1st Questionnaire Exemption Request No. 2013-1

Exemption for Lead as thermal stabilizer in Polyvinyl Chloride (PVC) used as base for substrates in amperometric, potentiometric and conductometric electrochemical sensors

Abbreviations and Definitions

IL – Instrumentation Laboratory Inc.

Background

The Öko-Institut together with Fraunhofer IZM has been appointed within a framework contract for the evaluation of applications for granting, renewing or revoking an exemption to be included in or deleted from Annexes III and IV of the new RoHS Directive 2011/65/EU (RoHS 2) by the European Commission.[1]

IL has submitted the above mentioned request for exemption which has been subject to a first evaluation. The information you have referred has been reviewed and as a result we have identified that there is some information missing and a few questions to clarify concerning your request.

Questions

1. The information provided with the application regards the use of lead as a thermal stabilizer in sensor cards used in the applicants GEM 3000 and GEM 4000 devices. Please explain the relation of the application discussed to the proposed wording, more specifically to “amperometric, potentiometric and conductometric electrochemical sensors” – please specify which aspects/applications of the discussed sensor cards fall under each of these terms.

   IL Response: Amperometric, potentiometric and conductometric electrochemical sensors are 3 subclasses of electrochemical sensors, used for measurement of different analytes in blood. All 3 types of sensors are built on the sensor cards used in the GEM 3000 and GEM 4000 devices. When evaluating alternative thermal stabilizers in the PVC sensor card, performance of all 3 types of sensors needs to be tested.

[1] Contract is implemented through Framework Contract No. ENV.C.2/FRA/2011/0020 led by Eunomia

2. The information provided with the application demonstrates various testing that was performed concerning possible substitutes for the lead thermal stabilizer, in the production of the sensor card.

   a) As most information is regarded as confidential, please summarize the performance of lead based cards in comparison with alternatives, to demonstrate in what respect possible alternatives cannot be used as substitutes.

      IL Response: Lead-based cards were compared to performance of cards made with alternative (non-lead) thermal stabilizers from at least 3 different commercial sources. The alternatives included PVC cards with organo-tin thermal stabilizers and other metal-based stabilizers, proprietary to the suppliers of the PVC resins. In all cases, performance of the sodium ion sensor in the GEM 3000 and 4000 was adversely affected, producing incorrect readings, in the presence of metal-based thermal stabilizers other than lead.

   b) In your answer please refer to the technical capabilities provided by lead as a thermal stabilizer and how possible substitutes perform in comparison.

      IL Response: PVC using lead as a thermal stabilizer does not interfere with performance of the sodium sensor in the GEM 3000 and GEM 4000 products. PVC sensor cards using organo-tin compounds as thermal stabilizers have been tested and interfere with proper functioning of the sodium sensor, resulting in incorrect readings. Lead-stabilized PVC does not interfere with sodium sensor readings.

   c) In your answers, please refer to possible substance-substitutes such as calcium-zinc, calcium stearate, zinc stearate, reducing the amount of lead to meet the RoHS substance restrictions, etc., as well as possibilities for substituting PVC so as to eliminate the need for using lead.

      IL Response: Current research is focused on completely eliminating lead from PVC by using non-metallic, organic thermal stabilizers. Work in this area is still preliminary and conclusions regarding suitability of organic thermal stabilizers for our application cannot be reached at this time.

   d) As it is understood that research into possible substitutes is on-going, please clarify what substances have been found unsuitable and which are considered for further research into substitution possibilities for lead in sensor cards.

      IL Response: Metal-based stabilizers, other than lead, have been found unsuitable. Early testing of non-metallic organic stabilizers is promising; however, more testing is required before a conclusion can be reached regarding suitability as a substitute for lead in sensor cards.

3. In page 7 of the request, attention is drawn to the existing RoHS 2, Annex IV Ex. 1a and exemption 1b. Please clarify the relevance of these exemptions to the application at hand.

   IL Response: Upon further review of RoHS 2, Annex IV, exemptions 1a and 1b, we have determined that the exemptions to not apply to the sensor card for the GEM 3000 and GEM 4000. Exemption 1a appears to exclude from the RoHS directive lead and cadmium in ion selective electrodes which are used for measurement of lead and cadmium, and leaded glass used glass pH electrodes. Exemption 1b applies to lead anodes for electrochemical oxygen sensors which are not used in the GEM 3000 and GEM 4000. The sensor cards of the GEM 3000 and GEM 4000 contain lead, but lead is not essential to electrochemical measurement processes.

4. In your application it is clarified that a different ratio of lead is used in sensor cards produced for GEM 3000 devices and for GEM 4000 devices. Respectively, the card weight is also different. It is also mentioned that as new models are developed, in light of research developments, it has been possible to reduce the amount of lead needed, and it is assumed that with time, less and less lead shall be required to provide the relevant qualities.

   a) Is it to be understood that GEM 4000 models are a more developed model that shall gradually replace GEM 3000 and other earlier models?

      IL Response: Yes, the GEM 4000 model is more developed and shall gradually replace the GEM 3000 and other earlier models.

   b) Do the different models provide the same functions, or does the (newer) GEM 4000 model have a different range of performance?

      IL Response: The GEM 4000 model offer an expanded range of performance compared to the GEM 3000 and earlier models.

5. The request is made for sensor cards used in a specific device, produced by a single manufacturer:

   a) Please state if additional manufacturers provide and market similar components / devices.

      IL Response: Yes, additional manufacturers provide and market similar devices.

   b) If so, please provide a list of such manufacturers and devices

      IL Response: Below is a list of the major manufacturers of such devices.

      - Radiometer Medical: ABL 800 and ABL 90 systems
      - Siemens Healthcare: Rapidlab 800 and Rapidpoint 500 systems

- Abbott Laboratories: i-STAT handheld monitors

c) If not, please state what other applications/devices/methods are in place in hospitals, clinics, etc., where GEM 3000 or GEM 4000 devices have not been acquired and provide a summary of the relevant advantages/disadvantages of each in comparison to the GEM systems.

6. In the application, an assumption is given as to how much time is estimated to be needed before a substitute is found. It is likewise stated that further time shall be needed for tasks such as redesign, reliability testing, product requalification as required by relevant Directives and production, before RoHS substance free sensor cards can be made available on the market. Please provide a summary of the time (in months/years) assumed to be needed for each of these stages. If relevant you may regard a range of time to demonstrate the impact of best case – worst case scenarios on the time needed for compliance.

IL Response: Below is an estimated time line considering both the GEM 3000 and GEM 4000 systems.

- Screening of several PVC formulations using substitute stabilizers: 6 months
- Supplier agreements, scale up, and verification of lot to lot consistency: 6 months
- Verification and validation of a final PVC formulation in GEM 3000 and 4000 systems (detail below): 9 months
    - Use life testing in the GEM 3000 and 4000 systems
    - Evaluation of interfering substances
    - Evaluation of limits of detection
    - Method comparison to prove equivalency with existing product
    - Clinical studies at customer sites
    - Shelf life (stability) equivalent to existing product
- Submission to and approval by regulatory agencies: 6 months
- Total: 27 months

7. As the IL request regards various aspects where confidentiality is an issue, please, if relevant provide a public and non-public version of your response.

Not applicable.