

Gaseous Chlorine Dioxide and the Myth of Corrosion[©]

The myth exists that chlorine dioxide (CD) gas is corrosive. Another myth is that CD is more corrosive than VHP. Both are not true. Liquid CD has been shown to be corrosive, but gaseous CD is different from liquid. ClorDiSys Solutions, Inc. (CSI) has done studies with computers and electronics and has found that they stand up to multiple exposures. Computers have been exposed to the gas for 25 cycles. This equates to 2 years of exposures assuming the decontamination is performed monthly. The fact is that Vapor HP is 1.9 times more corrosive based on the oxidation potential of 1.78 vs. 0.95 for CD. “Comparing CD with Other Sterilants: Table 1 summarizes key properties of oxidizing biocides to consider in choosing a sanitizing/sterilizing agent. As shown, CD is not as aggressive an oxidizer (oxidation potential data) as chlorine, ozone, peracetic acid, peroxide, or bleach — and it should be non-corrosive to common materials of construction.”

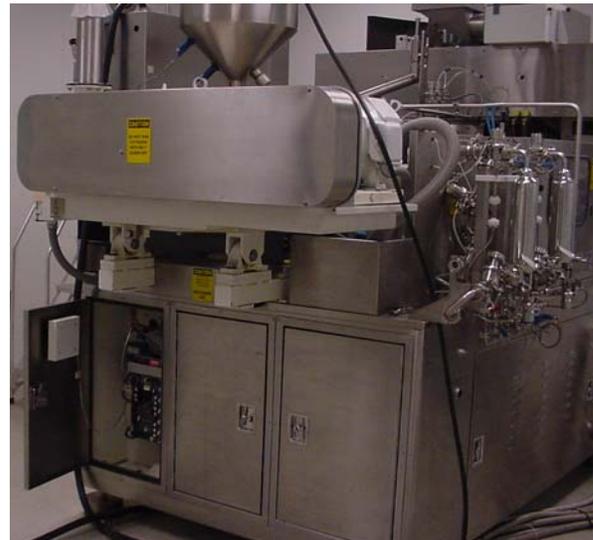
Table 1: Summarizing key properties of oxidizing biocides¹

Biocidal Agent	Oxidation Potential (volts)	Oxidation Capacity (electrons)
O3 (ozone)	2.07	2e ⁻
CH3COOOH (peracetic acid)	1.81	2e ⁻
H2O2 (hydrogen peroxide)	1.78	2e ⁻
NaOCl (sodium hypochlorite)	1.49	2e ⁻
ClO2 (chlorine dioxide)	0.95	5e ⁻

At CSI we tend to rely on external peer reviewed publications and customer testing as opposed to testing that was performed in house or paid for by CSI. This approach has allowed us to maintain a level of integrity and justification in stating CD is NOT corrosive. So the following are just some examples that are published in the literature.

Automated Liquid Packaging (ALP) now a Cardinal Health company has been using chlorine dioxide for years. A program of work has been initiated to further the understanding of the impact of the environment surrounding a Blow/Fill/Seal (BFS) machine upon the microbiological quality of process product. A BFS (Figure 1) machine takes raw plastic and Blows a mold, Fills the mold and Seals the container. A dedicated facility has been constructed to provide for the production and containment of dispersions of micro organisms in air of a room housing and operating the BFS machine. The room was built to contain aerosolized spores of different cell types, including bacterial endospores, Gram-positive and Gram-negative vegetative cells and yeast cells. Decontamination of the room and the housed BFS machine is accomplished through exposure to chlorine dioxide gas at a concentration of 1mg/L for 120 minutes.

“Following the qualification study, inspection of the BSF machine, and its subsequent operation, revealed little or no impact of the CD/air mixture at the 1.0 mg dm⁻³ level on the machine components and operating systems. Clearly, this is a critical finding as CD gas decontamination is to be regularly applied to BFS machinery within the Challenge Room. “²



*Figure 1
Blow/Fill Seal Machine*

The BFS machine has various materials and components exposed to CD. On the BFS are painted steel motors, variable frequency drives (controllers for motors), stainless steel surfaces, electronic controllers, copper wiring and various rubber, Teflon and Viton gasket materials.

At Amgen in Thousand Oaks, southern California CD was tested for efficacy, effectiveness and effects on materials. The effects on materials were performed using Raman spectroscopy. Various tests were performed on aseptic filling line isolators (figure 2), processing vessels (figure 3) and piping systems.



Figure 3
Stainless Steel
Processing
Vessel

“No corrosion is observed when using pharmaceutical-type materials such as high-grade 316SS (stainless steel) and 304SS, Lexan, and various other plastics such as Delrin, Teflon, and UHMWPE. No impact was observed on the exhaust system in this study. In a separate experiment, post exposure rinses of 304SS coupons in water for injection (WFI) showed no residual CD as measured using an HPLC method for detection of chlorides.”³



Figure 2
Aseptic Filling Line Isolator

At Johnson and Johnson where studies were performed in stainless steel isolators (figure 4), flexible walled PVC isolators (figure 5) and stainless steel sterilizers no corrosion was observed when using

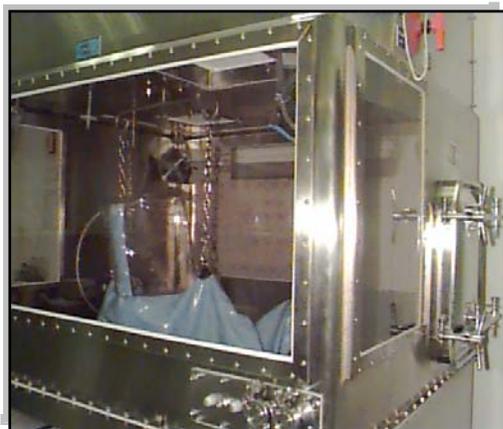


Figure 4
Stainless Steel Isolator

pharmaceutical-type materials such as 316 and 304 series stainless steel, Lexan, and other commonly used plastics including Delrin, Teflon, UHMWPE, Viton, and PVC.

“Additionally the impact of CD exposure on a number of polymeric materials and metals has been evaluated. Commonly used polymers such as ABS, nylon, PMMA,

polyethylene, polypropylene polystyrene, Teflon and Viton appear highly compatible. ... Stainless steel is compatible with CD.”⁴

Liquid Chlorine Dioxide

Liquid CD, however, is acidic and contains sodium chlorite impurities that both make it corrosive. Liquid CD creates the chlorine dioxide through acidification of sodium chlorite.

Common Liquid Generation Methods: Mixture of Base + Water + Activator = Acidified Sodium Chlorite + Chlorous Acid + Chlorine Dioxide⁵

Liquid CD is corrosive due to acids involved in the generation. Additionally liquid CD requires post exposure wipe down to remove the acidic solution that causes the corrosion. When using gaseous CD NO post exposure wipe down is necessary or required.

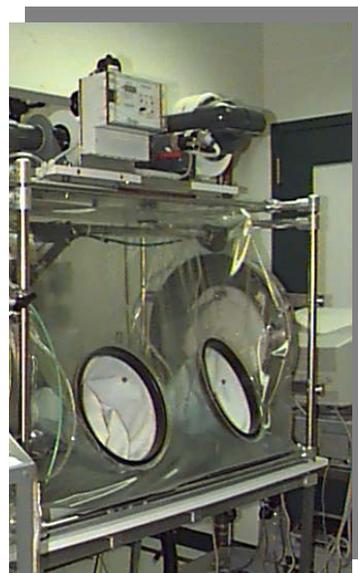


Figure 5
Flexible Walled PVC
Isolator

Gaseous CD used by CSI is created through a dry gas process:

CSI's Generation Method: Reagent (gas) + Sodium Chlorite (solid) = Chlorine Dioxide (gas) + Salt (solid)

(Only pure gas is delivered to the chamber, the salt solid remains in the CD Cartridge)

The method of generation of CD has a direct impact on its corrosiveness. Through experience most users know liquid CD is corrosive and the same can not be said about the gaseous form. In fact experience shows that gaseous CD is NOT corrosive like liquid CD. Furthermore dissolving the gas in water produces a CD solution that is both non acidic and contains no sodium chlorite impurities.

Vapor Hydrogen Peroxide Condensation

As many people are unaware vapor hydrogen peroxide condensation causes corrosion (figure 6). The VHP concentration is maintained below the condensation point to prevent condensation of VHP on the room surfaces and may therefore be referred to as a dry process. As VHP condenses its concentration increases. This increase in concentration causes corrosion. You may start with 31% - 35% hydrogen peroxide, but as it condenses on surfaces the concentration strengthens and this can cause surface damage.

"A preliminary study at an intentionally higher hydrogen peroxide injection rate resulted in hydrogen peroxide condensation and room surface damage, which demonstrated the adverse affects if the process was not adequately controlled. Following optimization according to the VHP 1000 cycle development guide, no further condensation or material incompatibilities were observed."⁶

Example of CD Users

The following pictures consist of customer applications that use chlorine dioxide gas to decontaminate either the room or chamber in the room:



*Figure 6
Surface damage due to hydrogen peroxide condensation. Condensation should not occur during the VHP decontamination process if adequately controlled (6)*



*Figure 7
Cloridox-GMP Installed to a Flexible Walled PVC Transfer Isolator*



*Figure 8
Operating Room Containing Various Electronics and Components*



*Figure 9
Transfer Isolator Filled with Components*



*Figure 10
Pharmaceutical IPQA (In-Process Quality Assurance) Lab with Various Electronics and Components*



*Figure 11
Pharmaceutical Chemistry Lab with Various Electronics and Components*



*Figure 12
Life Science Chemistry Lab with Various Electronics and Components*



*Figure 13
New Animal Facility (180,000 cu ft)
decontaminated in 7.5 hours*



*Figure 14
Room with Cage Changing Stations*



Figure 15
Room with BSC's and Microscopes



Figure 16
Room with Changing Stations and Racks



Figure 17
Animal Holding Room with Ventilated Racks



Figure 18
Large Animal Room



Figure 19
Pass Through Room with Equipment



Figure 20
Pass Through Room with Components

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- ² F. Leo, P. Poisson, C.S. Sinclair and A. Tallentire, "Design, Development and Qualification of a Microbial Challenge Facility to Assess the Effectiveness of BFS Aseptic Processing", PDA Journal of Pharmaceutical Science and Technology, Vol. 59, No. 1, January – February 2005.
- ³ Amnon Eylath, Donald L. Wilson, David Thatcher, and Anthony Pankau "Successful Sterilization Using Chlorine Dioxide Gas Part One: Sanitizing an Aseptic Fill Isolator", BioProcess International, Vol. 1, No. 7, JULY 2003.
- ⁴ J.B.Kowalski, "Sterilization of Medical Devices, Pharmaceutical Components, and Barrier Isolator Systems with Gaseous Chlorine Dioxide," in Sterilization of Medical Products, R.F.Morrissey and J.B.Kowalski, Eds. (Polyscience Publications, Champlain,NY, 1998), pp. 313–323.
- ⁵ MATERIAL SAFETY DATA SHEET CLIDOX-S® DILUTION, Pharmacal Research Laboratories Inc. www.pharmacal.com.
- ⁶ Anders Malmborg, Maria Wingren, Philippe Bonfield and Gerald McDonnell, "VHP takes its place in room decontamination", CleanRooms Volume: 15 Issue: 11 November 2001.