



LIGHTINGEUROPE

THE VOICE OF THE LIGHTING INDUSTRY

Request for an Exemption for Phototherapy lamps

under the RoHS Directive 2011/65/EU

Lead as activator in the fluorescent powder (1 % lead by weight or less) of discharge lamps when used as phototherapy lamps containing phosphors such as BSP ($\text{BaSi}_2\text{O}_5 : \text{Pb}$)

15 January 2015:



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2 Reason for application

LightingEurope submits this application to:

*request for an exemption for applications under **Annex IV***

LightingEurope proposes to clarify applications in Annex IV where UV lamps with similar spectrum based on BSP phosphors are used by adding an additional exemption application (proposal 1) or by adding the Phototherapy application to the existing exemption for photopheresis in Annex IV exemption nr. 34 (proposal 2)

Proposal 1:

Lead as activator in the fluorescent powder (1 % lead by weight or less) of discharge lamps when used for phototherapy lamps containing phosphors such as BSP ($BaSi_2O_5:Pb$)

Proposal 2:

lead as an activator in the fluorescent powder of discharge lamps when used for extracorporeal photopheresis- and phototherapy lamps containing BSP ($BaSi_2O_5:Pb$)

LightingEurope requests a duration of:

Maximum validity period

3 Summary of the exemption request

UV lamps with Lead as activator in the fluorescent material are used for many skin treatment applications e.g. tanning- and photo-therapies. These lamps use the same fluorescent material as the spectrum which is optimal for the application is typically similar.

With reference to the above, this request concerns a clarification on the use of Lead in BSP phosphor lamps in medical devices in Annex IV by adding phototherapy applications.

These medical lamp applications are used in the market already since many decades and have been shown to be crucial as a substantial group of patients need the typical spectrum of the light for a proper and effecting healing process and cannot be effectively treated by other technologies.

Several new technologies are evaluated, however, the spectrum of these lamps is different and insufficient and a long approval process is would be needed with a large group of patients to enable a proper approval process for these medical applications.

4 Technical description of the exemption request

4.1 Description of the lamps and their applications

4.1.1 Lamps covered by this exemption

- This exemption covers UV discharge lamps containing lead as activator in the fluorescent powder. These lamps are used for (medical) skin treatment such as PUVA phototherapy purposes (see brochures ^{1, 2})

PUVA phototherapy is a very specific application enabling effective skin treatments used in medical applications and is explained in the brochures; For instance, a photochemical treatment where a combination of a drug e.g. Psoralen in combination with UVA radiation is used to treat skin diseases as psoriasis, vitiligo, atopic dermatitis etc.

- These lamps are produced in many shapes e.g. T12, T8 and T5 diameters and single capped configurations.



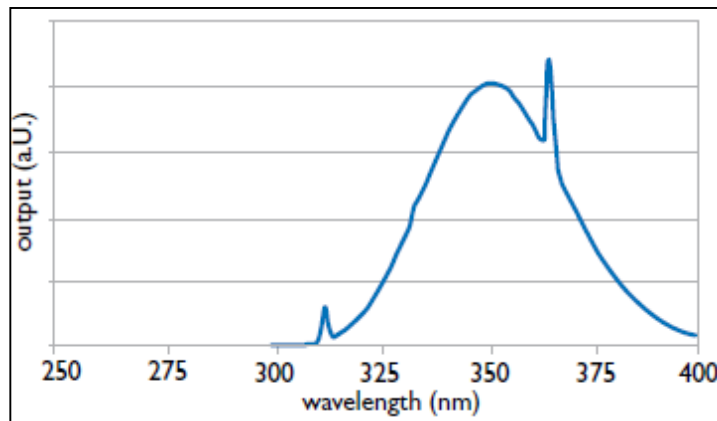
- The fluorescent materials (also named phosphors) contained in these lamps are manufactured from the same components but can vary in spectral discharge across the UVA and UVB spectrum.

¹ Brochure Philips:

http://www.lighting.philips.com/pwc_li/main/subsites/special_lighting/assets/pdf/Medical-treatment-with-phototherapy-2013.pdf

² Brochure LightSources: <http://www.light-sources.com/specialty/applications/medical-phototherapy-photonic-activated-dermatological-treatments-and-light-t>

Example of a typical UVA/UVB spectrum
of phototherapy-
photopheresis and tanning lamps



- The equipment requirements used for the application are governed by EU regulations concerning the allowable output of ultraviolet radiation permitted within a determined exposure time. The EU regulates and enforces equipment for UV treatment.
- PUVA phototherapy lamps and equipment have always used BSP phosphors (> 25 years). Extensive literature is available on the effectiveness of PUVA phototherapy with BSP containing lamps. No studies with effective results have been done with either fluorescent lamps with other phosphors, or other technologies (LED) giving UVA/UVB spectra. PUVA equipment release and approbation has always been based on extensive patient tests with lamps containing BSP
- The lamps are used for dermatological and phototherapeutic use under medical supervision and installed in dedicated phototherapy equipment.
- Although PUVA phototherapy lamps are very similar to tanning lamps in construction and incorporate lead-activated phosphors, they may have small differences in spectral distribution and exposure schedules depending on the application and the patient needs.
- Lead activated phosphors for tanning lamp applications are included in RoHS 2011/65/EU exemption 18(b) and are submitted for exemption upon expiration

July 2016. The phototherapy lamps included in this request were intentionally omitted at that time as they were exempt as medical devices.

- The typical lifetime of these lamps ranges from 600 to 1000 hours with a typical session time that ranges approximately from 5-30 minutes.
- These lamps are not used for the production of visible light so general lighting efficacy standards do not apply. UV output efficacy (UVA radiation out vs electrical power in) is typically between 15% and 25%, but the real measure is with what power the desired effect is reached (e.g. clearance rate for PUVA phototherapy lamps).
- The market demand PUVA phototherapy-lamps remain stable for the coming years.

4.1.2 Applications covered by this exemption

PUVA phototherapy lamps are light sources that produce ultraviolet light in the regions of the UVA and UVB spectrums. Their intent is to produce artificial sunlight to replicate sunlight exposure for the human body (similar to that as produced by the sun) yet applied in calculated doses as regulated by European regulations. It is estimated that over 90% of indoor UVA phototherapy lamps produced and used throughout Europe are manufactured with BSP (BaSi2O5:Pb phosphors containing 1% or less lead as an activator). There is no feasible alternative for this phosphor that will yield the same or similar results and has undergone the extensive European and US regulatory testing associated with the application of UVA phototherapy lamps using these phosphors. Over 80% of phototherapy lamps do NOT use BSP. These are so-called (Narrowband) UVB lamps. However a substantial group of patients cannot be effectively treated by (NB –)UVB – phototherapy. For this group, PUVA phototherapy is the only effective treatment therapy available, see references 3 & 4. Almost 100% of the medical skin treatment lamps using these phosphors are produced in the EU.

³ see <http://psoriasis-cure-now.org/uvb-puva/>,

⁴ Sami S. Yones; Roy A. Palmer; Trish T. Garibaldinos; John L. M. Hawk. “[Randomized Double-blind Trial of the Treatment of Chronic Plaque Psoriasis: Efficacy of Psoralen-UV-A Therapy vs Narrowband UV-B Therapy.](#)” Arch Dermatol 2006 142: 836-842.)



Examples of Phototherapy equipment

4.1.3 Annex II category covered by this exemption

List of relevant Annex II categories for this exemption

- | | | | | | |
|----------------------------|----------------------------|---------------------------------------|---------------------------------------|-----------------------------|-----------------------------|
| <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 | |
| <input type="checkbox"/> 6 | <input type="checkbox"/> 7 | <input checked="" type="checkbox"/> 8 | <input checked="" type="checkbox"/> 9 | <input type="checkbox"/> 10 | <input type="checkbox"/> 11 |

Application in other categories, which the exemption request does not refer to:

- Although the lamps submitted under this application are intended to be used in the category listed above, Lighting Europe lamp manufacturers cannot control the actual application and use of these in the market, nor do we believe it is appropriate to limit the potential application or the opportunities for new innovation.
- As such, these lamps may possibly be used in any categories of EEE covered by Annex 1 of the Directive.

4.2 Description of the substance

4.2.1 Substance covered by this exemption

LightingEurope is asking for exempting

☒ Pb ☐ Cd ☐ Hg ☐ Cr-VI ☐ PBB ☐ PBDE

4.2.2 Function of lead

Lead is used in the phosphor for UV radiation in phototherapy (medical) skin treatment lamps. The lead activator is required to allow the barium silicate phosphor to fluoresce. It transforms the 254 nm radiation to the requested UV (290nm-400nm) radiation. A fluorescent lamp uses phosphors which, when activated, will produce light in different wavelengths. The primary wavelengths of "light" produced by these lamps are in the UVA and UVB regions or 290-400nm. Lead is the primary activator for the barium silicate phosphors to fluoresce and is used in over 95% of the indoor low pressure mercury vapour fluorescent lamps used for tanning and certain medical applications, such as PUVA phototherapy

4.2.3 Location of lead in lamps

The lead is evenly distributed throughout the phosphor coating of the lamps to radiate in the range of 290-400nm when excited by radiation at 254nm. The lead content of the phosphors is less than 1% of the total weight of the phosphor.

4.2.4 Amount of lead

The phototherapy application is a small niche market compared to the total lighting market.

With respect to this exemption, the phosphor coating represents the homogenous material used in the fluorescent lamps. The lead content of the phosphor is less than 1% of the total phosphor weight.

There is no published data available for the quantity of phototherapy lamps entering the EU.

However, based on market estimations of LightingEurope the lead content of tanning lamps is limited to 2.5 kg of lead total per year entering into the EU.

4.2.5 Environmental assessments, LCAs

Additional information on environmental impact of the phototherapy lamps compared to alternatives is not available as no suitable alternate phosphor types are available that will yield the same result nor has undergone the regulatory testing of the EU or US. There are no statistical data available specific to the Life Cycle Analysis of UVA phototherapy lamps represented in this exemption request, however due to the relatively low market quantities for special lighting, the total environmental impact is expected to be limited. Research conducted about fluorescent lamps for general lighting applications does not specifically equate to these specialty lamps as they are not designed to produce visible light. Efficacies expressing the amount of visible light in Lumen per Watt, are normally related to e.g. fluorescent lamps for general lighting do not apply to PUVA phototherapy lamps. Cradle to grave estimates for the production of the components and the finished lamps in this exemption request are similar to those of general lighting fluorescent lamps.

We refer to the fact however that the use of lead as an activator of the phosphor in these lamps allows the transmission of the specific wavelengths of light to be emitted in such a fashion to be the most effective form for its purpose, which is not achievable with other phosphor types or other technologies. Therefore efficacies of any alternate product types would not be comparable. The potential substitution or replacement to other wavelengths or ultraviolet dosages would require revalidation of all existing equipment in the EU market or could cause the elimination of such equipment causing great hardship to the phototherapy patients that rely on this treatment and do not benefit from other forms of phototherapy products which do not contain lead activators in the specific phosphors. These current lamp types have been tested, studied and regulated in the EU and changes to these products would require a duplication of the clinical testing which has been compiled over years of study and regulation. It is further noted that the overall lead content of such lamps, as in general lighting, has been reduced in the past five years with the less than 0.2% lead content to allow for recycled glass in the glass envelop of the lamp.

5 Waste management

5.1 Waste streams

- ☒ Article is collected and sent without dismantling for recycling
- ☐ Article is collected and completely refurbished for reuse
- ☐ Article is collected and dismantled:
 - ☐ The following parts are refurbished for use as spare parts: _____
 - ☐ The following parts are subsequently recycled: _____
- ☐ Article cannot be recycled and is therefore:
 - ☐ Sent for energy return
 - ☐ Landfilled

UVA phototherapy lamps are in the scope of EU Directives 2002/96/EC - WEEE and 2012/19/EU– WEEE Recast. Take back systems are installed in all EU Member States: end users and most commercial customers can bring back the lamps free of charge. Lamps are collected separately from general household waste and separately from other WEEE waste. Also a dedicated recycling process exists for lamps.

European legislation on Waste Electrical and Electronic Equipment makes producers responsible for end of life products within this category as from August 13th, 2005. Target setting as consequence of the present legislation is 4kg per inhabitant per year for all categories.

European Lamp Companies have founded Collection & Recycling Organizations in the EU Member-States, with the objective to organize the collection and recycling of gas discharge lamps. Goal is to comply with present and probable future EU legislation and meet or exceed national targets.

In general the following channels have been established in the respective member-states providing countrywide coverage:

- Direct collection from professional installers:

Containers have been made available, ad hoc or permanently, and will be collected upon notification by the end user that the container is full.

- Collection through distribution:

Wholesalers place collection means at their premises respectively in their shops. Collection is done upon notification.

- Collection through municipalities:

Where infrastructure allows collection means are placed at municipality depots.

5.2 Amount of lead in WEEE

With respect to this exemption, the phosphor coating represents the homogenous material used in the fluorescent lamps. The lead content of the phosphor is less than 1% of the total phosphor weight.

There is no published data available for the quantity of phototherapy lamps entering the EU.

However, based on market estimations of LightingEurope the lead content of lamps is limited to 2.5 kg of lead total per year entering into the EU.

- ☐ In articles which are refurbished
- ☒ In articles which are recycled
- ☐ In articles which are sent for energy return
- ☐ In articles which are landfilled

6 Substitution

Can the substance of this exemption be substituted?

☐ Yes, by

☐ Design changes:

☐ Other materials:

☐ Other substance:

☒ No

Justification: see in below chapters

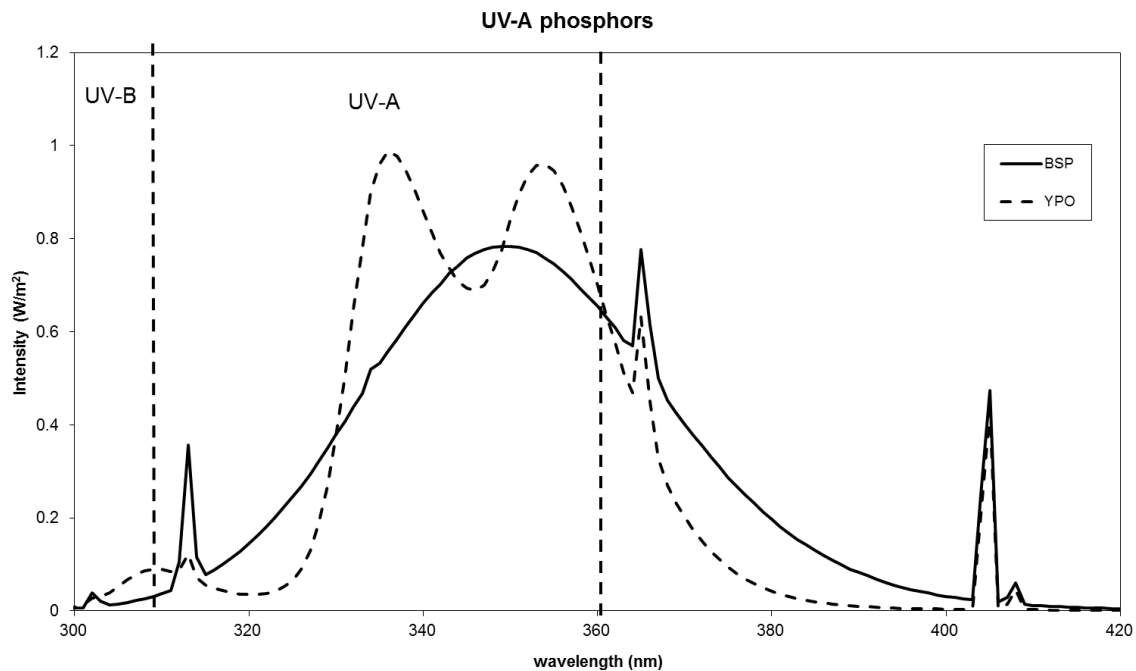
6.1 Substituting lead in the fluorescent powder of discharge lamps when used as PUVA phototherapy lamps

6.1.1 Spectrum incompatibility

The application for phototherapy equipment is strictly regulated in the EU. Any possible alternative to lead in BSP type of phosphor would need to fulfil following criteria:

- Lamp specification must be same w.r.t.
 - UVA and UVB output, and with that Erythema
 - Spectral power distribution
 - Compatibility (electrical/mechanical spec) must be OK
 - Reliability must be OK
 - Safety must be OK
- (Psoriasis) Clearance rate on phototherapy patients
- No (negative) side effects
- Economically feasible (cost of replacement technology)

Studies on alternative materials show that the only alternative material which comes close to these specifications is Cerium-doped YPO phosphor. Please see below spectrum of Ce doped YPO phosphor in comparison to BSP.



Graph: Emission spectrum of a Cerium-doped phosphor – UV lamp

Based on above measurement results, it can be concluded that:

1. The spectral power distribution shows differences in the UVA and UVB range.
2. The ratio for UVA and UVB output is different which is an important factor for effective phototherapy and is governed by EU regulations.
3. Therefore the Cerium based material has a lower expected treatment effectiveness, w.r.t. Erythema and NMSC (non-melanoma skin cancer).

The spectral incompatibility has resulted in a lack of interests by medical community. Therefore, no adequate tests and clinical studies have been set up on patients to prove the effectiveness from Ce doped YPO phosphor for PUVA phototherapy and no approbations for such equipment exist. Therefore, this Ce-based material is not allowed for this application.

6.1.2 UV output variations of Cerium phosphors in UV lamps

A second problem for the Ce doped phosphors is the variations of the UV output over the lamp length due to coating thickness. When fluorescent lamps are coated with a phosphor the thickness of the coating varies over the length of the lamp. For current UV-fluorescent coatings used, like BSP, the thickness variations do not lead to a severe inhomogeneous output. However, for Cerium doped phosphor this thickness difference leads to unacceptable UV output variations which will affect the skin treatment effectiveness (see table below).

	thin coated side		thick coated side	
	UVB		UVB	
1 P	594		325	
2 P	567		313	
3 P	614		322	
4 P	614		322	
5 P	604		350	
6 P	600		325	
7 P	595		301	
8 P	615		265	
9 P	599		283	
10 P	622		409	
AVG	602,4		321,5	
STDV	14,87	2%	36,96	11%
MAX	622,00		409,00	
MIN	567,00		265,00	
Range	55,00	9%	144,00	45%

Table: Thickness variations of Ce-doped coatings and the impact on UV output

6.2 Substituting fluorescent technology by mercury and lead free technology

In principle other technologies can be evaluated for replacing fluorescent technology for applications in PUVA phototherapy. One could think of e.g. LED, OLED, HID, and incandescent or halogen technology.

However, for any new technology one needs to address the replacement market (replacing lamps in existing fixtures) and the market for new equipment using the new technology.

The criteria to determine whether a new technology can replace existing fluorescent technology using BSP (and Hg) in existing equipment are:

- Lamp specification must be same w.r.t. spectral power distribution and UVA and UVB output
- Safety must be assured
- Compatibility must be assured (Electrical and mechanical specifications)
- Reliability must be assured
- Effective treatment results for phototherapy patients (e.g. clearance rates for psoriasis, effective chemotherapy, etc.)
- No (negative) side effects
- Economically feasible (cost of replacement technology)

For new equipment the similar criteria hold as above mentioned.

6.2.1 Feasibility of possible alternatives

In this paragraph we only discuss LED as an alternative radiation technology as Incandescent, halogen and OLED simply do not emit radiation in the UVA/UVB range.

LEDs in principle could be chosen as radiation technology for special purposes, provided the following criteria are fulfilled.

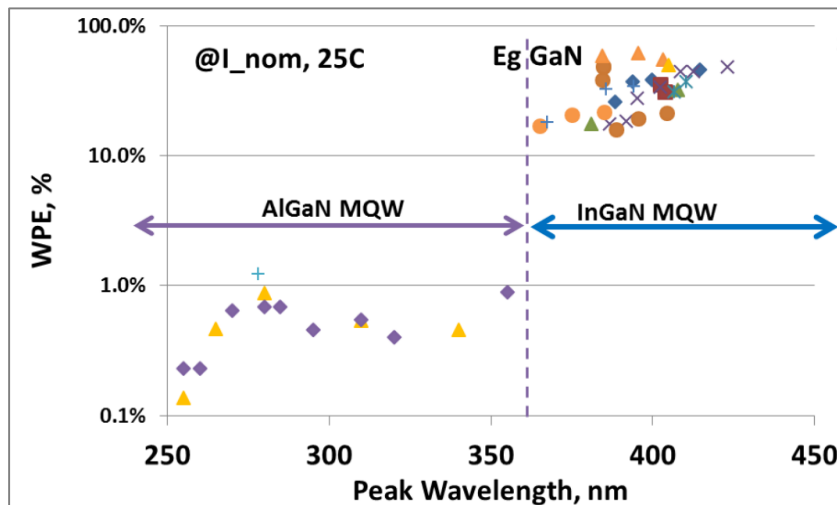
- Wall Plug Efficiency is comparable to fluorescent lamps
- Effectiveness is comparable to fluorescent lamps (i.e. same photo-therapeutic effect)
- Regulation/approbation is passed

In the following paragraphs each of these 3 criteria is discussed.

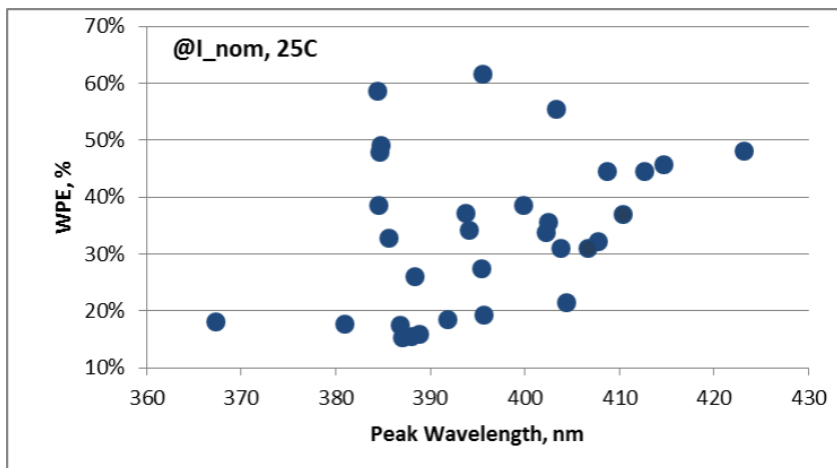
6.2.1.1 Wall Plug Efficiency

- a. In contrast to general lighting lamps, (compact) fluorescent lamps for special purposes emit radiation in UV or blue wavelength bands. LEDs for general lighting purposes are made of InGaN, a material that emits blue light which with the help of phosphors is converted into the desired visible wavelengths. Theory says you can only convert from shorter wavelengths to longer. It is therefore impossible to create UV light with LED material as used for visible light LEDs.
- b. There are other materials available from which LEDs can be made that generate UV light (like AlGaIn), however the efficiency (radiated power out / electrical power in) of LEDs with those materials is still very low. In the UVC (100-280nm) and UVB (280-315nm), the WPE (wall plug efficiency of LEDs are below 1%), where the wall plug efficiency of fluorescent lamps are close to 20% or even higher. See below pictures in which public data from several manufacturers are put together in one graph.

Graph: LEDs (UVC-Blue): WPE vs. wavelength (data of several manufacturers)



Graph: UVA-LEDs: WPE vs wavelength (data of several manufacturers)



Conclusion:

There is no comparable WPE for LEDs below 380 nm. Therefore, current LEDs are not suitable as a practical alternative for phototherapy.

6.2.1.2 Effectiveness data

For PUVA phototherapy applications no test results are available yet w.r.t. patient effectiveness to reach the desired effect in a comparison study between equipment using fluorescent lamps and equipment using LEDs.

For most of these applications that is not done yet as no promising LEDs were available. So effectiveness data are not available.

6.2.1.3 Regulation/approbation

CE conformity and other European directives for special purpose applications (like for instance approbation of medical devices for phototherapy and CE regulations on tanning lamps (CE 60335-2-27)) is based on fluorescent discharge lamps (with respect to safety and system responsibility). No CE conformity is available for other lamp technologies.

6.2.2 Availability of substitutes

UVA LEDs are available from several suppliers. However, as is clear from above efficiency is very low. No public roadmaps exist that predict when UVA LEDs with acceptable output and efficiency are available. Only after that design and development of LED based equipment can start and after that customer/patient tests could start.

6.2.3 Impacts of substitution

Apart from feasibility and availability also the potential impacts of substitution must be considered.

Amongst the impacts are:

- Environmental impact
- Health & Safety impact
- Socio-economic impacts
- Impact on innovation

In the following discussion each of these 3 criteria is discussed.

6.2.3.1 *Environmental impact of substitutes*

Though LED technology is developing at a rapid pace for general lighting, however there is today no viable LED alternative available for phototherapy applications. Therefore, this paragraph is not applicable.

6.2.3.2 *Health and safety impact of substitutes*

The UV fluorescent lamps in use today have undergone extensive testing and calibration in the equipment. Effect of Ce doped phosphor may have considerable impact on health and safety of customers if spread in output and spectrum is not in control. UV is known to be a risk factor in NMSC (non-melanoma skin cancer). Increasing spread in output of the equipment is not going to improve that.

For LED as alternative technology effects on health and safety will have to be investigated. It will be extremely costly to build up similar experience in case of PUVA therapy as with current BSP based PUVA fluorescent lamps.

6.2.3.3 *Socio-economic impact of substitution*

Economic effects related to substitution:

- ☒ Increase in direct production costs
- ☒ Increase in fixed costs
- ☒ Increase in overhead
- ☒ Possible social impacts within the EU
- ☒ Possible social impacts external to the EU
- ☒ Other:

It is expected that even if UVA LEDs become available with feasible specifications, PUVA phototherapy equipment becomes much more expensive. It will become therefore an economically unattractive solution and that will have significant impact on patients' lives.

The possibility for lead free technology for these lamps is not feasible for replacements lamps in existing equipment due to the scientific and clinical evaluations that would need to be done on every type of fixture or appliance that is in the field. This economic

burden this would impose on the small business owners such as tanning salons and dermatologists would cause the closing of many businesses. It can be imagined that new equipment could be changed to non-lead phosphors. However over 90%, and it is estimated that it may be as much as 99%, of the tanning and PUVA phototherapy phosphors are lead activated. There are no alternative non-lead activated phosphors available today that provide the same or equivalent spectral radiation.

There are no mercury free fluorescent technologies available to meet these spectral outputs. Also LEDs do not provide a good alternative as also these cannot be made with equivalent spectral output, nor with same output efficiency.

Social impacts

As there are no reliable substitutes if the renewal of the exemption is not allowed it would leave the patients in Europe that need PUVA phototherapy without suitable treatment.

It is estimated that almost 100% of these lamps used in Europe and even in the whole world are manufactured in Europe by fluorescent lamp companies. It is estimated that almost 80% of the phototherapy equipment sold in Europe is manufactured in Europe.

Other impact

Economic impact due to the loss of the entire PUVA Phototherapy application in Europe.

6.2.3.4 *Impact of substitution on innovation*

If UVA LEDs will become available in the future, new equipment will have to be developed and approbated for PUVA phototherapy.

6.2.4 Future trends of substitution

Given the market size in combination with strict regulations efforts to substitute BSP containing lamps are extremely limited.

Replacement of Lead by Cerium showed to be unsuccessful in earlier tests and no new insights have been created for other alternatives.

With respect to the current LED developments, some other UVA applications are already switching to LEDs but on medical applications the developments are limited. It is at this moment impossible to predict if and when UVA LED based equipment will become technically feasible. Additionally, patient tests and the approbation process would take a very long period. Therefore, we request an exemption for the maximum period.

6.3 Links to REACH, according to RoHS Directive Article 5(1)(a)

Do any of the following provisions apply to the application described?

no

- | | | |
|---|---|---------------------------------------|
| <input type="checkbox"/> Authorisation | <input type="checkbox"/> Restriction | <input type="checkbox"/> Registration |
| <input type="checkbox"/> SVHC | <input type="checkbox"/> Annex XIV | |
| <input type="checkbox"/> Candidate list | <input type="checkbox"/> Annex XVII | |
| <input type="checkbox"/> Proposal inclusion Annex XIV | <input type="checkbox"/> Registry of intentions | |

Provide REACH-relevant information received through the supply chain.

Not Applicable

7 Removal of lead from lamps

Can lead be eliminated?

☐ Yes.

☒ No.

It is not practical to remove the lead from these lamp types as the lead is required as an activator for the phosphors that produce the specific wavelengths of light necessary to provide the necessary spectrum and meet the clinical and regulated requirements imposed by the EU regulatory agencies.

8 Reduction of lead content of lamps

The less than 1% lead content of these lamps as a percentage of the weight of the homogenous phosphor material is needed to activate the phosphor. A reduction in the lead content would cause either a loss of output or not be sufficient to activate the phosphor. Subsequently, the lamp does not meet anymore the EU regulations.

9 Other relevant information

Medical equipment in Europe is subject to unscheduled auditing and measurement of the lamps and equipment which has been certified for use with lamps that are equivalent or the same as the lamps originally installed by the OEM. This equipment has undergone extensive testing to assure compliance with ultraviolet exposure schedules and the use of any other lamps than those substantially equivalents are restricted. It would be a significant financial burden if not impossible to the independent hospitals and dermatologists to try to retrofit their equipment and have each unit certified by the regulating bodies.

10 Information that should be regarded as proprietary

Above information is not proprietary.

If needed more detailed explanation and information can be given under confidentiality in separate discussions with the European Commission.