The Efficacy of Chlorine dioxide as a disinfectant

Cleanroom Disinfection Is Critical

- Gloved hand every 10 mins
- Disinfect materials coming in through the air locks i.e. spraying in
- Surfaces e.g. bench tops frequently as required during the day
- All floors daily/ walls weekly
- It is vital the correct disinfectant for the application and area is selected

Industry Expectations

- To rotate 2 disinfectants
- To have 1 sporicide
- Disinfectants to pass the EN standards
- To use a disinfectant that is effective within the ‘cleanroom drying time’

Disinfectant Selection Factors

- Efficacy
- Concentration
- Contact Time
- Temperature/Water Quality
- Surfaces/Compatibility
- Rotation/mode of action
- Manufacturer

Disinfectant Validation

- Establish what you want to achieve
- Check Manufacturers data
- EN results-1276,1650,13697,13704
- Test to the right contact time
- Test in-house micro-organisms to EN standard
- Routinely test any environmental isolates

Disinfectant Validation

- EN1276
  - Log 5 reduction (Bacteria) in 5 minutes, carried out in clean and dirty conditions. A suspension Test
- EN1650
  - Log 4 reduction (fungi) in 15, 30 minutes, carried out in clean and dirty conditions. A suspension Test
- EN13697
  - Log 4 reduction bacteria log 3 fungi. A Surface Test
- EN13704
  - Log 3 in 60 minutes. Sporicidal Test
Standard Organisms Used:

- **EN 1276 Bactericidal**
  - *S. aureus* ATCC 6538
  - *E. hirae* ATCC 10541
  - *P. Aeruginosa* ATCC 15442
  - *E. Coli* ATCC 10536
- **EN 1650 Fungicidal**
  - *C. Albicans* ATCC 10231
  - *A. Niger* ATCC 16404
- **EN 13704 Sporicidal**
  - *B Subtilis* ATCC 6633 Spores
- **EN 14476 Virucidal**
  - Adenovirus-5 and poliovirus-1

Contact Time

- Due to ventilation systems causing surface drying contact time should be REALISTIC
- Require a disinfectant which is effective within the drying time-check EN data
- An average drying time in a cleanroom is 5-8 minutes

Rotation of disinfectants

- EU GMP states where disinfectants are used, more than one type should be employed
- FDA Guidance on Aseptic Processing suggests a disinfectant programme should include a sporicide and trends should be monitored

Rotation of disinfectants

- Ideally disinfectants with different modes of action, ie different actives
- Rotate biocides
  - Weekly
  - Monthly
  - Sporicide for action point use

Modes of Action

Biocides for bacteria and fungi

- Alcohols
- Quaternary Ammonium Compounds (Quats or QAC’s)
- Phenols
- Amphoteric Surfactants
- Biguanides
  None of these has a sporicidal effect!
Sporicidal biocides
- Aldehydes
- Hypochlorites
- Hydrogen peroxide / peracetic acid blends
- Chlorine Dioxide

Chlorine Dioxide Chemistry

Tristel Chlorine Dioxide (ClO₂⁻):
- 2 safe components
- Organic acids (citric acid)
- Sodium chlorite

Innovation & Benefits
- Speed of activation: near instantaneous generation of required level of chlorine dioxide
- Organic activating solution
- Low concentrations (0.01 – 0.1%)
- Not an irritant to skin or respiratory system
- Non-carcinogenic, non-mutagenic
- Non-fixating and most effective against biofilm
- Safe to environment (decomposes to salt)

Chlorine dioxide – mode of action

ClO₂⁻ mode of action:
- Oxidising biocide
- Deactivates microorganisms:
  - penetrates the cell wall
  - inhibits protein synthesis, through disrupting the transport of nutrients
  - organism dies through lysis
- Effective against dormant organisms and spores

Efficacy of ClO₂⁻

- Approved using European Norms
- All tests performed in independent laboratories
- Tested in-use concentration
- Tested at commercially quoted time, not at 60 minutes required by the European Norms

Health & Safety of ClO₂⁻

- 2 inert components: Chlorine dioxide is generated at the point of use
- Toxicological tests performed confirm:
  - Not an irritant nor sensitiser to skin, eyes, respiratory system
  - Neutral pH
  - Biodegradable: decomposes to a salt solution
  - Radically different from chlorine:
    - does not chlorinate
    - non-carcinogenic, does not produce Trihalomethanes (THM)
Material Compatibility guidelines

**Good**
- High grade stainless steel (316)
- Tungsten
- Glass
- Timber and coating
- Polycarbonate
- Polypropylene
- Silicon
- Carbon fibres
- Plastic PETP, PVDF

**Poor**
- Aluminium
- Brass and brass plated steel
- Copper
- Chrome
- Mild steel
- Rubber

Summary

- Completely free of dangerous substances like aldehydes, acetic acids, alcohols or chlorine
- Maximum efficacy (sporicidal)
- Effective in minutes (5 minutes/30 seconds)
- Not an irritant or sensitizer
- Excellent precision: controlled dose for accurate concentration
  - One product, one concentration, one strength → Zero confusion
- Minimal packaging and storage space
- Ease of handling: de-skilled process for comfort and safety of use

Summary

- Establish what performance you require from your disinfectant prior to selecting
- Test in house environmental isolates
- Check all parameters of the ‘selection criteria’
- Ensure you have a complimentary rotational pair
- An effective sporicide must be validated

Any questions?