Exemption Request Form

Date of submission:09 December 2022

1. Name and contact details

1) Name and contact details of applicant:

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Company:	AMETEK MOCON Inc	Tel.:	+1. 763-493-7286
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Function:	New Products Development Engineering Manager	Address:	7500 Mendelssohn Ave N, Brooklyn Park, MN 55428, USA

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

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

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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:

Proposed wording:

Lead anodes in electrochemical Hersch cells for oxygen sensors for measurement of permeation

Duration where applicable: Until January 2028

☐ Other: _____

3. Summary of the exemption request / revocation request

Lead is used as the anode of a Hersch cell, electrochemical sensor which is used to measure the absolute oxygen permeation in industrial monitoring and control devices. Specifically, Hersch cells are used in the production of pharmaceutical products, medical applications such as wound dressings, assessment of the integrity of food packaging and solar panel lifespan calculations and improvements.

Hersch cells can detect oxygen in the range of 200ppt to 70ppm and is an absolute method of measurement (Coulometric) which removes the need to calibrate the sensor (which would be impossible to undertake at the extremely low levels of detection it undertakes).

Alternative lead-free technologies do not offer the same level of detection range as they require calibration and rely on membranes which limit the sensitivity of the sensor.

Alternative lead-free anodes are currently being trialled with some anode/ electrolyte combinations showing initial indications that suitable performance may be achievable. Additional testing of critical performance, followed by reliability and productionisation testing needs to be undertaken to determine if a lead-free solution can offer the required technical performance. As such, although an alternative lead-free solution is being actively sought, it is not yet known if any potential alternative is a viable technical solution and additional time is required to determine this.

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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: Hersch oxygen sensors for measurement of permeation in industrial monitoring and control devices

   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: 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: Absolute oxygen permeation measurement of film, membranes, and packaging.

4. Content of substance in homogeneous material (%weight): >99% lead

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

   4.075 kg of lead will enter the EU annually.

   Please supply information and calculations to support stated figure.
   Information is provided as confidential information

6. Name of material/component: Lead metal used as an anode in a Hersch cell

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?

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

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

The electrochemical reaction 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.

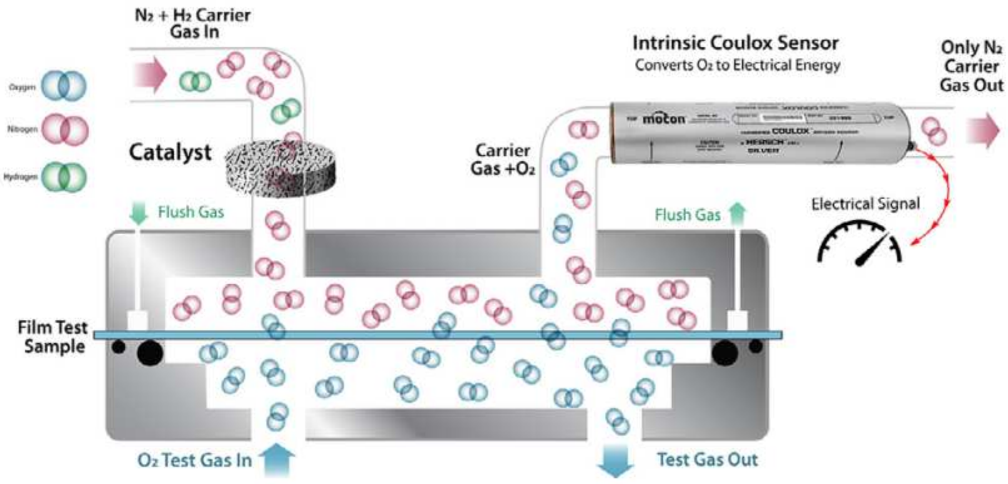

Figure 1 Schematic of test sampling

The electrolyte is potassium hydroxide (KOH). The cell with one mole of oxygen (22.4 litres at 0 ºC and 760 mmHg) produces four Faradays of current. With one Faraday = 96,500 Ampere-seconds, each mole of oxygen will produce 4 x 96,500 = 3.86×10^5 Ampere-seconds. One cc of oxygen in 24 hours = 0.000199 Amperes of current. This means that the sensor has a sensitivity as little as 100 picoamps and a repeatability of 500 picoamps.

There are several properties that are important in Hersch cells:

- Must follow Faraday's Law
- Oxygen efficiency measurement > 95%
- Flat discharge curve (accuracy) to enable the measurement of oxygen concentration below 100ppm, for example Hersch cells can detect oxygen in the range of 200ppt to 70ppm
- Absolute method of measurement (Coulometric) which removes the need to calibrate the sensor which would be impossible to undertake at the extremely low levels of detection it undertakes.
- High Energy Density which results in a sensor with a sensor life of at least a year for this oxygen permeation application at the varying ranges of detection.
- Inherent method of maintaining electrolyte health over years allowing an average sensor life of a year for most models, but for some this can be up to 4 years
- Temperature independent and able to operate in most sensor designs between 10-40^{o}C
- Sensor response (fast): <8 minutes to 99% of full reading
- Compatible with nitrogen, hydrogen, water vapor
- No corrosion of the anode when in contact with the electrolyte or secondary chemical reactions that negatively impact the lead reaction
- No chemical effects that cause excessive internal pressurisations of the sensor
- Size and format similar to current sensor
- Specific to Oxygen: Limited cross sensitivity to ensure that other reactions are not undertaken, and the sensor has high sensitivity
- Not affected by moisture, pressure changes or flow dependent.

MOCON supplies a number of different devices using Hersch cells to undertake permeability testing, with different models offering different technical characteristics, such as package testing under environmental conditions, film testing in standard ranges and conditions, high sensitivity film testing and high throughput film testing, with between 1 to 4 test cartridges containing Hersch cells per device. To the best of our knowledge MOCON is currently the only supplier of lead based Hersch sensors for the global market.

The sensitivity of Hersch cells are critical to the end users it serves as 89% of permeation measurements are made below 70ppm, with 60% of measurements below 2ppm and 10% below 20ppb.

Coulometric measurement allows for a calibration free methodology which is critical as there are no calibration standards available at the sensitivity range in which these devices operate. For example, the lowest level of NIST calibration gas is 1 Mole% oxygen (10,000 ppm) and the best "Certified" gas is about 10 ppm (± 20%) which is still 10,000 times higher than where the application requires accurate measurements.

MOCON Permeation Testing Analysers are the basis for many global permeability testing standards such as ASTM D3985: Standard Test Method for Oxygen Gas Transmission Rate Through Plastic Film and Sheeting Using a Coulometric Sensor and ASTM F1249: Standard Test Method for Water Vapor Transmission Rate Through Plastic Film and Sheeting Using a Modulated Infrared Sensor.

Hersch cells support a number of industries requiring high-sensitivity oxygen measurement, the following are indicative examples:

- Manufacture of certain pharmaceutical products which are sensitive to extremely low levels of oxygen
- Integrity of food packaging design- for example testing the permeation through packaging barrier material to ensure it is below 0.001 cc/m^2·day (0.36 ppb v/v) with an upper range of 200 cc/m^2·day (72 ppm v/v).
- Quantifying oxygen breathability for medical wound dressings to help minimise infections
- Lifespan of solar panels, which require a high oxygen barrier to ensure component integrity and in order to prolong the lifetime of the panels. Long-lasting Solar Panels are necessary to generate “green” energy; which results in benefits for the environment.

All of which require permeation measurements to be NIST traceable. It is also worthwhile bearing in mind certain industries such as solar panels, and organic light-emitting diode (OLED) industries would benefit from even lower levels of sensitives for their 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 is does not self-corrode in the absence of oxygen and does not produce a current without oxygen present. However, lead when within the cell reacts rapidly when in contact with oxygen, giving a fast response time to the sensor.

The solubility of lead metal in potassium hydroxide electrolyte is exceptionally low, therefore does not migrate to the sensing electrode, precipitate, or block the sensing electrode sights. This gives the Hersch cell extraordinarily long, stable sensitivity life, in the order of at least a year and up to 4 years for some designs.

The lead within the Hersch Cell allows for the “Coulometric” analysis and follows Faraday’s Law at ppt levels. This removes the need to calibrate at these extremely low levels, while providing a high degree of sensitivity.

Lead anodes in contact with the potassium hydroxide electrolyte do not create any secondary reactions, as such it does not affect the primary reaction which converts the oxygen concentration to a specific current measurement.

Gases such as hydrogen are not generated as part of the reaction when using lead, which would otherwise build up pressure and damage the sensor in the bypass state.

Energy Density of the lead anode in conjunction with the potassium hydroxide electrolyte are high which gives acceptable sensor life for this oxygen permeation application at the varying ranges of detection.

All of the above listed characteristics are essential, and any substitute must have all of them.

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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. End-of-life Hersch cell sensors are returned to the original manufacturer in the United States of America for recycling.

Please indicate where relevant:

☒ Article is collected and sent without dismantling for recycling 100% of the sensors which are returned are collected and sent without dismantling for recycling. Any sensors not returned to MOCON are assumed to be recycled according to local waste requirements.

☐ 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

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 4.075 kg calculated on the basis that the same number of articles placed on the market equates to those being 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

Alternative anode metals, with a combination of various acid and alkali electrolytes have been researched. The electrode potential of the anode needs to be similar to that of lead as otherwise the anodes create a galvanic couple with a small voltage between them which then gives a false and incorrect oxygen concentration. The voltage also creates a current between the anodes, hydrogen is generated, and the anodes self-corrode. That is not to say that certain applications cannot use reactive metals such as zinc, but the performance of these types of devices do not offer the required technical performance offered by lead based Hersch cells. Mocon is testing combinations of substitute anodes and electrolytes which is summarised in section 7 below.

Typical performance can be measured in terms of energy density (lifetime of the sensor), sensor efficiency, sensor response time, sensor selectivity, linearity so that the sensor is absolute and therefore does not require calibration and low electrical noise and baseline so that sensitivity is maximised.

Calibration methods

Almost all oxygen sensing technologies are indirect comparator types of measurements vs absolute due to the inclusion of a membrane or a capillary to keep the electrolyte from leaving the sensor. As a result of this these types of sensors are therefore only measuring a fraction (< 0.001%) of the total oxygen present. Inherently, this means they are far less sensitive to oxygen, and they are not measuring all of the analyte (O_2). If a sensor does not collect and measure all the analyte, then it needs to be calibrated because the sensor is only measuring some unknown fraction of the total oxygen. Sensors with membrane or capillaries have to be flow and temperature compensated and are sensitive to pressure transients. These dependencies add to the measurement uncertainty and effect reliability.

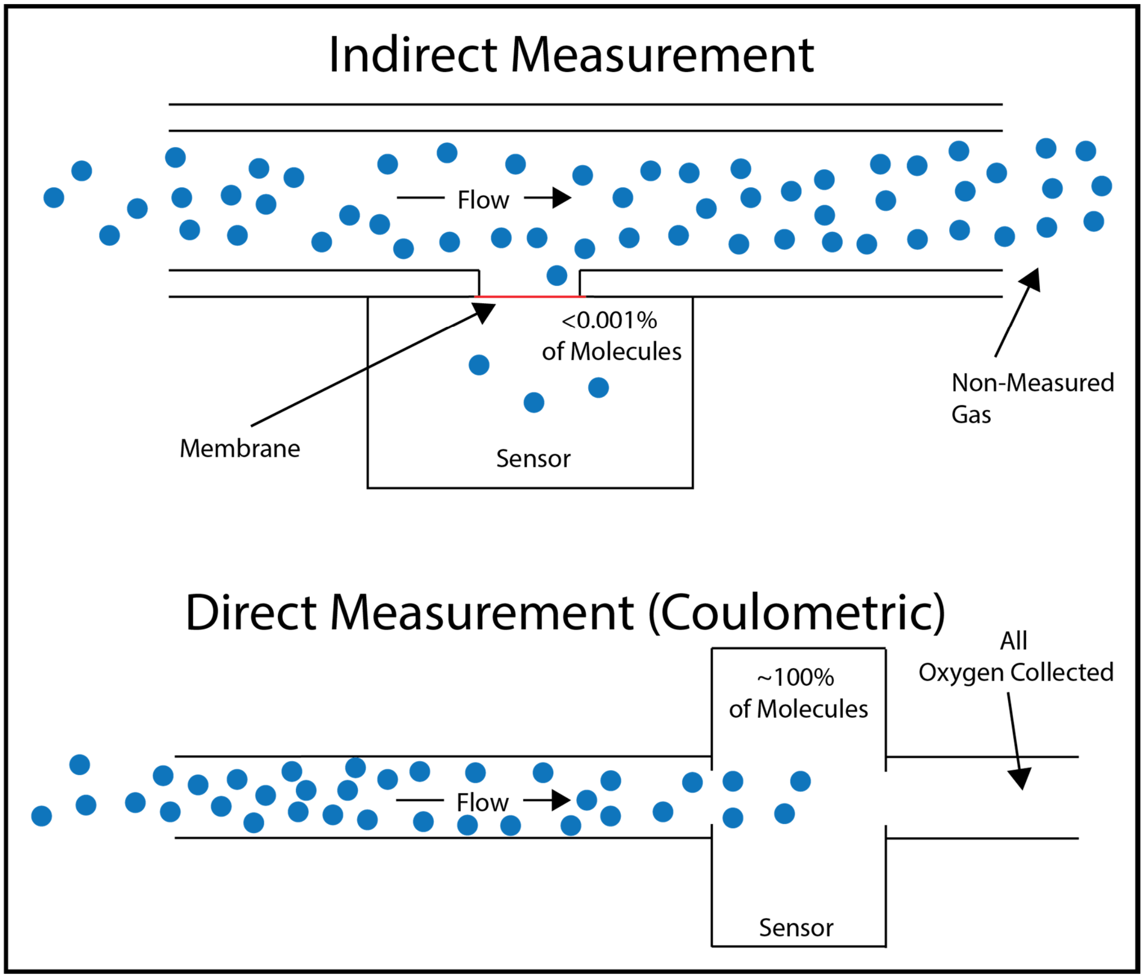

Figure 2 Comparing direct measurement vs indirect measurement.

This is the case for other types of electrochemical sensors such as ones used in online and offline process monitoring, headspace analysis in packaging material, Gas Mixing feedback control, Safety Monitors, Automotive Oxygen Sensors, Medical Device Oxygen Sensors, and Emissions monitors. As well as other technologies such as Tunable Laser Diodes, Zirconia, Thermal Conductivity Detectors (TCD), Pulsed Discharge Helium Ionization Detector (PDHID), and Optical Fluorescence, which are discussed more below. Also, lead anode galvanic sensors which have capillaries or diaphragms must be regularly calibrated.

To accurately calibrate the sensors a NIST traceable gas must be used. To the best of our knowledge, the lowest NIST Standard Reference Material which is available for purchase from NIST is 2 Mole % (20 000ppm). There are a few gas manufacturers who can make a lower value, but it must go through NIST's NIST Traceable Reference Material (NTRM). The manufacturer must make at least ten tanks which follow a NIST Traceable process. The data is sent to NIST and verified. The lowest oxygen concentration that NIST has seen done with this process is 10 000ppm +/- 1% relative with the most common level made being 210 000ppm. There are some manufacturers who claim they can make a NIST traceable gas down to 10ppm but when AMETEK MOCON contacted NIST they stated they have never seen a gas with an accurate oxygen concentration that low. Therefore, these claims of 10ppm are unable to be substantiated.

Even if it were possible to dilute the 10,000ppm gas to reach the lower concentrations the relative uncertainty would be multiplied down to the level of measurement, and therefore be unsuitable due to this uncertainty[1]. Further details are provided in the confidential submission. There is also the consideration that, the calibration system is also leak free and therefore no additional oxygen is able to enter into the system. As well as that the nitrogen mixing gas is also free of oxygen.

Due to all of these reasons it is highly unlikely that a reference gas to low enough oxygen levels is technically feasible and is why a calibration free method is so essential.

Membranes and capillaries are included in many sensors' designs as they increase the life of the sensor, but they all decrease the sensitivity of the sensor:

- Reduce electrolyte depletion (loss of water). Most electrochemical sensors use an aqueous electrolyte. Once the water evaporates the electrolyte doesn't conduct ions and the sensor no longer works. Without the barrier to water loss the sensor would dry out in about 2-3 weeks. As such there are sensor designs with the following types of barriers but these introduce other limiting factors:
    - A selective barrier that blocks water permeation but allows oxygen through. Teflon is one of the best selective barriers as it has a water/oxygen ratio of 1:2000. However, this reduces the amount of the original oxygen reaching the electrodes by 1000-10,000X.
      It is also noted that there is an upcoming per- and polyfluoroalkyl substance (PFAS) restriction under REACH which presumably will impact the use of Teflon, and therefore would be classified as a regrettable substitution.
    - A water barrier, which extended the life of the sensor to 1 or 2 years. However, this results in a significant loss of sensitivity, with the best results using this technology able to undertake testing to 100 ppm.
- Barrier are also used for the analyte which have the same implications as those listed for electrolyte. However, without the barrier the expected lifetime of a sensor relying upon a membrane or capillary without either of these in place is less than a day when exposed to room temperature conditions.

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[1] One difficulty is that the dilution gas, such as so-called "oxygen-free nitrogen" will contain oxygen at a low but unknown concentration. For example, https://www.agas.com/au/products-services/industrial-gases/oxygen-free-nitrogen-ofn/ This gas is reported to contain less than 10ppm of oxygen.

The following table aims to provide an analysis of some alternative oxygen sensors currently available on the market, and their sensitivity such that the difference in technical performance is easily identifiable.

Table 1 Comparing sensitivity of oxygen sensing devices with the Hersch cell

Technology	Detection range	Response Time	Carrier Gas Analyzed by Sensor	Sensor calibration required?	Notes
Hersch cell	200ppt to 70ppm	T90 <5 mins	100%	No	Absolute measurement, not affected by flow, temperature, or pressure
Tunable Laser Diodes[2]	Lowest limit 100 ppm	T90 <2 s	Only partial flow	Yes	-
Optical Fluorescence[3]	Lowest limit 100 ppm	T90 < 30s (typical)	Only partial flow	Yes	-
Optical Fluorescence[4]	Lowest limit 0.5 ppm	T90<3sec	Only partial flow	Yes	Affected by pressure
Optical Fluorescence [5]	Lowest limit 50ppm	T90< 2s	Only partial flow	Yes	Affected by humidity, pressure, and temperature
Zirconia[6]	Lowest limit 5000ppm	T90<4s	-	Yes	-
Zirconia[7]	100-1000000 ppm	T90<5s	Only partial flow	Yes	-
Thermal Conductivity Detectors (TCD)[8]	Lowest limit 5000ppm	T90<3s	Only partial flow	Yes	-
Pulsed Discharge Helium Ionization Detector (PDHID)	Due to column analysis the differentiation of oxygen and helium peaks is unable to be established[9] even though helium is normally used as the gas flow in the column				

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

This has been included in section 6(A).

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.

The length of a Hersch sensor development is a considerable undertaking due to the technical requirements the sensor has. For example, changing a single component in the cadmium version of the Hersch cell took 3 years to undertake and fully qualify.

Testing is underway to identify and qualify alternative a lead-free solution, details of the procedural steps are outlined in the confidential submission. Testing to determine the corrosion and chemical compatibility has been undertaken (Table 2), with more detailed observations shared in the confidential submission, identifying which potential alternatives are worthwhile taking forward for subsequent testing.

Table 2 Corrosion and chemical compatibility testing

Anode Material	Electrolyte	Observations
Anode Material 1	Electrolyte Material 1	Not suitable
Anode Material 14	Electrolyte Material 1	Not suitable
Anode Material 6	Electrolyte Material 1	Potential alternative to be taken forward for subsequent testing
Anode Material 5	Electrolyte Material 1	Potential alternative to be taken forward for subsequent testing

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

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

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

[5] TROXSP5 - PyroScience - PyroScience GmbH

[6] Zirconia Oxygen Sensor | O2 Sensor | Manufacturer (sstsensing.com)

[7] Dansensor CheckMate 3 - Benchtop Analyzers | AMETEK MOCON

[8] LFE OEM Thermal Conductivity Detector (TCD)

[9] 5988-6739EN.qxd (agilent.com)

Anode Material	Electrolyte	Observations
Anode Material 4	Electrolyte Material 1	Potential alternative to be taken forward for subsequent testing
Anode Material 11	Electrolyte Material 1	Not suitable
Anode Material 13	Electrolyte Material 1	Not suitable
Lead	Electrolyte Material 1	Suitable performance for benchmarking
Anode Material 3	Electrolyte Material 1	Not suitable
Anode Material 9	Electrolyte Material 1	Potential alternative to be taken forward for subsequent testing
Anode Material 2	Electrolyte Material 1	Not suitable
Anode Material 1	Electrolyte Material 2	Not suitable
Anode Material 6	Electrolyte Material 2	Potential alternative to be taken forward for subsequent testing
Anode Material 5	Electrolyte Material 2	Potential alternative to be taken forward for subsequent testing
Anode Material 4	Electrolyte Material 2	Potential alternative to be taken forward for subsequent testing
Anode Material 11	Electrolyte Material 2	Not suitable
Anode Material 13	Electrolyte Material 2	Not suitable
Lead	Electrolyte Material 2	Suitable performance for benchmarking
Anode Material 3	Electrolyte Material 2	Not suitable
Anode Material 9	Electrolyte Material 2	Potential alternative to be taken forward for subsequent testing
Anode Material 2	Electrolyte Material 2	Not suitable
Anode Material 6	Electrolyte Material 3	Potential alternative to be taken forward for subsequent testing
Anode Material 1	Electrolyte Material 3	Not suitable
Anode Material 14	Electrolyte Material 3	Not suitable

Anode Material	Electrolyte	Observations
Anode Material 5	Electrolyte Material 3	Potential alternative to be taken forward for subsequent testing
Anode Material 4	Electrolyte Material 3	Not suitable
Anode Material 11	Electrolyte Material 3	Not suitable
Anode Material 13	Electrolyte Material 3	Not suitable
Lead	Electrolyte Material 3	Suitable performance for benchmarking
Anode Material 3	Electrolyte Material 3	Not suitable
Anode Material 9	Electrolyte Material 3	Potential alternative to be taken forward for subsequent testing
Anode Material 2	Electrolyte Material 3	Not suitable

Energy density testing was then undertaken for potential alternatives, with details of the exact testing regime and more detailed results outlined in the confidential submission. The following Figures show how some of the potential alternatives perform, with a lead anode as comparison.

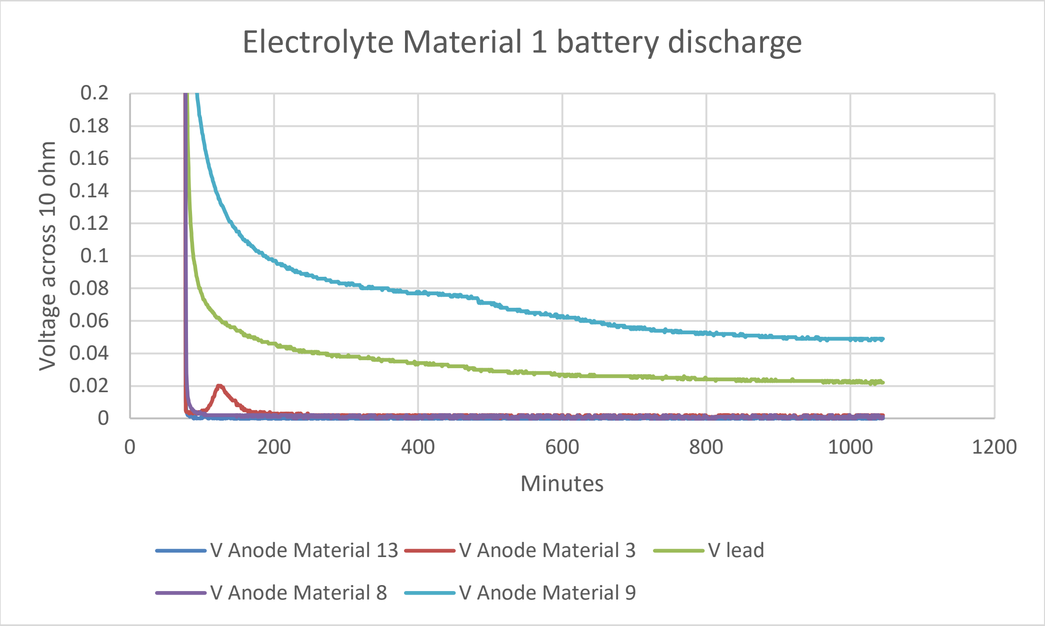

Figure 3 Electrolyte Material 1 battery discharge

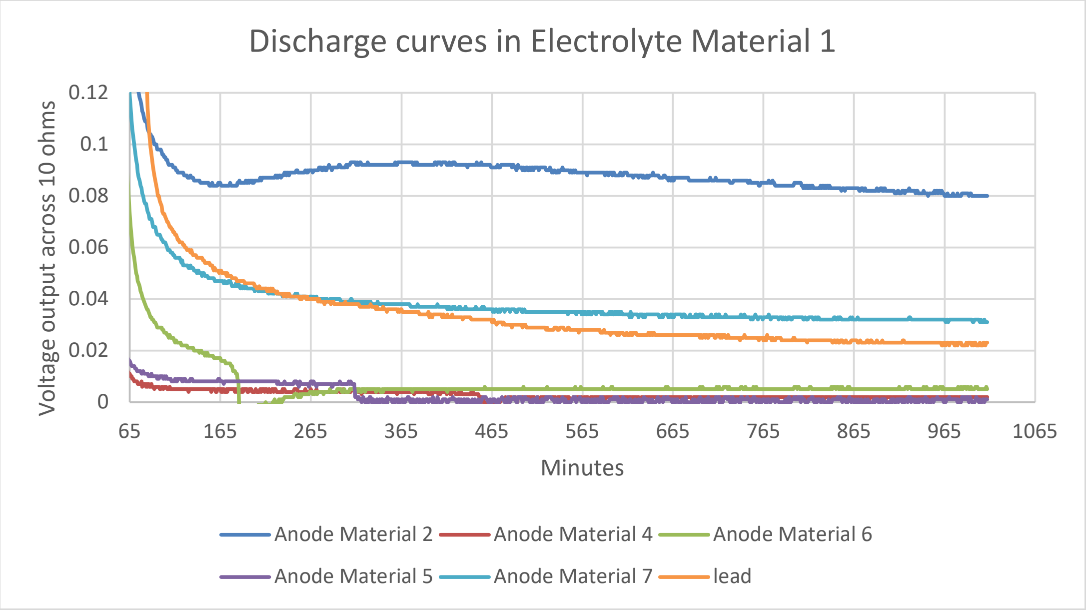

Figure 4 Discharge curves in Electrolyte Material 1

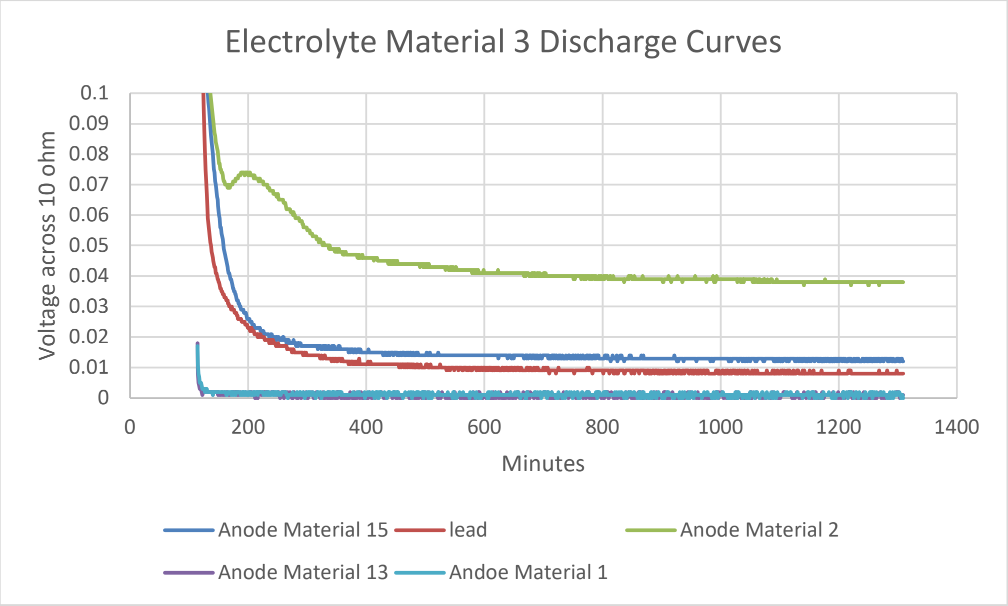

Figure 5 Electrolyte Material 3 Discharge Curves

Similar testing for the other potential alternatives was undertaken, with all testing summarized in Table 3.

Table 3 Energy Density Test Results Summary sorted by highest energy density

Anode Material	Electrolyte	Amp*Hours
Anode Material 9	Electrolyte Material 1	>2.48
Lead Plates	Electrolyte Material 1	>1.03
Anode Material 2	Electrolyte Material 1	>0.18
Anode Material 2	Electrolyte Material 3	>0.18
Anode Material 9	Electrolyte Material 1	>0.18
Anode Material 3	Electrolyte Material 3	0.16
Anode Material 15	Electrolyte Material 3	>0.12
Lead	Electrolyte Material 3	>0.12
Lead	Electrolyte Material 1	>0.11
Anode Material 7	Electrolyte Material 1	>0.10
Anode Material 1	Electrolyte Material 3	0.099
Anode Material 13	Electrolyte Material 3	0.094
Anode Material 5	Electrolyte Material 3	0.080
Anode Material 7	Electrolyte Material 3	0.075
Anode Material 4	Electrolyte Material 3	0.070
Anode Material 13	Electrolyte Material 1	0.067
Anode Material 9	Electrolyte Material 3	>0.064
Anode Material 8	Electrolyte Material 1	0.063
Anode Material 6	Electrolyte Material 1	0.059
Anode Material 3	Electrolyte Material 1	0.057
Anode Material 4	Electrolyte Material 1	0.055
Anode Material 5	Electrolyte Material 1	0.053

For the most promising combinations, a prototype Hersch oxygen sensor protype was made, such that it can be installed in an AMETEK MOCON OX-TRAN Analysers to test efficiency, response, background and note other reactions.

The results obtained to date are outlined in Table 4 (with some additional information included in the confidential submission). The results to date show that a number of the potential alternatives do not have the necessary technical characteristics and as such only some combinations will be taken forward for subsequent testing.

Table 4 Protype testing

Anode	Electrolyte	Cathode	Efficiency	Response time	Baseline	Other Reaction
Anode Material 2	Electrolyte Material 3	Cathode Material 1	Started at 70% but reduced rapidly	Acceptable	Acceptable	Possible other reaction
Anode Material 2	Electrolyte Material 1	Cathode Material 1	Not able to be tested*	Acceptable	Too High	Possible other reaction
Anode Material 3	Electrolyte Material 3	Cathode Material 1	Not able to be tested*	Acceptable	Too High	Other reaction occured
Anode Material 3	Electrolyte Material 1	Cathode Material 1	Not able to be tested*	Acceptable	Too High	Other reaction occured
Anode Material 9	Electrolyte Material 1	Cathode Material 1	Shows efficiencies in the 90% or higher	Acceptable	Low background	Acceptable
Anode Material 12	Electrolyte Material 1	Cathode Material 1	85% after 3 days	Needs improvement if taken forward	Testing to be completed	Acceptable
lead	Electrolyte Material 1	Cathode Material 1	>98.75% efficient	Acceptable	Low background	Acceptable
Anode Material 8	Electrolyte Material 1	Cathode Material 1	<5% efficient	Acceptable	Acceptable	Acceptable
Anode Material 9	Electrolyte Material 2	Cathode Material 1	83% efficient	Testing to be completed	Testing to be completed	Acceptable

* Not able to be tested as baseline was too high

Note that in Table 4, none of the possible substitutes equals the efficiency of lead. Therefore, there is no certainty that a suitable substitute will be identified, however, this work is continuing with the most promising materials.

Subsequent to this, accelerated life testing is planned to be undertaken on the prototype sensors selected to be taken forward, measuring the oxygen transmission rate of the film to ensure there is no drop off in efficiency. Testing for each sensor is a duration of 6 months. Two instruments are available for this testing so only two life tests can occur at one time during a 6-month period.

If sensors show suitable characteristics during the accelerated life testing, another key and usually defining characteristic is selectivity testing to ensure that potential alternative sensors do not respond to carrier gases.

After this the following testing is planned, but has not yet started for any of the potential alternatives:

- Sensitivity
- Linearity
- Backwards compatibility
- Manufacturability

After this stage of initial testing reliability testing and productionisation, also has to be undertaken as outlined in section 7B below.

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

The following table 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.

As outlined above the testing for the accelerated life testing and key parameter testing is currently underway, but still has a number of tests to be undertaken on the most promising potential alternatives.

Table 5 Qualification requirements

Stage	**Requirement**	**Indicative Timeframe**
1	Accelerated life testing as outlined above	6-12 months
1	Key parameter testing, such as response time, low level detection, sensitivity to other gases (such as hydrogen, nitrogen, and water vapour), linearity as outlined above and including the build and testing of protypes until the necessary technical performance is achieved.	18-24 months
2	Reliability testing	12-18 months
3	Productionisation	3-6 months
Total		3 ¼ years- 5 years

The above timelines are based on the assumption that suitable technical performance is able to be achieved with one of the currently identified potential alternatives and further process refinements or alternatives are not required to be undertaken. Until stage 1 and 2 testing is completed it is not known if an alternative is able to provide the necessary technical requirements as much of its viability depends on alternatives intrinsic chemical characteristics. As such there is some uncertainty in the timeline of qualification, with current estimates based on the best information available at the point of writing this request.

Reliability testing will include the following tests to ensure that the sensor is able to operate at the stated technical requirement for its lifetime and no other factors influence its operation:

- Shock and vibration testing to ensure that the sensor is not affected. Testing for this is estimated to take 2-3 months,
- Pressure loading of the sensor. Testing for this is estimated to take 2-3 months,
- Impact of exposure to H_2 and N_2 over extended periods of time to ensure that it does not affect the sensitivity of the sensor. The testing for this takes an estimated 3-6 months,
- Temperature cycling to replicate shipping and in service use. Testing for this is estimated to take 3-4 months, and
- Over-range recovery of the sensor to ensure the sensor is able to operate as effectively in the extreme conditions of the sensor. Testing for this is estimated to take 2-3 months.

Productionisation includes aspects such as:

- Securing the supply chain for the new materials,
- Changes in work instructions for sensor build,
- Manuscript updates,
- Changes in sensor checkout procedures,
- Bill of Materials changes for sensor,
- Assembly training,
- Part number creation,
- Sensor packaging design,
- Service and checkout training and
- Possible updates to instrument software.

As outlined above, although there are some initial signs that a lead-free alternative might be possible at this time, it cannot be confidently stated that an alternative material exists. It is only towards the end of the above outlined test period that this would be able to be stated.

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

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

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

☐ Authorisation

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

☐ Restriction

☐ Annex XVII
☐ Registry of intentions

☒ Registration- https://echa.europa.eu/registration-dossier/-/registered-dossier/16063

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: Substitution is currently technically impractical

2. Can the substance named under 4.(A)1 be substituted?
   - ☐ Yes.
     - ☐ Design changes:
     - ☐ Other materials:
     - ☐ Other substance:
   - ☒ No.

     Justification: Substitution is currently technically impractical
3. Give details on the reliability of substitutes (technical data + information): None yet 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:

There are several users of high-sensitivity Hersch oxygen sensors requiring high sensitivity measurements. Applications affecting human health and the environment include:

- The pharmaceutical industry uses Hersch cell sensors to ensure certain medications are protected from oxygen. This is required to maintain strength, and therefore public safety. The high instrument sensitivity is required to manufacture some medicines which are extremely sensitive to even trace amounts oxygen.
- Freshness and Safety in food packaging design, which requires ppt sensitivity, is the largest application of Hersch cell sensor technology. This affects consumer safety and potentially human health.
- The solar panel industry relies on ppt oxygen sensors instruments to measure their high oxygen barriers. Oxygen barriers are required to prolong the lifetime of the panels. Long-lasting Solar Panels are necessary to generate “green” energy, which results in benefits for the environment.
- Similarly, the OLED industry requires oxygen barriers to create OLED screens. Only very sensitive instruments using Hersch cells are capable of measuring at the levels they require.

⇨ Do impacts of substitution outweigh benefits thereof? Not applicable
Please provide third-party verified assessment on this: _____

(C) Availability of substitutes: n/a

a) Describe supply sources for substitutes: None 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? See above

(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:

If this exemption were to expire before an accurate and reliable alternative can be developed and commercialised, there would be a very significant risk to human health due to an ability to manufacture medicines at very low oxygen concentrations and because food safety would be compromised. Some manufacturing may not be possible without Hersch cells. It is not possible to quantify these impacts.

9. Other relevant information

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

_____

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:

_____