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Certificate of Analysis

Lab Ref No.: **PL2009-C33079** SN: **RS1098410439501986**

Kee Kai Loon
Microbiologist & Biotechnologist
Food Analyst No: MJMM 0469
AN1: RA1568732162076658

DURIO PPE SDN. BHD.
NO 16, JALAN TEMENGGONG,
81100 JOHOR BAHRU JOHOR
MALAYSIA

Date of Issue: 2020-12-28
Date of Received: 2020-09-28
Date of Completion: 2020-12-28

Sample Marking: Durio Disposable Surgical Mask

Cell line: L929 (ATCC CCL-1) is mouse fibroblast cell line purchased from ATCC
Positive control: 0.2 % Phenol
Negative control: 1 mg/ml Polyethylene

Test Summary:
The purpose of the assay was to evaluate the effect of the test item extract on the viability of L929 cells following exposure to a test item extract in accordance with ISO 10993-5:2009. The test item was extracted in cell culture media for 4 hours at 37 °C. L929 cells were exposeed to five concentrations (6.25, 12.5, 25, 50, 100%) of test item extract for 24 hours. The cytotoxicity was determined by assessing the cell viability through reduction of a tetrazolium salt to formazan crystals by metabolically active cells. The formazan crystals were dissolved and quantified by measuring absorbance at 570 nm and 650 nm (ref). Cell viability was obtained by dividing the mean optical density (OD) value of the test item with the mean OD of unexposed cells and multipied by 100.

Test Results

	Negative Control	Positive Control	Test item concentrations				
			6.25 %	12.5 %	25 %	50 %	100 %
OD (570 nm)	1.687	0.093	1.673	1.758	1.844	1.787	1.618
	1.795	0.111	1.621	1.466	2.180	1.725	1.601
	1.799	0.119	1.751	1.771	1.344	1.484	1.745
Mean	1.760	0.108	1.682	1.665	1.789	1.665	1.655
SD	0.063	0.013	0.065	0.173	0.421	0.160	0.079
Viability (%)	98.398	6.018	94.000	93.069	100.018	93.087	92.491

COA Authentication

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Certificate of Analysis

Lab Ref No.: **PL2009-C33079** SN: **RS1098410439501986**

Kee Kai Loon
Microbiologist & Biotechnologist
Food Analyst No: MJMM 0469
AN1: RA1568732162076658

The test item extract did not inhibit the viability of L929 cells at all tested concentrations following 24-hour exposure. Negative (polyethylene) and positive (phenol) controls performed as expected.

Based on the criteria of ISO 10993-5:2009, test item did not show cytotoxic effect under condition of this study.

Test Description	Unit	Result(s)	Method or Equipment Used
Cytotoxic effect (in vitro)#		Pass	MTT Assay based on ISO 10993-5:2009
Irritation effect of skin (in vivo)#		Pass	Animal Irritation Test based on ISO 10993-10:2010 (E) Clause 6.3.5.2 Single-Exposure Test
Effect of skin sensitization (in vivo)#		Pass	Dermal Sensitization Assay - Closed-Patch Test (Buehier Test) based on ISO 10993-10:2010

– END OF REPORT –

This Test Report is prepared according to our standard testing requirements and based solely on the samples submitted by you. We have made every reasonable effort to ensure the accuracy and reliability of the information provided herein. However, we shall not be deemed to have warranted or guaranteed the accuracy and reliability of the results contained in the Test Report under whatsoever circumstances. Neither shall we be liable and responsible for any loss or damage of whatever nature (direct, indirect, incidental, economical, punitive and consequential) caused or alleged to be caused by or in connection with and arising out of the use of or reliance on this Test Report.

COA Authentication

PRIMARY SKIN IRRITATION TEST REPORT

Prepared for:

Durio PPE Sdn. Bhd.
No 16, Jalan Temenggong,
81100 Johor Bahru,
Johor, Malaysia

Prepared by

MY CO2 (PG) Sdn. Bhd.
16, Lengkok Kikik 1,
Taman Inderawasih,
13600 Perai,
Penang, Malaysia

28 December 2020

TABLE OF CONTENTS

PRIMARY SKIN IRRITATION TEST REPORT

1. Introduction

Purpose

The test article identified below was evaluated to determine whether the test article would cause skin irritation following single topical application on rabbits.

Testing Guidelines

The study was conducted based on the International Organization for Standardization 10993:10 Biological Evaluationof Medical Devices, Part 10: Tests for irritation and skin sensitization.

Dates

Test article received	:	1 October 2020
Treatment start date	:	26 October 2020
Observations concluded date	:	29 October 2020

2. Materials

The test article provided by the sponsor was identified and handled as follows:

Test article name	:	Durio Disposable Surgical Face Mask
Test article identification	:	C33079
Physical description of the test article	:	Face mask
Storage condition	:	Room temperature

3. Test System

Species	:	Albino rabbit (Oryctolagus cuniculus)
Strain	:	New Zealand albino rabbit
Sex	:	Male
Body weight range	:	2.9-3.2 kg
Age	:	Adult, approximately 14 weeks age at experimentation
Acclimation period	:	Minimum 5 days
Number of animal	:	3
Identification method	:	Marking on body

4. Animal Management

Husbandry	:	Conditions conformed to Institutional Standard Operating Procedures.
Food	:	A commercially available rabbit feed was provided daily
Water	:	Water was provided ad libtium through species appropriate containers.
Housing	:	Animals were housed individually metal cages identified by a card indicating the test, sex, animal code and date dosed.
Environment	:	The animal housing room temperature and relative humidity was monitored daily. The temperature for the room was 23-27 ºC and 30-70% relative humidity. There were no significant temperature or relative humidity excursions that adversely affected the health of the animals.
Personnel	:	Associates involved were appropriately qualified and trained.
Selection	:	Only healthy, previously unused animals were selected.
Sedation,Analgesia or Anaesthesia	:	Sedation, Analgesia or anaesthesia was not necessary during the routine course of this procedure.
Veterinary care	:	In the unlikely event that an animal become injured, ill or moribund, care was conducted accordance with the Institutional Guidelines. The objective of the study was given due consideration in any decision and the study sponsor was advised.
IACUC	:	This procedure has been approved by USM Institutional Animal Care and Use Committee (IACUC). Any significant changes to this procedure were informed to and approved by IACUC prior to conduct.

5. Method

Exposure of albino rabbit's skin to the extracted test article and normal saline as control is accomplished by means of a patch test technique employing two intact sites on the back of each of the three albino rabbits. The skin on the back of the animals is clipped free of hair one day prior to testing. A sufficient distance on both sides of the spine is clipped for application and observation of all test sites (approximately 10 cm x 15 cm). The extracted test article and control were applied to each test skin site as shown in Figure 1. The application sites were then covered with gauze patches. The patches were secured with the help of adhesive tape and the entire trunk is occluded with a polyethylene sleeve. The test article and the control materials were held in contact with the skin under patch for a minimum of 4 h. At the end of contact time, the dressings were removedand the sites were marked. The sites of contact were washed with distilled water to remove the residual test substance.

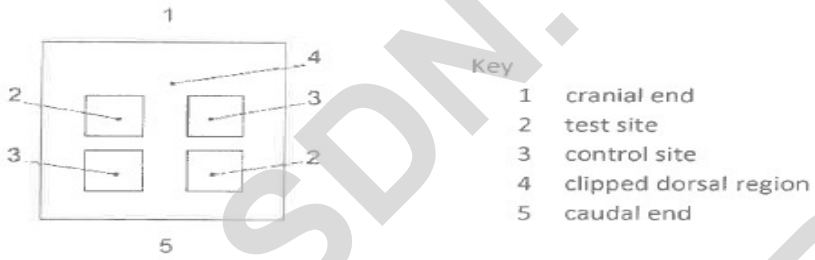

Figure 1 – Location of skin application sites

The appearance of each test site was monitored at 1 h, 24 h, 48 h, and 72 h following removal of the patches. Scoring for tissue reaction and oedema was done according to the classification system (refer to table in Appendix 1 – Scoring system for skin reaction). The scoring at 24 h, 48 h, and 72 h was used to determine the primary irritation index. The primary irritation index was charaterized by number (score) and description (response category) according to the guideline as shown in Appendix 2 (Primary irritation index categories in a rabbit).

6. Results

All animals appeared clinically normal throughout the study. The observations for each rabbit were presented in Appendix 3 – Scoring of test article for skin irritation. All three animals showed no erythema and oedema at 1 h, 24 h, 48 h, and 72 hfollowing removal of the patches. Likewise, no erythema or oedema was observed at the control sites throughout the study period.

The primary irritation index for test article was presented in Appendix 4.

Primary irritation index = 0
Response category = Negligible

7. Conclusion

Under the conditions of this study, the test article caused no erythema and oedemaon the skin of the rabbits. The response of test article was categorized as negligible. The test article met the requirements of the study.

8. References

International Organization of Standardization (ISO) 10993-10, Biological Evaluation of Medical Devices – Part 10: Tests for irritation and skin sensitization (2010).

International Organization of Standardization (ISO) 10993-2, Biological Evaluation of Medical Devices – Part 2: Animal Welfare Requirements(2006).

Appendix 1 – Scoring system for skin irritation

Reaction	Irritation Score
Erythema and eschar formation	
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate erythema	3
Severe erythema (beet redness) to eschar formation preventing grading of erythema	4
Oedema formation	
No oedema	0
Very slight oedema (barely perceptible)	1
Well-defined oedema (edges of area well-defined by definite raising)	2
Moderate oedema (raised approximately 1 mm)	3
Severe oedema (raised more than 1 mm and extending beyond exposure area)	4
Maximal possible score for irritation	8
Other adverse changes at the skin sites shall be recorded and reported	

Appendix 2 – Primary irritation index categories in a rabbit

Mean Score	Response Category
0 to 0.4	NegLigible
0.5 to 1.9	Slight
2 to 4.9	Moderate
5 to 8	Severe

Appendix 3 – Scoring of test article for skin irritation

Rabbit no.	Gender	Weight (kg)	Article	Observation	1 hour		24 hour		48 hour		72 hour	
					left	right	left	right	left	right	left	right
R 01	M	3.0	Test	ER	0	0	0	0	0	0	0	0
				ED	0	0	0	0	0	0	0	0
			Control	ER	0	0	0	0	0	0	0	0
				ED	0	0	0	0	0	0	0	0
R 02	M	2.9	Test	ER	0	0	0	0	0	0	0	0
				ED	0	0	0	0	0	0	0	0
			Control	ER	0	0	0	0	0	0	0	0
				ED	0	0	0	0	0	0	0	0
R 03	M	3.2	Test	ER	0	0	0	0	0	0	0	0
				ED	0	0	0	0	0	0	0	0
			Control	ER	0	0	0	0	0	0	0	0
				ED	0	0	0	0	0	0	0	0
Date					26/10/2020		27/10/2020		28/10/2020		29/10/2020	
Time					4:00 p.m.		4:00 p.m.		4:00 p.m.		4:00 p.m.	

***ER : Erythema *ED : Oedema**

Appendix 4 – Primary irritation index of test article

Rabbit no.	Total score		Primary irritation score		Primary irritation index*
	Test Article	Control	Test Article	Control	
R1	0	0	0	0	0
R2	0	0	0	0	
R3	0	0	0	0	

Total score = Sum of all ER and ED grades at 24 h, 48 h, and 72 h

Primary irritation score = Total score/6 (two test/observation sites, three time points)

Primary irritation index = Sum of primary irritation scores for all animals/3
(*When control is used, the primary irritation score for the control is calculated and subtracted from the score of the test article to obtain the primary irritation score)

SKIN SENSITIZATION TEST REPORT

Prepared for:

Durio PPE Sdn. Bhd.
No 16, Jalan Temenggong,
81100 Johor Bahru,
Johor, Malaysia

Prepared by

MY CO2 (PG) Sdn. Bhd.
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Taman Inderawasih,
13600 Perai,
Penang, Malaysia

28 December 2020

TABLE OF CONTENTS

SKIN SENSITIZATION TEST REPORT

1. Introduction

Purpose

The test article identified below was evaluated to determine whether the test article would elicit a delayed hypersensitivity response through its contact with the skin.

Testing Guidelines

The study was conducted based on the International Organization for Standardization 10993:10 Biological Evaluationof Medical Devices, Part 10: Tests for irritation and skin sensitization (Closed-patch test/Buehler test).

Dates

Test article received	:	5 November 2020
Treatment start date	:	10 November 2020
Observations concluded date	:	9 November 2020

2. Materials

The test article provided by the sponsor was identified and handled as follows:

Test article name	: Durio Disposable Surgical Face Mask
Test article identification	: C33079
Physical description of the test article	: Face mask
Stability Testing	: None
Expiration Date	: None
Strength, Purity and Composition	: Not applicable because test article has no active ingredient
Physical Description of the Test Article	: Face mask
Storage Conditions	: Room temperature
Extraction Vehicle	: 0.9% Sodium chloride USP solution (SC)
Control Article	: Extraction solution without the test article
Extraction Procedure	: The test article was cut into smaller pieces and filled to capacity with a total of 100 ml of extraction vehicle. The test article and control blank (extraction vehicle without the test article) was sealed to avoid loss of the vehicle during extraction. The test article and control blank was subjected to the extraction conditions at 121 ºC for 1 h following guidelines of ISO 10993-12.

Conditions of Extracts:

Vehicle	Treatment Group	Condition of Extract
SC	Test article	Clear
	Control blank	Clear

3. Test System

Species	:	Guinea pig (Cavia porcellus)
Strain	:	-
Sex	:	Male or female
Weight	:	222-278 g
Acclimation period	:	5-7 days
Number of animal	:	Ten for test article and five for control
Identification method	:	Marking on body

Justification of Test Management

Guinea pigs are used because they have been shown to be the best animal model for human allergic contact dermatitis. The use of guinea pig for the detection of skin sensitization is specified in the current ISO standard for evaluation of medical devices.

4. Animal Management

Husbandry	:	Conditions conformed to Institutional Standard Operating Procedures.
Food	:	A commercially available feed was provided daily
Water	:	Water was provided ad libtium through species appropriate containers.
Contaminants	:	Reasonable expected contaminant in feed or water did not have the potential to influence the outcome of this test.
Housing	:	Animals were housed in groups of 3 in polycarbonate cages identified by a card indicating the animal number, test, sex, and date dosed.
Environment	:	The animal housing room temperature and relative humidity were set at 23-27 ºC and 30-70% relative humidity.
Personnel	:	Associates involved were appropriately qualified and trained.
Selection	:	Only healthy, previously unused animals were selected.
Sedation,Analgesia or Anaesthesia	:	Sedation, Analgesia or anaesthesia was not necessary during the routine course of this procedure.
Veterinary care	:	In the unlikely event that an animal become injured, ill or moribund, care was conducted accordance with the Institutional Guidelines. The objective of the study was given due consideration in any decision and the study sponsor was advised.
IACUC	:	This procedure has been approved by USM Institutional Animal Care and Use Committee (IACUC). Any significant changes to this procedure were informed to and approved by IACUC prior to conduct.

5. Method

Prior to dosing, the animals were individually identified, weighed and arbitrarily assigned to a treatment group as shown below:

Treatment Group	Number of Animals	Sex	Route of exposure	Application per site
Test	10	Male/Female	Dermal area on the flank of the animal	25 mm x 25 mm square section backed with 4-ply gauze
Control	5	Male/Female	Dermal area on the flank of the animal	25 mm x 25 mm square section backed with 4-ply gauze

The test article was applied by a single topical application to a clipped untested area of each animal using appropriate patches soaked in the test article (extract). The test article was occlusively patched (the application unit was backed by hypoallergenic tape) for 6 h to the intact skin of 10 gunea pigs, once a week for three weeks for the induction phase. The control article was similarly patched to 5 guinea pigs as the control group. Fourteen days after the final induction patch, all the test and the control animals were challenged with the test article. The patches were removed after 6 h. All the sites were observed for the dermal reaction at 24 h and 48 h after patch removal. The animals were weighed at the beginning of the study. Any animal found dead was subjected to a gross necropsy of the viscera. After the test was completed, all animals were euthanized according to standard procedure.

6. Evaluation and Analysis

Mean body weight data were recorded for each treatment group. The application sites were assessed for erythema and oedema using the Magnisson and Kligman grading scale as given in **Appendix 1**. If during the observation period, none of the animals treated with the test extract exhibited a significantly greater reaction than the control animals, the test article met the requirements. Grades 1 or greater in the test group generally indicate sensitization, provided grades of less than 1 are seen on control animals. If grades of 1 or greater are noted on control animals, then the reactions of the test animals which exceed the most severe control reaction are presumed to be due to sensitization. In this case, re-challenge is recommended to confirm the results from the first challenge. The outcome of the test is presented as the frequency of positive challenge results in the test and control animals. A re-challenge can be carried out 1 week to 2 weeks after the first challenge. During the experimentation, the general health of the animals was also monitored daily and recorded.

7. Results

All animals appeared clinically normal throughout the study. There was no mortality recorded during the study. The grading for patch test reactions for each guinea pig for week 1, week 2, week 3 and challenge phase are presented in **Appendix 2**. Overall, no erythema and no oedema was observed on the skin of the guinea pigs. Animal identification, sex and body weight data are presented in **Appendix 3**. The daily observations of the general health of the animals are tabulated in tables as shown in **Appendix 4**.

Final test article score = 0

8. Conclusion

Under the conditions of this study, there was no mortality or evidence of delayed hypersensitivity response due to the test article. The response of the test article was categorized as negligible. The test article met the requirements of the study.

9. References

International Organization of Standardization (ISO) 10993-11, Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity (2017).

International Organization of Standardization (ISO) 10993-2, Biological Evaluation of Medical Devices – Part 2: Animal Welfare Requirements(2006).

International Organization of Standardization (ISO) 10993-12, Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials (2007).

Appendix 1 – Grading System for 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

Appendix 2 – Grading for patch test reactions of test article on week 1

ANIMAL/GROUP	HOURS FOLLOWING TEST ARTICLE PATCH REMOVAL	
	1st WEEK	
	24 HOURS	48 HOURS
G01T	0	0
G02T	0	0
G03T	0	0
G04T	0	0
G05T	0	0
G06T	0	0
G07T	0	0
G08T	0	0
G09T	0	0
G10T	0	0
G11C	0	0
G12C	0	0
G13C	0	0
G14C	0	0
G15C	0	0
DATE	11/11/2020	12/11/2020
TIME	4:00 p.m.	4:00 p.m.

Appendix 2 – Grading for patch test reactions of test article on week 2

ANIMAL/GROUP	HOURS FOLLOWING TEST ARTICLE PATCH REMOVAL	
	1st WEEK	
	24 HOURS	48 HOURS
G01T	0	0
G02T	0	0
G03T	0	0
G04T	0	0
G05T	0	0
G06T	0	0
G07T	0	0
G08T	0	0
G09T	0	0
G10T	0	0
G11C	0	0
G12C	0	0
G13C	0	0
G14C	0	0
G15C	0	0
DATE	18/11/2020	19/11/2020
TIME	4:00 p.m.	4:00 p.m.

Appendix 2 – Grading for patch test reactions of test article on week 3

ANIMAL/GROUP	HOURS FOLLOWING TEST ARTICLE PATCH REMOVAL	
	1st WEEK	
	24 HOURS	48 HOURS
G01T	0	0
G02T	0	0
G03T	0	0
G04T	0	0
G05T	0	0
G06T	0	0
G07T	0	0
G08T	0	0
G09T	0	0
G10T	0	0
G11C	0	0
G12C	0	0
G13C	0	0
G14C	0	0
G15C	0	0
DATE	25/11/2020	26/11/2020
TIME	4:00 p.m.	4:00 p.m.

Appendix 2 – Grading for patch test reactions of test article on week 4

ANIMAL/GROUP	HOURS FOLLOWING TEST ARTICLE PATCH REMOVAL	
	1st WEEK	
	24 HOURS	48 HOURS
G01T	0	0
G02T	0	0
G03T	0	0
G04T	0	0
G05T	0	0
G06T	0	0
G07T	0	0
G08T	0	0
G09T	0	0
G10T	0	0
G11C	0	0
G12C	0	0
G13C	0	0
G14C	0	0
G15C	0	0
DATE	9/12/2020	10/12/2020
TIME	4:00 p.m.	4:00 p.m.

Appendix 3 – Animal ID, Body Weight and Sex

TEST (T) ANIMAL ID, BODY WEIGHT AND SEX			CONTROL © ANIMAL ID, BODY WEIGHT AND SEX		
ANIMAL ID	**WEIGHT (g)**	**SEX**	**ANIMAL ID**	**WEIGHT (g)**	**SEX**
G01T	222	F	G11C	237	F
G02T	228	F	G12C	228	F
G03T	244	F	G13C	232	F
G04T	245	M	G14C	278	M
G05T	262	M	G15C	254	M
G06T	254	M			
G07T	267	M			
G08T	260	M			
G09T	251	M			
G10T	250	M			

Appendix 4 – Observation of the General Health of Animals (Test article group)

DATE*	TIME	GUINEA PIG NO (TEST)									
		G01	G02	G03	G04	G05	G06	G07	G08	G09	G10
5/11/2020	10:00 am	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H
6/11/2020	10:00 am	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H
7/11/2020	10:00 am	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H
8/11/2020	10:00 am	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H
9/11/2020	10:05 am	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H
10/11/2020	10:00 am	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H
11/11/2020	10:00 am	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H
12/11/2020	10:00 am	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H
13/11/2020	10:20 am	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H
14/11/2020	10:00 am	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H
15/11/2020	10:00 am	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H
16/11/2020	10:00 am	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H
17/11/2020	10:00 am	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H
18/11/2020	10:00 am	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H
19/11/2020	10:00 am	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H
20/11/2020	10:00 am	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H
21/11/2020	9:50 am	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H
22/11/2020	10:00 am	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H
23/11/2020	10:00 am	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H
24/11/2020	10:00 am	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H
25/11/2020	10:15 am	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H
26/11/2020	9:50 am	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H
27/11/2020	10:00 am	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H
28/11/2020	10:00 am	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H
29/11/2020	9:00 am	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H
30/11/2020	10:00 am	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H
1/12/2020	10:00 am	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H
2/12/2020	10:00 am	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H
3/12/2020	9:55 am	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H
4/12/2020	10:05 am	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H
5/12/2020	10:15 am	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H
6/12/2020	10:00 am	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H
7/12/2020	10:00 am	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H
8/12/2020	10:00 am	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H
9/12/2020	10:00 am	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H	A&H

*The date in bold indicates the date the test article patch was applied
A&H: Active & Healthy
S&W: Sicky & Weak
AB: Abnormal Behaviour
DI: Diarrhoea
D: Dead

Appendix 4 – Observation of the General Health of Animals (Control article group)

DATE*	TIME	GUINEA PIG NO (CONTROL)									
		G11	G12	G13	G14	G15					
5/11/2020	10:00 am	A&H	A&H	A&H	A&H	A&H					
6/11/2020	10:00 am	A&H	A&H	A&H	A&H	A&H					
7/11/2020	10:00 am	A&H	A&H	A&H	A&H	A&H					
8/11/2020	10:00 am	A&H	A&H	A&H	A&H	A&H					
9/11/2020	10:05 am	A&H	A&H	A&H	A&H	A&H					
10/11/2020	10:00 am	A&H	A&H	A&H	A&H	A&H					
11/11/2020	10:00 am	A&H	A&H	A&H	A&H	A&H					
12/11/2020	10:00 am	A&H	A&H	A&H	A&H	A&H					
13/11/2020	10:20 am	A&H	A&H	A&H	A&H	A&H					
14/11/2020	10:00 am	A&H	A&H	A&H	A&H	A&H					
15/11/2020	10:00 am	A&H	A&H	A&H	A&H	A&H					
16/11/2020	10:00 am	A&H	A&H	A&H	A&H	A&H					
17/11/2020	10:00 am	A&H	A&H	A&H	A&H	A&H					
18/11/2020	10:00 am	A&H	A&H	A&H	A&H	A&H					
19/11/2020	10:00 am	A&H	A&H	A&H	A&H	A&H					
20/11/2020	10:00 am	A&H	A&H	A&H	A&H	A&H					
21/11/2020	9:50 am	A&H	A&H	A&H	A&H	A&H					
22/11/2020	10:00 am	A&H	A&H	A&H	A&H	A&H					
23/11/2020	10:00 am	A&H	A&H	A&H	A&H	A&H					
24/11/2020	10:00 am	A&H	A&H	A&H	A&H	A&H					
25/11/2020	10:15 am	A&H	A&H	A&H	A&H	A&H					
26/11/2020	9:50 am	A&H	A&H	A&H	A&H	A&H					
27/11/2020	10:00 am	A&H	A&H	A&H	A&H	A&H					
28/11/2020	10:00 am	A&H	A&H	A&H	A&H	A&H					
29/11/2020	9:00 am	A&H	A&H	A&H	A&H	A&H					
30/11/2020	10:00 am	A&H	A&H	A&H	A&H	A&H					
1/12/2020	10:00 am	A&H	A&H	A&H	A&H	A&H					
2/12/2020	10:00 am	A&H	A&H	A&H	A&H	A&H					
3/12/2020	9:55 am	A&H	A&H	A&H	A&H	A&H					
4/12/2020	10:05 am	A&H	A&H	A&H	A&H	A&H					
5/12/2020	10:15 am	A&H	A&H	A&H	A&H	A&H					
6/12/2020	10:00 am	A&H	A&H	A&H	A&H	A&H					
7/12/2020	10:00 am	A&H	A&H	A&H	A&H	A&H					
8/12/2020	10:00 am	A&H	A&H	A&H	A&H	A&H					
9/12/2020	10:00 am	A&H	A&H	A&H	A&H	A&H					

*The date in bold indicates the date the test article patch was applied
A&H: Active & Healthy
S&W: Sicky & Weak
AB: Abnormal Behaviour
DI: Diarrhoea
D: Dead

Appendix 5 – Treatment Schedule

INDUCTION 1	DATE	TIME
Fur Clip	9/11/2020	10:00 am
Animal patched and wrapped	10/11/2020	10:00 am
Animal unwrapped	10/11/2020	4:00 pm

INDUCTION 2	DATE	TIME
Fur Clip	16/11/2020	10:00 am
Animal patched and wrapped	17/11/2020	10:00 am
Animal unwrapped	17/11/2020	4:00 pm

INDUCTION 3	DATE	TIME
Fur Clip	23/11/2020	10:00 am
Animal patched and wrapped	24/11/2020	10:00 am
Animal unwrapped	24/11/2020	4:00 pm

CHALLENGE	DATE	TIME
Fur Clip	7/12/2020	10:00 am
Animal patched and wrapped	8/12/2020	10:00 am
Animal unwrapped	8/12/2020	4:00 pm