BRA|CBE|019

Loughborough University

For Health and Safety Unit Use only ASSESSMENT NO.

RISK ASSESSMENT OF WORK WITH BIOLOGICAL MATERIALS

Please note the following before completing this form:

1. University Health and Safety Policy requires that risk assessment of all work with biological materials must be carried out in advance of work commencing. A key requirement of The Control of Substances Hazardous to Health Regulations (COSHH) is to assess the risks associated with any work activity involving the use of biological materials that may contain biological agents.
2. YOU SHOULD COMPLETE ALL OF PART A, THE APPROPRIATE SECTION(S) OF PART B, AND ALL OF PART C. THIS FORM SHOULD BE SUBMITTED TO THE HEALTH AND SAFETY UNIT FOR REVIEW (VIA YOUR DEPARTMENTAL SAFETY OFFICER)
3. It is the responsibility of the Principal Investigator to ensure compliance to these requirements and that this risk assessment remains valid.
4. This risk assessment form **IS NOT** for assessing the risks associated with **Genetically Modified Organism activities**.

Date Submitted:	26/02/2010	Date Approved:	09/03/2010

PART A: Please provide the following general information:

School/Department			
Department of Electronic and Electrical Engineering			
The Project			
Title of Project: **Combating Hospital Acquired Infections with Cold Gas Plasma**			
Project Reference Number: NIHR123 ???			
Person responsible for this work (*Principle Investigator*):			
Name: Professor Michael Kong		Position: Supervisor	
Department: Electronic & Electrical Engineering		University School: Electronic & Electrical Engineering/CBE	
Person conducting this assessment			
Name: Yvonne Sun		Position: Research Associate	
Department:	Electronic & Electrical Engineering	Date Risk Assessment Undertaken:	09.02.2010
Proposed Project Start Date:	01.02.2010	Proposed Project End Date:	31.05.2011

Assessment Review:
required at least once a year or immediately following any significant change to the project

	Review 1	Review 2	Review 3	Review 4	Review 5
Due Date					
Date Conducted					

A1 PROJECT SUMMARY

A1.1 Scientific Goals of the Project *Brief yet clear outline only*

Hospital Acquired Infections (HAI) are resulting in needless deaths and are draining the NHS of precious resources. Deep cleaning interventions are typically conducted periodically and the benefits they bring about are shortlived as re-colonisation by nosocomial bacteria following such campaigns has been shown to be rapid. Therefore, supplementary decontamination methods are required to preserve and enhance the disinfection levels achieved by the current deep cleaning strategy.

Nonthermal gas plasmas, often referred to as 'cold gas plasmas', comprise a mixture of highly reactive ions, atoms and free radicals. The aim of this project is to show the effectiveness of cold gas plasmas in inactivation on a range of microorganisms at different treatment times while no damage caused on human skin cells. To translate the biocidal effects of plasmas into benefits to the NHS, it can constitute a significant addition to current disinfection procedures.

A1.2 Description of the Experimental Procedures

Describe laboratory procedures to be used and highlight any non-standard laboratory operations

Treatment of a range of bacteria and human skin cells with cold atmospheric plasma to look at differences in resistances and changes in cell characterisations by varying plasma treatment conditions. This will involve manipulation of bacterial and cell samples according to the attached protocols and following Standard Operating Procedures.

All procedures will be conducted in accordance with the laboratory Quality Management System (QMS) requirements, Good Aseptic Technique, the local Code of Practice (COP) and the Loughborough University Biological Safety Policy.

PART B: Please provide information in one or more of the following sections, as appropriate. Only sections which you complete should be submitted:

Section 1: *micro-organisms (prions, viruses, bacteria, fungi, parasites in ACDP category 2 and pathogens controlled by the Department for the Environment, Food and Rural Affairs).* ***[Work with ACDP category 3 and 4 pathogens is not currently permitted in the University.]***

Section 2: *cell cultures, tissues, blood, body fluids or excreta*

Section 3: *plants and plant material*

Section 4: *animals and animal tissues*

SECTION 1: MICRO-ORGANISMS

B1.1 HAZARD AND RISK IDENTIFICATION: NATURE OF MICRO-ORGANISMS

*This information gives an indication of the **potential** harm that the biological material may cause*

B1.1.1 List all micro-organisms to be used

Name	Strain	ADCP cat*	Source
Bacillus subtilis	**ATCC6633/NCIMB8054**	1	National culture collection

see The Approved List of Biological Agents – available on the Health & Safety website

B1.1.2 Has any strain been genetically modified in any way?

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	NO
If Yes, complete Genetically Modified Organisms (GMO) Risk Assessment Form	

B1.2 DESCRIPTION OF RISK TO HUMANS

B1.2.1 The disease(s) caused to humans
Describe the type and severity of effects or disease(s) on human health (including colonisation, infection, allergy, toxin-mediated disease) by each of the agents or strains to be used

Indicate in the adjacent box if Not Relevant (N/R)		
Name	Type	Severity
Bacillus subtilis	Non pathogenic	N/R

B1.2.2 What is the likelihood of infection of this material? Indicate as None, Low Risk, Medium Risk, High Risk, Known Infected

Name of agent	Risk Category	Justification for Selection
Bacillus subtilis	None	Non pathogenic
		If none proceed to section B1.3

B1.2.3 Infectivity to humans
Describe ALL the route(s)of infection (relevant to the laboratory setting) and the minimum infectious dose(s) if known (eg percutaneous, mucocutaneous, inhalation, ingestion)

Name of agent(s)	**Route(s) of infection**	**Minimum infectious dose**

B1.2.4 Drug resistance
Is there any known or suspected drug resistance amongst the strains to be used? Identify & describe.

B1.2.5 Attenuation or increased virulence
Are the strains attenuated or do they have an increased virulence in any way?

Identify and describe:

B1.2.6 Ability to survive
In what form is the agent present eg spores or vegetative bacteria, and are there any issues about the agents robustness, including any resistance to chemical disinfectants?

Identify and describe:

B1.2.7 Most hazardous procedure?
Identify and describe the most hazardous procedure(s) to be used.

B1.3 HUMANS AT INCREASED RISK OF INFECTION

B1.3.1 Are there any pre-existing medical conditions that increase the risk associated with this agents listed in section 1.1 (including immunocompromised workers, pregnant workers, breast feeding mothers, diabetic workers)?

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	NO
If yes, Occupational Health must be consulted:	

B1.4. PROPAGATION OR CONCENTRATION OF ADVENTITIOUS AGENTS

B1.4.1 Give details of the volumes and concentrations of organisms to be used

Name & Strain	Volume	Concentration
Bacillus subtilis	1 ml filtered onto membranes 30 membranes maximum	1 E+9 CFU/ml

B1.5 ENVIRONMENTAL CONSIDERATIONS:

B1.5.1 Are any of the agents capable of causing disease or other harm in animals, fish or plants?

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	NO
If yes, describe briefly here (A separate risk assessment may be required if the agent to be used poses a significant risk to the environment):	

B1.5.2 Will there be any other environmental risks?

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	NO
If yes, describe briefly here (NOTE: A separate risk assessment may be required if the agent to be used poses a significant risk to the environment):	

B1.6 OTHER HAZARDS

B1.6.1 Are there any other hazards associated with this work? For example, hazardous chemicals, cryogenic gases ionising radiation.

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	YES
If yes, identify these: Plasma produces an ionised gas, UV radiation, radicals. Procedures described in SOP062-071.	
If yes, have these been risk assessed and any necessary approval obtained? Yes. This has been reviewed by the CBE Area Safety Advisor (Bob Temple). Reference to be assigned.	

SECTION 2: CELL CULTURES, TISSUES, BLOOD, BODY FLUIDS OR EXCRETA

B2.1 HAZARD AND RISK IDENTIFICATION: NATURE OF CELLS, TISSUES OR BODY FLUIDS

*This information gives an indication of the **potential** harm that the biological material may cause*

B2.1.1 List all cells or tissues to be used. *For cells indicate if primary, continuous or finite.*

Indicate in the adjacent box if Not Relevant (N/R)			
Cell or tissue type and ID	Organ Source	Species	From where will it be obtained?
PCS-201-012 Fibroblasts (primary)	Skin	Human	ATCC
PCS-200-011 Keratocytes (primary)	Skin	Human	ATCC

B2.1.2 List all blood, body fluids or excreta to be used

Indicate in the adjacent box if Not Relevant (N/R)			N/R
Material type and ID	Organ Source	Species	From where will it be obtained?

B2.1.3 Has any material listed in section B2.1.1 been genetically modified in any way?

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	NO
If Yes, complete Genetically Modified Organisms (GMO) Risk Assessment Form	

B2.1.4 Will material be screened for infectious agents (if from a cell culture collection answer B2.1.6)?

Indicate in the adjacent box as: Yes, No or Not Relevant (N/R)	NO
If Yes, provide details of the types of screening and agents screened for:	

B2.1.5 Will any clinical history (if relevant) be provided with this material?

Indicate in the adjacent box as: Yes, No or Not Relevant (N/R)	NO
If yes give details:	
If yes, will a policy of rejection of samples from diseased patients be adopted? Explain	
If yes, how will the information be disseminated in the course of the project?	
If yes, will this information be anonomised?	

B2.1.6 If obtained from a cell culture collection, is safety information provided?

Indicate in the adjacent box as: Yes, No or Not Relevant (N/R)	YES
If Yes, summarise here: Material Safety Data Sheets for these cells are attached. These cells are classified by ATCC as Biosafety level 1 (BSL-1) and they are non-hazardous, non-infecticious.	

B2.2 RISK TO HUMANS

B2.2.1 What is the likelihood of infection of this material? Indicate as None, Low Risk, Medium Risk, High Risk, Known Infected*

Cell type and ID	Risk Category	Justification for Selection
PCS-201-012 Fibroblasts	None	Non pathogenic
PCS-200-011 Keratocytes	None	Non pathogenic
		If low risk or none proceed to section B2.2.4

see The Managing the risks in laboratories and healthcare premises – available at
http://www.hse.gov.uk/biosafety/biologagents.pdf

B2.2.2 If medium or high risk (section B2.2.1), name and classify the Biological Agents this material could be infected with. List the biological agents and indicate the ACDP hazard group classification*

Name of Agent	Classification

see The Approved List of Biological Agents – available on the Health & Safety website or
http://www.hse.gov.uk/pubns/misc208.pdf.

B2.2.3 Describe the routes of infection (in humans) for these adventitious agents (place a 'X' in the relevant box)

Percutaneous	Mucocutaneous	Inhalation	Ingestion	N/R
				X
Details:				

B2.2.4 Are there any other biological hazards (other than adventitious infectious risk) associated with the materials e.g. tumourogenic cells

Indicate in the adjacent box as: Yes, No or Not Relevant (N/R)	NO
If Yes, describe:	

B2.3 HUMANS AT INCREASED RISK OF INFECTION

B2.3.1 Do any of the agents listed in section 2.1 present an overt risk to humans at increased risk (including immunocompromised workers, pregnant workers, breast feeding mothers)?

Indicate in the adjacent box as: Yes, No or Not Relevant (N/R)	NO
If yes, Occupational Health must be consulted:	

B2.4. PROPAGATION OR CONCENTRATION OF ADVENTITIOUS AGENTS

B2.4.1 Will any culturing of this material take place?

Indicate in the adjacent box as: Yes, No or Not Relevant (N/R)	YES
If yes, identify the cells and the conditions these will grow: Cells are cultured in growth medium and are adhered to petri dishes at appropriate concentration, then cells are incubated at static incubator at 37°C, 5% CO_2.	

B2.4.2 If culturing, will CD4+ cells be present. Describe what cells and for how long these cultures will be allowed to grow

Indicate in the adjacent box as: Yes, No or Not Relevant (N/R)	NO
If yes, explain:	

B2.4.3 If culturing, what is the maximum volume of culture grown?

Indicate in the adjacent box if Not Relevant (N/R)	
Per Flask $1x10^7$ cells	Per experiment 10-20 petri dishes

B2.4.4 Will the cells be manipulated in any way that could result in a concentration of any adventitious biological agent present?

Indicate in the adjacent box as: Yes, No or Not Relevant (N/R)	NO
If yes, explain:	

B2.5 WORKING WITH MATERIAL DONATED BY YOURSELF OR COLLEAGUES : Persons MUST NOT work with their own cells.

B2.5.1 Will any cells be donated by persons working in or has access to the lab?

Indicate in the adjacent box as: Yes, No or Not Relevant (N/R)	NO
If yes, explain what precautions are to be taken to prevent that person being exposed to the cells:	
If yes, where will this material be collected:	
If yes, provide justification for not using a safer source:	
If yes, how will confidentiality be assured:	
If yes, has Ethics Committee approval been obtained:	

B2.6 ENVIRONMENTAL CONSIDERATIONS:

B2.6.1 Are any of the agents capable of causing disease or other harm in animals, fish or plants?

Indicate in the adjacent box as: Yes, No or Not Relevant (N/R)	NO
If yes, describe:	

B2.6.2 Will there be any other environmental risks?

Indicate in the adjacent box as: Yes, No or Not Relevant (N/R)	NO
If yes, describe:	

B2.7 OTHER HAZARDS

B2.7.1 Are there any other hazards associated with this work? For example, hazardous chemicals, cryogenic gases ionising radiation.

Indicate in the adjacent box as: Yes, No or Not Relevant (N/R)	YES
If yes, identify these: Liquid Nitrogen, Trypan Blue, Virkon, DMSO (these will be separately assessed by COSHH and approval obtained before they are used) Plasma produces an ionised gas, UV radiation, radicals.	
If yes, have these been risk assessed and any necessary approval obtained? Use and Maintenance of Liquid Nitrogen Stores refers to SOP013 Safe handling and disposal of Trypan Blue refers to SOP029 Selection and Use of Virkon Disinfectant refers to SOP006 Safe handling of plasma source described in SOP062,071 (reviewed by the CBE Area Safety Advisor, Bob Temple. Reference to be assigned)	

PART C: CONTROL MEASURES

C1. CONTROL MEASURES

The risk of exposure must be prevented or adequately controlled to minimise the chance of harm arising. COSHH Regulations require minimum containment measures for laboratories handling organisms from the different ACDP hazard groups (http://www.hse.gov.uk/pubns/misc208.pdf)
The hazard group number typically indicates the level of containment (includes physical measures & working practices) that must be used for its handling).

C1.1 Preventing Exposure

C1.1.1 Substitution with a Safer Alternative

Is substitution with a safer alternative practical, by for example, replacement of a clinical strain or pathogen with one that is lab adapted? Provide reasons for your answer:

The micro-organisms (*Bacillus subtilis*) and cells (*PCS-201-012 and PCS-200-011*) are all non- pathogenic, so there is no need for substitution.

C1.1.2 Isolation/Segregation

(i) Is/Are the laboratory(s) to be used for this work to be shared with other workers not directly involved in this activity?

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	YES
If yes, provide details: Access to the Containment Level 2 CBE Laboratory Unit is restricted to authorised laboratory workers with appropriate training in accordance with documented local Code of Practice (COP) and Quality Management System (QMS) requirements for Containment Level 2 work activities involving biological materials. The laboratories are locked at all times outside of normal working hours to ensure safe storage of biological agents and unauthorised entry. Keys to the laboratories are only issued to authorised users. Access is also restricted to the building (swipe card) and CBE (key entrance) during normal working hours. Out of Hours/Lone working is logged and permitted subject to risk assessment. No cleaning personnel are permitted in the CBE Laboratory Unit. Access by other Non-Laboratory or maintenance personnel is subject to risk assessment and Permit-to-Work system documented in the local COP.	

(ii) Is access to the laboratory(s) to be used for this work restricted?

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	YES
If yes, provide details: Access is restricted to people with documented training (authorised access documented in each individual's training record) in accordance with the COP and QMS (see C1.1.2).	

C1.2 Controlling Exposure

C1.2.1 Are sharps (needles, blades, scissors, forceps, glass or capillary tubes) to be used at any stage during this activity?

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	YES

If yes, list the sharps:
Forceps, Glass universal bottles, Haemocytometers

If yes, justify there use – is there an alternative?:
It is local practice in the CBE laboratory unit that the use of sharps is avoided wherever possible. Glass items are replaced with plastic alternatives where possible, however the use of glass universal bottles and haemocytometers are necessary for this protocol.

If yes, describe there use and disposal:
Forceps will be used for transferring treated membranes into sterile universal bottles containing 10ml buffer (PBS). Universals are glass bottles used for the suspension of bacteria from the membranes after plasma treatment. Forceps are reusable and are decontaminated using 1% Virkon after use. All bottles will be transferred in secure containers out of the CBE (see C1.2.4). Haemocytometers will be used for cell counting and viability assessment (refer to SOP033-034). If any bottles, haemocytometers or coverslips are chipped, cracked or broken (see below), these are placed directly into a sharps containers conforming to BS 7320. Sharps bins are removed when three quarters full and contents rendered safe by autoclaving prior to their removal from site.

If yes, describe any additional precautions employed to reduce risk:

In order to minimise the likelihood of accidents arising as a result of poor working practices and to take the correct action in the event of any accident that may occur, all individuals using sharps are aware of, and must use, guidance detailed in the local CBE CoP.

Injuries from broken glass are avoided by ensuring (i) glassware is in good condition (without chips or cracks) before use, (ii) glass items are carried in a box or similar to minimise the risk of dropping them (iii) have a sharps bin available at the point of use to enable immediate disposal (iv) a procedure is in place for reporting, recording and follow up of all accidents and incidents involving sharps. Accident procedures for sharps and glass injuries are displayed in posters in all laboratories within the Unit (v) Specific procedures for handling contaminated broken glass are detailed in SOPs (SOP038 – Biological spill response).

C1.2.2 Containment and Ventilation

(i) Is the use of BSC required for the protection of the worker ie do the work procedures generate aerosols or splashes that pose a risk to workers?

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	YES

If yes, specify the type(s) and when they will be used:

A Class II Biological Safety Cabinet (located in Laboratory H29) will be used for all manipulations that may produce aerosols or splashes of Hazard Group (HG) 1 and 2 Biological Agents (BAs). Procedures to be carried according to SOP009, "Use and Maintenance of HERASAFE KS Class II BSC". This engineering control measure is specifically to protect the worker (when handling HG2 BAs) and ensure protection of research materials as part of a quality assurance discipline (when handling both HG1 and 2 BAs).

Samples of microbial and human skin cells for plasma treatment will be prepared as described by the protocol in the attached document. Plasma treatment of bacteria and human skin cells will occur in a specially designated Class II BSC in room H29 according to the following SOPs:

1) SOP062, "Use and Maintenance of Plasma Source System"
2) SOP071, "Use and Maintenance of Plasma Rig

(ii) Are there any requirements for room ventilation e.g. negative pressure, temperature control?

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	NO

If yes, specify:

C1.2.3 Transport and Storage within the laboratory

How and where are materials to be stored?

Primary cells are stored in liquid nitrogen and are cultured in static incubator while microbial cells are stored in fridge and are cultured in static/shaking incubator for the purposes of this experiment.

How will this material be transported within the laboratory e.g. between BSC and incubator? Detail the containment measures which will be used to prevent or contain accidental splashes or spills.

Bottles and Petri dishes that contain bacterial or cell culture will be secured in racks or sealed bags which will be placed inside secondary containers with a lid to contain spills from leaking or broken vessels. These will be transported and handled according to the following SOPs:

1) SOP005, "Storage and transport of Biological Materials"
2) SOP038, "Biological spill response"

C1.2.4 Local transport out of the laboratory

How will this material be transported on-site (e.g. research material between labs on campus or movement of waste containing viable agents e.g. to a remote autoclave? Detail the containment measures which will be used to prevent or contain accidental splashes or spills

Transfer into and out of the CBE Laboratory Unit is avoided wherever possible. If the transport is constrained within the University site. Material will be transferred into the Autoclave Room (H31) where the containment package will be decontaminated before transporting to other rooms. All transport will be subject to controlled procedures according to the local CoP and SOP005. Transport of research material between laboratories is done using sealed containers which are put into tube racks and trays and transported using trolleys according to the following SOPs. Waste potentially containing viable agents is not removed from the laboratories until it has been autoclaved.

1) SOP003, "Disposal of Biological Waste"
2) SOP005, "Storage and Transport of Biological Material"
3) SOP038, "Biological Spill Response"

C1.2.5 Shipment of Biological Material

Will this material be shipped elsewhere in the UK or abroad?

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	NO

If yes, give details to support compliance to the relevant regulation (e.g. category of material, correct packaging instruction):

C1.2.6 Receipt of material

If material will be received from other sites or organisations, what precautions are being taken to ensure that the material is shipped correctly?

Before accepting the package, receiving should examine the shipment for the following:

1) Integrity of the packaging - inspecting it for leakage, indicated by broken or improperly sealed containers or any other damage. Leaking or damaged packages must NOT be accepted. If evidence of leakage is found subsequent to acceptance, receiving personnel should:
   a) Not handle the package. It should only be handled by personnel trained in spill clean-up procedures and wearing appropriate personal protective equipment
   b) Isolate the area around the package
   c) Notify the recipients and the Area Safety Advisor
2) Proper paperwork and labelling: The label and accompanying documentation should be examined and this information given to the Laboratory Manager, the recipient or other designated personnel.
3) The package should be checked to ensure that its identity (product code and batch number) is the same as that on associated documentation.

Once accepted, receiver must place all packages in quarantine until identified, checked and logged in as described in this SOP by both the receiver and the recipient (see below). Samples arriving on ice, dry ice or labelled to require cold storage must be dealt with immediately.

Wear Personal Protective Equipment (PPE) including gloves, lab coat, and eye protection when opening packages containing potentially hazardous substances. Consult Risk assessment and COSHH forms for requirement for special precautions.

Have spill kit readily available to use in the event that a primary sample container is found damaged.

All procedures are detailed in the following SOPs:

1) SOP008, "Receipt of Hazardous Biological Material"
2) SOP042, "Receipt and Purchase of Chemicals and Solvents"

C1.2.7 Centrifugation

(i) If material is to be centrifuged will sealed buckets and rotors be used?	
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	YES

(ii) Where will these rotors/buckets be opened?

When the selected program has finished or in emergent event (follow the emergency stop procedure in SOP015), after the rotors has stopped, swivel the hand grip on the cover upwards, open the lid carefully and remove the buckets or rotor and transfer to the BSC. Spray and wipe external surfaces with a 1% solution of Virkon before moving to the BSC. Carefully open the sealed buckets or sealed rotor inside the BSC. All manipulation are referring to SOP015, "Use and Maintenance Of BOECO U-32R Bench Top Centrifuge".

(iii)Describe the procedures in place to deal with leaks and spillages in the centrifuge

Procedures for dealing with leaks and spillages are detailed in SOP015, "Use and Maintenance Of BOECO U-32R Bench Top Centrifuge".

C1.2.8 Incubators

If incubators are to be used, what type of incubator (e.g. shaking, static) is used and describe procedures to prevent and contain spillages.

Primary cells are cultured in static incubator (located in animal cell laboratory H25) while microbial cells are cultured in static/shaking incubator for the purposes of this experiment.
All procedures for dealing with the spillages are detailed in the following SOPs:

3) SOP079, "Use and Maintenance of the Heracell CO2 Incubator"
4) SOP038, "Biological Spill Response"

C1.2.9 Disinfection

Specify the type and concentration of disinfectants to be used:

The disinfectants were carefully chosen for effectiveness in use. The number of disinfectants in use is strictly limited to avoid errors and ambiguities in use and accidental mixing of compounds that may give rise to hazardous reactions or the formation of toxic products. Unless there are compelling reasons to do otherwise, Virkon (1% w/v) is the sole disinfectant used in the CBE Laboratory Unit other than 70% IMS which is used for general disinfection cleaning (SOP004) where Virkon cannot be used; for example stainless steel surfaces.

Virkon has a wide range of bactericidal, virucidal, fungicidal and sporocidal activities. Representative viruses from all the major virus families are inactivated by Virkon. Working solutions of 1% w/v have low toxicity and no irritancy. Selection and procedures detailed in the following SOPs:

1) SOP004, "General Laboratory Housekeeping"
2) SOP006, "Selection and Use of Virkon Disinfectant"
3) SOP039, "Storage, Handling and Disposal of Chemicals"

COSHH Risk Assessment reference for Virkon SAF/MM/1745

Have these disinfectants been validated for use with the recipient biological material?	
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	YES

If yes, describe the procedure:

For Hazard Group 1 and 2 Biological Agents it is normally sufficient to rely on the manufacturer's data, providing the recommended concentrations and contact times are used. Hence Virkon (1%) is used as per manufacturers instruction and according to standard procedures detailed in the following SOP:

1) SOP006, "Selection and Use of Virkon Disinfectant"

Further supporting evidence is provided in the following reference: Walker, A.J. et al. Letters in applied microbiology 15 (2): pg 80 (1992)

C1.2.10 Personal Protective Equipment (PPE)

(i) What type of lab coats will be worn and where will they be stored?
Side fastening Howie type lab coats are worn at all times within the Laboratory. They are stored outside the laboratory where the work will take place. Proper use of PPE is described in the following SOP:

1) SOP037, "Use of Personal Protective Equipment (PPE)"

(ii) What type of gloves will be worn and where will they be stored?

1. Autoclave gloves - stored in close proximity to the autoclave equipment in the Autoclave Room (H31)
2. Latex powder free gloves for general use - stored in the change rooms and/or point of entry to each laboratory within the CBE Laboratory Unit.

Correct use of PPE is described in SOP037, "Use of Personal Protective Equipment (PPE)

(iii) Describe any other PPE to be used:
1. Laboratory safety glasses (including those for spectacle wearers) 2. Face masks, in case of aerosol generation during plasma treatment. 3. Shoe protection for moving heavy equipment (if necessary) Correct use of the above PPE is described in SOP037, "Use of Personal Protective Equipment (PPE)"

C1.2.11 Hygiene Measures

Describe the hygiene facilities available and where they are located
1. Designated hand washing facilities are located in each laboratory change room and in the Analytical Laboratory (H23). The nearest hand washing facilities to H29 are located in H26. This is signposted on the wall in in H29. 2. Eye Wash stations are located next to each 'hand washing only' sink in each laboratory change room and in the Analytical Laboratory (H23). The nearest eye wash stations to H29 are located in H26. This is signposted on the wall in H29.

C1.2.12 Vaccination

Are effective vaccines available against any of the agents listed in Section1, 2, 3, or 4 of Part B?	
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	NO
If yes, describe:	

C1.2.13 Waste Treatment before Disposal

How must waste to be treated before disposal and how has it been validated as being effective?		
	Treatment before disposal	Validation
Liquid waste	Virkon sterilise (SOP003 – Disposal of biological waste)	According to manufacturers instructions; see section C2.1.9
Solid waste	Autoclave sterilise (SOP003 – disposal and disinfection of biological waste)	Treatment Cycle validated according to SOP024 & 025, " Use and maintenance of the Systec VX95 Autoclave No CBE44 and CBE 45"

C1.2.14 Autoclave sterilisation

If waste is treated by autoclave sterilisation then this section must be completed. If this section is not relevant then hatch the box			
	Type of waste	*Autoclave cycle (temp, cycle time)*	*Treatment monitor*
Liquid waste	*None*	*N/R*	*N/R*
Solid waste	Petri dishes with thin agar slabs	*121˚C for 20 min sterilisation time*	*Internal temperature probe to measure inside the container holding the solid waste being decontaminated.* Designated autoclave tape monitors
Location of autoclave	*Servicing details*	*Location of back-up autoclave*	*Designated area for storage of unsterilised waste*
Autoclave Room H31	Annual	H31 and H22	In secure cage within the Autoclave Room (H31)

C1.2.15 Liquid Waste Disposal

How will liquid waste be disposed of?
Before disposal, virkon will be used for disinfection (SOP003 – Disposal of biological waste).
As solid waste? N/R
Other? NONE

C1.2.16 Solid Waste Disposal

Describe the waste category and disposal route. *(For guidance refer* to http://www.environment-agency.gov.uk)

European Waste Catalogue Code	Categorisation		Disposal Method
		Hatch relevant box(es)	
18 01 01	Sharps	X	Sharps bin>autoclave sterilisation if known or potentially infected >clinical waste disposal (incineration)
18 01 02 [human]	Human body parts, organs, including blood bags and blood preserves and excreta (unless identified as medium or high risk or known infected in Section 2.16 of this RA in which case they must be pre-treated before disposal and classified 18 01 04 [sealed bins])		Rigid one way sealed tissue bins>incineration only
18 01 02 [animal]	Animal body carcases or recognisable parts ((unless identified as medium or high risk or known infected in Section 2.16 of this RA in which case they must be pre-treated before disposal and classified 18 01 04 [sealed bins])		Rigid one way sealed tissue bins > incineration only
18 01 03	Potentially or known infected lab wastes (including sharps) of HG2, GM Class 2, DEFRA Cat 2 or higher, that have not been pre-treated before leaving the site.		This is not a route of preference and is subject to special requirements
18 01 04 [bags]	Infected or potentially infected lab wastes that have been pre treated before leaving the site	X	Disinfection or sterilisation (as identified in C1.2.13) in the lab suite > placement in yellow clinical waste bags > clinical waste disposal (incineration)
18 01 04 [sealed bins]	Infected or potentially infected animal or human body parts, organs or excreta that have been pre treated before leaving site		Disinfection or sterilisation (as identified in C1.2.13) in the lab suite > placement in yellow one way sealed tissue bins > incineration)

C1.2.17 Work with Animals or Vectors (if none proceed to Section C1.2.18)

(i) Are animals or vectors to be infected with any of these biological agents?	
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	N/R
If yes, describe the procedure and describe where this aspect of the work will be conducted:	
(ii) Is shedding of infectious materials by the infected animals possible or expected?	
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	N/R

If yes, describe the routes of shedding, risk periods for such shedding and the additional precautions required to control exposure:
(iii) Who will perform the inoculations of animals/vectors? What training have they received?
Indicate in the adjacent box if Not Relevant (N/R) | N/R
Provide details of the training required:

C1.2.18 Bioreactor/Fermenters (if none proceed to Section C1.2.19)

Will a fermenter be used to culture a pathogen?
Indicate in the adjacent box as No, Yes or Not Relevant (N/R) | N/R
If yes, describe the size, and type of the fermenter.
(ii) Are any supplementary containment measures required, for example, the use of a BSC or spill tray.
Indicate in the adjacent box as No, Yes or Not Relevant (N/R) | N/R
If yes, describe:

C1.2.19 Other Control Measures Required?

NONE

C1.3 Emergency Procedures

C1.3.1 Describe the procedures in place for dealing with spillages *(specify disinfectants and any special containment for large volumes)*

Within the BSC:
Procedures for dealing with small and large spillages are detailed in the following SOPs:

1) SOP006, "Selection and use of Virkon Disinfectant"
2) SOP009, "Use and Maintenance of HERASAFE KS Class II BSC"
3) SOP038, "Biological Spill Response"

Labelled Biological Spill kits are located in each laboratory change room within the CBE Laboratory Unit. The nearest biological spill kit for use in H29 is located in H26. Signs are posted throughout the Laboratory Unit to enable workers to locate the nearest biological (and chemical) spill kits. Posters are also displayed in each laboratory within the Unit where a BSC is located to advise on spill response (inside the BSC) and reporting procedures.

Within the laboratory but outside the control measure e.g. BSC, spill tray
Procedures for dealing with small and large spillages are detailed in the following SOPs:

1) SOP006, "Selection and use of Virkon Disinfectant"
2) SOP038, "Biological Spill Response"

Labelled Biological Spill kits are located in each laboratory change room within the CBE Laboratory Unit. Signs are posted throughout the Laboratory Unit to enable workers to locate the nearest biological (and chemical) spill kits. Posters are also displayed in each laboratory within the Unit to advise on spill response (outside the BSC) and reporting procedures

Outside the laboratory e.g. during transport
Procedures for dealing with small and large spillages are detailed in the COP and the following SOPs:

1) SOP005, "Storage and Transport of Biological Material"
2) SOP006, "Selection and use of Virkon Disinfectant"
3) SOP038, "Biological Spill Response

Describe the procedures in place for an accidental exposure (if necessary describe different procedures for different types of exposure e.g. eye splash or percutaneous inoculation)

1. Procedures to respond to accidental exposure are detailed in SOP038, "Biological Spill Response" and the local COP. These are detailed in spill response posters located in each laboratory within the Unit. Accident procedures in the case of glass or sharps injury are described in the local COP and displayed in posters located in each laboratory within the Unit
2. Designated hand washing facilities are located in each laboratory change room and in the Analytical Laboratory (H23). Signs are posted in H29 and H30 to enable workers to locate the nearest hand wash facility.
3. Eye Wash stations are located next to each 'hand washing only' sink in each laboratory change room and in the Analytical Laboratory (H23). Signs are posted in H29 and H30 to enable workers to locate the nearest eye wash station.
4. A First Aid Kit is located outside the Laboratory Unit. Signs are posted throughout the Laboratory Unit to enable workers to locate the nearest Medical Kit. Contact details for First Aiders are posted in each laboratory within the Unit

Essential and Emergency Contact details are posted in each laboratory within the Unit.

C2 ASSIGNMENT OF CONTAINMENT LEVEL

The laboratory Containment Level is directly related to each of the 4 Hazard Groups; organisms categorised as HG1 (lowest hazard rating) should normally be handled in CL1 facilities (minimum level of containment), and likewise up to HG4 (highest hazard rating) in CL4 facilities (maximum level of containment). Where the identity or presence of a biological agent is not known the following rules apply: a) where uncertainty exists over the presence of pathogenic biological agent – minimum of CL2; b) where the presence of a pathogenic biological agent is known or suspected – minimum of Containment Level appropriate to the agent, where the assessment is inconclusive but where the activity might involve serious risk – minimum CL3

C2.1. What containment level is required for this work?

All procedures will be carried out under Containment level 2 (CL2) within the CL2 CBE Laboratory Unit. The work activities within this project involve biological agents (BAs) assessed as Hazard Group 1 but work will be carried out under the management standards imposed by the higher level (Containment level 2). This is for reasons other than worker protection; this includes the need to ensure research material protection (e.g. the use of a class II safety cabinet) and to impose a quality assurance discipline.

C2.2. Describe extra controls or derogation from certain controls
:

NONE

C3 FACILITIES

C3.1 Where will this work take place?

Room(s)	Building	Campus	Person in Control of area
CBE Laboratory Unit; Rooms H25, 27 and 29	Centre for Biological Engineering	Holywell Park campus	Professor Chris Hewitt Carolyn Kavanagh Bob Temple

C4 PERSONNEL

C4.1 Names of Personnel involved in the Project

Surname	Initials	ID	Position
Sun	Y	5014737	Research Associate

C4.2 Information, Instruction and Training

Describe the training that will be given to all those affected (directly or indirectly) by the work activity. Instruction should include the 'Local Rules' or 'Local Codes of Practice' which focus on the working instructions to be followed by all persons involved in the work activity to control or prevent exposure to hazardous biological agent(s). These should be written and readily available to all workers working at Containment Level 2. A formal record of training should be kept for all individuals working at Containment Level 2.

Formal records of training are kept for all workers authorised to work at Containment Level 2 (CL2) within the CBE CL2 Laboratory Unit. Instruction against local Code of Practice and QMS i.e. SOPs is provided to all authorised personnel. Include specific documented training where necessary ie use and maintenance of the Plasma Source (SOP071).

C4.3 Relevant Experience/Training:

Surname	Experience/Training
Sun	Documented in Personal Training file available for review in CBE office

C4.4 Other people who may be at risk from the activity e.g. cleaners, maintenance workers or other workers in shared laboratory

Details:

NONE: Cleaners and Maintenance workers are not authorised to enter the laboratory. All laboratory cleaning is undertaken by authorised personnel (i.e. CBE staff). Access for non-laboratory workers is subject to local permit-to-work procedures. If access is needed for essential maintenance of equipment for example a clean down and decontamination of the laboratories will be performed. This will be documented with decontamination certificates and the maintenance worker fully supervised according to SOP004; "General Laboratory Housekeeping" and the local Code of Practice. Two laboratory shut downs occur every year for a week for maintenance work to be done in the CBE Laboratory Unit. Prior to these shut down weeks a full deep clean decontamination will be performed in the all laboratory areas.

C5 OCCUPATIONAL HEALTH

C5.1 Vaccination

Is an effective vaccination available for any of the pathogens associated with this work? Advice can be obtained from the Occupational Health Adviser if required. All workers involved with handling unscreened blood, blood products and other tissues are recommended to have Hepatitis B immunization

Blood test and Hep B vaccination (if required) will be arranged by Wendy Jones in Occupational Health.

C5.2 Health Surveillance

Is health surveillance required? (Health surveillance is typically applied if working with a hazardous substance that: a) produces an identifiable disease or adverse health effect that can be related to exposure; b) there is a reasonable likelihood that the disease or effect may occur under the conditions of work, and c) there are valid techniques for detecting indications of the disease or effect).

University forms submitted.

C6. NOTIFICATIONS: Human Tissue Act

C6.1.1 Relevant material covered by the Human Tissue Act

Are any of the cell, tissues or fluids to be used covered by the Human Tissue Act?	
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	N/R

C6.1.2 Does This Work Have Ethical Approval? If Yes, Provide Details

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	N/R
Approval number:	
Date obtained:	Ethics committee name:

C6.1.3 Are other registrations/notifications required for this work? For example HSE notification under COSHH, Home Office notification under anti-terrorism, crime and security act etc

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	N/R
If Yes, give details:	

7. LICENSING REQUIREMENTS FOR ANIMAL PRODUCTS

C7.1.1 Are there any licensing requirements for this work?

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	N/R

NOTE: The regulations covering the import of animal products (including tissue cultures, tissues, body fluids or fractions thereof) are in a state of flux. See the DEFRA website for details.

UNLESS THIS SECTION IS NOT RELEVANT (N/R) ie THE INTENDED WORK DOES NOT USE ANIMAL PRODUCTS - CONSULT THE LU H&S OFFICE TO REVIEW APPLICATION REQUIREMENTS BEFORE ANY SUBMISSIONS

8. DECLARATION

*The declaration must be signed **before** submitting this assessment to the Departmental Safety Officer and University Biological Safety Officer*

I, the undersigned:

- confirm that all information contained in this assessment is correct and up to date
- will ensure that **suitable and sufficient instruction, information and supervision** is provided for all individuals working on the activity
- will ensure that no work will be carried out until this **assessment has been completed and approved** and that all necessary control measures are in place
- accept that for some Containment Level 2 and all CL3 activities **a statutory notification period of 20 days** may be required before work can commence
- that all information contained in this assessment must remain correct and up to date (the assessment should be **reviewed once a year** and whenever any **significant changes** to the work activity occur)
- will re-submit the assessment for approval if any significant changes occur

Name: Person conducting assessment	**Signature**	**Date**
Yvonne Sun	Yvonne Sun	**26-Feb-2010**
Name: Other signature (s) (if required – please state position)		
Paul Hourd (CBE QM)	Paul Hourd	01/03/10.
Name: Principal Investigator	**Signature**	**Date**
Prof. Michael Kong	M Kong	03/03/10.

9.APPROVAL		
Name: Departmental Safety Officer	**Signature**	**Date**
Name: University Biological Safety Officer	**Signature**	**Date**
C. J. Hewitt.	C Hewitt	9/3/10.

Protocol

Part A: Microbial Work

1. ***B.subtilis*** is the micro-organisms that will be used. These micro organisms are classed as a hazard group 1, which is a biological agent unlikely to cause human disease.
2. They will be vacuum filtered on to pre-sterilised membranes producing a total population of $1x10^9$ CFUs maximum on each membrane.
3. Each membrane containing the bacteria or spores is placed onto thin slabs of agar (technical agar no. 3) in small Petri dishes (~55m diameter) to fix down the membrane and left to dry for 60mins.
4. Each Petri dish containing bacterial or spore deposit are covered with the Petri dish lid then sealed with parafilm.
5. All sealed Petri dishes are placed inside Petri dish bags which are taped shut with autoclave tape. The Petri dish bags are then sprayed down with 70%IMS and placed inside a leak proof secondary sealable container that has been previously disinfected with 1% virkon and 70% IMS.
6. The secondary container is transported from H27 Microbial Culture Lab to H29 Biophotonics Lab by hand (according to procedures detailed in SOP005).
7. Universal bottles containing 10ml PBS which are used to resuspend the bacteria after plasma treatment are also transported to H29 Biophotonics Lab. The bottles will be placed in racks to keep them upright and stop the bottles banging together.
8. The **plasma rig (see procedures detailed in attached separated protocol)** is set up inside the BioSafety Class II Cabinet (Refer to SOP009 for using the safety cabinet correctly). All plasma rig parts that will go inside the BSC are to be sprayed down with 70% IMS and left for the detergent to completely dry off before placing inside the BSC.
9. The Petri dish bags are removed from the secondary container (outside the BSC). The sealed Petri dish samples to be treated are removed from the Petri dish bags and placed inside the safety cabinet.
10. Parafilm seals and Petri dish lids are removed inside the BSC just before plasma treatment in order to minimise exposure of the membranes to any outside cross contamination.
11. NOTE: Placing the plasma rig inside the safety cabinet for the plasma treatment may disrupt air flow inside the safety cabinet and may therefore compromise worker protection. However, samples containing HG1 biological agents are unlikely to cause human disease and minimal manipulation of the samples inside the BSC will minimise the likelihood of aerosols or splashes. The BSC will still offer some protection to both the worker and the work.
12. After completion of the plasma treatment the membranes are aseptically removed from the agar dish and transferred using forceps into the corresponding universal bottle containing 10ml PBS.
13. The agar dish is then placed inside an autoclave bag. Once all the samples have been treated the autoclave bag with all the waste agar plates are to be transported to the autoclave room for sterilisation. Refer to SOP005 and SOP003 for transport and disposal of biological waste.
14. Once the experiment is complete, plasma rig is to be removed from the class II safety cabinet. The plasma equipment is sprayed down with 70% IMS. The BSC is cleaned down and left switched on in accordance with SOP009.
15. Universal bottles containing the resuspended bacteria or spores are placed in racks which are then placed inside a suitable secondary container which has been cleaned with 70% IMS.
16. The container is then transported by hand to H27 for plating out and further analysis.

Part B: Cell Culture Work

1. ***Human Dermal Fibroblasts / Epidermal Keratinocytes*** are the cell lines that will be used. These cells are classified as Biosafety Level 1, which are not known to cause disease in healthy adult humans.
2. Seed cells on Petri dishes at optimal concentrations (determined by preliminary experiments) and incubated at 37°C, 5% CO_2 overnight to allow cells attach to the surface of Petri dishes.
3. All sealed Petri dishes are placed inside Petri dish bags which are taped shut with autoclave tape. The Petri dish bags are then sprayed down with 70%IMS and placed inside a leak proof secondary sealable container that has been previously disinfected with 1% virkon and 70% IMS.
4. The secondary container is transported from H25 Animal Cell Culture Lab to H29 Biophotonics Lab by hand (according to procedures detailed in SOP005).
5. The **plasma rig (see procedures detailed in attached separated protocol)** is set up inside the BioSafety Class II Cabinet (Refer to SOP009 for using the safety cabinet correctly). All plasma rig parts that will go inside the BSC are to be sprayed down with 70% IMS and left for the detergent to completely dry off before placing inside the BSC.

6. The Petri dish bags are removed from the secondary container (outside the BSC). The sealed Petri dish samples to be treated are removed from the Petri dish bags and placed inside the safety cabinet.
7. Parafilm seals and Petri dish lids are removed inside the BSC and the medium in each Petri dish containing cells are soaked out just before plasma treatment in order to minimise exposure of the membranes to any outside cross contamination.
8. NOTE: Placing the plasma rig inside the safety cabinet for the plasma treatment may disrupt air flow inside the safety cabinet and may therefore compromise worker protection. However, samples containing HG1 biological agents are unlikely to cause human disease and minimal manipulation of the samples inside the BSC will minimise the likelihood of aerosols or splashes. The BSC will still offer some protection to both the worker and the work.
9. After completion of the plasma treatment the appropriate amount of fresh growth medium are put in Petri dish.
10. Petri dishes containing cells are placed inside a suitable secondary container which has been cleaned with 70% IMS. The container is then transported by hand to H25 for further analysis.
11. Once the experiment is complete, plasma rig is to be removed from the class II safety cabinet. The plasma equipment is sprayed down with 70% IMS. The BSC is cleaned down and left switched on in accordance with SOP009.
12. Once all the samples have been treated, refer to SOP005 and SOP003 for transport and disposal of biological waste.

Protocol --- Use of Plasma Rig

The user is responsible for

- Ensuring that the plasma rig has a valid PAT test.
- Ensuring that the working area is kept clean during work and disinfected after the work has been completed. Work surfaces and surfaces of the components of the equipment should be wiped down using 1% Virkon solution (if appropriate) followed by 70% IMS.

PROCEDURE

1. Preliminary Actions

(i) Do not work alone in the facility. The biophotonics lab (H29) does not have windows, so let someone know that you will be performing experiments and arrange for periodic checks.
(ii) Make sure you have sufficient room to perform your experiment safely.
(iii) Remove any unnecessary flammable and/or explosive substance from the cabinet.
(iv) Inspect the plasma rig, especially its connecting wires, for signs of damage before its use. In case of damage do not use it and report it to your supervisor.

2. Setup

(i) Set the plasma rig inside the Safety cabinet. Make sure the two wires between the power supply unit and Petri dish electrode are not crossed and the lid is situated away from metallic objects. Refer to SOP009 for use and maintenance of BSC.
(ii) NOTE: The external high voltage electrode is embedded in silicon rubber on the Petri dish lid; the rubber acts as an insulator, objects touching the rubber may compromise its integrity. The Petri dish lid is enclosed within a transparent plastic chamber to avoid contact with high voltage.
(iii) Place the Petri dishes containing human skin cells inside the safety cabinet.
(iv) Ensure samples to be treated are positioned on some material that is non conductive and easy to move.

3. Operation

(i) Remove Petri dish lids of samples inside the BSC just before the plasma treatment in order to minimise exposure to any outside cross contamination.
(ii) Place Petri dishes (without lids) into the transparent plastic chamber which is designed to prevent any contamination of spillage from Petri dish.
(iii) For this particular plasma rig, the Voltage and Current are fixed cannot be changed in any case.
(iv) During plasma treatment the user should wear gloves to minimise skin exposure to the plasma systems UV, radicals and aerosols.
(v) Put the electrode connected lid onto the Petri dish and press the black button to switch on, which is the ONLY button on this plasma rig.

4. Shutdown

(i) After completing the biological experiment, turn off the switch button and electrical power.
(ii) Remove all equipment from inside the Class II BSC.
(iii) Clean the BSC and plasma rig after use. Refer to SOP009 for correct cleaning procedures.

5. Maintenance and Cleaning Procedure

(i) No special maintenance is required other than proper installation and operation.
(ii) Work areas MUST be kept clean during work and disinfected after the work has been completed. Work surfaces and non-metallic surfaces of the equipment should be wiped down using 1% Virkon solution (if appropriate) followed by 70% IMS. Use 70% ethanol to wipe metallic surfaces.

6. Equipment Malfunction

(i) If any part of the equipment fails or malfunctions, the user should contact the Supervisor or Responsible Person. With their permission the user should consult the Operator Instruction Manuals to access fault finding and troubleshooting procedures. Refer to SOP071 for more details on equipment fault finding and troubleshooting procedures.

P.Hourd@lboro.ac.uk

From: ATCC Technical Enquiries [ATCC-Tech@lgcstandards.com]
Sent: 19 February 2010 15:36
To: Yvonne Sun
Subject: Dermal Fibroblast Normal; Human, Neonatal (ATCC cat #PCS-201-012)

Dear Yvonne,

RE: Dermal Fibroblast Normal; Human, Neonatal (ATCC cat #PCS-201-012)

Thank you for your email. It is not specific - it will be a general MSDS for all Primary Cells. Thank you.

Regards,

Cynthia Akufo-Addo
Technical Support Specialist

LGC Standards
Queens Road
Teddington
Middlesex
TW11 0LY, United Kingdom
Tel: +44 (0)20 8943 7441
Fax: +44 (0)20 8943 8405
Email: ATCC-Tech@lgcstandards.com
Web: http://www.lgcstandards-atcc.org

----- Original Message -----

From: Yvonne Sun <Y.Sun3@lboro.ac.uk>
To: "ATCC Technical Enquiries" <ATCC-Tech@lgcstandards.com>
Date: Fri, Feb 19, 2010 3:33 pm
Subject: RE: Dermal Fibroblast Normal; Human, Neonatal (ATCC cat #PCS-201-012)

Dear Cynthia

Thanks for your email.

Is that MSDS specified for PCS-201-012, Dermal Fibroblast Normal, Human, Adult, since I will order another line PCS-200-011, Primary Epidermal Keratinocytes, Human, Adult as well.

However, I have to get MSDS of both lines to get Risk assessment approved in Uni before I can put order. If ATCC provides separated MSDS for each cell line, could you please request the MSDS for PCS-200-011 for me as well?

Many thanks

Yvonne

From: ATCC Technical Enquiries [mailto:ATCC-Tech@lgcstandards.com]
Sent: 19 February 2010 15:23
To: Yvonne Sun
Subject: Dermal Fibroblast Normal; Human, Neonatal (ATCC cat #PCS-201-012)

Dear Yvonne,

RE: Dermal Fibroblast Normal; Human, Neonatal (ATCC cat #PCS-201-012)

The ATCC BioSafety Officer has assured us that the Material Safety Data Sheet (MSDS) for the above item; will be available within 3-5 working days. I will forward to you as soon as it arrives. Thank you for your continued patience in the meantime.

Regards,

Cynthia Akufo-Addo
Technical Support Specialist

LGC Standards
Queens Road
Teddington
Middlesex
TW11 0LY, United Kingdom
Tel: +44 (0)20 8943 7441
Fax: +44 (0)20 8943 8405
Email: ATCC-Tech@lgcstandards.com
Web: http://www.lgcpromochem-atcc.com/

----- Original Message -----

From: ATCC Technical Enquiries
To: Y.Sun3@lboro.ac.uk
Date: Tue, Feb 16, 2010 3:07 pm
Subject: Dermal Fibroblast Normal; Human, Neonatal (ATCC cat #PCS-201-012)

Dear Yvonne,

RE: Dermal Fibroblast Normal; Human, Neonatal (ATCC cat #PCS-201-012)

Thank you for your email and interest in the above cells. We invite you to view product details (including origin, background, propagation protocols and literature references) online at http://www.lgcstandards-atcc.org.

ATCC® Number	Description	Designation
[ ] PCS-201-010	Dermal Fibroblast Normal; Human, Neonatal	*Homo sapiens* (human)

These cells are classified by ATCC as Biosafety level 1 (BSL-1). Those items in BSL-1 are not known to cause disease in healthy adult humans. BSL-1 classification is based on assessment of the potential risk using the Centers for Disease Control and Prevention 'CDC', U.S. Public Health Service guidelines, and background information provided by the original depositor:

- Centers for Disease Control and Prevention 'CDC' - http://www.cdc.gov/
- ATCC Biosafety Levels - http://www.lgcstandards-atcc.org/BiosafetyLevels/tabid/1157/Default.aspx

I have requested the Material Safety Data Sheet (MSDS) from ATCC, and will forward to you within 1-3 working days.

ATCC orders may be placed by email, fax or online to our UK Sales group at; atcc@lgcstandards.com / Fax: 44 (0)20 8943 8405.

- **Order Form - https://www.lgcstandards-atcc.org/Portals/5/PDF/Forms/ORDERFormUK.pdf**
- **Online Ordering - http://www.lgcstandards-atcc.org**

For materials which are part of the European stock; holding delivery times are typically 3-5 working days from order receipt. We are able to assist with permit requirements as necessary for many of the "controlled" materials in the ATCC collection. For ATCC products which are not able to be included in the European stock; delivery times are typically 2-3 weeks. Thank you.

Regards,

Cynthia Akufo-Addo
Technical Support Specialist

LGC Standards
Queens Road
Teddington
Middlesex
TW11 0LY, United Kingdom
Tel: +44 (0)20 8943 7441
Fax: +44 (0)20 8943 8405
Email: ATCC-Tech@lgcstandards.com
Web: http://www.lgcpromochem-atcc.com/

LGC Standards: The new name for LGC Promochem


Please consider the environment before printing this e-mail

----- Original Message -----

From: Yvonne Sun <Y.Sun3@lboro.ac.uk>
To: "atcc@lgcstandards.com" <atcc@lgcstandards.com>
Date: Thu, Feb 11, 2010 10:20 am
Subject: PCS-201-012

To whom it may concern,

Can you please send the safety information of these cell line PCS-201-012 (Dermal Fibroblasts; Normal, Human, Adult) to me,
then I can get risk assessment done before we order it, and could you please also advise me this cell line is Biosafety level I or II? Many thanks!

Looking forward to your reply

Kind regards
Yvonne

Dr Yiyang Sun
Department of Electronic and Electrical Engineering
Loughborough University
Ashby Road
Loughborough
Leicestershire
LE11 3TU
Tel: 01509227060
Email: y.sun3@lboro.ac.uk < mailto:y.sun3@lboro.ac.uk >

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and any copies from your computer and network.
LGC Limited. Registered in England 2991879.
Registered office: Queens Road, Teddington, Middlesex, TW11 0LY, UK

P.Hourd@lboro.ac.uk

From: C.L.Kavanagh@lboro.ac.uk
Sent: 03 March 2010 08:13
To: Paul Hourd
Subject: FW: Epidermal Keratinocytes; Human, Adult (ATCC cat#PCS-200-011)

Hi Paul

Information from Yvonne

Carolyn

From: Yvonne Sun [mailto:Y.Sun3@lboro.ac.uk]
Sent: 02 March 2010 17:00
To: Carolyn Kavanagh
Subject: FW: Epidermal Keratinocytes; Human, Adult (ATCC cat#PCS-200-011)

Hi Carolyn,

I've got reply from ATCC regarding the biosafety level of another human skin cell line in my project

PCS 200-011 human epidermal keratinocytes, adult

Could you please forward this info to Paul, many thanks!

Kind regards

Yvonne

From: ATCC Technical Enquiries [mailto:ATCC-Tech@lgcstandards.com]
Sent: 02 March 2010 15:36
To: Yvonne Sun
Subject: Epidermal Keratinocytes; Human, Adult (ATCC cat#PCS-200-011)

Dear Yvonne,

RE: Epidermal Keratinocytes; Human, Adult (ATCC cat#PCS-200-011)

Thank you for your email and interest in ATCC biomaterials. The above item is classified by ATCC as biosafety level 1 'BSL-1'. This and all other product information (including origin, background, propagation protocols and literature references) online at http://www.lgcstandards-atcc.org.

Thank you.

Regards,

Cynthia Akufo-Addo
Technical Support Specialist

LGC Standards
Queens Road
Teddington
Middlesex
TW11 0LY, United Kingdom
Tel: +44 (0)20 8943 7441
Fax: +44 (0)20 8943 8405
Email: ATCC-Tech@lgcstandards.com
Web: http://www.lgcstandards-atcc.org

LGC Standards: The new name for LGC Promochem


Please consider the environment before printing this e-mail

----- Original Message -----

From: Yvonne Sun <Y.Sun3@lboro.ac.uk>
To: "ATCC Technical Enquiries" <ATCC-Tech@lgcstandards.com>
Date: Mon, Mar 1, 2010 4:55 pm
Subject: RE: Epidermal Keratinocytes; Human, Adult (ATCC cat #PCS-200-011)

Dear Cynthia,

Could you please advise me the line PCS-200-011, Primary Epidermal Keratinocytes, Human, Adult

Is classified as Biosafety Level 1 or 2? I assumed that it is Bio-safety Level 1, however, I do need

this information confirmed by you. Many thanks!

Looking forward to your reply.

Kind regards

Yvonne

From: ATCC Technical Enquiries [mailto:ATCC-Tech@lgcstandards.com]
Sent: 19 February 2010 15:36
To: Yvonne Sun
Subject: Dermal Fibroblast Normal; Human, Neonatal (ATCC cat #PCS-201-012)

Dear Yvonne,

RE: Dermal Fibroblast Normal; Human, Neonatal (ATCC cat #PCS-201-012)

Thank you for your email. It is not specific - it will be a general MSDS for all Primary Cells. Thank you.

Regards,

Cynthia Akufo-Addo
Technical Support Specialist

LGC Standards
Queens Road
Teddington
Middlesex
TW11 0LY, United Kingdom
Tel: +44 (0)20 8943 7441
Fax: +44 (0)20 8943 8405
Email: ATCC-Tech@lgcstandards.com
Web: http://www.lgcstandards-atcc.org

----- Original Message -----

From: Yvonne Sun <Y.Sun3@lboro.ac.uk>
To: "ATCC Technical Enquiries" <ATCC-Tech@lgcstandards.com>
Date: Fri, Feb 19, 2010 3:33 pm
Subject: RE: Dermal Fibroblast Normal; Human, Neonatal (ATCC cat #PCS-201-012)

Dear Cynthia

Thanks for your email.

Is that MSDS specified for PCS-201-012, Dermal Fibroblast Normal, Human, Adult, since I will order another line PCS-200-011, Primary Epidermal Keratinocytes, Human, Adult as well.

However, I have to get MSDS of both lines to get Risk assessment approved in Uni before I can put order. If ATCC provides separated MSDS for each cell line, could you please request the MSDS for PCS-200-011 for me as well?

Many thanks

Yvonne

From: ATCC Technical Enquiries [mailto:ATCC-Tech@lgcstandards.com]
Sent: 19 February 2010 15:23
To: Yvonne Sun
Subject: Dermal Fibroblast Normal; Human, Neonatal (ATCC cat #PCS-201-012)

Dear Yvonne,

RE: Dermal Fibroblast Normal; Human, Neonatal (ATCC cat #PCS-201-012)

The ATCC BioSafety Officer has assured us that the Material Safety Data Sheet (MSDS) for the above item; will be available within 3-5 working days. I will forward to you as soon as it arrives. Thank you for your continued patience in the meantime.

Regards,

Cynthia Akufo-Addo
Technical Support Specialist

LGC Standards
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Web: http://www.lgcpromochem-atcc.com/

LGC Standards: The new name for LGC Promochem


Please consider the environment before printing this e-mail

----- Original Message -----

From: ATCC Technical Enquiries
To: Y.Sun3@lboro.ac.uk
Date: Tue, Feb 16, 2010 3:07 pm
Subject: Dermal Fibroblast Normal; Human, Neonatal (ATCC cat #PCS-201-012)

Dear Yvonne,

RE: Dermal Fibroblast Normal; Human, Neonatal (ATCC cat #PCS-201-012)

Thank you for your email and interest in the above cells. We invite you to view product details (including origin, background, propagation protocols and literature references) online at http://www.lgcstandards-atcc.org.

ATCC® Number	Description	Designation
[ ] PCS-201-010	Dermal Fibroblast Normal; Human, Neonatal	*Homo sapiens* (human)

These cells are classified by ATCC as Biosafety level 1 (BSL-1). Those items in BSL-1 are not known to cause disease in healthy adult humans. BSL-1 classification is based on assessment of the potential risk using the Centers for Disease Control and Prevention 'CDC', U.S. Public Health Service guidelines, and background information provided by the original depositor:

- Centers for Disease Control and Prevention 'CDC' - http://www.cdc.gov/
- ATCC Biosafety Levels - http://www.lgcstandards-atcc.org/BiosafetyLevels/tabid/1157/Default.aspx

I have requested the Material Safety Data Sheet (MSDS) from ATCC, and will forward to you within 1-3 working days.

ATCC orders may be placed by email, fax or online to our UK Sales group at; atcc@lgcstandards.com / Fax: 44 (0)20 8943 8405.

- **Order Form - https://www.lgcstandards-atcc.org/Portals/5/PDF/Forms/ORDERFormUK.pdf**
- **Online Ordering - http://www.lgcstandards-atcc.org**

For materials which are part of the European stock; holding delivery times are typically 3-5 working days from order receipt. We are able to assist with permit requirements as necessary for many of the "controlled" materials in the ATCC collection. For ATCC products which are not able to be included in the European stock; delivery times are typically 2-3 weeks. Thank you.

Regards,

Cynthia Akufo-Addo
Technical Support Specialist

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----- Original Message -----

From: Yvonne Sun <Y.Sun3@lboro.ac.uk>
To: "atcc@lgcstandards.com" <atcc@lgcstandards.com>
Date: Thu, Feb 11, 2010 10:20 am
Subject: PCS-201-012

To whom it may concern,

Can you please send the safety information of these cell line PCS-201-012 (Dermal Fibroblasts; Normal, Human, Adult) to me, then I can get risk assessment done before we order it, and could you please also advise me this cell line is Biosafety level I or II? Many thanks!

Looking forward to your reply

Kind regards
Yvonne

Dr Yiyang Sun
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