# Exemption Request Form

Date of submission: 15. 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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| Function: | Policy Manager | Address: | Rue de la Loi 82, 1040 Brussels, Belgium |


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: 1b

Proposed or existing wording: Lead anodes in electrochemical oxygen sensors

Duration where applicable: Maximum validity period (7 years)

☐ Other: _____

## 3. Summary of the exemption request / revocation request

We request the extension of exemption 1b of Annex IV for Lead anodes in electrochemical oxygen sensors used in monitoring and control devices. There is a wide variety of measurement methods for oxygen concentration. Galvanic oxygen sensors with lead anode are one of measurement methods of oxygen concentration. Galvanic oxygen sensors with lead anode are incorporated into analysis and measuring instruments for oxygen concentration measurement to provide rapid and accurate analysis and wide ranges of measurement. The technology is used by a wide variety of industry sectors, researchers and for educational purposes.

Galvanic sensors with lead anodes are available on the market; however, the technical requirements, such as, measurement range, accuracy and response time are not sufficient for some analysis and measuring instrument for oxygen concentration. The other substitutes are also not feasible technically.

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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: Analysis and measuring instruments for oxygen concentration

   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: 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 as an electrode in electrochemical oxygen sensors

4. Content of substance in homogeneous material (%weight): 97.5-99.9 wt%

5. Amount of substance entering the EU market annually through application for which the exemption is requested: We do not have information about overall of the market. Our amount of Lead of entering the EU market is 2 kg approximately.

Please supply information and calculations to support stated figure.

We are able to provide our calculation method as confidential information.

6. Name of material/component: Lead anodes in electrochemical oxygen sensors

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?**

Electrochemical oxygen sensors are essentially small fuel cells which use oxygen as fuel, and have a very small orifice to control the flow of gas into the cell. Within the cell, an electrochemical reaction occurs generating current which is proportional to the oxygen concentration.

For electrochemical oxygen sensors that uses lead as the anode (galvanic electrode method), a noble metal (typically gold or platinum, silver) is used at the cathode.

At the cathode:

$O_2 + 2H_2O + 4e^- \rightarrow 4\ OH^-$

At the lead anode:

$2Pb + 4\ OH^- \rightarrow 2PbO + 2H_2O + 4e^-$

The overall the reaction is:

$O_2 + 2Pb \rightarrow 2PbO$

The lead anode is consumed in a way that is similar to a battery and so these devices could be and some are used as batteries.

Lead has one main advantage that it does not corrode in the cell spontaneously and so does not produce a current in the absence of oxygen. Sensors based on lead have a reasonably long life and can be used typically for 1 to 2 years which is important for sensors which are in hard to reach areas where replacement opportunities are limited.

Another advantage of this type of sensor is that they do not consume power and so the batteries used in portable oxygen meters have long lives. The design of the device including the galvanic sensor has a circuit configuration in which the potential difference between both ends of the positive electrode and the negative electrode is calculated as an output because the sensor itself is a battery. The other methods described in 6 (A) 1 require a complicated circuit configuration different from the galvanic cell type.

The sensors are robust and can withstand vibration and shock without damage.[1]

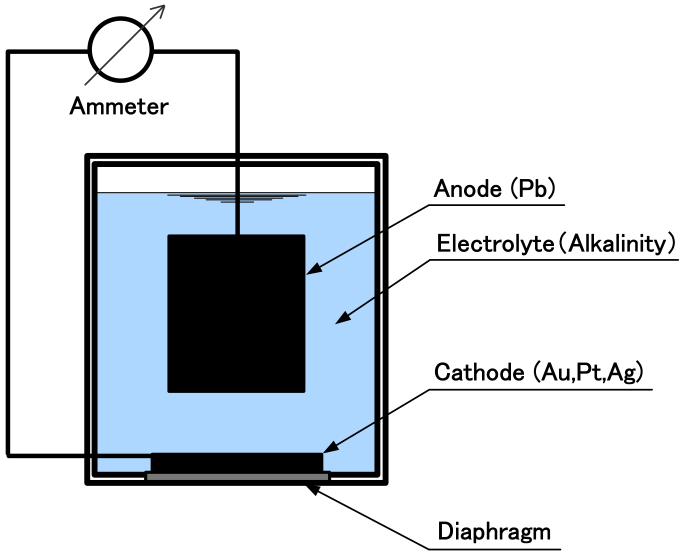


Figure 1: The example of schematic diagram of the diaphragm galvanic electrode method for measurement instrument of oxygen in liquids, gases and in air

Electrochemical oxygen sensors are incorporated with analysis and measuring instruments in order to analyse and measure the concentration of oxygen in liquids and air/gases.

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 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 applications listed below are categorized and are not exhaustive:

Analysis and measurement of dissolved oxygen in liquid is used in the following applications:

- Process control in the industrial facilities: use and control for production and manufacturing lines, as well as environmental protection to ensure hazardous gases are contained
- Use in laboratories; the research, quality control and other applications, applications including the research about anaerobic bacteria and the

[1] ERA Technology (2006) , Review of Directive 2002/95/EC (RoHS) Categories 8 and 9 – Final Report, 2006 , p.173 https://ec.europa.eu/environment/waste/weee/pdf/era_study_final_report.pdf

anti- oxidisation of food package by the a wide variety of sectors, researchers and for educational purposes.

- Quality control; control of oxygen concentrations in food packages and of drinking water and sewerage.
- Use for environment (pollution) analysis

・ Analysis and measurement of oxygen concentration in the air/gas for:

- Process control in the industrial facilities: use and control for production and manufacturing lines.
- Research in laboratories for applications such as monitoring of environmental test laboratories, and control of thermostatic ovens.
- Use for workplace control and security: security checks in workplace, such as, checks before work, and control of laboratories.
- Quality control; control of oxygen concentrations in food packages
- Use for environment (pollution) analysis; oxygen concentrations in the emission gases from vehicles and others.[2]

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

Please see 4(B).

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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 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

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[2] Japan 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

**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 ______

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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**

6. (A). 1 Electrochemical oxygen sensors other than galvanic electrode method

There are several types of electrochemical oxygen sensors other than the lead-based galvanic electrode method and these are listed below, although this is not exhaustive. Each alternative below has different properties to the sensors covered by this exemption with specific functionality not supported without the use of lead as an electrode. The functionalities, advantage and disadvantage are described below. Some of the methods below are suitable only to measure oxygen in liquids whereas others are suitable only to measure oxygen in gases.

6. (A). 1. 1 Polarographic Sensor

Polarographic type oxygen electrode functions are based on the relation of current and potential (polarogram), by imposing an applied voltage of flat region (plateau region) in a current-voltage characteristics curves.

Cathodic reaction: $O_2 + 2H_2O + 4e^- \rightarrow 4OH^-$ (1)

Anodic reaction: $4Cl^- + 4Ag \rightarrow 4AgCl + 4e^-$ (2)

As the reaction proceeds, the concentration of $Cl^-$ decreases in an electrolyte by the reaction (2) above, AgCl is generated on the surface of anode, and electrode reaction is impeded. Therefore, replacement of electrolyte and polishing are needed roughly yearly in order to remove AgCl from the surface of anode.

This type of sensor is not likely to be used for gas measurement. It is not suitable for measuring gas concentration in high temperature as the electrolyte will be evaporated. In contrast, it is suitable for liquid measurement as samples in are not likely to be high temperature as much as those in gas.

Instruments with polarographic sensors have 2 electric circuits, which one is for analysis and measurement and another is for power supply, although instruments with galvanic sensors have one electric circuit, which works both for measurement and for power supply. More energy is consumed, and more components are required for instruments with polarograhic sensors. In addition, output from an electric circuit is possible to cause dispersion of analysis and measurement. An instrument with two electric circuits is possible to cause dispersion more than an instruments with an electric circuit.

6. (A). 1. 2 Constant potential electrolytic sensor

Constant potential electrolysis method uses a sensor to measure the gas concentration by detecting current produced when gas is electrolyzed at the specific constant potential.

In the case of gas measurement, a constant potential electrolytic sensor may be used. This is a structure in which a working electrode (WE), a counter electrode (CE), and a reference electrode (RE) each composed of a gas permeable membrane and a noble metal catalyst which are in contact with the electrolyte solution and accommodated in a plastic container. The sensor needs to be driven using an external power supply (potentiostat circuit) and detects the electrolytic current generated between WE and CE while controlling the potential of the WE with reference to RE.

In the case of an oxygen sensor, by setting the potential of the WE to a predetermined negative value with reference to the RE, under an oxygen gas atmosphere, an oxygen reduction reaction occurs on the WE, and at the same time, an oxidation reaction of water occurs on the CE. At this time, ionic conduction occurs in the electrolyte and electronic conduction occurs in the external circuit. The electrolytic current (proportional to the oxygen concentration) generated at this time is converted into a voltage and displayed as the oxygen gas concentration.

The reaction formula

WE : $O_2 + 4H^+ + 4e^- \rightarrow 2H_2O$

CE : $2H_2O \rightarrow O_2 + 4H^+ + 4e^-$

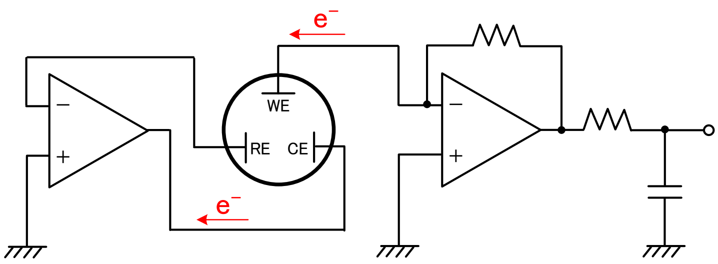


Figure 2 : Example of potentiostat principle diagram

A disadvantage of this method is that oxygen is generated at the CE and if this reaches the WE it will give false readings. If oxygen generated from CE stays inside the sensor, it may reach WE, which occurs in that case.

The galvanic sensor is a battery itself, and the potential difference between both ends of the positive electrode and the negative electrode is calculated as an output, so no special circuit is required. The constant potential electrolysis type has three electrodes (WE, CE, RE) of the sensor electrode, and operation is impossible with only the sensor alone. For the operation, it is necessary to apply a potential to WE with respect to RE, and to control this potential to be constant, and this special circuit (a potentiostat) is required. From this, the design as a detector is more complicated in the case of the potentiostatic electrolysis method, and the design variation of the potentiostat circuit may affect the measurement uncertainty. See the description about electric circuits in 6 (A).1.1.

### 6. (A). 1. 3 Fluorescence method

Fluorescence from a fluorescent material excited by light from a blue light-emitting diode (LED) is quenched by oxygen passed through a dissolved oxygen (DO) permeable layer. The higher the DO level is, the stronger the quenching phenomenon is and the less fluorescence is detected by the detector (light-receiving diodes). Oxygen (DO) enters the light-emitting material layer through a DO permeable layer made of silicon or some other material. This light-emitting material layer contains pyrene and other materials, which are excited by the blue light from the blue LED in the centre and emit fluorescence light. This fluorescence is quenched according to the amount of dissolved oxygen (DO) that reaches the light-emitting material layer, and the remaining fluorescence that was not quenched is received by light-receiving diodes. A light-receiving diode with a blue filter and another with a red filter are used. These diodes only detect the remaining fluorescence and calculate the DO level through mutual subtraction. In principle, higher DO levels cause noise and reduce the measurement accuracy. In this method, a blue LED with an emission wavelength of approximately 360 nm and light-receiving diodes that can detect approximately 0.001 second of light at a wavelength of approximately 800 nm are used.

Organic solvents cannot be analysed because fluorescence pigment melts into organic solvent.

Instruments with fluorescence sensors have 2 electric circuits, which one is for analysis and measurement and another is for power supply, although instruments with galvanic sensors have one electric circuit, which works both for measurement and for power supply. See the description about electric circuits in 6 (A).1.1.

### 6. (A). 1. 4 Zirconia sensors

These are designed for measurement of oxygen in gases and operates when it reaches over 350 to 700 degrees Celsius. Therefore, their use is highly specific to hot temperature uses only, with their main uses in flue gas monitoring and engine management because they can operate at higher temperatures than other types of oxygen sensor. They therefore consume power to maintain their operating temperature and their accuracy can be poor as their response is affected by a variety of other gases.[3] Due to the design it is also possible that the sensor is a safety risk due to its high operating temperature in applications where human contact may occur or it can become clogged with contamination such as oil and dirt and cease functioning.

### 6. (A). 1. 5 Paramagnetic sensors

These have been used for many decades and are widely used in limited applications. They rely on the relatively high magnetic susceptibility of oxygen which has paramagnetic behaviour. Sensors of the paramagnetic dumbbell type consist of a suspended glass dumbbell which rotates in a magnetic field according to the oxygen concentration of the surrounding gas. There are no consumables and these can measure oxygen in the range from 1 to 100%. Their main disadvantages are their larger size and are susceptible to movement such as the angle of instalment; therefore they are limited to some times of fixed installation. Another limitation is that paramagnetic sensor can also give large errors if other paramagnetic gases, such as, NOs are present. They also cannot be used close to the instruments which are susceptible to the magnetic field due

[3] ERA Technology (2006) , Review of Directive 2002/95/EC (RoHS) Categories 8 and 9 – Final Report, 2006 , p.175 https://ec.europa.eu/environment/waste/weee/pdf/era_study_final_report.pdf

to the powerful magnetic field and can be used only in stationary equipment (due to the delicate “balance” used in these sensors).[4]

### 6. (A). 2. Analysis and measurement of oxygen concentrations in the liquid and the air/gas

Galvanic electrode method with lead anode is able to use analyse and measure both dissolved oxygen in liquid and of oxygen in air /gas. Galvanic electrode method is suitable for portable and mobile analysis and measuring instruments. As the measuring time and the warm-up period before measurement, analysis and measuring instrument with galvanic electrode method are very short, they are ready for immediate analysis and measurement. The galvanic electrode method has a wide measurement range, and is stable for low oxygen concentration measurement.

#### 6. (A). 2.1. Analysis and measurement of dissolved oxygen (in liquids)

Analysis and measurement of dissolved oxygen is utilised with the instruments with galvanic electrode method mentioned in 4(B), and polarographic and fluorescence method mentioned in 6.(A).1. Comparison of the differences of specifications, advantages and disadvantages is the below:

Table 1. Comparison of types of oxygen sensors suitable for measurement in liquids; differences of specifications, advantages and disadvantages

| | **Galvanic** | **Poralograhic** | **Fluorescence** |
|---|---|---|---|
| Warm-up time | Negligible | 10 min.-1hour | Negligible |
| Advantages | External power supply for turn- on is not required. | Organic solvents usable | Reagents are not required. |
| Disadvantages | N/A | Requires a mechanism to apply voltage<br>battery and electicelectric board, requires power supply.<br>See 6. (A). 1. 1. | Organic solvents impossible to measure<br>Requires a mechanism to apply voltage<br>battery and electicelectric board, required for power supply. See 6. (A). 1. 3. |
| Accuracy and measurement range | 0.1ppb-50ppm | 0.1ppb-50ppm | 1ppb-20ppm |

Galvanic electrode method is most frequently used for analysis and measuring instruments for dissolved oxygen. The galvanic sensors can be

[4] ERA Technology (2006) , Review of Directive 2002/95/EC (RoHS) Categories 8 and 9 – Final Report, 2006 , p.175 https://ec.europa.eu/environment/waste/weee/pdf/era_study_final_report.pdf

incorporated with a wide variety of instruments from, small and portable instruments to large instruments.
The international standard "ISO5814 2012 Water quality — Determination of dissolved oxygen --- Electrochemical probe method" describes the probe of analysis and measuring instruments with lead/silver anode. Galvanic electrode method is used for the analysis and measurement according to the ISO 5814.

As a substitute candidate of lead anode, zinc has a suitable electrode potential and electrochemical potential. However, zinc is a much more reactive metal than lead and corrodes spontaneously, even in the absence of oxygen. This greatly shortens the life of the sensor and gives a continuous but variable background current so that low oxygen concentrations are impossible to measure.[5].

Although some products have already been commercialized with respect to zinc, the low oxygen concentration sensitivity of the ppb range is higher than that of products using lead, and replacement in the full concentration range has not yet been realized.

In the case of oxygen sensors for dissolved oxygen measurement, an anode sensor using zinc is available in some markets, but is limited as it cannot measure low concentrations of dissolved oxygen. In fact, there are applications that require continuous monitoring and batch measurement of low concentrations in process management such as monitoring the amount of dissolved oxygen to prevent corrosion inside a boiler, quality control to prevent oxidation of food, and research applications such as the culture of oxygen anaerobic bacteria. An anode sensor using lead is required in such cases that measurement and monitoring of low concentration oxygen is required.

In addition to zinc, there are research and academic reports with respect to antimony, bismuth, and antimony-bismuth alloys as alternatives to lead anodes, but there is very limited data on the measurement of such devices and there is no in-service data for long term behaviour.

6. (A). 2.2 Analysis and measurement of oxygen concentration in the air/gas

Analysis and measurement of oxygen concentration is utilised with the instruments with galvanic electrode method mentioned in 4(B), and constant potential electrolytic, zirconia, and paramagnetic methods mentioned in 6.(A).1.

[5] ERA Technology (2006) , Review of Directive 2002/95/EC (RoHS) Categories 8 and 9 – Final Report, 2006 , p.174 https://ec.europa.eu/environment/waste/weee/pdf/era_study_final_report.pdf

The comparison of differences of specifications, advantages and disadvantages for oxygen sensors used in gases is below:

Table 2 The comparison of differences of specifications, advantages and disadvantages for oxygen sensors used in gases

| | Galvanic | Constant potential electrolytic | Zirconia | Paramagnetic |
|---|---|---|---|---|
| Portability | Suitable | Suitable | Not suitable<br>Large votage and big power supply required, resulting in a big device | |
| Warm-up time | Negligible | The period depends on the structure of the detector<br>Dozens of min.to several hours approximately. | Heating a sensor takes time.<br>30min.to several hours approximately. | The stability of measurement takes time. Several hours approximately. |
| Advan-tages | Intrinsically safe explosion-proof structure can be designed relatively easily.<br>External power supply for turn- on is not required. | No impact from acid gas (carbon dioxide). | Suitable for the measurement of gas in high temperature, for example in engine exhausts. | Intrinsically safe explosion-proof structure can be designed. |
| Disadvan-tages | None | A drive circuit that controls the precise set potential is required.<br>See 6. (A). 1. 2 . | Requires safe design against high temperatures.<br>Requires external power supply for drive. | Influenced by equipment with magnetic field.<br>Requires an external power supply for driving.<br>Affected by other paramagnetic gases |

Galvanic electrode method is most frequently used for analysis and measuring instruments for oxygen concentration in the air/gas. The galvanic sensors can be incorporated with a wide variety of instruments such as, small and portable instruments and large instruments.

A galvanic cell type sensor using an anode other than lead for measuring oxygen concentration in gas is available on the market. However, the specifications, such as, response time, operational temperature range and accuracy, of these sensors do not fit the requirement of some analysis and measuring instruments for gas concentration. If the operation temperature range and accuracy are not sufficient, the performance of instruments becomes lower than that of existing instruments.

**Interfering gases in oxygen in gas concentration measurement**

A galvanic cell type sensor using an anode other than lead for measuring oxygen concentration in gas is on the market. However, before changing to a different type of sensor, manufacturers need to ensure that they give accurate results, especially when measuring oxygen in the presence of other gases that might interfere with the sensor’s behaviour to give incorrect results. When this interference gas is classified by use, there are various types such as “industrial process equipment", "research", "workplace environment management", "quality control", "environmental measurement", and the like. In addition, there are about 60 kinds of interference gases that might occur, and the concentrations of these gases existing for each application is different and so their effect will be different. The effect of these interference gases on galvanic cell type sensor using an anode other than lead will need to be fully verified by the combination of application and concentration.

The influence of the interference gas mainly affects the sensitivity and accuracy of oxygen concentration measurement (including an influence on a change in measurement behaviour caused by electrode deterioration) and also can impact the sensors lifetime. The expected lifetimes differ from the applications, and are mainly 2 years 3 years, and 5 years

Above all, the verification on the lifetime is evaluated for each application (for each type of interference gas), and the expected lifetime requires a long verification period. Furthermore, verification is needed for all likely interference gases, combinations of these gases, all possible concentrations of these gases as well as all possible oxygen concentrations.

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

Not available

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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.**

See 6.(A).

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

Galvanic lead-free sensors both for gas and for liquid are available on the market. However, for some specifications, measurement range, response time, operational temperature, and accuracy do not fit the requirements of instruments. Therefore, a period of time for searching for the qualification of the substitute of lead anode is required. We cannot predict the length of the specific period for searching for the substitute of lead anode.

Instrument manufacturers will launch the evaluation of functions as soon as the sensors fit the requirements. ERA Technology explains "The new product development time for many Category 8 and 9 products over 4 years and can be

7 years or longer."[6] This timeframe is required as the following needs to be undertaken:

- Durability testing;
- Reliability testing;
- Evaluation of performance in service;
- Instrument manufacturers will need to change electric circuit and mechanical design. The timeframe of completion for this will vary for each application and cannot be calculated;
- Establishment of production lines and,
- Submission for product specific approvals.

In addition to the above timeframes the following have to be undertaken which would be in addition:

- Undertake testing of the evaluation of interfering gas will be in addition to the period mentioned above (so > 7 years). In addition, the evaluation of durability and the organisation of purchasing, production and service;
- Some instruments for gas measurements of these gases are necessary to be explosion-proof specifications in some applications. If the sensor is replaced, the IECEx explosion-proof (IEC standard), ATEX explosion-proof (EN standard), and CE marking need to be updated or changed for explosion-proof certification and compliance with international standards conformity. It takes 1.5 years approximately.

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[6] 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

## 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 Lead is an SVHC.

■ Candidate list Lead is an SVHC

☐ Proposal inclusion Annex XIV

☐ Annex XIV

☐ Restriction

☐ Annex XVII

Lead 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

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

**(B) Elimination/substitution:**

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

☐ Yes. Consequences? _____

■ No. Justification: <u>See 6.(A).</u>

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

☐ Yes.

☐ Design changes:

☐ Other materials:

☐ Other substance:

■ No.

Justification: <u>See 6.(A).</u>

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

1) Environmental impacts: <u>Analysis and measuring instruments for oxygen concentration are used for environment and pollution monitoring. Galvanic sensors are cheaper than the other sensors, can be used for portable instruments, and enable rapid measurement. Instruments with galvanic sensors are accessible to users to keep monitoring the environment and</u>

pollution, and a wide variety of instruments should be available to conserve the environment.

2) Health impacts: Analysis and measuring instruments for gas are used for the safety control of work place. Galvanic sensors are cheaper than the other sensors, and can be used for portable instruments. Instruments with galvanic sensors are accessible to users to keep workplace safe, and a wide variety of instruments should be available to maintain the working environment.

3) Consumer safety impacts: N/A

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

**(C) Availability of substitutes:**

a) Describe supply sources for substitutes: ______ The sensors from the manufacturers can be applied to analysis and measuring instrument for measuring oxygen concentration:
For DO measurement: https://sensorex.com/product/do6400-dissolved-oxygen-sensor/
For gas measurement:
http://www.itg-wismar.de/index.php?content=rg1&app_id=5&il=4
However, some specifications do not fit the instruments. See 6(A).

b) Have you encountered problems with the availability? Describe: No information.

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? N/A

**(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

☐ Possible social impacts external to the EU

☐ Other: ______

⇨ 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 of other analysis and measuring instruments 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.

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