PRODUCTIP GUIDE
FOR SUPPLYING THE EU MARKET WITH UV-C LIGHTS

Introduction

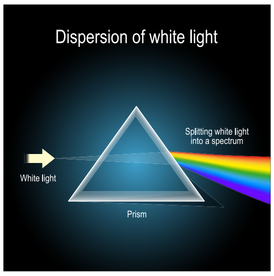
As a result of the Covid-19 (Corona) pandemic new and alternative disinfection methods are being discovered. Among these new methods there is UV-C light/radiation. At ProductIP we see many products with solutions using UV-C and have received many questions on this subject. For example, which legislation applies to UV-C, which standards should be applied, is UV-C for use in hospitals only, what are the dangers of UV-C, etc.. In this 'ProductIP guide for supplying the EU market with UV-C lights' we will provide you with introductory information on UV-C.

Subjects covered in this ProductIP guide are:

- What is light
- What is UVC
    - Germicidal effect of UV-C
- Use of UV-C in products
    - Current use of UV-C
    - How to apply UV-C safely
    - Precautions when using UV-C
    - Environmental risks
    - Apply standards to your product
    - Use of UV-C in companies as a disinfectant
    - Personal Protective Equipment (PPE)
- UV-C in the hospital sector
- Outlook
- How can ProductIP help?

What is light

In order to be able to explain what UV-C lighting is, it is helpful to first explain light in general. The main source of 'white' light is the sun. Part of the radiation from the sun is perceived by humans as visible light; the wavelength is between 400 to 700 nanometers (nm).
Using a prism this effect can be observed. A prism refracts light. A dispersive prism breaks white light up into its constituent spectral colours (the colours of the rainbow).



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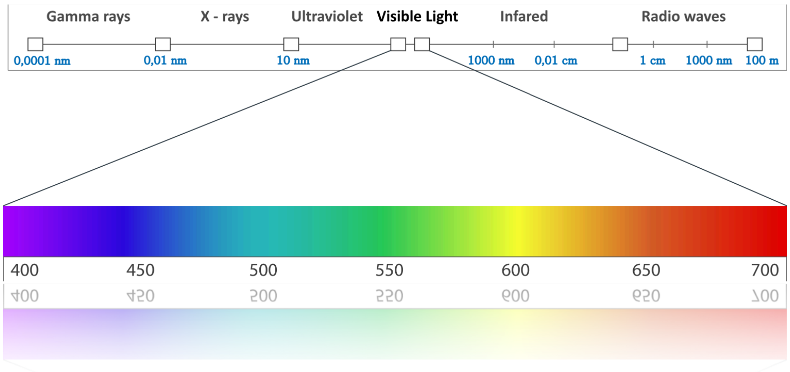
Visible light is however not the only 'light'. There is also Ultraviolet-light (UV-light), infrared light, X-rays, gamma-rays and radio-waves within the spectrum. Given the purpose of this document, we will not go into more detail on other light sources than Ultraviolet.

What is UV-C

Ultraviolet light (literally 'beyond violet') is invisible to the human eye and is divided into UV-A, UV-B and UV-C.



The UV spectrum is subdivided into 3 wavelength ranges:
UV-A from 315 to 400 nm
UV-B from 280 to 315 nm
UV-C from 200 to 280 nm

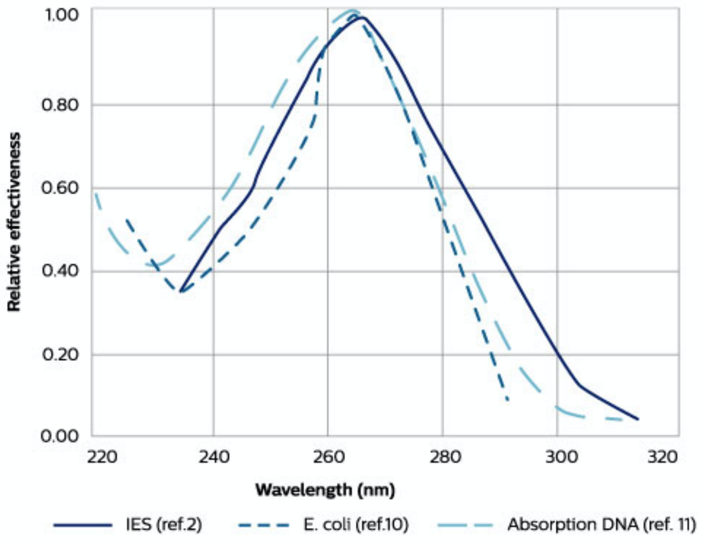
For some applications, the UV spectrum is also divided as 'Far UV', 'Vacuum UV' and 'Near UV'. However, the limits of this devisions vary according to the application (thermal physics, photochemistry, meteorology, optical design, etc.). In the scientific literature there are therefore different definitions for UV. In this guide we will use the most commonly known subdivisions into UV-A, -B and -C.

When light (or radiation) from the sun reaches the earth, UV-A radiation is let through and is not filtered. Circa 90% of UV-B is filtered and UV-C is completely filtered by the ozone-layer. Normally there is no UV-C light on earth. In 1877 it was discovered by British physiologist Arthur Downes and scientist Thomas Blunt, that UV-C light can be produced with artificial sources. Artificial sources are currently UVC-led's or mercury lamps.

Germicidal effect of UV-C

UV-A radiation can penetrate deeply into the skin and is thought to be responsible for up to 80% of skin ageing, from wrinkles to age spots. UV-B penetrates the skin less deeply, but can damage the DNA in our skin when exposed for an extended period. This would lead to sunburn and eventually in cases to skin cancer. The risks of UVA- and -B are relatively well know and can be 'solved' by using protective sun creams.

UV-C rays (with the wavelengths from 200 to 280 nm) are on the edge of ionising and non-ionising radiation. The wavelength of UV-C is very energetic and can break chemical bonds. UV-C rays are most photo-biologically active because of their optimal absorption by nucleic acids, amino acids and proteins. UV-C radiation can kill or inactivate many micro-organism species, preventing them from replicating. As can be seen in the graph, UV-C radiation is most effective at around 250-260 nm.



Source graph: lighting.philips.com

Due to its energetic nature and ability to break bonds, when materials are exposed to UV-C, there may also be photo-degradative effects. However, while damaging effects of UV-B radiation may take several hours, the effect of UV-C may possibly takes only a few minutes (due to its energetic nature), depending on thickness of the skin and the intensity of the UV-C.

Commercially available UV-C lamps often use the 254 nm wavelength because it is very well absorbed by organic molecules (including DNA, RNA): hence the germicidal effect. In other words, at around 260 nm, UV-C-light has the highest germicidal effect, but is also of the most health risk.

Use of UV-C in products

Artificially-produced UV-C light has already successfully been in use for many years as a germicide and bactericide. As mentioned, UV-C light can kill or disable the growth of micro-organisms like bacteria, viruses and other pathogens. It therefore provides for a non-chemical alternative to other disinfection methods, like using chlorine. The purifying effects are produced by wavelengths below 310 nm, with the optimum effect occurring at around 260 nm.

Current use of UV-C

UV-C is used in a range of applications, most commonly at a wavelength of 254 nm. It is often used for disinfection in wastewater treatment plants, laboratories and air-conditioning systems. Other applications are poolcleaners and in food and beverage industrial processes.

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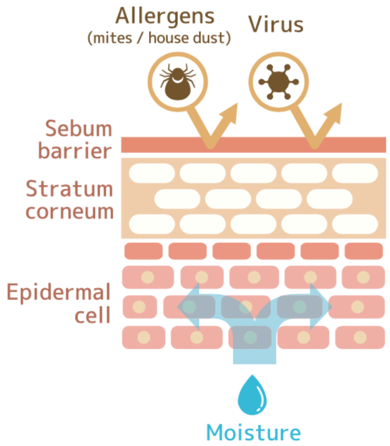
UV-C is also often used in medical and hospital settings to, for example, sterilise instruments, work surfaces and the air. As a result of the Covid-19 pandemic the 'commercial market' has discovered UV-C light as a germicide.

How to apply UV-C safely

The penetration depth of UV-C light into human skin is low; approximately 5% reaches the living cells in our skin, depending on the place of contact with the skin and thickness of the skin. The UV-C light will therefore come very little into contact with epidermal cells (living tissue). Most absorption takes place in the 'stratum corneum' (latin for horny layer) of the skin, this is the barrier that protects the underlying tissues.



It should be noted that the thickness of the skin can vary greatly per person and also as a function of age of a person. For example, the stratum corneum is thicker at the palm of the hand, but thinner on the back of the hand and at the wrist.

According to research from at Columbia University Irving Medical Center, UV-C light at a wavelength of 222 nm, might be safe for exposure to humans and exposure to the UV-C light at that wavelength would kill:

- 90% of airborne viruses in about eight minutes,
- 95% in 11 minutes,
- 99% in about 16 minutes, and
- 99.9% in 25 minutes.

It could thus be concluded that the health risks of UV-C depends on the intensity of the UV-C radiation, the wavelength of the light and the duration of the exposure. Most UV-C lights (however) operate at around 260 nm. Research into the hazardous effects of UV-C is underway in light of combating the Covid-19 pandemic. A wavelength of 220 nm might be (more) safe, but additional research is needed.

The general conclusion could be that short contact with UV-C may or may not result in immediate damage to the health. Exposure to higher wavelengths (nm), at around 260 nm, is probably, for disinfection purposes, more effective than exposure at around a wavelengths of 220 nm. But continuous exposure, as research from Columbia suggests for at least 11 minutes to kill 95% of airborne viruses, does likely result in health damage as the degrative aspect of

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UV-C may possibly takes only a few minutes. The advise would be to design products in such a way that people are always protected from exposure to UV-C light.

Precautions when using UV-C

Skin
Make sure that you avoid contact of UV-C with open wounds, avoid too short distances to the UV-C light and avoid high powered UV-C (also with intact skin). Also avoid contact with UV-C light where the skin is thin (as mentioned in the above). There are several risks reported with UV-C, the most commonly associated is the risk of erythema (redness of the skin). Further risks of not observing the precautions is DNA/RNA damage. Damage to DNA/RNA has potentially carcinogenic effects (potentially because not all bad cells will have a carcinogenic effect).

Eyes
Contact of UV-C light with the eyes may result in eye damage, for example Photokeratitis. This is a painful eye condition that occurs when the eyes have been exposed to invisible rays of UV-C similar to snow blindness or welder's flash (arc eyes). Like a sunburn on the skin, photokeratitis is commonly not detected until after the damage has occurred. Symptoms may include pain, swelling, tearing, sensitivity to bright lights, small pupils, blurriness, headaches, etc. In rare cases, even temporary colour changes in the vision may occur.

Environmental risks

Below 185 nm, UV-C produces the gas know as 'ozone'. UV-C light will ionise oxygen, producing ozone. Sometimes, this is exactly the primary goal, for example in water purification, but for most commercial purposes however, the production of ozone would be a detrimental side effect of a UV-C lamp. To prevent this detrimental side effect, most UV-C lamps are treated to absorb the 185 nm ozone emission.

Apply standards to your product

Up until the Covid-19 pandemic there was not much demand for UV-C lights. They were mainly used in hospital setting and for water purification (more on use in the hospital sector later).
Currently in the EU there are two important standards applicable to UV-C lighting:

1. EN ISO 15858:2016
2. EN 62471:2008.

Standard EN ISO 15858:2016 has been prepared by the technical committees for 'Cleaning equipment for air and other gasses' and 'Air filters for general air cleaning'.
Standard 62471 has been prepared by committee 'Lamps and related equipment'.

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1. EN ISO 15858
The scope of EN ISO 15858:2016 is:
"ISO 15858:2016 specifies minimum human safety requirements for the use of UVC lamp devices. It is applicable to in-duct UVC systems, upper-air in room UVC systems, portable in-room disinfection UVC devices, and any other UVC devices which may cause UVC exposure to humans. It is not applicable to UVC products used for water disinfection."
The standard provides guidance for maximum permissible UV-C exposure and personal safety training.

2. EN 62471:2008
The standards gives guidance for evaluating the photobiological safety of lamps and lamp systems including luminaires. Specifically it specifies the exposure limits, reference measurement technique and classification scheme for the evaluation and control of photobiological hazards from all electrically powered incoherent broadband sources of optical radiation, including LEDs but excluding lasers, in the wavelength range from 200 nm through 3000 nm.

Other harmonised standards that may be applicable to appliances that contain UV-C light are EN IEC 60335-2-27 and EN (IEC) 60335-2-65.

EN IEC 60335-2-27;
The standards deals with the safety of electrical appliances incorporating emitters for exposing the skin to ultraviolet or infrared radiation, for household and similar use. Appliances intended to be used in tanning salons, beauty parlours and similar premises, are also within the scope of this standard.

EN (IEC) 60335-2-65;
The standard deals with the safety of electric air-cleaning appliances, their rated voltage being not more than 250 V for single phase and 480 V for other appliances, for household purposes. Also includes appliances intended to be used by laymen in shops, in light industry and on farms.

Use of UV-C in companies as a disinfectant

The applicable EU-legislation to bear in mind is, amongst others, Directive 2006/25/EC[1]. The Directive lays down minimum requirements for the protection of workers from risks to their

[1] Directive 2006/25/EC of the European Parliament and of the Council of 5 April 2006 on the minimum health and safety requirements regarding the exposure of workers to risks arising from physical agents (artificial optical radiation) (19th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)

health and safety arising or likely to arise from exposure to artificial optical radiation during their work.
So when you want to apply UV-C radiation for its germicidal effect, you must at least comply to set exposure limits of Annex I, perform a risk assessment for workers exposed to artificial sources of optical radiation and provide worker information and training. Because a Directive in the EU is not directed at its citizens, but to its Member States, the Member States are obliged to adopt the Directive in the national legislation. For national exposure limits and possible penalties for not complying we refer to the national legislation for each EU member state.

Personal Protective Equipment (PPE)

Because the penetration depth of UV-C is low, the radiation can be absorbed by clothing, plastics and glass. When exposed to UV-C radiation, PPE covering all exposed areas is highly recommended, for example: UV-protecting eyewear and face shields.

Standards applicable to PPE for this use are:
- EN 170 (Personal eye-protection - Ultraviolet filters - Transmittance requirements and recommended use) and
- EN 14255-1 (Measurement and assessment of personal exposures to incoherent optical radiation - Part 1: Ultraviolet radiation emitted by artificial sources in the workplace).

In general it can be concluded that it is unlikely that UV-C exposure will result in acute damage, but the more exposed you are to the radiation, the more severe the symptoms will become. Wearing protective clothing can minimise the risk of damage due to exposure to UV-C radiation.

UV-C in the hospital sector

As mentioned under 'current use of UV-C', radiation from UV-C is often used in medical and hospital setting to, for example, sterilise instruments, work surfaces and the air. Research by Franklin Dexter[2] has learned that:
"UV-C is proven to reduce bacterial and viral contamination across a variety of health care settings by addressing both surface and air column disinfection, and this technology has been shown to reduce the incidence of both bacterial and viral health care–associated infections (HAIs)"

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[2] Franklin Dexter et al, Perioperative COVID-19 Defense: An Evidence-Based Approach for Optimization of Infection Control and Operating Room Management, Published online 2020 Mar 26, Source/link to source

The research also mentions that disinfection should not only be done with UV-C, as light beams can be blocked by obstacles. UV-C must reach the surface to be cleaned directly, in order to be effective. If the light waves are blocked by dirt or other objects, the blocked areas will not be disinfected. Organic contamination must first be cleaned before disinfectants, such as UV-C, can be applied.

In the hospital sector, UV-C is used for the disinfection of surfaces in 'empty' rooms in the final phase of disinfection. In any case, it is not used continuously. For the time being, UV-C is not used in the hospital sector for air disinfection because the contact time of the air with the UV rays seems to be too short to contribute to air disinfection.

Outlook

With the Covid-19 pandemic and the possible next waves of the pandemic, until there is a cure or vaccine found, it is our expectation that UV-C will become more popular. The standardisation organisations have already announced that they are aware of UV-C and its risks. It is therefore likely that more standards will be released in the future. We already notice that market surveillance authorities are focussing on UV-C devices due to the potential carcinogenic effectes of UV-C.

The first product alerts regarding UV-C devices have already been reported to Safety Gate: the rapid alert system of the European Commission for dangerous non-food products. On our blog 'Corona Timeline' we post on a weekly basis the reported UV-C devices and why they are reported.

For example: "The product emits an unsafe amount of UV-C and UV-B radiation (measured value: 1.15 W/m2). Consequently, a user in close proximity to the product will receive an unsafe dose of UV radiation to the eyes or the skin, increasing the risk of severe injuries or cancer. [...]"

There are also products being recalled that claim to provide radiation at UV-C wavelengths but in fact these products do not emit UV-C radiation. Consequently, these products will not kill bacteria or viruses, that could then reach the user, increasing the risk of infection.
Be sure to verify the wavelengths of your lamps before you claim any germicidal effect.

At ProductIP we monitor Safety Gate and the release of new standards and we will add these to our website and database to keep you informed. Users of the ProductIP platform will therefore know when a new standard applies to their product. Products that don't cause hassle, we will help!

How can ProductIP help?

Via our web-based solution you can instantly create a comprehensive regulatory checklist for non-food consumer products. This checklist is the core of a so-called technical file. Invited suppliers can upload the compliance evidence directly into this technical file. You sign off the references in the regulatory checklist with the uploaded information; certificates, test reports, declarations, bill of materials, etc. When relevant for the product you can create a CE declaration with a mouse click.

These technical files enable you to demonstrate to authorities, consumers, other stakeholders, that you are in control of product compliance in a way that is in line with the regulatory framework.

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