GIG CYMRU NHS WALES | Bwrdd Iechyd Prifysgol Hywel Dda University Health Board

# COSHH ASSESSMENT

## Substance-based

| | |
|---|---|
| Name of substance/product | CellStor 10% Neutral Buffered Formalin (10% NBF) 60mL pots |
| Manufacturer/Supplier<br>*Address, e-mail, emergency contact phone number* | CellPath Ltd., 80 Mochdre Enterprise Park, Newtown SY16 4LE, UK.<br>Tel.: +44 (0) 1686 611 333 e-mail: qhse@cellpath.co.uk<br>Emergency information service +44 (0) 7803 746 135 (24h/7d) |
| Description of substance<br>*Physical form, pack size, container* | Small pots of formalin supplied pre-filled with aqueous formalin, with patient label for completion, orange screw cap. Pot has 60mL total volume with 40mL formalin solution to allow room for specimen. Supplied in a shrink-wrapped cardboard tray of 25x pots, may be present in workplace individually. Pots made of polypropylene. |
| Describe the work process and relevant equipment | Specimens are taken from patients and placed into the pre-filled pots, these are then sent to the Pathology lab for analysis; Lab for final analysis may be off site. |
| Location/s of work process | Used in Outpatients Departments in HDdUHB; stored in Pathology departments; also present in other departments including Theatre, Eye Clinics, Minor Ops, Colposcopy. |
| Information sources<br>*Material Safety Data Sheet* | Material Safety Data Sheet; Instructions for Use (embedded left); CellPath website.<br>8782-prefilledpotsifu english.pdf |
| Persons at risk of exposure | Employees / Contractors [X] Patients / Service users [X] Visitors / Public [ ] |

**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*

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| Hazardous substances and concentration | Formaldehyde (1 to <5%) – concentration understood to be 3.7%<br>Methanol (1 to <5%) |

**Classification of hazards (GHS hazard pictograms, CLP Regulation)** – *MSDS Section 2.2;*

| | | |
|---|---|---|
| [ ] Acute toxicity (Cat 1 - 3)<br>Fatal if swallowed; Fatal in contact with skin<br>Fatal if inhaled; Toxic if swallowed;<br>Toxic in contact with skin; Toxic if inhaled; | [ ] Corrosive<br>May be corrosive to metals;<br>Causes severe skin burns and eye damage; | [ ] Hazardous to the environment<br>Very toxic to aquatic life with long lasting effects; Toxic to aquatic life with long lasting effects; |
| [X] Health Hazard (Cat 4)<br>May cause respiratory irritation;<br>May cause drowsiness or dizziness<br>**May cause an allergic skin reaction;**<br>Causes serious eye irritation;<br>Causes skin irritation; **Harmful if swallowed**;<br>Harmful in contact with skin;<br>**Harmful if inhaled;**<br>Harms public health and environment by destroying ozone in the upper atmosphere; | [ ] Flammable<br>Extremely flammable gas; Flammable gas;<br>Extremely flammable aerosol;<br>Flammable aerosol;<br>Highly flammable liquid and vapour;<br>Flammable liquid and vapour;<br>Flammable solid;<br>May also include the following substances: *pyrophoric; self-heating; self-igniting; those which produce flammable gas on contact with water;* | [ ] Explosive<br>Unstable explosive;<br>Explosive; mass explosion hazard;<br>Explosive; severe projection hazard;<br>Explosive; fire, blast, or projection hazard;<br>May mass explode in fire; |
| [X] Serious Health Hazard<br>May be fatal if swallowed and enters airways; Causes damage to organs;<br>May cause damage to organs;<br>May damage fertility or the unborn child;<br>Suspected of damaging fertility or unborn child; **May cause cancer;**<br>Suspected of causing cancer;<br>May cause genetic defects;<br>**Suspected of causing genetic defects;**<br>May cause allergy or asthma symptoms or breathing difficulties if inhaled; | [ ] Oxidising<br>May cause or intensify fire (oxidiser);<br>May cause fire or explosion (strong oxidiser); | [ ] Gas under pressure<br>Contains gas under pressure - may explode if heated;<br>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 | | | |

**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*

"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 pot unusable.

**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.*

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| How many people handle the substance? | Nursing staff only. **NREC** - Up to 10 staff in clinic, only 1 person handles substance at a time. |
| Duration of exposure per shift/day/week/month | Pot is only opened for enough tiome to deposit specimen. |
| Quantity prepared at a time | One pot is used at a time generally. |
| Quantity used per shift/day/week/month | Used only as/when needed (infrequent). |
| Storage location and quantity; type of storage unit | Locked cupboard in sluice room or COSHH cabinet. |

**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.*

Formaldehyde poses an additional risk to pregnant staff (and the unborn). Advise not to be handled by pregnant staff due, and pregnant staff must not be exposed to spillages or clean up spillages; 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 to reduce risk of accidental exposure. Pregnant staff should only handle substance if they provide informed consent (once informed of the risks) and this is documented on their Pregnancy Care Plan Form 2.

**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*

H302+332 - Harmful if swallowed or inhaled
H317 - May cause an allergic skin reaction.
H341 - Suspected of causing genetic defects.
H350 - May cause cancer.

**Can the substance be *eliminated or* substituted for a safer product/form/concentration/quantity?** *Complete COSHH assessment for current substance if still in use; substitute; then re-assess/assess new substance*

Formalin is an effective preservative for tissue samples and also hardens samples to aid dissection. The product has been designed to reduce exposure. At present there is no reasonable alternative known or in common use.

**Current Control Measures** - *MSDS Section 8.2 ; engineering controls ; action on failure of control measures ; servicing and maintenance of engineering controls;*

Ventilation of OPD is ~4 air changes per hour (ACH).
6 ACH is advised by HTM 03-01 for general ward areas.
It is unlikely that the Workplace Exposure Limit will be approached or exceeded due to the nature of the product and the way it it handled.

**Safe Systems of Work** – *Documented procedures (attach/reference) ; Information Training Instruction Supervision ; restrictions on Confined/Restricted Spaces and Lone Working ;*

- Substance is kept locked in a cupboard in a sluice room or in a COSHH cabinet.
- 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.
- Health Surveillance deemed not necessary due to the small quantities in use, low frequency of use, small duration/quanity/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. The conditions in the workplace do not make it likely that the disease will occur.

| **Health Surveillance and Exposure Monitoring** – *if Yes, state type* | | |
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| 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.*

None known.

**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.*

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|---|---|---|---|
| **Mask** | ☐ | **Eye protection** | EN 166 safety glasses with side protection if there is a splash risk |
| **Respirator** | ☐ | **Visor** | EN 166 visor as an alternative to safety glasses if there is a splash risk |
| **Gloves** | Nitrile ~~gloves~~ EN 374 ☒ | **Protective clothing** | Disposable apron |
| **Footwear** | ☐ | **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 though 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, Carbon dioxide. **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*

Since only one pot is generally used at a time, the risk of spillage is low and the quantity of spillage will be small. A dedicated spill kit for formaldehyde is preferred where larger volumes of formalin are used, in order to neutralise the substance and minimise vapour. This may be in the form of a formaldehyde spill kit, formaldehyde absorbent (and neutralising) powder/granules, or a formaldehyde neutralising absorbent pad. Follow instructions for spill kit. Wear apron and double glove. *However, due to small volume (10mL) a dedicated spill kit is not a requirement. Use ample paper towels to clean up spill so that liquid is well absorbed and towels do not trip. Dispose of in a small plastic bag which should then be placed in a yellow bag for incineration.*

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 separately to other waste, label appropriately, and dispose of in yellow bag. Investigate cause, Datix if needed, replenish spill kit. Communicate findings of investigation, apply any preventative measures identified.

<u>Spill kit for smaller spills:</u> GV Health MJZ019 Health Spill Pack orderable via Oracle. Suitable for spill volumes up to 1 litre. 1 spill = 1 pack, requires replacment after use.

Advise stocking 2 packs, so 1 is available if 1 is used.

| **Required storage conditions** - *MSDS Section 7; add relevant information from other sources.* | |
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| **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 - pot must not be used if there is a precipatate. |
| **Container** | Keep in original container. |
| **Incompatible substances** | Oxidisers. |
| **Conditions to avoid** | Avoid dropping containers. |

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| **Security** | Must be kept locked away. |

**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 | |

**Assessment of the risk** – *this must be based on current control measures*

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| 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 |

***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.

| **Remedial/Additional Control Measures & Safe Systems of Work** (add more lines if needed) | **Target date** | **Date completed** |
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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**

*Multiply the Likelihood by the Consequence to obtain the Risk Score.*
*To reduce Likelihood: Control measures, Safe Syetems of Work; To reduce Consequence: Elimination, Substitution;*
*If applying remedial/additional control measures, reassess the Risk Score below once all measures are in place.*

**Current Risk: Risk scoring of existing control measures**

| Likelihood rating | 2 | x | Consequence rating | 1 | = | RISK LEVEL | 2 |
|---|---|---|---|---|---|---|---|

**Residual Risk: Risk scoring after remedial/additional control measures are in place**

| Likelihood rating | n/a | x | Consequence rating | n/a | = | RISK LEVEL | n/a |
|---|---|---|---|---|---|---|---|

**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-accesss 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 implmented 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. |

| **Details of COSHH Assessment and reviews** | |
|---|---|
| **Assessor details** – *the person who conducted the initial COSHH assessment* | |
| **Name** | Gerard Sellek |
| **Job Title/Role** | Health, Safety & Security Officer |
| **Dept. / Ward** | Health, Safety & Security |
| **Locality / Directorate** | NQPE |
| **Hospital / Site** | Prince Philip Hospital |
| **Date** | 02/02/2022; minor updates 16/06/22 and 28/03/24 |
| **Review period** | 12 months |

**COSHH assessment reviews** – *carry out perdiocially 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.*

| **Review date** | **Reviewer name & role** | **Check for updated MSDS;** record relevant changes | **Findings, actions, and date of completion** |
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**Communication** – *how and where is this information shared and used e.g. IT IS (Information, Training, Instruction, Supervision)*

Staff using substance should read the COSHH assesssment and sign the reverse to document it.
Keep COSHH filte adjacent to COSHH cabinet.