Exemption Request Form

Date of submission: 20th January 2023

1. Name and contact details

1) Name and contact details of applicant:

Company: Alphasense

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

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This exemption application is submitted with the endorsement of the following companies and trade associations.

AFRISO	ANALOX
CoGDEM The Council of Gas Detection and Environmental Monitoring	factair
GAS DATA LISTEN · ANALYSE · INFORM	GDS TECHNOLOGIES
GEMLOG controls	smart GasDetection Technologies GfG
KANE®	mocon® / AMETEK®
QED™	Sensotran
SEWERIN	TROLEX

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

☐ 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:

Proposed wording: Lead anodes in capillary oxygen sensors

Duration where applicable: January 2027 for general applications,

July 2028 for ATEX rated products

☐ Other: _____

3. Summary of the exemption request / revocation request

Lead is used as the anode in capillary oxygen sensors which are used to measure oxygen gas in the range of 0-30% in fixed installations, personal monitoring devices and permeation measurements, such that an alarm is triggered if the oxygen levels are above or below a set threshold. Capillary sensors have minimal response to pressure, temperature and humidity, while having a short warm-up time and are self-powered. Other sensors, such as amperometric type sensors can be lead-free but are not able to offer these technical characteristics and are susceptible to high carbon monoxide (CO) and carbon dioxide (CO_2) concentrations and cannot be used in the absence of oxygen.

Alphasense and other sensor manufacturers have carried out research into substitute metals and none are drop-in replacements as outlined above.

More research is needed develop alternative sensors that offer suitable technical performance, after which the design and validation of analyser instruments including performance certification can be undertaken. Depending on the end use in question the level of redesign and testing will vary, with an estimated timeframe of at least 4 years for general applications and at least another 18-months subsequent to this for ATEX rated products.

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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:

   Capillary oxygen sensors in industrial monitoring and control devices

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: 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

   ☐ 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: Electrochemical oxygen concentration measurements

4. Content of substance in homogeneous material (%weight): 100% lead

5. Amount of substance entering the EU market annually through application for which the exemption is requested:

   <5 tonnes lead per annum enters the EU market.

   Please supply information and calculations to support stated figure.

   Based on estimates from The Council of Gas Detection and Environmental Monitoring (CoGDEM), with some assistance from its members, an estimated 5 tonnes lead per annum is placed on the EU market. This value is calculated for the O2A2 format which consists mostly of sensors sold into the industrial safety and emissions monitoring markets but is not limited to capillary sensors only.

The relative proportion of the sensors used in applications in scope of the renewal compared to those which are not included is not known, so it can only be stated that <5 tonnes of lead per annum is placed on the EU market.

This is based on the assumption that 10 g of lead is used per sensor which deemed as an average amount.

6. Name of material/component: Lead metal used as an anode in capillary sensors

7. Environmental Assessment: n/a

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?

Capillary sensor are electrochemical sensors with two electrodes; a lead anode and an inert cathode which are immersed in an alkaline electrolyte. The anode and cathode reactions are:

Cathode: $O_2 + H_2O + 4e^- \rightarrow OH^-$

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

The electrochemical reason generates an electrical current which flows through the cell which is proportional to the amount of oxygen entering the sensor in accordance with Faraday's Law. The current is measured by a load resistor which is between the cathode and anode which measures the resulting voltage drop.

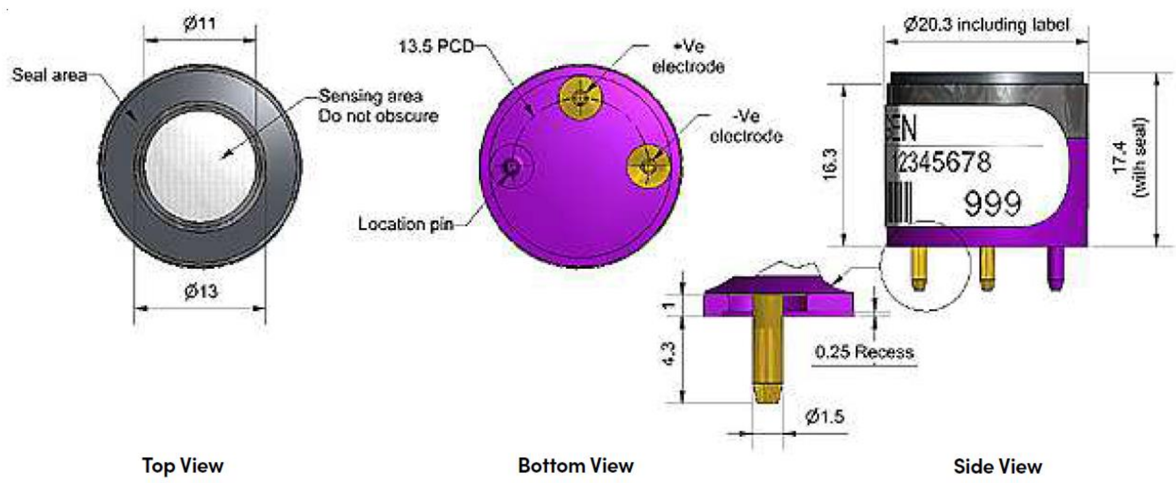

Figure 1 Schematic of capillary sensor, with lead in the anode (-ve electrode) and dimensions in mm.

Capillary sensors measure oxygen in the range of 0-30% in fixed installations and personal monitoring devices, such that an alarm is triggered if the oxygen levels are above or below a set threshold. These devices have their performance specified by ISO 50104 - Electrical equipment for the detection and measurement of oxygen - Performance requirements and test methods.

Unlike other sensor designs which use a membrane which the oxygen must permeate through, capillary oxygen barrier uses a small hole (<200 µm in diameter) such that it can be detected by the electrodes. The electrolyte used in capillary sensors is potassium acetate, and lead anode in a wool form.

Capillary sensors are also used in permeation measurements operate under the same principle as the capillary sensors described above, with the capillary hole larger in diameter to allow the measurement to levels of oxygen such as 20ppb. The larger hole size allows for a larger amount of signal to be gathered and therefore a lower level of detection is possible. The only other design difference from the other capillary sensor types is a metal housing to limit oxygen permeation through the housing.

There are several properties that are important to capillary sensors:

- Able to measure oxygen within the range of 0-30%
- Sensor output of 100µA in ambient conditions which limits the transient sensor response when undergoing pressure changes during which time the sensor cannot be used in. For example, a sensor output of 20µA would take that much longer to stabilise after pressure disturbances than a 100µA output. More information on this is outlined in the confidential information submission.
- Operating temperature range of -30 to +50°C
- Low output dependence with temperature, as shown in Figure 2
- Minimal response to pressure changes in the ranges of 80 – 120 kPa, as shown in Figure 3
- Operable time of over two years before lead fuel is exhausted (for the major sensor types[1])
- A warmup time of <2 mins for portable instruments
- High surface area of the electrode to ensure a suitable sensor lifetime
- Self-powered systems, without the need for external power sources, allowing detection to be undertaken within seconds and start up times of a few minutes
- Mechanical stability of the device such that it can be dropped and still function as intended

[1] It should be noted that some smaller format sensors have a reduced lifetime due to the size limitations, but these are only used within specific applications.

- Some applications, such as automotive, biogas and boiler flue exhaust monitoring, there are additional requirements for carbon monoxide and carbon dioxide poison resistance
- Some applications are limited as to the sensor size the design can accommodate, for example portable devices such as personal monitoring devices would soon become unwieldly if the senor was larger.
- Some end uses are also operable within explosive atmospheres so need to be compliant to the requirements of the ATEX Directives.

For capillary sensors used for oxygen transmission rate through packaging or other barrier layers, for applications such food and pharmaceuticals, it is essential that the sensor is able to measure to very low levels of detection (20ppb) and able to operate at 0% oxygen concentrations.

Temperature dependence:

Figure 2 shows that although temperature dependence has some effect on the device, the impact is limited as the rate of the gas diffusion through the capillary is only weakly temperature dependent. This change is due to the change is gas viscosity with temperature. However, such dependence is minimal and the dependence on temperature is highly repeatable.

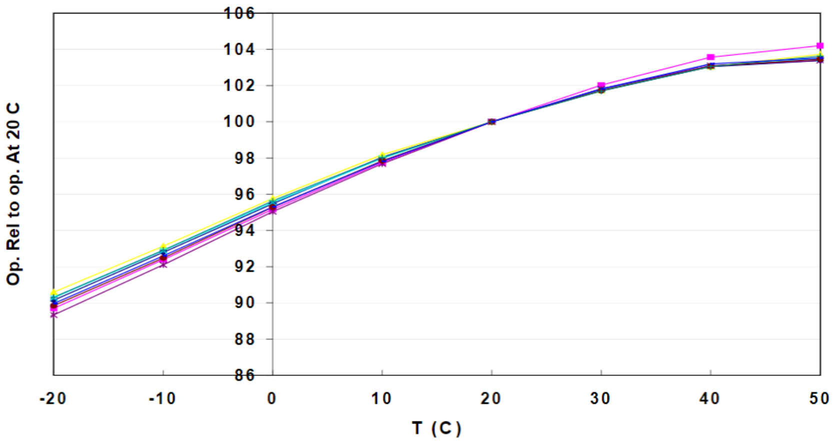

Figure 2 Temperature dependence for capillary oxygen sensors against the output from the sensors as a percentage of the output at 20°C, showing high repeatability between sensors tested

Temperature dependence, including to especially cold temperatures is important as industrial capillary oxygen sensors may be used in portable safety oxygen monitors which operate outdoors or in fixed installations at industrial facilities that may not be heated above the surrounding environments, such as mining operations or oil drilling riggs. This can include northern countries such as Finland, which where according to the Finnish Meteorological Institute winter temperatures can be below -30°C. As Alphasense is a manufacturer of sensors, the relative proportion of applications which are used in these temperatures is unknown, but still offers a key technical requirement utilised by our customers.

Pressure dependence:

The amount of oxygen available for the reduction at the cathode depends on the oxygen concentration in the air, and not the oxygen partial pressure. As such the sensor output is nearly independent of ambient pressure.

These types of devices are used in applications where the steady state pressure undergoes substantial changes, for example an oxygen monitor in a deep mine shaft taken to the surface. The capillary sensors have a temporary transient pressure response which the oxygen monitors are designed to ignore. On the contrary, designs which rely upon partial pressure by using membranes, have an output which is always proportional to the partial pressure and therefore cannot be used in these applications.

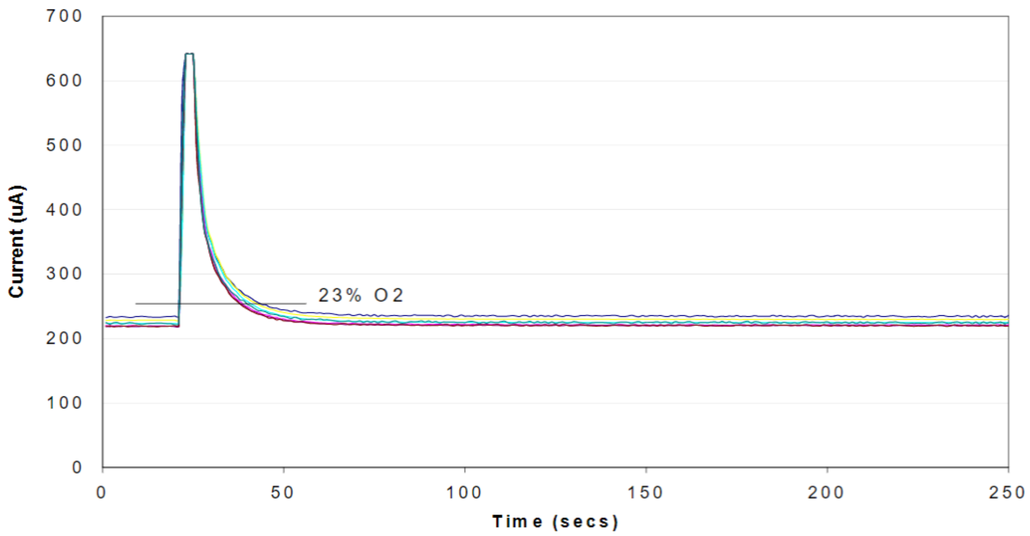

Figure 3 Capillary sensor response when subject to a 10kPa instantaneous positive pressure step.

The sensors are used within gas detection devices as a consumable part, with devices typically having a lifetime of about 8-10 years, with some devices having a lifetime of decades.

Capillary sensors are used in the following applications:

- Portable instruments that are either mains or battery powered for monitoring health and safety.
- Fixed installations for monitoring health and safety
- Automotive exhaust monitoring (portable and fixed instruments)
- Boiler flue monitoring (portable and fixed instruments)
- Biogas monitoring in anaerobic digestion plants (portable and fixed instruments)
- Permeation measurements of packaging of food and pharmaceutical packing (fixed instruments)

Capillary lead oxygen sensors are also used as spare parts for instruments already placed on the market as on average the sensor needs to be replaced every two years. Instruments using sensors can have a lifetime of decades, and therefore require replacement oxygen sensors in order to maintain its functionality. It is hard to estimate the number of legacy instruments currently on the market but is estimated to be in the tens of thousands and is more likely in the hundreds of thousands, with many of these applications being for safety critical applications.

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

Lead in electrochemical sensors is ideal as it does not self-corrode in the absence of oxygen, so does not produce a current without oxygen present. However, lead reacts rapidly when in contact with oxygen, giving a fast response time to the sensor with devices having a t90 value between 5 and 10 seconds.

Capillary lead sensors are able to operate in the absence of oxygen for prolonged periods of time as they do not require reference electrodes.

The sensors based on lead do not require power to operate, unlike other sensor types, which allows the sensor as a consumable part to have a relatively long lifetime, typically for 1 to 3 years which is important for sensors which are in hard-to-reach areas where replacement opportunities are limited.

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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.)

End-of-life capillary sensors are returned to manufacturers for disposal.

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: 100% of sensors
☐ Article cannot be recycled and is therefore:
  ☐ Sent for energy return
  ☐ Landfilled

2) 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 <5 tonnes of lead per annum

☐ 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

Lead substitutes in electrochemical sensors

Research has been carried out and published with alternative anode metals and with various acid and alkali electrolytes. Metals that have been investigated include antimony, bismuth, copper, tin and its alloys, zinc and aluminium.

Research has shown[2] that the more reactive metals such as tin, zinc and aluminium are unsuitable as they are thermodynamically unstable in suitable electrolytes. Electrolytes such as potassium hydroxide and other alkali solutions, acidic solutions such as phosphoric acid and caesium carbonate solution (mildly alkali) have been investigated. When a reactive metal anode is combined with an inert cathode, the two different materials generate a galvanic couple which creates a small voltage with the electrode potential of the anode such that they self-corrode, generating a current and generate hydrogen. This generated current between anode and cathode gives a false and incorrect oxygen concentration.

Despite this, limited number of commercial galvanic lead-free oxygen sensors are available, which unlike some other methods is suitable for portable and mobile analysis and measuring instruments. However, their technical performance is different than those covered by this exemption, as outlined in Table 1.

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[2] Lead-Free Galvanic Oxygen Sensors. A Conceptual Approach, Cornel Cobianu, et. al (Honeywell). CAS (International Semiconductor Conference) 2012, Abstract from https://www.semanticscholar.org/paper/Lead-free-galvanic-oxygen-sensors-%E2%80%94-A-conceptual-Cobianu-Serban/e4cfb461b42eba465ee2410d5637bf7453079bf6

Research with less reactive metals such as copper, bismuth and antimony has also been reported, but no commercial products have been developed. The reason why these metals are not used in commercial sensors could be that they can form thin oxide coatings (e.g. during storage before use) which may act as a barrier to further oxidation and so hinder or prevent further electrochemical reaction.

Lead may be the optimal anode choice in electrochemical sensors because it does not self-corrode in the absence of oxygen (such as aluminium and zinc) but it responds rapidly when in contact with oxygen, unlike copper, which reacts and then rapidly passivates so stops working. Nobel metals such as gold and silver do not respond at all as they do not react with oxygen from air.

Table 1 Comparison of lead containing and lead-free partial pressure galvanic oxygen sensors

Sensor	Current output	Operating temperature	Environmental dependence
Lead containing capillary sensor	100 µA in ambient conditions	- 30° to + 50°C	Minimal temperature dependence.
ITG sensor[3] (using a barrier system)	Not listed	0° to 50°C	Pressure, temperature, and humidity dependence[4].
Honeywell Envitec[5]	7-13 µA in ambient conditions	0° to 50°C	Pressure, temperature, and humidity dependence.
Figaro[6]	10-15mV	5° to 40°C	Comparatively more affected by pressure and temperature than a capillary lead oxygen sensor.

Response of partial pressure galvanic lead-free sensors tested from – 30 to +50°C was tested by Alphasense, as shown in Figure 4. This shows that despite the thermistor, the output swings widely across the full range compared with lead oxygen.

[3] I-01-Rev_022012 (it-wismar.de)

[4] I-01 Appl Note (it-wismar.de)

[5] OOA Envitec Gas Sensors | Honeywell

[6] ke-lf_product information(fusa)_rev06.pdf (figarosensor.com)

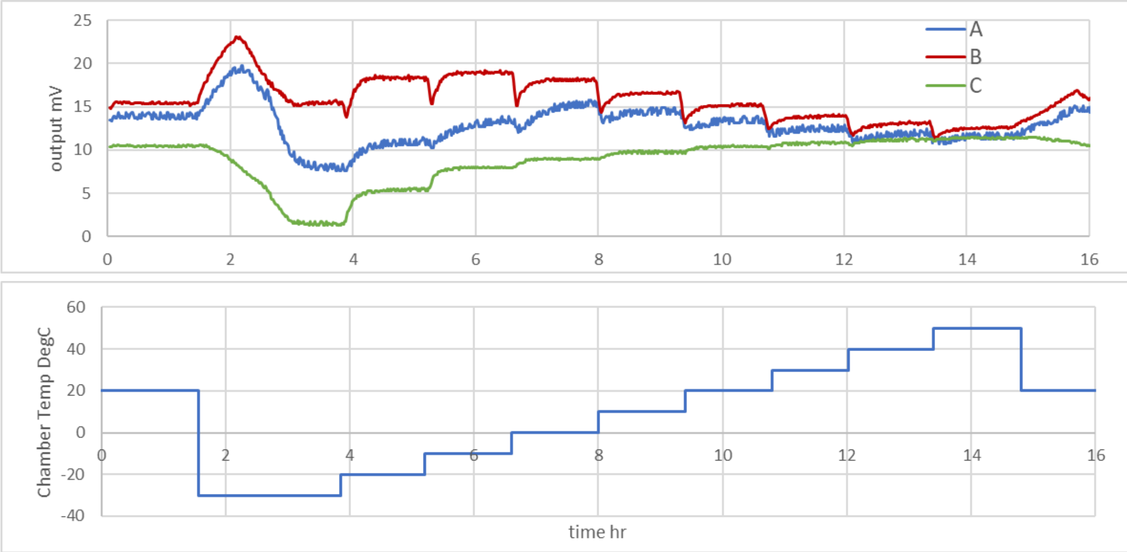

Figure 4 Response of partial pressure galvanic lead-free sensors tested from – 30 to +50°C

The Response of partial pressure galvanic lead-free sensors to a pressure step of 25 kPa was tested by Alphasense, as shown in Figure 5.

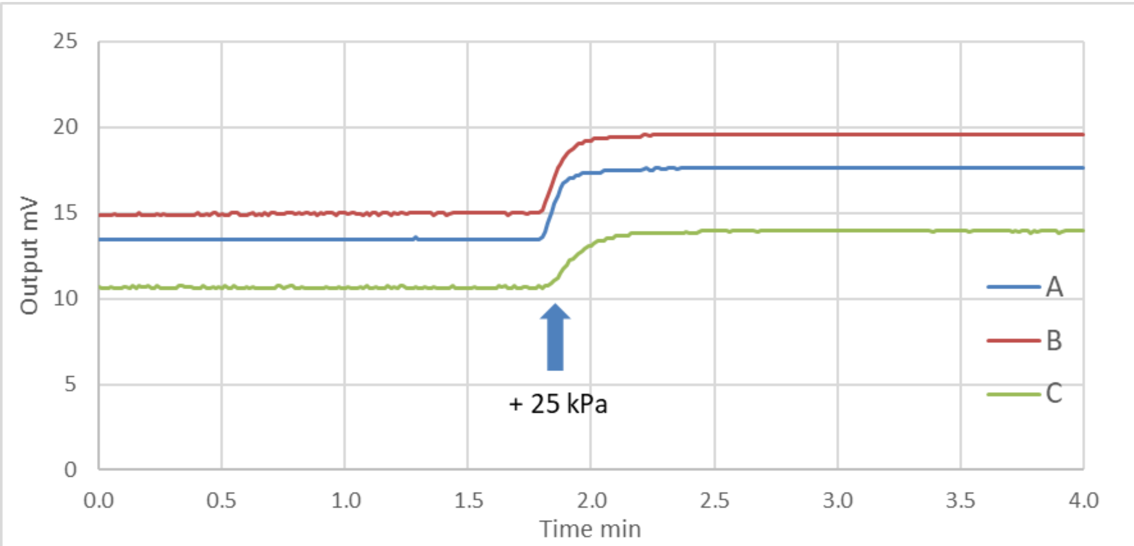

Figure 5 Partial pressure galvanic lead-free sensors to a pressure step of 25 kPa at 60 s in air

There is also a considerable size difference between the Alphasense detector and alternative designs, as show in Figure 6. It is estimated that the sensor on the left has around 2.5 x increase in volume.

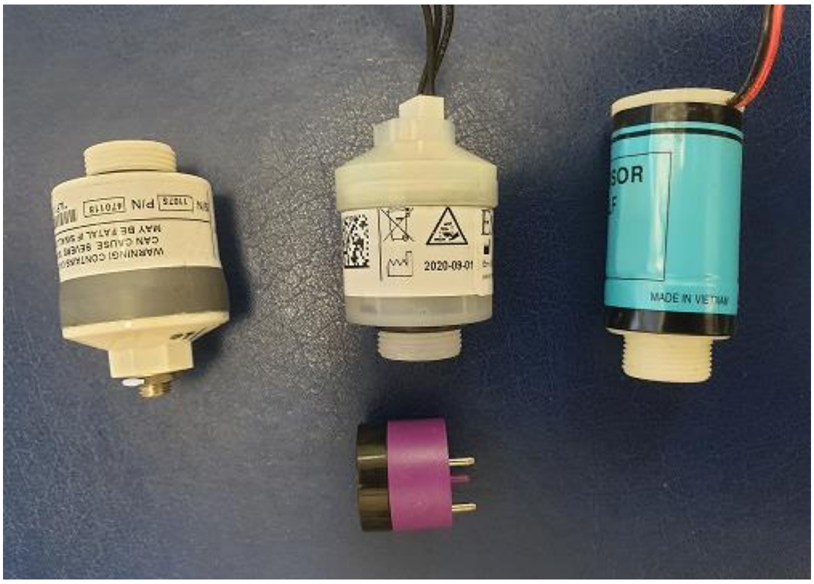

Figure 6 Comparison of an Alphasense O2A2 (which is the same dimensionally as Alphasense A series and elsewhere as 4 series) sensor and the galvanic lead free partial pressure sensors

As can be seen from the technical differences in each sensor, the current lead-free alternative does not offer the necessary technical performance required for the application sensors covered by this application serve and therefore cannot be considered as viable alternatives.

Alternative Sensor Types

There are of course other sensor types other than partial pressure galvanic sensors, however these do not offer the same combination of technical characteristics, as discussed below.

Amperometric type sensors measure current as a result of the electrochemical reaction. The sensor operates on an oxygen pump principle where oxygen is consumed at one electrode (the working electrode) and produced at another (the counter electrode) with a reference electrode. These can be used in a number of different applications to great effect, but have the following disadvantages:

- Most sensors require power to be applied constantly. If power is lost the internal cavity space will equilibrate with the oxygen content in the air. When power is restored depending on the length of time without power, 15 mins to many hours is required for the output to be stabilised.
  In comparison, galvanic sensors being self-powered need only have the pins of the device connected to remain operable and so there is no wait when power is restored to display the correct output. See Figure 7 for details of one amperometric sensor as an example.
- Susceptible to high carbon monoxide (CO) and carbon dioxide (CO_2) concentrations, which is important for automotive, biogas and boiler flue sectors. The recovery time in CO_2 conditions were longer when compared with capillary lead oxygen sensors as outlined in Table 2 and Table 3. In addition to this there was reduced sensitivity of amperometric sensors following exposure to CO above 10000 ppm which can last several hours.
  Capillary lead oxygen sensors do not have this susceptibility.
- Require a reference electrode to operate to correctly maintain working electrode polarisation and drive the oxygen pump. Due to this, amperometric sensors cannot operate in an absence of oxygen for prolonged periods of time as the reference electrode requires oxygen to work. Galvanic sensors do not require reference electrodes so can operate in the absence of oxygen.

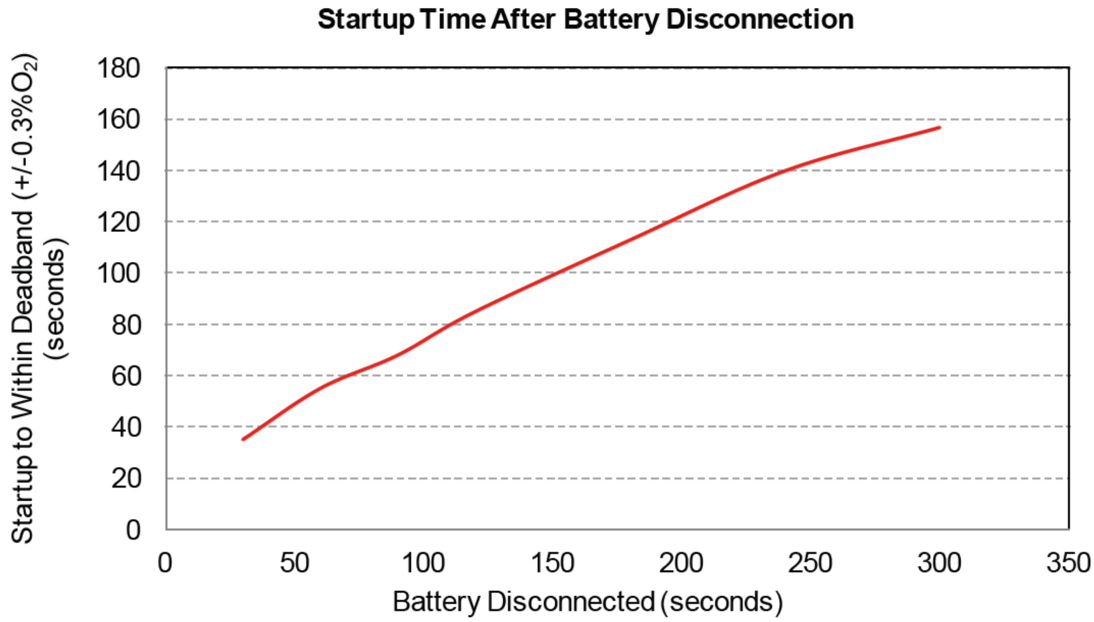

Figure 7 Warm up times of amperometric lead-free oxygen sensor outlining start up time after battery disconnection

		Lead Free Sensor % O2	Lead Based Sensor % O2
	Starting Value	20.94	20.94
Cycle	1	20.28	20.91
	2	20.08	20.90
	3	20.02	20.91
	4	19.99	20.91
	5	19.98	20.90
	6	19.99	20.90
	7	19.97	20.91
	8	19.96	20.90
	9	19.96	20.90
	10	19.94	20.91

Table 2 Comparison of lead-free and lead based sensor response when exposed to 8 – 15 % CO_2

Elapsed Time (minutes)	Reading % O2
12	19.94
18	19.82
20	17.71
23	19.48
28	19.29
32	19.96
37	20.39
42	20.57
51	20.71
60	20.78
68	20.82
85	20.87
104	20.91
126	20.94

Table 3 Recovery time of lead-free sensors to a ~20.91 reading for O_2, in comparison lead based sensors always returned to this value within 3 minutes.

Partial pressure sensors are a different type of electrochemical sensor (available in lead containing and lead-free containing versions) which but instead uses a membrane, such as Teflon, and inert electrodes in their construction.

The membrane is included in the design of the sensor as it increases the life of the sensor. The rate of gas diffusion through the membrane is linearly proportional to the partial pressure of the oxygen on the two sides of the membrane, following Fick's Law. Since oxygen is reduced at the cathode, the partial pressure on the cathodic side of the membrane is virtually zero, giving a driving force which is linearly dependent on oxygen partial pressure, so the rate of gas diffusion (and hence sensor output) is linearly dependent on the oxygen partial pressure.

However, all of these devices which rely on membranes all have the following characteristics:

- Any change in atmospheric pressure affects linearly the oxygen partial pressure, so partial pressure sensors are linearly dependent on ambient pressure.
- Since the gas must diffuse through a solid polymer membrane, the rate of diffusion is dependent not only on the gas partial pressure but also on the diffusivity of the membrane. The diffusivity of polymer membranes has a high temperature dependence, typically 2 to 3%/K; this is usually corrected by using a thermistor sensor inside the body of the oxygen sensor to compensate for temperature changes. However, during thermal transients the membrane diffusivity and compensating temperature sensor will not be in phase and significant thermal transient errors can result.
- Since diffusion through a polymer membrane is slower than through a capillary the response time (as t90) of partial pressure sensors is typically[7] 20 to 40 seconds, in comparison devices using this exemption have a t90 value between 5 and 10 seconds.

There are other types of oxygen sensors based on alternative technologies which are briefly discussed:

- **Fluorescence**- a fluorescent material is excited by a LED and quenched by oxygen which passes through a permeable layer (membrane). The higher the oxygen content the stronger the quenching and the less fluorescence is detected by the light receiving diode. At high oxygen levels the measurement accuracy decreases due to noise and requires power to operate. See Table 4 for a more detailed review of performance characteristics.
- **Tuneable diode laser absorption spectroscopy sensors (TDLAS**)- a laser absorption technique which is based on the reduction of the measured signal intensity of a laser diode. Tuneable diode lasers have a sophisticated sub-micron structure and need for precise temperature control to maintain the selected frequency. Due to its reliance on absorption the technique is limited in terms of sensitivity due to background noise. See Table 4 for a more detailed review of performance characteristics.
- **Zirconia sensors –** These are solid state electrochemical sensors based on yttria stabilised zirconia through which oxygen ions can diffuse when operated at high temperature (400-600^{o}C). As such they are used with gases at temperatures between 350-700^{o}C only. Require power to operate and due to interactions with other gases can have poor accuracy.

[7] It is recognised that there are some devices on the market with a quicker response time than 20 seconds, as a result of specific design features, however this is not true for all designs and it an important technical offering of Alphasense sensors.

- **Paramagnetic**- able to measure oxygen content between 1-100% due to the paramagnetic behaviour of oxygen. The measurement requires a suspended glass dumbbell which rotates in a magnetic field according to the oxygen concentration of the surrounding gas. As such the equipment is large and susceptible to effects from the installation angle and therefore can only be used in fixed installations. Other magnetic interference, either from other equipment, or paramagnetic gases such as NO_x can also affect the results.

Table 4 Comparing sensitivity of oxygen sensing devices

Technology	Sensor type	Operating temperature	Environmental dependence
Lead galvanic capillary sensor	Membrane free so measures 100% of the gas flow	- 30º to + 50ºC	Minimal temperature and pressure dependence
Optical Fluorescence[8]	Only partial flow	-30º to +60ºC	Affected by pressure and temperature
Optical Fluorescence[9]	Only partial flow	0º to +40°C	Affected by pressure
Optical Fluorescence[10]	Only partial flow	0º to +50ºC	Affected by humidity, pressure, and temperature
Tuneable Laser Diodes[11]	Only partial flow	0º to 250ºC (600ºC with additional thermal barrier)	Affected by pressure and temperature

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

Not applicable. There are no lead-free drop-in replacements that can be used.

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7. Proposed actions to develop possible substitutes

[8] Optical Oxygen Sensors | Luminescence-based optical technology (sstsensing.com)

[9] Product: Ultra-Trace Oxygen Sensor Spot SP-PSt9 (presens.de)

[10] TROXSP5 - PyroScience - PyroScience GmbH

[11] Oxygen Gas Analyzer: GPro 500 (mt.com)

(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.

As outlined in section 6, there are alternative oxygen sensors which do not rely on RoHS restricted substances, however these can only be used in specific uses. For example, lead-free partial pressure galvanic oxygen sensors have pressure and humidity dependence and amperometric type sensors require power, are susceptible to high carbon monoxide (CO) and carbon dioxide (CO_2) concentrations and cannot be used in the absence of oxygen.

Alphasense and other sensor manufacturers have carried out research into substitute metals and none are drop-in replacements as outlined above.

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

More research is needed to firstly develop alternative sensors that offer suitable technical performance, after which the design and validation of analyser instruments needs to occur. EU instrument manufacturers are varied, and we are unable to provide details for the full market, however all will need to be certified for their performance and depending on the end use in question the level of redesign and testing will vary.

For example, the testing of alternatives have to consider and evaluate the effects of other gases which might occur during the products lifetime, for oxygen sensors up to 60 kinds of interference gases might occur, with different concentration levels depending on the application. The effects of the gases and their relevant concentrations need to be fully verified as they can influence the sensitivity and accuracy of the oxygen concentration measurement.

In addition to this many applications require instrumentation be ATEX certified.

The following tables provides an estimation on the expected timeframes for the development of an alternative, it is important to note that the following are based on the concept that each test will 'pass' first time. If any further development is required to resolve technical issues the timeframes outlined would be much longer.

Development of lead-free galvanic capillary oxygen sensor

Currently no sensor of this type exists on the market, so it is not certain if a technical alternative is possible. The initial phase of testing will determine if an alternative is viable by testing parameters such as the following:

- Development of core chemistry- 12-18 months
- Sensor house development, including the tooling required for such sensors- 6 months
- Optimisation of the design, including aspects such as the review of differing wetting layers and electrical contacting parts in the sensor- 6 months
- Performance and accelerated life testing- 12 months

Some of this testing can be undertaken in parallel so the overall timeframe is estimated to be around 2-2.5 years.

Field testing of sensors is critical as it involves testing the performance in variable conditions with regard to temperature and pressure, mechanical shock testing, vibration and drop testing. As well as ensuring the performance in the presence of interfering gases. However, if all of these tests identify a suitable alternative then the timeline outlined in Table 5 provides an estimated of how long this would take.

Performance testing to ISO 50104 and certification mandates 23 tests, including the following tests:

- Stability testing: 63 days for fixed and transportable equipment and 20 days for portable equipment
- Environmental testing including pressure, humidity and temperature
- Unpowered storage conditions impact on performance
- Checks on the calibration curve and repeatability of testing
- Checks for air velocity and flow rate (for pump sampling)
- Vibration, drop-testing, warm-up time, time to response
- Power supply variations
- Electro-magnetic compatibility (EMC)
- Performance in other gases
- Verification of software and digital component
- Operation at or below lower limit of detection range

Given the wide range of tests required, the overall time to complete all of the tests will vary with the availability of environmental chambers, gas supply facilities and personnel to undertake the work, and has to be scheduled around other work using the same facilities. As such there is some uncertainty over the timeline estimated.

Table 5 Lead-free galvanic capillary oxygen gas concentration measurement

Development stage	Time required
Sensor manufacture and development	2-2.5 years
Field testing of sensors	12 months
Evaluation by instrument manufactures	6 months +
Performance testing to ISO 50104 and certification	6-12 months
ATEX Approval	18 months - 2 years
Total	4 – 5 years For ATEX rated products: 5.5 - 7 years

Development of lead-free amperometric oxygen sensor

Some instrument manufacturers are migrating to amperometric lead-free oxygen sensors already (when the end use application allows for this). Given the technical differences in amperometric sensors as described above for other applications additional time as outlined in Table 6 is required.

It should be noted that there may be technical characteristics which will be intrinsically different with this using an amperometric sensor compared to galvanic capillary sensors, which may offer decreased technical performance not acceptable by certain customers.

Table 6 Lead-free amperometric oxygen gas concentration measurement

Development stage	Time required
Redesign of instruments (in parallel with the below)	12 months
Evaluation by instrument manufactures	6 months +
Redesign of key performance parameters to be undertaken in consultation/testing with end product customers e.g. warm up time	12-24 months
Performance testing to ISO 50104 and certification	6-12 months
ATEX Approval	18 months - 2 years
Total	3 - 4.5 years For ATEX rated products: 4 - 6 years

Requested extension

Given that the majority of the capillary industrial market is expected to change to amperometric sensors when the technical issues are resolved, we would request the exemption be granted for another 4 years to allow for the necessary testing and development to occur in general applications. For applications which are ATEX rated, we would request that the exemption be granted for another 5.5 years.

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

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

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

☐ Authorisation

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

☐ Restriction

☐ Annex XVII
☐ Registry of intentions

☒ Registration

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

(B) Elimination/substitution:

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

☐ Yes. Consequences? _____

☒ No. Justification: _____

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

☐ Yes.

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

☒ No.

Justification:

Substitutes have different performance characteristics and so are unsuitable

3. Give details on the reliability of substitutes (technical data + information): Not applicable

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

1) Environmental impacts: _____
2) Health impacts: If oxygen sensors were no longer available there could be serious harm to workers which use them both as portable devices and in fixed installations.
3) Consumer safety impacts:

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

(C) Availability of substitutes:

a) Describe supply sources for substitutes: Alternatives do not offer the same technical performance and so are unsuitable

b) Have you encountered problems with the availability? Describe: _____

c) Do you consider the price of the substitute to be a problem for the availability?

☐ Yes ☒ No

d) What conditions need to be fulfilled to ensure the availability? _____

(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: Oxygen sensors provide key safety functionality to many different industries and without them worker safety it impacted. If these industries choose to operate without the sensors there is the potential of death from asphyxiation from working in enclose spaces, mines etc. If the industries are unable to operate without the sensors there could be the loss of certain operations within the EU and consequentially the loss of jobs. A quantitative estimate is not able to be provided due to the widespread and dispersive impacts these would have.

9. Other relevant information

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

_____

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10. Information that should be regarded as proprietary

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

_____
