Exemption Request Form

Date of submission: 02/10/2019

1. Name and contact details

1) Name and contact details of applicant:

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2) Name and contact details of responsible person for this application (if different from above):

Company: _____ Tel.: _____
Name: _____ E-Mail: _____
Function: _____ Address: _____

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2. Reason for application:

Please indicate where relevant:

- ☒ Request for new exemption in: Annex IV
- ☐ Request for amendment of existing exemption in
- ☐ Request for extension of existing exemption in
- ☐ Request for deletion of existing exemption in:
- ☐ Provision of information referring to an existing specific exemption in:
  - ☐ Annex III ☐ Annex IV

It should be noted that there are similarities to the application submitted by GE healthcare[1] for DEHP in cable strain relief for MRI coils, but this application extends the scope of the request. The GE application was submitted separately and was not commented upon during consultation as the testing of alternatives as described in Section 6 was underway and it was previously expected that an alternative would be

[1] *https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_17/application_GE_Global_Operations_RoHS_17_Application_Form_Strain_relief_DEHP_20180912.pdf*

qualified by 2021, however biocompatibility testing indicated the alternative identified at this time was not suitable, so more time will be needed.

No. of exemption in Annex III or IV where applicable: _____

Proposed or existing wording: **Bis-(2-ethylhexyl) phthalate (DEHP) in plastic components in MRI detector coils**

Duration where applicable: **Until January 2025**

☐ Other: _____

3. Summary of the exemption request / revocation request

COCIR (European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry) request an exemption to extend the time period to replace the existing materials of DEHP-plasticised components used for Magnetic Resonance Imaging (MRI) coil assemblies with an alternative material or by design modifications required to attain adequate performance. Tests using currently identified alternative materials show that they would either adversely affect image quality or are not biocompatible, so cannot touch patients' skin, which is impractical with this application. There would also be negative health and socio-economic impacts without this exemption that are explained in Section 8 of this request.

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4. Technical description of the exemption request / revocation request

(A) Description of the concerned application:

1. To which EEE is the exemption request/information relevant?

Name of applications or products: Medical Magnetic Resonance Imaging (MRI) equipment and associated imaging coils

a. List of relevant categories: (mark more than one where applicable)

☐ 1	☐ 7
☐ 2	☒ 8
☐ 3	☐ 9
☐ 4	☐ 10
☐ 5	☐ 11
☐ 6	

b. Please specify if application is in use in other categories to which the exemption request does not refer:

c. Please specify for equipment of category 8 and 9:

The requested exemption will be applied in

☐ monitoring and control instruments in industry
☐ in-vitro diagnostics
☒ other medical devices or other monitoring and control instruments than those in industry

2. Which of the substances is in use in the application/product?

(Indicate more than one where applicable)

☐ Pb ☐ Cd ☐ Hg ☐ Cr-VI ☐ PBB ☐ PBDE

☒ DEHP

3. Function of the substance: DEHP is added to polymers to provide flexibility

4. Content of substance in homogeneous material (%weight): 2-30%

5. Amount of substance entering the EU market annually through application for which the exemption is requested: Data from one manufacturer: 14kg DEHP annually. Details about the calculation are CONFIDENTIAL and provided as a separate file. COCIR has no additional data from other manufacturers (apart from data already submitted by GE)

Please supply information and calculations to support stated figure.

This calculation uses confidential sales data so it is provided as a separate confidential document

6. Name of material/component: Bis-(2-ethylhexyl) phthalate (DEHP) plasticised components used within MRI coils. Examples of which are shown in Figure 1

7. Environmental Assessment: _____

LCA: ☐ Yes

☒ No. Currently there is no identified alternative, which has the required performance and biocompatibility as outlined in Section 6

(B) In which material and/or component is the RoHS-regulated substance used, for which you request the exemption or its revocation? What is the function of this material or component?

Magnetic Resonance Imaging (MRI) is a medical technique used to obtain three-dimensional images of soft tissue and organs of the human body. MRI uses a very powerful circular electromagnet into which the patient is inserted and is exposed to a powerful magnetic field to produce 3D images. “Radio Frequency (RF) send and receive coils” are located around the patient and inside the magnetic field and these transmit RF signals that excite magnetised protons in soft tissue and organs of the patient. The protons in molecules of the patient then emit characteristic signals that are received and measured by these coils. Many hundreds of

different types of receive coils are made for imaging specific parts of the body and each type of MRI uses its own types of receive coil. Receive coils are made, for example, for heads, hands, arms, feet, etc. The receive coils are connected via cables to the MRI scanner and the coil itself is placed over the section of the patient being imaged. Image quality depends on the strength of the magnetic field and so magnetic fields of up to 8 Tesla are used.

MRI functions by detecting protons (hydrogen atoms in molecules of the human body) and so will be sensitive to protons in coil materials or any component that are close to the patient. Components such as cable covers are designed to minimise any effect on image quality, which requires polymers and their additives to have weak proton signals such that image quality is not detrimentally affected.

Plastic materials require the use of plasticisers such as DEHP as otherwise their mechanical properties are unsuitable for use, for examples unplasticised PVC is hard and inflexible at room temperature. DEHP imparts flexibility to ensure that the article remains durable and intact throughout its intended service life. With the exact amount of DEHP contained in each material dependant on the component type and its required flexibility requirements.

DEHP-plasticised components are utilised in components such as cable covers, bushings and mattress covers as external sheathing material, as well as sandwiched between flame retardant material in a flexible belt, examples of which are shown in Figure 1.

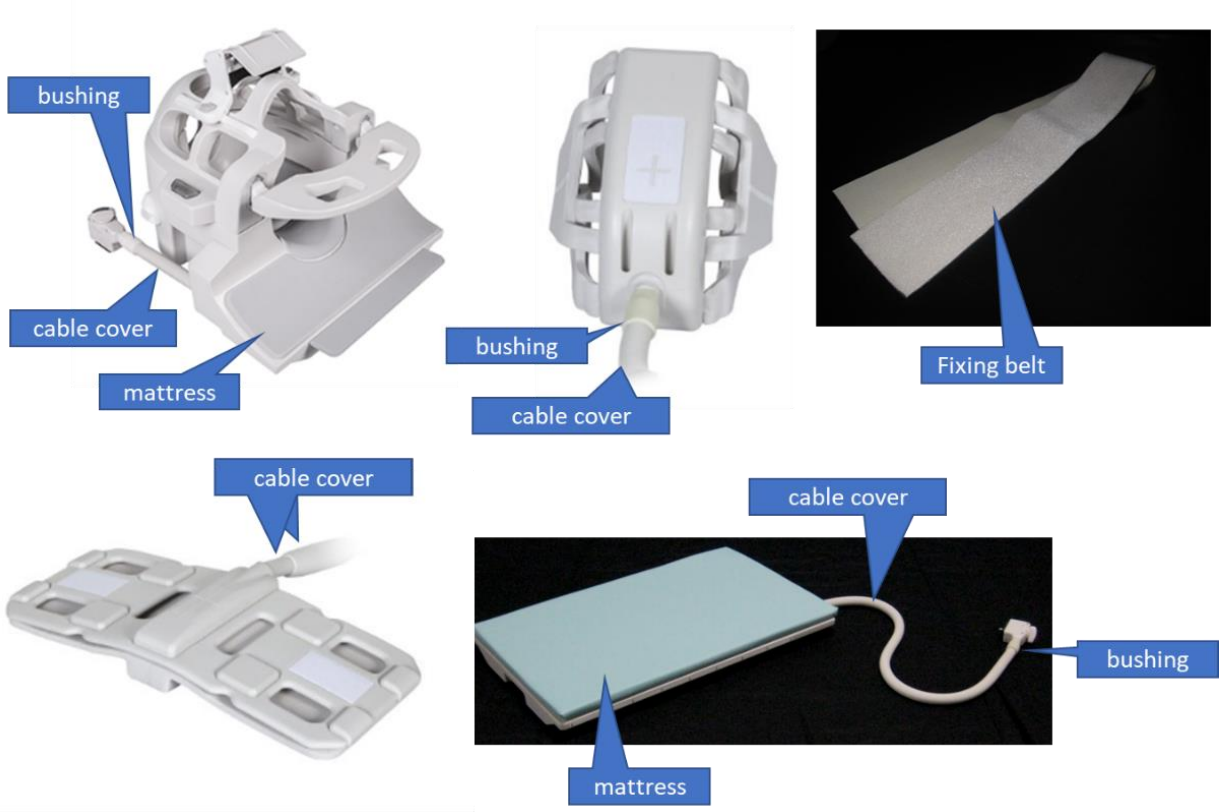

Figure 1. MRI coils showing cable cover, bushing and mattress locations

The function and requirements of the material include the following:

- Easily fabricated, e.g. by solvent and heat welding (not possible with several alternatives) to allow highly complex parts to be formed. Incorporation of the plasticiser must be straightforward so that the quality of the material can be maintained and does not vary. Compatibility is related to the polarity of the plasticiser and polymer, which must be similar for both to achieve maximum compatibility;
- Robust mechanical properties:
    - Good flexibility and does not "kink" which is of particular importance to cable covers;
    - Suitable tensile properties include the modulus of the polymer, which impacts the stiffness of the material which is of particular importance to bushings;
    - Durable to ensure that medical equipment does not fail when it is needed for treatment of patients and has a lifetime of at least 6 years; and
    - Provide a sufficiently robust barrier to ensure that the patient is not exposed to the metallic materials of coils as this can cause burns.
- The plasticiser must remain within the polymer during the expected lifetime and should not exude from the bulk materials to leak sticky material onto outer surfaces, known as stability or permanence of the plasticiser;
- Electrically insulating;
- Components will be periodically cleaned and sterilised, which is of particular importance for mattress covers and fixing belts that are more likely to be in contact with patient's skin. The required properties of the phthalate is that they should have very low rates of migration from the components into body fluids (i.e. sweat). Medical equipment manufacturers have many decades of experience with DEHP-plasticised components and so understand how the plasticiser behaves and which cleaning chemicals can be used;
- The polymer and all additives including the plasticiser must be acceptable for use in medical devices. New materials must comply with biocompatibility requirements according to ISO 10993 "Biological evaluation of medical devices", before they can be used. The testing demonstrates that the component that comes into contact with the patient can perform its intended function without resulting in any adverse effect to a patient. The biocompatibility of a device depends on several factors, including:
    - The chemical and physical nature of the component materials;
    - The types of patient tissue that will be exposed to the device; and
    - The duration of exposure.

  Therefore, any testing is specific to the classification of the device that considers component function, material and processing method. Well-characterised materials widely used in industry can produce unexpected reactions if processed in a way that leads to contamination, degradation, or leaching of toxic compounds into a patient. Biocompatibility testing can include cytotoxicity, sensitization, irritation or

intracutaneous reactivity, systemic toxicity, subchronic toxicity, genotoxicity, etc.

- Low proton signal to avoid interfering with the MRI image;
- Low distortion of magnetic fields to avoid interfering with the magnets that align the protons in the body; and
- The material shall not build up electrostatic energy that could be released during imaging which would hamper the MRI causing distortion of the image.

DEHP toxic effects are well publicised within the main stream media, the clinical view under pinning this stance is based on limited animal studies and there is still uncertainty over mechanisms of DEHP toxicity in animals and their extrapolation to humans. It is recognised that a lack of data does not lead to a conclusion that DEHP is without adverse effects which is of particular importance to high-risk groups of patients and the use of DEHP in components, which could lead to prolonged exposure (e.g. feeding tubes for neonates) and as a result, phthalates such as DEHP are regulated in medical devices by the Medical Devices Directive and Regulation. However, it is important to note that there are no reports concerning any adverse effects in humans following exposure to DEHP-PVC, even in neonates or other groups of relatively high exposure[2]. Given the MRI coil component use is not invasive or is expected to be in contact with the patient for prolonged periods, the DEHP exposure will be significantly lower than those discussed in literature which focuses on medical uses such as catheters or blood bags. The principal route of human exposure to DEHP is oral (mainly from food) and some recent estimates for the average total daily individual ambient exposures to DEHP of 3–30 g/kg/day (in a 70-kg adult) have been proposed. These intake approximations indicate that the general population is exposed to DEHP at levels that are 3–4 orders of magnitude lower than those observed to cause adverse health effects in animal studies[3]. This would not include exposure due to medical treatment but due to the limited exposure to the DEHP component this is likely to have minimal impact.

In addition to these, each of the DEHP-plasticised components require particular combinations of characteristic performance which are detailed in Table 2.

[2] https://ec.europa.eu/health/archive/ph_risk/committees/scmp/documents/out43_en.pdf

[3] https://www.atsdr.cdc.gov/toxprofiles/tp9.pdf

Table 1. DEHP-plasticised component requirements

Component	Component Specific Function	Long term flexibility for moving	Suitable Stiffness	No damage degrade during use	No kink on cable	Electrically insulating	No electro static build up	Durable for sweat and sanitizing agent	Low proton signal	Bio compatibility ISO10993
Cable cover	Patient isolation from cable, reducing likelihood of RF burns	✓		✓	✓	✓	✓	✓	✓	✓
Mattress	Comfort in patient positioning. Patient isolation from metallic parts of coil, reducing likelihood of RF burns	✓		✓			✓	✓	✓	✓
Fixing Belt	Reducing patient movement during scan	✓		✓			✓	✓	✓	✓
Bushing	Fixing both end of cable cover to coil and connector		✓	✓	✓	✓	✓	✓	✓	✓

All of the DEHP-plasticised MRI components isolate the patient from the metallic parts of the coil to ensure that the MRI, through thermal damage, does not harm the patient. Thermal damage can occur through a variety of mechanisms as outlined in publications such as the Journal of Magnetic Resonance Imaging[4], of which contact with coils and the formation of closed loops is of particular impact. Specific examples have been stated where cardiac monitoring electrodes which were not cleared for MRI use caused 3rd degree burns[5] (Report Number 2110898-2018-00048); highlighting the important role that correct coil component material and design play in patient safety.

Items such as cable covers and mattress covers are necessary to prevent the patient coming into contact with the coil and create local RF hot spots. RF hot spots can lead to localised heating and thermal injury due to energy absorption resulting in burns to the patient. The bushing provides further protection against patient access to the coil, ensuring that the inner metallic conductor cable is not exposed from the cable cover. Without protections such as these, thermal damage attributable to unsuitable patient protection in a MRI, allowing patients touching MRI coils, can be experienced and is regularly noted in the "Manufacturer and User Facility Device Experience portal"[6].

Another mechanism in which thermal injury can occur in MRI's is through the generation of RF, which is able to induce currents in conductive material. Through electromagnetic induction in a conductive material, a "closed loop" can be formed. As the current in the closed loop encounters the area of highest resistance, sufficient heat can be generated to induce thermal injury. Closed loops can result from any conductive material such as cables crossing other cables; which the cable covers and bushings are intended to limit through their inherent stiffness, as well as skin-to skin contact, which is managed through addition of insulating material such as the mattress. There have been cases where patients were burned due to skin-to-skin contact causing a closed loop to be formed resulting in secondary degree burns[7].

(C) What are the particular characteristics and functions of the RoHS-regulated substance that require its use in this material or component?

Refer to Section 4(B)

5. Information on Possible preparation for reuse or recycling of waste from EEE and on provisions for appropriate treatment of waste

1) Please indicate if a closed loop system exist for EEE waste of application exists and provide information of its characteristics (method of collection to ensure closed loop, method of treatment, etc.)

[4] https://onlinelibrary.wiley.com/doi/full/10.1002/jmri.1088?sid=nlm%3Apubmed

[5] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7486790&pc=DRX

[6] www.accessdata.fda.gov

[7] https://www.mdedge.com/ccjm/article/136626/imaging/second-degree-burn-after-mri

MRI coils are very commonly returned to the original manufacturer for refurbishment and reuse. However, the DEHP-plasticised components will be disposed of by recycling at end of life.

2) Please indicate where relevant:

☐ Article is collected and sent without dismantling for recycling
☐ Article is collected and completely refurbished for reuse
☐ Article is collected and dismantled:
  ☐ The following parts are refurbished for use as spare parts:
  ☐ The following parts are subsequently recycled:
☒ Article cannot be recycled and is therefore:
  ☒ Sent for energy return
  ☐ Landfilled

3) Please provide information concerning the amount (weight) of RoHS substance present in EEE waste accumulates per annum:

☐ In articles which are refurbished _____
☐ In articles which are recycled _____
☒ In articles which are sent for energy return 14kg
☐ In articles which are landfilled _____

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6. Analysis of possible alternative substances

(A) Please provide information if possible alternative applications or alternatives for use of RoHS substances in application exist. Please elaborate analysis on a life-cycle basis, including where available information about independent research, peer-review studies development activities undertaken

There are in theory two potential alternative paths to identify alternatives to DEHP-plasticised components:

a) Utilise a different plasticiser to DEHP for each of the material types; or

b) Qualify an alternative polymer, which does not require a plasticiser such as DEHP.

For either of these pathways, both of which are discussed in detail below, the substitute material will need to demonstrate all of the requirements as listed in Section 4(B) and of particular importance is biocompatibility, due to the nature of the parts, and any impact on MRI image quality.

Some MRI coil manufacturers have qualified alternatives to DEHP-plasticised components, however the requirements to which they are tested to will be specific to the proprietary design of the MRI. Once an alternative is identified by the methodology outlined below, biocompatibility and reliability testing, as outlined by Table 8, needs to be undertaken which

will not be completed before July 2021.

Alternative polymer:

Due to the increasing number of substance restrictions and potential restrictions that affect PVC[8] and the other materials utilised, some medical device manufacturers are reluctant to use an alternative based on the current materials, as they will not want to be forced to substitute again in the future. Alternative polymers that have been evaluated by a COCIR member and the associated advantages and disadvantages compared to the currently utilised plastic is discussed below.

Table 2. Assessed mechanical and electrical properties of potential alternative polymers

Polymer	Advantage	Disadvantage
EPDM (Ethylene-Propylene diene monomer rubber rubber)	Excellent aging resistance, electrical insulation and resistance to chemicals is generally good	Fair physical strength properties but might not be suitable for all applications; Poor flame resistance; Failed biocompatibility testing
EPDM for food (a different grade to the above material)	Likely to be similar to EPDM	As EPDM failed biocompatibility testing, EPDM for food is likely to fail also so not a suitable alternative.
Urethane rubber	Tough and flexible, even at low temperature; Good water and chemical resistance	Poor electrical properties; Biocompatibility currently unknown but is under investigation
Silicone Rubber	Good chemical resistance; Highly flexible	Reduced mechanical properties with material wearing quicker; Attracts static Biocompatibility currently unknown

Another key parameter of an alternative polymer is the effect of the polymer on the MRI image to minimise the image distortion. Testing was undertaken to measure the proton signal of alternative polymer using field echo sequence with shot echo time with Table 4 detailing the "relative image intensity ratio" from the polymer versus air. The larger the ratio the more

[8] *For example the proposed RoHS restriction of diantimony trioxide*

distortion to the MRI image with any increase in ratio of the alternative negativtly impacting image quality and performance of the MRI.

Table 3. Assessed image intensity of potential alternative polymers

Current Polymer		Alternative Polymer			
Polymer	**Intensity ratio**	**Polymer**	**Intensity ratio**	**Increase in ratio**	**% higher**
CSM	7.1	EPDM	77.8	70.7	995.8
CR	5.5	Urethane rubber	6.9	1.4	25.5
NBR/PVC	2.2	Silicon rubber	12.6	10.4	472.7

The testing demonstrates that the currently identified potential alternative all have an increase in relative image intensity ratio. With EPDM and silicon rubber showing a significant increase affecting the image quality. Beyond those which were tested by COCIR members the following Table 5 outlines a literature review of potential polymers, outlining typical mechanical, electrical and image intensity values based on common compositions.

Table 4. Theoretical potential alternative polymer comparison

Polymer	**Advantage**	**Disadvantage**	**MRI signal**
Polyethylene (PE)	Low dielectric loss and high initial dielectric strength; so minimal impact on image quality of MRI scans	Relatively stiff and inflexible therefore unsuitable for cables or mattress covers; Thermal expansion coefficient three times higher than PVC; Poor resistance to cracking, which is particularly important as liquid chemicals e.g. cleaners tend to accelerate the cracking process	Higher than PVC
Cross-linked Polyethylene (XLPE)	Low dielectric loss (but higher than PE); so minimal impact on image quality of MRI scans; Good resistance to cracking, which is particularly important as liquid chemicals e.g. cleaners tend to accelerate	Relatively stiff and inflexible therefore unsuitable for cables or mattress covers; Thermal expansion coefficient two times higher than PVC	Higher than PVC

	the cracking process		
EPR (ethylene propylene rubber)	More flexible than PE and XLPE; Lower thermal expansion	Medium to high dielectric loss, therefore affecting image quality of MRI scans; Poor tear resistance and easily damaged due to its softness	Significantly higher than PVC
Fluoropolymers	Several types available. Very flexible, thermally stable and chemical resistant	Poor cut through resistance. Susceptible to cold flow when stressed (bent) over tight radius, so is too easily damaged; Emits very toxic and corrosive gases in fires	Lower than PVC

Consequentially although there may be polymers available in the future, which could be suitable for component use in MRI coils, this requires further testing. Until the testing has been completed alternative materials cannot be used, the timeframes of qualification are outlined in Section 7(B).

In addition to the above discussed parameters biocompatibility testing will need to be undertaken on an alternative polymer which demonstrates the required properties. Biocompatibility testing is both time-consuming and complex due to the large number of potential tests, which need to be considered and then undertaken according to ISO 10993.

Alternative Plasticisers

Alternatives to DEHP as a plasticiser are increasingly being used by the electrical industry, especially substitutes for DEHP-plasticised PVC, however these are not approved for human skin-contact medical use and each has a unique combination of properties. However, to ensure that every opportunity for alternative material to DEHP has been identified, the following section outlines the investigations being undertaken by industry.

A key parameter for alternative plasticisers is the viscosity, which effects the flexibility of a plasticised polymer. A low viscosity plasticiser tends to result in a more flexible plastic than the same weight percent addition of a higher viscosity plasticiser. Polymer formulators have some scope to alter the plasticiser used, but this usually means that the plastic needs to be completely reformulated as the concentrations of other ingredients, such as flame retardants, fillers, pigments, stabilisers, etc. will all need to be adjusted to ensure that all of the essential properties of the material can be achieved. This is not straightforward and can take a considerable time to carry out. Other important properties of the plasticiser are:

- Inertness with other ingredients of the plastic formulation;

- It must plasticise the polymer sufficiently (to make it flexible) and the plasticised plastic must be stable (i.e. the plasticiser must not separate to leave brittle hard polymer) Some plasticisers can exude out of polymers (to give sticky coatings) or they may be volatile and so evaporate;
- Very low toxicity – not always easy to determine, especially with newer substances;
- Biocompatibility to check patent safety and equipment performance are not negatively affected; potentially involving extensive testing, validation and/or clinical trials.

There are hundreds of plasticisers that are commercially available, including phthalates, however very few will plasticise the materials and provide all of the required properties. Many of the available plasticisers are not benign, for example, most short alkyl chain phthalates, such as dipentyl phthalate or dihexyl phthalates are classified as Substance of Very High Concern (SVHC), due to being category 1B reproductive toxins, under REACH and as such are not suitable alternative plasticiser.

Diethylhexyl terephthalate (DEHT) has been investigated by MRI manufacturers as it has a similar chemical structure to DEHP so it was hoped that it would not have a large negative effect on the MRI proton signal while still giving similar flexibility. However, DEHT viscosity is higher than that of DEHP (65 mPa.s at 25°C compared with 56.6[9]) so more plasticiser needs to be added to the plastic to achieve the same flexibility. MRI proton signal intensity measurement was undertaken by GE with two grades of flexibility of PVC[10]. DEHP-PVC and DEHT-PVC were compared by GE and the 'relative image intensity ratio' (the larger this ratio the more distortion to the MRI image) from the polymer versus air was measured. Measurements of the increase in proton signal (expressed as ratio) were made within a range of "flip angles" because not only is image intensity important, but also contrast between materials is also important (intensity and image contrast both vary with flip angle). Results are shown below:

Table 5. Results for more flexible materials, durometer value 65

Flip angle	1	2	3	4	5	6	7	8	10	15
DEHP ratio	10	17	17	17.1	15.7	15.1	13	12.4	9.9	6.2
DEHT ratio	10.8	19.4	19	21	19.9	18.4	15.4	15.2	11.4	7.4
Increase in ratio	0.8	2.4	2	3.9	4.2	3.3	2.4	2.8	1.5	1.2
% higher	8.0	14.1	11.8	22.8	26.8	21.9	18.5	22.6	15.2	19.4

[9] http://www.lemonchem.com/wap_product_detail_en/id/10.html

[10] https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_17/application_GE_Global_Operations_RoHS_17_Application_Form_Strain_relief_DEHP_20180912.pdf

Table 6. Results for less flexible materials, durometer value 90

Flip angle	1	2	3	4	5	6	7	8	10	15
DEHP ratio	1.6	2	1.7	1.9	1.8	1.8	1.5	1.4	1.1	1
DEHT ratio	1.8	2.4	2.5	2.5	2.3	2.1	1.8	1.8	1.5	1.1
Increase in ratio	0.2	0.4	0.8	0.6	0.5	0.3	0.3	0.4	0.4	0.1
% higher	12.5	20.0	47.1	31.6	27.8	16.7	20.0	28.6	36.4	10.0

The above results of the 65 durometer material with DEHT-PVC show that this has an even higher image intensity than DEHP-PVC, which indicates that it could give inferior imaging performance compared to DEHP-PVC. The DEHT-PVC material with durometer of 65 has too strong a signal for use close to the imaging zone as the relative image intensity values are more than 4.0. Material with this signal strength would therefore need to be used at least 30 cm away from the imaging zone where it has no detrimental effect, which is not suitable for some of the applications.

The results with the less flexible 90 durometer material also show that DEHT-PVC gives a higher proton signal intensity than DEHP-PVC. Although all values from the 90 durometer material are within the 4.0 ratio limit, they are mostly higher than the ideal 1.2 limit with both materials (except at flip angles of 15°), but values are much closer to the 1.2 ideal ratio with DEHP-PVC than with DEHT-PVC. DEHT-PVC is again therefore inferior to DEHP-PVC so could affect image quality, especially when components are used within close proximity to the imaging zone.

The most likely explanation for these results is that protons (hydrogen atoms) in the plasticiser molecules give much stronger MRI signal intensity than protons in the PVC polymer. This is indicated because 65 durometer PVC contains more plasticiser than the less flexible 90 durometer material and gives a stronger proton signal. The intensity of protons in the diethylhexyl alkyl groups of the terephthalate and the phthalate may be similar, but due to the higher viscosity of DEHT, a higher concentration must be used to achieve the same flexibility as DEHP-PVC to achieve the 90 durometer value. This result therefore indicates that other plasticisers that are more viscous than DEHP are also likely to have stronger MRI signal intensity (as higher concentrations would be needed) and so would be less suitable than DEHP. The viscosity values of the two most commonly used substitutes for DEHP, as they are the most chemically and physically similar to DEHP, are higher than DEHP, as shown below:

Table 7. Viscosity of phthalate plasticisers

Phthalate	Viscosity (source of data)
DEHP	56.6 mPa.s (25°C), from Eastman SDS
DiNP (di-isononyl phthalate)	85 – 100 mPa.S (20°C), from ExxonMobil datasheet

DiDP (di-isodecyl phthalate)	110 – 125 mPa.S (20°C), from ExxonMobil datasheet

At present, it appears that DEHT-PVC will be inferior to DEHP-PVC due to the more intense proton signal and so other more viscous plasticiser, such as DiNP and DiDP will also be inferior. The biocompatibility of DEHT-PVC is presently unknown but as MRI proton signal intensity was inferior, alternative materials may be preferred.

The additional consideration of how alternative plasticisers migrate into the various fluids that they may come into contact (such as cleaning and sterilisation chemicals) has very little data. Some research has been published on migration rates into food and into artificial sweat, but there is no published data for the other fluids and so long term reliability is not known.

Impact on Healthcare in the EU

Healthcare in the EU will be impacted if particular MRI coils cannot be purchased by EU hospitals because approved substitutes are not available. When a hospital buys an MRI scanner, it will also buy the coils that it believes will be frequently needed, but in the future, they may need to buy additional coils to image other parts of patient's bodies. Each MRI model will be made and sold over many years; a period much longer than is typical for consumer products. It is common for one model to be sold for over 10 years and the same types of coils designed for this MRI will be made and sold during this period and for several years after the last MRI of this model is sold. MRI scanners generally can only use only the original MRI manufacturers' coils. Therefore, without this exemption, many types of coil will no longer be available to EU hospitals so that many patients' illnesses cannot be diagnosed by MRI.

Without this exemption, some manufacturers will have to make many types of coil designs obsolete in the EU because DEHP free coils so far cannot be made that meet all essential criteria and so there are none that are approved for use in the EU. Where this occurs, the hospitals and their patients will be affected negatively by their inability to provide MRI scan examination to patients, unless this exemption is accepted.

If hospitals are unable to buy the current wide range of MRI coils for their MRI scanners that they already own, the waiting times for receiving an examination are bound to increase and many patient's conditions would be more difficult to diagnose and treat as other less suitable methods would have to be used, if this is even at all possible. For example, a whole body coil can be used to examine all parts of a patient's body, but the detail obtained for a small area such as a foot is significantly less than that which can be obtained by a dedicated foot coil. In addition, the time required to obtain a scan of a whole patient is much longer than a foot scan and this can cause delays in treating other patients, as MRI demand often exceeds their availability. Other techniques may not be suitable, for example, CT (Computed Tomography) is used to obtain 3-dimensional images of patients, but the information it provides is not the same as from MRI images, not to consider the unnecessary exposure to radiation.

A report from the Clinical Imaging board outlines that one MRI scanner typically treats around 7,300 patients per year (based on UK use in 2017)[11]. The impact described above on healthcare for patients can therefore affect over 2 million patients in Europe per year (based on the number of currently identified affected designs) who could not be treated using the most suitable diagnostic equipment.

Another potential impact on healthcare could be the forced adoption of a less performing material, e.g. inferior image quality or shorter lifetime. Given the limited time left for substitution and the difficulties explained above, manufacturers may be forced to adopt a less performing alternative to avoid not being able to supply coils. This could result in less precise diagnostic results or inferior reliability that prevents patients from being treated when needed if defects occur. However, producing coils that are knowingly less reliable is not permitted by the Medical Devices Regulation and could result in withdrawal of EU approvals.

Impact of retarding new product innovations and development

Another impact from substitution is described here. Medical device manufacturers are aware that the availability of trained engineers is limited and employers can choose whether these work on substitution or on new product development. Recruiting additional experienced engineers is difficult, as most of these will already be working for their competitors, so having to expend more effort on substitution can have a negative impact on innovation, which can negatively impact on future health of EU citizens as explained below.

Diverting engineers away from new product development to modifying existing coil designs could negatively affect the future health of EU citizens. This is because the only reason for development of new medical devices is to produce new designs with superior diagnostic capability or superior medical procedures and treatments. In the example of MRI, one innovation has been to develop digital coils to replace analogue coil designs. One manufacturer claims that digital coils have better signal to noise ratio than analogue designs[12]. Other MRI developments such flexible and adaptive coils to adapt to different patient sizes while maintaining optimum image quality and multituned coils to allow different imaging techniques without changing coils are outlined in the Journal of Magnetic Resonance Imaging[13].

These types of improvement in performance results in clearer images that enable doctors to be able to detect tumours and other harmful conditions much earlier and this improves the likelihood of recovery and recovery is likely to be faster and so incur smaller costs to hospitals.

[11] https://www.rcr.ac.uk/sites/default/files/cib_mri_equipment_report.pdf

[12] https://www.philips.co.uk/healthcare/education-resources/technologies/mri/dstream

[13] Gruber B, Froeling M, Leiner T, Klomp DWJ. RF coils: a practical guide for nonphysicists. J Magn Reson Imaging 2018:48:590-604.

This type of development would not be possible or would at best be delayed if the engineers were diverted to redesign existing products for compliance purposes, but without performance improvement, as would be the case with alternatives to DEHP in coils. Quantitative life cycle comparison of the following two scenarios is not possible:

a) Developing new medical devices; or

b) Replacing DEHP plasticised components.

This is because the positive and negative impacts of each scenario are not directly comparable with each other and the potential impacts for hypothetical future developments cannot be quantified. However, these two scenarios can be compared qualitatively, as outlined below.

New medical products should usually have a smaller overall health and environmental impact to older designs because medical device manufacturers try to avoid using hazardous substances in new designs as is required by a Medical Device Regulation standard[14].

The largest potential benefit from new medical device development is at the use life cycle phase where the new technique will improve the health of EU citizens. There is no health benefit from replacement of DEHP during the use phase, as the coils should have identical functions and performance.

Although it is not possible to compare quantitatively the development of a hypothetical new medical device with replacement of DEHP-plasticised components, it is clear that new medical device development could potentially give a more significant overall benefit than DEHP replacement.

(B) Please provide information and data to establish reliability of possible substitutes of application and of RoHS materials in application

Assessment of alternative materials is outlined in Section 6(A).

7. Proposed actions to develop possible substitutes

(A) Please provide information if actions have been taken to develop further possible alternatives for the application or alternatives for RoHS substances in the application.

Research using several alternative polymer types has been undertaken to

[14] This is required by Medical Devices standard EN 60601-1-9:2007 “Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design”

determine the suitability of these substitutes as outline in Section 6(A).

(B) Please elaborate what stages are necessary for establishment of possible substitute and respective timeframe needed for completion of such stages.

Medical device manufacturers need the following steps:

1. Identify suitable alternative materials;
2. Measure MRI image intensity;
3. Carry out biocompatibility testing; and
4. Manufacture components for MRI coil assemblies and carry out reliability testing.

If results are satisfactory, medical device manufacturers are obliged by Medical Device legislation to carry out internal verification and in some circumstances, requesting re-approval may be required. For this type of change, the most likely requirement is re-verification for each MRI coil design that is changed. The timescale needed for substitution of a component for one MRI coil is:

Table 8. Substitution Timescale

Phase	Elapsed time for one coil design
Identify materials	Currently underway, timescales dependant on finding suitable materials to criteria in Section 4 (B)
Biocompatibility and other tests	Ca. 6 months per material being altered to DEHP free
Reliability testing	6 months to a year
Verification and global approvals if needed	Up to 2 years

The timescale for redesign of many different types of MRI coils would be much longer than for one coil, although only a representative selection of coil assemblies would need to be fully evaluated and verified. Manufacturers predict that as long as a suitable substitute material can be identified, full substitution of DEHP plastic with a DEHP-free material could be complete during 2022. However, if currently researched substitutes are discovered to be unsuitable, this exemption will be needed for longer, potentially up to 2025, to evaluate different alternatives.

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8. Justification according to Article 5(1) (a):

(A) Links to REACH: (substance + substitute)

1) Do any of the following provisions apply to the application described under (A) and (C)?

☐ Authorisation

☒ SVHC
☒ Candidate list
☐ Proposal inclusion Annex XIV
☒ Annex XIV

☐ Restriction

☒ Annex XVII- DEHP is restricted only in childrens' and childcare products, so not applicable. Entry 51 of Annex XVII to Regulation (EC) No 1907/2006 shall not apply to 'medical devices within the scope of Directives 90/385/EEC, 93/42/EEC or 98/79/EC or parts thereof'. MRI are scoped within 93/42/EEC and therefore this is not applicable.

☐ Registry of intentions

☒ Registration

2) Provide REACH-relevant information received through the supply chain.
Name of document: DEHP registration: https://echa.europa.eu/registration-dossier/-/registered-dossier/15358

(B) Elimination/substitution:

1. Can the substance named under 4. (A) 1 be eliminated?
   ☐ Yes. Consequences? _____
   ☒ No. Justification: Outlined in Section 6(A)
2. Can the substance named under 4. (A)1 be substituted?
   ☐ Yes.
   ☐ Design changes:
   ☐ Other materials:
   ☐ Other substance:
   ☒ No.
   Justification: Outlined in Section 6(A)
3. Give details on the reliability of substitutes (technical data + information): Refer to Section 6(A)
4. Describe environmental assessment of substance from 4.(A)1 and possible substitutes with regard to
   1) Environmental impacts: See Section 6 (A)
   2) Health impacts: See Section 6 (A)
   3) Consumer safety impacts: See Section 6 (A)

⇨ Do impacts of substitution outweigh benefits thereof? See Section 6(A)

Please provide third-party verified assessment on this:

(C) Availability of substitutes:

a) Describe supply sources for substitutes: Although many flexible polymers are available, they cannot be used until the work described above has been carried out and they are proven to meet all of the essential criteria outline in Section 4(b)

b) Have you encountered problems with the availability? Describe: Suitable substitutes have not yet been identified

c) Do you consider the price of the substitute to be a problem for the availability?

☐ Yes ☒ No

d) What conditions need to be fulfilled to ensure the availability? Additional time to investigate and qualify alternative substances

(D) Socio-economic impact of substitution:

⇨ What kind of economic effects do you consider related to substitution?

☐ Increase in direct production costs

☒ Increase in fixed costs- for research, testing and re-approvals

☐ Increase in overhead

☒ Possible social impacts within the EU- Section 6(A) outlines fully. Negative impact if hospitals cannot buy additional medical coils. A report from the Clinical imaging board outlines that one MRI scanner typically treats around 7,300 patients per year (based on UK use in 2017). COCIR estimates that the impact described above on healthcare for patients can therefore affect over 2 million patients in Europe per year (based on the number of currently identified affected designs). An additional 9 million patients would be affected by GE's exemption request[7] if that too were not to be granted. A proportion of which, if hospitals are unable to buy the current full range of coils, diagnosis and treatment times will be longer and some alternative method that have to be used which may be less effective.

☐ Possible social impacts external to the EU- Currently most countries do not limit DEHP so no impact

☐ Other: _____

⇨ Provide sufficient evidence (third-party verified) to support your statement: _____

9. Other relevant information

Please provide additional relevant information to further establish the necessity of your request:

_____

10. Information that should be regarded as proprietary

Please state clearly, whether any of the above information should be regarded to as proprietary information. If so, please provide verifiable justification:

The method used to calculate the amount of DEHP uses sales data that is company confidential and so is submitted separately