealed no erythema. The body weights were unaffected by test item extracts.

Conclusion: Based on the above results, the graded (Magnusson and Kligman grading scale) score was 0. The comparison of the skin reaction (at the challenge phase) of the test item treated animals with those of the Vehicle control group animals show that the test item "Spun melt PP Nonwoven Fabric" is classified as "Non-sensitizer" to Guinea Pigs under the stated experimental condition.

11. STUDY COMPLIANCE

The study was performed in compliance with the following:

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

12. STUDY GUIDELINES

The design of this study was based on the study objective 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 10993-10: 2021 – Biological Evaluation of Medical Devices Part: 10 Tests for Skin Sensitization.

13. IAEC APPROVAL

This protocol has been approved by Liveon Biolabs Private Limited Institutional Animal Ethics Committee (IAEC). IAEC approved protocol number: LBPL-IAEC-054-10/2022.

14. ANIMAL WELFARE 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 attached as Annexure 16.

None of the animals got injured, ill or moribund during the conduct of the study.

15. AMENDMENTS AND DEVIATIONS

There was no amendment and deviation occurred during conduct of study.

16. SAFETY PRECAUTIONS

The personnel involved in study conduct wore all necessary personnel protective equipment like gloves, head cap and face mask in addition to protective body garments and 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	:	Human Use in Gwon, Drapes,CSR, Wraps,diapers or sanitary pads
Site of Contact	:	Skin
Duration of contact with human body	:	6-12 hours
Material Category (As per ISO10993 Part 1)	:	Surface medical device
Weight in g (without packaging)	:	35gm.
Material safety data sheet	:	Yes
Certificare of Analysis	:	Yes
Storage Condition	:	Ambient (+19 to +25° C)
Test Item Code by Sponsor	:	KTEXSM001
Batch No.	:	2220524A
Date of Manufacture	:	24/05/2022
Date of Expiry	:	2 Years from date of manufacturing
Sterility Status	:	Non-Sterile (Autoclave Method).
Test Item Manufactured & Supplied by	:	KTEX NONWOVENS PVT LTD Sdurvey no.241, opp. Khamta village bus stop Rajkot-jamnagar highway-360 110, Guarat

The Sponsor is responsible for authenticity of the test item and no further characterization of test item was performed at Liveon Biolabs Private Limited. The test item details are as per the TIIS, Certificate of Analysis and Material safety data sheet provided by the sponsor. The TIIS Certificate of Analysis and Material safety data sheet is included in the Annexure 7, Annexure 8 and Annexure 9 respectively.

17.1.2 Test System

Animal Species	:	Guinea Pig (*Cavia porcellus*)
Strain	:	Dunkin Hartley
Justification for Selection of Species	:	The Guinea pig has been the animal of choice for predictive sensitization tests for several decades and also as per ISO 10993-10: 2021 specification.
Source	:	In-house breed animals
Age at treatment	:	7-13 Weeks old
No. of Groups	:	4
Total No. of Animals	:	30 Female(Female were Nulliparous and Non-Pregnant)
Body weight range at treatment	:	319.28– 371.19g

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 20.0–22.9°C and relative humidity of 44-69%.The photoperiod was 12 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 records were included in the study report and kept in raw data.

17.1.3.3 Housing

Individual animal was housed in a standard polycarbonate cages (Cage size approximately Length 43 X Breadth 29 X Height 18 cm) with stainless steel mesh top, feed was provided in feed hoppers and drinking water with stainless sipping tubes. Clean sterilized corn cob was provided as bedding material.

The corn cob was analyzed periodically for fungal and microbial contaminations. The latest analysis reports of bedding material were included in the study report as in Annexure 10 and Annexure 11.

17.1.3.4 Diet and Water

AF- 1000M Guinea pigs Diet manufactured by Krishna Valley Agrotech LLP was provided *ad libitum* to Guinea pigs.

Deep bore-well water subjected to filtration by reverse osmosis and UV sterilized, was provided *ad libitum* to guinea pigs in polycarbonate bottles with stainless steel sipper tubes and Vitamin C Supplement was provided by mixing with water.
There are no known contaminants in the food and RO water provided to the animals. The analysis report was included in the Study Report

The latest analysis report of feed and RO water was included in the Annexure 12, Annexure 13, and Annexure 14 & Annexure 15.

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 5 days prior to treatment. During acclimatization animals were observed daily once for clinical signs and twice daily for mortality and morbidity. 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 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, acclimatization start and acclimatization end date.

During treatment period (Permanent identification), each animal was identified by body marking using 1 % turmeric solution. The cages were identified with cage cards indicating study number, animal accession number, study code, species, strain, sex, experiment start date and experiment end date.

17.1.4.3 Randomization and Grouping

The animals for the experiment were weighed and arranged in ascending order of their body weights. Animals were randomized during acclimatization using body weight stratification method of randomization and are grouped accordingly such that the mean body weight did not vary ± 20 percent among the groups on the Day 1 of administration. The unused animals were euthanized by carbon di oxide asphyxiation.

17.1.4.4 Clipping of Animals

For induction phase, the fur of the animals was closely clipped before 24 hrs before the treatment from shoulder region (an area of 3 cm x 5 cm). For challenge phase, the fur was closely clipped from the required flank region [80 sq cm (10cm x 8 cm)] 24 hrs before treatment. In both the cases care was taken to avoid abrasion on the skin.

17.2 Method

17.2.1 Experimental Procedure

17.2.1.1 Study Design

The following study design was adopted for the study:

Group	Description	Color of Cage cards	Number of Animals and sex	Animal Accession No.	
				From	To
G1a	Polar Vehicle Control	White	5 F	GPb3194	GPb3198
G2a	Polar Test Item Extract	Pink	10 F	GPb3199	GPb3208
G1b	Non-Polar Vehicle Control	White with dots	5 F	GPb3209	GPb3213
G2b	Non-Polar Test Item Extract	Pink with dots	10 F	GPb3214	GPb3223

Note: a: Polar groups; b: Non-polar groups; F: Female

17.2.1.2 Positive Control Response Validation

Reliability test was conducted, using 2-Mercaptobenzothiazole as a positive control. Results are attached as Annexure 2.

17.2.1.3 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).

Vehicle Name	Batch and Lot No.	Manufactured Date	Expiry Date	Manufactured By
0.9% Nacl – Polar Vehicle	1124208	09/2022	08/2025	Aculife health care private limited
Sesame oil – Non Polar Vehicle	G/P1	24/10/2022	23/01/2024	KLF Nirmal Industries Pvt. Ltd.

17.3 Test Procedure

17.3.1.1 Preparation of Test Item Extract

The Test Item was non-sterile in condition before Extraction it was sterilized by Autoclave 121°C.

The Test Item was Irregularly shaped device hence extraction ratio 0.2g/ml was selected for extraction and the contact period of Test Item was Limited contact

hence the extraction condition was selected (37 ± 1) °C for (72 ± 2) hours as per ISO 10993-12:2021 (Annexure 1).

About 2g of test item was weighed and transferred to the beaker containing 10mL of 0.9% NaCl Similarly, About 2g of test item was weighed and transferred to the beaker containing 10mL of sesame oil. For respective control extract 10 mL of respective vehicles were taken into beaker without adding test item and were subjected to extraction in orbital shaker incubator at 110 rpm as per mentioned in below table.

Before extraction, beakers were sterilized. Test item in respective Polar and non-polar Vehicles were observed for clarity of extraction and found to be clear without any particles during pre- and post-extraction period.

Note: The unused test item not used for extraction, stored in container. Similarly, the left over extract and test item which is used for extraction after dosing were stored in a container and sent for disposal.

Date	Test Item Taken (g)	Polar vehicle (mL)	Test Item Taken (g)	Non-Polar vehicle(mL)
28/12/2022	2.0157	10	2.0469	10
04/01/2023	2.0098	10	2.0203	10
18/01/2023	2.0198	10	2.0171	10

17.3.1.2 Extraction Conditions

Vehicle and extraction condition is as depicted below:

Date/phase	Vehicle	Extraction Temperature (in °C)			Total Extraction Time	Extract appearance
		Set value	Maximum	Minimum		
From 28/12/2022 to 31/12/2022 Intradermal induction phase	Polar Vehicle control	37.0	37.1	37.0	70 hours and 60 mins	Clear
	Polar test item extract	37.0	37.1	37.0		
	Non-Polar Vehicle control	37.0	37.1	37.0		
	Non-Polar test item extract	37.0	37.1	37.0		
From 04/01/2023 to 07/01/2023 Topical induction phase	Polar Vehicle control	37.0	37.1	37.0	71 hours and 07 mins	Clear
	Polar test item extract	37.0	37.1	37.0		
	Non-Polar Vehicle control	37.0	37.1	37.0		
	Non-Polar test item extract	37.0	37.1	37.0		
From 18/01/2023 to 21/01/2023 Challenge phase	Polar Vehicle control	37.0	37.1	37.0	72 hours and 41 mins	Clear
	Polar test item extract	37.0	37.1	37.0		
	Non-Polar Vehicle control	37.0	37.1	37.0		
	Non-Polar test extract	37.0	37.1	37.0		

pH of polar and Non-polar test item extract and control was checked using pH strips and measured between 6 – 7 before and after extraction.

17.3.1.3 Intradermal Induction Phase

The animals of test groups (G2a and G2b) and control group (G1a and G1b) were injected with polar and non-polar test item extracts and polar and non-polar vehicle controls respectively. The animals were injected at the shoulder region with 0.1 mL per injection of 3 pairs of intradermal injections. Injections 1 and 2 were given near the head region at least 1 cm apart and injections 3 were given 2 cm apart towards caudal part of the body.

Annexure 3: Site of intra-dermal injections in the Guinea pig for maximization test of Magnusson and Kligman.

Site A: 1st pair of injection
Site B: 2nd pair of injection
Site C: 3rd pair of injection
FCA details: Manufactured By: Sigma Aldrich
Lot. No.:SLCL6285

Polar Vehicle Control (G1a)

- Site 'A' was injected intradermally with 0.1 mL of 1:1 mixture (v/v) of Freund's Complete Adjuvant (FCA) in Physiological saline.
- Site 'B' was injected intradermally with 0.1 mL of polar vehicle control.
- Site 'C' was injected intradermally with 0.1 mL of 50% v/v polar vehicle control in 1:1 mixture (v/v) of FCA in in Physiological saline.

Non-Polar Vehicle Control (G1b)

- Site 'A' was injected intradermally with 0.1 mL of 1:1 mixture (v/v) of FCA in Physiological saline
- Site 'B' was injected intradermally with 0.1 mL of non-polar vehicle control.
- Site 'C' was injected intradermally with 0.1 mL of 50% v/v non- polar vehicle control in 1:1 mixture (v/v) of FCA in in Physiological saline.

Polar Test Item Extract (G2a)

- Site 'A' was injected intradermally with 0.1 mL of 1:1 mixture (v/v) of FCA in Physiological saline
- Site 'B' was injected intradermally with 0.1 mL of undiluted polar test item extract.
- Site 'C' was injected intradermally with 0.1 mL of 50% v/v undiluted polar test item extract in 1:1 mixture (v/v) of FCA in in Physiological saline.

Non-Polar Test Item Extract (G2b)

- Site 'A' was injected intradermally with 0.1 mL of 1:1 mixture (v/v) of FCA in Physiological saline
- Site 'B' was injected intradermally with 0.1 mL of undiluted non-polar test item extract.
- Site 'C' was injected intradermally with 0.1 mL of 50% v/v undiluted non-polar test item extract in 1:1 mixture (v/v) of FCA in in Physiological saline.

17.3.1.4 Topical Induction Phase

On day 7, the treated area was observed for irritation, as there was irritation at site 1 and site 3.

On day 8, both vehicle controls and the test item extracts were applied topically using approximately 2 cm X 4 cm = 8 cm^2 of absorbent cotton gauze the application is done as per below mentioned table.

G1a:	Filter paper or absorbent cotton gauze dipped in Polar Vehicle Control
G2a:	Filter paper or absorbent cotton gauze dipped in undiluted Polar Test Item Extract
G1b:	Filter paper or absorbent cotton gauze dipped in Non-Polar Vehicle Control
G2b:	Filter paper or absorbent cotton gauze dipped in Undiluted Non-Polar Test Item Extract

Patches were removed after 48 hours of application and wiped with RO water and details were included in the raw data and study report.

17.3.1.5 Challenge Phase

After 14 days, completion of the topical induction phase (i.e., Day 21), fur was removed from left and right flank areas using electric clipper.

On day 22, the absorbent cotton gauze (2 cm x 4 cm) was impregnated with 0.5mL respective Vehicle control and test item extract as below:

G1a	Anterior Right Flank	Polar Vehicle Control
	Anterior Left Flank	Undiluted Polar Test Item Extract
G2a	Anterior Right Flank	Polar Vehicle Control
	Anterior Left Flank	Undiluted Polar Test Item Extract
G1b	Anterior Right Flank	Non-Polar Vehicle Control
	Anterior Left Flank	Undiluted Non-Polar Test Item Extract
G2b	Anterior Right Flank	Non-Polar Vehicle Control
	Anterior Left Flank	Undiluted Non-Polar Test Item Extract

The patches were secured with semi occlusive dressing. Patches were removed after 24 hours and wiped with RO water and details were included in the raw data and study report (Annexure 4).

17.3.1.6 Re-challenge Phase

Re-challenge phase was not done as there was no signs of any irritation were observed during challenge phase.

18. OBSERVATIONS

18.1 Body Weight

Individual animal body weights were measured on the first day of acclimatization (at receipt), prior to initiation of the treatment (Day 1) and on study termination (Day 25).

18.2 Mortality , Morbidity and Clinical Signs

Animals were observed twice daily for mortality, morbidity and once daily for clinical signs throughout the acclimatization and observation period. As there were no clinical signs observed hence the animals were observed once for morbidity and mortality during weekends and holidays.

18.3 Grading of Skin Reaction

Induction Phase (Intradermal and Topical Application)

The skin reactions were observed in both the control and test animals at 24 hrs. and 48 hrs,after the intradermal administration.

The skin reactions were observed of the control and test animals at 1 hr., and 24 hours, post removal of dressing after induction (topical application). The skin reactions for erythema and oedema were observed and recorded according to Draize method as per Annexure 5.

Challenge phase

The skin reactions were observed in both the test and control animals at 24 hrs and 48 hrs, after removal of dressing in the challenge phase. The skin reactions for erythema were observed and recorded according to Magnusson and Kligman grading as per Annexure 6.

19. RESULTS

19.1 Body Weights

Refer to Table 2 and Appendix 2.

There were no changes in body weight (g) and body weight gain (%) in the test animals when compared to respective vehicle control during the study period.

19.2 Mortality , Morbidity and Clinical Signs

Refer to Table 1 Appendix 1.

There were no mortality, Morbidity and clinical signs observed in any of the animals during the study period.

19.3 Grading of Skin Reactions

Refer to Table 3 and Appendix 3.

Induction Phase (Intradermal and Topical Application)

On Day 2 (24 hours) post intradermal injections all animals are normal and Day 3 (48 hours) post intradermal injections, very slightly erythema and oedema (barely perceptible) was observed in all the control and test group animals.

On Day 10 and Day 11 Post topical application, all the animals of control and test group showed no skin reactions.

Challenge phase

Animals of control and test group showed no skin reactions to the challenge exposure during the 24 hours and 48 hours observations after the patch removal of challenge application.

20. CONCLUSION

Based on the above results, the graded (Magnusson and Kligman grading scale) score was 0. The comparison of the skin reaction (at the challenge phase) of the test item treated animals with those of the Vehicle control group animals show that the test item "Spun melt PP Nonwoven Fabric" is classified as "Non-sensitizer" to Guinea Pigs under the stated experimental condition.

21. DATA COMPILATION

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

22. ANIMAL EUTHANASIA AND DISPOSAL

At the end of experiment period all the animals were sacrificed using carbon dioxide asphyxiation. The carcasses were stored in deep freezer and disposed through Medicare Environmental Management Pvt. Ltd.

23. 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

24. 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.

25. 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 10993-10: 2021-Biological Evaluation of Medical Devices-Part 10: Tests for Skin Sensitization.
- ISO 10993-12:2021-Biological Evaluation of Medical Devices-Part 12: Sample preparation and reference materials.
- The Standard Operating Procedures of Test Facility and the mutually agreed Study Plan.

Table 1. Summary of Mortality, Morbidity and Clinical Signs

Refer to Appendix 1.

Group	Treatment	Number of Animals	Mortality and Morbidity	Clinical Signs
G1a	Polar Vehicle Control	05	0/05	1
G2a	Polar Test Item Extract	10	0/10	1
G1b	Non-Polar Vehicle Control	05	0/05	1
G2b	Non-Polar Test Item Extract	10	0/10	1

1- Normal; 0/5 = 0 denotes no mortality/morbidity out of 5 animals

0/10 = 0 denotes no mortality/morbidity out of 10 animals

Table 2. Summary of Body Weights (g) and Body Weight Gain (%)

Refer to Appendix 2.

Group & Treatment	Body Weights (g)			Body Weight Change (%)
	Day 1		Day 25	Day 1-25
G1a & Polar Vehicle Control	Mean	322.98	380.68	17.87
	± SD	2.26	2.06	1.00
	N	05	05	05
G2a & Polar Test Item Extract	Mean	339.58	392.81	15.68
	± SD	3.39	4.93	1.09
	N	10	10	10
G1b & Non-Polar Vehicle Control	Mean	328.08	452.89	38.02
	± SD	2.32	17.05	4.43
	N	05	05	05
G2b & Non-Polar Test Item Extract	Mean	355.76	398.18	11.71
	± SD	7.74	15.87	4.11
	N	10	10	10

SD: Standard Deviation; N= Number of Animals per Group

Table 3. Summary of Skin Reactions Scoring after Induction Phase

Refer to Appendix 3.

Group & Sex	Treatment	Intradermal Induction				Topical Induction			
		After Intradermal injection				After Removal of the patches			
		At 24 hrs		At 48 hrs		1 hour		24 hours	
		ERY	EDE	ERY	EDE	ERY	EDE	ERY	EDE
G1a & Female	Control	0*/05	0*/05	04*/05	05*/05	0*/05	0*/05	0*/05	0*/05
G2a & Female	Treated	0*/10	0*/10	07*/10	09*/10	0*/10	0*/10	0*/10	0*/10
G1b & Female	Control	0*/05	0*/05	04*/05	05*/05	0*/05	0*/05	0*/05	0*/05
G2b & Female	Treated	0*/10	0*/10	09*/10	10*/10	0*/10	0*/10	0*/10	0*/10

Key: ERY-Erythema, EDE-Oedema

Note: - * - Represents the number of animals showing Skin reactions out of the total number of Animals in induction phase of each group.

Table 4. Summary of Skin Reactions Scoring after Challenge Phase Patch Removal

Refer to Appendix 4.

Group & Sex	Treatment	Skin Reaction Scoring	
		24 Hours after Challenge	48 Hours after Challenge
G1a & Female	Control	0*/05	0*/05
G2a & Female	Treated	0*/10	0*/10
G1b & Female	Control	0*/05	0*/05
G2b & Female	Treated	0*/10	0*/10

Note: - * - Represents the number of animals showing sensitization response out of the total number of animals challenged in each group.

Appendix 1. Individual Animal Mortality, Morbidity and Clinical Signs

Group/Sex & Treatment	Animal No.	Day													
		1	2	3	4	5	6	7	8	9	10	11	12	13	14
G1a/F & Polar Vehicle Control	GPb3194	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	GPb3195	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	GPb3196	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	GPb3197	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	GPb3198	1	1	1	1	1	1	1	1	1	1	1	1	1	1
G2a/F & Polar Test Item Extract	GPb3199	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	GPb3200	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	GPb3201	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	GPb3202	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	GPb3203	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	GPb3204	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	GPb3205	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	GPb3206	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	GPb3207	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	GPb3208	1	1	1	1	1	1	1	1	1	1	1	1	1	1
G1b/F & Non-Polar Vehicle Control	GPb3209	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	GPb3210	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	GPb3211	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	GPb3212	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	GPb3213	1	1	1	1	1	1	1	1	1	1	1	1	1	1
G2b/F & Non-Polar Test Item Extract	GPb3214	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	GPb3215	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	GPb3216	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	GPb3217	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	GPb3218	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	GPb3219	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	GPb3220	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	GPb3221	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	GPb3222	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	GPb3223	1	1	1	1	1	1	1	1	1	1	1	1	1	1

F: Female; 1- Normal; there were no mortality/morbidity occurred in the study.

Appendix 1. (Contd.,) Individual Animal Mortality, Morbidity and Clinical Signs

Group/ Sex & Treatment	Animal No.	Day										
		15	16	17	18	19	20	21	22	23	24	25
G1a/F & Polar Vehicle Control	GPb3194	1	1	1	1	1	1	1	1	1	1	1
	GPb3195	1	1	1	1	1	1	1	1	1	1	1
	GPb3196	1	1	1	1	1	1	1	1	1	1	1
	GPb3197	1	1	1	1	1	1	1	1	1	1	1
	GPb3198	1	1	1	1	1	1	1	1	1	1	1
G2a/F & Polar Test Item Extract	GPb3199	1	1	1	1	1	1	1	1	1	1	1
	GPb3200	1	1	1	1	1	1	1	1	1	1	1
	GPb3201	1	1	1	1	1	1	1	1	1	1	1
	GPb3202	1	1	1	1	1	1	1	1	1	1	1
	GPb3203	1	1	1	1	1	1	1	1	1	1	1
	GPb3204	1	1	1	1	1	1	1	1	1	1	1
	GPb3205	1	1	1	1	1	1	1	1	1	1	1
	GPb3206	1	1	1	1	1	1	1	1	1	1	1
	GPb3207	1	1	1	1	1	1	1	1	1	1	1
	GPb3208	1	1	1	1	1	1	1	1	1	1	1
G1b/F & Non-Polar Vehicle Control	GPb3209	1	1	1	1	1	1	1	1	1	1	1
	GPb3210	1	1	1	1	1	1	1	1	1	1	1
	GPb3211	1	1	1	1	1	1	1	1	1	1	1
	GPb3212	1	1	1	1	1	1	1	1	1	1	1
	GPb3213	1	1	1	1	1	1	1	1	1	1	1
G2b/F & Non-Polar Test Item Extract	GPb3214	1	1	1	1	1	1	1	1	1	1	1
	GPb3215	1	1	1	1	1	1	1	1	1	1	1
	GPb3216	1	1	1	1	1	1	1	1	1	1	1
	GPb3217	1	1	1	1	1	1	1	1	1	1	1
	GPb3218	1	1	1	1	1	1	1	1	1	1	1
	GPb3219	1	1	1	1	1	1	1	1	1	1	1
	GPb3220	1	1	1	1	1	1	1	1	1	1	1
	GPb3221	1	1	1	1	1	1	1	1	1	1	1
	GPb3222	1	1	1	1	1	1	1	1	1	1	1
	GPb3223	1	1	1	1	1	1	1	1	1	1	1

F: Female; 1- Normal; there were no mortality/morbidity occurred in the study.

Appendix 2. Individual Animal Body Weights (g) and Body Weight Gain (%)

Group & Treatment	Sex	Animal No.	Body Weights (g) on days		Body Weight Gain (%)
			Day 1	Day 25	Day 1-25
G1a & Polar Vehicle Control	F	GPb3194	319.28	381.78	19.58
		GPb3195	322.96	377.91	17.01
		GPb3196	323.08	379.23	17.38
		GPb3197	324.65	381.53	17.52
		GPb3198	324.95	382.97	17.86
G2a & Polar Test Item Extract	F	GPb3199	336.86	388.11	16.25
		GPb3200	335.21	382.12	13.99
		GPb3201	336.85	396.10	17.59
		GPb3202	338.28	392.21	15.94
		GPb3203	340.96	395.22	15.91
		GPb3204	340.95	396.91	16.41
		GPb3205	341.08	391.02	14.64
		GPb3206	341.25	395.22	15.82
		GPb3207	343.26	392.12	14.23
		GPb3208	344.09	399.03	15.97
G1b & Non-Polar Vehicle Control	F	GPb3209	326.28	382.21	31.68
		GPb3210	326.99	381.92	36.69
		GPb3211	327.08	383.07	37.23
		GPb3212	327.96	387.91	42.21
		GPb3213	332.08	387.02	42.31
G2b & Non-Polar Test Item Extract	F	GPb3214	345.60	390.11	12.88
		GPb3215	346.28	396.12	14.39
		GPb3216	352.09	383.09	8.80
		GPb3217	354.28	372.29	5.08
		GPb3218	355.16	382.22	7.62
		GPb3219	356.28	406.22	14.02
		GPb3220	356.18	406.18	15.17
		GPb3221	355.26	410.20	16.89
		GPb3222	365.28	415.27	15.01
		GPb3223	371.19	420.10	7.27

F - Female

Appendix 3. Individual Animal Induction Phase Skin Reactions

Animal No.	Group/ Sex	(Intradermal induction) Observations post administration									(Topical Application–Boosting) Observation at post removal of the test patch at injection site			
		Injection site No.	24 hrs.				48 hrs.				1 hour		24 hours	
			ERY		EDE		ERY		EDE		ERY	EDE	ERY	EDE
			L	R	L	R	L	R	L	R	Shoulder region		Shoulder region	
GPb3194	G1a/F	A	0	0	0	0	0	1	0	0	0	0	0	0
		B	0	0	0	0	0	0	0	0				
		C	0	0	0	0	0	0	1	0				
GPb3195		A	0	0	0	0	0	0	1	0	0	0	0	0
		B	0	0	0	0	0	0	0	0				
		C	0	0	0	0	1	0	0	0				
GPb3196		A	0	0	0	0	0	1	0	0	0	0	0	0
		B	0	0	0	0	0	0	0	0				
		C	0	0	0	0	0	0	0	1				
GPb3197		A	0	0	0	0	1	0	0	0	0	0	0	0
		B	0	0	0	0	0	0	0	0				
		C	0	0	0	0	0	0	1	0				
GPb3198		A	0	0	0	0	0	0	1	0	0	0	0	0
		B	0	0	0	0	0	0	0	0				
		C	0	0	0	0	0	0	0	1				
GPb3209	G1b/F	A	0	0	0	0	0	0	0	1	0	0	0	0
		B	0	0	0	0	0	0	0	0				
		C	0	0	0	0	0	0	1	0				
GPb3210		A	0	0	0	0	0	1	0	0	0	0	0	0
		B	0	0	0	0	0	0	0	0				
		C	0	0	0	0	0	0	1	0				
GPb3211		A	0	0	0	0	0	0	1	0	0	0	0	0
		B	0	0	0	0	0	0	0	0				
		C	0	0	0	0	1	0	0	0				
GPb3212		A	0	0	0	0	0	0	0	1	0	0	0	0
		B	0	0	0	0	0	0	0	0				
		C	0	0	0	0	1	0	0	0				
GPb3213		A	0	0	0	0	0	1	0	0	0	0	0	0
		B	0	0	0	0	0	0	0	0				
		C	0	0	0	0	0	0	0	1				

Key: F-Female, ERY-Erythema, EDE-Oedema, L-Left, R-Right, 0-No Erythema/ No Oedema, 1-very slight erythema/oedema

Appendix 3. (Contd.,) Individual Animal Induction Phase Skin Reactions

Animal No.	Group/ Sex	(Intradermal induction) Observations post administration									(Topical Application–Boosting) Observation at post removal of the test patch at injection site			
		Injection site No.	24 hrs.				48 hrs.				1 hour		24 hours	
			ERY		EDE		ERY		EDE		ERY	EDE	ERY	EDE
			L	R	L	R	L	R	L	R	Shoulder region		Shoulder region	
GPb3199	G2a/F	A	0	0	0	0	0	0	1	0	0	0	0	0
		B	0	0	0	0	0	0	0	0				
		C	0	0	0	0	0	0	0	1				
GPb3200		A	0	0	0	0	0	1	0	0	0	0	0	0
		B	0	0	0	0	0	0	0	0				
		C	0	0	0	0	1	0	0	0				
GPb3201		A	0	0	0	0	0	1	0	0	0	0	0	0
		B	0	0	0	0	0	0	0	0				
		C	0	0	0	0	0	0	0	1				
GPb3202		A	0	0	0	0	0	0	1	0	0	0	0	0
		B	0	0	0	0	0	0	0	0				
		C	0	0	0	0	0	0	0	1				
GPb3203		A	0	0	0	0	1	0	0	0	0	0	0	0
		B	0	0	0	0	0	0	0	1				
		C	0	0	0	0	0	0	0	1				
GPb3204		A	0	0	0	0	1	0	0	0	0	0	0	0
		B	0	0	0	0	0	0	0	0				
		C	0	0	0	0	0	0	1	0				
GPb3205		A	0	0	0	0	0	0	0	1	0	0	0	0
		B	0	0	0	0	0	0	0	0				
		C	0	0	0	0	1	0	0	0				
GPb3206		A	0	0	0	0	0	0	0	1	0	0	0	0
		B	0	0	0	0	0	0	0	0				
		C	0	0	0	0	1	0	0	0				
GPb3207		A	0	0	0	0	0	1	0	0	0	0	0	0
		B	0	0	0	0	0	0	0	0				
		C	0	0	0	0	0	0	0	1				
GPb3208		A	0	0	0	0	0	1	0	0	0	0	0	0
		B	0	0	0	0	0	0	0	0				
		C	0	0	0	0	0	0	1	0				

Key: F-Female, ERY-Erythema, EDE-Oedema, L-Left, R-Right, 0-No Erythema/ No Oedema, 1-very slight erythema/oedema

Appendix 3. (Contd.,) Individual Animal Induction Phase Skin Reactions

Animal No.	Group/ Sex	(Intradermal induction) Observations post administration									(Topical Application– Boosting) Observation at post removal of the test patch at injection site			
		Injection site No.	24 hrs.				48 hrs.				1 hour		24 hours	
			ERY		EDE		ERY		EDE		ERY	EDE	ERY	EDE
			L	R	L	R	L	R	L	R	Shoulder region		Shoulder region	
GPb3214	G2b/F	A	0	0	0	0	0	0	0	1	0	0	0	0
		B	0	0	0	0	0	0	0	0				
		C	0	0	0	0	1	0	0	0				
GPb3215		A	0	0	0	0	0	1	0	0	0	0	0	0
		B	0	0	0	0	0	0	0	0				
		C	0	0	0	0	0	0	1	0				
GPb3216		A	0	0	0	0	0	0	0	1	0	0	0	0
		B	0	0	0	0	0	0	0	0				
		C	0	0	0	0	0	1	0	0				
GPb3217		A	0	0	0	0	1	0	0	0	0	0	0	0
		B	0	0	0	0	0	0	0	0				
		C	0	0	0	0	0	0	1	0				
GPb3218		A	0	0	0	0	0	0	1	0	0	0	0	0
		B	0	0	0	0	0	0	0	0				
		C	0	0	0	0	0	1	0	0				
GPb3219		A	0	0	0	0	1	0	1	0	0	0	0	0
		B	0	0	0	0	0	0	0	0				
		C	0	0	0	0	0	0	1	0				
GPb3220		A	0	0	0	0	1	0	1	0	0	0	0	0
		B	0	0	0	0	0	0	0	0				
		C	0	0	0	0	0	0	1	0				
GPb3221		A	0	0	0	0	0	0	0	1	0	0	0	0
		B	0	0	0	0	0	0	0	0				
		C	0	0	0	0	0	1	0	0				
GPb3222		A	0	0	0	0	0	0	0	1	0	0	0	0
		B	0	0	0	0	0	0	0	0				
		C	0	0	0	0	1	0	1	0				
GPb3223		A	0	0	0	0	0	1	0	0	0	0	0	0
		B	0	0	0	0	0	0	0	0				
		C	0	0	0	0	0	0	1	0				

Key: F-Female, ERY-Erythema, EDE-Oedema, L-Left, R-Right, 0-No Erythema/ No Oedema, 1-very slight erythema/oedema

Appendix 4. Individual Animal Skin Reactions Scoring after Challenge Phase Patch Removal

Animal No.	Sex	Group	(Challenge) Observation at post removal of the test patches at right and left flank			
			24 hours		48 hours	
			ERY		ERY	
			Test Site	Control Site	Test Site	Control Site
GPb3194	F	G1a	0	0	0	0
GPb3195			0	0	0	0
GPb3196			0	0	0	0
GPb3197			0	0	0	0
GPb3198			0	0	0	0
GPb3199	F	G2a	0	0	0	0
GPb3200			0	0	0	0
GPb3201			0	0	0	0
GPb3202			0	0	0	0
GPb3203			0	0	0	0
GPb3204			0	0	0	0
GPb3205			0	0	0	0
GPb3206			0	0	0	0
GPb3207			0	0	0	0
GPb3208			0	0	0	0

Key: F-Female, ERY-Erythema, 0-No Visible Change.

Appendix 4. (Contd.,) Individual Animal Skin Reactions Scoring after Challenge Phase Patch Removal

Animal No.	Sex	Group	(Challenge) Observation at post removal of the test patches at right and left flank			
			24 hours		48 hours	
			ERY		ERY	
			Test Site	Control Site	Test Site	Control Site
GPb3209	F	G1b	0	0	0	0
GPb3210			0	0	0	0
GPb3211			0	0	0	0
GPb3212			0	0	0	0
GPb3213			0	0	0	0
GPb3214	F	G2b	0	0	0	0
GPb3215			0	0	0	0
GPb3216			0	0	0	0
GPb3217			0	0	0	0
GPb3218			0	0	0	0
GPb3219			0	0	0	0
GPb3220			0	0	0	0
GPb3221			0	0	0	0
GPb3222			0	0	0	0
GPb3223			0	0	0	0

Key: M-Female, ERY-Erythema, 0-No Visible Change.

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. Study Details and Result of Reliability Check

Liveon Biolabs

POSITIVE CONTROL STUDY SUMMARY

Study Number: LBPL/G-2436 (TX)

Test Item Name (Positive Control): 2-Mercaptobenzothiazole

Lot No.: MKCN 6664

Experimental Period: 24/09/2022 to 24/10/2022

Valid Upto: 15/05/2023

The study was conducted to evaluate the skin sensitivity and reliability of the Test Item "2-Meracaptobenzothaizole" by the Guinea pig maximization test (GPMT) in guinea pigs as per ISO 10993-10:2021 - Biological evaluation of medical devices - Part 10: Tests for Skin Sensitization and OECD Guideline No.406.

This study was performed using 30 animals that were grouped into two groups 10 (05 males /05 females) for the control group and 20 (10 males/10females) for the treatment group. Fur of all the animals of both the groups were clipped, 24 hours prior to induction (induction and topical application) exposure as well as challenge exposure of the test item. On Day 1, intradermal induction phase was conducted. During intradermal induction administration, animals of control (G1) were injected with three pairs of intradermal injections [Injection A) Freund's complete Adjuvant +Physiological saline (1:1), Injection B) 80 % Ethanol and C) 1:1 mixture of injection A and injection B on the either side of midline on shoulder region. Animals of test group (G2) were injected with three pairs of intradermal injections [Injection A) Freund's complete Adjuvant +Physiological saline (1:1), Injection B) 5 % (w/v) of the test item formulated in 80 % ethanol and C) 5 % (w/v) of the test item formulated in 1:1 mixture (v/v) of FCA+ Physiological saline on either side of the midline on the shoulder region. The skin reactions were observed on Day 2 (24 hours post intradermal administration) and Day 3 (48 hours post intradermal administration) and recorded as per Draize method.

Topical induction was carried out on Day 8 using a filter paper with 0.5 mL of 80 % Ethanol for control animals and 0.5 mL of 50% (w/v). The test item was applied to the test animals on the dorsal region and secured with non-irritant adhesive tape for 48 hours. On Day 10 (1-hour post patch removal) and Day 11 (24 hours post patch removal) skin reactions for erythema and oedema were observed and recorded as per the Draize method.

Challenge exposure was carried out on Day 22 (after completion of 14 days of the topical induction phase, Patches of filter papers loaded with 0.5 mL of 80% Ethanol was applied to the anterior right flank of animals and 0.5 mL of 25 % (w/v) test item was applied to the anterior left flank of all animals of both test and control groups. Patches were held in contact for 24 hours by a semi occlusive dressing.

Annexure 2. Cont., Study Details and Result of Reliability Check

Liveon Biolabs

Results:

There were no mortality, morbidity, bodyweight loss and clinical signs observed in control and test groups during the experimental period.

Challenge Application:

Refer Table 1

09/20 Animals had score of 1 (Discrete or patchy erythema) at 24 hours and 48 hours observations after the patch removal of test patches in challenge phase.

The Skin sensitization rate was 45% at 24 and 48 hours post treatment respectively.

The comparison of the skin reactions (at challenge phase) of the test item treated animals with those of the control group animals showed that the test item "2-Meracaptobenzothaizole" is classified as "Moderate-sensitizer" under the experimental condition tested.

Conclusion:

Based on the results of this study, 2-Meracaptobenzothaizole" is classified as "Moderate-sensitizer" to Guinea Pigs according to Magnusson and Kligman grading scale.

Table – 1: Positive Control (2-Mercaptobenzothiazole) Challenge Phase Data

Group	Concentration (%w/v)	Application Site	Challenge Phase		
			Time (hours)	Skin Reaction Response	Sensitization Rate (%)
G1 (Vehicle Control)	0.5 mL of 25% 2-MBT	Anterior Right Flank	24	0*/10	0
			48	0*/10	0
G2 (Test Item)	0.5 mL of 25% 2-MBT	Posterior Right Flank	24	9*/20	45
			48	9*/20	45

2-MBT: 2-Mercaptobenzothiazole

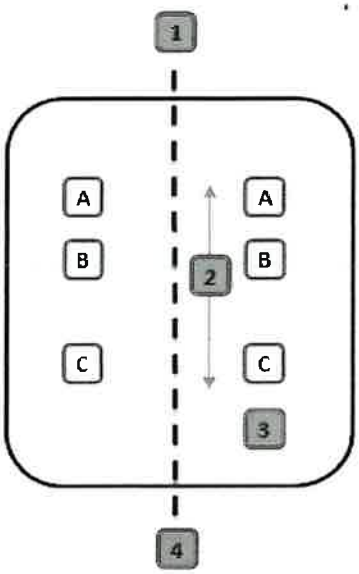
Note: * Represents the number of animals showing sensitization response out of the total number of animals challenged in each group.

The next reliability (Positive Control) study will be conducted on April 2023.

16/11/2022

Study Director
Sign and Date

Annexure 3. Intradermal Injection and Topical Patch Application Sites Diagram

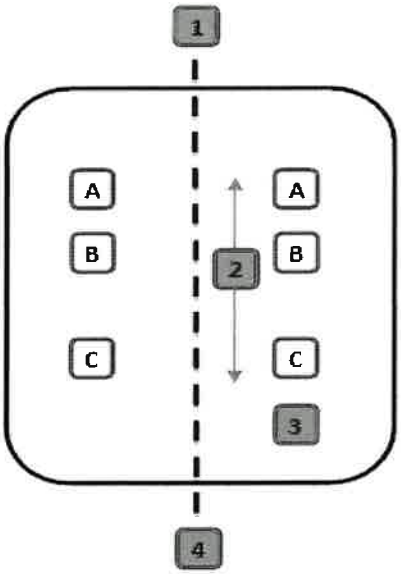


Treatment Animals

A: 1:1 v/v of FCA + physiological saline

B: Undiluted test item extract

C: 1:1 v/v of A + B



Control Animals

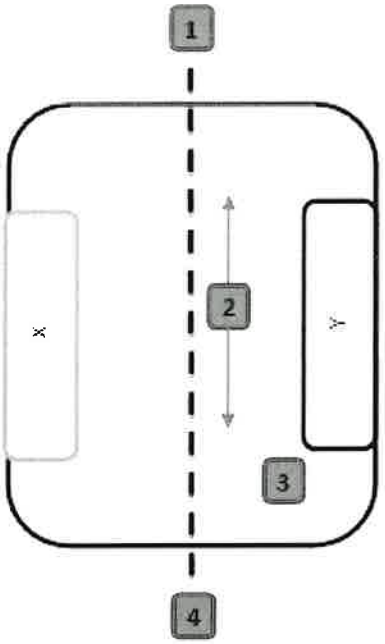
A: 1:1 v/v of FCA + physiological saline

B: Vehicle only

C: 1:1 v/v of A + B

1. Cranial End
2. Intradermal Injection Sites
3. Clipped Intrascapular Region
4. Caudal End

Annexure 4. Challenge Phase at Flanks of Animal



All Animals

X: Treatment Animal Site C

Y: Control Animals Site C

1. Cranial End
2. Intradermal Injection Sites
3. Clipped Intrascapular Region
4. Caudal End

Annexure 5. Evaluation of Skin Reactions (Draize Method)

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

Maximum Possible Score – 4

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

Maximum Possible Score – 4

Annexure 6. Magnusson and Kligman Grading Scale for the Evaluation of Challenge Patch Test Reactions

Patch Test Reaction	Grading Scale
No visible change	0
Discrete or patchy erythema	1
Moderate and confluent erythema	2
Intense erythema and/or swelling	3

Annexure 7. 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 7. (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 8. 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	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/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 9. Material safety data sheet

KTE
Partners in Growth

Poly propylene 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:

KTE
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MATERIAL DATA SHEET (MSDS)
Poly prpylene nonwoven fabric

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

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.

KTE
Partners in Growth

Poly propylene nonwoven fabric

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

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 10. Contaminant Analysis Report of Bedding Material

SMSLA

SMS LABS SERVICES PRIVATE LIMITED

TEST REPORT

TC 6118

ULR - TC611822000010596F
Report No : FD22050367-01

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

Annexure 10. (Contd.,) Contaminant Analysis Report 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

Annexure 10. (Contd.,) Contaminant Analysis Report 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

Annexure 11. 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 12. Contaminant Analysis Report of Feed

SMSLA

SMS LABS SERVICES PRIVATE LIMITED

TEST REPORT

TC-6118

ULR - TC611822000010597F
Report No : FD22050367-02

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	: Guinea Pig Feed	Sample Sent on	: 27 May 2022
Sample Quantity	: 500gm x 1No	Sample Received on	: 28 May 2022
Sample Identification	: Batch No: 523, 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	1.03
2	Carbohydrates	SMSLA/FD/SOP/011	g/100g	60.01
3	Crude Fat	IS 7874 (Part 1)	g/100g	3.02
4	Crude Fibre	IS 7874 (Part 1)	g/100g	12.43
5	Crude Protein	AOAC 2001.11	g/100g	18.00
6	Moisture	IS 7874 (Part 1)	g/100g	9.99
7	Phosphorus	IS 7874 (Part 2)	g/100g	1.01
8	Total Ash	IS 7874 (Part 1)	g/100g	8.98
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. Karthigavel
Authorized Signatory - Chemical

Annexure 12. (Contd.,) Contaminant Analysis Report of Feed

SMSLA

SMS LABS SERVICES PRIVATE LIMITED

TEST REPORT

TC-6118

ULR - TC611822000010597F
Report No : FD22050367-02

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)

A. Kavitha
Authorised signatory - Chemical

Annexure 12. (Contd.,) Contaminant Analysis Report of Feed

SMSLA

SMS LABS SERVICES PRIVATE LIMITED

TEST REPORT

TC-6118

ULR - TC611822000010597F
Report No : FD22050367-02

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	Profenofos	SMSLA/LS/SOP/02	mg/kg	BLQ(LOQ:0.01)
Trace Metal Elements				
51	Arsenic	SMSLA/IS/SOP/01	mg/kg	BLQ(LOQ:0.1)
52	Cadmium	SMSLA/IS/SOP/01	mg/kg	BLQ(LOQ:0.1)
53	Lead	SMSLA/IS/SOP/01	mg/kg	BLQ(LOQ:0.1)
54	Magnesium	SMSLA/IS/SOP/05	mg/kg	0.21298
55	Mercury	SMSLA/IS/SOP/01	mg/kg	BLQ(LOQ:0.1)
56	Potassium	SMSLA/IS/SOP/05	mg/kg	1.3500
57	Sodium	SMSLA/IS/SOP/05	mg/kg	0.2375
58	Zinc	SMSLA/IS/SOP/01	mg/kg	53.10

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

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

K. Elakkiyathasan
Authorized Signatory - Chemical

A. Kanagavel
Authorized Signatory - Chemical

Annexure 13. Analysis Report for Feed

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

Date of Sampling: 29/11/2022 Date of Reporting: 03/12/2022

Sl. No.	Summary of Findings	Results
1	Name / Source	Guinea Pig feed from Krishna Valley
2	Batch No.	551
3	Total viable organisms	<1 X 10^4 CFU/g
4	Fungi	<1 X 10^4 CFU/g
5	Mesophilic spores	<1 X 10^4 CFU/g
6	*Salmonella* sp.	
7	*E. coli.*	
8	*Coliforms*	

Remarks: ———

Analyzed by: 03/12/2022 Sign. and Date

Verified by: 03/12/2022 Sign. and Date

Annexure 13. (Cont.,) Analysis Report for Feed

Krishna Valley Agrotech LLP
An ISO 9001:2015 & GMP Certified Company
Corporate Office: Bungalow No. 8, Acacia Garden 1, Magarpatta City, Pune 411028
Customer Care No: 120-6106713, Website: www.kvat.co.in

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

AF-1000M Guinea Pig Diets (Autoclavable)

CERTIFICATE OF ANALYSIS

Lot No : 551

Date of manufacture: 15.11.2022

Expiry date: 14.05.2023

Report date: 17.11.2022

Authorized signatory

Proximate analysis

Analysis	Result %
Crude Protein	17.40
Ether extract	3.90
Crude Fiber	11.10
Moisture	8.98
Calcium	0.82
Phosphorus	0.72
Total ash	7.80
Gross Energy	3.0 Kcal/gm

Heavy Metals			
Arsenic	0.12	ppm	1.00
Cadmium	0.03	ppm	0.50
Lead	0.08	ppm	1.50
Mercury	0.02	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/ 05,00,1.1.2020

Annexure 14. Contaminant Analysis Report 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

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

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

SMSLA

SMS LABS SERVICES PRIVATE LIMITED

TEST REPORT

TC-6118

ULR : TC611822000009121
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

Annexure 14. (Contd.,) Contaminant Analysis Report 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
Senior Chemist

Annexure 14. (Contd.,) Contaminant Analysis Report 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

Annexure 14. (Contd.,) Contaminant Analysis Report 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

Annexure 15. 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 QA 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)

PLSOP-MIC-004
Version No.: 04

Annexure 16. 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 17. Study Plan

STUDY PLAN

STUDY TITLE

SKIN SENSITIZATION STUDY OF POLAR AND NON-POLAR EXTRACTS OF SPUN MELT PP NONWOVEN FABRIC USING GUINEA PIGS MAXIMIZATION TEST (GPMT)

TEST GUIDELINE: ISO 10993-10:2021

STUDY NO.: LBPL/NG-2641 (TX)

STUDY CODE: GPMT

STUDY DIRECTOR

Ms. Rangalakshmi G.R

SPONSOR

KTEX NONWOVENS PVT. LTD.
SDURVEY 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.

Annexure 17. (Contd.,) Study Plan

Liveon Biolabs

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1. OBJECTIVE

The objective of this toxicity study is to assess the potential skin sensitization and biocompatibility of a polar extract (physiological saline) and non-polar extract (sesame oil) of "Spun melt PP Nonwoven Fabric" by injecting both polar extract and non-polar extract as a single intradermal injection to evaluate the possibility of hyperreactive skin (visible reactions i.e. erythema/Oedema) followed by topical induction (erythema/Oedema) and challenge Phase for skin reaction (erythema) in guinea pigs. This test also provides information on health hazards likely to arise from acute exposure by the intended clinical route in humans.

2. STUDY DETAILS

Study Title	:	Skin Sensitization Study of Polar and Non-Polar Extracts of Spun melt PP Nonwoven Fabric using Guinea Pigs Maximization Test (GPMT).
Study Number	:	LBPL/NG-2641 (TX)
Study Code	:	GPMT
ULR No.	:	TC-679422000001263F
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	:	Ms. Rangalakshmi G.R
Study Veterinarian	:	Dr. Sunkad Meghana
Sponsor Representative	:	Mr.Mustanshir vohra

4. STUDY SCHEDULE

Study Initiation Date	:	22/12/2022
Experiment Start Date	:	26/12/2022
Acclimatization Period	:	26/12/2022 to 30/12/2022
Treatment Dates	:	Intradermal induction phase: 31/12/2022 Topical induction phase : 07/01/2023 Challenge phase: 21/01/2023
Experiment End Date	:	24/01/2023
Draft Report to Sponsor	:	Latest by 02/02/2023
Study Completion Date	:	Latest by 02/03/2023 or Within a week after receiving comments for draft report from sponsor.

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
Cm	:	Centimeter
dB	:	decibel
FCA	:	Freund's Complete Adjuvant
hr/h(s)	:	Hour (s)
IAEC	:	Institutional Animal Ethics Committee
ISO	:	International Organization for Standardization
IEC	:	International Electrotechnical Commission
GPMT	:	Guinea Pigs Maximization Test
g.	:	Gram
mL	:	Millilitre
No.	:	Number
rpm	:	Revolutions Per Minute
SDS	:	Sodium Dodecyl Sulphate
Sign.	:	Signature
TIIS	:	Test Item Information Sheet
UV	:	Ultraviolet
<	:	Less than

Note: The additional Abbreviations and symbols (if any) will be provided in the Study Report

6. QUALITY ASSURANCE UNIT RESPONSIBILITIES

The Quality Assurance Unit of 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

This study will be performed in compliance with the following:

- ISO/IEC 17025:2017, General Requirements for the Competence of Testing and Calibration Laboratories.
- The 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 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 10993-10:2021 - Biological Evaluation of Medical Devices-Part 10: Tests for Skin Sensitization.

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-054-10/2022. 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 human 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.

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-Q01
Intended use of device in Human	:	Human Use in Gwon, Drapes ,CSR Wraps, diapers or sanitary pads
Site of Contact	:	Skin
Duration of contact with human body	:	6-12 hours
Material Category (As per ISO10993 Part 1)	:	Surface medical device
Weight in g (without packaging)	:	35gm.
Material Safety Data Sheet	:	Yes
Certificate of analysis	:	Yes
Storage Condition	:	Ambient (+19 to +25° C)
Test Item Code by Sponsor	:	KTEXSM001
Batch No.	:	2220524A

Date of Manufacture	:	24/05/2022
Date of Expiry	:	2 Years from date of manufacturing
Sterility Status	:	Non-Sterile (Autoclave Method).
Test Item Manufactured & Supplied by	:	KTEX NONWOVENS PVT LTD Sdurvey no.241, opp. Khamta village bus stop Rajkot-jamnagar highway-360 110, Guarat

The Sponsor is responsible for authenticity of the test item and no further characterization of test item will be performed at Liveon Biolabs Private Limited. The test item details mentioned are as per the TIIS, Certificate of Analysis and Material safety data sheet provided by the sponsor. The TIIS Certificate of Analysis and Material safety data sheet is included in the Annexure 6, Annexure 7 and Annexure 8 respectively.

13.1.2 Test System

Animal Species	:	Guinea Pig (*Cavia porcellus*)
Strain	:	Dunkin Hartley
Justification for Selection of Species	:	The Guinea pig has been the animal of choice for predictive sensitization tests for several decades and also as per ISO 10993-10: 2021 specification.
Source	:	In-house breed animals
Age at treatment	:	7- 13 Weeks (exact age will be provided in the report)
No. of Groups	:	4
Total No. of Animals	:	30 Male / Female (Female will be Nulliparous and Non-Pregnant)
Body weight range at treatment	:	300-500g(Exact animals body weight will be provided in the Study Report) At the commencement of treatment, the weight variation of guinea pig used will not exceed ± 20% of the mean body weight.

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 at 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

Individual animal will be housed in a standard polycarbonate cages(Cage size approximately - (Length 43 X Breadth 29 X Height 18 cm) with stainless steel mesh top, food will be provided in feed hoppers and drinking water with stainless sipping tubes. Clean sterilized bedding material will be provided as bedding material. The corn cob will be analyzed periodically for fungal and microbial contaminations. The latest analysis reports of bedding material will be included in Study Report.

13.1.3.4 Diet and Water

AF- 1000M Guinea pigs Diets manufactured by Krishna Valley Agrotech LLP will be provided *ad libitum* to Guinea pigs or others to specify in the report.

Deep bore-well water subjected to filtration for reverse osmosis and UV sterilized, will be provided *ad libitum* to guinea pigs in polycarbonate bottles with rubber corked stainless steel sipper tubes and Vitamin C Supplement will be provided by mixing with water.

Based on the latest analytical certificate/s available, there are no known contaminants in the food and RO 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 guinea pigs will be acclimatized at least for 5 days before start of the treatment. During acclimatization animals will be observed at least once daily. Veterinary examination will be performed before selecting 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 body marking using 1 % turmeric solution and potassium permanganate solution. The cages will be identified with cage cards indicating study number, animal accession number, study code, species, strain, sex, treatment start date and experiment end date etc.

13.1.4.3 Randomization and Grouping

The animals for the experiment will be weighed and arranged in ascending order of their body weights. Animals will be randomized during acclimatization using body weight stratification method of randomization and are grouped accordingly such that the mean body weight will not vary ± 20 percent among the groups on the Day 1 of administration. Guinea pig with extreme body

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weights and/or not selected for the treatment will be excluded. Grouping will be done during the acclimatization period.

13.1.4.4 Clipping of Animals

For induction phase, the fur of the animals will be closely clipped approximately 24 hrs before the treatment from shoulder region (at least an area of 3 cm x 5 cm). For challenge/re-challenge phase, the fur will be closely clipped from the required flank region [approximately 80 sq cm (10 cm x 8 cm)] approximately 24 hrs before treatment. In both the cases care will be taken to avoid abrasion on the skin. If required, the fur will be re-clipped to facilitate observation or to accommodate repeated exposure.

13.2 Methods

13.2.1 Experimental Procedures

13.2.1.1 Study Design

The following study design will be adopted for the study:

Group	Description	Color of Cage cards	Number of Animals and sex	Animal Accession No.	
				From	To
(G1a)	Polar Vehicle Control	White	5 M/F	GPb3194	GPb3198
(G2a)	Polar Test Item Extract	Pink	10M/F	GPb3199	GPb3208
(G1b)	Non-Polar Vehicle Control	White with dots	5 M/F	GPb3209	GPb3213
(G2b)	Non-Polar Test Item Extract	Pink with dots	10M/F	GPb3214	GPb3223

Note: a: Polar groups; b: Non-polar groups; M: Male; F-Female

13.2.1.2 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 polar and non-polar Vehicles used will be recorded in the raw data and presented in the study report.

13.2.1.3 Positive Control Response Validation

The results of latest positive control response validation study will be presented in study report as an Annexure.

13.3 Test Procedure

13.3.1 Preparation of Test Item Extract

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

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The Test Item is Irregularly shaped device hence extraction ratio 0.2g/ml will be selected for extraction and the contact period of Test Item is Limited contact (≤24h) hence the extraction condition will be selected (37 ± 1) °C for (72 ± 2) hours as per ISO 10993-12:2021 (Annexure 1):

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.

13.4 Treatment

13.4.1 Intradermal Induction Phase

Preparation of Polar Vehicle Control (Group G1a)

- Site 'A' will be injected intradermally with 0.1 mL of 1:1 mixture (v/v) of FCA in physiological saline /distilled water.
- Site 'B' will be injected intradermally with 0.1 mL of polar Vehicle Control.
- Site 'C' will be injected intradermally with 0.1 mL of 50 % v/v polar Vehicle Control in 1:1 mixture (v/v) of FCA in physiological saline.

Preparation of Non-Polar Vehicle Control (Group G1b)

- Site 'A' will be injected intradermally with 0.1 mL of 1:1 mixture (v/v) of FCA in physiological saline /distilled water.
- Site 'B' will be injected intradermally with 0.1 mL of non-polar Vehicle Control.
- Site 'C' will be injected intradermally with 0.1 mL of 50 % v/v non-polar Vehicle Control in 1:1 mixture (v/v) of FCA in physiological saline.

Preparation of Polar Test Item Extract (Group G2a)

- Site 'A' will be injected intradermally with 0.1 mL of 1:1 mixture (v/v) of FCA in physiological saline / distilled water.
- Site 'B' will be injected intradermally with 0.1 mL of undiluted polar test item Extract.
- Site 'C' will be injected intradermally with 0.1 mL of 50 % v/v undiluted polar Test Item extract in 1:1 mixture (v/v) of FCA in physiological saline.

Preparation of Non-Polar Test Item Extract (Group G2b)

- Site 'A' will be injected intradermally with 0.1 mL of 1:1 mixture (v/v) of FCA in physiological saline /distilled water.

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- Site 'B' will be injected intradermally with 0.1 mL of undiluted non-polar test Item Extract.
- Site 'C' will be injected intradermally with 0.1 mL of 50 % v/v undiluted Non-Polar Test Item Extract in 1:1 mixture (v/v) of FCA in physiological saline.

Administration

The animals of control groups (G1a and G1b) and test groups (G2a and G2b) will be injected with polar and non-polar Vehicle Control and polar and non-polar test item extracts, respectively. The animals will be injected at the shoulder region with 0.1 mL per injection of 3 pairs of intradermal injections. Injections 1 and 2 will be given near the head region at least 1 cm apart and injection 3 will be given 2 cm apart towards caudal part of the body as per Annexure 2.

Site A: 1st pair of injection
Site B: 2nd pair of injection
Site C: 3rd pair of injection
Details of FCA will be included in the raw data and Study Report.

13.4.2 Topical Induction Phase

On day 7 ± 1 i.e., after completion of the Intradermal Induction phase, irritation of the treated area will be observed for erythema and Oedema. If the irritation is not produced/observed on skin over the injection sites (i.e., same area of Intradermal Induction Phase) and that sites will be massaged with 10% (w/w) SDS in petroleum jelly to provoke a mild acute inflammation (discoloration of injection site). After 24 ± 2 hrs of SDS application, any remaining SDS residue will be gently removed with cotton gauze. If any irritation is observed (erythema and Oedema) after 7 ± 1 day, SDS will not be applied. If not also, SDS will not applied and switch over challenging phase.

After removal of SDS, test Item extract with Vehicle Control (i.e., respective Vehicle Control and test item extract will be prepared separately similar to intradermal induction phase) and will be applied on to each animal of intradermal region by topical application using absorbent cotton gauze (approximately 2 cm X 4 cm = 8 cm^2) dipped with respective Vehicle Control and test item extract as per Annexure 2, and It will be secured in position by adhesive tape wound around the torso. The details of treatment are as mentioned below.

G1a:	Filter paper or absorbent cotton gauze dipped in Polar Vehicle Control
G2a:	Filter paper or absorbent cotton gauze dipped in undiluted Polar Test Item Extract
G1b:	Filter paper or absorbent cotton gauze dipped in Non-Polar Vehicle Control
G2b:	Filter paper or absorbent cotton gauze dipped in Undiluted Non-Polar Test Item Extract

Remove the semi-occlusive dressing and patches after 48 ± 2 hrs of application and wiped dressed with RO / distilled water and details will be included in the raw data and study report.

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13.4.3 Challenge Phase

On Day 14 ± 1 after completion of the topical induction phase (i.e., Day 21), fur from both anterior flank region, which is not treated during the induction phase will be clipped from all the animals.

On Day 22, the filter paper/ absorbent cotton gauze of approximate size of 8 cm^2 (2 cm x 4 cm) will be dipped in the respective control vehicle and test item extract as per Annexure 3. The dipped filter paper/ absorbent cotton gauze will be applied to the respective group as below:

G1a	Anterior Right Flank	Polar Vehicle Control
	Anterior Left Flank	Undiluted Polar Test Item Extract
G2a	Anterior Right Flank	Polar Vehicle Control
	Anterior Left Flank	Undiluted Polar Test Item Extract
G1b	Anterior Right Flank	Non-Polar Vehicle Control
	Anterior Left Flank	Undiluted Non-Polar Test Item Extract
G2b	Anterior Right Flank	Non-Polar Vehicle Control
	Anterior Left Flank	Undiluted Non-Polar Test Item Extract

Remove the semi-occlusive dressing and patches after 24 ± 2 hrs of application and wiped dressed with RO / distilled water and details will be included in the raw data and study report.

13.4.4 Re-challenge Phase

If the response is equivocal, re-challenge will be recommended to confirm the results from the first challenge. The outcome of the test will be presented as the frequency of positive challenge results in treatment and Vehicle Control animals.

Re-challenge will be done to confirm the results of first challenge under following conditions:

- The scores of Vehicle Control animals are greater than one.
- Greater number of animals shows response, but intensity of the reaction is not greater than Vehicle Control group.

The second challenge (i.e., a re-challenge), will be done one week after the first challenge. The posterior part of both flank region of the animal which is not treated previously during the induction or challenge phase will be used for the re-challenge. The test patches will be applied in a similar way as that of the first challenge.

14. OBSERVATIONS

14.1 Body Weight

Individual animal body weight will be measured on the first day of acclimatization (at receipt), prior to initiation of the treatment (Day 1) and at termination of the study.

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14.2 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.

14.3 Grading of Skin Reactions

14.3.1 Induction Phase (Intradermal and Topical Application)

The skin reactions will be observed of the control and test animals at (24 ± 2) hrs, (48 ± 2) hrs, after the intradermal administration.
The skin reactions will be observed of the control and test animals at (1± 0.5) hrs, and (24± 2) hours, post removal of dressing after induction (topical application). The skin reactions for erythema and Oedema will be observed and recorded according to Draize method as per Annexure 4.

14.3.2 Challenge phase

The skin reactions will be observed of the test and control animals at (24 ± 2) hrs., (48 ± 2) hrs. After removal of dressing in the challenge/re-challenge phase. The skin reactions for erythema will be observed and recorded according to Magnusson and Kligman grading as per Annexure 5.

15. EVALUATION CRITERIA

- The skin reactions for erythema and Oedema will be observed and recorded according to grading. If the Magnusson and Kligman grades of test group animals are 1 or greater compared to respective Vehicle Control group animals, it indicates sensitization due to test sample.
- If grades of control group animals are 1 or greater compared to test item group animals, it indicates sensitization due to Vehicle Control samples.
- If the response is equivocal, re-challenge will be done to confirm the results from the first challenge.
- If the test group animals have a greater number of animals showing a response than the controls, although the intensity of the reaction is not greater than that exhibited by the respective Vehicle Control, a re-challenge will be carried out to define the response clearly. It will be carried out 1 week to 2 weeks after the first challenge.

16. ANIMAL EUTHANASIA AND DISPOSAL

After the completion of the experiment, the animals will be sacrificed using carbon dioxide asphyxiation and the carcasses will be sent to disposal through Medicare Environmental Management Pvt. Ltd or others to be specify in the study report.

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 Study report as per the standard reporting format.

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 Guinea pigs, 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 material and RO water quality and analysis reports
- Descriptions 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 clinical signs and Guinea Pigs showing signs of toxicity (if any) including mortality, nature, severity ,skin reaction and duration of effects)
- Individual weights of Guinea Pigs
- Pathology data (if done).
- Conclusion.
- A description of all circumstances if any, that may have affected the quality or integrity of the study.
- All 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 17. (Contd.,) Study Plan

19. STUDY PLAN DISTRIBUTION

The Final Study Plan will be distributed as follows:

Copy No. 1/2 – Archives, Liveon Biolabs Private Limited

Copy No. 2/2 – Sponsor

20. 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

21. ARCHIVING

All study-related records, Study Plan, Raw Data, Study Report, Study Plan amendment and Deviation (if any) and the test item samples will be maintained in the archives of Liveon Biolabs Private Limited 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 test facility management will coordinate with the sponsor for further course of action on archived material.

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 10993-10:2021: Biological evaluation of medical devices-Part 10: Tests for Skin Sensitization.
- 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.
- The Standard Operating Procedures of Test Facility and the mutually agreed Study Plan.

Annexure 17. (Contd.,) Study Plan

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23. STUDY PLAN APPROVAL

The Study Plan for the Study No.: 'LBPL/NG-2641 (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):

Ms. Rangalakshmi G.R
Study Director
(Sign. & Date)

Quality Assurance Unit
(Sign. & Date)

Test Facility Management
(Sign. & Date)

For KTEX NONWOVENS PVT LTD. (Sponsor):

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

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 17. (Contd.,) Study Plan

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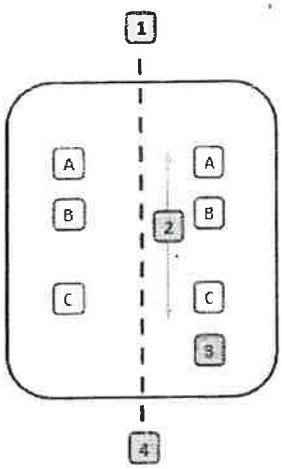
Annexure 2. Intradermal Injection and Topical Patch Application Sites Diagram

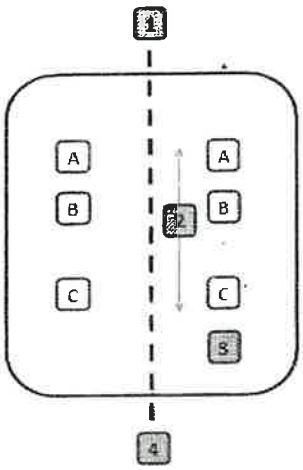


Treatment Animals

A: 1:1 v/v of FCA + Physiological saline

B: Undiluted test item extract

C: 1:1 v/v of A + B



Control Animals

A: 1:1 v/v of FCA + Physiological saline

B: Vehicle control only

C: 1:1 v/v of A + B

1. Cranial End
2. Intradermal Injection Sites
3. Clipped Intrascapular Region
4. Caudal End

Annexure 17. (Contd.,) Study Plan

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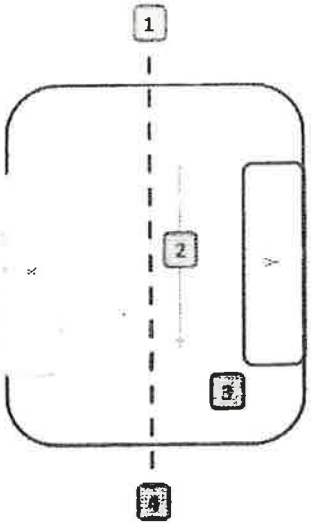
Annexure 3. Challenge Phase at Flanks of Animal



All Animals

X: Treatment Animal Site C

Y: Control Animals Site C

1. Cranial End
2. Intradermal Injection Sites
3. Clipped Intrasoapular Region
4. Caudal End

Annexure 17. (Contd.,) Study Plan

Annexure 4. Evaluation of Skin Reactions (Draize Method)

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

Maximum Possible Score – 4

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

Maximum Possible Score – 4

Annexure 17. (Contd.,) Study Plan

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Annexure 5. Magnusson and Kligman Grading Scale for the Evaluation of Challenge Patch Test Reactions

Patch Test Reaction	Grading Scale
No visible change	0
Discrete or patchy erythema	1
Moderate and confluent erythema	2
Intense erythema and/or swelling	3

Annexure 17. (Contd.,) Study Plan

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Annexure 6. 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 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 (-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 17. (Contd.,) Study Plan

Annexure 6. (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 mils 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 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 17. (Contd.,) Study Plan

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Annexure 7. Certificate of Analysis

Ktex Nonwovens Pvt. Ltd.

POLYPROPYLENE SPUNBONDED NON WOVEN FABRICS

CERTIFICATE OF ANALYSIS

Doc No: KN/CD/QA/FT/02
Rev No.: 03
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@ 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.

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

Annexure 17. (Contd.,) Study Plan

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Annexure 8. Material Safety Data Sheet

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

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Annexure 8. (Contd.,) Material Safety Data Sheet

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 17. (Contd.,) Study Plan

Annexure 8. (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.

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Annexure 8. (Contd.,) Material Safety Data Sheet

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

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.

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