Safety Documentation

Please select the forms you require by selecting the check boxes below.
You can select more than one.

☑ **Method Statement** ☑ **Risk Assessment** ☑ **Chemicals COSHH**

Once you have made your selections, scroll down and complete the forms.

Buttons: [+] will add a row to a list [X] will delete a row from a list

You may save this file to a local drive at any time.
When you have finished, save the file to a local drive and email it to your supervisor for authorisation.

Supervisors - There is a sign-off section at the end of the document set that must be completed.

Staff may "self authorise", (as a supervisor), but the forms must still be submitted to the DSO for approval.

IMPORTANT:

YOU ***MUST NOT*** START ANY PRACTICAL WORK UNTIL THESE FORMS HAVE BEEN RETURNED TO YOU WITH **BOTH** YOUR SUPERVISOR's AND DSO's APPROVAL SIGNATURES ATTACHED.

Please complete these fields

School or Service	School of Aeronautical, Automotive, Chemical and Materials Engineering
Department	Department of Materials
Originator name	Ria Rawla
email address	r.rawla-20@student.lboro.ac.uk
Location	Wolfson TW 1.011
Project / Activity / Task	Testing of Porcine Mitral Valves and Printed Scaffold
Supervisor Name	Sotiris Korossis

Version : 2.34

Loughborough University
Department of Materials
Safety Method Statement

Loughborough University

Reference: SAF/MEME/7841

Location: Wolfson TW 1.011

Originator: Ria Rawla

Project / Activity / Task: Testing of Porcine Mitral Valves and Printed Scaffold

What equipment will be used in this activity?	+
Instron tensile testing machine	x
Ruler	x
Forceps	x
Dissection Tray	x
Sterilin™ Polystyrene Containers	x
Polypropylene Round Buckets with Plastic Handle- 5.6 L	x
Disposable scalpel	x
Disposable single unit scalpels	x
Chemgene wipes	x
Tensile Testing rig	x
Scissors	x

What training must be completed to do this activity?	+
Use of Instron equipment for mechanical testing	x
Sharps use	x
Biological spill response	x
Decontamination and disposal of biological waste	x
Hand tools use	x

What chemicals are being used? (These must be included in the COSHH Form)	+
1% Vikron	x
70% IMS	x
Chemgene	x
Phosphate Buffer Solution (PBS)	x
Penicilin or Streptomycin	x

Spill and accident procedures.	+
Container with 1% Virkon Solution	x

Procedure in the event of an emergency. (How to leave the process in a safe condition in such an event)	+
Dispose scalpels in sharps bin	x
Put heart valve tissue in a container with PBS.	x
Dispose contaminated gloves.	x

Safety Method Statement (Continued)

Leave note with a name of the operator and sate mentioning not to move anything from the area. If fire alarm sounds continuously, make equipment safe then evacuate the building. Only return when informed that it is safe to do so	x

References.	+
CBE code of practice, SOP003, SOP037, SOP038	x

Detailed sequential description of the process

Process step	Precautionary measures and comments	+
Wear all PPE mentioned	Check if PPE is damaged and replace if need be	x
Put in a container 1% Virkon	Pour solutions with care avoiding spillages. If there is a spillage follow SOP038.	x
Prepare dissection tray	Put some absorbent paper towel underneath the tray.	x
Remove samples from container in which it has been stored using forceps.	Avoid spillages	x
Place tissue or printed scaffold on the dissection tray	Be cautious, so the organs will not slip from your hands.	x
Cut the tissue or printed scaffold using a pair of scissors, so you can place it as membrane on the dissection tray.	Be cautious using scissors.	x
Cut the tissue or printed scaffold using scissors or scalpel depending on the user's convenience to the desired dimensions.	Do not cross hands to avoid cutting or puncturing yourself. Use disposable single unit scalpels and open sheath from the side of the handle. If disposable single unit scalpels are not available, place the scalpel on the handle maintaining the scalpel in the protective sheath. In any case, wear cut-resistant glove level 5 on hand that does not hold the scalpel.	x
Loosen the screws of the holder and place the cut tissue or printed scaffold in place.	Be careful not to lose the screws.	x
Place the screws back on the holder and place the holder on the testing machine.	Be careful not to damage the machine.	x
Loosen the screws of the holder that are required for the tesing to commence.	Be careful not to damage the machine.	x
Test the samples according to the SOP for machine and after you have put down the protective guard.	Do not initiate testing with out putting the guard down and making sure no one has their hands near the testing area to avoid crashing them.	x
After the ending of the test, put the guard up and remove holder.		x
Remove samples from holder and prepare the holder to be used again.	Be careful not to drop the tissue. In case of an accident disinfect the area.	x
Immerse used animal tissue sample in 1% Virkon solution overnight.	According to CBE code of practice and SOP003.	x
Repeat steps 6-11.		x
At the end of the procedure discard the scalpels in sharps bin.	Put the disposable single unit scalpel in the bin placing the blade part in first. Otherwise, use scalpel bleade remover to remove blade from handle and dispose it in sharps bin.	x
If there are no more samples to use. Disinfect holder, scissors and dissection tray briefly with 1% Virkon, wash with water, then clean using Chemgene wipe and finally, clean using 70% IMS.	According to CBE code of practice and SOP003.	x
Put all contaminated gloves and tissues in yellow bag for disposal.	According to SOP003.	x

Safety Method Statement (Continued)

Process step	Precautionary measures and comments	+
The next day dispose tissue left in 1% Virkon in yellow bag and pour Virkon down the sink.		x
		x
		x
		x
		x
		x
		x
		x
		x

Loughborough University
Department of Materials

Risk Assessment

Reference: SAF/MEME/7841

Location: Wolfson TW 1.011

Originator: Ria Rawla

Project / Activity / Task: Testing of Porcine Mitral Valves and Printed Scaffold

Is this process risk assessment for a : ☑ Laboratory / Workshop ☐ General use ☐ Event

Category 1: Machinery & work equipment:				
Design and Construction	Mechanical hazards	Electrical hazards	Radiation hazards	+
N/A	Crushing	Electrical test lables current	N/A	x
N/A	Cutting/Shearing	N/A	N/A	x
Category 2: Workplace				+
Confined work area (striking objects)				x
Category 3: Hazardous and/or Harmful substances				+
Irritant substances				x
Category 4: Work activity				+
Use of hand tools				x
Category 5: Work organisation				+
N/A				x

Explain the risks associated with these hazards

People / Groups at risk: Operator only — x

Enter risk details here:-	Impact	Probability	Risk Score
Crushing hands while running the test	Very Harmful	Unlikely	High

What are the control measures?	Lowers Impact	Lowers Probability	+
Wear PPE Bring down the protective guard/safety shield of the machine ensure that hands are clear before activating Be aware of trap/pinch points Know engineered safety controls including E stop Receive training from Technical support in the lab in the correct use of the Instron and the safe mounting of samples	Significantly	Significantly	x

Residual Risk: Low

People / Groups at risk: Operator only — x

Process Risk Assessment Form (Continued)

Enter risk details here:-	Impact	Probability	Risk Score
Cut wounds that can lead to infection and nerve damage	Very Harmful	Unlikely	High
What are the control measures?	**Lowers Impact**	**Lowers Probability**	**+**
Wear Cut-resistant gloves - level 5 Be trained in correct dissection techniques	Significantly	Significantly	x
			Residual Risk: Low

People / Groups at risk	Operators and people in proximity	x

Enter risk details here:-	Impact	Probability	Risk Score
Aerosols from disinfectants	Harmful	Likely	High
What are the control measures?	**Lowers Impact**	**Lowers Probability**	**+**
Wear lab PPE suitable for testing purposes - include nitrile gloves, lab coat, goggles - if necessary FFP2 face mask	Significantly	Significantly	x
			Residual Risk: Low

People / Groups at risk	Operator and people in proximity	x

Enter risk details here:-	Impact	Probability	Risk Score
Slips trips and falls on the level	Slightly Harmful	Highly Unlikely	
What are the control measures?	**Lowers Impact**	**Lowers Probability**	**+**
Keep working area clear and tidy Remove potential trip hazards from the floor Clean any spills up immediately utilising absorbent materials and recommended disinfectants etc.	None	None	x
			Residual Risk:

People / Groups at risk	Operator only	x

Enter risk details here:-	Impact	Probability	Risk Score
Electric shock	Harmful	Unlikely	Medium
What are the control measures?	**Lowers Impact**	**Lowers Probability**	**+**
Instron to be within current PAT inspection date Visual inspection of cables and connectors for wear or damage prior to use	Slightly	Slightly	x
			Residual Risk: Low

+ Add another Risk

Who may be at risk as a result of this activity?

Personnel Group	Maximum (Task setup/ Re-configuration)	High (Performing the task)	Medium (Observing the task)	Low (Present, but not involved)	Lone Working (Out of hours)	No Exposure Permitted	Total
Academic Staff	1	0	0	0	0	0	1

Process Risk Assessment Form (Continued)

Personnel Group	Maximum (Task setup/ Re-configuration)	High (Performing the task)	Medium (Observing the task)	Low (Present, but not involved)	Lone Working (Out of hours)	No Exposure Permitted	Total
Technical Staff	1	0	0	0	0	0	1
Research Staff (PDRA)	0	0	0	0	0	0	0
Research Students (PhD)	0	0	0	0	0	0	0
Students (Undergraduate / MSc)	0	1	0	0	0	0	1
Visitors	0	0	0	0	0	0	0
Others - Over-type as needed	0	0	0	0	0	0	0
Total	2	1	0	0	0	0	3

With these controls in place, the risk is:

The activity is LOW RISK - and is effectively controlled

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Department of Materials

COSHH Form

Reference: SAF/MEME/2077

Location: Wolfson TW 1.011

Originator: Ria Rawla

Project / Activity / Task: Testing of Porcine Mitral Valves and Printed Scaffold

CHEMICAL NAME

Penicillin / Streptomycin

CAS No. Penicillin / Streptomy

W.E.L. (Itel / stel)

Amount used		Period of use (hrs)	The process is:	Physical State		Exposure Potential	Hazard Rating
5	ml	48	Closed	Non-Volatile Liquid	☐ Eyes ☑ Skin ☐ Inhaled ☑ Ingested	Low	High

OVERALL RISK: Medium

This chemical has a high health risk associated with it.

Hazard Statement and Description	Precaution Statement and Description
H302 Harmful if swallowed.	P280 Wear protective gloves/protective clothing/eye protection/face protection.
H317 May cause an allergic skin reaction.	
Justify the use of this chemical:	Penicillin-Streptomycin is used in saline to inhibit bacterial contamination. If the tissues get contaminated, they will have to be disinfected and discarded without being used for assessment.
How will the precautions listed above be implemented?	
Wear PPE - nitrile gloves, lab coat and goggles	
Special Storage and Containment Measures	**Disposal Method**
Store in fridge at 0-4°C for short of period of time or in freezer at -20°C for prolonged period of time.	Aqueous waste - Check with Technician or Supervisor
How will spillages be dealt with?	*Please note: any material used to clean up a spill of hazardous material must also be disposed of as hazardous material.* Click here to see spill procedures

+ Add another chemical

Statement of work (Process to be undertaken)

The tissues or printed scaffolds will not get contaminated with bacteria and can be used for further assessment. The PBS containing 1% penicillin /streptomycin is going to be prepared by the designated research associate in CBE, room H25.

Show image

Personal protection requirements not covered in the precaution statements above.

Appropriate clothing (long trousers and skirts), closed shoes

Sources of information and references

https://www.sigmaaldrich.com/MSDS/MSDS/DisplayMSDSPage.do?country=GB&language=en&productNumber=P0781&brand=SIGMA&PageToGoToURL=https%3A%2F%2Fwww.sigmaaldrich.com%2Fcatalog%2Fproduct%2FSIGMA%2FP0781%3Flang%3Den

Reference to **existing approved** Risk Assessment

Virkon CBE/COSHH/39
IMS CBE/COSHH/36
Chemgene CBE/COSHH/242
SAF/MEME/7791

With the current controls, the risk of using these chemicals is: Medium

Supervisor to check that the process involving the safe use of these chemicals has been satisfactorily evaluated

Loughborough University

Supervisor and Departmental Safety Office (DSO) Sign-off.

Supervisors

Please check the documents above and if you want to approve them:

1) Electronically sign this document
2) Save it to a local drive (You will be prompted to do this)
3) eMail the signed document to the DSO.

DSO

Please review the documents above and if you want to approve them:

1) Enter the reference numbers as appropriate
2) Electronically sign this document
3) Save it to a local drive (You will be prompted to do this)
3) eMail the signed document to the originator

IF YOU DO NOT WANT TO AUTHORISE THE FORMS,

Please do not sign the form, but click the "Not Approved" check-box and return it to the originator by email stating why and what you expect them to do to put it right in the comments box below.

Not Approved ☐

Supervisors Signature: Professor Sotiris Korossis — Digitally signed by Professor Sotiris Korossis Date: 2023.11.16 14:37:31 Z

Form Reference Numbers

Risk Assessment	Method Statement	COSHH Assessment
SAF/MEME/7841	SAF/MEME/7841	SAF/MEME/2077

DSO Signature: Keven G Smith — Digitally signed by Keven G Smith Date: 2023.11.21 16:01:13 Z

This document set must be reviewed and re-approved at the following times:

1) After the first occurrence of the activity described above (Review only)
2) After any change to the procedure or reagents used
3) After any incident resulting from this activity
4) At least annually from the date of approval

Next Review: 21 Nov 2024

Review comments