



# Photobiological Safety of Lighting Products







Photobiological Safety of Lighting Products - Blue Light Hazard

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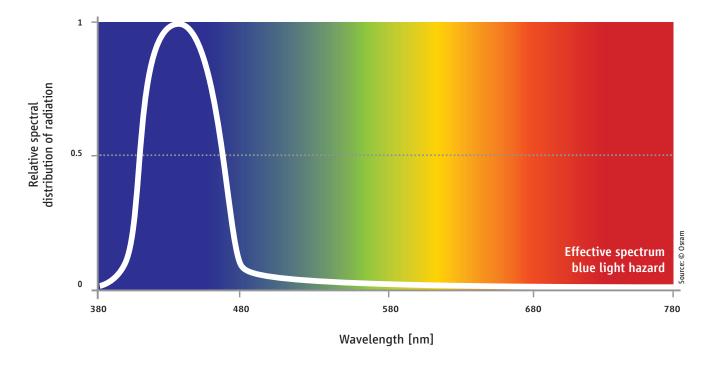
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#### 1. Introduction

The present publication is restricted to the consideration of blue light hazard (risk to the human eye) as part of the optical radiation assessment of light sources and luminaires, as these aspects were not previously included in the lighting product safety standard requirements. It reflects the current status of the standards and the deliberations in the specialist bodies.

Blue light hazard is the potential risk of photochemical damage to the retina caused by radiation, especially in the 400 nm to 500 nm wavelength range.

Fig. 1: Spectrum of blue light hazard



#### 2. Legal Basis

Table 1: Directives and laws relevant to blue light hazard			
EU directives/regulations	National legislation		
Product Safety Directive (2001/95/EC)	Geräte- und Produktsicherheitsgesetz (ProdSG)		
Low Voltage Directive (2006/95/EC)	Geräte- und Produktsicherheitsgesetz (ProdSG) mit 1. Verordnung zum ProdSG		

The German Product Safety Act (ProdSG) which came into force in November 2011 (the national implementation of various directives including the European General Product Safety Directive (GPSD), 2001/95/EC and the Low Voltage Directive (LVD), 2006/95/EC), stipulates in the basic safety principles of the first ordinance of the Act that no radiation-related hazards shall arise from light sources and luminaires (GPSGV No. 1, § 2, paragraph 2, 4b). The **product safety** requirements apply for all electrical equipment; the Low Voltage Directive applies for all products with rated voltages from 50 V to 1000 V alternating voltage (and/or 75 V to 1500 V direct voltage) (exceptions include equipment used in explosive atmospheres, in medical technique, on ships, in aircraft or in railways). The Product Safety Directive together with the Low Voltage Directive therefore constitute the legal basis for safety consideration (see Table 1).

In addition, in its "Directive on the minimum health and safety requirements regarding the exposure of workers to risks arising from physical agents (artificial optical radiation)" (2006/25/EG) the European Union has established a further legal basis for the European Community.

The German Ordinance on Workplaces (Arb-StättV) applies for work places and does not cover the product-related assessment of light sources and luminaires. Conversely, however, the product information can and shall be used for the risk analysis of work places.

#### 3. CE marking of Light Sources and Luminaires

#### 3.1 Application of European directives

Electrical equipment may only be put into circulation in the EU if the basic requirements of the applicable EU directives (implemented in national laws) have been observed. This includes the photobiological safety of the products. The CE marking indicates to the authorities (for whom it is exclusively intended) that the product conforms to the relevant directives in cases where these require CE marking. Under the Low Voltage Directive the manufacturer assumes responsibility for applying the CE marking. Observance of the requirements shall be checked and their fulfilment be documented in the EC conformity declaration and the technical test reports.

In most cases light sources and luminaires are subject to the EC Low Voltage Directive, the EMC Directive, the ErP Directive and other relevant directives; in the case of blue light hazard, it is exclusively the GPSD and the LVD which apply. The Module A conformity assessment procedure is prescribed in the directives. Module A stipulates that the manufacturer solely can assume responsibility for monitoring and testing the technical design and production, without any involvement of a notified body.

Under the "New Approach" of the European Union, protection objectives are defined in the EU directives. Concrete descriptions of the product requirements can be found in the European standards. The EU Official Journal publishes the EN standards related to the directives. This links the directives to the product requirements. According to the current version of the LVD, decisive for the presumption of conformity of a standard is its publication by a national standards organisation and not the listing in the Official Journal.

Where harmonised standards are applied, it is presumed that the requirements of directives and laws are fulfilled. There is no obligation to apply the standards. As far as the market surveillance authorities are concerned, the burden of proof is reversed and placed upon the manufacturer or importer if the standard has been deviated from (safety by other means). Accordingly it is advisable to apply the harmonised standards. However, such application does not absolve the manufacturer of his obligation to assess the risk of particular characteristics of his product which may not be covered by the standard, and to reduce this risk if necessary.

EU website of the listed standards for the Low Voltage Directive (list provided for information purposes only; acceptance as European standard is decisive for presumption of conformity):

http://ec.europa.eu/enterprise/policies/european-standards/documents/harmonisedstandards-legislation/list-references/low-voltage/index\_en.htm

If the product under review does not fall within the CE marking obligation (e.g. low voltage halogen lamps with reflectors), then the CE mark may not be used.

## 3.2 Proof of conformity through use of harmonised standards

The product standards have been harmonised and so, too, has the standard for assessing photobiological safety under the Low Voltage Directive. The transition period for DIN EN 62471:2009 expired in September 2011, since when conformity with the predecessor standard DIN EN 60825-1 has no longer counted as the basis for presumption of conformity.

## 4. Standards and Certification

Revision status of blue light hazard safety standards

Table 2: Safety standards	(revision Status o	of blue light hazard	d safety standards) and	VDE certification

Short title	International standard	DKE (German version of the European standard)	VDE certification
Incandescent lamps — Safety — Tungsten filament lamps for domestic and similar general lighting purposes	IEC 60432-1:2011	Draft standard DIN EN 60432-1/A2; VDE 0715 1/A2:2011	possible
Incandescent lamps – Safety – Tungsten halogen lamps for domestic and similar general lighting purposes	IEC 60432-2:2012	Draft standard DIN EN 60432-2/A2; VDE 0715-2/A2:2011	possible
Incandescent lamps — Safety — Tungsten halogen lamps (non-vehicle)	IEC 60432-3:2012	Draft standard DIN EN 60432-3/A3; VDE 0715-11/A3:2011	possible
Self-ballasted lamps for general lighting services — Safety	Draft 34A/1540/CDV for IEC 60968	Draft standard DIN EN 60968/A3; VDE 0715-6/A3:2012 under preparation	possible
Double-capped fluorescent lamps – Safety	Draft 34A/1536/CDV for IEC 61195	Draft standard DIN EN 61195/A1; VDE 0715-8/A1:2012 under preparation	possible
Single-capped fluorescent lamps — Safety	Draft 34A/1538/CDV for IEC 61199	Draft standard DIN EN 61199-100; VDE 0715-9-100:2012 under preparation	possible
Induction lamps – Safety	Proposal under preparation	-	-
High intensity discharge lamps — Safety	Draft 34A/1600/CDV for IEC 62035	-	possible
Miscellaneous lamps	IEC 61549:2012	Draft standard DIN EN 61549/A3; VDE 0715-12/A3:2011	possible
LED modules for general lighting - Safety	Draft 34A/1554/CD for IEC 62031	-	possible
Self-ballasted LED-lamps > 50 V — Safety	Proposal 34A/PRESCO (ASZ)101 – Attachment 03 to IEC 62560 under consultation	-	possible
Self-ballasted LED-lamps ≤ 50 V — Safety	Draft 34A/1582/NP		possible
LED-lamps without integrated ballast — Safety	Proposal 34A/PRESCO (ASZ)101 – Attachment 03 under consultation	-	possible
Double-capped LED lamps — Safety	Proposal 34A/PRESCO (ASZ)101 — Attachment 03 under consultation	-	possible
Luminaires – General requirements and tests	Draft 34D/1064/CDV together with proposal 34A/PRESCO (ASZ)101 – Attachment 04	-	possible
Photobiological safety of lamps and lamp systems	IEC 62471:2006	DIN EN 62471; VDE 0837-471:2009	Test report
Photobiological safety of lamps and lamp systems - Manufacturing requirements			Test report
Assessment of blue light hazard	IEC/TR 62778:2012	-	Test report

VDE mark certification is possible for DIN-EN standards with VDE classification and FDIS-status (Final Draft International Standard) standards. Certification using the ENEC symbol will be possible as soon as the corresponding European standard has been included in ENEC PD 301 Annex B.

The "dow" (date of withdrawal), indicating the final withdrawal of the predecessor standard, is given in the successor standard for European standards which are to be withdrawn. The "doc" (date of cessation) is listed as the date on which the acceptance of the presumption

of conformity ended for the replaced standard in the list of standards in the Official Journal of the EU. The "doc" and "dow" are generally the same date.

The VDE Institute informs certificate holders (VDE/ENEC symbols) roughly one year before the "doc" or "dow" date if a certificate is about to become invalid due to a standard being withdrawn. Certificate holders then have the possibility to change their certificate over to the new standard in the remaining time.

# 5. Assessment of Blue Light Hazard from Lamps and Lamp Systems

When assessing the photobiological hazard arising from optical radiation, a distinction is made between the different wavelength ranges (UV, visible and IR radiation). The main focus here is on the depth of penetration into human tissue. Only the skin and eyes are affected as optical radiation does not penetrate deep into tissue.

**UV and IR radiation** is absorbed by the outer layers of tissue. The hazard and the stated maximum limits depend on the illuminance generated by a light source or the luminaire and not on its physical dimensions. This means that the risk varies depending on the distribution of the illuminance and the square of the distance (i.e. halving the distance to the source quadruples the risk).

The situation is different with **blue light hazard.** This radiation penetrates the cornea of the eye and is focused on the retina by the eye lens. Accordingly, the hazard is dependent upon the size of the source and the maximum limits are expressed in terms of radiance. Small sources with high luminance are focused by the eye as a small dot onto the retina and where they generate a locally

high risk, whereas the identical level of power radiated from an expansive area is distributed across a larger surface thereby reducing the risk. The luminance of a source depends on its distance, although the assessed risk is not directly linked to the varying distance. Only when there is sufficient distance to the light source or luminaire do the constant unconscious and involuntary movements of the eye (saccades) result in "blurring" on the retina, hence reducing the risk.

The German standard DIN EN 62471 "Photobiological safety of lamps and lamp systems" distinguishes between two types of measurement. The risk classification for general purpose lighting is to be conducted at a distance which yields an illuminance of 500 lx (minimum 200 mm). A distance of 200 mm is recommended for all other applications of lamps.

The following risk groups are defined in DIN EN 62471:

- No risk (risk group 0 RG 0):
   The lamp or luminaire represents no photobiological hazard.
- Low risk (risk group 1 RG 1):
   Assuming normal behaviour on the part of the user, the lamp or luminaire represents no hazard is use.
- Medium risk (risk group 2 RG 2):
   Due to the natural reaction to look away from bright light sources, or by thermal discomfort the lamp or luminaire represents no hazard.
- High risk (risk group 3 RG 3):
   The lamp or luminaire represents a hazard even in instances of transient or brief radiation.

The maximum lengths of exposure to UV, visible and IR radiation for the individual risk groups are given in DIN EN 62471; these are used to calculate the emission thresholds.

In assessing blue light hazard in particular, it emerged that the standard was possibly open to interpretation, which could result in differing risk ratings.

Following discussions among experts in the TC-34 bodies, a simplified solution was sought and published as IEC/TR 62778. This stipulated that measurements of blue light hazard must always be taken at a distance of 200 mm.

It is impossible for luminance to be increased by optics, reflectors etc., meaning that the light source itself (e.g. lamp, LED etc.) represents the maximum hazard and the classification of the light source can be assumed for the luminaire.

If risk group 2 is reached, a flow diagram in IEC/TR 62778 shows a method by which an increase in distance between the observer and the luminaire (light source) can yield a threshold illuminance E<sub>thr</sub> thereby reaching the non-critical risk group 1 rating. The appendix of IEC/TR 62778 also contains tables showing the threshold values for luminance and illuminance, depending on the colour temperature of the light source or luminaire. Using these threshold values it is possible to classify a light source without having to take any measurements.

Incandescent, halogen, linear fluorescent and compact fluorescent lamps for general lighting do not come into risk group 2 on account of their technology. According to the relevant product safety standards (including draft standards, see Table 2), it is not necessary to assess the blue light hazard.

# 6. Marking of Blue Light Hazard of Lamps and Luminaires

Marking requirements for blue light hazard in accordance with standards and drafts in Table 2

ight source	Measure, labelling
Incandescent lamps, tungsten halogen lamps, all fluorescent lamps (compact, with and without integrated ballast, linear), induction lamps	No labelling is required for these light sources as no hazard can arise.
Special tungsten halogen lamps (for projection photography, stage lighting and special applications)	These light sources are always labelled with the pictogram shown on page 10.
Low and high intensity sodium-vapour discharge lamps	No labelling is required for these light sources as no hazard can arise.
Mercury vapour high intensity including blended lamps and metal halide lamps (all with coated or matt outer bulb)	No labelling is required for these light sources as no hazard can arise.
High-intensity mercury vapour and metal halide lamps with clear outer bulb	These light sources are always labelled with the pictogram shown on page 10.
LED modules	The light source shall be classified and measured if necessary. Labelling is not necessary if an RG 0 or RG 1 rating is given. Above RG 1, the distance is given at which the threshold illuminance $E_{thr}$ returns the product to RG 1.
LED lamps, retrofit	These lamps may only be specified as RG 0 or RG 1 products as, like the lamps they are replacing, they must not present a risk. Labelling is not required.
LED lamps, non-retrofit	The light source shall be classified and measured if necessary. Labelling is not necessary if an RG 0 or RG 1 rating is given. Above RG 1, the distance is given at which the threshold illuminance E <sub>thr</sub> returns the product to RG 1.



Fig. 2: Apparatus for measuring photobiologically effective radiation

Type of luminaire	Measures, labelling
Luminaires for children, mains connected nightlights	<ul> <li>If light sources are used which carry no E<sub>thr</sub> and/or no pictogram, neither measurement nor labelling of the luminaire is necessary.</li> <li>For safety reasons, a fully assembled luminaire may only have an RG 0 or RG 1 rating.</li> <li>Light sources with a rating above RG 1 may only be used if they are not visible during maintenance work.</li> </ul>
Portable luminaires, hand lamps	<ul> <li>If light sources are used which carry no E<sub>thr</sub> and/or no pictogram, neither measurement nor labelling of the luminaire is necessary.</li> <li>If light sources are used which feature E<sub>thr</sub> details or pictograms, the pictogram must be applied to the exterior of the luminaire or it must be proved, by measuring the fully assembled luminaire, that the threshold limit for RG 1 is not exceeded.</li> <li>If, during maintenance work on the opened luminaire, it is possible to look at the light source, the pictogram of the light source must then be visible</li> </ul>
Fixed luminaires	<ul> <li>If light sources are used which carry no E<sub>thr</sub> and/or no pictograph, neither measurement nor labelling of the luminaire is necessary.</li> <li>If using light sources with E<sub>thr</sub> details, this figure can be used for the written information or a value can be determined by measuring the fully assembled luminaire. No written information is necessary in the case of RG 0 and RG 1.</li> <li>If light sources with pictograms are used, an E<sub>thr</sub> value must be determined by measuring the fully assembled luminaire. No written information is necessary in the case of RG 0 and RG 1.</li> <li>If the equivalent distance for E<sub>thr</sub> in a completely sealed luminaire is &gt; 0,2 m, the assembly instructions must contain the following (or similar) note: "The luminaire should be mounted so that prolonged staring at the luminaire from a distance of less than x m is unlikely."</li> <li>If, during maintenance work on the opened luminaire, it is possible to look at the light source, the pictogram of the light source must then be visible.</li> </ul>



Pictogram: Do not stare at the light source/luminaire!

The labelling of lamps with regard to their photobiological safety is dictated by the relevant standard; i.e. in the technical documentation accompanying LED modules and on the packaging of all lamps

### 7. Summary

Standards help in the implementation of legal requirements. This also applies to the assessment of blue light hazard. By incorporating the relevant requirements into the product safety standards, it is not necessary to apply IEC 62471 or DIN EN 62471. The measuring and labelling of light sources and luminaires can be dispensed with entirely or be reduced

to a minimum. The blue light assessment of the light source may be used for the blue light assessment of luminaires, as this hazard cannot be increased through luminaire designs.





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