



Decontamination Safety

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Safety is a complex issue, and in order to fully understand safe use of decontamination agents, it must be examined from many different aspects.

Safety in the laboratory has always been a priority, which is why decontamination technology has advanced over the last ten years to meet the growing needs of lab animal research facilities. Chlorine dioxide gas (CD gas) arrived over ten years ago as the newest commercially available decontamination method. It is still the most recent high-level sterilant on the market, a true gas capable of eliminating all viruses, bacteria, fungi, and their spores; even when hidden beneath, behind, and in-between objects. Some people believe that CD gas is unsafe. Those people are correct. In fact, no method of decontamination is safe, as their sole purpose is to effectively kill organisms; bacterial, viral, human, or otherwise. Each decontaminating agent does, however, have different properties which must be taken into account when looking at safety issues.

Safety Threshold and Typical Use Concentration

One of the first aspects to note is the agent's 8-hr time weighted average (TWA) allowable exposure limit. CD gas has a low 8-hr TWA concentration of 0.1 ppm according to OSHA. At first glance this looks comparatively worse than the 8-hr TWA for both vapor phase hydrogen peroxide (VPHP) (1.0 ppm) and formaldehyde (0.75 ppm). To get the full perspective on this safety characteristic, however, the typical use concentrations must also be examined. CD gas is typically used at a concentration of 360 ppm, while VPHP has a typical concentration of around 750 ppm, and formaldehyde has a use concentration of around 8000 ppm. Looking at these two values in tandem shows that while CD gas has a lower 8-hr TWA, each decontaminating agent is used at concentrations greatly in excess of their 8-hr TWA. Operating at concentrations significantly higher than the 8-hr TWA, leakage of any decontaminant is dangerous and must be monitored throughout the decontamination cycle.

Leak Detection and Safety

As all methods are used at dangerous levels, the ease and ability to detect leakage is a very valuable aspect regarding how safe a decontaminating agent is. For the two gaseous methods, CD gas and formaldehyde, as well as vapor phase hydrogen peroxide, chemical sensors and personal safety badges are available. Chemical sensors can either be handheld and portable, or fixed to a wall.

Leak detectors can work very well, but will only work in areas where a sensor exists. It is easy for those performing decontaminations to have a chemical sensor with them to ensure their own safety and to check for leakages. It becomes unrealistic to place chemical sensors throughout a facility, or for all individuals working near the space being decontaminated to have them. This is especially true for a busy facility where many people can pass by the space being

decontaminated during the duration of the cycle.

The ability to smell the decontaminating agent allows for those not directly associated with the decontamination event to be aware of any unsafe situations. Chlorine dioxide gas has an odor threshold equal to its 8-hr TWA safety level. Most people recognize the smell of chlorine. This can alert workers to potential exposure, whether they are near a chemical sensor or not. Formaldehyde is similar in that it has an odor threshold of 0.8ppm, just above its 8-hr TWA. OSHA states that no odor threshold was determined for hydrogen peroxide. Facility workers must then rely on chemical sensors to gauge if VPHP leakage and exposure levels are above safe levels.

Cycle Lengths and Aeration Times

The length of a decontamination cycle can also be an important factor in safety. The quicker the cycle, the less chance there is for a dangerous situation to occur. When considering the cycle length, the total time from when the setup was started to when it is safe to enter and operate within the space must be counted. This includes the aeration of the agent and the cleanup of any residues left by the decontamination method as those can be dangerous as well.

Both CD gas and VPHP can have similar exposure lengths (the time when an agent is dwelling at the prescribed concentration), which are shorter than those of formaldehyde. Formaldehyde decontamination can include long aeration times (over ten hours), neutralization, and a wipe-down step to eliminate the residual chemical. CD gas and VPHP are both residue-free processes. One of the first commercial uses of CD gas was by Johnson and Johnson to sterilize implantable contact lenses. For that application it had to be proven that CD gas did not leave a measurable residue, such that the contact lenses would be safe to implant into a human eye. While VPHP does not leave a residue, it does condense and absorb into some plastics and other cellulose materials. This absorbed chemical amount lingers in materials and can take many hours to fully aerate out of them.

It is important to determine that there is no chemical remaining when the decontaminated area is re-entered by animals or personnel. Factoring in standard aeration times, CD gas has a quicker overall cycle time as it does not condense out on surfaces or get absorbed into materials. In the event of catastrophic leakage, this becomes extremely important as it means CD gas would be completely removed more quickly.

	Chlorine Dioxide	Formaldehyde	Hydrogen Peroxide
International Agency for Research on Cancer	No	Confirmed Human Carcinogen (2006) ²	No ⁴
American Conference of Governmental Industrial Hygienists	No ⁵	Suspected Human Carcinogen (2007) ⁶	A3- Confirmed Animal Carcinogen (2001) ³
National Toxicology Program	No ¹	Known to be a Human Carcinogen (2011) ¹	No ¹

Table 1: Carcinogenicity of Decontamination Methods

(Click Image For A Larger Version)

Carcinogenicity

Residues and left-over chemicals become an even greater issue when dealing with carcinogens. Residual chemicals, especially residual carcinogens, can be dangerous and even deadly to workers and animals within the vivarium.

On June 10, 2011 formaldehyde was listed as a known human carcinogen by the U.S. National Toxicology Program (NTP)¹ after years of being classified as a suspected human carcinogen. This agrees with the International Agency for Research on Cancer (IARC) which had previously listed formaldehyde as a known human carcinogen.² VPHP is listed as a Confirmed Animal Carcinogen with Unknown Relevance to Humans by the American Conference of Governmental Industrial Hygienists (ACGIH).³ THE IARC lists hydrogen peroxide as not classifiable as to its carcinogenicity to humans.⁴ Chlorine dioxide is not classified by the ACGIH,⁵ IARC or NTP¹ as a carcinogen of any kind.

Efficacy

Above all else, the most important aspect of the safety of a decontaminating agent is its efficacy. It might sound obvious, but if a decontaminating agent does not kill all of the organisms within a space, that space can be dangerous to enter. Both CD gas and VPHP are registered with the U.S. EPA as sterilants, able to kill all viruses, bacteria, fungi and their spores. Formaldehyde is no longer registered with the U.S. EPA as a sterilant, so it can no longer be used for that purpose. In order to be fully effective, the agent must be able to reach all surfaces and get into all crevices, while at the proper concentration level for a sufficient length of time. Chlorine dioxide, being a true gas along with formaldehyde, has observable properties that aid in their use as decontaminating agents. Among those:

- Gases flow readily from one space to another and occupy all available space
- Gases assume the shapes of their containers
- Two or more gases form homogeneous mixtures in all proportions (air is a homogeneous mixture of nitrogen, oxygen, and minor amounts of other gases).
- Gases diffuse rapidly.

These properties allow CD gas and formaldehyde to naturally fill the space being decontaminated with a uniform concentration, leaving no surface or volume untouched. Adding to this the EPA registration of CD gas as a sterilant, CD gas achieves a sterilization-level reduction of organisms and spores, ensuring total effectiveness.

Hydrogen peroxide is a liquid at room temperatures and vaporized for use as a space decontaminant. With a boiling point of 302 o F, once hydrogen peroxide is introduced to the space it will start to cool and condense into the liquid phase as condensate. The speed at which this condensation happens depends on the temperature of the room, the dew point, surface temperatures, and various other factors. This natural tendency to condense can impede the vapor distribution throughout the space. It has been previously noted that hydrogen peroxide vapor is poor at passive diffusion because of hydrogen bonding characteristics⁷ and active measures must be taken to aid in its distribution. The use of auxiliary fans, rotating nozzles, or high speed injectors are the most common methods to facilitate this. Auxiliary fans must be placed in such a manner to ensure that no dead spots of airflow are present. Small openings and crevices can still present challenges to vapor distribution, with common difficult areas such as behind pictures, around equipment, and into pockets such as drawers and other compartments.

CD gas is highly soluble and does not hydrolyze in water. This means that chlorine dioxide remains in solution as a dissolved gas within water. Because of this, CD gas is able to decontaminate water and the surfaces beneath it, allowing for greater flexibility and efficacy. Hydrogen peroxide is miscible in water and dissolves completely to dilute the concentration of the sterilant. This dilution can cause the concentration of hydrogen peroxide to fall below its

sporicidal concentration and limit its efficacy in water. As the first step of any decontamination procedure is to perform a physical cleaning to remove bioburden, it is likely that some water puddles accumulate. CD gas allows for the complete decontamination of such areas, ensuring the effectiveness of the decontamination and the safety of the room post-treatment.

Equipment Location

The location of the equipment can be a factor in the safety of a process as well. CD gas generation equipment is kept outside of the area being decontaminated, while VPHP and formaldehyde are traditionally generated within the space. VPHP generators are kept inside of rooms being decontaminated as the distances the vapor can travel are short due to condensation issues and poor passive diffusion. Keeping generation equipment physically accessible to workers during a decontamination cycle allows for safety measures to be enacted directly on the equipment in the form of closing valves and/or powering down the equipment. This becomes extremely important for (hopefully) unlikely cases where a catastrophic event occurs.

Conclusion

Safety is an all-encompassing term, and must be treated as such. When dealing with decontamination agents, no single factor is sufficient to determine relative safety. Total cycle times, worker exposure alerts both mechanical and by smell, residues, effectiveness, and access to equipment are all part of the process. Ignoring any of these important aspects can leave the door open to potential hazards.

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