

19/01/2023

Mr. H. ENGELKAMP  
Policy Officer RoHS Directive  
European Commission  
Directorate-General for the Environment  
B3 – From Waste to Resources  
Breydel 2 – Avenue d'Auderghem 19  
B-1040 Brussels/Belgium

Dear Mr Engelkamp,

Alphasense is submitting the attached RoHS exemption renewal request. We are aware that there has been a recent review of this exemption under Pack 21, but this did not consider the types of instruments and sensors that we produce.

The following have been recommended for renewal of exemption 1b as part of the Pack 21<sup>1</sup> study:

1(b)(I) Lead anodes in electrochemical sensors that measure oxygen concentrations of inhaled and/or exhaled air for patients, and that are consumables in medical devices put on the market before 26 May 2024.

1(b)(II) Lead in galvanic oxygen sensors in monitoring and control instruments that are not handheld devices, (a) designed for the measurement of oxygen in gases with a response time <3s (t95) and (b) sensors designed for the measurement of dissolved oxygen in concentrations below 30 ppb

However, neither of these proposed exemption renewals cover the necessary uses of lead anodes in electrochemical oxygen gas sensors that are used in instruments produced by Alphasense because of the following reasons.

The wording of 1(b)(I) is limited to measuring the oxygen concentration of inhaled and or exhaled air for patients in medical devices. Our exemption renewal request only covers industrial monitoring and control instrument applications.

The wording of 1(b)(II) is limited to measuring the oxygen concentration within a less than 3s response time and with a dissolved oxygen concentration of less than 30 ppb. Alphasense's sensors and associated instruments have a fast response time but this cannot be characterised as being in less than 3 seconds. The sensors are designed to measure oxygen gas concentrations up to 30%. These sensors measure oxygen concentrations in gas mixtures, not dissolved oxygen gas. Furthermore, the proposed expiry date is much too soon for the development of substitutes, especially where ATEX approvals are required.

We hope this clarification is useful and if there is any other information which is useful for the review of our application, please let us know.

Yours sincerely,



Richard Dudeney