

Questionnaire Exemption Request No. 2013-1

Exemption for Lead as a Stabilizer in the Sensor Card Used in the Cartridges for the GEM Family of Critical Care analysers

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

Instrumentation Laboratory Inc. (IL) has applied for an exemption for

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

The applicant explains that the sensor card is used in the cartridges of the GEM family of Critical Care Analysers. The GEM analyser is used for blood testing and serves as a critical analytical instrument in Hospital Labs, Operating Rooms, Emergency Rooms and point of care at bedside across the Global and EU Health Care Sector.

The disposable cartridge functions as the heart of the GEM analyser where the actual testing process takes place. The sensor card is the primary unit of the cartridge and represents a complicated and compact technological unit whose function is based on electrochemical processes taking place on the sensor card during the testing process allowing real time reporting and documentation of testing results.

The sensor card in the disposable cartridge is made of polyvinyl chloride (PVC). Use of PVC as the sensor card material dates back to the 1980s when the GEMStat and GEM 6 analysers were first launched, and the same moulded card has been carried forward to the currently manufactured analysers (GEM Premier 3000, GEM Premier 3500, GEM Premier 4000 and GEM Premier 5000). The sensor card is located in the disposable cartridge which is used in these instruments. Lead is used as a thermal stabilizer in the production of the PVC cards and thus would require an exemption to enable devices to remain in use once the substance restrictions of RoHS apply.

The applicant puts forward the following main arguments.

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

- Possible substitutes for lead in this application are not known to the applicant. Research into possible substitutes has not yet resulted in the elimination of lead, making substitution impractical.
- Alternatives that have been tested affect the performance of the sensors and would therefore compromise the performance of the device if applied.
- The GEM analyser technology is explained to have advantages over traditional testing technologies (such as AQC) by significantly reducing the time needed for the testing process and enhancing the convenience of use. The reduced testing time will, in critical situations, improve significantly patient safety by producing rapid and correct results thereby reducing the need for Doctors interpretation of results and the need for repeat testing.

For details, please check the applicant's exemption request at:

<http://rohs.exemptions.oeko.info/index.php?id=181>

This exemption request has been subject to a first completeness and plausibility check. The applicant has been requested to answer additional questions and to provide additional information (c.f. link above).

The objective of this consultation and the review process is to collect and to evaluate information and evidence according to the criteria listed in Art. 5 (1) (a) of Directive 2011/65/EU (RoHS II), which can be found under:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011L0065:EN:NOT>.

If you would like to contribute to the stakeholder consultation, please answer the following questions:

Questions

1. The applicant has proposed the following wording for this exemption:

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

As the applicant has indicated that the relevant application falls under the scope of Annex I Category 8 (medical devices), should an exemption be granted it is to be added to Annex IV of the RoHS directive.

- a. Do you agree with the scope of the exemption as proposed by the applicant? Please suggest an alternative wording and explain your proposal, if you do not agree with the proposed exemption wording.
 - b. Please state whether you either support the applicant's request or whether you would like to provide argumentation against the applicant's request. In both cases provide detailed technical argumentation / evidence in line with the criteria in Art. 5 (1) (a) to support your statement.
2. Despite on-going research, the applicant states that it has not been possible at present to identify a suitable substitute for lead based stabilizers used in the PVC sensor cards without compensating the performance of the cards.
- a. Please provide information concerning possible substitutes or developments that may enable reduction, substitution or elimination, at present or in the future, of lead used in thermal stabilizers applied in PVC sensor cards.
 - b. Please state if other materials besides PVC could be used to fabricate the sensor cards so as to eliminate the need for using lead as a thermal stabilizer.
 - c. If relevant, please clarify how much time is anticipated to be needed for completing the various stages required to enable substitution or elimination.
 - d. Please indicate if the negative environmental, health and/or consumer safety impacts caused by substitution are likely to outweigh the environmental, health and/or consumer safety benefits. If existing, please refer to relevant studies on negative impacts caused by substitution.

In case parts of your contribution are confidential, please clearly mark relevant text excerpts or provide your contribution in two versions (public /confidential).

Finally, please do not forget to provide **your contact details** (Name, Organisation, e-mail and phone number) so that Öko-Institut/Fraunhofer IZM can contact you in case there are questions concerning your contribution.