How did Disinfectant Residues turn from Friend to Foe?

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ECOLAB

Residues Management

Agenda

- Regulatory Expectations – Focus for Authorities
- Potential Impact of Residues
- Residue Determination – Visually Clean
- Residue Determination – Beyond Visually Clean
- Conductivity testing – Materials and method
- Residue removal techniques
- Conclusions

FOCUS ON RESIDUE MANAGEMENT

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*"Residue buildup **can lead to mixing chemistries of disinfectants thus interfering with the expected efficacy** or altering the external layer of the material so that the initial efficacy studies are no longer an accurate representation of the disinfectant's action on that surface/material."*

Potential Impact of Residues

AUDIT WARNINGS

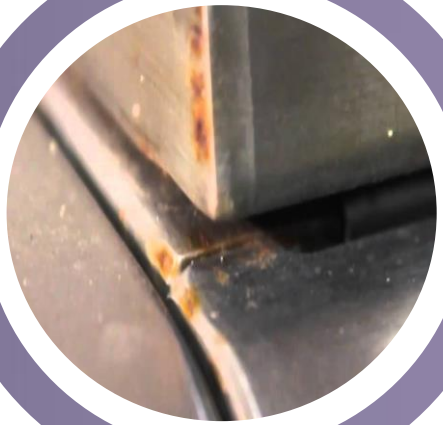
Inspectors tend to define it as minor to major (FDA Form 483)

SAFETY

Slippery floors, sticky surfaces, attack of PPE (gloves)

HEALTH

Inhalation or skin sensitization due to volatile (by-) products

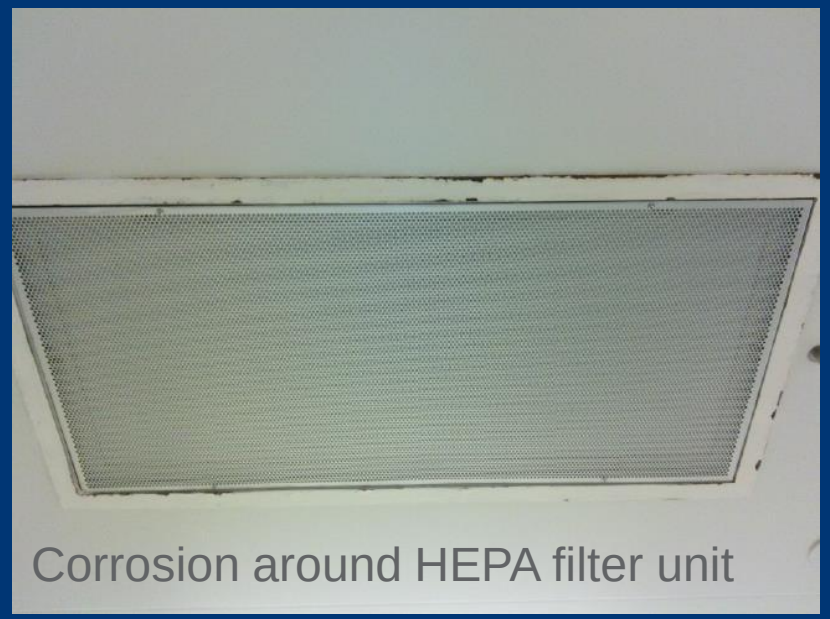


COMPABILITY

Corrosion of equipment and materials, chemical reactions

Residues in Cleanrooms

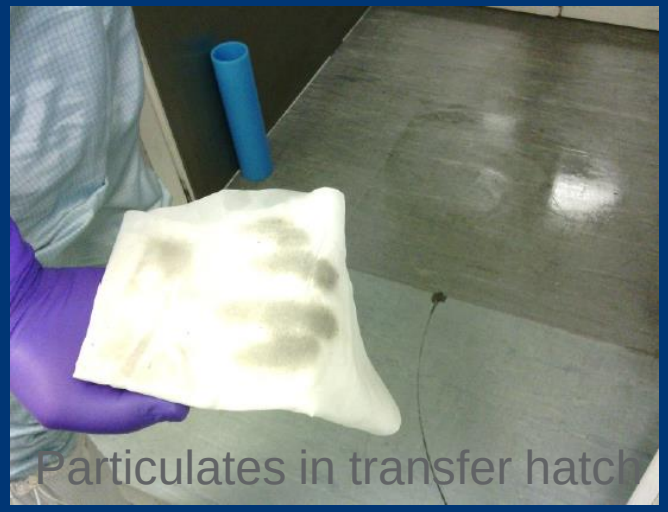
Discoloration around floor coving



Corrosion around HEPA filter unit

Degradation on door

Residues on wall and table



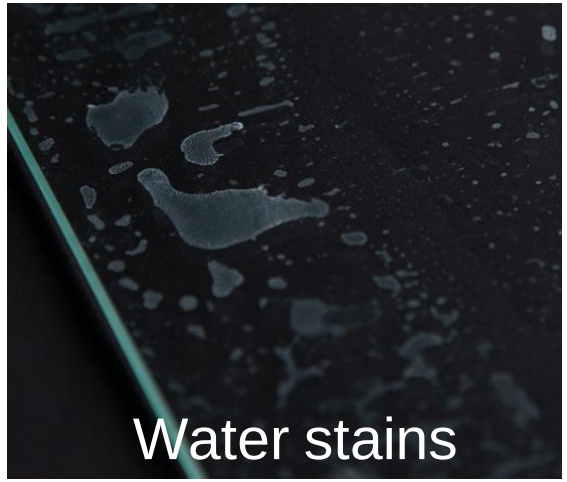
Particulates in transfer hatch

Discoloration of cleanroom shoes

Residue Determination – Visually Clean

- Visibility is a subjective measure
- The visibility of residues to the naked eye is often linked to accumulation over time and strongly dependent on:
  - Light conditions
  - Surface type
  - The method of application (spraying, wiping or mopping)

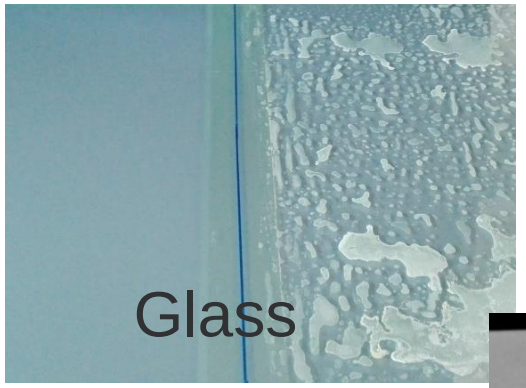
Type of residues

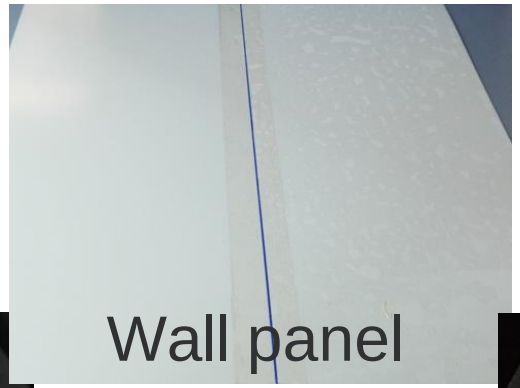


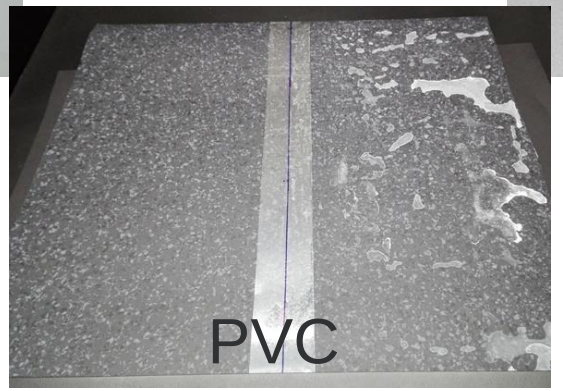
Residue Determination – Visually Clean

Detecting residues

- Surface dependent.
- Chlorine product applied 5 times on standard surfaces:







Residue Determination – Beyond Visually Clean

- Various methods and techniques are available :
  - HPLC, Gas Chromatography, Titration, UV, IR or Conductivity

- The benefit of using the Conductivity method is having an immediate result
- Conductivity is a practical tool to quantify residues in real-time:
  - Sample collection by wetted wipes
  - Read-out of results in minutes

- Use high purity and low polarity wipe for a highest recovery rate (100% polyester wipe for example)
- 100% polyester wipes have a better residues release

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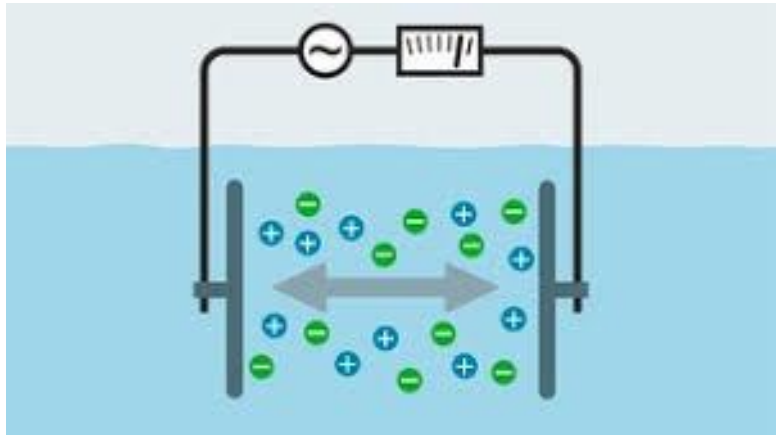
Conductivity Testing: Materials & Method

Conductivity Testing

- Conductivity displays amount of **ionic species** in an **aqueous solution**
- Conductivity **correlates to** amount of **residues** – but not all residue are ionic
- Residues removed from surface by wiping – Wipes placed in Water
- **Linear correlation** of amount of residue to amount of water – **dilution effect**
- **Results reproducible** – even after successive application + measurement



Conductivity testing - Material

Conductivity meter

- To measure conductivity, a standard portable handheld device is most suitable

Conductivity testing - Method

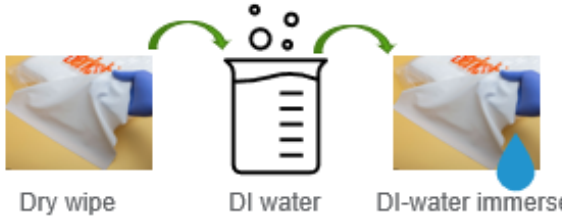
Procedure for Wiping and Conductivity testing

Step 1:

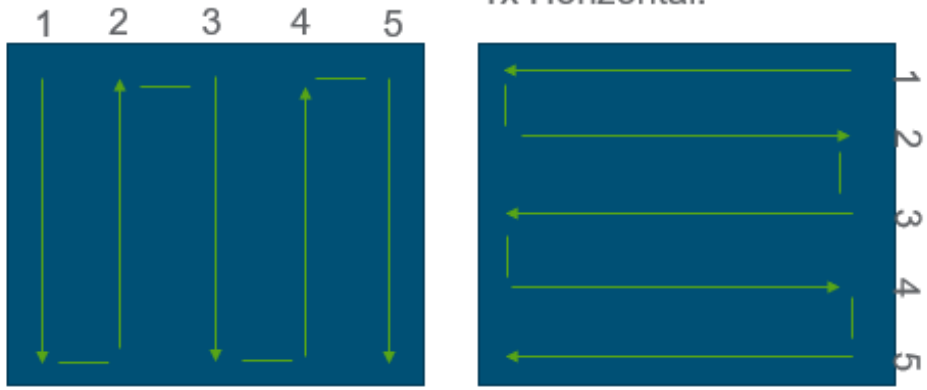
Fill beaker with 100 mL DI water and measure conductivity value of DI-water only for reference

Beaker with 100 ml DI-water

Step 2: Wipe over the dried test surface with DI-immersed wipe (put in the pre-filled beaker) – Berkshire 100% Polyester wipe



Wipe over dried surface



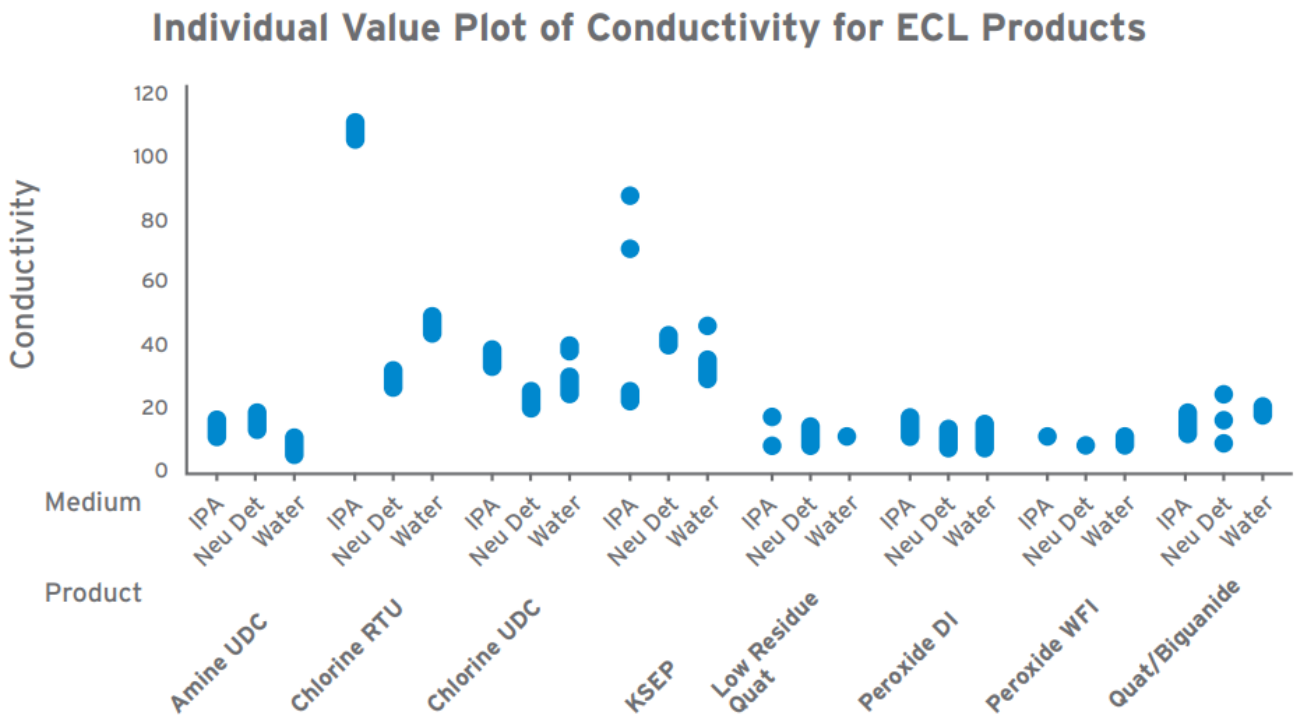
Step 3:

Put the wipe into the beaker and measure the conductivity of water with the wipe inside.

Residue Removal Techniques

Residue Removal Techniques

What is the best multi purpose rinsing agent to use for the removal of residues?



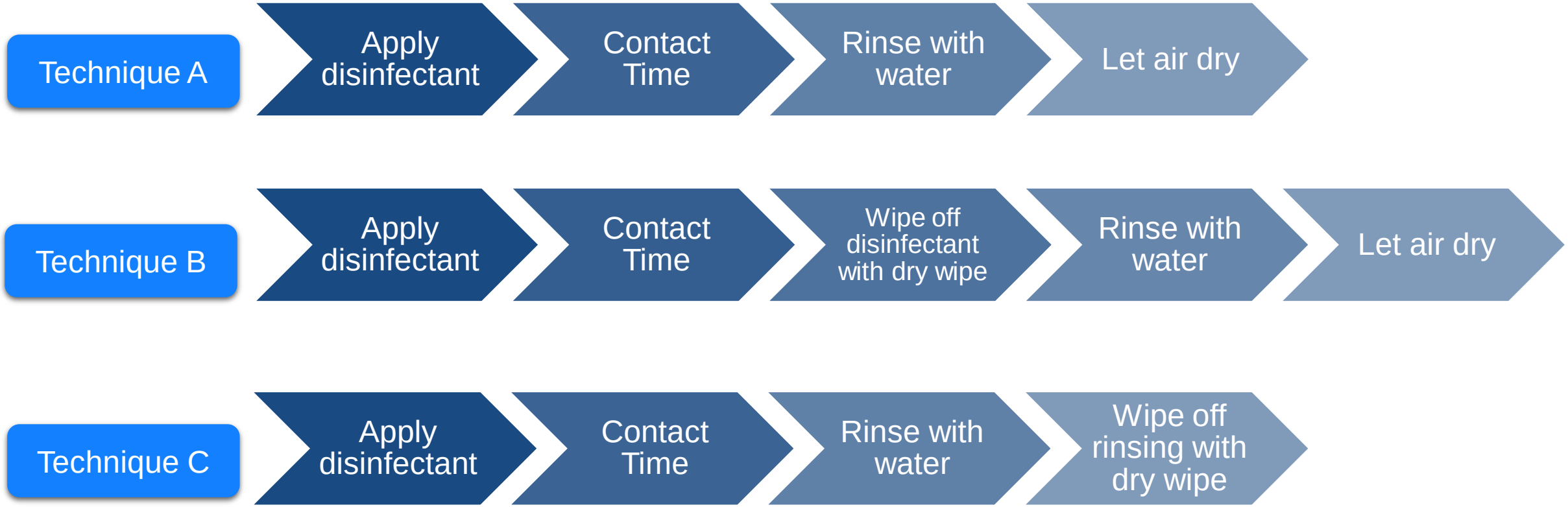
Test method :

- A defined amount of the disinfectant was applied to a stainless-steel plate, dried, and a conductivity swab taken.
- The rinsing agent to be tested was then applied once and a conductivity swab taken by wiping the surface.
- Graph shows the remaining conductivity after rinsing with each of the cleaning agents.
- On average the results show that in general water removes significantly more residues than IPA

Figure 1: Remaining conductivity [µS] resulting from the remaining residues after rinsing of the Klercide products with each of the 3 rinsing agents, with minimal 2 and up to 4 replicates per product.

Residues Removal Techniques

What is the best technique for removal of residues



Residues Removal Techniques

What is the best technique for removal of residues

Table 1: Results using Technique A - Use of a rinsing agent for residue management of each Klercide product, determined by conductivity, of the remaining residues, using Technique A

Product Name	Name Used In Fig. 1	Residue On Evaporation Of Klercide [Ppm]	Best Rinsing Agent	Reduction In (%)
Klercide Low Residue Quat	Low Residue Quat	400	Water / Ipa	51*
Klercide Amine UDC	Amine UDC	2000	Water	70
Klercide Quat / Biguanide	Quat/Biguanide	6800	All	85
Klercide Sporicidal Low Residue Peroxide WFI	Peroxide WFI	10	Water	53
Klercide Sporicidal Low Residue Peroxide DI	Peroxide DI	56	Water	61
Klercide Sporicidal Enhanced Peroxide	KSEP	15000	Water / Ipa	55*
Klercide Sporicidal Active Chlorine	Chlorine RTU	19000	All	94
Klercide Sporicidal Active Chlorine UDC	Chlorine UDC	12000	All	90

* Improved residue management can be achieved with Technique C (immediately wipe dry after rinsing with water) as shown in Table 2

Residues Removal Techniques

What is the best technique for removal of residues

Table 2: Results using the recommended Residue Management Technique C - First rinse with cleaning agent and then wipe dry

	Best Rinsing Agent	Reduction By (%)
Klercide Low Residue Quat	Water + Dry Wipe	64
Klercide Sporicidal Enhanced Peroxide	Water + Dry Wipe	89

- **Conclusion**

Protocol 3 gave much better results, which was shown in a conductivity reduction of almost 90%.

This residue management technique (rinse by mopping with water and dry immediately) has been developed delivering outstanding results: supported by both objective data and visual assessment.

Residue Management

CONCLUSIONS

Residue management has become a highlight given recent regulatory developments

The Standard is “*Visually Clean*” for non-product contact surfaces, but visual assessment can prove difficult and ambigous

A simple method based on conductivity can aid evaluating residues on surfaces to build a robust residue management regime

Thank you for your attention

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