ClorDiSys

BETA-LACTAM INACTIVATION

Chlorine Dioxide Gas Equipment and Services

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Eliminate the risk of allergic exposure

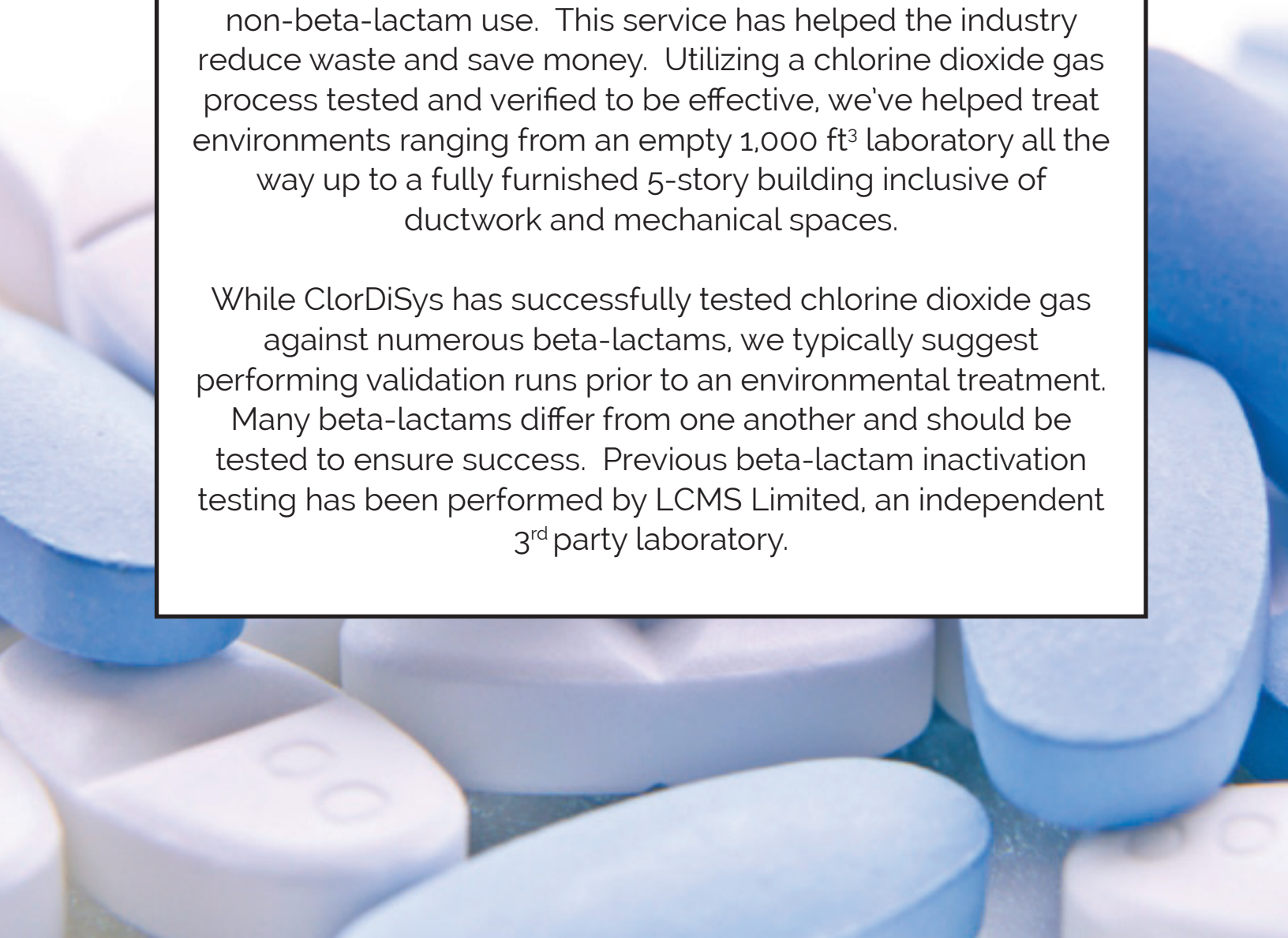
Repurpose equipment and facilities for non-beta-lactam production

ClorDiSys

ClorDiSys Solutions, Inc. was established in 2001 in New Jersey. Chlorine dioxide gas sterilization technology was commercialized at Johnson and Johnson, where our founders were part of the development team. We are focused on providing reliable, highly effective decontamination products and services around the world.

Since 2006, ClorDiSys has been helping pharmaceutical companies treat equipment and environments containing beta-lactams such that they may be repurposed for non-beta-lactam use. This service has helped the industry reduce waste and save money. Utilizing a chlorine dioxide gas process tested and verified to be effective, we've helped treat environments ranging from an empty 1,000 ft^3 laboratory all the way up to a fully furnished 5-story building inclusive of ductwork and mechanical spaces.

While ClorDiSys has successfully tested chlorine dioxide gas against numerous beta-lactams, we typically suggest performing validation runs prior to an environmental treatment. Many beta-lactams differ from one another and should be tested to ensure success. Previous beta-lactam inactivation testing has been performed by LCMS Limited, an independent 3^{rd} party laboratory.



WHAT IS CHLORINE DIOXIDE?

Chlorine dioxide (CD) is a greenish-yellow gas with a chlorine-like odor recognized since the beginning of the 20th century for its disinfecting properties. It is widely used as an antimicrobial pesticide and an oxidizing agent in drinking water in addition to whitening paper for the pulp and paper industry. ClorDiSys' chlorine dioxide gas is registered with the US EPA as a sterilizer (EPA Reg #80802-1), which is defined as able "to destroy or eliminate all forms of microbial life including fungi, viruses, and all forms of bacteria and their spores. ClorDiSys uses chlorine dioxide gas for its broad efficacy against microorganisms. It is applied in a number of different applications and industries to provide a 6-log (99.9999%) sterilization level decontamination. The rapid sterilizing activity of CD is present at ambient temperature and across a wide range of gas concentrations.

Measured and Controlled

Due to its yellow-green color, chlorine dioxide gas can be measured using a photometer. A photometer measures the absorbance of the gas (darker color = higher concentrations) which allows for a highly accurate, repeatable, and reliable measurement to ensure tight process control.

True Gas at Room Temp

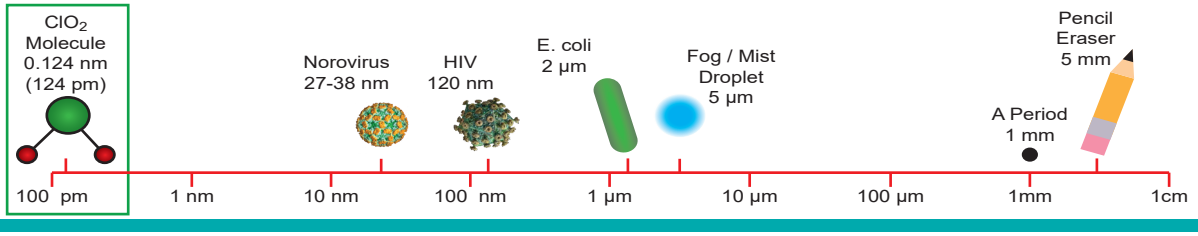
Chlorine dioxide is a true gas at room temperatures which enables it to fill the space it is contained within evenly and completely, just like oxygen in air. This property is essential when trying to eradicate pathogens from an area, as the gas will get everywhere and not allow anything to "hide" from it.

Different from Chlorine

While "chlorine" is in its name, chlorine dioxide gas is VERY different. Chlorine dioxide's method of kill is oxidation, where chlorine kills through chlorination. Therefore, unlike chlorine, chlorine dioxide does not produce environmentally undesirable organic compounds and is safer on materials.

With a molecular size smaller than the smallest virus, chlorine dioxide gas reaches deeper into crevices than organisms can hide.

MOLECULAR SIZE MATTERS



CHLORINE DIOXIDE SAFETY

SELF ALERTING ODOR

The best safety feature with CD is that it is self-alerting. CD has an odor threshold at or below the 8-hour Time Weighted Average (TWA) of 0.1 ppm, so the user is self-alerted to exposure at a low level and the reliance on external sensors is not as imperative as it is with odorless chemicals.

CARCINOGENICITY

Chlorine dioxide gas is not considered to be carcinogenic by any health agency. CD gas is used to treat fruits, vegetables, poultry, and other foods as well as drinking water.

BETA-LACTAM INACTIVATION APPLICATIONS

Chlorine dioxide gas is able to reach and kill all organisms because it naturally fills the area it is introduced into evenly and completely and penetrates deeper into crevices than pathogens can hide. Chlorine dioxide gas treatment allows for areas and equipment previously used for beta lactam production to be used for non-beta-lactam activities, saving lots of money compared to building new facilities.

Repurposing a Room
Repurposing a Suite
Repurposing a Building
Recycling Used Equipment
Tent equipment within a room
Treat within a trailer or shipping container
Ship equipment to ClorDiSys for treatment

CASE STUDIES

EQUIPMENT on a TRAILER

One of the first commercial applications for beta-lactam inactivation was the treatment of used equipment being removed from a beta-lactam production facility. The equipment was pulled out and placed into a trailer for chlorine dioxide gas treatment. The treatment took 7 hours from start to finish. Upon completion, swabs were taken to ensure that no beta-lactams could be recovered. After clearance, the trailer was brought to the new destination where the equipment could be safely installed without the risk of cross-contamination.

REPURPOSED FACILITIES

A two-story, 41,000 ft^3 beta-lactam production building was being decommissioned and turned into a general training facility. In order to ensure that all visitors would be safe from allergic reaction to the beta-lactam previously being produced, chlorine dioxide gas treatment was performed. The whole building was treated over the course of 2 days (setup on the first day, treatment and cleanup on the second) including its ductwork and mechanical space. Post-treatment swab testing performed by the facility showed zero recoverable beta-lactams, and the renovation was approved to take place.

A four-story, 570,000 ft^3 fully furnished beta-lactam production building was being repurposed to produce a different product. Chlorine dioxide gas treatment was employed in order to ensure safe production of the new antibiotic. The whole building was treated over the course of 3 days (setup on the first and second day, treatment and cleanup on the third) including its ductwork and mechanical space. Post-treatment swab testing showed zero recoverable beta-lactams, and the new production process was allowed to begin.

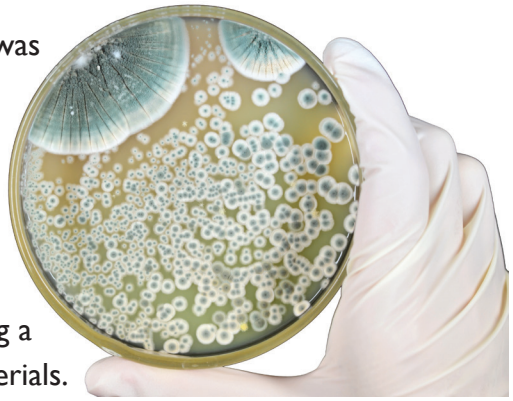
LABORATORY

A 2,500 ft^3 laboratory space had a fermenter contaminated from previous beta-lactam R&D work. Rather than simply treat the fermenter, the facility decided it was safer to treat the whole laboratory in case the contamination was elsewhere too. After sealing the laboratory off from the adjoining spaces, it was treated with chlorine dioxide gas. Over the course of 12 hours, the entire project was completed from setup to cleanup. Post-treatment swabs came back negative for the beta-lactam, and the laboratory was able to use the fermenter once again.

COVID-19 VACCINE FACILITY

A 220,000 ft^3 beta-lactam production facility was being repurposed for use in manufacturing and storing a vaccine against COVID-19. In order to safely produce the vaccine, they needed to ensure that no residual beta-lactam was present which could contaminate the vaccines or affect the workers. Following a two-day treatment (setup on the first day, treatment and cleanup on the second), swab testing came back negative for beta-lactams and the installation of new equipment was allowed to begin.

BETA-LACTAM TESTING PERFORMED



In 2006, in partnership with a leading pharmaceutical company, testing was performed to see whether chlorine dioxide gas could achieve a 3-log reduction of beta-lactams for the repurposing of equipment into a non-beta-lactam setting.

A test protocol was developed between the pharmaceutical company and a third party research laboratory. Chemical coupons were manufactured by the research laboratory and consisted of impregnating a cocktail of eight types of beta-lactams onto three different carrier materials. Chosen due to their prevalence in the manufacturing and laboratory environments, carriers were made out of polycarbonate plastic (lexan), stainless steel (304 L, passivated), and aluminum (non-anodized). A single square-profiled channel approximately 0.5 - 1.0 mm deep and wide was machined lengthwise along the center on one side of each coupon to simulate the presence of beta-lactam residues in cracks and crevices. The eight beta-lactams were chosen to represent a sampling of those on the equipment driving the study as well as some other common beta-lactams. They consisted of beta-lactams from the penicillin, cephalosporin, and carbapenum groups. From the penicillin group, Penicillin G, penicillin V, ampicillin, and amoxicillin were included. Cefadroxil, cefazolin, and cephalexin were incorporated from the cephalosporin group, and Imipenem was included from the carbapenum group. Each chemical indicator contained 5 µg/mL (5 ppm) inoculated within the machined channel. The inoculums were dried on the carriers prior to treatment with chlorine dioxide gas.

Test cycles were performed at a number of different chlorine dioxide gas concentrations and treatment times. Upon completion, treated indicators along with positive controls were shipped back to the laboratory for extraction and evaluation using liquid chromatography and mass spectrometry. Multiple successful cycle combinations were found, with a minimum chlorine dioxide gas dosage of 7,240 ppm-hours of exposure found to be the requirement to achieve a 3-log reduction.

CUMULATIVE PPM-HOURS PER INACTIVATION CYCLE

Inactivation Cycle	CD Concentration (mg/L)	Exposure Time (hours)	Cumulative ppm-hours	Beta-Lactams Inactivated
1	1	6	2172	3/8
2	3	6	6516	5/8
3	**5**	**4**	**7240**	**8/8**
4	**5**	**6**	**10860**	**8/8**
5	7	2	5068	4/8
6	**7**	**4**	**10136**	**8/8**
7	**7.5**	**4**	**10860**	**8/8**
8	9	2	6516	6/8
9	**30**	**4**	**43440**	**8/8**

ClorDiSys

Microbial Decontamination Products and Services

PROVIDING THE SAFEST AND MOST EFFECTIVE DECONTAMINATION SOLUTIONS AVAILABLE SINCE 2001

Complete Decontamination with Chlorine Dioxide Gas

In the pharmaceutical and medical device industry, contamination control and sterility are crucial components to maintaining the highest level of quality products expected of these companies. ClorDiSys Solutions offers many chlorine dioxide-based decontamination products and services to preserve product integrity and consumer trust. Our chlorine dioxide gas is registered with US Environmental Protection Agency (EPA Reg# 80802-1) as a sterilant and is able to inactivate all forms of antimicrobial life, including spores. Our process has also been validated and proven to be effective at inactivating beta-lactams including penicillins, cephalosporins, and carbapenums on equipment or in rooms, so that there is no risk of allergic exposure. After inactivation, facilities can be easily repurposed and equipment can be reused for non-beta-lactam pharmaceutical products with no risk of contamination.

ClorDiSys Solutions is a worldwide leader in contamination control.

Founded in 2001, ClorDiSys utilizes the most effective method of decontamination available, chlorine dioxide gas, as well as ultraviolet light for less critical environments. Our chlorine dioxide gas decontamination process was developed in the pharmaceutical industry at Johnson and Johnson™, where our founders were part of the development team. Keeping the same high standards for purity, quality, and efficacy, ClorDiSys provides solutions for operating cleaner and safer than ever before by eliminating pathogens from the hardest to reach locations without leaving a residue or additional clean up.

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