

Cleaning & disinfection in a Cleanroom

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Michael Richter



Overview



- ▲ The need and consequences of using a disinfectant
- ▲ The cleaning and disinfection SOP



Why do we need a disinfectant?

EFFICACY

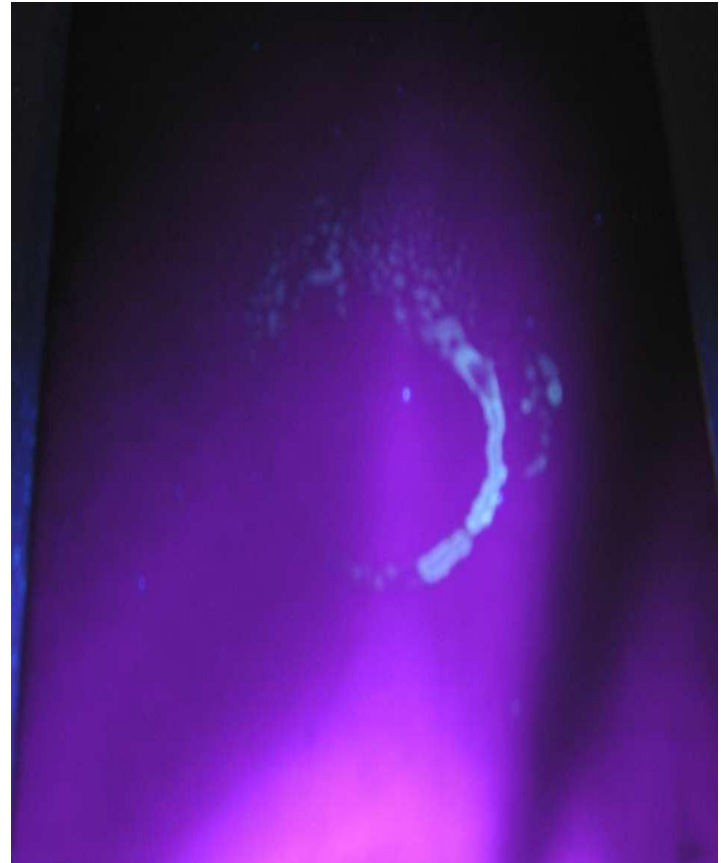
- ▲ The consequences of using a disinfectant that you see everyday (free of charge!) are:
 - Residues
 - Corrosion
 - Operator complaints
 - Increased workload for QA department
- Each of these consequences reduces your profit

Residues



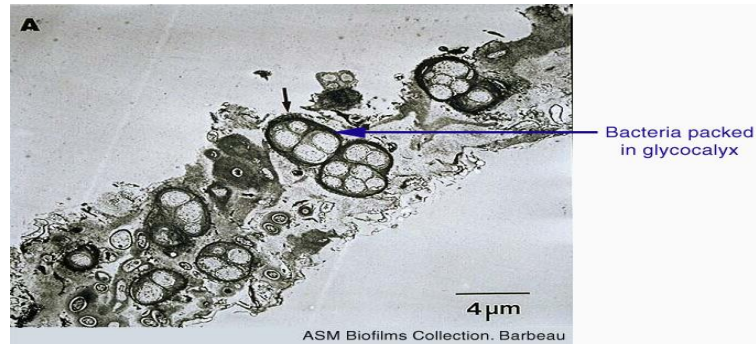
▲ You have two options:

1. You do NOT rinse
2. You rinse



1. No Rinsing

- A cosmetic issue
- EM results errors : sticky floor (more sticky than Petri Dish?)
- Disinfection variances?
- Cross contamination from lower to higher grade and chance it will contaminate a final manufactured batch



2. Rinsing



- ▲ Manpower : how much does a person cost per hour : 50 – 80€ ?
- ▲ Cost of the rinsing liquid :
 - Alcohol : sterile or non sterile
 - Water : sterile ?
 - Origin of the H₂O
 - How to transfer
 - H&S issue : slippery
 - Contamination risk
 - What to do with the waste water?
- ▲ Additional mopheads, new sterile buckets
- ▲ QA needs more SOP's
- ▲ Rinsing or Diluting?
- ▲ How is it validated : cost
- ▲ The more SOP's the more difficult questions from audits
- ▲ STOP production : cost 1 hour of production : 5.000 to 100.000€ or more?
- ▲



Corrosion



▲ You have two options:

1. You do NOT rinse
2. You rinse



1. No rinsing



You have the same issues as with the residues:

- Discoloration
- EM results ?
- Particles release
- Cross Contamination
- Disinfection variances

And...



▲ You have extra cost of buying new SS materials.

2. Rinsing



You have the same issues as with the Residue discussion

- ▲ Manpower
- ▲ Extra alcohol or extra water
- ▲ Extra mopheads and buckets
- ▲ Rinsing or Diluting
- ▲ QA SOP's and validation
- ▲ NO production



Operators

- ▲ Bad smell
- ▲ Irritation
- ▲ H & S issues



→ CONSEQUENCES OF THIS :

- ▲ More protective garments
- ▲ Install special procedures
- ▲ People dislike the product :
 - Dilution errors
 - Frequency of sporicidal use decreases



Optimize QA work and SOPs



- ▲ Raw materials (concentrate) + water
 - Quality of the water
 - Dilution
- ▲ Cleanroom cost for the dilution
- ▲ Transfer into other cleanrooms.
- ▲ Packaging
- ▲ Sterilisation
- ▲ Certificate of analysis, sterility, stability
- ▲ Equipment (filters, autoclave,)
- ▲ Personnel
- ▲ Regulations
- ▲ Forecast and planning of production



Which disinfectants to chose?

- ▲ Your decision should be driven by a TCO review
 - To improve performance
 - To decrease production cost



Cleaning and disinfection procedures

There are two types of surface:

▲ Small surfaces (critical surfaces) such as:

- production line
- LAF
- Isolator
- Door handles
- Gloves



▲ Large surfaces:

- Floors
- Walls
- Ceilings





Best Practice :

- First Clean
- Then Disinfect

Everyday? Depends on situation !!



Small surfaces procedure



Ready to use product with limited rinsing:

	Monday	Tuesday	Wednesday	Thursday	Friday
Product	Alcohol				Neutral Detergent
Rinsing	NO rinsing				WFI H2O or high grade alcohol. If needed
Product					Sporocidial

Small surfaces procedure



Ready to use product with limited rinsing:

▲ Alcohol:

- non corrosive + non irritant + no residues

▲ Neutral detergent :

- non ionic
- non corrosive + non irritant + moderate residues

▲ Sporocidal

- H₂O₂
- non corrosive + no residues

Large surfaces procedure



	Monday	Tuesday	Wednesday	Thursday	Friday
Product	Low residue broad spectrum disinfectant				Neutral detergent
Rinsing	NO Daily Rinsing				WFI H2O or high grade alcohol → If needed
Product					Sporocidal

Large surfaces procedure



Ready to use product with limited rinsing:

▲ Broad spectrum disinfectant

- Low QUAT, non corrosive, non irritating, minimal residues

▲ Neutral detergent :

- non ionic
- non corrosive + non irritant + moderate residues

▲ Sporocidal

- H₂O₂
- non corrosive + no residues

Or

- Active Chlorine
- Need for a rinsing step

Back up / Shut down procedure



Ready to use product, rinsing is recommended:

	Back up or after shut down
Product	Neutral Detergent
Rinsing	WFI or high grade alcohol recommended
Product	Sporocidal
Rinsing	WFI or high grade alcohol recommended

▲ Neutral detergent

- non ionic , non corrosive, non irritating, moderate residues

▲ Sporocidal

- Active Chlorine
- Need for a rinsing step

Added value services



- ▲ We have a team of validation experts which are available for supporting your Efficacy Validation testing
- ▲ SiteCheck support



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Questions?

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