

1st Questionnaire Exemption No. 18b (renewal request)

Exemption for „Lead as activator in the fluorescent powder (1 % lead by weight or less) of discharge lamps when used as sun tanning lamps containing phosphors such as BSP (BaSi₂O₅:Pb)“

Abbreviations and Definitions

BSP	<i>BaSi₂O₅ :Pb</i> also known as silicic acid (H ₂ Si ₂ O ₅), barium salt (1:1), lead-doped
CE	Cerium
Pb	Lead
LEU	LightingEurope

Background

The Oeko-Institut and Fraunhofer IZM have been appointed within a framework contract¹ for the evaluation of applications for the renewal of exemptions currently listed in Annexes III of the new RoHS Directive 2011/65/EU (RoHS 2) by the European Commission.¹

LightingEurope (LEU) has submitted a request for the renewal of the above mentioned exemption, which has been subject to a first evaluation. The information you have referred has been reviewed and as a result we have identified that there is some information missing and have formulated a few questions to clarify some aspects concerning your request.

Questions

1. The application you have submitted states *“It is estimated that over 90% of indoor tanning 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 the tanning lamps using these phosphors.”*
 - a. Please detail what lamps are used in the remaining 10% of indoor tanning applications.

Answer: LightingEurope

In the Oeko questionnaire, question 5, Lighting Europe has prepared a calculation of the number of tanning lamps entering the EU annually. We have summarized in this confidential information the total market. The estimated number of non-BSP lamps

¹ Contract is implemented through Framework Contract No. ENV.C.2/FRA/2011/0020 led by Eunomia

is approximately one and a half percent (1.5%) of the total. These non-BSP lamps emit only a narrow bandwidth of the UVA spectrum and no-UVB and do not produce the required action spectrum required for tanning response. As evidenced by the market size there is limited use of such lamps and when used is always in conjunction with BSP phosphor lamps to generate the total UVA and UVB spectrums needed to initiate a tanning response.

- b. Do such lamps contain RoHS substances and if so how do the amount thereof compare with the amounts of RoHS substances contained in BSP based lamps?

Answer: LightingEurope

The only other RoHS substance in the lamps is mercury. The mercury content remains similar or the same as the BSP lamps and are subject to the same RoHS regulations.

- c. Assuming that the RoHS substance amounts of these alternatives are comparable or lower than their BSP containing counterparts, why are these type of lamps insufficient for use for a wider range of tanning applications?

Answer: LightingEurope

UV intensity at the wavelength of 350nm is crucial in order to get skin pigmentation (tanning result). The UV output of the lamps with narrow band UVA phosphor is negligible at that important wavelength so it is insufficient for use for a wider range of tanning applications.

2. In Section 4.1.3 of your application you state that categories 8 and 9 are N/A (non-applicable), however further down it is stated that the exemption will be applied in “*other medical devices or other monitoring and control instruments than those in industry*”. The evaluation team is aware of another exemption in Annex IV for special medical applications. Likewise LEU have requested an exemption for lead in lamps using BSP used for a wider range of medical applications. It is thus assumed that all medical applications of such lamps (i.e. applications that fall under Cat. 8 on the basis of the RoHS definitions for medical devices) are to be covered in exemptions to fall under Annex IV (assuming the requested exemption is granted).

- a. Please explain this inconsistency in your request, particularly on the basis of current Annex IV exemption and of your request for an additional Annex IV exemption.

Answer: LightingEurope

The indication of our check mark in Section 4.3 that the requested exemption would be applied in “*other medical devices or other monitoring and control instruments than those in industry*” was an error and oversight in our review of the application. Lighting Europe was intending at one point to include medical lamps in this request but was then advised that we should do so as a new exemption request. We are not requesting any exemption for the use of lead activated phosphor tanning lamps for such medical devices in this application. We have submitted a request for a new exemption for medical lamps using lead activated phosphors under Annex IV and can be found on OKO website: <http://rohs.exemptions.oeko.info/index.php?id=223>.

- b. Please clarify the differences between BSP lamps used for tanning purposes relevant for this exemption request and BSP lamps used for medical applications covered by the Annex IV exemption and your Annex IV requested exemption. Please refer for example to the wattage differences and the dimension differences providing detailed data to allow making a distinction between lamps relevant for each of the applications.

Answer: LightingEurope

As above noted we are withdrawing the inadvertent request for use of tanning lamps in other medical devices or other monitoring and control instruments than those in industry. However, technically there is no difference between BSP phosphors used for medical purposes and BSP phosphors used for tanning purposes. Both lamp categories may have the same diameter and same wattage range in principle. Medical lamps may also be used in smaller lengths, diameters and wattages for partial body or spot treatment. The phosphor types may use the same components with a very similar or different blend to produce a specific UV output. In medical applications these would be called PUVA lamps and produce broad band UVA output. These lamps would be marked accordingly. The differences are in the field of application, in marking of the lamps and in the way to market.

- c. Please clarify if there are uses of such lamps that fall under Cat. 9, to support your above statement and why they would be relevant for this request.

Answer: LightingEurope

Tanning lamps requested under this exemption by Lighting Europe members are not designed, intended, or marketed for category 9 equipment.

3. On page 8 the following statement is included: *“LightingEurope believes that lamps covered by exemption 4f might not belong to category 5 equipment only if it is specifically designed as part or component of only one specific other category and there is no intended possibility to use it in others. Examples for the latter case are specific lamps for medical equipment, which have a certain special function in such equipment only, e.g. lamps for vitreoretinal surgical systems.”* Please clarify the reference to Ex. 4f and to the *vitreoretinal surgical systems* in the context of the request to renew Ex. 18b, which only concerns use of BSP lamps in tanning devices.

Answer: LightingEurope

The comment in Section 4.1.3 is a general comment regarding the use of lamps and therefore applied in “lighting equipment” (category 5) which in a broad sense would include tanning equipment and the lamps used therein to produce artificial sunlight. Lighting Europe used this same entire comment in the application for exemption renewal of 4(f) and the reference in this application of 4(f) should have been changed to 18(b). We apologize for the confusion and the references you questioned. We can however say that the sizes and wattages of certain tanning lamps can be the same as PUVA type of medical lamps for which Lighting Europe has submitted a separate application for the use of BSP phosphors in those medical lamps. The manufacturers of tanning lamps do not market tanning lamps for use in medical equipment and therefore do not request any exemption for the use of tanning lamps in medical equipment. The reference in the renewal application of

“vitreoretinal surgical systems” was intended to give an example of a specific lamp type that could only be used in a specific piece of medical equipment.

It is explained that “Lead is used in the phosphor for UV radiation in tanning lamps. The lead activator is required to allow the barium silicate phosphor to fluoresce.” Please explain what the unique properties are of lead and of the phosphor used that are relevant for generating the relevant spectrum? What is the scientific reason for the relation between these two substances that has not yet been found in other combinations tested of phosphors and activating substances? If relevant, please refer to the atomic/molecular structure and nature of the activator/phosphor.

Answer: LightingEurope

Besides BaSi₂O₅:Pb, below lead doped phosphors are known as UV emitting phosphor.

SrBaMgSi₂O₇:Pb 370nm

BaZn₂Si₂O₇:Pb 303nm

BaMg₂Si₂O₇:Pb 290nm

All above phosphors are doped with lead, but the emission wavelength depends on the chemical composition of base substance. To get an efficient emission at 350nm which is effective for sun tanning purpose, only BaSi₂O₅ can be used as for base substance. On the other hand, only lead (Pb) and Europium can be a doper for Barium Silicate Phosphor, but Barium Silicate emits 520nm when it's activated by Europium. So the only selection to get 350nm is BaSi₂O₅:Pb.

4. Can you provide a calculation to clarify how you have reached the estimation that 250 kg of Pb are placed on the market per annum through this application?

Answer: LightingEurope

This information is submitted confidentially by the members of Lighting Europe solely for the use of Oeko. According to the market estimates of the Lighting Europe member companies, the number of fluorescent tanning lamps entering the EU market is approximately 4 million units per year. The typical phosphor usage for T12 lamps is 6g/lamp. Taking into account that approximately 98.5% of the lamps made with BSP and the BSP contains maximum 1% lead it leads us to the sum of 240kg.

5. It is mentioned that “*The potential substitution or replacement... would require revalidation of all existing equipment in the EU market... would require a duplication of the clinical testing which has been compiled over years of study and regulation.*”

- a. Please provide a roadmap for substitution to clarify what stages would need to be performed once a candidate was found suitable before an alternative product could be placed on the market.

Answer: LightingEurope

As we had indicated in the summary of the exemption request “The lamps, and equipment they are installed in, are governed by EU regulations concerning the allowable output of ultraviolet radiation permitted within a determined exposure time. The EU regulates and enforces tanning equipment and the installed lamps which are marked on the lamps by a specific “X, Y” code system for the erythemally-weighted UV radiation in accordance with EN standard 61228 Ed.2 (2008-01). The lamps are installed in various commercial- and residential indoor tanning equipment. This can be in the form of a sun tanning bed or booth or a table top appliance for facial tanning. The abovementioned EN standard forms the basis of lamp marking, and is required. It clearly limits room for substitution by lead-free phosphors. The regulatory demands come from the LVD ADCO group, see below reference.

Ref. website: http://ec.europa.eu/enterprise/electr_equipment/lv/guides/index.htm

Declaration of the LVD ADCO Group

At the 18th meeting of the LVD Administrative Co-operation working group (ADCO) in Brussels on the 14th November 2006 the following was unanimously agreed by the Member States present:

- The Scientific Committee on Consumer Products (SCCP) Opinion on: Biological effects of ultraviolet radiation relevant to health with particular reference to sun beds for cosmetic purposes represents the basis for good engineering practice in Europe in relation to the safety matters for such products.

- The recommendations shall be applied with effect six months from the publication of this Declaration.
- The maximum erythemal-weighted irradiance should not exceed 11 SED/h (0.3 W/m²). Published on 22 January 2007” Any substitution of lamps would require the lamps meet the X/Y codes established by the EN standard and as discussed in the application there are no known lead-free phosphor types which can satisfy the requirements. Alternate products that can satisfy this requirement are not known at this time to the members of Lighting Europe.

- b. For each stage please estimate the time needed for its completion and possible overlaps with other stages (e.g., what stages can be performed in parallel).

Answer: LightingEurope

In this exemption renewal request we are of the opinion that there is no feasible non-lead activated phosphor available. Alternate technology such as LED, which we have indicated is not available, would require new equipment designs by the manufacturer which would have to be supported by evidence of meeting the EU standards cited above.

6. On page 14 lamp specifications that need to be fulfilled by substitutes are detailed. Please provide explanatory information and/or quantified information for each of the named parameters/aspects so that it is clear what needs to be fulfilled by candidate substitutes.

For example:

- a. Please provide a performance indicator with the relevant threshold for aspects such as UVA and UVB output, and Erythema or for spectral power distribution, so that it is clear above or below what threshold performance is required.

Answer: LightingEurope

The requirements are provided in the EN standard 61228 that the maximum erythemal-weighted irradiance should not exceed 11 SED/h (0.3 W/m²).

- b. Please explain what is meant by Erythema?

Answer: LightingEurope

Erythema means (from the Greek *erythros*, meaning red) is redness of the skin caused by different impacts, for instance ultraviolet radiation.

- c. Please provide a summary of what is meant with terms such as “X/Y coding system” for tanning lamps according to EN 60335-2-27, to allow stakeholders a quick understanding of the various aspects.

Answer: LightingEurope

Each tanning device in Europe has an original equipped lamp (OEM lamp). The OEMs have validated and tested the equipment with such lamp. This lamp’s X/Y code labelled on the device and all the replacement lamps have to be equivalent in X/Y code with the original OEM lamp. This is what we meant X/Y coding system. Part 22.111 in the standard.

- d. Please explain what is meant with “No (negative) side effects”, when a quick look at the websites of manufactures clarifies that tanning lamps can have negative side effects in some cases².

Answer: LightingEurope

The comment was made in answer to the question of substituting fluorescent technology by lead free technology. The use of an alternate lead free phosphor, if possible, or an alternate technology, if possible, that produced the same spectral output as the lead phosphor lamps currently manufactured may present the same risks and therefore the same cautions used for the lead activated phosphor tanning lamps would need to be taken. Any additional risks or concerns that an alternate product would impose would need to be weighed and dealt with accordingly.

- 7. Please provide a figure and explanations clarifying the acceptable spectral variations of candidate substitutes in comparison with the BSP spectrum and in comparison with the Ce doped YPO phosphor to give context to the “Graph: Emission spectrum of a Cerium-doped phosphor – UV lamp” and to clarify the performance requirement related to spectral compatibility.

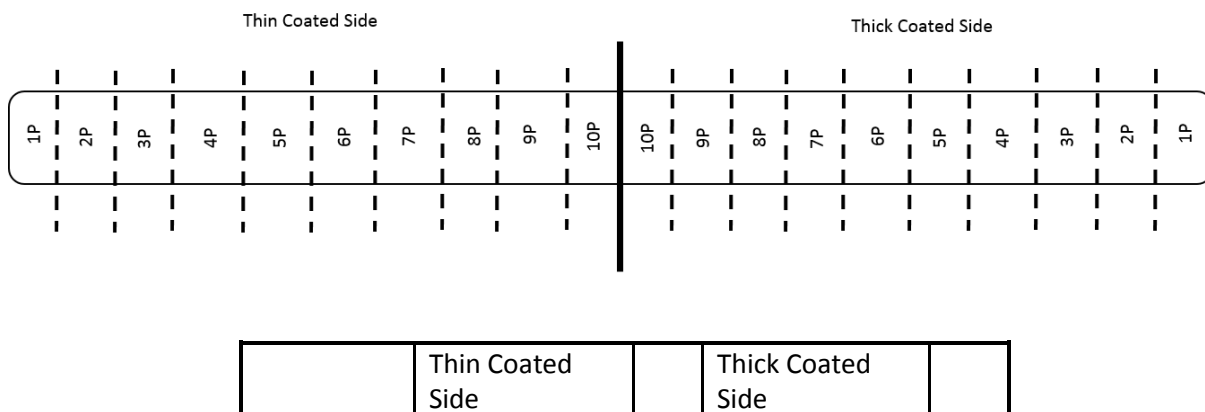
Answer: LightingEurope

The substitute candidate should have exactly the same spectral distribution curve and power effectiveness like BSP phosphor because this is the only way to avoid of clinically re-test all the tanning devices on the EU market.

- 8. Please provide explanatory information for “Table: Thickness variations of Ce-doped coatings and the impact on UV output”, and complete units and titles where these are missing.

Answer: LightingEurope

The coating process technology does not allow consistent application of the Ce doped phosphors from top to bottom or one end of the lamp to the other end. Please note the difference in coating weights can be as much as 50% variation which is unacceptable as it would cause an uneven distribution of the spectral output. The above chart shows measurement results of 10 separate cut sections of a lamp coated with Ce doped phosphor.



² For example see FAQ page of Light-Tech Light Sources under: <http://www.light-sources.com/?q=tanning/education/faqs:> Relevant Questions: Is tanning safe?; if i never can get a tan outside because i burn can i get a tan indoors?; do i have to wear eye protection when tanning indoors?; etc.

Piece of glass (each 9cm)	UVB (uW/cm ²)		UVB (uW/cm ²)	
1	594		325	
2	567		313	
3	614		322	
4	614		322	
5	604		350	
6	600		325	
7	595		301	
8	615		265	
9	599		283	
10	622		409	
AVG	602.4		321.5	
STDV	15.67	2%	38.96	11%
MAX	622		409	
MIN	567		265	
RANGE	55.00	9%	144.00	45%

9. It is mentioned that in theory substitutes could be developed in the future on the basis of new technologies such as LED, OLED, HID. Though explanations are provided to show why this is currently not practical, it is possible that future developments could allow this in the coming years. Please provide a roadmap to clarify what stages would be needed once an alternative technology is found that provides sufficient spectral output and other relevant performance requirements, before alternatives could come onto the market, eliminating the need for BSP lamps. Please estimate for each stage how much time would be required for its completion and explain if certain stages could be performed in parallel. E.g., please detail duration of needed testing and certification, time needed for developing and approving new standards etc.

Answer: LightingEurope

As Lighting Europe members are not manufacturing LED, OLED tanning lamps, it would not be appropriate and we are not capable to provide roadmap for UV LED developments.

We've monitored the market and found that the present UV LED technology can't substitute BSP LFL tanning lamps.

It is understood that BSP has been added to the candidate list of SVHC. Furthermore registrations exist for this substance. Please provide REACH-relevant information in this respect.

Answer: LightingEurope

The substance falls under REACH since the phosphor content per lamp content is (in some cases?) above the 0.1% weight by weight basis. The BSP is described in REACH as: Substance Name: Silicic acid (H₂Si₂O₅), barium salt (1:1), lead-doped [Silicic acid, barium salt, lead-doped] EC Number: 272-271-5 CAS number: 68784-75-8.

Please note that answers to these questions are to be published as part of the available information relevant for the stakeholder consultation to be carried out as part of the evaluation of this request. If your answers contain confidential information, please provide a version that can be made public along with a confidential version, in which proprietary information is clearly marked.