Consultation Questionnaire Exemption Request 2021-2

Exemption Request for „Bis (ethylhexyl) phthalate (DEHP) as a plasticizer in polyvinyl chloride (PVC), serves as a base material for amperometric, potentiometric and conductometric electrochemical sensors which are used in in-vitro diagnostic medical devices for the analysis of whole blood"

Abbreviations and Definitions

XX wt %	Following a number, this formulation refers to the percent weight of a substances from a component or from the homogenous material within which it is contained, depending on used formulation.
COCIR	European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry
CMR1345	Polymer resin that is discussed as a potential substitute for PVC
DEHP	Di-/Bis-(ethylhexyl) phthalate
EEE	Electrical and Electronic Equipment
IL	Instrumentation Laboratory
ISE	Ion selective electrodes
PVC	Polyvinylchloride
RoHS	Directive 2011/65/EU on the Restriction of Hazardous Substances in Electrical and Electronic Equipment

Background

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

Instrumentation Laboratory (IL) & Intertek Health, Environmental & Regulatory Services have submitted a request for the renewal of the above-mentioned exemption, which has been subject to an initial evaluation. A summary of the main argumentation for justifying the request is provided below The applicant has been requested to answer additional questions and to provide additional information, available on the request webpage of the stakeholder consultation (http://rohs.exemptions.oeko.info/index.php?id=371).

For further details, please check the applicant's exemption request under the above link.

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

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 2), 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 read the summary of the argumentation provided and answer the questions that follow.

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

1.1. Background

DEHP is used as a plasticizer for the resin formulation of PVC. This polymer serves as a basis for disposable cartridges and sensor cards for electrochemical measurements of biochemical analytes and parameters in human blood such as pH, pCO_2, Na^+, K^+, Ca^{2+} or lactate.

The EEE in which the sensor cards are used in and for which Instrumentation Laboratory (hereafter referred to as IL) and Intertek Health, Environmental & Regulatory Services (hereafter referred to as Intertek) request the exemption for IL's GEM Premier 4000 diagnostic medical analyser. The application belongs to EEE Cat. 8. The request does not cover any other uses of DEHP containing PVC.

The applicant requests a new exemption for the described use of DEHP in PVC for sensor cards for the GEM Premier 4000 proposing the following wording „*Bis (ethylhexyl) phthalate (DEHP) as a plasticizer in polyvinyl chloride (PVC), serves as a base material for amperometric, potentiometric and conductometric electrochemical sensors which are used in in-vitro diagnostic medical devices for the analysis of whole blood*".

The exemption is requested for EEE Cat. 8 for a validity period of three years.

History of the exemption

In the RoHS Pack 17 study in 2019/20, COCIR had requested a new exemption for „*Bis (ethylhexyl) phthalate (DEHP) in ion selective electrodes for point of care analysis of ionic substances in human body fluids".* The study recommended to grant the exemption for Annex IV with a slightly adapted wording: "*Bis(2-ethylhexyl) phthalate (DEHP) in ion selective electrodes applied in point of care analysis of ionic substances present in human body fluids and/or in dialysate fluids*".

The wording in the Commission Delegated Directive (EU) 2021/1980, published in the Official Journal of the European Union on 15.11.2021, is identical to the recommendation given by the consultant in RoHS Pack 17 report ("*Bis(2-ethylhexyl)phthalate(DEHP) in ion-selective electrodes applied in point of care analysis of ionic substances present in human body fluids and/or in dialysate fluids. Expires on 21 July 2028*").

Due to differences in wording of the future Ex. 45 Annex IV and the wording of the requested exemption, it needs to be clarified if the present exemption request is an extension of scope or already covered under the Pack 17 exemption. For technical description of both applications, the one for which Ex. 45 was applied for and the application under present review, please refer to chapter 1.2.1.

Volume of DEHP to be placed on the EU market through the exemption

The amount of the substance entering the EU market annually through the application [GEM Premier 4000 cartridges] for which the exemption is requested is stated to be 1-10 kg. This estimation does not cover cartridges of analysers other than the GEM Premier 4000.

According to IL/Intertek, the size of one cartridge is 25 x 16,5 x 16 cm and a typical cartridge weight is 4.08 kg (Answers to clarification questions). Based on the content of the substance in homogeneous material being 1.14 wt % for the GEM Premier 4000 cartridges, each unit cartridge contains 46,5 g of DEHP.

1.2. Technical description

1.2.1. The GEM Premier 4000

The applicant manufactures a diagnostic medical analyser, the GEM Premier 4000. The instruments are used to measure the blood of patients and provide an accurate measurement of specific analytes as detailed in column 1 of Table 1-1. Within the analyser, the measurements are performed based on four different type of quantification methods, namely potentiometric, amperometric, conductometric, and spectrometric. While amperometric, potentiometric and conductometric quantification require an electrode, spectrometric measurements are based on effects of the analyte after a light-induced excitation, thus, work without any electrode.

The electrodes and spectrometric components are part of the cartridge. Regarding the component in which DEHP is used, the applicant specifies that '*the heart of the GEM Premier 4000 is the sensor card where the electrochemical measurements [author's note: namely potentiometric, amperometric and conductometric] of the […] analytes take place'.* The typical sensor cards weight is 5.1 g, thus small and light in comparison with the cartridge's weight of ~ 4kg. The sensor cards *'have an additional additive, DEHP, which is part of the resin [currently PVC] formulation'* (Exemption Request): DEHP functions as a plasticizer to facilitate the injection molding process of PVC, the host material. An important requirement of the functionality of DEHP and its substitutes is that it should not interfere with the measurement of analytes.

An overview over the range of analytes, the corresponding quantification method, and whether they are relevant for the assessment of the present exemption request for DEHP is provided in Table 1-1.

Table 1-1: Measurement spectrum of the GEM Premier 4000

Analytes	Quantification method	Utilize an electrode using DEHP
pH	Potentiometric (ISE*)	Yes
pCO_2	Potentiometric (ISE)	Yes
pO_2	Amperometric	Yes
Na^+	Potentiometric (ISE)	Yes
K^+	Potentiometric (ISE)	Yes
Ca^{++}	Potentiometric (ISE)	Yes
Cl^-	Potentiometric (ISE)	Yes
Hematocrit	Conductometric	Yes
Glucose	Amperometric	Yes
Lactate	Amperometric	Yes
tHb	Spectrophotometric	No

Analytes	Quantification method	Utilize an electrode using DEHP
O_2Hb	Spectrophotometric	No
COHb	Spectrophotometric	No
MetHb	Spectrophotometric	No
HHb	Spectrophotometric	No
tBili	Spectrophotometric	No

* Ion selective electrode

Source: Answers to Clarification Questions received 19.11.2021

The consultants understand that these cartridges containing DEHP are consumables of the analysers, specifically the GEM Premier 4000, which are nevertheless to be considered as electrical and electronic equipment (EEE)[2]. The applicant clarifies that '*one sensor card is used for up to 30 days or 450 whole blood sample measurements. Each sample measurement provides simultaneous results for multiple analytes. Therefore, each sensor card is used to report up to 4500 measured concentrations (450 whole blood samples x 10 analytes)*' (answers to clarification questions). They are disposed of after the respective number of analyses has been completed. In addition, the cartridges are designed specifically for the GEM Premier 4000. It is understood that generally sensor cards must be compatible with the type of analyser model that are already being used by hospitals in the EU. In this sense, the consultants understand that the exemption is at least in part 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.

1.2.2. Comparison to application evaluated in RoHS Pack 17

Following the explanation in chapter 1.1, the use of DEHP in the sensor card of GEM Premier 4000 cartridges will be evaluated in relation to the application for which an exemption was requested in RoHS Pack 17, which can be found on the consultation webpage, and granted in the Commission Delegated Directive (EU) 2021/1980. To facilitate an easier overview of the comparison, we summarize some data related to the two different applications.

Based on the applicant's explanations it is understood that within one cartridge four methods of quantifications of 16 parameter in total are performed for one single sample. Thereof 6 parameters are measured with a potentiometric electrode (pCO2, pH, Na+, K+, Cl-, and Ca2+). Its speciality is the fact that a so-called ion-selective electrode (ISE) is required based on the definition of an ISE being a sensor composed of an electrode with a selective membrane that seals to an underlying substrate. Asked whether it is right to understand that the sensor card applied in the GEM Premier 4000 is more than an ISE, the applicant further explains that '*not all of sensors on the GEM Premier 4000 sensor card meet the definition of ISE defined above. The amperometric sensors differ because the membrane does not provide selectivity and instead utilizes enzymes to convert analytes of interest to measurable signals, and the conductometric sensor for hematocrit does not utilize a membrane at all.'* (Answer to clarification questions).

Based on the ROHS pack 17 report, the point of care (PoC) analysers presented by COCIR can quantify the comparable analytes and parameters, e.g. partial pressure of carbon dioxide (pCO2), pH, concentration of sodium and potassium ions. Quantification is based on an DEHP-containing

[2] 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 29.10.2021).

ion-selective electrode as well. It is understood that cartridges of the PoC analysers presented by COCIR in 2018/9 do not include other sensors including DEHP-containing parts. As mentioned earlier, the exemption requested in 2018 by COCIR was granted (Ex. 45) with the following wording "*Bis(2- ethylhexyl) phthalate (DEHP) in ion selective electrodes applied in point of care analysis of ionic substances present in human body fluids and/or in dialysate fluids*"[3] and expires on 28.July 2028.

In 2018, in its exemption request, COCIR expressed that "*DEHP is used as a membrane solvent for the ISE*". The general composition of the membranes is detailed as "*29 wt % PVC, 70 wt % DEHP and an ionophore that imparts specificity for the particular ion of interest*" (RoHS Pack 17 report). In contrast to the membrane specifications provided by COCIR, IL/Intertek specifies the content of substance in homogeneous material to be 1.14 wt % for the GEM Premier 4000 cartridges.

Asked whether the current applicant IL/Intertek sees a possibility to merge Ex. 45 and the new exemption requested, the applicant proposed to remove the references to '*ion selective*' and '*ionic*' resulting in the following wording: "*Bis(2-ethylhexyl) phthalate (DEHP) in electrodes applied in point of care analysis of substances present in human body fluids and/or in dialysate fluids*".

1.3. Applicant's justification for the requested exemption

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

The applicant claims that substitution is not yet possible, providing a roadmap ("project plan") and proposes that DEHP can be replaced within the coming 3 years. However, the applicant explains the choices for current materials and substances as follows: PVC is uses as sensor card material and membrane used (i.e., PVC) should be of the same material to resist the solvent used in this analytical process. As to DEHP, it increases flexibility and reduces brittleness of PVC to improve durability and reliability in injection moulding. Furthermore, DEHP does not interfere with the analyte measurements which is a crucial pre-condition for alternatives for DEHP.

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 cartridges.

A project plan has been submitted that structures the research for substitution of DEHP in the cartridges. The consultant understands that the applicant's research has two directions: A drop-in-substitute for DEHP in the PVC and an alternative resin/polymer that does not require DEHP or rather allows the substation of the same. According to the project plan, various resins that should substitute PVC were tested in 2016/17 from which one (CMR 1345) was selected as a top candidate to conduct a study of alternatives for DEHP. Three drop-in-alternatives for DEHP, namely Mineral oil, Ester lubricant V-DSP and Acrylic processing aid, were compared in an LCA. A clarification question shall verify whether this is correctly summarized.

[3] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32021L1980 (accessed 25.11.2021, published in the Official Journal of the European Union on 15.11.2021)

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

Preliminary results of a life cycle analysis of the current GEM Premier 4000 sensor card and identified alternatives are included as Annex to the application. Based on the preliminary report a full LCA for substitution of DEHP is promised to be submitted and will be based on the alternative substances used in the CMR1345 resin: Mineral oil (CAS# 8042-47-5), Ester lubricant, V-DSP (CAS#14117-96-5,) and Acrylic processing aid (CAS# 9063-87-0),

Preliminary results suggest that the three alternatives (for DEHP) are comparable to those of DEHP: '*Considering 18 environmental impact measures, the picture is mixed, with no substance being best by all measures. It should be noted that these are theoretical impacts assuming the substance all reaches the environment, but in the case of the sensor card the substance is encapsulated in the card.*'

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*" (Exemption Request) and no additional references or evidences are provided as to socioeconomic effects due to the finding that this is "*not relevant as alternatives are currently not available*"" (Exemption Request). Asked in the clarification question to further comment socioeconomic impacts, the applicant replied:

- "*If the exemption application is rejected those instruments would need to be removed from service and disposed of.*
- *New capital equipment would need to be purchased by healthcare providing institutions.*
- *The new equipment would need to be validated by the healthcare providers.*
- *Hospital staff would need to be trained to operate the new equipment.*
- *Demand for this volume of equipment and installation activities could not be met in a short period of time and resulting in lack of availability of testing capacity."*

2. Questions for stakeholders

1. The applicant has requested an exemption, proposing the following wording formulation for a duration of 3 years:

   "Bis (ethylhexyl) phthalate (DEHP) as a plasticizer in polyvinyl chloride (PVC), serves as a base material for amperometric, potentiometric and conductometric electrochemical sensors which are used in in-vitro diagnostic medical devices for the analysis of whole blood."

   In light of the currently published Commission Delegated Directive (EU) 2021/1980, the subsequent review aims at clarified whether the current (IL/Intertek's) and the exemption request resulting in the new Ex. 45 through (EU) 2021/1980 can be summarized.

   a. Against this background, does your organisation has a preference for:

      - the current wording of Ex. 45 ("*Bis(2-ethylhexyl) phthalate (DEHP) in ion selective electrodes applied in point of care analysis of ionic substances present in human body fluids and/or in dialysate fluids*");

- the wording requested by IL/Intertek in this exemption request („*Bis (ethylhexyl) phthalate (DEHP) as a plasticizer in polyvinyl chloride (PVC), serves as a base material for amperometric, potentiometric and conductometric electrochemical sensors which are used in in-vitro diagnostic medical devices for the analysis of whole blood*");
- the wording suggested by IL/Intertek when asked under which conditions they see a possibility to merge Ex. 45 and their requested wording (the proposed deleted words are marked in red and crossed out) ("*Bis(2-ethylhexyl) phthalate (DEHP) in ~~ion selective~~ electrodes applied in point of care analysis of ~~ionic~~ substances present in human body fluids and/or in dialysate fluids*")
- Please suggest an alternative wording and explain your proposal if you do not agree with the proposed exemption wordings.

b. Do you agree with the scope of the exemption as proposed by the applicant?

c. Do you agree with the validation period requested?

d. Please explain why you either support the applicant's request or object to it. To support your views, please provide detailed technical argumentation / evidence in line with the criteria in Art. 5(1)(a) to support your statement.

2. Through the following questions we would like to understand better the situation of the market of point of care analyzers, the cartridges used and the included sensors.

a. Please describe the market of blood measurement instruments. If known, please point out substantiate your view with references, or point out the references to the study team.

b. The amount of DEHP to be placed on the market in the EU as detailed in chapter 1.1 only refers to the sensor cards used by the GEM Premier 4000. Please estimate the total amount of DEHP entering the EU market through the total segment of (DEHP- containing) cartridges for blood analysers.

c. Please explain whether the exemption requested is necessary to guarantee the cartridges' supply of analysers on the market only, or whether new analysers / new models use cartridges that contain DEHP-containing sensors as well?

d. We understand that the GEM Premier 4000 contains four different sensors, if you are a manufacturer of comparable analysers, please fill the table below. Please note, that in case that proprietary information is concerned if information is provided on the bases of models, an aggregated version and a separate confidential version with e.g. 3 different models can be provided.

Model	Electrodes in the cartridge	ISE? (yes or no)	DEHP contained?	Which analytes covered?	Further comments
#1	Potentiometric				
	Condumetric				
	Amperometric				

Model	Electrodes in the cartridge	ISE? (yes or no)	DEHP contained?	Which analytes covered?	Further comments
	Spectrophotometric				
	Other: please detail				

3. The consultant is aware that point of care analysers exist that do not contain DEHP in any part, sensor or cartridge. In the following, when requesting information on alternatives for DEHP, the consultant seeks for information on options for substitution DEHP through which the analyser, in this case the GEM Premier 4000, can further be used. The consultant is not searching for substitution on the level of the application. Please provide information concerning possible substitutes for *"Bis (ethylhexyl) phthalate (DEHP) as a plasticizer in polyvinyl chloride (PVC), serves as a base material for amperometric, potentiometric and conductometric electrochemical sensors which are used in in-vitro diagnostic medical devices for the analysis of whole blood"*

    a. on the level of the material, thus, the substitution of PVC.

    b. on the level of the plastiziser, thus, the drop-in-substitution of DEHP.

4. 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. Please estimate possible amounts of waste to be generated through a forced substitution should the exemption not be granted. In this respect, please clarify whether devices placed on the market before the 22 July 2021 could still be serviced through the spare parts provision stipulated in the Directive under Article 4.

    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 – manufacture, supply chain, retail, etc.

    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, end-users).

5. Please provide any further information and/or data that you think is of importance to substantiate your views.

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

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