

## Clarification Questionnaire Exemption Request 2022-1

***Exemption Request for „Lead as a thermal stabilizer in polyvinyl chloride (PVC) used as base material in amperometric, potentiometric and conductometric electrochemical sensors which are used in in-vitro diagnostic medical devices for the analysis of Creatinine and Blood Urea Nitrogen (BUN) in whole blood”***

### Instrumentation Laboratory answers - **Non-confidential** version

#### Abbreviations and Definitions

BUN	Blood Urea Nitrogen
CHO	Cyclohexanone
CMR1345	Colour master resin 1345. It is the polymer resin that is discussed as a potential substitute for PVC
EEE	Electrical and Electronic Equipment
IL	Instrumentation Laboratory
LCA	Life Cycle Assessment
POC	Point of Care
PVC	Polyvinyl Chloride
RoHS	Directive 2011/65/EU on the Restriction of Hazardous Substances in Electrical and Electronic Equipment
TBLS	Tribasic Lead Sulphate
THF	Tetrahydrofuran
%wt	Percentage by weight

#### Background

The Oeko-Institut has been appointed by the European Commission, within a framework contract<sup>1</sup>, for the evaluation of applications for exemption from Directive 2011/65/EU (RoHS), to be listed in Annexes III and IV of the Directive.

Your organisations (Instrumentation Laboratory (IL) & Intertek Health, Environmental & Regulatory Services) have submitted a request for a new exemption, which has been subject to an initial evaluation. A summary of the main argumentation for justifying the request is provided below as a first basis to be used in the stakeholder consultation planned as part of this assessment.

---

<sup>1</sup> The contract is implemented through Framework Contract No. ENV.B.3/FRA/2019/0017, led by Ramboll Deutschland GmbH.

**Please read the summary of the argumentation provided to ensure that your line of argumentation has been understood correctly and provide answers to the questions that follow that address aspects requiring additional information and/or clarification.**

## 1. Summary of argumentation of applicant on the justification of the exemption

### 1.1. Background

Lead (Pb) is a constituent material (6.5%wt) in the polyvinyl chloride (PVC) sensor card of the disposable cartridge used with the GEM Premier ChemSTAT analyser, which was released in December 2019. The current production sensor card resin contains Pb-based thermal stabilizer (tribasic lead sulphate, TBLS). TBLS is required for heat stability during injection moulding, i.e., to prevent breakdown of the PVC resin during high temperature injection moulding process required to produce the sensor card. The sensor card is a vital component in the GEM Premier ChemSTAT cartridges as it contains the electrochemical sensors used for measuring and reporting concentrations of critical care analytes in blood (pH, pCO<sub>2</sub>, Na<sup>+</sup>, K<sup>+</sup>, Ca<sup>++</sup>, Cl<sup>-</sup>, glucose, lactate, haematocrit, creatinine, blood urea nitrogen and tCO<sub>2</sub>).

The applicant requests a new exemption for the described use of Pb in PVC for sensor cards for the GEM Premier ChemSTAT proposing the following wording *“Lead as a thermal stabilizer in polyvinyl chloride (PVC) used as base material in amperometric, potentiometric and conductometric electrochemical sensors which are used in in-vitro diagnostic medical devices for the analysis of Creatinine and Blood Urea Nitrogen (BUN) in whole blood”*.

The application is part of a medical device which is under the scope of RoHS Annex I, category 8 (medical devices). The exemption is requested for a validity period of 24 months. The request does not cover any other uses of Pb containing PVC.

### History of the exemption

An exemption is currently listed in RoHS annex IV for lead as a thermal stabiliser in polyvinyl chloride (Ex. 41 Annex IV). The exemption was initially granted in 2015, by Delegated Directive (EU) 2015/573, following an assessment of a request for a new exemption submitted by IL. The exemption was set to expire on 31 December 2018. Later, IL applied for a renewal of the exemption, whose extension was assessed during 2017-2019 (Oeko-Institut e.V. Institute for Applied Ecology, Fraunhofer-Institut for Reliability and Microintegration 2019). The assessment recommended the renewal until 1 April 2023, if the Commission agrees that environmental impacts of substitution justify an exemption, or an 18-month transition period in case of revocation.

According to the Commission Delegated Directive (EU) 2020/366 of 17 December 2019, the actual wording is *“Lead as a thermal stabiliser in polyvinyl chloride (PVC) used as base material in amperometric, potentiometric and conductometric electrochemical sensors which are used in in-vitro diagnostic medical devices for the analysis of blood and other body fluids and body gases”*. The expiry date of the exemption is 31 March 2022.

A renewal request was not made for this exemption 18 months ahead of its expiration and it is thus expected to expire shortly.

## Volume of Pb to be placed on the EU market through the exemption

The amount of the substance entering the EU market annually through the application for which the exemption is requested is stated to be 0.5-10 kg. Moreover, the applicant states “As the newest product in the GEM family, GEM Premier ChemSTAT contributed less than 0.5 kg of lead annually in 2020”. The consultants understand that the GEM Premier ChemSTAT was only recently released to the market, explaining the difference between the 2020 volume of Pb and the estimated range.

### 1.2. Technical description

The applicant manufactures a diagnostic medical analyser, the GEM Premier ChemSTAT. The instruments are used to measure the blood of patients and provide an accurate measurement of specific analytes. The applicant details pH, pCO<sub>2</sub>, Na<sup>+</sup>, K<sup>+</sup>, Ca<sup>2+</sup>, Cl<sup>-</sup>, glucose, lactate, hematocrit, creatinine, BUN and tCO<sub>2</sub> in this respect. The GEM Premier ChemSTAT enables rapid risk stratification and prioritization of acutely ill patients in the Emergency Department and other point-of-care locations. Furthermore, the addition of creatinine and BUN measurements to GEM Premier ChemSTAT aid in the diagnosis, monitoring and treatment of renal dialysis and metabolic diseases.

According to the submitted application, the GEM Premier ChemSTAT analyser offers a single, disposable measurement cartridge which can be stored up to 5 months at room temperature. Regarding the component in which Pb is used, the applicant specifies that “the sensor card is a vital component in the GEM Premier ChemSTAT cartridges as it contains the electrochemical sensors used for measuring and reporting concentrations of critical care analytes in blood”.

The consultants understand that these cartridges, containing Pb, are consumables of the analysers, specifically the GEM Premier ChemSTAT, which are nevertheless to be considered as electrical and electronic equipment (EEE)<sup>2</sup>. Cartridges are used for analysis for a limited duration and are disposed of after the analysis has been completed. The consultant understands that the exemption is concerned with the provision of such cartridges on the EU market, so as to ensure that devices already on the market can continue to be operated until a substitute is developed that is “reverse compatible” with such devices.

### 1.3. Applicant’s justification for the requested exemption

#### 1.3.1. Availability of alternatives (Substitution or Elimination, roadmap to substitution, reliability of substitutes)

CMR 1345 has been selected as a RoHS-compliant sensor card resin candidate for GEM Premier ChemSTAT. IL is testing CMR 1345 to ensure this sensor card resin change does not negatively impact the analytical performance characteristics, patient safety or effectiveness of the device, specifically for the sensors unique to the ChemSTAT platform – creatinine and BUN. A roadmap (“project plan”) for the substitution of Pb is provided by the applicant. According to the plan, the Controlled Distribution of RoHS Resin will be accomplished by the end of 2023 (Q3-Q4).

The applicant claims to have experienced a delay in developing a RoHS compliant material caused by changed hospital needs during the COVID-crises, i.e., the increased analyser and cartridge demand due to the critical role of blood gas analysis in the management of hospitalized patients with COVID-19. Thus, the applicant will not meet the expected date of March 2022, which was reported

---

<sup>2</sup> Cartridges are consumables with an equipment constituent meeting the specific definition of EEE in Article 3(1) and 3(2) of RoHS 2, comparable e.g., to printer cartridges, see FAQ 7.4. <https://ec.europa.eu/environment/system/files/2021-01/FAQ%20key%20guidance%20document%20-%20RoHS.pdf> (last accessed 10.03.2022).

already in the application for renewal assessed within RoHS Pack 14 (IL - Instrumentation Laboratories 2017). Indeed, the applicant claims that *“due to the necessary shift in focus to meet customers’ high demands, fewer GEM ChemSTAT RoHS sensor cards and cartridge were manufactured for research and development testing”*. The consultant understands this to mean that testing was delayed as manufactured cards and cartridges were prioritised for use in health facilities. The unique features of GEM ChemSTAT require additional due diligence, thus extending the duration of the tests necessary for substitution. The applicant asserts that *“the increased complexity of Creatinine and BUN sensor designs make these new sensors more difficult to manufacture than sensors on other GEM platforms”*. Furthermore, *“the GEM Premier ChemSTAT was designed with unique reagents requiring more complex sensor calibration process”*. Finally, *“additional effort is required to ensure the analytical performance claims (Method Comparison, Precision, Use Life and Shelf Life) are met with the sensor card resin change”* because of *“the limited clinical data available on this newest product using the current production resin”*.

However, the applicant explains the choices for current materials and substances as follows: membrane adhesion to the PVC is a critical requirement for sensor function and claimed use life and shelf life. PVC has specific advantages as a sensor card material for the electrochemical sensors used in the GEM Premier ChemSTAT. Sensor membranes used for certain sensors (Creatinine, Blood Urea Nitrogen, Glucose, Lactate, Na<sup>+</sup>, K<sup>+</sup>, Ca<sup>++</sup>, pH, pCO<sub>2</sub>) are based on polymer membranes and are solvent cast directly on the sensor card from a solution of tetrahydrofuran (THF) and cyclohexanone (CHO). Because THF/ CHO is a strong solvent for the PVC card, there is strong adhesion between the cast membranes and the PVC card.

According to the applicant, *“any change to the sensor card resin can directly impact analytical performance characteristics of the GEM Premier ChemSTAT”*, as well as *“the raw sensor results to inform the GEM Premier ChemSTAT intelligent Quality Management System (iQM™), which ensures high quality and accurate blood measurements”*.

Compared to other analytical methods and instruments that test human blood for the respective analytes and parameters, the advantage of this technology over others are explained to be the following: according to the applicant, the instrument combines an intelligent quality management (iQMTM), a disposable measurement cartridge and regular testing of the sensor cards.

The alternative considered to replace Pb in the product consists of a combination of three substances, \_\_, were compared in an LCA.

From the application, it emerges that *“other competitive solutions on the market in the EU for POC creatinine measurements are either single use (generating more waste) or require burdensome consumables with different on-board stabilities and refrigerated storage conditions. Moreover, the competitive analyzers need hands-on time to be maintained and/or troubleshooted as often as daily or weekly basis. Conversely, the GEM Premier ChemSTAT is a self-contained system requiring very little operator interaction”*.

### 1.3.2. Environmental and health arguments (also LCA aspects)

The results of a life cycle analysis of the current additive (i.e., Pb) of the GEM Premier ChemSTAT sensor card and the identified alternative are included as Annex to the application. The overall conclusion is that the LCA provides evidence that Pb has lower environmental impact (in terms of the results produced by LCA) than the combined alternatives \_\_.

No environmental and health arguments are provided in addition to the LCA.

### 1.3.3. Socioeconomic impacts

The applicant does not refer to socioeconomic impacts of substitution, as “*alternatives are currently not available*” and no additional references or evidence are provided as to socioeconomic effects due to the finding that this is “*not relevant as alternatives are currently not available*”.

However, the applicant claims that “*without this submission being approved, the supply of point-of-care (POC) GEM Premier ChemSTAT analyzers that support hospitals and laboratories in the EU will be jeopardized, negatively impacting several hospitals in the EU Health Care Sector. If an exemption is not granted, it would require a delay in patient care as all hospitals using the GEM Premier ChemSTAT would need to convert to an alternate technology. This would require additional training on competitive analyzers, elevating risk of mistakes which may pose a threat to patient safety, thereby increasing cost to all EU Health Care currently using the GEM Premier ChemSTAT*”.

## 2. Clarification Questions

1. According to your application, the GEM Premier ChemSTAT analyser was commercially released in December 2019.

- a) Is it correct to assume that the exemption is concerned with the provision of sensor cards on the EU market, so as to ensure that devices already on the market can continue to be operated? Or alternatively, does new equipment also require Pb-containing sensor cards in this case?

IL Response: Both existing and new GEM Premier ChemSTAT instruments require the use of Pb-containing sensor cards.

- b) According to your application, GEM Premier ChemSTAT contributed less than 0.5 kg of lead annually in 2020. However, this amount will increase, according to the forecast for 2022 (0.5-10 kg). The consultants understand that this is due to the fact the GEM Premier ChemSTAT was only recently released. Please, confirm this understanding.

IL Response: Correct. The forecast for GEM Premier ChemSTAT is increasing after product launch in 2019. The increase in annual lead contribution is driven by the number of instruments sold, and there will be no change to lead content per cartridge.

- c) Due to the earlier applications of IL for Pb in PoC, it is clear that the company has been aware of the necessity to substitute Pb for over 10 years and working in this direction. Could you explain why this new device was designed with Pb-containing sensor cards? How long has the device been in development, before being commercially released?

IL Response: Development of RoHS compliant resin for sensor card on the GEM Premier family of analyzers is a continual process, in which newly developed products build on released products. A RoHS-compliant material was in exploration phase (candidate RoHS resin was not finalized) during ChemSTAT development prior to design lock. Therefore, the development of Creatinine and BUN sensors was continued on Pb-based resin. Due to the complex nature of Creatinine and BUN sensor designs and the increased interaction of sensor enzymes with the PVC resin compared to other sensors on the GEM platform, a parallel path was taken to develop creatinine sensors on established Pb-based sensor cards while selecting a RoHS compliant resin based on well-established sensors. This parallel path was chosen to quickly iterate and finalize RoHS compliant resin selection on all other GEM Premier platforms first. Efforts to convert GEM Premier ChemSTAT to RoHS material ramped up immediately after launch in 2019 and are actively being pursued.

2. The consultant understands that the cartridges are used for analysis for a limited duration and are disposed of after the analysis has been completed. Please, clarify the duration of the use life of the cartridges.

IL Response: Each cartridge has a use-life of 21 days or 450 samples, whichever is reached first.

3. The consultant understands that IL has experienced increased analyser and cartridge demand due to the critical role of blood gas analysis in the management of hospitalized patients with COVID-19. Therefore, the RoHS project for the substitution of Pb in the GEM Premier ChemSTAT has been delayed.

- a) According to your application, *“due to the necessary shift in focus to meet customers’ high demands, fewer GEM ChemSTAT RoHS sensor cards and cartridge were manufactured for research and development testing”*. The consultant understands this to mean that testing was delayed as manufactured cards and cartridges were prioritised for use in health facilities. Please, clarify the number of cards intended for testing which were sent to medical facilities.

IL Response: A single manufacturing line is responsible for sensor cards (i.e. all cards, both production cards and experimental Lead-free cards) for all GEM product lines (i.e. not only the GEM ChemSTAT analyzer). As a result of COVID-19, the increase in demand for all GEM cartridges increased by\_. This demand exceeded the capability of the manufacturing facility, and this meant that dedicated runs of non-production material needed to be deprioritized. 12 planned runs of 60 cards each (720 total cards) of RoHS material were delayed, leading to delays in verification and validation studies. There are construction projects in progress at Instrumentation Laboratory to expand the manufacturing capability, and the RoHS efforts have continued despite the delay.

- b) According to your application, *“the above-mentioned delays were of particular impact for GEM Premier ChemSTAT due to additional technical challenges unique to this platform that require additional due diligence”*. In the context of the supply of resources, the wording “due diligence” usually refers to environmental and social conditions. However, we assume that here a different type of *due diligence* is meant. Can you explain it better?

IL Response: In this context due diligence is meant to cover the extensive testing required to ensure our claims are maintained to ensure patient safety and compliance with applicable EU safety and performance regulations for medical devices. GEM ChemSTAT is the only Instrumentation Laboratory device with BUN, tCO<sub>2</sub> and Crea analytes reported, therefore additional testing was required as no data or experience with these sensors could be leveraged from our other on-market devices.

4. The data that you provide as to the volume of use of lead is understood to concern only IL devices on the EU market. Please estimate how much lead can be placed on the market through the use of the required exemption by all manufacturers of equipment using such PVC sensor cards.

IL Response: Unfortunately, we do not have knowledge of the exact technologies used in the competitive devices and are unable to provide estimates related to equipment using PVC sensor cards containing Lead.

5. The consultant understands that a \_ is an alternative to lead, as additive of PVC. We understand that the substitution of the additive would be feasible, but the environmental impact would increase (as proved by the LCA in appendix F).

a) Please, confirm that a combination of \_ is used as an additive in CMR 1345.

IL Response: This is correct.

b) Please, clarify in which component(s) the resin CMR 2151 (mentioned in appendix E) is used.

IL Response: The resin CMR 2151 is our current production resin and is used in the GEM Premier ChemSTAT sensor card. The GEM Premier ChemSTAT system has two primary components: the instrument and a disposable, multi-use cartridge (PAK). The cartridge (PAK) houses the sensor card, solutions, sampler, and waste bag. The sensor card serves as a substrate for a set of electrochemical sensors. There is one sensor card contained in each cartridge.

6. As part of the evaluation, socio-economic impacts shall also be compiled and evaluated. For this purpose, please provide details in respect of the following

a) Provided that the exemption request is rejected, please provide an estimate of socioeconomic impacts with a special focus on impacts for health facilities.

IL Response: See answers below.

b) Please estimate possible impacts on employment in total, in the EU and outside the EU, should the exemption not be granted. Please detail the main sectors in which possible impacts are expected – for example PVC sensor card manufacturers and manufacturers of in-vitro diagnostic medical devices for the analysis of blood, supply chain, retail, etc

IL Response: We don't have any data specific for the GEM ChemSTAT instrument with respect to impact on employment in the EU and outside the EU however taking into account the expected negative economic impact as detailed below in our answer to question 6c) it is clear that a substantial negative impact on employment for both suppliers and our own company cannot be avoided.

c) Please estimate additional costs associated with a forced substitution should the exemption not be granted, and how this is divided between various sectors (e.g., private, public, industry: manufacturers, suppliers, retailers).

IL Response: We don't have data specific for the GEM ChemSTAT instrument, however based on the socio-economic Analysis provided as part of our REACH Authorization application submitted in 2019 for the GEM Premier 4000 and 5000 analyzers (non-confidential version is submitted together with this document) it can be estimated that the combined negative economic impact in terms of the GEM ChemSTAT instrument will be more than 1,5 million euro per year for period up to 12 years. This includes the negative impact for both our company, as well as the negative impact on our suppliers and customers (Health Care Institutions) based in the EEA. The negative impact also includes the monetized negative impact on employment and the benefit for our competitors supplying alternative instruments.

It should be noted that the Socio-Economic Analysis is based on the current number of GEM ChemSTAT analyzers in use today – however as the analyzer has only recently

been released for the EU market and as an increase in demand is expected the negative socio-economic impact is likely to be much higher than the above estimated amount.

- d) Please estimate possible amounts of waste to be generated through a forced substitution should the exemption not be granted.

IL Response: \_

7. The consultant understands that on the market there are other manufacturers offering creatinine measurements, but they are either single use (generating more waste) or require burdensome consumables with different on-board stabilities and refrigerated storage conditions.

- a) Please, clarify which PoC analysers of other manufacturers also measure creatinine and BUN, and if a competing solution for measuring BUN exists.

IL Response: The following competitive solutions exist for creatinine and BUN:

Competitors offering creatinine and BUN:

- iSTAT (single use cards): CHEM8+ for creatinine and BUN. Crea for creatinine. EC8+ and 6+ for BUN.
- Epoc (single use card)
- ABL90 Flex w/Crea (multi-use, multi-cartridge)
- Nova Stat Profile Prime (multi-use, multi-cartridge)

Competitors offering only creatinine:

- ABL800 Flex (traditional laboratory-style system)
- Nova StatSensor (single use strip)

- b) Is it correct to understand that the only alternative is single use, meaning that the multi-use ones do not measure creatinine and/or BUN?

IL Response: This is not correct. Please refer to the list of competitive solutions in question 7(a). The competitive solutions that are not single use either required multiple cartridges with the on-board stability and refrigerated storage issues described above (ABL90 Flex with Crea and Nova Stat Profile Prime), or are traditional laboratory analyzers requiring highly trained operators (ABL800 Flex).

- c) Can you give more details on the benefits of shifting from single-use ones to multi-use?

**IL Response:** Benefits of a multi-use cartridge are the following:

- Multi-use cartridges automate the most labor- and skill-intensive processes, reducing sampling errors and cartridge waste
- Multi-use cartridges can be coupled with quality management software that ensures performance and integrity of each cartridge. Single use cartridges are limited to QC checks on one or more cartridges per lot
- Multi-use cartridges do not consume tests with QC checks. Single use cartridges must be used as part of the QC process and are not able to be used for patient tests
- Multi-use cartridges reduce burden of inventory management with just one PAK for up to 450 tests rather than 450 individual cartridges.



If you think there is anything else that is relevant in addition to the questions above, please summarise it under this point.

**In case parts of your answers are confidential, please provide your answers in two versions (public /confidential). Please also note, however, that requested exemptions cannot be granted based on confidential information!**

### 3. Bibliography

IL - Instrumentation Laboratories (2017): Exemption Request Form for the renewal of Ex. 41 of Annex IV of Directive 2011/65/EU. Available online at [http://rohs.exemptions.oeko.info/fileadmin/user\\_upload/RoHS\\_pack\\_14/Annex\\_IV\\_Ex\\_41/Application/RoHS\\_Form\\_V\\_Revised\\_final\\_non\\_confidential.pdf](http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_pack_14/Annex_IV_Ex_41/Application/RoHS_Form_V_Revised_final_non_confidential.pdf).

Oeko-Institut e.V. Institute for Applied Ecology, Fraunhofer-Institut for Reliability and Microintegration (2019): Study to assess eight (8) exemption requests in Annexes III and IV to Directive 2011/65/EU: “Renewal of exemptions III.41, IV.37, IV.41, and requests for new exemptions for lead and DEHP in certain NRMM engines applications, lead in solder and hexavalent chromium to be used in mass spectrometers, lead in certain thermal cutoff fuses and lead in solders of certain applications used to identify radiation” (Pack 14) –Final - amended. Under the Framework Contract: Assistance to the Commission on technical, socio-economic and cost-benefit assessments related to the implementation and further development of EU waste legislation. Available online at <https://data.europa.eu/doi/10.2779/285833>.