

Disclaimer

"The information contained in this presentation is intended solely for your personal reference, is strictly confidential and may not be disclosed without the permission of Amira Srl (the "Company"). Such information is subject to change without notice, its accuracy is not guaranteed and the Company makes no representation regarding, and assumes no responsibility or liability for, the accuracy or completeness of, or any errors or omissions in, any information contained herein."



- Amira who we are
- V-PHP biodecontamination vs other methods
- Why H_2O_2 ?
- Limit and Benefit of the Technology





- We are a key player in the controlled contamination environment sector.
- We produce and distribute state-of-the-art instruments for particle and microbiological monitoring suitable for different industries such as life sciences, pharma, university, electronic.
- We offer high-quality solutions developed for and with our customers.
- We are a dynamic, motivated and talented team.

About us

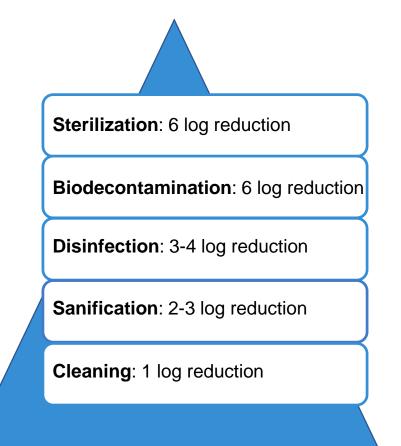


Biodecontamination

βίος, -ου, δ (anciant greek) = Life

De + Contamino (anciant latin) = to take out the dirty

Bio-Decontamination = to take out any life form





Biodecontamination

Who needs it

Any environment sensitive to microbiological contamination

- Pharmaceutical aseptic production, Microbiological laboratories
- Isolators, autoclaves, pass-boxes
- BioSafety applications, Fermentation labs, Hospitals, etc...



Biodecontamination: different chemical methods

Ethylene oxide

 Largely used in pharma & hospital biodecontamination processes



- Only applicable in hermetically sealed environments
- Flammable, carcinogen and toxic

Formaldehyde

- Historically used in pharma & hospital biodecontamination processes
- High level of carcinogenicity for humans
- Residual left on surfaces



Chlorine dioxide

Mainly used in potable water decontamination processes



- Only applicable in hermetically sealed environments
- When broken down by light and water forms toxic chlorine gas and highly corrosive hydrochloric acid

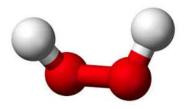
Nitrogen dioxide

- New method for biodecontamination
- Only applicable in hermetically sealed environments
- Carcinogen, toxic and pollutant





Hydrogen Peroxide



Environmental friendly

Non cancerogenic

ROS able to achieve sterilization

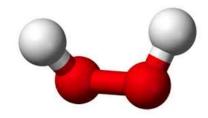
Old and very well known molecule

Easy to find on the market

Full approved by FDA, EPA, USP



Hydrogen Peroxide



VAPOUR

In physics a **vapour** is a substance in the <u>gas</u> phase at a <u>temperature</u> lower than its <u>critical point</u>, which means that the vapor can be <u>condensed</u> to a <u>liquid</u> by increasing the <u>pressure</u> on it without reducing the temperature.

- Easy to distribute
- No residues
- High material compatibility (gas)

AEROSOL, SPRAY, DRY FOG, ...

An <u>aerosol</u> is a suspension of tiny particles of liquid, solid, or both within a gas.

- Not easy to distribute
- Residues after evaporation
- Possible compatibility risk for material (liquid)



V-PHP material compatibility – International literature



All Category 2 and 3 materials demonstrated sufficient compatibility with H2O2 vapor.

No visual or functional changes were noted for any Category 4 equipment that had been exposed to H2O2, regardless of concentration and run conditions.

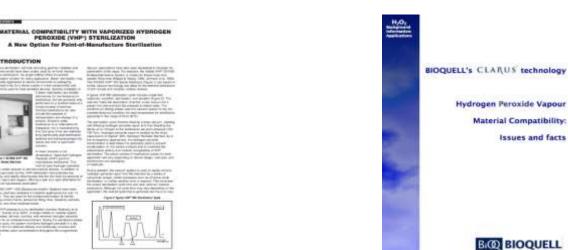
Title: Compatibility of Material and Electronic Equipment with Hydrogen Peroxide and Chlorine Dioxide Fumigation

Date: 2010

The physical and chemical properties of the materials showed little to no change following exposure. The process did not affect material's strength or cause embrittlement of any of the elastic materials tested. Chemical results showed no changes observed with the test samples.

Title: MATERIAL COMPATIBILITY WITH VAPORIZED HYDROGEN PEROXIDE (VHP®) STERILIZATION

Date: 2002



A series of tests to ascertain the effect of hydrogen peroxide (H2O2) vapour on various commonly encountered materials. The test cycles are intentionally designed to be generally more destructive than the actual gassing environment.

Title: Hydrogen Peroxide Vapour Material Compatibility: Issues and facts



V-PHP - benefits and limits

BENEFITS

- Non-toxic
- No residues
- Good material compatibility
- Good comparative safety profile
- Accepted by FDA, USP and EPA
- Good history of use / efficacy data
- Easy to test with biological indicators

LIMITS

- Works in closed environment
- Efficacy affected by presence of organic and inorganic materials
- Aeration time affected by absorbing materials

