












HYWEL DDA UNIVERSITY HEALTH BOARD

 Bwrdd Iechyd Prifysgol Hywel Dda University Health Board		<h2 style="margin: 0;">COSHH ASSESSMENT</h2> <h3 style="margin: 0;">Substance-based</h3>		
Name of substance/product	CellStor 10% Neutral Buffered Formalin (10% NBF) 1 litre/5 litre bulk liquid for manual dispensing.			
Manufacturer/Supplier Address, e-mail, emergency contact phone number	CellPath Ltd., 80 Mochdre Enterprise Park, Newtown SY16 4LE, UK. Tel.: +44 (0) 1686 611 333 e-mail: qhse@cellpath.co.uk Emergency information service +44 (0) 7803 746 135 (24h/7d)			
Description of substance Physical form, pack size, container	Plastic 1 litre/5 litre jerry can of 10% formalin dispensed/used in Theatre/Day Surgery; filled pots used elsewhere for specimen preservation. Clear liquid, characteristic odour. Odour threshold is very close to the Workplace Exposure Limit (~1ppm).			
Describe the work process and relevant equipment	Substance is dispensed into white plastic tubs either by manual pouring or using a pump, in a suitable fume cabinet (recirculating cabinet fitted with an aldehyde carbon filter). Tanks in pumped cabinets are manually filled. Specimens are taken from patients, placed into the pre-filled tubs, suitably labelled, then sent for analysis;			
Location/s of work process	Used in Day Surgery Unit/Theatre at each of the four acute sites: PPH, GGH, WGH, and BGH. Pots filled by Theatre/DSU (not as robust as the 60mL version) may also be present anywhere where biopsies are taken e.g. gynae, OPD, W&CH. Pots with samples are transferred to GGH Pathology/histology labs for processing/analysis.			
Information sources Material Safety Data Sheet	Material Safety Data Sheet; Instructions for Use (embedded left); CellPath website.  8782-prefilledpotsifu_english.pdf			
Persons at risk of exposure	Employees / Contractors <input checked="" type="checkbox"/>	Patients / Service users <input checked="" type="checkbox"/>	Visitors / Public <input type="checkbox"/>	
Hazardous substances – MSDS Section 3.1 & 3.2; proprietary products may only give a concentration range if a biological agent: species/type e.g. bacterium, fungus, virus, BBV, Hazard Group (HG1, HG2, HG3, HG4) where known/relevant				
Hazardous substances and concentration	Formaldehyde (1 to <5%) – concentration understood to be 3.7% Methanol (1 to <5%)			
Classification of hazards (GHS hazard pictograms, CLP Regulation) – MSDS Section 2.2;				
 <input type="checkbox"/> Acute toxicity (Cat 1 - 3) Fatal if swallowed; Fatal in contact with skin Fatal if inhaled; Toxic if swallowed; Toxic in contact with skin; Toxic if inhaled;	 <input type="checkbox"/> Corrosive May be corrosive to metals; Causes severe skin burns and eye damage;	 <input type="checkbox"/> Hazardous to the environment Very toxic to aquatic life with long lasting effects; Toxic to aquatic life with long lasting effects;		
 <input checked="" type="checkbox"/> Health Hazard (Cat 4) May cause respiratory irritation; May cause drowsiness or dizziness May cause an allergic skin reaction; Causes serious eye irritation; Causes skin irritation; Harmful if swallowed; Harmful in contact with skin; Harmful if inhaled; Harms public health and environment by destroying ozone in the upper atmosphere;	 <input type="checkbox"/> Flammable Extremely flammable gas; Flammable gas; Extremely flammable aerosol; Flammable aerosol; Highly flammable liquid and vapour; Flammable liquid and vapour; Flammable solid; May also include the following substances: <i>pyrophoric; self-heating; self-igniting; those which produce flammable gas on contact with water;</i>	 <input type="checkbox"/> Explosive Unstable explosive; Explosive; mass explosion hazard; Explosive; severe projection hazard; Explosive; fire, blast, or projection hazard; May mass explode in fire;		
 <input checked="" type="checkbox"/> Serious Health Hazard May be fatal if swallowed and enters airways; Causes damage to organs; May cause damage to organs; May damage fertility or the unborn child; Suspected of damaging fertility or unborn child; May cause cancer; Suspected of causing cancer; May cause genetic defects; Suspected of causing genetic defects; May cause allergy or asthma symptoms or breathing difficulties if inhaled;	 <input type="checkbox"/> Oxidising May cause or intensify fire (oxidiser); May cause fire or explosion (strong oxidiser);	 <input type="checkbox"/> Gas under pressure Contains gas under pressure - may explode if heated; Contains refrigerated gas - may cause cryogenic burns or injury;		
Hazards not covered by other criteria - MSDS Section 9, plus physical properties				
Asthmagen	Mutagen	Asphyxiant	By-product (curing/drying, decomposition, reaction)	Other hazard (specify)
	X			

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Physical form of substance – some substances may be present in more than one form at the same time e.g. solvents, fuel							
Solid	Liquid	Gas	Vapour	Aerosol/Mist	Fume	Dust	Other (specify)
	X		X				
Other relevant details – include appearance, relevant physical or chemical properties							
<p>"Formalin" refers to a solution of 37% formaldehyde. Therefore 10% formalin is 3.7% formaldehyde. Solution is neutral buffered by a phosphate buffer, methanol is present as a stabiliser. Density is 1.021g/mL. Low storage temperature may result in formation of a white precipitate, which renders substance unusable.</p>							

Route of Exposure - MSDS Section 4; also based on process, substance form, and equipment			
Inhalation	Contact/absorption): skin, eyes	Ingestion	Injection
X	X	X	

Level of exposure/contact - approximates or weekly/monthly average use is acceptable if usage is variable.	
How many people handle the substance?	Theatre nursing staff including scrub nurses and Sisters.
Duration of exposure per shift/day/week/month	Exposure duration is short but occurs several times during a shift. Exposure is minimal when filling in cabinet. Exposure is under 15 minutes when filling tanks (BGH only) or whenpots are opened.
Quantity prepared at a time	Small to large volumes according to type of operation being conducted.
Quantity used per shift/day/week/month	Used as/when is required quantities.
Storage location and quantity; type of storage unit	Stored in sluice room or room where formalin cabinet is located. GGH (in COSHH cabinet). Sluice room in Theatre is secure storage.
Does the substance pose additional risk to vulnerable staff/others in the workplace – additional control measures; health considerations; information accessibility; Risks to others in workplace e.g. vapour drawn into ventilation systems.	
<p>As a precaution: must not be handled by pregnant staff; pregnant staff must not be exposed to substance (liquid or vapour); pregnant staff must be kept away from spillages and stored substance. Ensure storage cupboard is suitably marked, and ensure pregnant staff are aware of this substance, where it is used, and how it is stored as a preventative measure in order to reduce risk of accidental exposure.</p> <p>Existing controls are sufficient to control exposure, but these are precautionary due to the risks of formalin. Informed consent must be gained and documented if pregnant staff voluntarily handle substance. Health Board does not "ban" substances but uses informed consent or informed avoidance decided by staff member. Risk is greater than 60mL pots due to larger quantities.</p>	

Workplace Exposure Limits (WELs) - MSDS Section 8; HSE EH40; please indicate n/a where not applicable. Control measures must reduce exposure to below WEL. If there is no WEL, exposure must be ALARP – As Low As Reasonably Practicable.				
Substance name	STEL (15 min)		TWA (8-hour)	
	ppm	mg/m ³	ppm	mg/m ³
Formaldehyde	2	2.5	2	2.5
Methanol	250	333	200	266
Risks to Health from Identified Hazards – MSDS Section 2.2; Hazard (H) statements - H200-H290 list physical hazards; H300-H373 list Health Hazards; H400-433 list Environmental Hazards				
<p>H302+332 - Harmful if swallowed or inhaled; H317 - May cause an allergic skin reaction; H341 - Suspected of causing genetic defects; H350 - May cause cancer;</p>				
Can the substance be eliminated or substituted for a safer product/form/concentration/quantity?				
<p>Complete COSHH assessment for current substance if still in use; substitute; then re-assess/assess new substance</p> <p>Formalin is an effective preservative for tissue samples and also hardens samples to aid dissection. The process has been designed to reduce exposure, and the substance is handled either in a fume cabinet or in a well ventilated space. The main exposure risk is from spillage/leakage from the pots during dispensing or during transportation/use. At present there is no reasonable alternative known or in common use.</p>				
Current Control Measures - MSDS Section 8.2 ; engineering controls ; action on failure of control measures ; servicing and maintenance of engineering controls;				
<p>Serviced fume hood with activated carbon filter ; 6 ACH is advised by HTM 03-01 for general ward areas, >20 ACH in Theatre environment. It is unlikely that the Workplace Exposure Limit will be approached or exceeded due to the nature of the product and the way it is handled, and workplace ventilation.</p>				
Safe Systems of Work – Documented procedures (attach/reference) ; Information Training Instruction Supervision ; restrictions on Confined/Restricted Spaces and Lone Working ;				

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- Dispense in a fume hood only; use in a well ventilated area.
- Only allow the container to remain open for as short a period of time as practicable.
- Take practical measures suitable to the specific environment/use to prevent spillage.
- Generally small quantities in use, low frequency of use, small duration/quantity/manner of any exposure. Higher exposure will occur during a spillage but use of a spill kit with appropriate PPE will reduce the exposure and therefore risk.









Health Surveillance and Exposure Monitoring – if Yes, state type

Is Health Surveillance by Occupational Health required?	(Yes/No)	No
Is Exposure Monitoring required?	(Yes/No)	No

Details of previous exposure monitoring - e.g. dust and vapour measurements. Include: date/s, contractor/s, aspects monitored, results/outcome, frequency, remedial actions. Reference the report and attach.

Health Surveillance deemed not necessary due to the small quantities in use, low frequency of use, small duration/quantity/manner of any exposure. The conditions in the workplace do not make it likely that the associated disease will occur (suspected carcinogen).

Personal Protective Equipment - MSDS Section 8.2; state type & standard; make & model if supplied; PPE is not a control measure; PPE must be worn if there is residual risk (after control measures), or if there is risk of exposure if control measures fail.

 Mask	<input type="checkbox"/>	 Eye protection	EN 166 safety glasses with side protection
 Respirator	Half mask with A1+Form filter if necessary to clean up large spills. <input checked="" type="checkbox"/>	 Visor	EN 166 visor as an alternative to safety glasses
 Gloves	Nitrile gloves EN 374 <input checked="" type="checkbox"/>	 Protective clothing	Disposable apron
 Footwear	<input type="checkbox"/>	 Other (state type)	

First Aid Measures - MSDS Section 4; acceptable to copy directly from MSDS; add relevant information from other sources; First Responder Advice may be needed for certain substances/situations.

If inhaled	If breathing is irregular or stopped, immediately seek medical assistance and start first aid actions. Provide fresh air.
In case of skin contact	Wash with plenty of soap and water
In case of eye contact	Remove contact lenses, if present and easy to do. Continue rinsing. Irrigate copiously with clean, fresh water for at least 10 minutes, holding the eyelids apart.
If ingested	Rinse mouth with water (only if the person is conscious). Do NOT induce vomiting.
If injected	Not a likely route of entry. Use of scalpels may result in cuts so substance may enter body through open wound.
First Responder Advice	General: Be aware of spills, remove contaminated clothing as appropriate.

Fire action – MSDS Section 5; acceptable to copy directly from MSDS; add relevant information from other sources

Suitable extinguishing media: Water spray, BC-powder, CO2. **Unsuitable extinguishing media:** Water jet

Actions in the event of a Spill or Accidental Release - MSDS Section 6; spill training, required spill kit contents, rehearsals, who to contact in the event of an accidental release

Risk due to dispensing of product into pots; pots leaking (due to incorrectly sealed lids, or being dropped). A dedicated spill kit for formaldehyde is preferred where larger volumes of formalin are used, in order to neutralise the substance and minimise vapour. These are present in Theatre, HSDU, and Pathology. Small spills (up to 120mL); cover spill with excess paper/pads, clean with paper towels, double-bag waste. Spill kits: chemical spill kit, formaldehyde spill kit, formaldehyde absorbent, neutralising liquid/granules, or a formaldehyde neutralising absorbent pad. Follow instructions for spill kit. Wear apron and double glove. Mark/communicate location of spill, evacuate immediate/wider area if needed, and ventilate if safe to do so. Stop spread of spill, isolate source, stop spill, clean up and decontaminate. Bag up waste, label appropriately, and dispose of in yellow bag. Investigate cause, Datix if needed, replenish spill kit. Communicate findings of investigation, apply preventative measures.

Required storage conditions - MSDS Section 7; add relevant information from other sources.

Location	Minimum: locked marked cupboard; ideally a marked locked COSHH cabinet.
Temperature	Above 15°C and below 35°C. Storage in a cold location causes formation of white precipitate – substance must not be used if there is a precipitate (QC issue).
Container	Keep in original container.
Incompatible substances	Oxidisers.
Conditions to avoid	Avoid dropping containers.
Security	Must be kept locked away or kept in a secure location. Theatre is a department with controlled access so the risk of accidental exposure to non-theatre staff is low.

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Disposal of Substances & Contaminated Containers - MSDS Section 13; Environmental or Health and Safety Team can advise on disposal. Please also consult HDUHB Waste Management Policy 258.

Waste type	Licenced contractor	HDUHB waste stream (e.g. black bag, tiger stripe, etc.)	Other (state)
Substance in original container (full/part-used/residue)	X	-	-
Empty container	-	Yellow bag	-
Contaminated waste (e.g. cloths, used spill kit)	-	Yellow bag	-

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Assessment of the risk – this must be based on current control measures						
Are all the control measures described above currently in place ?				Yes/No	Yes	
Is exposure adequately controlled with all current control measures?				Yes/No	Yes	
<i>If: required control measures are not in place, additional controls are needed to adequately control the risk, reasonable additional controls can further reduce the risk, specify these and completion dates below.</i>						
Remedial/Additional Control Measures & Safe Systems of Work <small>(add more lines if needed)</small>				Target date	Date completed	
If the exposure is not adequately controlled with all current control measures, work must cease until suitable and sufficient controls are in place.						
Risk scoring						
<i>Multiply the Likelihood by the Consequence to obtain the Risk Score.</i>						
<i>To reduce Likelihood: Control measures, Safe Systems of Work; To reduce Consequence: Elimination, Substitution;</i>						
<i>If applying remedial/additional control measures, reassess the Risk Score below once all measures are in place.</i>						
Current Risk: Risk scoring of existing control measures						
Likelihood rating	4	x	Consequence rating	1	=	RISK LEVEL 4
Residual Risk: Risk scoring after remedial/additional control measures are in place						
Likelihood rating	3	x	Consequence rating	1	=	RISK LEVEL 3
Likelihood rating						
Consequence rating		1 Rare	2 Unlikely	3 Possible	4 Likely	5 Almost certain
	5 Catastrophic	5	10	15	20	25
	4 Major	4	8	12	16	20
	3 Moderate	3	6	9	12	15
	2 Minor	2	4	6	8	10
	1 Negligible	1	2	3	4	5
Risk level	Risk score	Response				
Low risk	1 to 3	Action only if low cost remedy, easy to implement. Re-access if process/procedure, guidance or legislation changes, keep under review.				
Moderate risk	4 to 6	Action that is cost effective in reducing the risk, planned and implemented with a reasonable timeframe.				
High risk	8 to 12	Urgent action to remove or reduce the risk. To be escalated to senior management.				
Extreme risk	15 - 25	Immediate action to remove or reduce risk. Consideration to be given to stopping process. Inform the Departmental or Premises Manager and the Health, Safety & Security Department.				

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Details of COSHH Assessment and reviews			
Assessor details – <i>the person who conducted the initial COSHH assessment</i>			
Name			
Job Title/Role	Health, Safety & Security Officer		
Dept. / Ward	Health, Safety & Security		
Locality / Directorate	Estates & Facilities		
Hospital / Site	Prince Philip Hospital		
Date	02/02/2022, minor update 16/06/22; H&S review 16/01/26		
Review period	12 months		
COSHH assessment reviews – <i>carry out periodically or when any significant aspect changes (e.g. substance, process, personnel, equipment, location). If a new process, review after 3 or 6 months or when process is established; set review period based on level of residual risk. Reviews should not be carried out by the person who was the most recent assessor/reviewer.</i>			
Review date	Reviewer name & role	Check for updated MSDS; record relevant changes	Findings, actions, and date of completion
Communication – <i>how and where is this information shared and used e.g. IT IS (Information, Training, Instruction, Supervision)</i>			