FINAL REPORT

SKIN SENSITIZATION STUDY OF NANOMASK™ FACE MASKS IN GUINEA PIGS (CLOSED –PATCH (BUEHLER) TEST METHOD)

Nucro-Technics' Study No. 367875

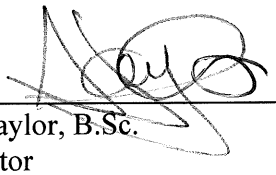
FOR

PRESCIENT^{X}
900 Maple Grove Road, Unit 1
Cambridge, Ontario, Canada
N3H 4R7

REPORT APPROVAL

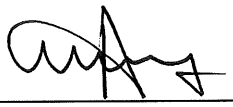
The skin sensitization study of NanoMask™ FaceMask in guinea pigs was conducted at Nucro-Technics in accordance with Nucro-Technics' Study Plan No. PRE/367875, applicable Nucro-Technics' Standard Operating Procedures and in compliance with the OECD Principles of Good Laboratory Practice (1) and the Good Laboratory Practice of the United States Food and Drug Administration (2). Stability, characterization, identity and verification of the test item as received and tested were the responsibility of the study Sponsor.

NUCRO-TECHNICS



Simon R. Taylor, B.Sc.
Study Director

FEB. 12/21
Date



Albert Licollari, D.V.M., Ph.D., DABT
Director, Toxicology Laboratories

Feb 12/21
Date

TABLE OF CONTENTS

List of Tables

List of Appendices

QUALITY ASSURANCE STATEMENT

Inspections of Nucro-Technics' Study No. 367875 entitled "Skin Sensitization Study of NanoMask™ Face Masks in Guinea Pigs (Closed-Patch (Buehler) Test Method)" were conducted on the following phases by the Quality Assurance Unit of Nucro-Technics. Inspection results were reported to the Study Director and facility management as indicated below.

Inspection Date	Phase Inspected	Date Submitted to Study Director and Management
October 27, 2020	Test item audit; test item application and animal receiving records audit	October 27, 2020
January 19, 2021; January 25, 2021	Raw data and draft report	January 26, 2021
February 12, 2021	Final Report	February 12, 2021

The methods, results and data contained in this report accurately reflect the procedures followed and raw data collected during the study.

Kristin Lopez, B.Sc.
Quality Assurance Associate

February 12, 2021
Date

Aldona Kenthol
Quality Assurance Associate

February 12, 2021
Date

SUMMARY

A skin sensitization study of the test item, NanoMask™ Face Mask in guinea pigs, was conducted by Nucro-Technics according to Study Plan No. PRE/367875.

The test item, NanoMask™ Face Masks, was composed of three components, Face Mask filter, TPE Seal and TPE Headband. Ten animals were used for each test item component, five negative control animals were used for each test item component, and five animals were used for the positive control group. Each component of the test item was prepared by cutting the components into 2.85 cm x 2.80 cm portions (approximately 8 cm^2) with the exception of the headband which was cut into five 2.80 cm long strips (representing a 2.80 cm x 2.85 cm portion).

For the Induction phase, the test site of each animal in each Test Group was moistened with sterile Water for Injection USP (WFI) to ensure good contact, then an approximately 8 cm^2 portion of the test item component was applied directly onto the prepared clipped left upper back region of each guinea pig. The patches were held in contact by occlusive dressings for a 6-hour exposure period. After exposure, the occlusive dressings and the patches were removed and the skin was cleansed with WFI. Any skin reactions were observed and graded. This procedure was performed three days a week for three weeks.

The animals in the Negative Control Group were subjected to similar procedures as the animals in the test item treated groups with the exception that the gauze patches were substituted for the test item.

The animals in the Positive Control Group were subjected to similar procedures as the animals in the test item treated group with the exception that the positive control item, 0.3% w/v solution of DNCB in acetone/alcohol (1:1), was substituted for the test item and that the positive control item was applied for a total of three induction treatments over a three week period. Patches of sterile gauze (approximately 8 cm^2) were saturated with the positive control item and applied.

Thirteen days after the last application, all animals were challenged by applying the test item component onto the clipped untreated right upper back region of each test and corresponding control animal. The positive control item, 0.1% w/v solution of DNCB in acetone/alcohol (1:1), was applied to the untreated right upper back region of the Positive Control Group of animals. The test and the control items were applied in the same manner as during the induction phase, for a 6-hour exposure period.

At 22 hours after the challenge exposure, the challenge area was cleared of hair and cleaned. At least 2 hours after removing the hair, the skin reactions were observed and graded. Approximately 48 hours after removal of the challenge patches, the skin

reactions were again graded.

None of the animals from any of the Test Groups or corresponding Negative Control Groups exhibited any skin or other abnormal reactions after the challenge phase. All five animals in the Positive Control Group had skin reactions after the challenge phase, ranging from moderate and confluent erythema to intense erythema and swelling.

Under the conditions of this study, each component of the test item, NanoMask™ Face Mask, showed no evidence of sensitization.

1. STUDY INFORMATION

1.1 Study Title

Skin Sensitization Study of NanoMask™ Face Masks in Guinea pigs (Closed-Patch (Buehler) Test Method)

1.2 Study Objective

This study assessed the skin sensitizing potential of the components of NanoMask™ Face Mask by the Guinea Pig Closed-Patch (Buehler) Test Method.

1.3 Nucro-Technics' Study No.

367875

1.4 Test Facility

Nucro-Technics
2000 Ellesmere Road, Unit # 16
Scarborough, Ontario, Canada
M1H 2W4
Tel.: (416) 438-6727
Fax: (416) 438-3463

Study Director	Simon R. Taylor, B.Sc. Address as cited for Test Facility Email: taylor@nucro-technics.com
Facility Management	Albert Licollari, D.V.M., Ph.D., DABT Director, Toxicology Laboratories Address as cited for Test Facility Email: licollari@nucro-technics.com
Quality Assurance	Aldona Kenthol Quality Assurance Associate Kristin Lopez, B.Sc. Quality Assurance Associate

1.5 Sponsor

PRESCIENT^{X}
900 Maple Grove Road, Unit 1
Cambridge, Ontario, Canada
N3H 4R7

Sponsor's Representative	Barry Hunt President & CEO, PRESCIENT^{X} Address as cited for the Sponsor Tel. No.: (519)-749-5267 Email: barry@prescientx.com

1.6 Study Dates

Study Initiation:	October 22, 2020
Experimental Start:	October 22, 2020
Experimental Completion:	November 27, 2020
Study Completion:	February 12, 2021

2. TEST AND CONTROL ITEMS

2.1 Test Item

The NanoMask™ Face Mask was composed of the following components:

- Face Mask filter – A white coloured filter that is used as the base mask for covering the mouth and nose.
- TPE Seal - An opaque rubber seal that lines the filter and is used to seal the filter to the facial area.
- TPE Headband – White rubber straps used to allow a snug fit of the mask to the head.

Each of these three components were tested. As these components are all part of one functioning unit, the following information was applied to each component:

Lot No.:	20-272-1
Storage Conditions:	Stored at room temperature
Date of Manufacture:	Sept. 28, 2020
Expiry Date:	Sept. 28, 2022
Handling Precautions:	Standard Laboratory Precautions
Manufacturer:	Prescient[x]
Supplier:	Prescient[x]

2.2 Positive Control Item

Name:	1-chloro-2, 4-dinitrobenzene (DNCB)
CAS No.:	97-00-7
Lot No.:	STBF4847V
Expiry Date:	January 2022
Storage Conditions:	Ambient Temperature (15-30ºC)
Handling Precautions:	As per MSDS
Supplier:	Sigma Chemical Company

Name:	Ethyl Alcohol
Lot/Batch No.	030517
Expiry Date:	April 2021
Storage Conditions:	Ambient Temperature (15-30ºC)
Handling Precautions:	Standard Laboratory Procedure
Supplier:	Commercial Alcohols

Name:	Acetone
Lot/Batch No.	105538
Expiry Date:	April 2023
Storage Conditions:	Ambient Temperature (15-30ºC)
Handling Precautions:	Standard Laboratory Procedure
Supplier:	Caledon Laboratory Chemicals

2.2.1 Positive Control Item Preparation

For the induction phase, a 0.3% w/v solution of DNCB in acetone/alcohol (1:1) was prepared by accurately weighing a 0.6001 g portion of DNCB and dissolving in 100.0 mL of ethyl alcohol and 100.0 mL of acetone.

For the challenge phase, a 0.1% w/v solution of DNCB in acetone/alcohol (1:1) was prepared by accurately weighing a 0.1003 g portion of DNCB and dissolving in 50.0 mL of ethyl alcohol and 50.0 mL of acetone.

The positive control solutions were stored at 2-8ºC until required.

2.3 Test Item Characterization

Documentation of the identity, strength, purity, composition, and stability for the test item was on file with the Sponsor. A Certificate of Analysis and statement of stability is included in Appendix II.

The Sponsor has appropriate documentation on file concerning the method of synthesis, manufacture or derivation of the test item, and this information is available to the appropriate regulatory agencies should it be requested.

2.4 Test Item Inventory and Disposition

Records of the receipt, distribution, and storage of the test item were maintained. Unused portions of the test item were discarded as per instructions from the Sponsor at the end of the study.

3. TEST SYSTEM

3.1 Test System

Species / Sex:	*Cavia porcellus* (guinea pig) / males
Strain:	HA(BR)
Source:	Charles River Canada
Body Weight Range:	329.2-393.4 g
Number of Animals:	30 animals (Test group – 10 animals/each test item component) 15 animals (Negative Control group – 5 animals/each test item component) 5 animals (Positive Control group – 5 animals)
Acclimatization Period:	5 days
Age at Study Start:	33-39 days old
Animal Identification:	Colour coding, cage labels

3.2 Animal Housing and Maintenance

Guinea pigs were housed in separate quarters in solid bottom cages, 5 per cage. Individual animals were identified by colour coding; the animal number and group number also appeared on the outside of each cage to preclude mix-up. The animal room environment was controlled (targeted ranges: temperature 18ºC to 26ºC, relative humidity 30-70% minimum 10 air changes per hour) and monitored. The photo-cycle was 12 hours light and 12 hours dark.

Upon arrival all animals were submitted to a general physical examination and all were found healthy and were admitted. LabDiet Guinea Pig Diet and water were offered *ad libitum* throughout the acclimatization and study periods. The cage cleaning schedule, air filtration and recirculation, health checks and facility maintenance were carried out in accordance with the applicable Nucro-Technics Standard Operating Procedures, and such activities were recorded in the animal room records.

Animals were housed and maintained according to the AAALAC International Guide for the Care and Use of Laboratory Animals, CCAC Guidelines for Care and Use of Experimental Animals and Nucro-Technics' Standard Operating Procedures.

3.3 Animal Selection / Preparation

The test population of animals was selected from newly arrived, previously unused guinea pigs.

The animal preparation involved the clipping of the left upper back region of each animal the day prior to the first induction application each week, and prior to the challenge.

3.4 Justification for Selection of Test System

The test system is internationally recognised and acceptable to regulatory authorities requiring skin sensitization testing.

4. EXPERIMENTAL DESIGN

4.1 Method

The method used for conducting this study is the accepted standard described in Biological Evaluation of Medical Devices Part 10: Tests for Irritation and Sensitization (3). The study was conducted in accordance with Nucro-Technics' Study Plan No. PRE/367875, Appendix I.

4.2 Main Study

4.2.1 Induction Phase:

Test Item Preparation

Each component of the test item was prepared by cutting the components into 2.85 cm x 2.80 cm portions (approximately 8 cm^2) with the exception of the headband which was cut into five 2.80 cm long strips (representing a 2.80 cm x 2.85 cm portion).

Day 0 - Test Group (10 animals/component)

The test site was moistened with 0.05 mL of sterile Water for Injection USP (WFI) to ensure good contact, then the test item component was applied directly onto the skin over an 8 cm^2 area and covered with a gauze patch. The application was applied onto the prepared clipped left upper back region of each guinea pig. The patches were held in contact occlusively using 3M Blenderm surgical tape and the trunk of the guinea pig was tightly wrapped using 3M Coban self-adherent wrap and secured at the ends with Zonas porous tape for a 6 ± 0.5-hour exposure period. After 6 hours, the occlusive dressings and the patches were removed and the skin was cleansed with WFI. Any skin reactions were observed and graded. This procedure was performed on three days a week for three weeks.

Day 0 - Negative Control Group (5 animals/component)

The animals in the Negative Control Group were subjected to similar procedures as the animals in the test item treated group with the exception that the gauze patches were used instead of the test item.

Day 0 - Positive Control Group (5 animals)

The animals in the positive control group were subjected to similar procedures as the animals in the test item treated group with the exception that the positive control item, 0.3% w/v DNCB in acetone/alcohol (1:1) was substituted for the test item and that the positive control item was applied for a total of three induction treatments over a three week period. Patches of sterile gauze (approximately 8 cm^2) were saturated with the positive control item and applied.

4.2.2 Challenge Phase:

Test and Control Groups

Thirteen days after the last application, all animals were challenged by applying the test item component onto the clipped untreated right upper back region of each test and corresponding negative control animal.

The positive control item at a concentration of 0.1% w/v DNCB in ethanol/acetone was applied to the untreated right upper back region of the positive control group of animals. The test and the control items were applied in the same manner as during the induction phase, for a 6 ± 0.5-hour exposure period.

Observations - Test and Control Groups

At 22 hours after the challenge exposure, the challenge area was cleared of hair and cleaned. A minimum of 2 hours after removal of hair, the skin reactions were observed and graded. Approximately 48 hours after removal of the challenge patches, the skin reactions were again graded.

The skin reactions were graded according to Table 1.

Table 1. Grading Scale

Magnusson and Kligman Grading Scale For The Evaluation of Challenge Patch Test Reactions (3)	
Reaction	**Numerical Grading**
No visible change	0
Discrete or patchy erythema	1
Moderate and confluent erythema	2
Intense erythema and swelling	3

4.2.3 Evaluation of Results

Grades of 1 or greater in the test group generally indicate sensitization, provided grades of less than 1 are seen on negative control animals. If grades of 1 or greater are noted on negative control animals, then the reactions of test animals which exceed the most severe negative control reaction are presumed to be due to sensitization.

5. RESULTS

The dermal sensitization test results from the challenge phase and initial and final body weights are included in Appendix III.

All animals appeared normal throughout the study. All animals gained body weight over the study period.

None of the animals from any of the test groups or corresponding negative control groups exhibited any skin or other abnormal reactions after the challenge phase.

All five animals in the positive control group had skin reactions after the challenge phase. One animal had a grade of 3 (intense erythema and swelling) and four animals had a grade of 2 (moderate and confluent erythema).

6. CONCLUSION

Under the conditions of this study, the test item components of NanoMask™ Face Masks, showed no evidence of causing any sensitization in Guinea pigs.

7. ARCHIVE

The original copy of the study plan, all raw data, and a copy of the final report will be stored in the Nucro-Technics' archives for 6 years. After 6 years, the Sponsor will be notified. As per the Sponsor's instructions (to be submitted in writing), records will be disposed of, retained for an additional fee or returned to the Sponsor.

Health Canada recommends that sponsors store all documentation, study plan, raw data and final report of each study in support of an approved drug product for a minimum of 10 years (from the market notification date) and a longer period when required by the Food and Drug Regulations (4).

8. REFERENCES

1) OECD Principles of Good Laboratory Practice and Compliance Monitoring, OECD, ENV/MC/CHEM (98) 17, 1998.

2) United States Food and Drug Administration, CFR Title 21 Part 58 - Good Laboratory Practice Regulations for Nonclinical Laboratory Studies, 2019.

3) Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Sensitization, ANSI / AAMI / ISO 10993-10, 2010.

4) Guidance Document: Non-Clinical Laboratory Study Data Supporting Drug Product Applications and Submissions: Adherence to Good Laboratory Practice, Health Canada, Health Products and Food Branch, April 30, 2010.

Appendix I

Study Plan

- **Study Plan No. PRE/367875**

CONFIDENTIAL

STUDY PLAN

SKIN SENSITIZATION STUDY OF NANOMASK™ FACE MASKS IN GUINEA PIGS (CLOSED –PATCH (BUEHLER) TEST METHOD)

STUDY PLAN NO.: PRE/367875

FOR

PRESCIENT^{X}
900 Maple Grove Road, Unit 1
Cambridge, Ontario, Canada
N3H 4R7

This study will be conducted in accordance with the OECD Principles of Good Laboratory Practice (1) and the Good Laboratory Practice of the United States Food and Drug Administration (21 CFR Part 58) (2).

/lc **Oct 22, 2020**

TABLE OF CONTENTS

List of Tables

1. STUDY INFORMATION

1.1 Study Title

Skin Sensitization Study of NanoMask^{TM} Face Masks in Guinea Pigs (Closed – Patch (Buehler) Test Method)

1.2 Study Objective

This test is intended to assess the skin sensitizing potential of the components of NanoMask^{TM} Face Masks by the Guinea Pig Closed-Patch (Buehler) Test Method.

1.3 Nucro-Technics' Study Number

367875

1.4 Test Facility

Nucro-Technics
2000 Ellesmere Road, Unit # 16
Scarborough, Ontario, Canada
M1H 2W4
Tel.: (416) 438-6727
Fax: (416) 438-3463

Study Director	Simon R. Taylor, B.Sc. Address as cited for Test Facility Email: taylor@nucro-technics.com
Facility Management	Albert Licollari, D.V.M., Ph.D., DABT Director, Toxicology Laboratories Address as cited for Test Facility Email: licollari@nucro-technics.com
Quality Assurance	Aldona Kenthol Quality Assurance Associate

1.5 Sponsor

PRESCIENT^X
900 Maple Grove Road, Unit 1
Cambridge, Ontario, Canada
N3H 4R7

Sponsor's Representative	Barry Hunt President & CEO, PRESCIENT^X Address as cited for the Sponsor Tel. No.: (519)-749-5267 Email: barry@prescientx.com

1.6 Proposed Study Dates

Experimental Start:	October 22, 2020
Experimental Completion:	November 28, 2020
Audited Draft Report Due:	The week of December 14, 2020
Final Report Due:	Within 30 working days after receiving Sponsor's comments on the draft report.

2. TEST AND CONTROL ITEMS

2.1 Test Item

The NanoMask[TM] Face Mask is composed of the following components:

- Face Mask filter – A white coloured filter that is used as the base mask for covering the mouth and nose.
- TPE Seal - An opaque rubber seal that lines the filter and is used to seal the filter to the facial area.
- TPE Headband – White rubber straps used to allow a snug fit of the mask to the head.

Each of these three components will be tested. As these components are all part of one functioning unit, the following information will apply to each component:

Lot No.:	20-272-1
Storage Conditions:	Store at room temperature
Date of Manufacture:	Sept 29, 2020
Expiry Date:	Sept 28, 2022
Handling Precautions:	Standard Laboratory Precautions
Manufacturer:	Prescient[x]
Supplier:	Prescient[x]

2.2 Positive Control Item

Name:	1-chloro-2, 4-dinitrobenzene (DNCB)
CAS No.:	97-00-7
Lot No.:	STBF4847V
Concentration:	DNCB to be prepared as a 0.3% w/v solution in acetone / alcohol (1:1) for the Induction Phase and as a 0.1% w/v solution for the Challenge Phase.
Storage Conditions:	Solutions stored at 2-8°C
Handling Precautions:	As per MSDS
Supplier:	Sigma Chemical Company

2.3 Test Item Characterization

Documentation of the identity, strength, purity, composition, and stability for the test item will be on file with the Sponsor. A Certificate of Analysis and statement of stability will be provided for inclusion in the final report.

The Sponsor will have appropriate documentation on file concerning the method of synthesis, manufacture or derivation of the test item, and this information is available to the appropriate regulatory agencies should it be requested.

2.4 Test Item Inventory and Disposition

Records of the receipt, distribution, and storage of the test item will be maintained. Any unused portion of the test item will be returned to the Sponsor at the end of the study, unless further studies of the test item are to be conducted, or unless otherwise requested by the Sponsor. Any disposal will be approved by the Sponsor and will be documented in the raw data.

3. TEST SYSTEM

3.1 Test System

Species / Sex:	*Cavia porcellus* (guinea pig) / either sex
Strain:	HA(BR)
Source:	Harlan Sprague Dawley or Charles River Canada
Body Weight Range:	300 g - 500 g *
Number of Animals:	Test group – 10 animals/each test item component Negative Control group – 5 animals/each test item component Positive Control group – 5 animals
Acclimatization Period:	Minimum 5 days*
Age at Study Start:	Approximately 5 weeks*
Animal Identification:	Colour coding, cage labels

* Actual values will be documented in the final report.

3.2 Animal Housing and Maintenance

Guinea pigs will be housed in separate quarters in solid bottom cages, 3-5 per cage. Individual animals will be identified by colour coding; the animal number and group number will also appear on the outside of each cage to preclude mix-up. The animal room environment will be controlled (targeted ranges: temperature 18ºC to 26ºC, relative humidity 30-70% minimum 10 air changes per hour) and monitored. The photo-cycle will be 12 hours light and 12 hours dark.

Upon arrival all animals will be submitted to a general physical examination and only those found healthy will be admitted. LabDiet Guinea Pig Diet (or other approved source) and water will be offered *ad libitum* throughout the acclimatization and study periods. The cage cleaning schedule, air filtration and recirculation, health checks and facility maintenance will be carried out in accordance with the applicable Nucro-Technics Standard Operating Procedures, and such activities will be recorded in the animal room records.

Animals will be housed and maintained according to the AAALAC International Guide for the Care and Use of Laboratory Animals, CCAC Guidelines for Care and Use of Experimental Animals and Nucro-Technics' Standard Operating Procedures.

3.3 Animal Selection / Preparation

The test population of animals will be selected from newly arrived, previously unused guinea pigs.

The animal preparation will involve the clipping of the left upper back region of each animal (generally within 24 hours to 4 hours) prior to test item and control applications. Test sites may be re-clipped to facilitate observation and/or to accommodate repeated exposures.

3.4 Justification for Selection of Test System

The test system is internationally recognised and acceptable to regulatory authorities requiring skin sensitization testing.

4. EXPERIMENTAL DESIGN

4.1 Method

The method used for conducting this study is the accepted standard described in Biological Evaluation of Medical Devices Part 10: Tests for Irritation and Sensitization (3).

4.2 Main Study

4.2.1 Induction Phase:

Test Item Preparation

Each component of the test item will be prepared by cutting the components into pieces of approximately 8 cm^2.

Day 0 - Test Group (10 animals/component)

The test item (or the test site in cases of hydrophobic materials) will be moistened with sterile Water for Injection USP to ensure good contact, then it will be applied directly onto the skin over an 8 cm^2 area and covered with a gauze patch, or will be applied onto gauze patches, which will then be applied to the skin. The application will be onto the prepared clipped left upper back region of each guinea pig. The patches will be held in contact by occlusive dressings for a 6 ± 0.5-hour exposure period. After 6 hours, the occlusive dressings and the patches will be removed and the skin will be cleansed with a suitable vehicle. Any skin reactions will be observed and graded. This procedure will be performed on three days a week for three weeks.

Day 0 - Negative Control Group (5 animals/component)

The animals in the Negative Control Group will be subjected to similar procedures as the animals in the test item treated group with the exception that the gauze patches will be substituted for the test item.

Day 0 - Positive Control Group (5 animals)

The animals in the Positive Control Group will be subjected to similar procedures as the animals in the test item treated group with the exception that the positive control item will be substituted for the test item and that

the Positive Control Item will be applied for a total of three induction treatments over a three week period. Patches of sterile gauze (approximately 8 cm^2) will be saturated with the positive control item and applied.

4.2.2 Challenge Phase:

Test and Control Groups

Fourteen days (± 1 day) after the last application, all animals will be challenged by applying the test item onto the clipped untreated right upper back region of each test and corresponding control animal. The positive control item at a concentration of 0.1% w/v DNCB in ethanol/acetone will be applied to the untreated right upper back region of the Positive Control Group of animals. The test and the control items will be applied in the same manner as during the induction phase, for a 6 ± 0.5-hour exposure period.

Observations - Test and Control Groups

At 24 hr ± 2 hr after the challenge exposure, the challenge area will be cleared of hair and cleaned. A minimum of 2 hr after removal of hair, the skin reactions will be observed and graded. Approximately 48 hr ± 2 hr after removal of the challenge patches, the skin reactions will be again graded.

The skin reactions will be graded according to Table 1.

Table 1. Grading Scale

Magnusson and Kligman Grading Scale For The Evaluation of Challenge Patch Test Reactions (3)	
Reaction	**Numerical Grading**
No visible change	0
Discrete or patchy erythema	1
Moderate and confluent erythema	2
Intense erythema and swelling	3

Note: Other adverse changes at the skin sites will be recorded and reported.

4.2.3 Evaluation of Results

Grades of 1 or greater in the test group generally indicate sensitization, provided grades of less than 1 are seen on negative control animals. If grades of 1 or greater are noted on negative control animals, then the

reactions of test animals which exceed the most severe negative control reaction are presumed to be due to sensitization.

Occasionally, the test group has a greater number of animals showing a response than in the negative control group, although the intensity of the reaction is not greater than that exhibited by the controls. In these instances, a rechallenge may be necessary to define the response clearly. If necessary, a rechallenge shall be carried out 1 week to 2 weeks after the first challenge. The method used shall be as described for the first challenge, using an untested area on the flank of the animal.

5. QUALITY SYSTEMS

5.1 Quality Assurance Monitoring

The Quality Assurance Unit of Nucro-Technics will audit the study and records of the audits will be maintained. Nucro-Technics will permit an authorized Sponsor Representative to inspect the facility and monitor the study conducted without previous notice, during regular working hours.

5.2 Study Plan Amendments/Communications

Any untoward changes occurring during the conduct of the study will be communicated to the Sponsor's Representative by phone or email and discussed. All mutually-agreed necessary changes to the study plan or study would be documented in the form of a study plan amendment and authorized by the Study Director of Nucro-Technics and the Sponsor's Representative. Due to the nature of the study, if the Sponsor's Representative cannot be reached immediately or there is insufficient time to contact the Sponsor's Representative, the Study Director will take all steps necessary to ensure continuance and viability of the study. If such action is taken, the Study Director will notify the Sponsor's Representative thereafter, as soon as possible. Copies of any study plan amendment will be sent to the Sponsor's Representative, whose formal approval will be indicated by the return of one signed copy to Nucro-Technics.

5.3 Standard Operating Procedures

The standard operating procedures used in this study are kept on file at Nucro-Technics.

5.4 Government Inspections

Nucro-Technics agrees to notify the Sponsor/Sponsor's Representative of any Government Inspection with respect to this study. No records of the study will be made available to the inspectors without written permission from the Sponsor/ Sponsor's Representative.

5.5 Final Report

The following information and data will be included in the final report:

- name and address of the facility performing the study and the dates on which the study was initiated, started and completed

- objectives and procedures stated in the approved study plan, including any changes to the original study plan
- test system
- statistical methods employed for analyzing the data
- the test item, identified by name and/or lot number, strength, quality and purity
- methods used
- results obtained
- data evaluation

One audited draft report (electronic copy in word format) will be issued to the Sponsor's Representative. Subsequent to receipt of any mutually agreed changes and/or corrections one copy of a final report (one bound and one electronic copy) will be issued.

If no requested revisions or instructions to finalize the report have been communicated by the Sponsor within six months after issuance of the draft report, the draft report will be issued as a signed final report.

If an electronic copy of the study plan, the report or another study document is provided by Nucro-Technics, the executed paper document is considered the official master document. If there is a discrepancy between an electronic copy and the corresponding master document, the master document will be considered the official document.

5.6 Amendment(s) to the Final Report

Corrections or additions to a final report will be in the form of an amendment by the Study Director. The amendment will clearly identify that part of the final report that is being added to or corrected, and the reasons for the correction or addition, and will be signed and dated by the Study Director.

5.7 Maintenance of Records

The study records will be maintained at Nucro-Technics for 6 years and will include:

- A copy of the study plan and amendment (s) if applicable
- All raw data generated during the study
- A copy of the final report and amendment (s) if applicable

After 6 years, the Sponsor will be notified. As per the Sponsor's instructions (to be submitted in writing), records will be disposed of, retained for an additional fee or returned to the Sponsor.

Health Canada recommends that sponsors store all documentation, study plan, raw data and final report of each study in support of an approved drug product for a minimum of 10 years (from the market notification date) and a longer period when required by the Food and Drug Regulations (4).

5.8 Animal Care Committee Approval

This study plan will be assessed by the Animal Care Committee of Nucro-Technics. Animals used in this research will be treated in accordance with the principles described in the current "Guide for the Care and Use of Experimental Animals" as published by the Canadian Council on Animal Care. This study does not duplicate previous experiments.

6. REFERENCES

1) OECD Principles of Good Laboratory Practice and Compliance Monitoring, OECD, ENV/MC/CHEM (98) 17, 1998.

2) United States Food and Drug Administration, CFR Title 21 Part 58 - Good Laboratory Practice Regulations for Nonclinical Laboratory Studies, 2019.

3) Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Sensitization, ANSI / AAMI / ISO 10993-10, 2010.

4) Guidance Document: Non-Clinical Laboratory Study Data Supporting Drug Product Applications and Submissions: Adherence to Good Laboratory Practice, Health Canada, Health Products and Food Branch, April 30, 2010.

7. STUDY PLAN APPROVAL

This study plan has been approved by:

Simon R. Taylor, B.Sc.
Study Director
Nucro-Technics

OCT. 22/20
Date

Albert Licollari, D.V.M., Ph.D., DABT
Director, Toxicology Laboratories
Nucro-Technics

Oct 22, 2020
Date

Barry Hunt
President & CEO
PRESCIENT[X]

OCT 22, 2020
Date

and reviewed by:

Aldona Kenthol
Quality Assurance Associate
Nucro-Technics

October 22, 2020
Date

Appendix II

Certificates of Analysis

Certification of Analysis

Product Name	Face Mask Filter	**Storage Conditions**	Room Temperature (15°-30°C)
Materials	Polypropylene (melt blown)	**Handling**	Normal Standard GMP
Date of Manufacture	September 28, 2020	**Expiry Date**	September 28, 2022
Supplier	Prescient[x]	**LOT code**	20-272-1

Materials provided for the Face Mask Filter shall remain stable until September 28, 2022. Prescient[x] shall request re-test of material that on or before September 1, 2022.

I hereby certify the products have been inspected prior to shipment and found to be in good condition for testing.

Patricia Mazurek

Patricia Mazurek
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Quality System Manager
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Certification of Analysis

Product Name	TPE Seal	**Storage Conditions**	Room Temperature (15°-30°C)
Materials	Thermoplastic Elastomer -LC AA6-872D	**Handling**	Normal Standard GMP
Date of Manufacture	September 28, 2020	**Expiry Date**	September 28, 2022
Supplier	Prescient[x]	**LOT code**	20-272-1

Materials provided for the Face Mask Filter shall remain stable until September 28, 2022. Prescient[x] shall request re-test of material that on or before September 1, 2022.

I hereby certify the products have been inspected prior to shipment and found to be in good condition for testing.

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Certification of Analysis

Product Name	TPE Headband	**Storage Conditions**	Room Temperature (15°-30°C)
Materials	Thermoplastic Elastomer	**Handling**	Normal Standard GMP
Date of Manufacture	September 28, 2020	**Expiry Date**	September 28, 2022
Supplier	Prescient[X]	**LOT code**	20-272-1

Materials provided for the Face Mask Filter shall remain stable until September 28, 2022. Prescient[X] shall request re-test of material that on or before September 1, 2022.

I hereby certify the products have been inspected prior to shipment and found to be in good condition for testing.

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Appendix III

Dermal Sensitization Test Results

DERMAL SENSITIZATION TEST

CHALLENGE PHASE

Study No.: 367875

Date: November 25, 2020
Test Item: Face Mask filter (NanoMask™)
Test Item Preparation: Cut 2.8 cm x 2.85 cm pieces
Elements of Observation: Erythema and Oedema after unwrap
Group: Test (Face Mask filter) (~ 8 cm^2/patch/site)

Treatment / Volume	Obs. Time (Hrs)	Animal Number									
		1	2	3	4	5	6	7	8	9	10
Average Score											
TEST ITEM CHALLENGE 2.8 x 2.85 cm/ Site	24	0	0	0	0	0	0	0	0	0	0
	48	0	0	0	0	0	0	0	0	0	0

	1	2	3	4	5	6	7	8	9	10
Individual Body Weight (g)	367.0	373.3	368.0	365.4	378.0	357.1	368.2	361.2	367.4	377.4
Final Body Weight (g)	500.1	618.3	602.0	598.2	601.3	602.1	605.2	596.2	587.1	603.2

DERMAL SENSITIZATION TEST

CHALLENGE PHASE

Study No.: 367875

Date: November 25, 2020
Control Item: Blank Gauze
Control Item Preparation: Cut 2.8 cm x 2.85 cm pieces
Elements of Observation: Erythema and Oedema after unwrap
Group: Negative Control (Blank gauze) ~ 8 cm^2/patch/site ---- Face Mask filter group

Treatment / Volume	Obs. Time (Hrs)	Animal Number				
		11	12	13	14	15
Average Score						
CHALLENGE 2.8 x 2.85 cm / Site of Test Item	24	0	0	0	0	0
	48	0	0	0	0	0

	11	12	13	14	15
Individual Body Weight (g)	360.1	366.4	361.2	393.4	375.3
Final Body Weight (g)	598.0	596.6	601.4	608.1	614.2

DERMAL SENSITIZATION TEST

CHALLENGE PHASE

Study No.: 367875

Date: November 25, 2020
Test Item: TPE Seal (NanoMask™)
Test Item Preparation: Cut 2.8 cm x 2.85 cm pieces
Elements of Observation: Erythema and Oedema after unwrap
Group: Test (TPE Seal) (~ 8 cm^2/patch/site)

Treatment / Volume	Obs. Time (Hrs)	Animal Number									
		16	17	18	19	20	21	22	23	24	25
Average Score											
TEST ITEM CHALLENGE 2.8 x 2.85 cm / Site	24	0	0	0	0	0	0	0	0	0	0
	48	0	0	0	0	0	0	0	0	0	0

	16	17	18	19	20	21	22	23	24	25
Individual Body Weight (g)	377.3	361.2	359.3	376.0	361.4	356.0	387.3	392.3	365.2	382.1
Final Body Weight (g)	534.2	530.6	555.0	564.0	536.0	627.0	556.0	609.1	625.2	483.0

DERMAL SENSITIZATION TEST

CHALLENGE PHASE

Study No.: 367875

Date: November 25, 2020
Control Item: Blank Gauze (NanoMask™)
Control Item Preparation: Cut 2.8 cm x 2.85 cm pieces
Elements of Observation: Erythema and Oedema after unwrap
Group: Negative Control (Blank gauze) ~ 8 cm^2/patch/site ---- TPE Seal group

Treatment / Volume	Obs. Time (Hrs)	Animal Number				
		26	27	28	29	30
Average Score						
CHALLENGE 2.8 x 2.85 cm / Site of Test Item	24	0	0	0	0	0
	48	0	0	0	0	0

	26	27	28	29	30
Individual Body Weight (g)	378.2	369.0	329.2	383.0	367.1
Final Body Weight (g)	563.3	589.5	454.5	560.6	549.1

DERMAL SENSITIZATION TEST

CHALLENGE PHASE

Study No.: 367875

Date: November 25, 2020
Test Item: TPE Headband (NanoMask™)
Test Item Preparation: Cut 2.8 cm length pieces, 5 pieces per test site
Elements of Observation: Erythema and Oedema after unwrap
Group: Test (TPE Headband) ~ 8 cm^2/patch/site

Treatment / Volume	Obs. Time (Hrs)	Animal Number									
		31	**32**	**33**	**34**	**35**	**36**	**37**	**38**	**39**	**40**
Average Score											
TEST ITEM CHALLENGE 2.8 cm length pieces, 5 pieces / Site	24	0	0	0	0	0	0	0	0	0	0
	48	0	0	0	0	0	0	0	0	0	0

	31	**32**	**33**	**34**	**35**	**36**	**37**	**38**	**39**	**40**
Individual Body Weight (g)	366.1	374.4	369.3	385.4	371.0	352.0	349.0	367.4	381.4	367.1
Final Body Weight (g)	510.2	570.0	554.1	571.5	511.0	514.0	593.0	503.0	520.0	542.1

DERMAL SENSITIZATION TEST

CHALLENGE PHASE

Study No.: 367875

Date: November 25, 2020
Control Item: Blank Gauze (NanoMask™)
Control Item Preparation: Cut 2.8 cm x 2.85 cm pieces
Elements of Observation: Erythema and Oedema after unwrap
Group: Negative Control (Blank gauze) ~ 8 cm^2/patch/site ---- TPE Headband group

Treatment / Volume	Obs. Time (Hrs)	Animal Number				
		41	42	43	44	45
Average Score						
CHALLENGE 2.8 x 2.85 cm / Site of Test Item	24	0	0	0	0	0
	48	0	0	0	0	0

	41	42	43	44	45
Individual Body Weight (g)	354.4	341.4	357.3	375.2	362.2
Final Body Weight (g)	553.2	600.1	570.5	545.9	526.5

DERMAL SENSITIZATION TEST

CHALLENGE PHASE

Study No.: 367875

Date: November 25, 2020

Positive Control Item: 0.1% DNCB

Positive Control Item Preparation: Sterile gauze saturated with DNCB

Elements of Observation: Erythema and Oedema after unwrap

Group: Positive Control (0.3% DNCB) ~ 8 cm^2/patch/site

Treatment / Volume	Obs. Time (Hrs)	Animal Number				
		46	47	48	49	50
Average Score						
CHALLENGE Sterile gauze saturated ~ 8 cm^2 / Site	24	2	2	3	2	2
	48	1	1	2	1	1

	46	47	48	49	50
Individual Body Weight (g)	362.4	348.1	332.2	346.1	371.0
Final Body Weight (g)	557.2	534.4	493.2	567.0	597.2