JHG ANALYTICAL SERVICES LIMITED

Unit 9 Airside

Boeing Avenue

Airport Business Park

Killowen

Waterford X91 FX50

Republic of Ireland. Tel: +353 51 364103 Mob: +353 85 1379 880 Fax: +353 51 364039

TEST REPORT **REPORT NO.: 20-06-17039**

CHEMICAL/MICROBIOLOGICAL ANALYTICAL REPORT

Nature of Product: Face Mask Sanitiser Sample.

Date of Report: 25th. June 2020.

Sample Reference: Sursol Face Mask Sanitiser Sample BN 11428.

Sample Volume: 1 x 250mls.

McKlords Limited
1, Bodelwyddan
Denbighshire
LL1855X
Wales
United Kingdom

For the Attention of: Mr. Akshay Vijayan.

Contact No. 01 745585995

Email: akshay@mcklords.com.

Date of Sample: 16th. June 2020.

TEST REPORT **REPORT NO.: 20-06-17039**

Part A – Product Safety Microbiological Analysis

Sample Reference: Sursol Face Mask Sanitiser Sample.

Method of Analysis: Manual Pour Plate Method

Microbiological Analysis

Parameter	Method of Analysis	Method Reference	Units	Reported Levels
Staph. aureus	Pour Plate Count	APHA 9222	CFU/ml.	ND
Salmonella spp.	Pour Plate Count	APHA 9222	CFU/ml.	ND
Listeria spp.	Pour Plate Count	APHA 9222	CFU/ml.	ND
Bacillus cereus	Pour Plate Count	APHA 9222	CFU/ml.	ND
Clostridia spp.	Pour Plate Count	APHA 9222	CFU/ml.	ND
Enterobactericeae	Pour Plate Count	APHA 9222	CFU/ml.	ND
Esch. Coli	Pour Plate Count	APHA 9222	CFU/ml.	ND
Yeasts/Molds	Pour Plate Count	APHA 9222	CFU/ml.	ND

Part B – Product Safety Chemical Analysis

Sample Reference: Sursol Face Mask Sanitiser Sample.

Method of Analysis: Inductively Coupled Plasma – Optical Emission Spectroscopy ICP-OES

Heavy Metals Analysis

Parameter	Method of Analysis	Method Reference	Units	Reported Levels
Mercury as Hg.	Cold Vapour AAS	EC 1881	CFU/ml.	< 0.002
Chromium as Cr.	ICP-OES	EC 1881	CFU/ml.	< 0.002
Arsenic as As.	ICP-OES	EC 1881	CFU/ml.	< 0.0005
Cadmium as Cd.	ICP-OES	EC 1881	CFU/ml.	< 0.003
Nickel as Ni.	ICP-OES	EC 1881	CFU/ml.	< 0.002
Lead as Pb.	ICP-OES	EC 1881	CFU/ml.	< 0.002

TEST REPORT **REPORT NO.: 20-06-17039**

Part C – Product Safety Chemical Analysis

Sample Reference: Sursol Face Mask Sanitiser Sample.

Method of Analysis: High Performance Liquid Chromatography-Mass Spectrometry HPLC-MS-MS

Pesticide Residues Analysis

Parameter	Method of Analysis	Method Reference	Units	Reported Levels
Organochlorine	HPLC-MS-MS	APHA 6630	µg/ml.	< 0.002
Organophosphorus	HPLC-MS-MS	APHA 6630	µg/ml.	< 0.002
Organonitrogen	HPLC-MS-MS	APHA 6630	µg/ml.	< 0.050
Carbamate Pesticides	HPLC-MS-MS	APHA 6630	µg/ml.	< 0.030
Pyrethroid Residues	HPLC-MS-MS	APHA 6630	µg/ml.	< 0.001
Organotin	HPLC-MS-MS	APHA 6630	µg/ml.	< 0.002

Part D – Product Safety Chemical Analysis

Sample Reference: Sursol Face Mask Sanitiser Sample.

Method of Analysis: High Performance Liquid Chromatography-Photodiode Array Detection HPLC-PDA

Aflatoxins/Mycotoxins Analysis

Parameter	Method of Analysis	Method Reference	Units	Reported Levels
Ochratoxin	HPLC-PDA	EC 401	µg/ml.	< 0.01
Aflatoxins Scan	HPLC-PDA	EC 401	µg/ml.	< 0.01
B1	HPLC-PDA	EC 401	µg/ml.	< 0.002
B2	HPLC-PDA	EC 401	µg/ml.	< 0.05
G1	HPLC-PDA	EC 401	µg/ml.	< 0.001
G2	HPLC-PDA	EC 401	µg/ml.	< 0.005

TEST REPORT **REPORT NO.: 20-06-17039**

Part E – Product Safety Chemical Analysis

Sample Reference: Sursol Face Mask Sanitiser Sample.

Method of Analysis: Method of Analysis: Gas Chromatography- Flame Ionization Detection GC-FID

Residual Solvents

Parameter	Method of Analysis	Method Reference	Units	Reported Levels
Methanol	GC-FID	Shimadzu HS-GC-FID	mg/ml.	< 0.05
Pentane	GC-FID	Shimadzu HS-GC-FID	mg/ml.	< 0.02
Diethyl Etyher	GC-FID	Shimadzu HS-GC-FID	mg/ml.	< 0.008
Acetone	GC-FID	Shimadzu HS-GC-FID	mg/ml.	< 0.03
Acetonitrile	GC-FID	Shimadzu HS-GC-FID	mg/ml.	< 0.05
Dichloromethane	GC-FID	Shimadzu HS-GC-FID	mg/ml.	< 0.001
n-Hexane	GC-FID	Shimadzu HS-GC-FID	mg/ml.	< 0.02
Ethyl acetate	GC-FID	Shimadzu HS-GC-FID	mg/ml.	< 0.05
Chloroform	GC-FID	Shimadzu HS-GC-FID	mg/ml.	< 0.005
Benzene	GC-FID	Shimadzu HS-GC-FID	mg/ml.	< 0.002
Tetrachloromethane	GC-FID	Shimadzu HS-GC-FID	mg/ml.	< 0.001
1,2-Dichloroethane	GC-FID	Shimadzu HS-GC-FID	mg/ml.	< 0.001
Heptane	GC-FID	Shimadzu HS-GC-FID	mg/ml.	< 0.02
Trichloroethylene	GC-FID	Shimadzu HS-GC-FID	mg/ml.	< 0.02
Toluene	GC-FID	Shimadzu HS-GC-FID	mg/ml.	< 0.002
Xylenes (Total)	GC-FID	Shimadzu HS-GC-FID	mg/ml.	< 0.002

TEST REPORT **REPORT NO.: 20-06-17039**

Part F – Product Quality Chemical Analysis

Sample Reference: Sursol Face Mask Sanitiser Sample.

Method of Analysis: Accelerated Stability Analysis using ComBase Software.

STABILITY TESTING PROGRAMME

Stability Testing was performed to test the Bacterial and Chemical integrity of the finished product. Demonstrating both the absence of Pathogenic bacteria and undesirable Chemical agents in the product are the safest ways of avoiding consumer cases of illness. The finished report may be used as an excellent sales tool as it indicates that the product is shelf stable and free of Pathogenic bacteria for the estimated time.

TESTING REGIME

An initial sample was tested for the following Microbiological Series when the samples were first received. After Microbiological Analysis, the sample was dispatched to the Chemistry Laboratory, where it underwent a series of Chemical contaminant tests, as well as a suite of Physical and Sensory assessments. The remaining samples underwent the same testing regime at agreed time points and the testing programme continued until the product reached the end of its Shelf-Life.

Microbiological	Chemical	Physical	Sensory
Total Aerobic Count @ 22^{o} C	*Hydroxyl Value*	*Water Activity*	*Smell*
Total Aerobic Count @ 37^{o} C	*Peroxide Value*	*pH Value*	*Taste*
Esch. Coli	*Free Fatty Acid*	*Conductivity*	*Texture*
Salmonella spp.	*TBA Rancidity*		*Colour*
Enterobacteriaceae	*TOTOX Value*		
Coagulase (+) Staphylococcus			
Listeria Monocytogenes			
Clostridium Perfringens			
Campylobacter spp.			
Pseudomonas spp.			

STABILITY TEST CONDITIONS

METHODOLOGY:	STABILITY (Ambient)
DATE OF COMMENCEMENT OF TESTING:	18th. June 2020
DATE OF CONCLUSION OF TESTING:	25th. June 2020
DATE OF REPORT:	25th. May 2020
DATA ANALYSIS:	EXCEL 2007 Spreadsheet
TEMPERATURE OF TESTING:	Ambient Temperature.
SAMPLE PREPARATION:	No Preparation.
STABILITY METHOD:	Micro/Rancidity/Chemical
DATE OF SAMPLE:	16th. June 2020
PRODUCT CODE:	BN11428

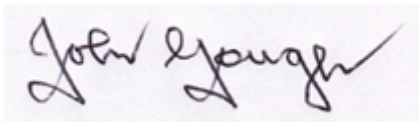
STABILITY CERTIFICATE FOR

Sursol Face Mask Sanitiser

This is to certify that the product

'Sursol Face Mask Sanitiser'

When stored under recommended Ambient conditions and, if the packaging is unopened and undamaged, is guaranteed to have a Stability of 48 months from Date of Production.

Signed :___  _____ Technical Director

JHG Analytical Services Limited

Killowen

Waterford X91 FX50

Republic of Ireland.

Dated: 25th. June 2020

TEST REPORT **REPORT NO.: 20-06-17039**

Part G – Microbiological Challenge Testing

Method of Analysis: Full Microbiological Assessment.

Standard 1: BS EN 1500:2013

DESCRIPTION

This standard BS EN 1500:2013 Chemical disinfectants and antiseptics. Hygienic hand Sanitizers. Test method and requirements is classified in these ICS categories:

71.100.35 Chemicals for industrial and domestic disinfection purposes
11.080.20 Disinfectants and antiseptics

This European Standard specifies a test method simulating practical conditions for establishing whether a product for hygienic hand-rub reduces the release of transient microbial flora on hands when rubbed onto the artificially contaminated hands of volunteers. Attention is drawn to the fact that tests on human volunteers are the subject of legal provisions in certain European countries/regions. This European Standard applies to products for hygienic hand-rub for use in areas and situations where disinfection is medically indicated. Such indications occur in patient care, for example: - in hospitals, in community medical facilities and in dental institutions, - in clinics of schools, of kindergartens and of nursing homes; and may occur in the workplace and in the home. It may also include services such as laundries and kitchens supplying products directly for the patient. EN 14885 specifies in detail the relationship of the various tests to one another and to "use recommendations".

TEST REPORT **REPORT NO.: 20-06-17039**

Part G – Microbiological Challenge Testing

Method of Analysis: Full Microbiological Assessment.

Standard 2: BS EN 1276:2009

DESCRIPTION

Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas.

Chemical disinfectant and antiseptic products that form a homogeneous, physically stable preparation when diluted with hard water or, in the case of ready-to-use products, with water. It applies to products that are used in food, industrial, domestic and institutional areas excluding areas and situations where disinfection is medically indicated and excluding products used on living tissues.

Description of Test

Pseudomonas aeruginosa, Escherichia coli, Staphylococcus aureus and *Enterococcus hirae* are the required test organisms.

A sample of product is added to a test suspension of bacteria in the presence of an interfering substance.

Organisms are exposed to the test solution at 20 ± 1°C for 5 minutes ± 10 seconds

At the end of contact time a portion is withdrawn and the bactericidal action of the test substance is neutralised.

The number of viable bacteria is determined following serial dilution and enumeration on an appropriate agar. The reduction in viability is calculated.

TEST REPORT **REPORT NO.: 20-06-17039**

Part G – Microbiological Challenge Testing

Method of Analysis: Full Microbiological Assessment.

Standard 3: BS EN 13697:2013

EN 13697 is a phase 2 step 2 carrier test performed on surface disinfectants intended for use without mechanical action in the medical area, food, industrial, domestic and institutional areas to test the efficacy of the product against bacteria and/or fungi. Efficacy against bacteria is mandatory for disinfectants in these areas.

The standard refers to the parameters to be observed when testing products intended for surface disinfection without mechanical action. This includes the test microorganism, test temperature, carrier, contact time and interfering substance. Test microorganism refers to the mandatory list of microbes that must be used in the test to determine the antimicrobial activity of the product:
Staphylococcus aureus
Escherichia coli
Escherichia hirae
Pseudomonas aeruginosa

Staphylococcus aureus is a Gram-positive, spherical-shaped, facultative anaerobe. Staphylococcus species are known to demonstrate resistance to antibiotics such as methicillin. S. aureus pathogenicity can range from commensal skin colonization to more severe diseases such as pneumonia and toxic shock syndrome (TSS). S. aureus is commonly used in several test methods as a model for gram positive bacteria. It can be difficult to disinfect but does demonstrate susceptibility to low level disinfectants.

Escherichia coli is a Gram-negative, rod shaped, facultative anaerobe commonly found in the gastrointestinal tract of mammals. Although most serotypes of this microorganism are harmless there are pathogenic groups of E. coli such as enterohemorrhagic (EHEC), verocytotoxin producing (VTEC) and Shiga-like toxin producing (STEC) that can cause a multitude of illnesses. E. coli is relatively susceptible to disinfection when dried on a surface, yet it can be a challenging microorganism to mitigate in solution.

Test microorganisms are prepared in liquid culture medium for bacteria or on agar for fungi. The suspension of test microorganism is standardized, as needed, by dilution in a buffered saline solution. Test and control substances are dispensed in identical volumes to sterile vessels. Independently, Test and Control substances are inoculated with each test microorganism, then mixed and incubated. Control substances are immediately harvested and represent the concentration present at the start of the test, or time zero. At the conclusion of the contact time, a volume of the liquid test solution is harvested and chemically neutralized. Dilutions of the neutralized test solution are assayed using appropriate growth media to determine the surviving microorganisms at the respective contact times. Reductions of microorganisms are calculated by comparing initial microbial concentrations to final microbial concentrations.

TEST REPORT **REPORT NO.: 20-06-17039**

Part G – Microbiological Challenge Testing

Method of Analysis: Full Microbiological Assessment.

Standard 4: EN 14476:2013

This European Standard specifies a test method and the minimum requirements for virucidal activity of chemical disinfectant and antiseptic products that form a homogeneous physically stable preparation when diluted with hard water - or in the case of ready-to-use products, i. e, products that are not diluted when applied,- with water. Products can only be tested at a concentration of 80 % (97 %, with a modified method for special cases) as some dilution is always produced by adding the test organisms and interfering substance.

This European Standard applies to products that are used in the medical area in the fields of hygienic hand-rub, hygienic hand-wash, instrument disinfection by immersion, surface disinfection by wiping, spraying, flooding or other means and textile disinfection.

Th viruses listed are non-enveloped viruses and Enveloped viruses, the non-enveloped variety are more resistant to chemical disinfectants compared to enveloped viruses. Poliovirus is the most resistant among non-enveloped viruses and manufacturers often struggle to attain efficacy against this microorganism. If EN 14476 is performed against all four non-enveloped viruses for a hand product and it passes the test for adenovirus or norovirus but fails against poliovirus, the product is deemed as limited spectrum virucidal or limited virucidal. For a product to be fully virucidal or acknowledged as capable of inactivating all enveloped and non-enveloped viruses, it must be effective against adenovirus, norovirus and poliovirus. Instrument and surface disinfectants intended for the medical area however, must pass the test against all four non-enveloped viruses.

Challenge Micro-Organism	**Exposure (Minutes)**	**Mean Log_{10} Reduction**
Adenovirus (Fully)	60 minutes	4
Norovirus (Fully)	60 minutes	5
Poliovirus (Fully)	60 minutes	5
Parvovirus (Fully)	60 minutes	5
RNA Enveloped Viruses	60 minutes	4
DNA Enveloped Viruses	60 minutes	5

TEST REPORT **REPORT NO.: 20-06-17039**

Part G – Microbiological Challenge Testing

Method of Analysis: Full Microbiological Assessment.

Efficacy Data – In Vitro

This analysis is used to evaluate the antimicrobial effectiveness of the test product using exposure to 30 challenge micro-organism strains. The challenge inoculum is introduced to the test product at time zero. A volume of the sample is placed in neutralizing media for 15 seconds. Standard Plate Count techniques are used to enumerate viable challenge micro-organisms.

Challenge Micro-Organism	Exposure (Minutes)	Mean Log_{10} Reduction
Acinetobacter baumannii	60 minutes	4
Bacteroides fragilis	60 minutes	4
Burkholderia cepacia	60 minutes	4
Campylobacter jejuni	60 minutes	5
Citrobacter freundii	60 minutes	4
Clostridium perfringens	60 minutes	5
Enterobacter areogenes	60 minutes	5
Enterococcus faecalis	60 minutes	4
Enterococcus faecium	60 minutes	5
Escherichia coli	60 minutes	5
Escherichia coli (0157:H7)	60 minutes	4
Haemophilus influenzae	60 minutes	3
Klebsiella pneumoniae	60 minutes	5
Lactobacillus plantarum	60 minutes	4
Listeria moncytogenes	60 minutes	4
Micrococcus luteus	60 minutes	4
Proteus hauseri	60 minutes	5
Pseudomonas aeruginosa	60 minutes	4

Salmonella enteritidis	60 minutes	4
Serratia marcescens	60 minutes	5
Shigella dysenteriae	60 minutes	3
Shigella sonnei	60 minutes	4
Staphylococcus aureus	60 minutes	5
Staphylococcus aureus (MRSA)	60 minutes	5
Staphylococcus epidermidis	60 minutes	5
Staphylococcus haemolyticus	60 minutes	5
Streptococcus pneumoniae	60 minutes	5
Streptococcus pyogenes	60 minutes	4
Yeasts/Molds	60 minutes	
Candida albicans	60 minutes	3
Candida tropicalis	60 minutes	3

Conclusions: Very effective reduction of Gram-Positive and Gram-Negative bacteria and Yeasts/Molds was shown by this sample.

TEST REPORT **REPORT NO.: 20-06-17039**

Part G – Microbiological Challenge Testing

Method of Analysis: Full Microbiological Assessment.

Efficacy Data – In Vivo

This analysis is used to evaluate the antimicrobial effectiveness of the test product using Laboratory Personnel as per methodology specified in the International Standard.

Ten subjects utilized the test product using a Health-Care Personnel Handwash Procedure after exposure to ten consecutive contaminations. Serratia marcescens was the marker organism used for contaminations. The Standard requires products to achieve a minimum of 2 $\log_{10}$ reduction after one application and 3 $\log_{10}$ reduction after 10 applications.

Result 1.

Application No.	Test Product Log_{10} Reduction	Control Product Log_{10} Reduction
1 only	3	3
10 only	5	5

Result 2. (Duplicate)

Application No.	Test Product Log_{10} Reduction	Control Product Log_{10} Reduction
1 only	3	3
10 only	4	5

Result 3. (Triplicate)

Application No.	Test Product Log_{10} Reduction	Control Product Log_{10} Reduction
1 only	3	3
10 only	5	5

TEST REPORT **REPORT NO.: 20-06-17039**

Part H – Physical, Chemical & Technical Properties.

Method of Analysis: Various Analytical Instrumentation.

Physical, Chemical & Technical Properties

Test	Test Method	Result
Colour	Colorimetric	Colourless (<10 APHA)
Odour	Sensory	Neutral
Acidity	Electrometry	<0.25 µeq/g
Alkalinity	Electrometry	<0.10 µeq/g
Rel. Density	Densitometry	1.125
Effect of Light	Spectrometric	None
Effect of Temp.	Visual	92^{o}C B.P.
Effect of Humidity	Visual	None
Emulsifiability	Turbiscan Technology	Low
Re-emulsifiability	Turbiscan Technology	Low
Emulsion Stability	Turbiscan Technology	Good
Dust/Fines	Membrane Filtration	< 0.0003%
Particle Sizing	Malvern Particulates	< 100 particles/ml.
Foaming	Foaming Apparatus	Low
Burning Rate	Pensky Martens Flash Point	
Physical Compatibility	CHG Surgical swab	Compatible
Chemical Compatibility	CHG Surgical swab	Compatible
Glove Compatibility	Latex/Nitrile/Vinyl	Compatible
Dissolution		Full Solubility
Viscosity	Brookfield Digital Viscometer	1.58 mPas @ 20^{o} C.
Surface Tension	Contact Angle Test Measurement	25.5 dynes/cm @25^{o}C
Auto-Ignition Temperature	Setaflash Closed-Cup Apparatus	360^{o}C
Solubility in Water	Saturation concentration Measurement	100% soluble

TEST REPORT **REPORT NO.: 20-06-17039**

Part I – Irritancy Data and Allergy Test Assessment.

Method of Analysis: In Vivo Assessment.

Irritancy Data and Allergy Test Results

Test: Evaluation of skin irritation potential in humans.

Results expressed: On a scale 0 - 4, where Johnson's Baby Oil is used as control value = 0.25.

Result of Hand Sanitizer: 0.58

Conclusion: This product has a low potential for skin irritation and allergic contact dermatitis.

TEST REPORT **REPORT NO.: 20-06-17039**

Assessment Conclusion

All test methods were performed in accordance with the requirements of ISO: IEC 17025.

The test results relate only to the product listed in this report.

Stability of product: This product complies with relevant legal regulations.

Based on the information derived, the Chemical/Microbiological assessment shows the sample to be assessed as Microbiologically safe and free of any forbidden hazardous Chemical components and contaminants.

Having completed and passed this test, Sursol Face Mask Sanitiser Sample from McKlords UK Limited can be labelled as tested to BS.EN 1276:2009, BS.EN 13697 and BS.EN 14476 standards and specifications in support of any claim relating to the test and data reported.

Face Mask Sanitiser Sample Product from McKlords UK Limited possesses maximum antimicrobial effect against all the Gram-positive as well as Gram-negative bacteria used in the assessment. The assessment found this Sanitizer to have an efficacy of not less than 99.99% bacterial and virucidal reduction including corona virus and enveloped virus.

Comment on Results

The test product containing Benzalkonium chloride produced a marked reduction in colony-forming units at each of the 3 time points tested, whereas the comparator containing Alcohol produced less than 1-$\log_{10}$ reduction over the same time. The differences were highly significant.

Analytical Assessor

John Gough B.Sc. M.Sc.

Assessor Credentials

B.Sc (Hons) in Analytical Chemistry with Quality Management.

M.Sc in Environmental Chemistry.

Full Member of Royal Society of Chemistry (RSC).

J.W. GOUGH

_____

Technical Signatory. **Dated: 25th. June 2020**