Chlorine Dioxide Workshop Presentation

Mark A. Czarneski
Director of Technology
ClorDiSys Solutions, Inc.

Overview

1. Define Chlorine Dioxide
2. What is the Process
3. Chlorine Dioxide Summary
4. Exploration of Applications

What is Chlorine Dioxide (CD)?

Properties:
- Yellow-Green Gas
- Water Soluble
- Boiling Point 11°C
- Tri-atomic Molecule
- Molecular Weight 67.5

1. Ability to be monitored in real time with a photometric device. Not subject to condensation or affected by temperature gradients.
2. Ability to penetrate water (not all sterilants can penetrate water, vapors cannot).
3. Chlorine dioxide is a “true gas” at room temperatures; which means excellent distribution and penetration.

Chlorine Dioxide Time Line

- 1811: First Preparation of Chlorine Dioxide
- 1920: Recognized as a Gaseous Chemosterilizing Agent
- 1984: First Registered with the US-EPA for use as a sterilant

- Worldwide consumption of chlorine dioxide – 4.5 million lbs/day (2.04 million kg/day).
- 743,000 lbs (337,000 kg) released to atmosphere in 2000.
- Example: Maine allows 3 lb’s/hour (1.4 kg/hour) of CD to be emitted.

Current Sterilizer (Sporicides) Registration with US-EPA as of January 2009

More than 5000 antimicrobial products are currently registered with the US-EPA. Only 40 agents are registered as a Sterilant.

<table>
<thead>
<tr>
<th>Agent</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethylene Oxide</td>
<td>24</td>
</tr>
<tr>
<td>Sodium Chlorite (chlorine dioxide)</td>
<td>4</td>
</tr>
<tr>
<td>Hydrogen Peroxide Based</td>
<td>12</td>
</tr>
<tr>
<td>Total</td>
<td>40</td>
</tr>
</tbody>
</table>

http://www.epa.gov/oppad001/chemregindex.htm

Types Antimicrobial Pesticides

Sterilizers (Sporicides): Used to destroy or eliminate all forms of microbial life including fungi, viruses, and all forms of bacteria and their spores. Spores are considered to be the most difficult form of microorganism to destroy. Therefore, EPA considers the term Sporicidal to be synonymous with “Sterilizer.”

Disinfectants: Used on hard inanimate surfaces and objects to destroy or irreversibly inactivate infectious fungi and bacteria but NOT necessarily their spores. Disinfectant products are divided into two major types: hospital and general use.

Sanitizers: Used to reduce, but not necessarily eliminate, microorganisms from the inanimate environment to levels considered safe as determined by public health codes or regulations.

Antiseptics and Germicides: Used to prevent infection and decay by inhibiting the growth of microorganisms. Because these products are used in or on living humans or animals, they are considered drugs and are thus approved and regulated by the Food and Drug Administration (FDA).

http://www.epa.gov/oppad001/ad_info.htm
Current Sodium Chlorite (Chlorine Dioxide) Sterilizer Registration

For Anthrax cleanup Under Section 18 of FIFRA, EPA exempted Sabre Technologies from any provision of EPA registration requirement for sale or use.

http://www.epa.gov/oppad001/chemregindex.htm

Company | Product Name | Registration | Ingredient | Sterilization Use
---|---|---|---|---
Alcide Corp | Alcide Export 6:1:1 – Base | 1677-216 | 1.520% | Immersed in solution for 10 hours @ 20 deg C
ClorDiSys Solutions, Inc. | CSI CD Cartridge | 80802-1 | 78.8% | Follow System Operations Guide
Englehard Corp | Aseptrol S10-Tab | 70060-1 | 58.8% | Immersed or soak in 1000 ppm solution for min 1 hour
Pharmacal Research Laboratories Inc | CLIDOX-S BASE | 8714-0 | 0.85% | 1:3:1 Solution for 5 hours @ 25 deg C

Chlorine Dioxide Gas

- Easy process: place generator outside the room or chamber
- Dry gas generation process:
  
  \[ \text{Cl}_2 (g) + 2\text{NaClO}_2 (s) = 2\text{ClO}_2 (g) + 2\text{NaCl} (s) \]
- 1 Gas Generator for approximately 70,000 cu ft.
- True Gas (boiling point +11°C)
- Requires RH 65+% in the room
- Short cycle times (rooms 3-4 hours)
- Short contact times (isolators 0.5-2 hours)
- Non – Flammable
- Low concentrations (360-1800 ppm)

Gaseous CD is not the same as Liquid CD

- Liquid CD creates the chlorine dioxide through acidification of sodium chlorite
  
  \[ \text{Acidified Sodium Chlorite + Peracetic Acid + Chlorine Dioxide} \]
- Liquid CD is corrosive due to acids involved in the generation process
- Gaseous CD is created through a dry gas process
  
  \[ \text{Cl}_2 (g) + 2\text{NaClO}_2 (s) \rightarrow 2\text{ClO}_2 (g) + 2\text{NaCl} (s) \]
- Only pure gas is delivered to the chamber, the salt solid remains in the CD Cartridge

Comparison of liquid vs. gas showed a 3.7 log reduction with liquid CD and a 7.4 log reduction with gaseous CD with equal concentrations and exposure times

Oxidation Potential of Several Biocidal Agents

<table>
<thead>
<tr>
<th>Biocidal Agent</th>
<th>Oxidation Potential (volts)</th>
<th>Oxidation Capacity (electrons)</th>
</tr>
</thead>
<tbody>
<tr>
<td>( \text{O}_3 ) (ozone)</td>
<td>2.07</td>
<td>2e–</td>
</tr>
<tr>
<td>( \text{CH}_3\text{COOOH} ) (peracetic acid)</td>
<td>1.81</td>
<td>2e–</td>
</tr>
<tr>
<td>( \text{H}_2\text{O}_2 ) (peroxide)</td>
<td>1.78</td>
<td>2e–</td>
</tr>
<tr>
<td>( \text{NaOCl} ) (sodium hypochlorite)</td>
<td>1.49</td>
<td>2e–</td>
</tr>
<tr>
<td>( \text{ClO}_2 ) (chlorine dioxide)</td>
<td>0.95</td>
<td>5e–</td>
</tr>
</tbody>
</table>

The above table summarizes key properties of oxidizing biocides. As shown, CD is not as aggressive an oxidizer (oxidation potential data) as chlorine, ozone, peracetic acid, hydrogen peroxide, or bleach — and it is non corrosive to common materials of construction.

The fact is that Vapor HP is 1.9 times more corrosive.


What is the Process?
The Chlorine Dioxide Decontamination Process

- Pre-Conditioning
  - Chamber Leak Test and Raise RH 65%
- Conditioning
  - Dwell time at RH SP
- Charge
  - Raise CD Concentration 1 - 5 mg/L
- Exposure
  - Dwell time at CD SP
- Aeration
  - Remove CD Gas 12-15 air exchanges

ClorDiSys Solutions, Inc.
Chlorine Dioxide Workshop Presentation

Chlorine Dioxide Generation Technology

\[ \text{Cl}_2(g) + 2\text{NaClO}_2(s) \rightarrow 2\text{ClO}_2(g) + 2\text{NaCl}(s) \]

- Performed in solid phase
- Gas generated on demand
- Self-Contained reagents
- Simple to replace consumables
- Only pure gas is delivered to the chamber, the salt solid remains in the CD Cartridge

Chlorine Dioxide D-Value Studies (Bacillus atropheus)

<table>
<thead>
<tr>
<th>Carrier</th>
<th>concentration mg/L</th>
<th>D-Value minutes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kinguard (plastic)</td>
<td>5</td>
<td>1.7</td>
</tr>
<tr>
<td>Paper 991</td>
<td>5</td>
<td>1.6</td>
</tr>
<tr>
<td>Paper 10</td>
<td>10</td>
<td>0.75</td>
</tr>
<tr>
<td>Paper 20</td>
<td>20</td>
<td>0.27</td>
</tr>
<tr>
<td>Paper 30</td>
<td>30</td>
<td>0.12</td>
</tr>
</tbody>
</table>

Condition time 70% for 30 minutes
Condition 75% for 30 minutes

D-Value is the time to achieve a 1 log reduction of microorganisms.
1 Log = 90% Reduction
2 Log = 99% Reduction
3 Log = 99.9% Reduction
4 Log = 99.99% Reduction
5 Log = 99.999% Reduction
6 Log = 99.9999% Reduction

Sample CD Antimicrobial Spectrum of Activity

Vegetative Bacteria:
- Staphylococcus aureus
- Pseudomonas aeruginosa
- Salmonella choleraesuis
- Mycobacterium smegmatis
- E.Coli
- Listeria Monocytogenes

Bacterial Spores:
- Bacillus atrophaeus *
- Bacillus stearothermophilus
- Bacillus pumilus
- Clostridium sporogenes

Fungi:
- Aspergillus niger
- Candida albicans
- Trichophyton mentagrophytes

Viruses:
- Herpes simplex Type I (lipid)
- Polio Type II (non-lipid)
- Parvo Virus

* CD Indicator Organism

Chlorine Dioxide Summary

- Biocidal at Low Concentration and Ambient Temperature
- Efficacious under vacuum or at atmospheric pressure
- Gas Distributes Rapidly
- Gas Penetrates crevices
- Process Tolerates Temperature Fluctuations
- Non-flammable at Use Concentrations
- No Liquids
- Self-contained Reagents
- Short Cycles

- Size Scalable
  - Range of Target Volumes
  - Long Distances
- No Measurable Residuals
- Rapid Aeration (Low-Use Concentration and Minimal Adsorption)
- Gas Concentration is Easily and Accurately Monitored
- No manual wiping required
- No neutralization required
- No mixing of solutions

Tyvek/mylar envelopes
Example Application:

Mix-fill, measuring and packaging process Isolators

Total Decontamination Cycle Time - 1.5 hrs (including chamber leak testing)
Run 2-3 times per day

Component Load Transfer Isolator (25 ft³)
Total 31 ft³ (0.9m³) with docking station

Total Decontamination Cycle Time - 1 hour 20 minutes

Workstation Isolator (350 ft³ - 10m³)

Filling Line Isolator (250 ft³ - 7m³)

There were a total of 25 biological indicators (Bacillus subtilis) placed throughout the chamber and load with NO positives.

There were a total of 24 biological indicators (Bacillus subtilis) placed throughout the chamber and load with NO positives.

Workstation Isolator / Autoclave Interface isolator and Autoclave (Total Decontamination Cycle Time - 1 hour 52 minutes)
ClorDiSys Aseptic Filling Room
115 sq m (20,000 ft² – 566.3 m³)

Pharmaceutical Aseptic Filling Suite
15,000 ft² (424 m²)

Microbial Challenge Room [BFS]
(6000 ft² - 170 m³)

Sterilization of Storage Tank with Piping

Decontamination of New Facility (Japan)

Chlorine Dioxide Gas
has good material compatibility

For example………
Various Equipment

31

Gaseous Chlorine Dioxide Decontamination Machine

Transmission Cryo-Electron Microscope (JEOL Cryo-TEM)

$3,000,000

Automated Guided Vehicle (AGV)

Various Equipment

How Effective is the Process?

When you HAVE to be sure
ClorDiSys Solutions, Inc.
Chlorine Dioxide Workshop Presentation

BI Location Inside Open and Closed Cabinets

Both BI’s Killed

BI's Killed

BI Location Inside Closed Drawer

Both BI’s Killed

BI’s Killed

BI Location Behind Equipment

Both BI’s Killed

BI’s Killed

BI Location Under Equipment

Both BI’s Killed

BI’s Killed
BI Location Under Equipment

Both BI's Killed

BI Placed UNDER Equipment

BI Location Between Components

Both BI's Killed

BI Placed Between Components

BI Location Inside Bottle 2nd Shelf Interior Bottle

Both BI's Killed

BI Placed Inside Bottle 2nd Shelf Middle

BI Location Between Packages / Components

Both BI's Killed

BI Placed Between Components

Summary

Safest fumigant available (odor detection, fast cycle time, low concentration levels, non-carcinogen)

Fastest cycle times (start to finish)

Most complete Penetration and Distribution

Most Flexible Process (rooms, BSC’s, HEPA Housing, Duct work, isolators, suite of rooms, etc)

Sterilant process

EPA Approved process

NSF Approved process

Prepared by:
Mark A. Czarneski
Director of Technology
ClorDiSys Solutions, Inc
www.clordisys.com
PO Box 549
Lebanon, NJ 08833
Phone: 908-236-4100
Fax: 908-236-2222
e-mail: markczarneski@clordisys.com