1st Questionnaire Exemption Request No. 2015-3

Exemption for „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 (BaSi2O5 :Pb)“

Answers of LightingEurope - March 2015

Abbreviations and Definitions

Pb Lead

BSP (BaSi2O5: Pb)

Background

The Oeko-Institut has been appointed within a framework contract[1] for the evaluation of an application for granting an exemption to be included in or deleted from Annexes III and IV of the new RoHS Directive 2011/65/EU (RoHS 2) by the European Commission.[1]

LightingEurope has submitted the above mentioned request for 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 a few questions to clarify concerning your request.

Questions

1. It is understood from the application, that an exemption is requested for medical devices (Category 8): "*The phototherapy lamps included in this request were intentionally omitted at that time as they were exempt as medical devices*." Article 3 of the RoHS directive provides the following definitions for medical devices falling under Category 8 and Sub-Category 8 In-vitro:
   "*(21) 'medical device' means a medical device within the meaning of point (a) of Article 1(2) of Directive 93/42/EEC and which is also EEE;*
   (22) 'in vitro diagnostic medical device' means an in vitro diagnostic medical device within the meaning of point (b) of Article 1(2) of Directive 98/79/EC;"
   Please confirm if all uses of BSP (BaSi2O5 :Pb) phosphor lamps, for which the exemption is requested, fall under Category 8, as well as if any of these fall under Sub-Category 8 In-vitro.

   LE: Yes it falls under category 8 (21) but not under sub category 8 (22)

2. As explained in question 1, it is understood that all applications for which an exemption has been requested are medical devices. However, in chapter 4.1.3, where the Annex I

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

categories for which this exemption is requested are listed, Category 9 has also been specified.

a. Are these lamps also used in Category 9 EEE (monitoring and control instruments)?
b. If yes, please provide information to justify an exemption for such uses, as the current application is said to only describe lamps used in Cat. 8 medical devices.

LE: LightingEurope does not have enough information on applications under Category 9, using the same kind of BSP phosphors, as these applications are covered by companies which are not members of LightingEurope.

3. In the application, it is stated "*However, based on the 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*". This estimation is based on the market share of tanning lamps, also mentioned in other parts of the application: E.g., "*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…*" An exemption for BSP (BaSi2O5 :Pb) phosphor lamps used in tanning applications is currently listed in Annex III of the Directive (Ex. 18(b). It is thus understood that the use of such lamps for tanning applications would not be considered a Category 8 application.
   a. Please explain the relation between tanning lamps and UV discharge lamps used in Cat. 8 medical devices?
   b. Please confirm that this request for exemption does not cover the tanning lamp applications in the scope of Ex. 18(b)2. If this is not the case, please explain on what basis such applications are understood to be in Cat. 8.

   LE: The tanning lamps and the medical lamps use similar lead activated BSP type phosphors, with small differences in the spectrum (a small amount of other phosphors) but clearly different in lamp wattage meaning different lengths of the tube and designed for instance with a different glass type.

   LE: The equipment for phototherapy is designed and approved and certified for specifically designed lamps with a dedicated spectrum (based on BSP type phosphors) and it is not allowed to use other lamp types / phosphors in this equipment. A lamp designed and labelled for sun tanning use shall not be used for medical use. Vice versa, a lamp designed and labelled for medical use shall not be used for sun tanning. We confirm that this exemption is only meant for phototherapy and does not cover sun tanning applications. For tanning lamp applications, LightingEurope has applied in parallel for a renewal of exemption 18b. Although we might have requested for a scope widening of the 18b exemption (to clarify the use of BSP for phototherapy- and sun tanning applications), however we opted for applying for a new exemption for phototherapy applications under Annex IV.

4. It is stated that "there is no published data available for the quantity of phototherapy lamps entering the EU".

[2] RoHS Annex III Ex. 18(b): "*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 (BaSi 2 O 5 :Pb)*"

a. As it is understood that tanning lamps are not relevant to this request, please explain how data concerning the EU market share of tanning lamps can be used to estimate the market share of similar lamps used for other purposes.
b. Under what assumptions has the 2.5 kg of lead estimation been made?
c. Please clarify how this amount (2,5 kg of lead) was calculated.

LE: Indeed tanning lamps are not part of this exemption and the reference to "tanning lamps" is actually a typo in the text under 4.2.4 and should be "phototherapy lamps". See below a new proposed text change yellow highlighted and the old wording strikethrough:

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

LE: As there is no published data available and LightingEurope does not collect data on a systematic and regular manner for this small subcategory of phototherapy specialty lamps. We applied the method of expert estimations of the total amount of the sold lamps in the market by LightingEurope members. The amount of 2.5 kg is based on the estimated available market estimations. The market size for the phototherapy application is relatively stable.

Since the views on the size of the market from the different companies are company confidential we can only share these estimations confidentially.

5. In chapter 5.1 Waste Streams, it is mentioned that "*lamps are collected from general household waste and separately from other WEEE waste*"
   a. How are lamps for which this exemption is requested collected and recycled? Would they be separated from medical waste streams?
   b. Why is household waste mentioned? Are the medical applications relevant for this request used only at medical facilities or also by private consumers in their households?

LE: The lamps are mainly installed and replaced by professional installers and should not end up in medical waste streams. The installers are instructed to recycle the spent lamps under WEEE directives.
The lamps are collected outside (separately) from general household waste stream. This is lamp is not used in general households and therefore will not end up in the household stream. The lamps should be recycled as normal low pressure fluorescent lamps and labelled accordingly for recycling

Chapter 6.1.1 Spectrum Incompatibility states that, *"Therefore the Cerium based material has a lower expected treatment effectiveness, w.r.t. Erythema and NMSC (non-melanoma skin cancer)."*

a) Please confirm if clinical studies were performed concerning the use of Ce doped YPO phosphor in applications for treating "*Erythema and NMSC (non-melanoma skin cancer)"*?
b) If not, on what basis can it be assumed that the treatment effectiveness would be too low? Please explain what research results support this conclusion.

LE answers:

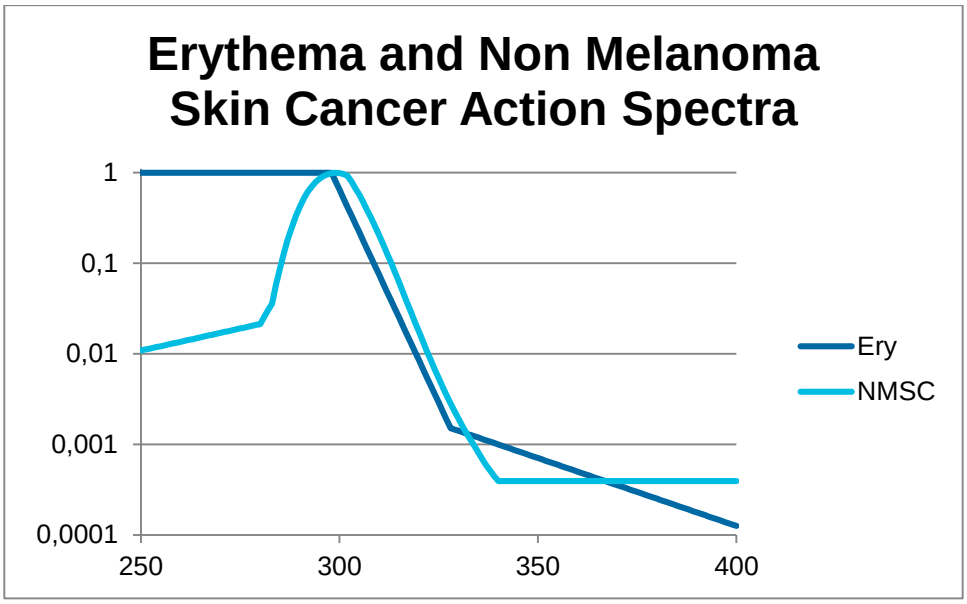
1. **In the question under a) it looks as if Phototherapy lamps are used for treating erythema and NMSC. However that is not the case. Erythema and possibly NMSC are side effects of Phototherapy. Treating skin diseases (like psoriasis) with phototherapy will lead to unwanted erythema (skin reddening) and a risk of creating NMSC (non-melanoma skin cancer).**
2. **No clinical studies were performed concerning the use of Ce doped YPO-phosphor in phototherapy applications, because of the risk mentioned under next point 3.**
3. **Based on a theoretical comparison, it can be concluded that Ce doped YPO phosphor will lead to more (unwanted) effects of NMSC for the same erythema dose, which is a measure for the therapeutic effect. For this reason no clinical trials have been started because it is known beforehand that the patients would run the risk on non-melanoma skin cancer.**
   The erythema sensitivity curve and the NMSC sensitivity curve are known from clinical studies[3],[4] and standardized and given below[5],[6]. Multiplying the spectra as given in 6.1.1 with the erythema and NMSC sensitivity gives the conclusion that NMSC dose is higher for Ce doped YPO than for BSP, for the same erythema which is a measure for the therapeutic effect (IEC TC61).

[3] A.F. McKinlay and B.L. Diffey, A reference spectrum action spectrum for ultraviolet induced erythema in human skin, CIE Journal, 6(1), 17-22 (1987)

[4] F.R. de Gruijl and J.C. van der Leun, Estimate of the wavelength dependency of ultraviolet carcinogenesis in humans and its relevance to the risk assessment of a stratospheric ozone depletion, Health Physics, 67(4), 319-325, 1994.

[5] ISO 17166:1999 Erythema reference action spectrum and standard erythema dose

[6] ISO 28077:2006 (CIE S019/E:2006) Photocarcinogenesis action spectrum (non-melanoma skin cancers)



6. Chapter 6.2 regards *"Substituting fluorescent technology by mercury and lead free technology".* Is their currently any research into substitution technologies which are free from both mercury and lead?
   a) Please clarify what is meant.
   b) Do you know of research and development initiatives of such lamps, which are free of mercury and lead and would suit some or all of the applications for which this exemption is requested? Can potential candidates be named?

   LE: We presumed that we already explained your question in chapter 6.2.1 of the exemption request.
   As is clarified in Chapter 6.2 (6.2.1) the only substitution technology (for mercury- and lead-containing discharge lamps) that might one day be possible is UVA LED technology. In chapter 6.2.1 the status of this technology is described. There is no research going on for mercury-free discharge lamps as the unique combination between the use of mercury in the discharge and the use of Lead in the phosphor is essential to create the required spectrum. The need of mercury in efficient fluorescent lamps is explained and covered in many exemption requests, such as exemptions for special purpose: 2b4, 1f or 18b (see section 4.2.2: function of mercury in lamps).

   Should this information not be sufficient, we prefer to have a telephone call to clarify above topics in more detail.

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.