

vital vio

White Paper

**Overview of the Safety and Efficacy
of VioSafe[®] Visible Light Disinfection**

INTRODUCTION:

Vital Vio is pioneering a new category of disinfection: Continuous Disinfection. Current cleaning and disinfection procedures – whether hourly, daily, weekly, etc. – are not providing adequate protection against harmful and costly bacteria, mold and fungi. Vital Vio’s VioSafe® technology works around the clock and in between routine cleaning activities, continuously killing microorganisms. Our technology harnesses specific wavelengths of visible light which are proven to be deadly to bacteria, mold and fungi, but completely safe for people, pets and plants.

Concerns about efficacy and safety are always appropriate when exploring new technologies. Working with our research partners, accreditation bodies and customers we have demonstrated a positive safety profile in four (4) areas of concern that have been raised, specifically:

- Ultra Violet (UV) Radiation
- Blue Light Hazard
- Antibacterial Resistant “Superbugs”
- “Good” Bacteria

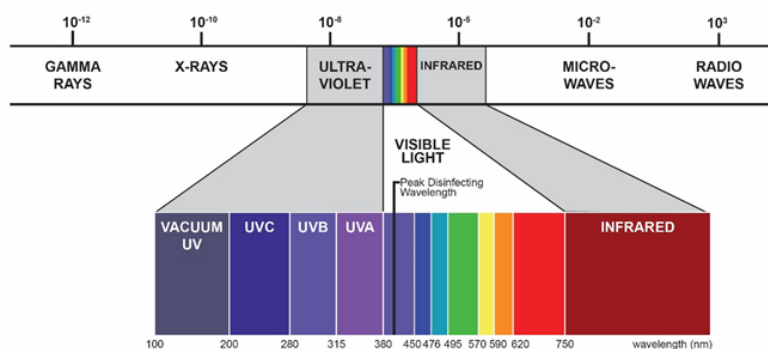
This paper will address Vital Vio’s safety profile within each of these areas.

THE DIFFERENCES BETWEEN VIOSAFE® TECHNOLOGY AND ULTRA VIOLET (UV) LIGHT:

Vital Vio’s technology harnesses the visible light spectrum, which is 380 – 750 nm. Vital Vio’s LEDs are custom engineered and manufactured to emit *no* UV radiation. Specifically, our LEDs are engineered to produce an abundance of light in the 400 – 420 nm range, which has been scientifically proven to kill bacteria, fungi, and mold/mildew.

It does this by activating particular types of porphyrin molecules that are present in microbial cells, but not in humans. When activated, the porphyrins produce excessive Reactive Oxygen Species; such as singlet oxygen, hydrogen peroxide, and hydroxyl groups, which build up within the cells and become toxic to them, causing the destruction of multiple structures within the cell and ultimately leading to cell death. Because the types of porphyrin molecules found in humans and other animals are not photoactivated by light in the 400 – 420 nm range VioSafe light used for room illuminance has no negative impact on, and is perfectly safe for, people, pets and plants.

Multiple scientific, peer reviewed studies have exposed mammalian and human cells to these wavelengths and have shown that antimicrobial irradiance levels do not cause damage to them¹⁻⁵. (In addition, all of these studies were also conducted at much higher intensities of light than our products produce.)



[Figure 1]: Ultra Violet Light occurs from 100 – 380nm, Visible Light from 380 – 750nm.

By contrast, UV occurs in the 10 – 380 nm range. The wavelengths that are most germicidal and therefore most commonly used for sterilization or disinfection occur from 200-280 nm, which is known as UV-C.

UV-C light works as a disinfectant by penetrating much further into the nucleus of microbes, destroying nucleic acids and therefore disrupting their DNA. The DNA damage accumulates leaving cells unable to perform vital functions and causing cell death. Because humans also have DNA in our cells, and because that DNA is damaged by UV-C wavelengths, UV-C light at disinfecting or sterilizing doses is not safe for human exposure. UV-C can only be used when areas are unoccupied, or in spaces that are contained and have no risk of human exposure. In addition, unlike UV light, VioSafe light does not break down the chemical bonds in plastics, gaskets, insulation, and similar materials, making it ideal for applications where the caustic effects of UV are undesirable or impractical.

In summary, Vital Vio’s VioSafe® technology is not UV, it is within the visible light spectrum and acts using a different mechanism than UV, is safe, and can be used to protect continuously.

| | VioSafe® Technology | UV-C Technology |
|-------------------------------|-----------------------------|---|
| Wavelength | 400-420 nm | 200-280 nm |
| Mechanism of Action | Unique Porphyrin Activation | DNA Damage |
| Affect Materials? | No effect | Degradative |
| How Often Disinfecting | Continuous | Intermittent |
| Type of Clean | Disinfection | Disinfection/Sterilization depending on use |

VIOSAFE MEETS INTERNATIONAL ELECTROTECHNICAL COMMISSION SAFETY STANDARDS FOR UV, BLUE LIGHT, INFRARED AND THERMAL EXPOSURE

The International Electrotechnical Commission (IEC) prepares and publishes the primary international standards for electrical, electronic and related technologies. Underwriter’s Laboratories (UL) conducts photobiological safety assessments using IEC standards. UL tested Viosafe against IEC 62471 - Photobiological Safety of Lamps and Lamp Systems – and VioSafe technology met every standard for safe, continuous and unrestricted exposure for humans.

IEC 62471 is focused on safety of the skin and eyes in eight (8) areas related to UV hazard, blue light hazard, temperature hazard and infrared hazard. The specific categories are:

- ✓ Actinic UV hazard exposure limit for the skin and eye
- ✓ Near-UV hazard exposure limit for eye
- ✓ Retinal blue light exposure limit
- ✓ Retinal blue light hazard exposure limit – small source
- ✓ Retinal thermal hazard exposure limit
- ✓ Retinal thermal hazard exposure limit – weak visual stimulus
- ✓ Infrared radiation hazard exposure limit for the eye
- ✓ Thermal hazard exposure limit for the skin

For each of these assessments, VioSafe® was shown to be in what the IEC calls, “Exempt Group (RG 0), where no optical hazard is considered reasonably foreseeable, even for continuous, unrestricted use.”

VIOSAFE TECHNOLOGY DOES NOT RISK CREATING “SUPERBUGS”

Antibiotic resistant bacteria – so called “superbugs” – have been identified by the World Health Organization as, “one of the biggest threats to global health, food security, and development today.”¹¹ We are confident VioSafe technology does not and will not contribute to this global threat and instead can provide additional layers of protection against the spread of these germs.

In the simplest of terms, antibiotics and VioSafe work in very different ways, with antibiotics affecting a single “target” and VioSafe affecting multiple “targets” within a microorganism. Microbes have proven effective at mutating to resist a single target, but not multiple targets.

Antibiotics operate by targeting a singular molecule or function within a cell; a component of either DNA synthesis, cell wall synthesis, or protein synthesis. Bacteria are then able to generate one of four resistance mechanisms: antibiotic inactivation, target modification, altered permeability, or the bypass of that part of the metabolic pathway⁷. These mechanisms become effective because resistance is needed against only the single target within the cell.

By contrast, VioSafe technology disinfects through the photoactivation of the ubiquitous and critical building blocks of the cell, specifically, porphyrin molecules, which then produce reactive oxygen species (ROS). These ROS cause irreparable damage intracellularly by affecting numerous targets simultaneously, including DNA, RNA, proteins, and lipids⁶. It would be very difficult for microbes to produce enough mutations that did not kill the cell to result in resistance.

This has been demonstrated in several studies that look at the potential for the development of resistance to visible light disinfection technology by targeted microorganisms^{5,8,9}. Each of these studies tested different bacterial strains, including MRSA and *E. coli*. The bacteria cells were exposed to the disinfection wavelengths and the surviving cells were collected, re-grown to higher amounts, and re-exposed to the lights. This was repeated for as many as 20 cycles, and none of the species tested showed any development of resistance by the end of the longer-term exposures. This lack of resistance after repeated exposure shows that the development of resistance to the light disinfection is not likely to occur, especially on the surface environments our lights are designed to disinfect.

VIOSAFE’S IMPACT ON “GOOD BACTERIA”

The 400-420nm wavelength that is effective at killing microbes does not distinguish between microbes. All species currently tested that are killed by VioSafe technology contain the unique porphyrin molecules; there is no difference in those molecules between bacteria that are beneficial and those that are pathogenic to humans. Human flora can be found all over the body, including skin, gut, respiratory tract, and more.

THE GUT

The gut has the largest number of microbes and the largest variety relative to any other area on/in the human body. Because VioSafe light penetrates only the first few layers of the epidermis, bacteria in the gut are not exposed to VioSafe’s disinfecting effects. Therefore, there is no risk to or detrimental effect on gut or other beneficial bacteria within the human body, when people are exposed to VioSafe light.

THE SKIN

Microbes that compose normal skin flora of humans can be found in three main areas: sebaceous, moist, and dry. They can be found on or within the layers of the epidermis and within glands or hair follicles¹⁰. Because Vital Vio's technology only penetrates the first few layers of the skin, any flora deeper than this will not be exposed or affected.

More importantly, since most of our body surface is covered by clothing most of the time, only a small percentage of our skin is likely to be exposed to disinfecting light at any one time, most frequently the face and hands. Therefore, only microbes on exposed skin have any chance of being affected, and these areas are quickly repopulated from covered areas, or from the environment, through the normal course of human activity. This is similar to what we experience while showering, washing hands, or using antibacterial gels.

VioSafe has been tested by UL to meet the standards set by the IEC as safe for continuous exposure to the skin, and there is no evidence of and no reason to suspect any negative effects on skin flora from VioSafe[®] technology.

CONCLUSION:

Vital Vio's mission is to protect as many people and the places they live and work as possible. We take safety and safety concerns seriously. Four areas of concern related to VioSafe technology have been thoroughly investigated:

- Ultra Violet (UV) Radiation
- Blue Light Hazard
- Antibacterial Resistant "Superbugs"
- So-called "Good" Bacteria

Working with our research partners, accreditation bodies and customers, and backed by our own and independent research and scientific and clinical studies we have demonstrated a positive safety profile in each of these areas.

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