Exemption Request Form

Date of submission: 17-11-2014

1. Name and contact details

1) Name and contact details of applicant:

Company: FEI Company
Name: Casper Kruijer
Function: RoHS Program Manager
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2) Name and contact details of responsible person for this application (if different from above):

Company:
Name:
Function:
Tel.:
E-Mail:
Address:

2. Reason for application:

Please indicate where relevant:

- Request for new exemption in: **Annex IV**
- 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:
- Proposed or existing wording: The suggested title of this requested exemption is; “Lead in High Voltage Cables and Cable Assemblies for a rated voltage higher than 250kV DC and to be used in Electron Microscopy applications, containing up to 4% lead by weight”.
- This includes the maximum 7 years expiry period.
- Duration where applicable: Minimum 7 years
- Other: High Voltage cables don’t fall under definition “cables” according article 3(5) Although rated higher than 250V these cables are used as interconnect cables between electronic modules of single EEE instead of connecting two or more EEE.

3. Summary of the exemption request / revocation request

Allow the use of lead to a maximum of 4% by weight in High Voltage Cables and Cable Assemblies for a rated voltage higher than 250kV DC and to be used in Electron Microscopy applications.

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: TEM Electron Microscopes are considered to be in Category 9 of RoHS2 and therefore these products need to be RoHS compliant by 22nd July 2017. In TEM Electron Microscopes there are several products that need a 300 kV High Voltage to operate and to generate the needed energy for the electron beam. The High voltage module generates this voltage and this needs to be transferred to the TEM column. For this transfer a High Voltage cable is needed. There are very few suppliers who can make >250KVcables and up till now we have not found any supplier who can supply this cable being RoHS compliant (for voltages up till 250kV RoHS compliant cables are available).

Typical use-case of >250KV cables are in Power-plants, outside scope RoHS..

The current cable used consists of a compound of lead and oxygen (Pb3O4) and this compound is used to improve the thermal stability of the insulation material and therefore the lifetime of this cable. For FEI application the Pb3O4 might be not required but we don't know that for sure, what we understand that the primary reason for lead oxide is heat conduction since the original purpose of this cable is electric power transport and it can handle 3x15 Amp at 300 kV, while for our purpose we need the 300kV (very stable) at pico-amperes of current so heat dissipation can be ignored. However it could very well turn out that because of the lead oxide also the reliability and stable voltage is enabled, tests with alternatives have to confirm this.

Due to the need for high precision and stability, all electron microscope parts need to be very reliable and robust and as a result have very long useful lifetimes.
Usage by TEM electron Microscopes is a small percentage of total WW market hence drive commitment to develop >250KV cables requires a relative large investment on Cat9 products, whilst environmental impact will be relative small. Furthermore finding alternatives for FEI might be more difficult since power plant requirements, the main customers of these cables are much different from Electron Microscopy requirements.

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

1	7	
2	8	
3	9	**YES**
4	10	
5	11	
6		

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

c. Please specify for equipment of category 8 and 9:
The requested exemption will be applied in

- monitoring and control instruments in industry YES
- 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

3. Function of the substance:
Lead – compound of lead and oxygen (Pb3O4) and this compound is used to improve the thermal stability of the insulation material of this cable and therefore the lifetime of the cable. Proven lifetime of cables is close to technical life time of electron microscopes. A new to develop >250KV RoHS compliant cable the reliability is uncertain hence environmental impact is uncertain with respect to of use energy in production thereof

4. Content of substance in homogeneous material (% weight): ~2 % Lead compound in the polymer-insulation compound (exact percentage is unknown, since the recipe of the insulation is a company secret but can be described as follows:
Main parts: polymer (EPR), inorganic filler (china clay)

5. Amount of substance entering the EU market annually through application for

which the exemption is requested:
The estimates are for FEI's products only. The quantity of lead that will be present in high voltage cables is estimated to be about 30kg Pb per year.

Please supply information and calculations to support stated figure.

6. Name of material/component: Lead – compound of lead and oxygen (Pb_3O_4) in polymer insulation material of cable

7. Environmental Assessment:
LCA: Yes
No – N/A

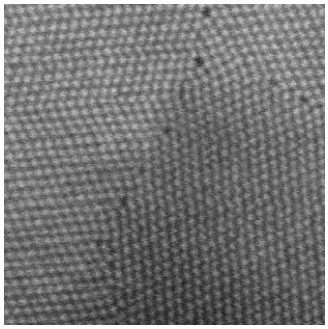
(B) In which material and/or component is the RoHS-regulated substance used, for which you request the exemption or its revocation? What is the function of this material or component?

Transmission electron microscopes (TEM) are instruments that are used for research and development and for investigating defects and failures. They are used to obtain images of items and materials which can have good depth of field, three-dimensional and can be very high magnification. They are also capable of obtaining chemical composition information and TEM can also provide crystal structure information of materials.

The 300kV TEM equipment is considered to be the most advanced configuration of our TEM family and this equipment gives the highest image resolution commercially available. As example the TEAM project can be mentioned, in which FEI contributed.

Picture 1: TEM equipment

Objects are most commonly examined by visible light as the human eye is sensitive to these wavelengths range. There are however two limitations of visible light which are the maximum magnification and the depth of field at high magnification. Objects and features that have a size that is similar to and smaller than the wavelength of light are invisible and so cannot be seen with visible light microscopes. As magnification increases, focusing becomes more critical and so the images are clear only within a very small distance range (the depth of field) and they appear to be two dimensional. Magnification of 1000 times is about the maximum that is achievable with visible light microscopes, which is good enough to see human blood cells of ~ 1 micron diameter, whereas imaging of micro-organisms such as viruses and bacteria and features on modern integrated circuits, etc. need much higher magnification. These limitations are overcome by replacing visible light by a beam of electrons which have extremely short wavelengths and so much higher magnification is possible. Features as small as one tenth of a nanometre, which is the size of individual atoms, can be seen with TEM.



Picture 2: TEM image of an atom structure

Very thin specimens are needed for TEM as the electron beam needs to pass through the sample before being focussed onto the detector. TEM can be used to view real images from the beam that passes through the specimen or diffraction patterns from crystals in the sample, which give composition information.
Modern TEM's are very complex instruments consisting of many complex precision engineered parts as well as the control electronics. Complex electrical circuits are used to generate and control the high energy electron beam, to accurately control the position of the specimen mounted on a "stage" and the electronic optics that control and focus the electron beam. The 300kV TEM equipment is considered to be the most advanced configuration of our TEM family and this equipment gives the highest image resolution commercially available. Usually, the interior must have a high vacuum as air scatters and blocks the electron beam. The image can be created electronically using the characteristics properties of the detected electrons or X-rays, such as their energy and intensity. Standard images are black and white and represent the intensity from each location on the surface of the object but false colour images can be created using special software which is based on the energy or wavelength of the detected electrons or X-rays.
The use of 300KV is to give the electron beam enough energy to penetrate the sample and generate enough information from this sample. A lower energy than 300KV is in the most advanced application technical not possible.

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

300 kV high voltage cables are used as interconnect cables between EEE modules in TEM to transfer the high voltage from the tank that generates the voltage to the field emitter gun in the column. Typically the distance between tank and column is 5 meters. The high voltage must be very stable since fluctuation in voltage will result in image fluctuations and poor image quality. To achieve ppm high voltage stability, the cable needs very specific characteristics which only few suppliers can achieve. The currently used cable has these characteristics and one of the features to achieve this is a special compound used in the cable core. Exact details on material characteristics are not available to FEI, since the supplier sees this as 'trade secret', we do however know that there is ~2 % Lead compound in the rubber-insulation (exact percentage is unknown, since the recipe of the insulation is a company secret) can be described as follows:

Main parts:

- polymer (EPR)
- inorganic filler (china clay)

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 exist for EEE waste of application exists and provide information of its characteristics (method of collection to ensure closed loop, method of treatment, etc.)

A closed loop return system already exists and is in operation for FEI's electron microscopes and their component parts. The electron microscopes are highly complex instruments that must be repaired and maintained by highly trained and qualified engineers who are approved by FEI. When an electron microscope is repaired and a part needs to be replaced, the engineer will return the used parts to FEI and will use refurbished parts from FEI to replace the parts that they remove. In this way, FEI can ensure that their parts are under their control from manufacture to end of life in a closed loop. They are able manage the entire product cycle so that uncontrolled use or disposal of FEI's parts will not occur. FEI take-back used parts from customers world-wide, then repair and refurbish if necessary or alternatively organise environmentally safe disposal by professional recyclers if the parts cannot be reused.

As FEI's electron microscopes are very complex, maintenance and repairs by unqualified personnel is highly unlikely and so FEI are able to ensure that there is a closed loop system for a very high percentage of parts of their products.
Current cables >250KV are reliable parts and proven lifetime is close to technical lifetime of TEM Electron Microscopes.

2) Please indicate where relevant:

- Article is collected and sent without dismantling for recycling
- Article is collected and completely refurbished for reuse YES
- Article is collected and dismantled:
  - The following parts are refurbished for use as spare parts: YES
  - 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. - 30kg of lead per year from high voltage cables.
- In articles which are recycled
- In articles which are sent for energy return
- In articles which are landfilled

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

Currently FEI is working in close cooperation of cable supplier to find an >250KV RoHS compliant cable, until now unsuccessful. Developing a >250KV RoHS compliant cable would require an economical unbalanced investment relative low impact on worldwide usage of lead free >250KV cables.
Major impact is in the uncertain reliability often to be proven after years of usage. Impact in event of reliability issues is of a larger scale as lead-time of finding alternative gets harder investment will increase.

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

Substitute parts must be equally reliable to those currently in use. As the reliability of current cables is close to lifetime of EM microscope (often >15yrs) reliability of alternative cannot be guaranteed to be equal, even if an alternative could be found.

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.
Lead: Current actions involve High Voltage cable re-design at the Supplier and using RoHS compliant substitute materials. This redesign is a Supplier activity since FEI is not a cable supplier and therefore we are completely dependent on the Supplier's expertise in this matter. The 'normal' users for these types of cables are Power facilities that generate energy for Industry and House hold. These types of cables are used to transport electrical energy over large distances underground. In the eyes of the Supplier, FEI is seen as a small Customer that uses this cable and therefore we have little 'bargain power' to convince the Supplier of

developing a RoHS compliant derivative of the current used cable. Therefor it's foreseeable that the investment costs of a new cable will be taken by FEI.

(B) Please elaborate what stages are necessary for establishment of possible substitute and respective timeframe needed for completion of such stages.
To be RoHS compliant FEI needs to receive validated and reliable cables by early 2016 (duration of building TEM microscope is up to 6 quarter)
Reliability testing needs minimal 5 years to have in a degree equal proven reliability.
Stages for substitution are (timeline is a rough indication):

1) 300kV Cable development — early 2016
2) Design end connectors to this new cable — mid 2016
3) Test performance on High Voltage stability — end 2016
4) Test long term stability and reliability of the cable assembly — end 2017/mid 2022

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 — No
- SVHC — No
- Candidate list — No
- Proposal inclusion Annex XIV — No
- Annex XIV — No
- Restriction — No
- Annex XVII — No
- Registry of intentions — No
- Registration — Not applicable

2) Provide REACH-relevant information received through the supply chain.

(B) Elimination/substitution:

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

- Yes. Consequences?
- No. Justification: -

No, please see answers to previous questions

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

Yes.

- Design changes:
- Other materials:
- Other substance:

No.

Justification: No please see answers to previous questions

3. Give details on the reliability of substitutes (technical data + information):
No, please see answers to previous questions

4. Describe environmental assessment of substance from 4.(A)1 and possible substitutes with regard to

1) Environmental impacts: YES, explained below:

2) Health impacts:
3) Consumer safety impacts:

- Do impacts of substitution outweigh benefits thereof? Yes,

The cable Supplier indicated that there will be potential substitute filler materials which are RoHS compliant. Since the FEI application for this cable is very sensitive for small variations in performance (conductivity, inductivity, capacitance, etc) we need to test the new filler material thoroughly on reliability and this will take a long time. Furthermore FEI is only sourcing a very small amount of this cable on yearly basis, so the changes needed for RoHS compliancy have low priority at the supplier, who needs to setup a new production line.
If this new production line is not finished in time, the FEI tests will not be completed before the RoHS implementation date for Category 9 products (Electron Microscopes) which is 22nd July 2017. This would mean we cannot put High End TEM Electron Microscopes on the European market and this will hinder or block advanced Research at our Customers which are typically Universities and Research Center in the EU.

(C) Availability of substitutes:

a) Describe supply sources for substitutes: this is a Supplier expertise
b) Have you encountered problems with the availability? Describe: Likely a substitute is available but equal reliability is very uncertain.
c) Do you consider the price of the substitute to be a problem for the availability? Yes the investment needs to be amortized on the substitute
d) What conditions need to be fulfilled to ensure the availability? The performance of the substitute filler material in the cable must be equivalent to the current cable and especially degradation over a longer time is seen as a big risk. The reliability cannot be guaranteed what could have a big impact on progress of advanced Research at Universities and Research Centres in EU.

(D) Socio-economic impact of substitution: Without this exemption, it will for EU Research not be possible to make the same progress as Research Centres in the rest of the world. This is because EU users of electron microscope will not be able to use the High End Electron Microscope equipment after mid 2017 while Research Centres in non-EU Countries can use this kind of equipment. Since the 300kV TEM is the most advanced Electron Microscope commercially available, this will have a tremendous impact for Advanced Research in EU

- 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, loss of Advanced Research in EU, loss of PhD jobs, loss of University- and Research Departments in EU, loss of jobs in EU for Electron Microscopy developers and manufacturers
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:
None

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: Calculations have been taken out of this document so no proprietary- and / or confidential business information anymore in this document.