Exemption Request Form

Date of submission: 17. January, 2020

1. Name and contact details

1) Name and contact details of applicant:

Company:	JBCE - Japan Business Council in Europe aisbl	Tel.:	02.286.5330
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This exemption application is submitted with the endorsement of the business associations listed below:

Japan Analytical Instruments Manufacturers' Association (JAIMA)	Japan Electric Measuring Instruments Manufacturers' Association (JEMIMA)

2. Reason for application:

Please indicate where relevant:

☐ Request for new exemption in:

☐ Request for amendment of existing exemption in

☒ Request for extension of existing exemption in Annex IV

☐ 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: 1a of Annex IV

Proposed or existing wording:

Lead in pH glass electrodes and ion selective electrodes equipped with a pH glass electrode

Duration where applicable: Maximum validity period (7 years)

☐ Other: _____

3. Summary of the exemption request / revocation request

The current exemption is for both lead and cadmium in ion selective electrodes and pH glass electrodes, however JBCE requests renewal only for lead as it has no knowledge of electrodes that contain cadmium.

pH meters are used by a wide variety of purposes including use in laboratories, process control, quality control, workplace safety, environment (pollution) analysis.

Over the last 14 years, pH electrode manufacturers have carried out research into lead-free glass pH electrodes and this work has been successful for many designs. However where complex or unusual shapes of electrode are required, lead-free glass causes cracks during the manufacturing process that result in premature failure. Therefore, this exemption is needed for these designs.

pH electrodes are also used as components inside electrodes for analysis of substances, such as ammonia and this exemption is also needed for these electrodes.

Lead-free pH glass electrodes are available on the market. However, lead in glass of pH glass electrode is required in order to create intermediate layer for the connection between stem tube and pH-responsive glass or pH glass membrane. Some complicated shapes explained in this document cannot be formed without lead and currently there is no alternative technology that allow glass to be substituted.

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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: Lead in pH glass electrodes and ion selective electrodes equipped with a pH glass electrode

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

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

b. Please specify if application is in use in other categories to which the exemption request does not refer: Category 8

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 in pH glass electrodes and ion selective electrodes equipped with a pH glass electrode. Lead is required in order to form intermediate layer for the connection between stem tube and pH-responsive glass or pH glass membrane for complex shapes.

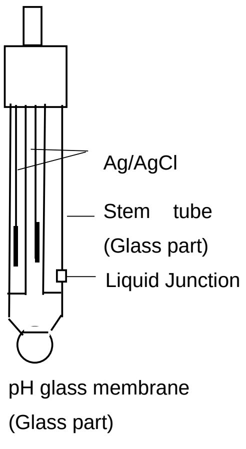
4. Content of substance in homogeneous material (%weight): The average is 10.4 % weight approximately, and the maximum is 29 %weight approximately.

5. Amount of substance entering the EU market annually through application for which the exemption is requested: JBCE does not have access to all EU data. pH glass electrodes and ion selective electrodes are made by many manufacturers and are used in a wide range of final products and markets, it is therefore impossible to provide a precise figure of the amount of lead included in glass of all pH electrodes supplied in the EU. However due to the developments of lead-free alternatives for some designs of electrodes it would be reasonable to expect that the annual quantity of lead used is reduced from the previous exemption request even if the exact amount cannot be calculated. The amount entering the EU market annually from manufacturers of JBCE members has been calculated to be approximately 14 g.

   Please supply information and calculations to support stated figure.

   The calculation method is based on confidential information which shall be provided separately.

6. Name of material/component: Lead in pH glass electrodes and ion selective electrodes equipped with a pH glass electrode



7. Environmental Assessment: _____

   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 RoHS regulated substance used is lead (Pb) in pH glass electrodes and ion selective electrodes equipped with a pH glass electrode. The description below illustrates the function of pH glass electrode and ion selective electrode:

<**Final product and measurement principle**>

The generic name of the product is: pH glass electrode.

As for the principle of pH measurement, the interphase potential theory and the diffusion potential theory are dominant, but it is considered that the interphase potential is generated. The principle is that the silanol groups formed in the hydrated layer on the pH-responsive glass surface respond to hydrogen ions, and the potential generated across pH-responsive glass affected by the hydrogen ion concentration[1] is measured with a potentiometer.

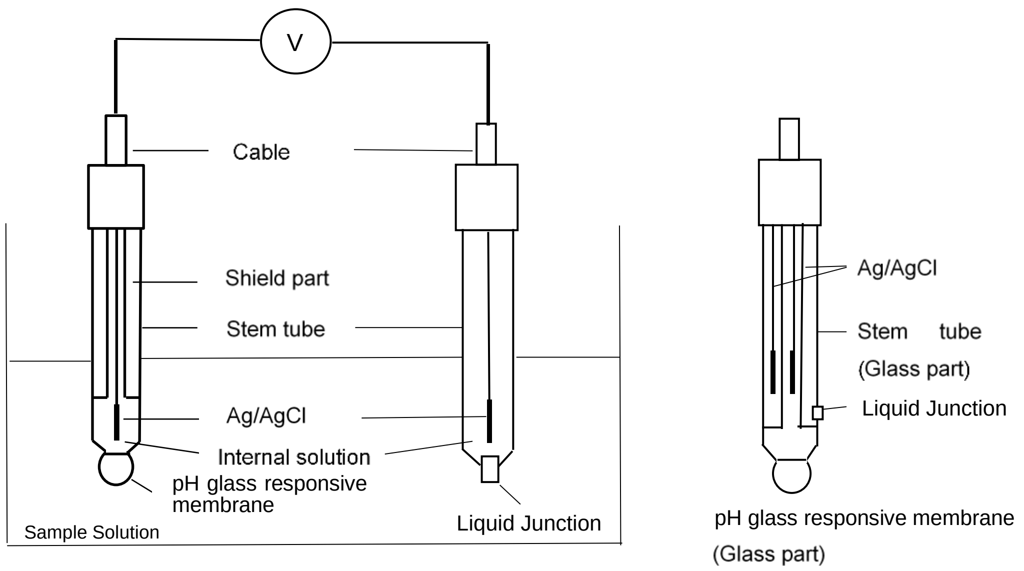


Figure.1 Configuration example of a pH electrode

In Figure. 1, diagrams of pH measurement with pH glass electrode and a reference electrode, as well as a structure of pH glass combination electrode (pH electrode combined with a reference electrode) are shown. .

[1] To be precise, the measured electrode potential is proportional to the "activity" of the hydrogen ions, which is similar to the concentration.

The structure of an ion selective electrode equipped with a pH glass electrode is shown in Figure. 2.

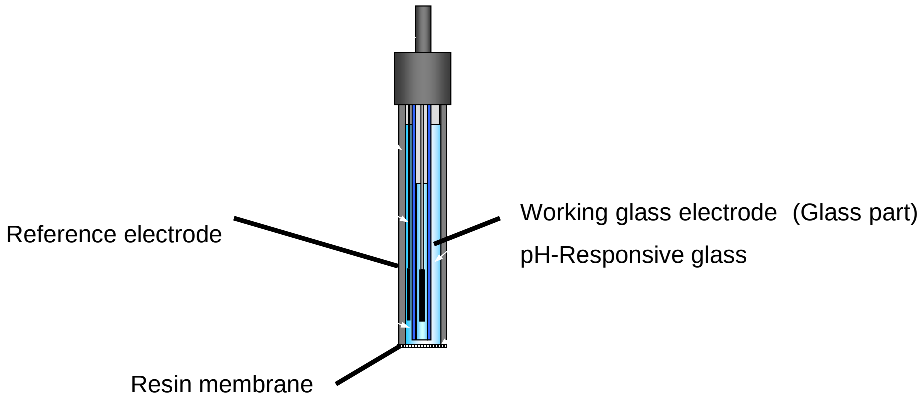


Figure 2 Configuration example of ion-selective electrode equipped with a pH glass electrode

Diaphragm type ion selective electrode (ammonia electrode) contains a pH glass electrode and a reference electrode. In this case, ammonia gas migrate through the membrane, and is changed to ammonium ions in an alkaline internal solution. Ammonium ions are measured by the change in pH and converted into ammonia concentration.

<Applications of pH meters>

Analytical and measuring instruments are designed to analyse and measure qualitative and quantitative aspects of the compositions, properties, structures, and states of substances. Qualitative and quantitative information of substances is the basis of today’s science and technology, and its applications are expanding the categories (fields) including living environments, global environments, medical and health care, space exploration and the others.

The pH meter is one of the most widely used instruments with a wide variety of purposes. The applications listed below are categorized and are not exhaustive:

- Use in laboratories of universities, companies, research institutes, educational institutions, and quality control in manufacturing industries;
- Process control in the industrial facilities: use and control for production and manufacturing lines;
- Quality control; control of pH in food, drinking water and sewerage;
- Use for workplace control and safety for safety check before work; and
- Use for environment (pollution) analysis. [2]

< Why lead is needed for pH glass electrodes and ion selective electrodes equipped with a pH glass electrode>

In pH glass electrode, there are pH responsive glass and stem tube glass, which are joined as shown in Figure. 1. The pH responsive glass is a glass that selectively responds to hydrogen ions and has a special composition containing about 30 mol% of an alkali metal such as Lithium. This glass generally has a linear thermal expansion coefficient of 100×10^{-7} / degree or more due to its high alkalinity. The glass is joined by heat with a stem glass tube which is a different kind of glass with electrically insulating character. Typical thermal expansion coefficient of the stem glass tube is 94×10^{-7} / degree.

At the joint of the two different glasses with different thermal expansion coefficients, it is easy for cracks to occur shortly after manufacturing due to temperature change or static fatigue. To prevent the cracks, after stem tube glass and pH-responsive glass are joined by heat, air pressure is manipulated to expand and contract the pH responsive glass several times so that an intermediate layer is formed between the two different types of glasses. When there is enough intermediate layer formed, no cracks occur and the electrode is able to be manufactured without failure.

However, it is difficult to form an intermediate layer in the case of electrodes that have complicated shape, for example flat responsive glass type, microelectrode type, or needle tip type. The complicated shape of these electrodes allow unique functionality which would not be able to be achieved without this shape, which is discussed further below. Since the shape of responsive glass of these electrodes are complicated, it is necessary to join the responsive glass membrane and stem glass tube in very short time, otherwise the shape of the glasses are deformed

[2] Japanese Analytical Instruments Manufacturers' Association (JAIMA), *分析機器の手引き*, 2016 p.3 Excerpted,revised and translated by JBCE https://www.jaima.or.jp/resource/jp/tebiki/pdf/tebiki2016.pdf#page=1

due to the heat. Due to the limited time to form an intermediate layer between the response glass membrane and the stem glass tube cracks can easily occur.

On the other hand, in case lead containing glass is used as stem glass tube, no cracks occur even if there is a limited processing time to allow for an intermediate layer to be formed. The reason is that lead is an element which has a low chemical potential, and so rapidly diffuses into different types of glass at the time of bonding to form an intermediate layer even in a short time. This is the reason why lead is needed for electrodes with complicated shapes.

The accessory pH electrode is always required for analysis and measurement. Among pH glass electrodes, flat type electrode is indispensable for some measurements such as for paper production, and ammonia electrode (this contains a flat pH electrode inside the ammonia electrode) is indispensable for air volume control in a microbial treatment tank for domestic wastewater. Needle type electrode is indispensable for the management of meat, rice, etc., and microelectrode type is indispensable for cell culture and measurement of pharmaceutical microtubes. If the pH electrode cannot be used in the above-mentioned places of use quality and safety of the products cannot not ensured, it is impossible to predict the negative impacts that may come into social life in the long and short term but they would be wide reaching and varied due to the large number of uses the electrode are deployed in.

Flat type electrode

Flat type electrode is used for measuring the pH of a thin film such as paper, and is measured by penetrating a small amount of water into paper (Figure. 3). Measurement is performed by bringing a film into contact with the surface of a flat object. Ammonia electrode has a flat pH responsive glass electrode inside. The flat membrane is joined to stem glass tube. The place where cracks are likely to occur is the joint between the responsive glass and the stem tube. The reason of the cracks is that the upper part of the joint portion of the stem tube is on the thread during manufacture and heat cannot be applied to the stem tube with a burner. The responsive glass and the stem tube have different thermal coefficient of expansion

(TCE) values and so cracks are likely to occur, unless lead glass is used as the stem glass tube.

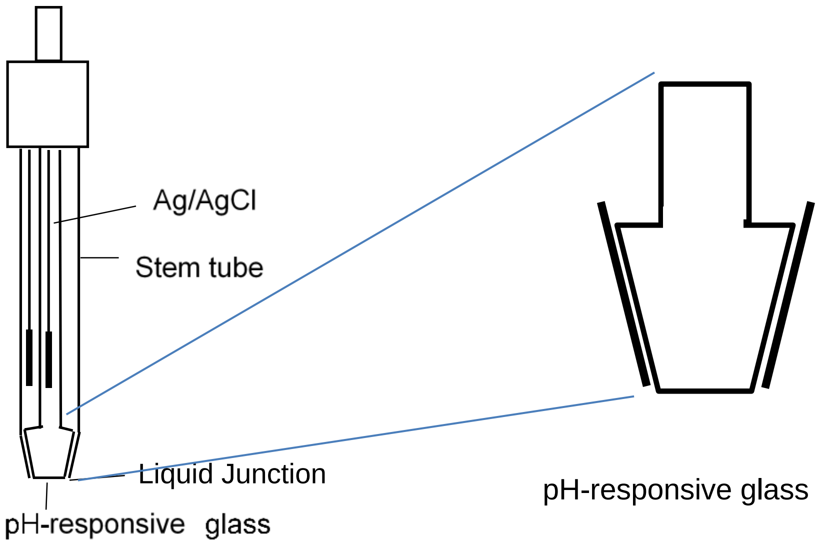


Figure. 3 Flat type example configuration

Microelectrode type

In case of microelectrode type (Figure. 4)., since the pH responsive glass membrane is small, it is necessary to make the glass composition rich in lithium oxide in order to reduce the responsive glass resistance to 300 MΩ or less, which is necessary for the electrode to function correctly as well as being a measurement method standard of the Japan Measurement Act. A large amount of lithium oxide inevitably increases the linear thermal expansion coefficient. Since the linear thermal expansion coefficient difference with the stem tube glass is large, cracks are likely to occur. Lead is what eases the stress between the two glass types.

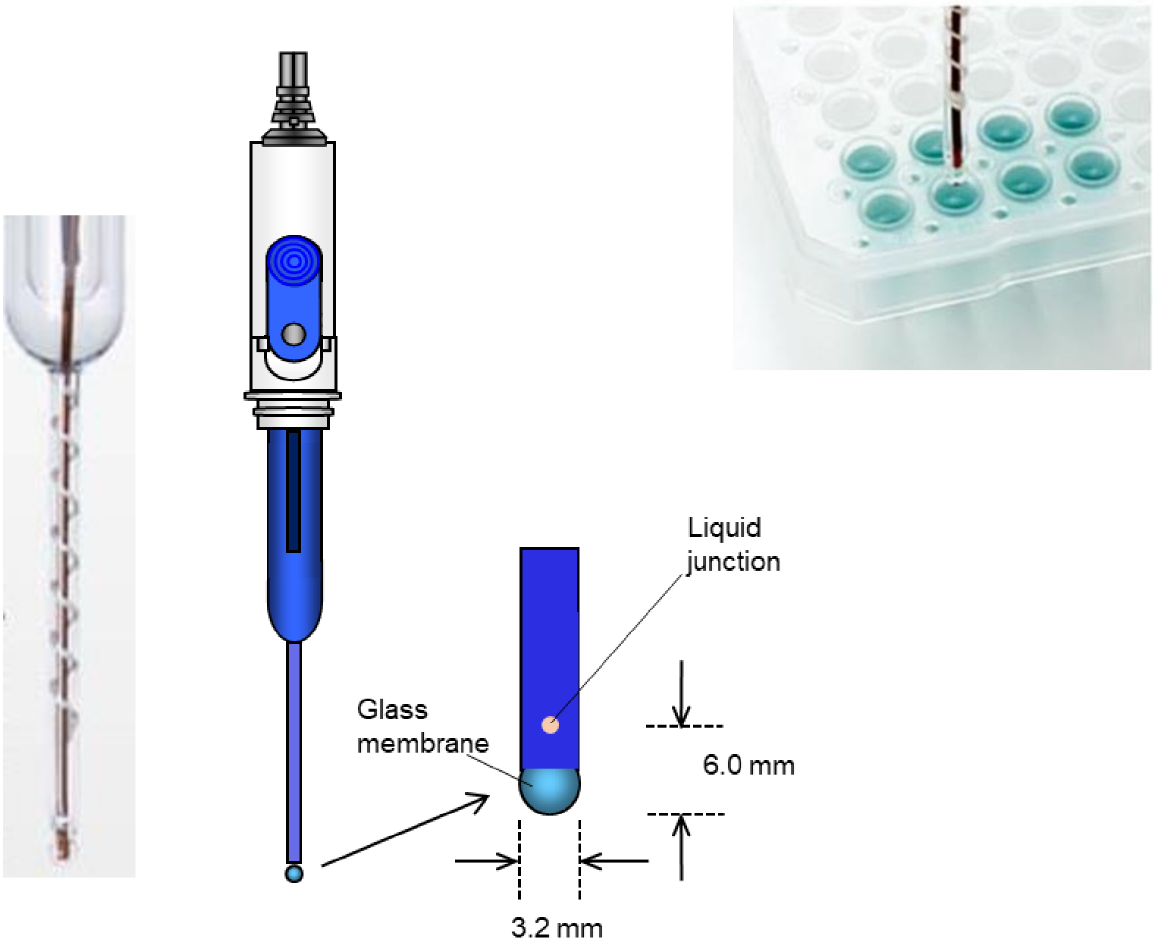


Figure. 4 Microelectrode type example configuration

Needle type

In case of needle type, the stem tube is rotated with a lathe, the responsive glass is melted with a burner and placed on the stem tube. The shape is processed into the needle shape while gradually stretching the molten glass (Figure. 5) and therefore is unable to be heated further to join the glasses and form an intermediate layer without the use of lead. The place where the crack is likely to occur is the joint between the responsive glass and the stem tube, unless lead glass is used. This electrode has a sharp tip, to allow pH measurement by inserting it into a soft solid such as cheese or yogurt.

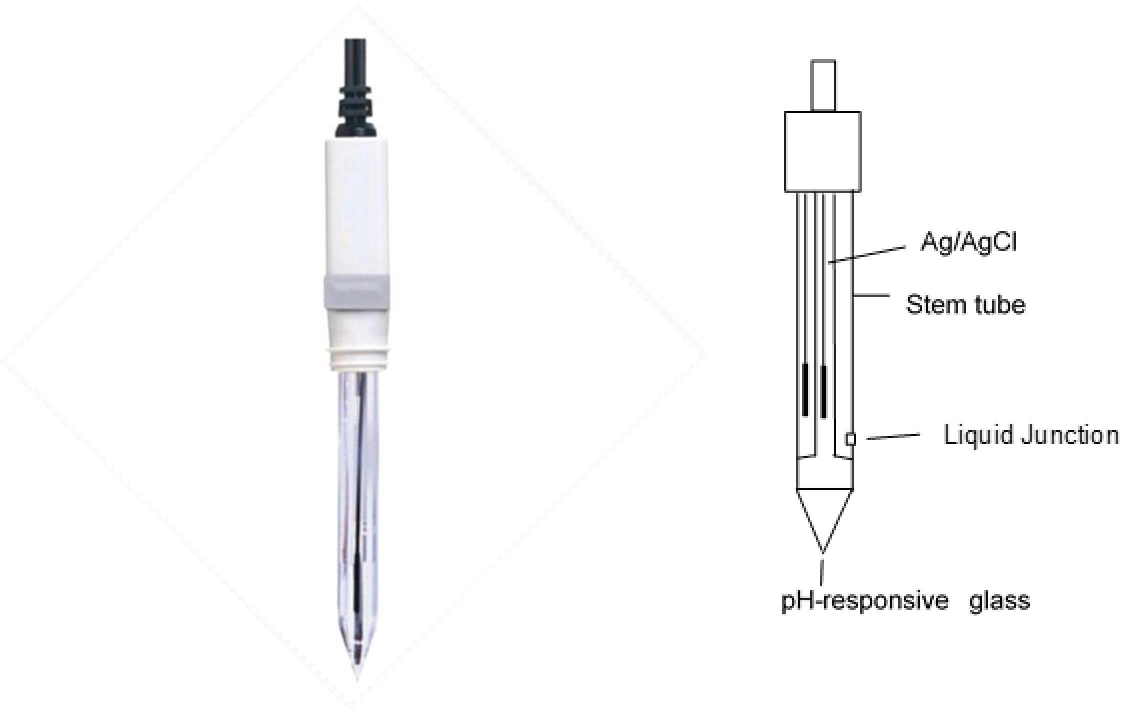


Figure. 5 Needle type example configuration

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

<Characteristics and physical properties of lead glass and lead-free glass>

Lead glass has been used for stem tube glass of pH glass electrode. One of the reasons is that the thermal expansion coefficient of lead glass is close to that of pH responsive glass. Generally, it is said that the difference of the coefficient should be within 10% for joining different kinds of glass firmly. Table 1 shows the thermal properties of typical lead glass and lead free glass. Since the thermal expansion coefficient of our pH responsive glass is 95 to 110 × 10^{-7} / K, bonding with lead glass is possible without any problem. Lead free glasses seem to have no problem because of their similar thermal expansion coefficients, however, they have different thermal characteristics other than expansion coefficient. For example, the softening point is higher at 665 and 720 ^{o}C, whereas lead glass is 625 ^{o}C, which differs by 40 ^{o}C or more. This difference means that the rate of shrinkage is different in the cooling process, so that higher strain stress is generated and cracks between different glasses are more easily occurred. This is the reason why lead-free glass is difficult to use for stem glass.

Table 1 Comparison of thermal properties of lead glass and lead-free glass[3]

Glass Type	Stem GLASS		
Characteristic	L-29(NEG) *1 Lead Glass	PS-94(NEG) *2 Lead free glass	Schott AR GLASS *3 Lead free glass
Thermal expansion coefficient at 30-380℃ (×10^{-7}/K)	94	94.5	91.0
Density ×10^3kg/m3	3.05	2.57	2.50
Strain point ℃	395	440	-
Annealing temperature ℃	435	480	530
Softening point ℃	625	665	720
Working point ℃	965	980	1040
WT% of PbO	29	None	None

Another reason is that lead glass is easily bonded to pH responsive glass firmly. This is because lead glass diffuses toward pH responsive glass and form an intermediate layer between the two glasses. Figure 6 is the result of line chemical analysis of lead in the bonding interface determined by EDX (energy dispersive X-ray analysis), which shows a distribution of lead in the glass. Figure 7 is a SEM (electron microscope) photograph of the joint of lead glass and pH responsive glass. As shown in the photograph, lead diffuses and makes a bonding interface layer which is seen on the image as a double line.

On the other hand, in Figure 8 using lead free glass, the interface is a sharp boundary as shown on the image as one clear line. This means that the compatibility between the two glasses is small and does not have enough

[3] Sources of data *1 Appendix_L-29_specifications.pdf

*2 Nippon Electric Glass, Product Guide, 2014, p. 38 (21 of pdf), https://www.neg.co.jp/assets/file/exhibition/2014/141007/ex_141007_141007.pdf This page was last accessed on 28 December 2019.

*3 https://www.us.schott.com/tubing/english/product_selector/#!/region--us/lang--english/product--8350 This page was last accessed on 26 December 2019.

intermediate layer. In this case the bonding is performed only at the interface, and the bonding strength is weak and cracks can more easily occur.

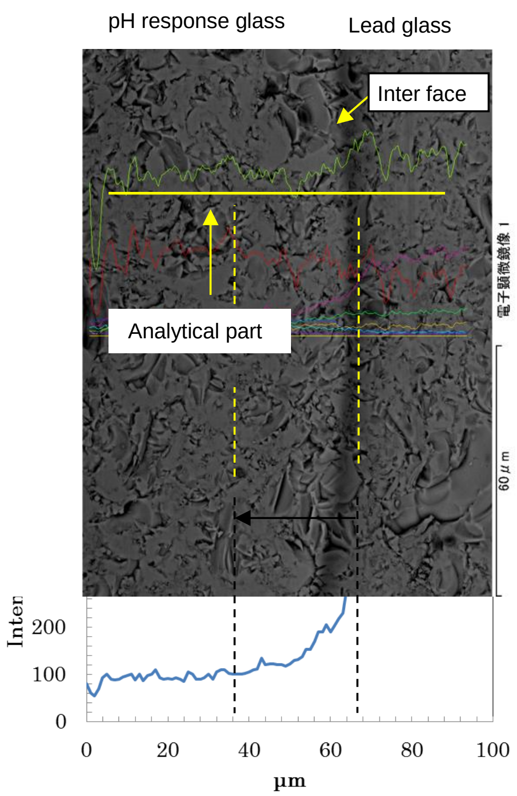


Figure 6 Analysis of lead distribution in the joint between lead glass and pH response glass

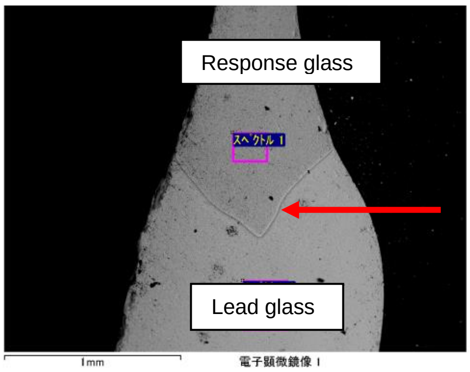


Figure 7 SEM photograph of the joint between lead glass and pH response glass showing the diffuse interface layer

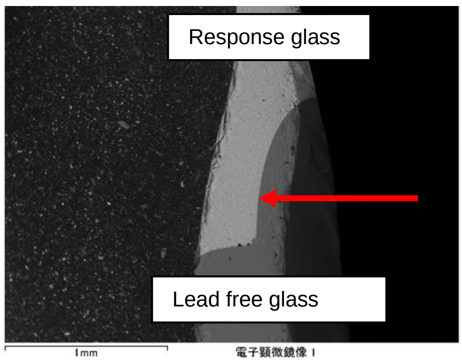


Figure 8 SEM photograph of the joint between lead free glass and pH response glass

Source of pictures: a JBCE member company

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.)

No closed loop exists

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 _____

☐ 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

<Difficulties of manufacturing pH electrodes with lead-free glass>

So far we have promoted lead-free pH electrodes, and electrodes that are simple in shape such as general-purpose electrodes that are possible to process already with lead-free glass (examples are shown in Section 7(A). However, electrodes which have complicated shape are still using lead glass due to technical manufacturability difficulties as described in section 4. Attempts to use lead-free glass in the designs shown above in Section 4(B) were unsuccessful.

Since there is no diffusion of elements such as lead when lead-free glasses are used, the joint interface becomes clear and cracks are likely to occur. The pH glass electrode measures the pH of an aqueous solution of acid or alkali. Ions contained in these measurement samples can enter the glass bonding interface and cause cracks after several weeks to several months (hereinafter, cracks that generate cracks over time are referred to as static fatigue cracks). Analyzing these phenomena by fluorescence analysis and optimizing the processing conditions can be improved to a large extent the ability to withstand crack formation. Conventional pH glass electrodes are able to be manufactured by blowing glass which has lead below the regulated value.

However, pH electrodes which have a special shape (as described in section 4 (B)) has been devised to increase the alkali content of the response glass to lower the electrical resistance, and but this has the disadvantage of having a larger linear thermal expansion coefficient than lead glass. If a lead-glass support stem tube is used, the difference in expansion coefficient does not become a problem, but if a lead-free glass is used, the difference in TCE causes cracks. Because there is no lead diffusion (intermediate layer), static fatigue cracks are likely to occur at the joint bond between the tube glass and the responsive glass.

One difficulty is that lead-free glass is much less flexible at the highest temperature that can be used to bond the stem glass tube to the pH sensitive glass. If the temperature is raised to further soften the glass, the stem glass becomes too soft and distorts so it is impossible to make complex shapes. Trials with the pH electrode types shown in Section 4(B) resulted within a few hours of making the bonds, cracks will form within the bonds due to the stresses within the glass as it cools.

As a consequence of a higher softening temperature the more complex geometries of Flat type electrodes, Needle type electrodes and Microelectrode type lead free glasses are unable to be used as the higher temperature causes the deformation of the electrode during manufacturing.

<Alternative technology for pH measurement>

Other potential alternatives to lead-glass pH electrodes are other types of pH measurement. These are explained and compared below. The listed methods are shown as examples and not exhaustive.

ISFET Electrode（ISFET：Ion Sensitive Field Effect Transistor）

Metal oxide semiconductor can be used instead of pH responsive glass membrane, and potential generated depending on hydrogen ion concentration in sample is measured. It can be used in almost the same measurement range as the conventional electrode with responsive glass membrane. Since the surface is stronger than glass membrane, and because there is no need to use glass for stem tube, the strength and the design of the liquid contact part has advantage compared to conventional glass electrode.

However, there are some problems. One is that the plastic body is damaged by many organic solvents or other similar substances. Another is that when using a common measuring equipment for conventional glass electrode, ISFET requires another signal conversion circuit, which increases the size of instruments and electric power consumption. Lifetime of batteries of portable instruments is shorter than the instruments with glass pH electrodes. Furthermore, the measured value is affected by light during measurement because of its semiconductor property, and so ISFET is not suitable for outdoor measurement or measurements in bright areas. Another problem is that the shape cannot be completely flat. Consequentially ISFET cannot be considered an alternative method of conventional glass electrode.

pH measurement using fluorescent dye

In this method, pH is measured by measuring the amount of emitted fluorescence according to the hydrogen ion concentration in sample solution. Since it is not necessary to use reference electrode, there is no concern that potassium chloride (KCl) solution derived from reference electrode will flow out to sample solution, which is particularly useful for measurement in a closed system.

However, this also has some problems. One is that the range in which pH can be measured is narrow, and in some cases only pH 4 to 10 can be measured. Its measurement resolution is also low, making it difficult to see the difference in the order of 0.01 or 0.001. In addition, since it is affected by the influence of sample temperature and concentration of ions contained therein, it can be used only to know trends in limited situations. As described above, fluorescent method cannot be an alternative method of conventional glass electrode.

Table 2 Comparison of glass membrane and potential alternatives

	Glass membrane	ISFET	Fluorescence
Response location	pH Response glass	Semiconductor (metal oxide compounds)	Fluorescent dye
Necessary equipment	Voltmeter (high impedance)	Signal coverter circuit	Fluorescence measurement
Measurement range	-2 to 16	0 to 14	4 to 10
pH resolution	0.001	0.001	0.1
Body material	Glass or Plastic	Plastic	Plastic
Influencing factors	-	Outer light	Outer light Ion concentration Temperature

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

Reliability issues are described above in sections 4(B) and 6(A).

As described in Section 6 (A), general-purpose electrodes have already almost been substituted by lead-free. In case of complicated shaped electrodes, however, it is necessary to change the composition of the responsive glass to adapt lead-free glass, and time is required for trial and evaluation test.

Furthermore, since it is necessary to change the manufacturing method, it takes time to study the method and ensure the reliability of the method of manufacturing and ensure that the end product has the desired reliability.

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.

Most electrodes with simple shapes such as general-purpose electrodes can now be made with lead-free glass. In addition, new electrodes such as ion-selective field effect transistors (ISFET) have been developed. But ISFET[4] has a resin body, which can be damaged by organic solvent, chlorine and other chemicals that can permanently damage the ISFET chip, so glass electrode is still needed in many applications. In addition to this, ISFET do not offer the same stability and accuracy afforded by glass electrodes, they have demonstrated drifting issues and are sensitive to direct sunlight (and artificial light) due to its semi-conductive nature.

For this reason, some lead glass electrodes, such as electrodes with complicated shapes, are necessary for specific applications.

The lead-free electrodes below are listed and not exhaustive. All of these are made of lead free stem tube glass and lead free pH responsive glass, so that they do not contain any lead. Most major models have achieved lead-free, including the following examples.

Table 3 Examples of pH electrodes using lead free glass

Type of Tip	**Model**	**Characteristics**
Dome shape		Standard dome-shaped pH electrode for general laboratory application. The ϕ 12mm dome-shaped tip provides strength in all directions, reducing damage concerns.
		Dome-shaped long pH electrode for large containers or long tubes. The dome-shaped tip provides strength in all directions, reducing damage concerns. Electrode: 283mm length, 8mm diameter
		Standard dome-shaped pH electrode for industrial application. The ϕ 12mm dome-shaped tip provides strength in all directions, reducing damage concerns.

[4] ISFET is a pH electrode that does not use glass and is a semiconductor sensor

<table>
<tr><td rowspan="2">Sleeve type</td><td></td><td>pH electrode with a sleeve as a junction between internal solution and measurement sample. The liquid junction is designed with a movable sleeve that prevents clogging.
It shows stable readings even in highly viscous samples and non-aqueous solutions (e.g., solvents, cosmetics, paints). pH responsive glass size is ϕ8mm.</td></tr>
<tr><td></td><td>pH electrode with a sleeve as a junction between internal solution and measurement sample. The liquid junction is designed with a ϕ8mm fixed sleeve.
it shows stable readings even in highly viscous samples or non-aqueous solutions (e.g., solvents, cosmetics, paints) in industry use.</td></tr>
<tr><td rowspan="2">Plastic protective body</td><td></td><td>General purpose pH electrode having plastic protective body in which ϕ4mm stem glass tube and pH responsive glass. The following models have similar shape. Version available for analysis of:
for tap water
for Fluoric acid
High alkaline sample</td></tr>
<tr><td></td><td>General purpose pH electrode having plastic protective body in which stem glass tube and pH responsive glass. This type has gel type internal solution and no need to refill it. It is ideal for field and industry use.</td></tr>
<tr><td>Tip exchange type</td><td></td><td>Tip exchange type pH electrode having plastic protective body in which ϕ6.2mm stem glass tube and pH responsive glass. The following models have similar shape. Version available for analysis of:
for Fluoric acid;
for High alkaline sample; and
for oily sample.</td></tr>
</table>

All lead-free glass pH electrodes do not have sharp points, do not have flat ends and are not thin. It has not been possible to substitute lead in these designs.

Efforts are underway to make these electrodes without lead or reduced lead content, however more time and effort is required. The example electrodes below contains lead glass and the list is not exhaustive.

Figure 12 List of pH electrodes using lead glass

Type	Model	Characteristics
Micro size		Micro pH electrode for low volume sample. The tip size ϕ3mm can measure low volume sample as low as 50μL.
Needle type		Needle tip electrode for food industry. The stem tube size is ϕ12mm.
Flat type		Flat pH responsive glass electrode for flat surface measurement. The ϕ12mm size flat glass is suitable for measuring samples in shallow containers (e.g., petri dishes) and gelatinous samples (e.g., nutrient agar). Also useful for pH measurement of meat, skin, leather, paper, leaves and cloth.
		Ammonium ion electrode equipped with a pH electrode inside which has ϕ6mm flat surface response glass.

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

Glass of pH electrode and ion selective electrode require the intermediate layer in the glass. There is currently no known way of creating an intermediate layer in the complex geometries described in Section 4 (B) without lead. Therefore, we cannot say the specific period for searching for the composition of a lead-free glass substitute. Based on industry knowledge of category 9 product development as outlined in the below.

ERA Technology reports "The new product development time for many Category 8 and 9 products over 4 years and can be 7 years or longer" [5] this length of qualification timeframe is expected as instrument manufacturers will need to undertake engineering changes and evaluate the functionality of the alternative solution. The change would also mandate the update of global approvals, one of which is the submission of change of products as required by the Measurement Act of Japan. We cannot specify the period of the schedule but due to the complex nature of the product expect this to be over 7 years.

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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 Lead oxide in is the entry 63 'Lead and its compounds'. The scope is limited to jewellery articles. The entry 63 shall not apply to articles within the scope of Directive 2011/65/EU.

☐ Registry of intentions

☐ Registration

Lead is in glass of electrode. Glass is exempted from the Registration according to the Annex V of Regulation (EC) No. 1907/2006

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

(B) Elimination/substitution:

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

☐ Yes. Consequences? _____

☒ No. Justification: There are no current alternatives that provide a technical solution

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[5] ERA Technology (2006) , Review of Directive 2002/95/EC (RoHS) Categories 8 and 9 – Final Report, 2006, p.29 https://ec.europa.eu/environment/waste/weee/pdf/era_study_final_report.pdf

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

   ☐ Yes.

   ☐ Design changes:

   ☐ Other materials:

   ☐ Other substance:

   ☒ No.

   Justification: See Section 6(B).

3. Give details on the reliability of substitutes (technical data + information): Not applicable as there is no technical alternative currently available
4. Describe environmental assessment of substance from 4.(A)1 and possible substitutes with regard to
   1) Environmental impacts: _____
   2) Health impacts: _____
   3) Consumer safety impacts: _____

⇨ Do impacts of substitution outweigh benefits thereof? Not applicable for this application

Please provide third-party verified assessment on this: _____

(C) Availability of substitutes:

a) Describe supply sources for substitutes: No suitable substitute glass is available

b) Have you encountered problems with the availability? Describe: Not applicable

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? _____

(D) Socio-economic impact of substitution:

⇨ 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 If this exemption is not renewed, reliable pH electrodes (described in section 4(B)) could no longer be sold in the EU which will prevent many EU industries from operating and pollution could not be prevented (e.g. as water quality could not be monitored). EU industry would be at a very significant competitive disadvantage and there would likely be significant loss of EU jobs.

☒ Possible social impacts external to the EU The submission of the change of products are required by Measurement Act of Japan.

☐ Other: N/A

⇨ Provide sufficient evidence (third-party verified) to support your statement: N/A

9. Other relevant information

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

N/A

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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:

The amount of regulated substances entering in EU in 4.(A). 5 is calculated with the data of exportation to EU from individual companies. Exportation data of individual companies is confidential and should be protected.

The foot note *1 of Table 1 Comparison of thermal properties of lead glass and lead-free glass in 4(c) contains confidential information on supply chain.
