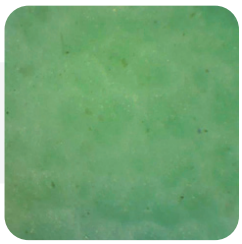
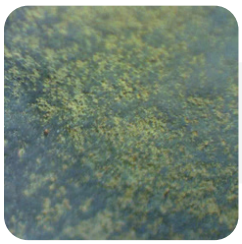
BRAIN WAVE SOLUTIONS

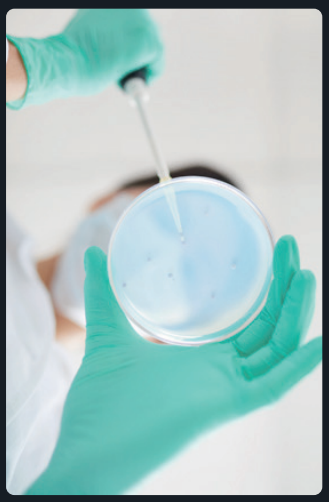
Biodegradation mechanism and characteristics

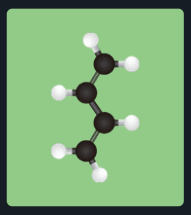
Before Degradation



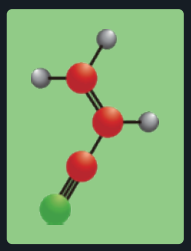


After Degradation





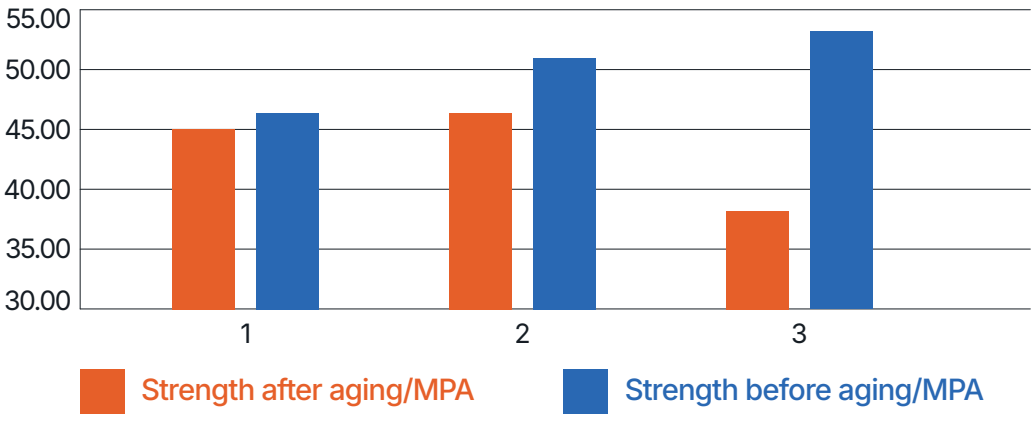
Butadiene: Butadiene monomer is present as the gaseous state in the atmosphere, which can be degraded by chemically induced hydroxyl free radicals, ozone or nitro free radicals. In addition, It is moderately mobile in soil and easily volatilized to the atmosphere by significant volatility. It has biodegradable but weakly bioconcentrating.



Acrylonitrile: Acrylonitrile is used by microorganisms in two main ways :

1. Acrylonitrile is first converted to acrylamide by nitrile hydrase, and then converted to acrylic acid by amidase;
2. Acrylic acid is produced directly under the action of nitrile hydrolase. Finally, it is absorbed and metabolized into CO2 and water by microorganisms

Tensile Strength/MPA



The introduction of degradation additives does not affect nitrile gloves' overall mechanical properties and aging resistance!

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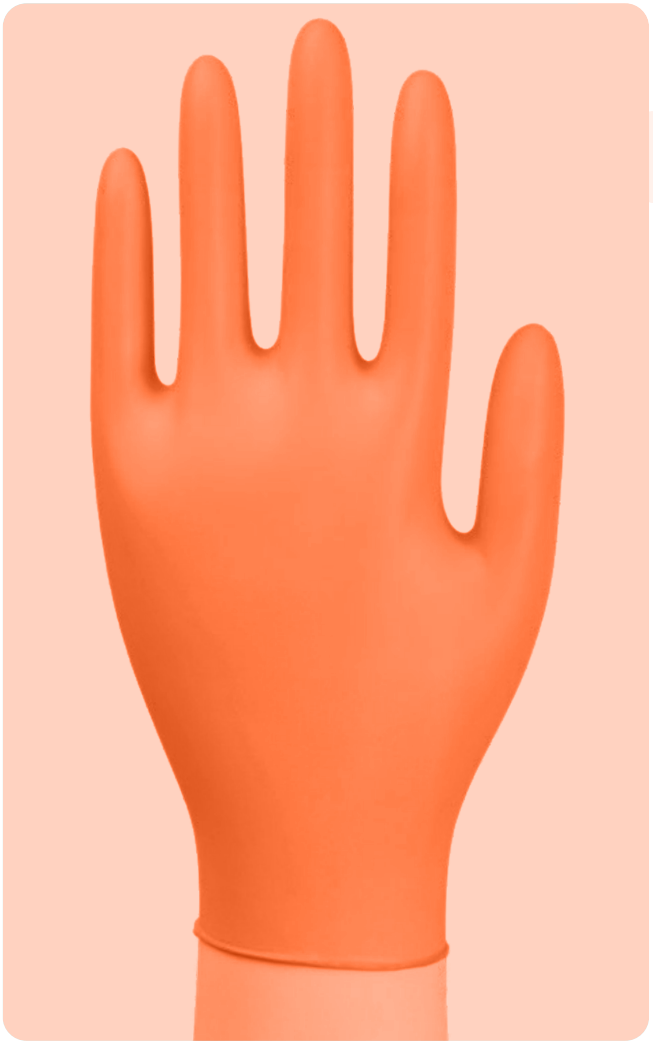
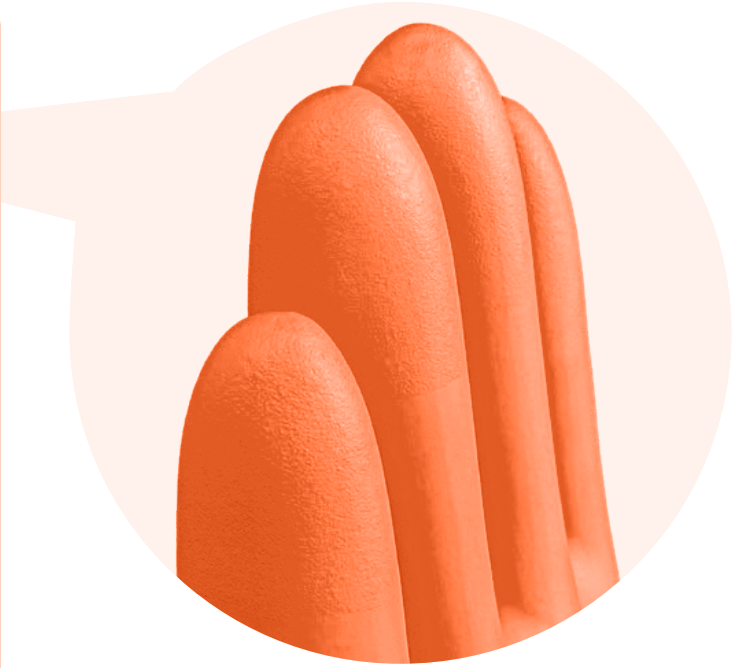
Biodegradable Nitrile Examination Gloves





Textured Fingertips

OEM · LATEX · NON STERILE · AQL 1.5

Biodegradable Nitrile Examination Gloves are specially designed to biodegrade in both anaerobic and aerobic conditions in landfills.

Features

1. 100% Nitrile, Biodegradable, Powder Free,Surface-Chlorinated
2. Available in green, blue, blue violet
3. Beaded cuff ensures easy donning and prevent roll down
4. Textured fingertips enhanced wet and dry grip
5. Decreased risk of allergies
5. Excellent chemical splash protection
6. Protection against bacteria and fungi
7. Superior strength with better puncture resistance
8. Excellent tactile sensitivity

Standard Quality

EN374	EN 455	ASTM D6319	ASTM D5511

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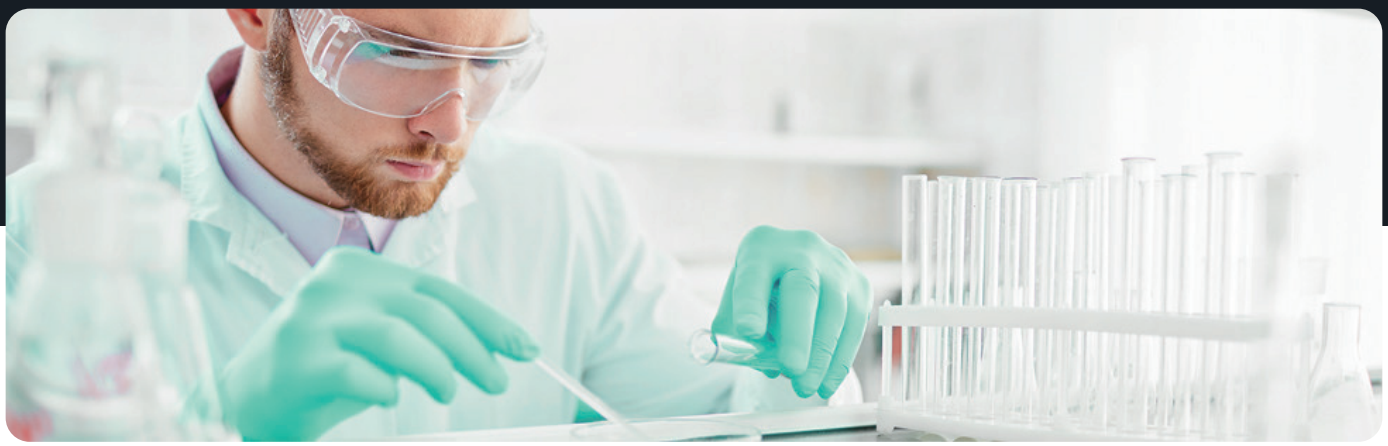

Specification

2.5 Mil Biodegradable Nitrile Gloves

Glove Length (mm/inches)
min: 240 / 9.5

Palm Thickness (mm/mil):
0.06±0.02/2.4±0.8

Finger Thickness (mm/mil):
0.09±0.02/3.5±0.8

Unite Weight (g):
S 3.0±0.3g
M 3.3±0.3g
L 3.6±0.3g
XL 4.0±0.3g

3 Mil Biodegradable Nitrile Gloves

Glove Length (mm/inches)
min: 240 / 9.5

Palm Thickness (mm/mil):
0.08±0.02/3.2±0.8

Finger Thickness (mm/mil):
0.12±0.02/4.8±0.8

Unite Weight (g):
S 4±0.3g
M 4.4±0.3g
L 4.7±0.3g
XL 5±0.3g

4.0 Mil Biodegradable Nitrile Gloves

Glove Length (mm/inches)
min: 240 / 9.5

Palm Thickness (mm/mil):
0.10±0.02/4.0±0.8

Finger Thickness (mm/mil):
0.16±0.02/6.4±0.8

Unite Weight (g):
S 5±0.5g
M 5.5±0.5g
L 6±0.5g
XL 6.5±0.5g

Application

CHEMOTHERAPY	MEDICAL	DENTISTRY	PET CARE
LABORATORY	JANITORIAL	HOUSEHOLD	HAIRDRESSING
INDUSTRIAL	DIY	FOOD HANDLING	

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Medical Devices Registration Receipt

Anlage 1
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00381686

Allgemeine Anzeigepflicht nach §§ 25 und 30 Abs. 2 MPG
General Obligation to Notify pursuant to §§ 25 and 30 (2) Medical Devices Act, MPG

Formblatt für Medizinprodukte, außer In-vitro-Diagnostika
Form for Medical Devices except In Vitro Diagnostic Medical Devices

Zuständige Behörde / Competent authority			
	Code **DE/CA20**		
	Bezeichnung / Name **Bezirksregierung Düsseldorf, Dezernat 24**		
	Staat / State **Deutschland**		Land / Federal state **Nordrhein-Westfalen**
	Ort / City **Düsseldorf**		Postleitzahl / Postal code **40474**
	Straße, Haus-Nr. / Street, house no. **Cecilienallee 2**		
	Telefon / Phone **+49-211-4750**		Telefax / Fax **+49-211-4752671**
	E-Mail / E-mail **dez24.mpg@brd.nrw.de**		

Anlage 1
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00381686

Anzeige / Notification			
	Registrierdatum bei der zuständigen Behörde Registration date at competent authority **21.04.2022**		Registriernummer / Registration number **DE/CA20/00186672**
	Rechtsgrundlage / legal basis ☐ Medizinprodukte (93/42/EWG bzw. 90/385/EWG) / German Medical Device Act (93/42/EWG or 90/385/EWG) ☐ Artikel 120(3) Verordnung (EU) 2017/745 (Legacy Device) / Article 120(3) Regulation (EU) 2017/745 (Legacy Device) ☒ Verordnung (EU) 2017/745 (MDR) / Regulation (EU) 2017/745 (MDR)		
	Typ der Anzeige / Notification type ☒ Erstanzeige / Initial notification ☐ Änderungsanzeige / Notification of change ☐ Widerrufsanzeige / Notification of withdrawal		
	Frühere Registriernummer bei Änderungs- und Widerrufsanzeige Previous registration number if notification has been changed or withdrawn		
	Anzeigender nach § 25 MPG / Reporter pursuant to § 25 Medical Devices Act, MPG ☐ Hersteller / Manufacturer ☒ Bevollmächtigter / Authorised Representative ☐ Einführer / Importer ☐ Verantwortlicher für das Zusammensetzen von Systemen oder Behandlungseinheiten nach § 10 Abs. 1 und 2 MPG / Assembler of systems or procedure packs pursuant to § 10 (1) and (2) Medical Devices Act, MPG ☐ Betrieb oder Einrichtung (aufbereiten) nach § 25 Abs. 1 MPG i. V. m. § 4 Abs. 2 MPBetreibV Institution (processing) pursuant to § 25 (1) Medical Devices Act, MPG in connection with § 4 (2) MPBetreibV ☐ Betrieb oder Einrichtung (sterilisieren) nach § 25 Abs. 2 i. V. m. § 10 Abs. 3 MPG Institution (sterilizing) pursuant to § 25 (2) in connection with § 10 (3) Medical Devices Act, MPG		

Anzeigender / Reporting organisation (person)			
	Code **DE/0000049303**		
	Bezeichnung / Name **Share Info GmbH**		
	Staat / State **Deutschland**		Land / Federal state **Nordrhein-Westfalen**
	Ort / City **Düsseldorf**		Postleitzahl / Postal code **40549**
	Straße, Haus-Nr. / Street, house no. **Heerdter Lohweg 83**		
	Telefon / Phone **01795666508**		Telefax / Fax
	E-Mail / E-mail **Eu-rep@share-info.cn**		

Sicherheitsbeauftragter für Medizinprodukte nach § 30 Abs. 2 MPG 9) **Safety officer for medical devices pursuant to § 30 (2) Medical Devices Act, MPG**			
	Bezeichnung / Name **Jiehan Li**		
	Staat / State **Deutschland**		Land / Federal state **Nordrhein-Westfalen**
	Ort / City **Kaarst**		Postleitzahl / Postal code **41564**
	Straße, Haus-Nr. / Street, house no. **Windvogt 38**		
	Telefon / Phone **017670057022**		Telefax / Fax
	E-Mail / E-mail **jiehanl@hotmail.com**		

Vertreter / Deputy (optional)			
	Bezeichnung / Name		
	Telefon / Phone		Telefax / Fax
	E-Mail / E-mail		
	☒ Erstanzeige / Initial notification ☐ Änderungsanzeige / Notification of change		

Medizinprodukt (Erstmaliges Inverkehrbringen) / Medical device (First placing on the market)	
	Klasse / Class ☒ I ☐ I - steril / sterile ☐ I - mit Messfunktion / with measuring function ☐ I - steril und mit Messfunktion / sterile and with measuring function ☐ I - Wiederverwendbare chirurgische Instrumente / Reusable surgical instruments ☐ I - Wiederverwendbare chirurgische Instrumente und steril / Reusable surgical instruments and sterile ☐ I - Wiederverwendbare chirurgische Instrumente mit Messfunktion / Reusable surgical instruments with measuring function ☐ I - Wiederverwendbare chirurgische Instrumente mit Messfunktion und steril / Reusable surgical instruments with measuring function and sterile ☐ IIa ☐ IIb ☐ III ☐ III - hergestellt unter Verwendung von Gewebe tierischen Ursprungs im Sinne der Verordnung (EU) Nr. 722/2012 manufactured utilising tissues of animal origin in terms of Commission Regulation (EU) No 722/2012 ☐ Aktives implantierbares Medizinprodukt / Active implantable medical device ☐ Aktives implantierbares Medizinprodukt - hergestellt unter Verwendung von Gewebe tierischen Ursprungs im Sinne der Verordnung (EU) Nr. 722/2012 Active implantable medical device - manufactured utilising tissues of animal origin in terms of Commission Regulation (EU) No 722/2012
	App (Software auf mobilen Endgeräten) ☐ ja / yes ☒ nein / no
	Nummer(n) der Bescheinigung(en) / Certificate number(s)
	Handelsname des Produktes / Trade name of the device **Nitrile examination gloves**
	Produktbezeichnung / Name of device
	Nomenklaturcode / Nomenclature code
	Nomenklaturbezeichnung / Nomenclature term
	Kategoriecode / Category code **03**
	Kategorie / Category **Zahnärztliche Produkte**
	Kurzbeschreibung deutsch / German short description **Die Nitril-Untersuchungshandschuhe sind zum Tragen an den Händen von medizinischem und ähnlichem Personal vorgesehen, um eine Kontamination zwischen medizinischem Personal und dem Körper des Patienten zu verhindern. Dies ist ein puderfreies, unsteriles Gerät zum einmaligen Gebrauch.** **Modell: KG-1303, KG-1104, KG-1106, KG-1107, BIO-G01, BIO-G02, BIO-G05**

Kurzbeschreibung englisch / English short description
The nitrile examination gloves are intended to be worn on the hands of health care and similar personnel to prevent contamination between health care personnel and the patient's body. This is a single-use, powder-free, non-sterile device.
Model: KG-1303, KG-1104, KG-1106, KG-1107, BIO-G01, BIO-G02, BIO-G05

Medizinprodukte (Aufbereiten) / Medical devices (Reprocessing)

☐ Semikritische Medizinprodukte / Semicritical medical devices
☐ Gruppe A / Group A
☐ Gruppe B / Group B

☐ Kritische Medizinprodukte / Critical medical devices
☐ Gruppe A / Group A
☐ Gruppe B / Group B
☐ Gruppe C / Group C
Nummer der Bescheinigung / Certificate number

Sterilisationsverfahren / Sterilisation procedures
☐ Dampfsterilisation / Steam sterilisation
☐ Gassterilisation / Gas sterilisation
☐ Strahlensterilisation / Radiation sterilisation
☐ andere / others
Angewandtes Verfahren / Applied procedure

Ich versichere, dass die Angaben nach bestem Wissen und Gewissen gemacht wurden.
I affirm that the information given above is correct to the best of my knowledge.

Ort / City: **Duesseldorf**

Datum / Date: **2022-04-21**

Name: **Jiehan Li**

Unterschrift / Signature

Bearbeitungsvermerke / Processing notes
Nur von der zuständigen Behörde auszufüllen / To be filled in only by the competent authority

Bearbeiter / Person responsible	Telefon / Phone

ASTM-D5511 Biodegradable Level Test Reports

intertek
Total Quality. Assured.

Sample Description:
The submitted sample said to be :
Item Name : **(1) Nitrile gloves**
(sample information was provided by the applicant)

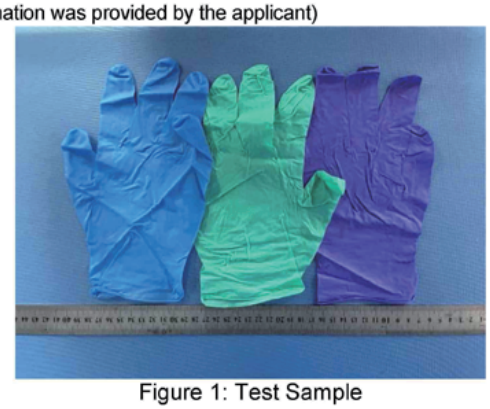

Figure 1: Test Sample

Tests conducted:
As requested by the applicant, refer to attached page(s) for details.

Authorized by:

Jingyi Jiang
Manager
For Intertek China

Intertek Testing Services Shenzhen Ltd.
深圳天祥质量技术服务有限公司

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www.intertek.com.cn

Test Report Number: SZHH01677022

Tests Conducted

1 PROJECT DESCRIPTION

NITRILE GLOVES sample was submitted for testing under standard ASTM D5511. This test method covers the determination of the degree and rate of anaerobic biodegradation of plastic materials in high-solids anaerobic conditions. The test materials are exposed to a methanogenic inoculum derived from anaerobic digesters operating only on pretreated household waste. The anaerobic decomposition takes place under high-solids (more than 30 % total solids) and static non-mixed conditions. This test method is designed to yield a percentage of conversion of carbon in the sample to carbon in the gaseous form under conditions found in high-solids anaerobic digesters, treating municipal solid waste.

2 INOCULUM COLLECTION AND CONDITIONING

The anaerobic digested sewage sludge (Figure 2) mixed with household waste. To make the sludge adapted and stabilized during a short post-fermentation at 53°C, the sludge was pre-incubated (one week) at 53°C. This means that the concentrated inoculum was not fed but allowed to post ferment the remains of previously added organics allowing large easily biodegradable particles were degraded during this period and reduce the background level of biogas from the inoculums itself.

Figure 2: Anaerobic microbial inoculum

3 INOCULUM PROPERTIES

A sample of the anaerobic digested sewage sludge was analyzed for pH, percent dry solids, and volatile solids, as well as, the amount of CO_2 and CH_4 evolution during the testing. Table 1 lists the results of this initial testing.

(to be continue)

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4 METHODOLOGY

Test Required: ASTM D5511 Standard Test Method for Determining Anaerobic Biodegradation of Plastic Materials Under High-Solids Anaerobic-Digestion Conditions

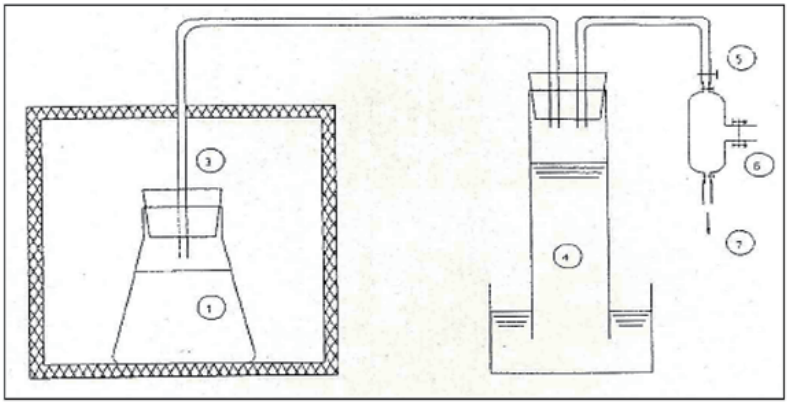
Inoculum Medium: Remove enough inoculum (approximately 15 kg) from the post-fermentation vessel and mix carefully and consistently by hand in order to obtain a homogeneous medium. Test three replicates each of a blank (inoculum only), Positive control (Reference material) (thin-layer chromatography cellulose), negative control (optional), and the test substance being evaluated.

Manually mix 1000 g wet weight (at least 20 % dry solids) of inoculum in a small container for a period of 2 to 3 min with 15 to 100 g of volatile solids of the test substance or the controls for each replicate. For the three blanks containing inoculum only, manually mix 1000 g of the same inoculum in a small container for a period of 2 to 3 min with the same intensity as was done for the other vessels containing test substance or controls. Determine the weight of the inoculum and test substance added to each individual Erlenmeyer flask accurately. Add the mixtures to a 2-L wide-mouth Erlenmeyer flask and gently spread and compact the material evenly in the flask to a uniform density.

After placing the Erlenmeyer flask in incubator, connect it with the gas collection device. Incubate the Erlenmeyer flasks in the dark or in diffused light at 52°C (62°C) for thermophilic conditions, The incubation time shall be run until no net gas production is noted for at least five days from both the Positive control (Reference material) and test substance reactors. Control the pH of the water used to measure biogas production to less than two by adding HCl.

5 ANAEROBIC DIGESTER SETUP FOR THE PLASTIC BIODEGRADATION

The biodegradation testing of sample was performed in the digester as shown in the (Figure-3).



1. Digester
2. Incubator
3. Gas outlet
4. Gas collector
5. Valve
6. Gas Sampling
7. Gas Discharge

Figure-3: Digester setup

(to be continue)

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6 RESULT

The most important biochemical characteristics of the inoculum such as pH, Volatile Fatty Acids, NH4+-N— and dry solids were studied.

Table 1: Results of Initial testing of the anaerobic digested sewage sludge

Parameters	Requirement	Actual results
pH	7.5 to 8.5	7.58
Kjeldahl nitrogen	0.5 to 2 g/kg wet weight	1.44
Dry Solids at 105 ˚C	>20%	44.00
Volatile Solids at 550 ˚ C	Below 1 g/kg wet weight	0.78

The biogas volume in the gas sampling bag was measured (Table- 2). Presence of gas in the gas collector of Positive control (Reference material) indicated that the inoculum was viable and gas displacement was observed both in Positive control (Reference material) and Test Sample.
ASTM D 5511 states that for the test to be considered valid, the Positive control (Reference material) must achieve 70 % within 30 days with deviation less than 20% of the mean between the replicates.
Positive control (Reference material) showed 71.57% on 27th day with less than 20% of the mean difference between the replicates.
The gas displacement observed after 90 days is as shown in the table below.

Table-2: Biogas volume of the evolved gas during the biodegradation process at 90 days

Biodegradation Test	Total Volume 90 days (mL)
Inoculum	3490
Positive control (Reference material)	10160
NITRILE GLOVES	5490

Colonization of bacteria at some places were observed under the microscope (Fig-4). This shows the process of biodegradation has begun.

(to be continue)

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Test Report Number: SZHH01677022

Tests Conducted

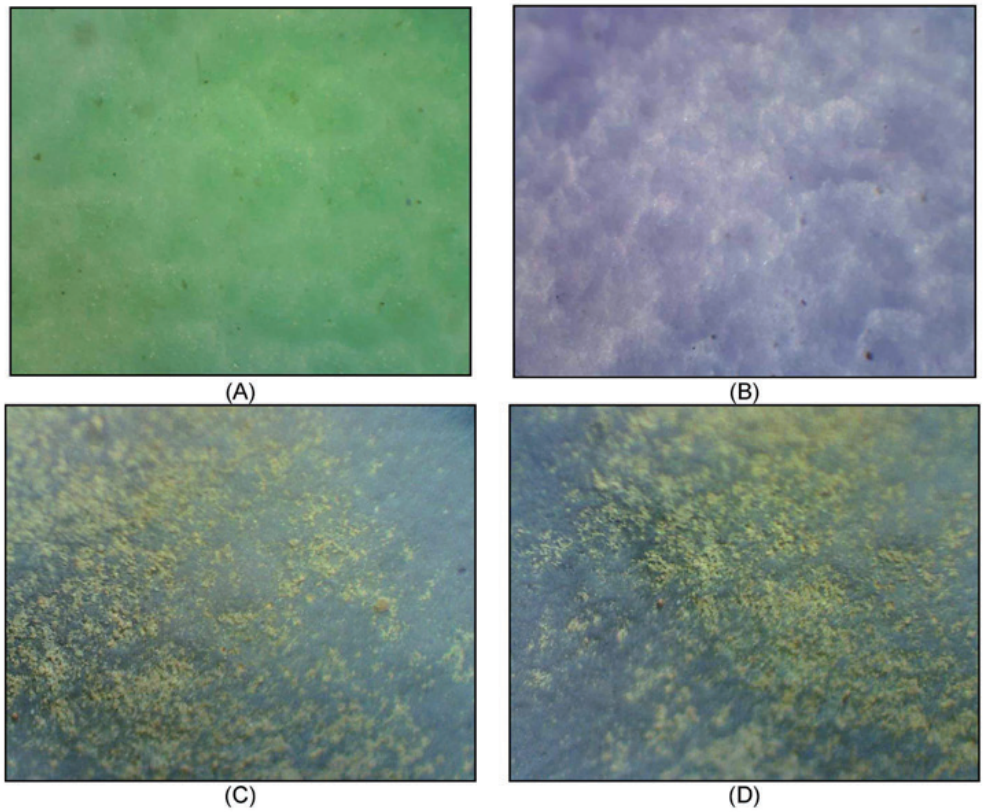

Figure 4: Microscopic image of Test samples Before and After 90 days Incubation Condition

A & B – Unexposed Test Sample NITRILE GLOVES to anaerobic biodegradation process
C & D – Exposed Test Sample NITRILE GLOVES to anaerobic biodegradation process

The percent biodegradation of Positive control (Reference material) and Test sample was calculated by the measured cumulative carbon dioxide and methane production from each flask after subtracting carbon dioxide evolution and methane evolution from the blank samples at the end of 90 days of testing. Calculations were based on Total Organic Carbon obtained of both Positive control (Reference material) and Test sample.

(to be continue)

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Tests Conducted

Table-3: Percentage biodegradability of Test sample with respect to Positive control (Reference material) Cellulose.

Group	Inoculum control	Positive control (Reference material)	NITRILE GLOVES Sample
Weight	1001 ml	10.1255 g	10.3572 g
Total volume (ml)	3490.00	10160.00	5490.00
% CH_4	13.60	45.00	24.30
Volume of CH_4 (ml)	474.64	4572.00	1334.07
weight of CH_4 (g)	0.3114	2.9992	0.8751
% CO_2	16.70	46.60	27.20
Volume of CO_2 (ml)	582.83	4734.56	1493.28
Weight of CO_2 (g)	1.1540	9.3744	2.9567
Total weight of carbon in grams	0.5451	4.7805	1.4547
Theoretical weight of carbon in grams (Ci)	-	4.2598	6.9238
Biodegradation	-	0.9943	0.1314
% Biodegradation	-	99.43	13.14

Table 4: Percent weight loss of NITRILE GLOVES sample.

Average Initial Weight (grams)	10.3572
Average Final Weight (grams)	9.2745
Percent Weight Loss (%)	10.45

The Percent weight loss was calculated based on the initial weight and final weight of the test sample after the 90 days study.

Biodegradation of the samples determined based on conversion of carbon from the test material to carbon in the gaseous phase (CH_4 and CO_2) can be observed in graph 1 and graph 2a & 2b.

(to be continue)

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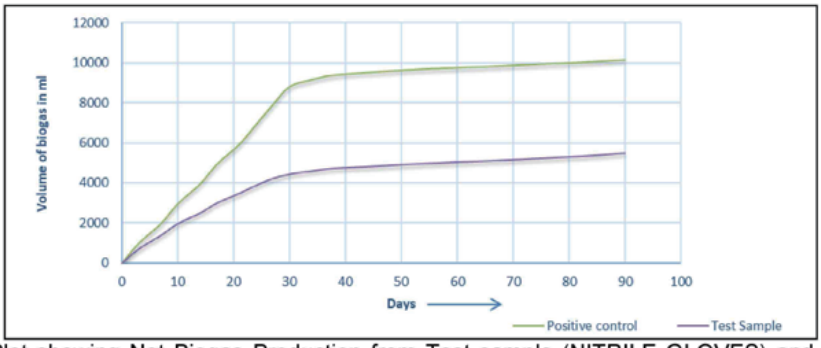
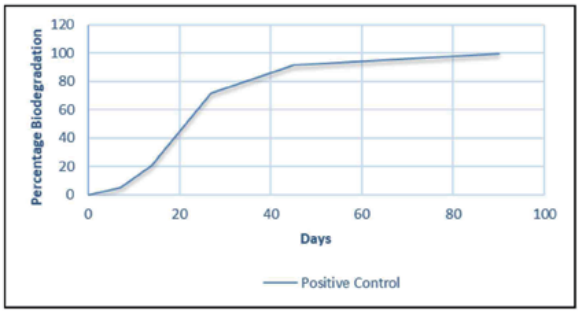
Test Report Number: SZHH01677022

Tests Conducted



Graph-1: Plot showing Net Biogas Production from Test sample (NITRILE GLOVES) and Positive control (Reference material- Cellulose)



Graph-2a: The percent biodegradation of the Positive control (Reference material- Cellulose) determined based on conversion of carbon from cellulose to carbon in the gaseous phase (CH_4 and CO_2)

(to be continue)

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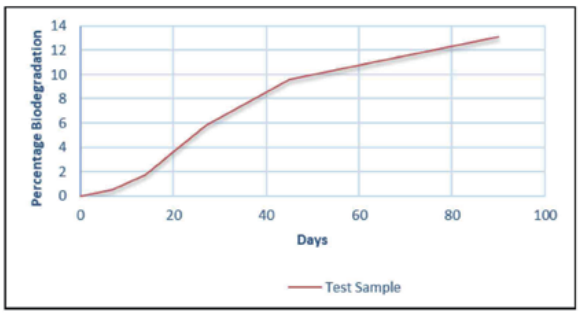

Graph-2b: The percent biodegradation of the Test sample (NITRILE GLOVES Sample) determined based on conversion of carbon from the Test material to carbon in the gaseous phase (CH_4 and CO_2)

7 CONCLUSION

Considering the cumulative gas production as observed in Table 2 & 3 and its analysis indicates that the process of biodegradation has occurred in NITRILE GLOVES Sample. After 90 days of incubation, the level of biodegradation for the Positive control (Reference material) was 99.43 % while the NITRILE GLOVES Sample showed 13.14 %.

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End of report

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