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NARVA Lichtquellen GmbH + Co. KG

Industriegebiet Nord | Erzstraße 22 | D-09618 Brand-Erbisdorf | Germany

Exemption Request Form

Date of submission: 2020-01-13

1. Name and contact details

1) Name and contact details of applicant:

Company:	NARVA Lichtquellen GmbH + Co. KG	Tel.:	0049 37322 170
Name:	Dr. Olaf Hansen	E-Mail:	Dr.Olaf.Hansen@narva-bel.de
Function:	CEO	Address:	Erzstraße 22 09618 Brand – Erbisdorf Germany

2) Name and contact details of responsible person for this application (if different from above):

Company:	NARVA Lichtquellen GmbH + Co. KG	Tel.:	0049 37322 17263
Name:	Caroline Seidel	E-Mail:	c.seidel@narva-bel.de
Function:	Product Management	Address:	Erzstraße 22 09618 Brand - Erbisdorf Germany

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2. Reason for application:

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Please indicate where relevant:

- ☐ Request for new exemption in:
- ☐ Request for amendment of existing exemption in:
- ☒ Request for extension of existing exemption in:
- ☐ Request for deletion of existing exemption in:
- ☐ Provision of information referring to an existing specific exemption in:
  - ☒ Annex III ☐ Annex IV

No. of exemption in Annex III or IV where applicable: 18.b and 18b. I

Proposed or existing wording: existing

Duration where applicable: maximum validity period required

- ☐ Other: _____

3. Summary of the exemption request / revocation request

The exemption in directive 2011/65/EU expires on 21.07.2021 for annex III 18b. and 18b.I.

Narva Lichtquellen GmbH + Co.KG submits this application to:

request for extension of existing exemption no. 18b. and 18b.I

Narva Lichtquellen GmbH + Co.KG proposes to continue using the existing wording which is:

18b. 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).

18b(I) Lead as activator in the fluorescent powder (1 % lead by weight or less) of discharge lamps containing phosphors such as BSP (BaSi2O5:Pb) when used in medical phototherapy equipment

Narva Lichtquellen GmbH + Co.KG requests a duration of:

Maximum validity period required

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4. Technical description of the exemption request / revocation request

(A) Description of the concerned application:

1. To which EEE is the exemption request/information relevant?

Name of applications or products: Fluorescent lamps for sun tanning and medical application

a. List of relevant categories: (mark more than one where applicable)

☐ 1	☐ 7
☐ 2	☒ 8
☐ 3	☐ 9
☐ 4	☐ 10
☒ 5	☐ 11
☐ 6	

b. Please specify if application is in use in other categories to which the exemption request does not refer: _____

c. Please specify for equipment of category 8 and 9:

The requested exemption will be applied in

☐ monitoring and control instruments in industry

☐ in-vitro diagnostics

☒ other medical devices or other monitoring and control instruments than those in industry

2. Which of the six substances is in use in the application/product?

(Indicate more than one where applicable)

☒ Pb ☐ Cd ☐ Hg ☐ Cr-VI ☐ PBB ☐ PBDE

3. Function of the substance:

Lead activator in the fluorescent powder is required to allow the barium silicate phosphor to emit UV radiation. It transforms the 254 nm radiation to the designed UV (290 nm-400 nm) radiation and it is used in over 95 % of the indoor low pressure fluorescent lamps in tanning and certain medical applications. It emits mainly UVA radiation around the peak wavelength of 350 nm that is crucial in order to initiate immediate skin pigmentation.

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4. Content of substance in homogeneous material (%weight):
   lead in the fluorescent powder: 1 % lead by weight or less

5. Amount of substance entering the EU market annually through application for which the exemption is requested:
   There are no published data available for the amount of tanning lamps for the EU market.

6. Name of material/component: barium disilicate, doped with lead, abbreviation: BSP, formula: BaSi2O5:Pb

7. Environmental Assessment: unknown
   LCA: ☐ Yes
   ☐ No

(B) In which material and/or component is the RoHS-regulated substance used, for which you request the exemption or its revocation? What is the function of this material or component?

The lead is used as activator in the BSP phosphor.

(C) What are the particular characteristics and functions of the RoHS-regulated substance that require its use in this material or component?

The lead activator is required to allow the barium disilicate phosphor to emit UV radiation. It transforms the 254 nm radiation to the designed UV (290 nm-400 nm) radiation and it is used in over 95 % of the indoor low pressure fluorescent lamps in tanning and certain medical applications. It emits mainly UVA radiation around the peak wavelength of 350 nm that is crucial in order to initiate immediate skin pigmentation (see (EU) 2019/177).

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5. Information on possible preparation for reuse or recycling of waste from EEE and on provisions for appropriate treatment of waste

1) Please indicate if a closed loop system exists for EEE waste and provide information of its characteristics (method of collection to ensure closed loop, method of treatment, etc.)

In Germany exists a closed loop system for fluorescent lamps - LIGHTCYCLE.

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2) Please indicate where relevant:

☒ 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

3) Please provide information concerning the amount (weight) of RoHS substance present in EEE waste accumulates per annum:

☐ In articles which are refurbished	_____
☒ In articles which are recycled	detailed information by LIGHTCYCLE
☐ In articles which are sent for energy return	_____
☐ In articles which are landfilled	_____

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6. Analysis of possible alternative substances

(A) Please provide information if possible alternative applications or alternatives for use of RoHS substances in application exist. Please elaborate analysis on a life-cycle basis, including where available information about independent research, peer-review studies development activities undertaken

Tanning equipment is strictly regulated in the European Union and any possible alternative to the lead doped UVA phosphor BSP would have to fulfil criteria on reliability, safety and health risk concerns. Currently, there are no such alternatives available (see (EU) 2019/177).

(B) Please provide information and data to establish reliability of possible substitutes of application and of RoHS materials in application

See 6. (A)

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7. Proposed actions to develop possible substitutes

(A) Please provide information if actions have been taken to develop further possible alternatives for the application or alternatives for RoHS substances in the application.

none

(B) Please elaborate what stages are necessary for establishment of possible substitute and respective timeframe needed for completion of such stages.

The development of lamp phosphors is very mature and it is very unlikely that a new phosphor with an emission spectrum and radiation intensity identical to BSP will be found. The chances of success are extremely low as so many combinations of materials have already been prepared and evaluated. Research could be carried out but it is likely to be at least three years, the length of a PhD research project, before any alternatives are available for clinical trials.

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Basic science and non-clinical studies	**2 years**
Preliminary clinical trial	4 years
Evaluation of results	6 months
Larger clinical trial	5 years
Evaluation of results	6 months
Medical Device Directive approval	1 year
Drug approval /can be concurrent with device approval	(1 year)
Total without development of a new type of phosphor	13 years

Once approval is granted, patients are monitored for a further 5 years (post treatment follow up) to ensure that the change to the treatment is safe and effective. If any evidence is found that it is not safe, the approval can be withdrawn.

Source:
Assistance to the Commission on Technological Socio-Economic and Cost-Benefit Assessment Related to Exemptions from the Substance Restrictions in Electrical and Electronic Equipment (RoHS Directive), Final Report, Report for the European Commission DG Environment under Framework Con-tract No ENV.C.2/FRA/2011/0020

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8. Justification according to Article 5 (1) (a):

(A) Links to REACH: (substance + substitute)

1) Do any of the following provisions apply to the application described under (A) and (C)?

☐ Authorisation

- ☒ SVHC
- ☒ Candidate list
- ☐ Proposal inclusion Annex XIV
- ☐ Annex XIV

☐ Restriction

- ☐ Annex XVII
- ☐ Registry of intentions

☐ Registration

2) Provide REACH-relevant information received through the supply chain.
Name of document:

Total lead content in LP- 67xx.pdf

(B) Elimination/substitution:

1. Can the substance named under 4. (A) 1 be eliminated?

☐ Yes. Consequences? _____

☒ No. Justification: Lead is the only activator for the BSP phosphor to achieve the required UVA spectrum with peak wavelength at 350 nm and the needed radiation intensity. Only this phosphor is able to provide the desired effects and to meet the clinical and regulated requirements imposed by the EU regulatory.

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2. Can the substance named under 4. (A) 1 be substituted?

☐ Yes.

☐ Design changes:
☐ Other materials:
☐ Other substance:

☒ No.

Justification: Currently there is no alternative phosphor with same wavelength range and radiation properties available. A complete new UV irradiation system does not exist in the foreseeable future.

3. Give details on the reliability of substitutes (technical data + information): unknown
4. Describe environmental assessment of substance from 4. (A) 1 and possible substitutes with regard to

   No substitute is known for a comparison

   1) Environmental impacts: /
   2) Health impacts: /
   3) Consumer safety impacts: /

⇨ Do impacts of substitution outweigh benefits thereof?
Please provide third-party verified assessment on this: _____

(C) Availability of substitutes:

Substitutes are not available.

a) Describe supply sources for substitutes: _____
b) Have you encountered problems with the availability? Describe: _____
c) Do you consider the price of the substitute to be a problem for the availability?
   ☐ Yes ☐ No
d) What conditions need to be fulfilled to ensure the availability? _____

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(D) Socio-economic impact of substitution:

Substitutes are not available.

⇨ What kind of economic effects do you consider 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: _____

⇨ Provide sufficient evidence (third-party verified) to support your statement: _____

9. Other relevant information

Please provide additional relevant information to further establish the necessity of your request:

_____

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10. Information that should be regarded as proprietary

Please state clearly whether any of the above information should be regarded to as proprietary information. If so, please provide verifiable justification:

_____
