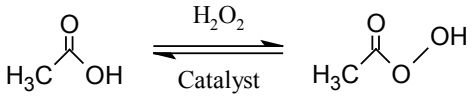
REVOX®

CONTRACT STERILIZATION SERVICES

Describing Peracetic Acid Vapor Sterilization

Peracetic Acid as a Biocide.

REVOX sterilization technology uses a room temperature vapor composed of three active compounds; hydrogen peroxide (H_2O_2), acetic acid and peracetic acid (PAA). PAA is formed by the reaction of acetic acid and H_2O_2 with the addition of a catalyst; these compounds exist in equilibrium and their eventual decomposition results in oxygen, carbon dioxide and water.



Acetic Acid Peracetic Acid

PAA was introduced as an antibacterial agent in 1955 and is used extensively in the food industry and for disinfecting sewage sludge[1]. Although all three compounds provide antimicrobial activity, PAA delivers the most according to the Canadian Journal of Microbiology[2]. PAA is a highly biocidal oxidizer that maintains its efficacy in the presence of organic soil while also removing surface contaminants[3]. As with any gas sterilization process, the system can only sterilize surfaces that are contacted by the sterilant.

The REVOX sterilization process includes mechanisms to confirm the efficacy of the sterilization system. Testing with multiple organisms reveals that biological indicators (BIs) should be inoculated with *Geobacillus stearothermophilus*; Minntech QP 202596 finds that *G. stearothermophilus* is the most resistant organism (MRO). These BIs ensure that inactivation of this organism will result in kill of other microbes. A chemical monitoring strip that detects the active ingredient is used routinely as an additional process control for REVOX contract sterilization.

Mode of Action.

The mechanism of action of PAA is thought to function as other oxidizing agents, i.e., it denatures proteins, disrupts cell wall permeability, and oxidizes sulfhydral and disulfide bonds in proteins, enzymes, and other metabolites[4]. The PAA vapor interacts with numerous cellular constituents breaking them down and inactivating routine functionality. With the disintegration of the bacterial cell wall, internal components will no longer be contained and are unable to organize. Proteins are rapidly attacked by PAA through oxidation of amino acids to carbonyls, particularly tryptophan, cysteine and methionine[5].

Microbiocidal Activity.

PAA will inactivate gram-positive and gram-negative bacteria, fungi, and yeasts in <5 minutes at <100 ppm. In the presence of organic matter, 200-500 ppm is required. For viruses, the dosage range is wide (12-2,250 ppm), with poliovirus inactivated in yeast extract in 15 minutes with 1,500 to 2,250 ppm. Bacterial spores in suspension are inactivated in 15 seconds to 30 minutes with 500 to 10,000 ppm (0.05 to 1%)[4].

Dr. Michelle Alfa, Clincial Microbiologist, along with her co-workers, compared a PAA system with ethylene oxide (ETO) and demonstrated the high efficacy of such a PAA system. Only the PAA system was able to completely kill 6-$\log_{10}$ of *Mycobacterium chelonae, Enterococcus faecalis,* and *B. atrophaeus* spores with both an organic and inorganic challenge[6]. Like other sterilization processes, the efficacy of the process can be diminished by soil challenges and test conditions[7].

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Uses of Peracetic Acid.

The ideal sterilization system involves an active component with high microbiocidal activity, a wide range of compatibility with materials, operation at temperatures that do not affect the product or packaging, low/no residuals, safe to use for operators, and short processing times. REVOX Contract Sterilization Services uses a chamber at room temperature (18 - 30°C), has a wide range of material compatibility, maintains a low level of residual that breaks down into oxygen & water and provides turnaround times as quickly as same day. REVOX sterilization technology can be used to terminally sterilize medical, pharmaceutical and industrial products.

REVOX Contract Sterilization Services utilize peracetic acid technology.

References.

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