Hydrogen Peroxide vs Formalin technology

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Aims

- Decontamination
  - Fumigation operations
- Formaldehyde
- Automated hydrogen peroxide systems
- Other technologies
- CoPI and New guidance
Decontamination

• Definition
  – *Reducing microbial contamination to an acceptable level*
  – Not (necessarily) sterilisation

• Circumstances
  – Emergencies during normal operations
  – Planned shutdowns (with associated preparation)
Available technologies

- **Surface decontamination**
  - Any liquid disinfectant
  - Wipe, mop or spray
- **Fumigation**
  - Gas
  - Vapour
  - Mist (Fogging)
Application

Microbiological safety cabinets

High containment laboratories
Fumigation

- Planned exercise
- Appropriate controls in place
- Named, trained personnel
- Agreed plan
- Method that is known to be effective in the circumstances of use
Guidance

• The management, design and operation of microbiological containment laboratories

• Safe working and the prevention of infection in clinical laboratories and similar facilities

• Managing the risks
Formaldehyde

• Advantages
  – Long experience of successful use to decontaminate rooms and safety cabinets
  – Inexpensive and easy to handle
  – Simple to use and easy to detect
  – Claimed broad spectrum efficacy
  – Effective against *M. tuberculosis*
Formaldehyde

- Disadvantages
  - Slow acting, poor penetration
  - Removal at end of decontamination
  - Strictly regulated in some countries
  - Health effects
    - Toxic, carcinogenic
    - Reacts with chlorine to form bis-chloromethyl ether
    - Paraformaldehyde deposition
Method

- Formalin (38-40% formaldehyde) and water in a thermostatically controlled unit
- Safety cabinets (60mL Formalin, 60mL tap water per m³, 24g/m³)
- Rooms (100mL Formalin, 900mL tap water per 1000ft³ (27m³), 1.5g/m³)
- Visible condensation
- No neutralisation
US method

- Evaporation of paraformaldehyde (10.6g/m³, 0.3g/ft³)
- Separate humidification to 60-85% and heating to >21.1°C
  - Can take days
- Neutralise with ammonium carbonate
- (1.1-1.3g/g of paraformaldehyde)
- Regulatory approval (EPA) may be required
Bombing

- Historical method
  - Formalin and water and crystals of potassium permanganate
  - Vigorous reaction
  - Shown to be ineffective
  - NOT recommended
Health effects

• Exposure
  – 0.1 – 5 ppm
    • burning of the eyes, tearing
    • general irritation of upper respiratory passages
  – 50 - 100 ppm
    • Pulmonary oedema, pneumonitis, death
• International Agency for Research on Cancer (IARC)

“Overall, the working group concluded that the results of the study of industrial workers in the USA, supported by the largely positive findings from other studies, provided sufficient epidemiological evidence that formaldehyde causes nasopharyngeal cancer in humans.”
HSC`s advisory committee on toxic substances

• Working group on action to control chemicals (WATCH)
  – “Formaldehyde has probably caused nasopharyngeal cancer”
  – “It is probable that formaldehyde exposure has caused nasopharyngeal cancer in humans, via a mechanism to which it can be predicted that chronic inflammation (provoked by irritancy) and genotoxicity contributed”
Formaldehyde

- HSE to produce further advice and guidance
  - CHAN
  - Possible re-classification
- Potential occupational carcinogen
- Prevent exposure
  - Engineering controls
  - Stringent work practices
Reclassification

• July 2005, Toxicology Unit, INRS, France
• Current classification
  – Carc. Cat.3; R40
• Proposed classification
  – Carc. Cat 1; R49
“Epidemiological studies show an elevated risk for tumour induction at the site of contact by inhalation of formaldehyde with a convincing body of evidence to establish a causal relationship for nasopharyngeal cancers.”
Biocidal Products Directive (98/8)

- All products on the EU market before May 2000 had to be identified
  - Existing active substances
- Identified
  - Companies not supporting
  - Cannot be placed on the market after 1st September 2006
- Notified = intention to support
  - Full package of data on toxicology, its fate and behaviour in the environment etc
Biocidal Products Directive (98/8)

- Support
  - Notified active substances
  - 23 product types
- EC have set deadlines for submission of dossiers on active substance and the associated product type
Biocidal Products Directive (98/8)

• Each active substance has been allocated to a Member State for evaluation
  – Completeness check (3 months)
  – Evaluation of both dossiers (within 12 months)
  – Inclusion in Annex 1 of BPD

• Annex 1 will be a positive list of all active substances that can be used in biocidal products
Formaldehyde

• Has been notified as an active substance in many different product types
• For part 3 of the review programme
  – Formaldehyde notified in PTs 1-6 and 13
  – PT2 Private area and public health area disinfectants
• A dossier must be submitted by 31st July 2007
Formaldehyde

• If dossier submitted
  – Evaluation document will only be available for discussion between MS by 31\textsuperscript{st} July 2008

• If dossier \textbf{not} submitted
  – Other companies or MS may support (3 months to notify their intention)
  – If dossier \textbf{not} taken over products containing formaldehyde in the unsupported areas will have to be removed from the market (18mths)
  – Product \textbf{not} available after January 2009
Hydrogen Peroxide

How VHP biodecontamination works....

- Vaporization
- Cold Sterilization Process
- Sporicidal at Low Concentrations (Typically 1-2 mg/l at 25°C)
- Non-Toxic By-products

$2H_2O_2 \rightarrow 2H_2O + O_2$
“Wet versus Dry”

- **Dry (VHP)**
  - Concentration of VHP is maintained below the condensation point
  - Four phases:
    - Dehumidification
    - Conditioning
    - Sterilisation
    - Aeration

- **Wet**
  - Layer of hydrogen peroxide micro-condensation on all exposed surfaces
  - Three phases:
    - Pre-conditioning
    - Gassing
    - Aeration
Efficacy and validation

- Broad spectrum, rapid antimicrobial
- Efficacy affected by presence of organic and inorganic materials (e.g. proteins, lipids)
- Presence of blood
- *Mycobacterium* species
- Catalase producers
Efficacy

- Efficacy dependant on a number of factors
- Pre-cleaning (or disinfection) before gaseous disinfection is recommended to reduce microbial concentration and dilute presence of protective agents
- Control and understanding of the process is essential
Validation

• Type, scope and source of contamination
• Reflect worst case conditions
  – Most resistant organism on the most resistant material
• Documentation
• Risk assessment
• Information, instruction and training
Chlorine dioxide

• Short lived highly reactive oxidising gas
• Disrupts proteins, interferes with protein synthesis and membrane transport
• Successfully used on a very large scale for building decontamination
• Lack of peer reviewed studies
• Being developed as laboratory gaseous disinfectant
Ozone:

- Highly effective disinfectant of aqueous systems
- Highly reactive
- High concentration required to produce sporocidal effects
- Will harm and destroy materials used in containment facilities if used at a high concentration
- Not used at present as a laboratory gaseous disinfectant
New guidance

“Fumigation operations in microbiological containment laboratories: guidance on the available technologies and their application”
Status

- Draft version
- Consultation exercise
  - Key stakeholders
  - Fit-for-purpose
- Amendments
- Meet with interested parties
- Publication on the HSE website
Community of practice and interest

- Bio-decontamination CoPI
- Continue dialogue
- Develop a network of interested parties
- Learn from each other
- Keep up to date with future developments
- Valuable resource for anyone developing guidance
Bio-decontamination CoPI

• Delegates and others are asked to express their interest in joining this CoPI by sending an email to:
  – germs.gmos@hse.gsi.gov.uk

• A formal invitation and password will then be supplied by the organiser

• Details on how to use the CoPI will appear when you first register
Think Bike!!!

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