

TECHNOTES

by  **Texwipe**[®]
An ITW Company



Disinfection procedures

are essential to ensure that **no infectious pathogens** can be **transmitted** to patients from the pharmaceutical manufacturing environment.

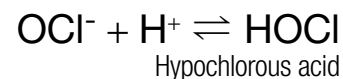
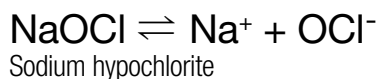
Bru-Clean: The Mo' Better Bleach

Role of Disinfectants in Critical Cleaning

A disinfectant is intended to destroy or inactivate one or more specific microbial group(s) in a given environment. According to the CDC definition, disinfection is a process that eliminates many or all pathogenic microorganisms, except bacterial spores, on inanimate objects¹. Disinfection procedures are essential to ensure that no infectious pathogens can be transmitted to patients from the pharmaceutical manufacturing environment. To have maximum effectiveness, it is important to ensure judicious selection and proper use (per-EPA label) of a disinfectant in any facility.

Use of Liquid Bleach

Bleach is a commonly used chlorine-based disinfectant due to its widespread availability and long history. Several bleach products are registered as disinfectants with the EPA, with specified kill claims. The active ingredient in Liquid Bleach is hypochlorous acid (HOCl), in the form of sodium hypochlorite as below:



However, despite its common use, Liquid Bleach is not a particularly suitable disinfectant for use in critical cleaning applications for the following reasons:

1. Limited shelf life and stability

The extent to which available chlorine is either consumed or decays over time is accelerated by the storage of Liquid Bleach. This means that the kill claims made on the EPA label are no longer valid at the reduced active chlorine concentrations. This necessitates either off-label use through extended contact times, or the addition of excess Liquid Bleach to the dilution water to return the solution to the correct active chlorine concentration. It is often recommended to measure the active chlorine concentration of Liquid Bleach prior to use for this reason.

These outcomes and additional procedures are undesirable in a life science environment where the effectiveness of disinfection is a core ingredient of product safety.

2. Corrosiveness:

Chlorine-containing solutions are strong oxidizers and can be corrosive to personnel and surfaces. Stainless steel surfaces that are commonly found in life science manufacturing environments are corroded by Liquid Bleach and need to be wiped (with water) following disinfection.

Decay of Active Chlorine in Bleach

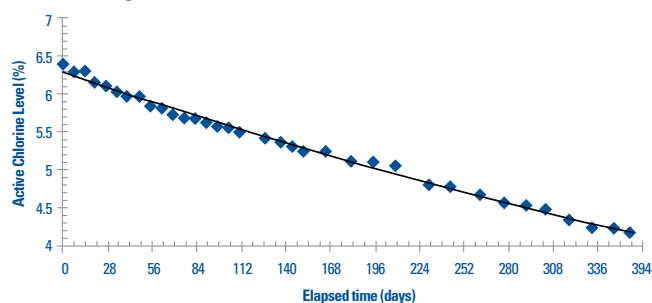


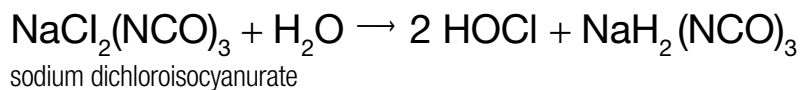
Figure 1. Active Chlorine Level in Liquid Bleach as a Function of Time. Liquid Bleach was assayed for its active chlorine level approximately weekly. From these data, the half-life for Bleach was determined to be 605 days with a 99.5% correlation.



Bru-Clean: The Mo' Better Bleach

Bru-Clean as an Alternative to Liquid Bleach

Bru-Clean TbC™ is a tablet comprised of sodium dichloroisocyanurate (NaDCC) as the active ingredient. It is a premeasured tablet that, when added to one gallon of water, creates a disinfectant solution of available chlorine. Therefore its germicidal mechanism of action is similar to Liquid Bleach. Bru-Clean TbC is an EPA registered disinfectant (71847-2-106).



Use Concentrations

Bru-Clean is a pre-measured tablet that generates the disinfectant solution by dissolving it in 1 gallon of water. The resulting solution has an available chlorine concentration of 937 ppm. Since the tablet is conveniently pre-scored, it can be readily halved to generate lower volume solutions at the same concentration. The disinfecting solution is generated at time of use, hence the concentration of available chlorine remains stable at 937 ppm and delivers the expected germicidal efficacy, as per its EPA label.

In contrast, Liquid Bleach concentrate directly out of the gallon jug that one can typically source from any catalog or store for purposes of hard surface disinfection is a 5.25% sodium hypochlorite (NaOCl) solution. This solution carries a theoretical available chlorine concentration of 50,000 ppm. As per EPA registration label use directions, Liquid Bleach may be used at 10% (1:10), 5% (1:20) or 1% (1:100) dilutions, depending on the product. This would translate into solutions that are approximately 5000 ppm, 2500 ppm and 500 ppm respectively.

Comparison of Kill Claims

Germicidal activity of Liquid Bleach is a direct function of the concentration of available chlorine. The intrinsic variability in the available chlorine concentration of Liquid Bleach solutions translates into uncertainty surrounding the germicidal kill claims that are made based on testing according to the EPA "as directed" concentration.

In contrast, the concentration of the Bru-Clean TbC™ solution is a reliable 937 ppm at point of use. A comparative analysis of kill claims per EPA labels for Bru-Clean at 937 ppm and Liquid Bleach at 2400 ppm indicates very similar germicidal activities as indicated in Table 1. It is important to note that EPA label claims only reflect the organisms tested at a given concentration. The absence of a kill claim against a particular organism does not automatically mean that the product is ineffective, instead it only indicates that it was not tested against that bug.

Bru-Clean

is a tablet comprised of
**sodium
dichloroisocyanurate**
which generates
hypochlorous acid (HOCl)
as the active ingredient.



However, it is significant to note that at the much lower 937 ppm active chlorine concentration, Bru-Clean carries a 10 min contact time claim against *Mycobacterium tuberculosis var. bovis* (TB), while Liquid Bleach only carries the same claim at 5000 ppm. It is important to recognize that the germicidal activity of Liquid Bleach will be critically dependant on the exact concentration at time of use, which is unpredictable based on its reduced stability and limited shelf life.

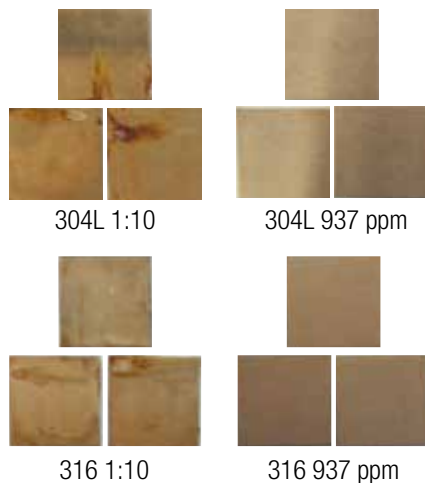
Corrosion of stainless steel surfaces

We performed corrosion testing of 304L and 316L Stainless Steel surfaces using both Liquid Bleach and Bru-Clean. Liquid Bleach was found to cause significantly more corrosion at use concentrations of 5000 ppm and also at 1000 ppm compared to 937 ppm for Bru-Clean². The consequence of the corrosion of stainless steel work surfaces by Liquid Bleach is that one must replace these surfaces more frequently in the cleanroom, which is not cost effective. Also, it becomes advisable to wipe surfaces clean of any bleach residues left behind after treatment to minimize corrosive effects.

Corrosive nature of liquid bleach (safety hazard)

The higher the concentration of available chlorine, the greater is the corrosive safety hazard to the personnel handling the bleach. Since Bru-Clean has a similar germicidal kill profile at much lower concentration that is predictably stable at point of use, it is a safer product to use and more desirable for disinfection.

Figure 2: Comparison of the effect of Liquid Bleach and Bru-Clean on 304L and 316 Stainless Steel coupons at recommended use concentrations of 10% and 937 ppm respectively



Microbe	Bleach		Bru-Clean 937 ppm
	ppm	minutes	minutes
Bacteria			
Clostridium perfringes USDA			10
Enterococcus faecalis Vancomycin Resistant			10
Escherichia coli O157:H7	2,400	10	10
Klebsiella pneumoniae	2,400	10	10
Legionella pneumophila	2,400	10	
Mycobacterium tuberculosis var. bovis	5,000	10	10
Pseudomonas aeruginosa	2,400	10	10
Salmonella enterica	2,400	10	10
Shigella dysenteriae	2,400	10	
Staphylococcus aureus	2,400	10	10
Staphylococcus aureus (MRSA)	2,400	10	10
Staphylococcus aureus (GRSA)			10
Staphylococcus epidermidis			10
Streptococcus dysgalactiae			10
Streptococcus pyogenes	2,400	10	
Streptococcus uberis			10
Virus			
Adenovirus Type 2	2,400	10	
Avian Influenza Type A	2,400	10	10
Canine Parovirus	2,400	10	10
Cytomegalovirus	2,400	10	
Feline parovirus	2,400	10	
Hepatitis A virus (HAV)	2,400	10	10
Herpes Simplex Types 1			10
Herpes Simplex Types 2	2,400	10	
HIV-1 (AIDS virus)	2,400	2	10
Influenza A2	2,400	10	
Norovirus			10
Poliovirus type 1			10
Respiratory Syncytial Virus (RSV)	2,400	10	
Rhinovirus Type 17	2,400	10	
Rhinovirus Type 37	2,400	10	
Rotavirus WA	2,400	10	
Rubella virus	2,400	10	
Varicella zoster virus	2,400	10	
Fungus			
Candida albicans	2,400	10	
Trichophyton mentagrophytes	2,400	10	10
Aspergillus niger	2,400	10	

Table 1: Comparison of kill claims for Bleach and Bru-Clean at use concentrations



Bru-Clean: The Mo' Better Bleach

References

1. *Guideline for Disinfection and Sterilization, 2008*; W.A. Rutala and D.J. Weber, HICPAC; www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf
2. *Are your stainless steel surfaces being corroded by liquid bleach?* (2011) W. Hollands and J. Postlewaite, manuscript submitted for publication

Convenience

Liquid Bleach typically comes in gallon jugs that weigh more than 9 lb. each. As purchased by the case loads, it is heavy and inconvenient to transport and must be stored under appropriate conditions, otherwise the reduction in available chlorine is even more significant. Then, at time of use, the concentration of active chlorine may not be what it is intended to be as per the EPA label given the natural degradation that occurs.

In contrast, Bru-Clean comes in a convenient, pre-measured, pre-scored lightweight tablet that delivers a 937 ppm available chlorine reproducibly and reliably at point of use. There is no measurement, dilution and filtering of solutions involved. The tablet is merely dropped in water and is ready to use.

Conclusions

Bru-Clean TbC™ is a convenient and less corrosive alternative to Liquid Bleach and has a longer shelf life. It produces a more stable concentration of the available chlorine at 937 ppm which results in more reliable germicidal activity.

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