Application Form

Exemption Request Form

Date of submission: 29 June 2017

1. Name and contact details

1) Name and contact details of applicant:

Company:	EUROMOT	Tel.:	32-2-893-21-40
Name:	John Mortell	E-Mail:	john.mortell@euromot.eu
Function:	Manager, Technical and Regulatory Affairs	Address:	Rue Joseph Stevens 7 1000 Bruxelles, Belgium

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

Company:	EUROMOT	Tel.:	32-2-893-21-40
Name:	John Mortell	E-Mail:	john.mortell@euromot.eu
Function:	Manager, Technical and Regulatory Affairs	Address:	Rue Joseph Stevens 7 1000 Bruxelles, Belgium

This exemption request is submitted with the support of:

EUROMOT	The European Association of Internal Combustion Engine Manufacturers
NATIONAL ASSOCIATION OF Manufacturers (see separate letter)	National Association of Manufacturers
AEM ASSOCIATION OF EQUIPMENT MANUFACTURERS	AEM – Association of Equipment Manufacturers
OPEI OUTDOOR POWER EQUIPMENT INSTITUTE	OPEI – Outdoor Power Equipment Institute

2. Reason for application:

Please indicate where relevant:

☒ Request for new exemption in: Annex III

☐ 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

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

Proposed or existing wording: Bis (2-ethylhexyl) phthalate in rubber parts such as O-rings, seals, vibration dampers, gaskets, hoses, grommets and cap-plugs that are used in engine systems including exhausts and turbochargers that are designed for use in equipment that is not designed solely for consumer use.

Duration where applicable: Maximum validity period

☐ Other: _____

3. Summary of the exemption request / revocation request

Rubber plasticised with DEHP is used in engines as hoses, tubes, seals, gaskets, O-rings, vibration dampers, grommets and as cap-plugs. These used to act as flexible connections between parts of engine systems and must be reliable for the normal lifetime of the equipment which is at least 10 years. Engines that are not designed solely for consumers may be used continuously for many years or for long periods daily for many years, whereas consumer products, such as grass trimmers (“strimmers”), may only be used for one hour per week and only during the summer. Rubber parts in engines experience relatively severe conditions of temperature, vibration, abrasion and will be in contact with a variety of aggressive fluids, gases and solid materials. Although research into substitute plasticiser in PVC has been carried out primarily by the food and electronics industries, there is no published research with rubbers in the conditions experienced in engines. As a result reliability of potential substitute materials cannot be assured.

Although there are many types of rubber and plasticiser on the market, the combination of properties of DEHP in a specific rubber cannot be achieved by a 1:1 drop-in replacement plasticiser or with a different type of rubber as all relevant properties of substitutes will be different to DEHP. Therefore considerable research and testing is needed and has started to replace DEHP in rubbers, but this will take an expected eight years to complete assuming that the first materials selected prove to be reliable, but this cannot be guaranteed. If a selected material is found to be unreliable, then selection and testing will need to start again from the beginning which will extend the period required beyond the currently predicted eight years.

---

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: ______

   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: Not applicable to equipment specifically designed for consumer use or in equipment that is excluded from the scope of RoHS

   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 ten substances is in use in the application/product?

   (Indicate more than one where applicable)

   ☐ Pb ☐ Cd ☐ Hg ☐ Cr-VI ☐ PBB ☐ PBDE

   ☒ Bis (2-ethylhexyl) phthalates – DEHP

3. Function of the substance: Softener and plasticiser in polymeric materials, especially types that are classified as synthetic rubbers

4. Content of substance in homogeneous material (%weight): Typically 2 – 30%, depending on application. Typically there are two main ranges, about 2 – 10% DEHP

in rubber parts such as hoses, O-rings and seals and about 10 – 30% DEHP in rubber coatings on gaskets.

5. Amount of substance entering the EU market annually through application for which the exemption is requested: **1 tonne DEHP per year**
   Please supply information and calculations to support stated figure.
   - Average weight of components 10grams
   - Average DEHP concentration in components 5%
   - Average number of parts per engine 30

   Calculated average mass of DEHP per engine = 10g x 5% x 30 = 15 grams / engine
   - Estimated number of engines requiring this exemption[1] = 68,000 per year

   Calculated amount of DEHP in engines placed on the EU market annually is 1 tonne (68,000 x 15 grams)
   Estimated global quantity
   Proportion of global engine sales that are in Europe estimated to be 8%[1].
   Calculated quantity of DEHP in global; engine sales per year = 12.5 tonnes

6. Name of material/component: DEHP-plasticised rubbers used for O-rings, vibration dampers, gaskets, seals, grommets, hose, tubes and cap-plugs, designed for use in engines

7. Environmental Assessment: Not needed as exemption required due to reliability being not assured
   LCA: ☐ Yes
   ☒ No

(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?

Materials

Plasticisers such as bis-(2-ethylhexyl) phthalate (DEHP) are added to polymers, resins, paints, inks, sealants and potting materials to provide flexibility. DEHP is

[1] Value from EUROMOT's RoHS exemption request for lead in engine bearings. This however excludes the relatively small number of engines used in equipment that is typically leased to both consumers and professionals. As these are not used only by professionals, these are not excluded from RoHS as "professional non-road mobile machinery" as defined by the RoHS directive. It has not been possible to determine the number of these products, but it is believed that the amount of DEHP in this relatively small number of products is very small compared to the estimated quantity of 1 tonne per year.

added to a variety of materials, in particular to synthetic rubbers of various types used for parts that are used in engines.

One of the most common uses of DEHP by the electronics industry has been as a plasticiser in PVC which was previously widely used by the electronics industry in cable insulation and labels, such as the labels of electrolytic capacitors. DEHP and the other RoHS-restricted phthalates, in particular Dibutyl phthalate (DBP) is used in sealants and adhesives that are used to construct electronic components. Partly because DEHP and DBP are REACH SVHCs and also because of the forthcoming RoHS restriction, research has been carried out by cable and electronic component manufacturers to develop alternatives. There are still many cables and components on the market globally that still contain DEHP or DBP and it is challenging for engine manufacturers to determine where DEHP and the other restricted phthalates are used.

Efforts by engine manufacturers has established that DEHP is used as a plasticiser in several types of rubbers, in particular chloroprene rubber and NBR (neoprene) rubber, but also in EPDM, ECO rubber and others. Each type of plasticised rubber material has a unique combination of physical and chemical properties that make them suitable for specific uses in engines. There has been almost no research carried out (according to rubber component suppliers and from a literature search) to study and compare the properties of these types of rubbers with alternative plasticisers whereas there has been considerable research on the properties of substitutes for DEHP in PVC. Measurements of the properties of rubbers with DEHP and potential substitute plasticisers do not appear to have been carried out as very few publications are available on these materials. Although there are many publications available on DEHP in PVC, these are usually difficult to interpret as they are mostly tested by the food or health industries using food simulants or saliva so that the results cannot directly be applied to conditions inside or attached to engines. This lack of useful data is a concern because the properties of rubbers in engines needs to be known to ensure that reliability is not negatively affected as a result of substitution.

Types of rubber materials used

It has been established that DEHP-plasticised rubbers are used as hoses, tubes, gaskets, seals, vibration dampers, grommets, cap-plugs and “O”-rings in engines. Nitrile rubbers (NBR) which are copolymers of acrylonitrile and butadiene are widely used by the automotive industry and in engines as they can withstand a wide temperature range and they are resistant to engine fluids. NBR rubbers with a high acrylonitrile content have the advantage of superior resistance to hydrocarbon-based engine oils. Chloroprene rubbers (also called nitrile) are also widely used in all types of engines. Other rubbers that are used and which can contain DEHP include EPD and ECO rubbers.

These materials will experience large temperature ranges, down to as low as -40°C in some parts of the EU (e.g. northern Finland in winter) and up to over 150°C inside or close to the engine. These materials will come into contact with engine fluids, such as lubricating oil, coolant (water & anti-freeze, which are glycols and alcohols), brake fluid, transmission fluid, etc. as well as rain water and environmental contaminants. The rubber parts must retain their properties and not significantly change during the life of the engine which should be at least 10 years and preferably much longer.

Significant changes in properties of the rubber would occur if the plasticiser were to be lost from the rubber, such as by migrating out of the rubber into an engine fluid as this would be likely to cause early failure of the engine. An important property of rubber parts that contain plasticisers used in engines such as rubber hoses, gaskets, vibration dampers, grommets, seals, "O"-rings, etc. is their modulus values (Young's modulus), which is related to its springiness or stiffness and the ability to maintain a critical seal. This property must be correct to ensure that these rubber parts prevent leaks of fluids, which can occur if the rubber stretches, loses stiffness or cracks due to becoming brittle. Changing to a different plasticiser will usually have an impact on this property and alternative types of flexible polymers that do not contain plasticisers will also have very different modulus values. Differences in flexibility, chemical resistance or modulus will make alternatives unsuitable and unreliable in specific applications. This is discussed in answer to Q6.

Component types and designs

Uses of these rubber engine components are as follows:

- Engines contain many flexible rubber **hoses**. These are used for transferring liquids and gases, often under pressure, from one location to another. Fluids include fuel (e.g. diesel), lubricating oils and coolant. Gases may include natural gas (fuel) and air. Hoses will be exposed to the fluids or gases that they are intended to carry, but are also exposed to materials that occur where they are used. For example, leaks of engine oil and other fluids from one location can contaminate hoses elsewhere and so the hose material must be resistant to all materials that they may come into contact. They must also not be affected by the environment in which they are used, which can be dirty building sites, chemical plant, oil refineries, etc. There are also additional stresses due to the surrounding environment including vibration and heat from continuous use. Any change in the physical properties of the material could cause early failure. Cracks could occur if the rubber were to harden causing leaks. If the material were to become softer, high internal pressure could cause distortion and damage to the hose wall, causing leakage.

  Flexible hoses are used because there can be movement between one part of the equipment and another. For example, the engine will vibrate and twist when under power whereas fluid reservoirs and heat exchangers do not move as they are connected to other parts of the equipment. Flexible hose connections allow permanent connections to be made that are not damaged by the continuous flexing that will occur. Metal pipe connections have the disadvantage that metals suffer from cyclic fatigue when exposed to continuous flexing movements which results in cracks and early failure. Flexible hoses are also used to accommodate movement caused by heat expansion and contraction which would damage rigid tubing connections. For example the turbo oil feed and return lines must have a flexible section to allow for this movement.

Rubber vent tubes (a type of hose) contain DEHP and are used to ventilate the crankcase. These are essential for fuel economy and must be resistant to lubricants that can escape from the crankcase into the vent tube. If the lubricant were to degrade the vent tube, these would fracture and could drop off.

The image below shows an example of where hoses are used on an exhaust gas recirculation system of a diesel engine.

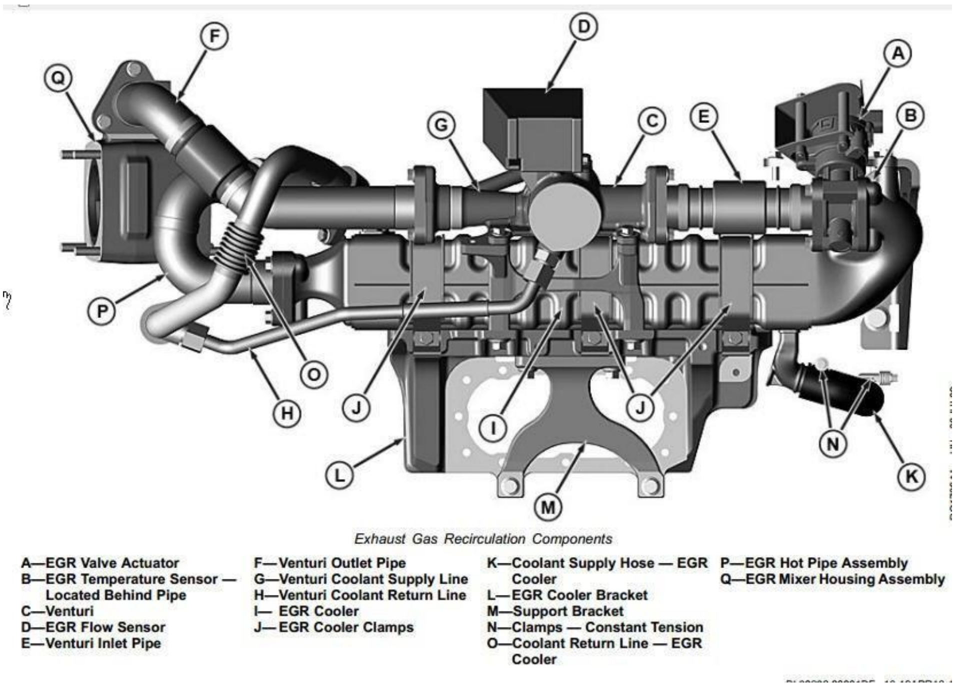

Figure 1. Example of locations of hoses used on an exhaust gas recirculation system of a diesel engine

- **Gaskets** are used for creating a seal between two parts of the engine. Each engine will contain many different gaskets each having a different design and materials that are selected for each specific application. Only some of the gaskets in an engine will contain materials that contain phthalates. For example, head gaskets need to be resistant to high temperature so are usually make from metals such as steel and graphite although some include rubber gaskets (usually neoprene) and another type is steel with a coating of ECO rubber. The steel gives dimensional rigidity and the rubber creates the seal.

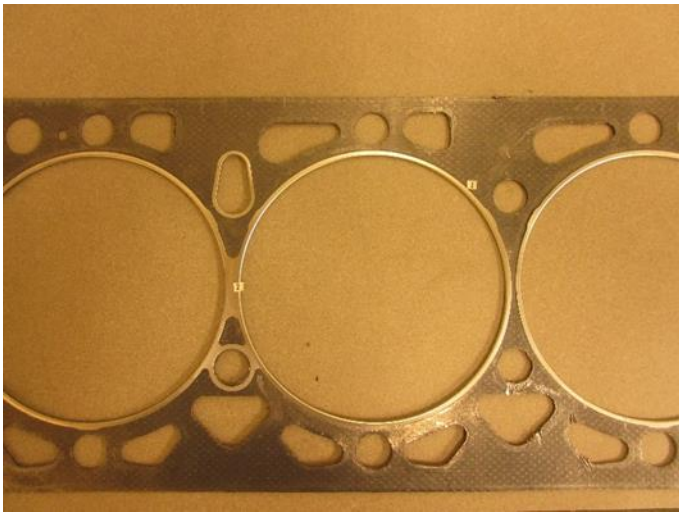

Figure 2. Image of engine head gasket

Figure 3. Image of a rubber coated paper gasket.

It is common to use plasticised rubber coated gaskets to seal accessory components which are gear driven to allow lubrication of the gears to promote service life but the gasket must be robust and oil resistant to work through the life of the engine without leaking. The rubber coatings contain phthalates to give flexibility. Another typical application is covers for items which are serviceable such as an engine thermostat which for the environment that the machine is to be used calls for a different temperature range of thermostat. In cold environments a slow opening and higher temperature thermostat is need, where in hot environments the thermostat may be switched to a faster opening and lower temperature to better cool the engine. These gaskets must not fail by leaking very hot fluid under pressure and which is potentially a burn risk to users. Therefore, again, chemical, temperature, and vibration stresses are playing a factor in the rubber materials reliable operation

The image below shows an example of where engine gaskets are used.

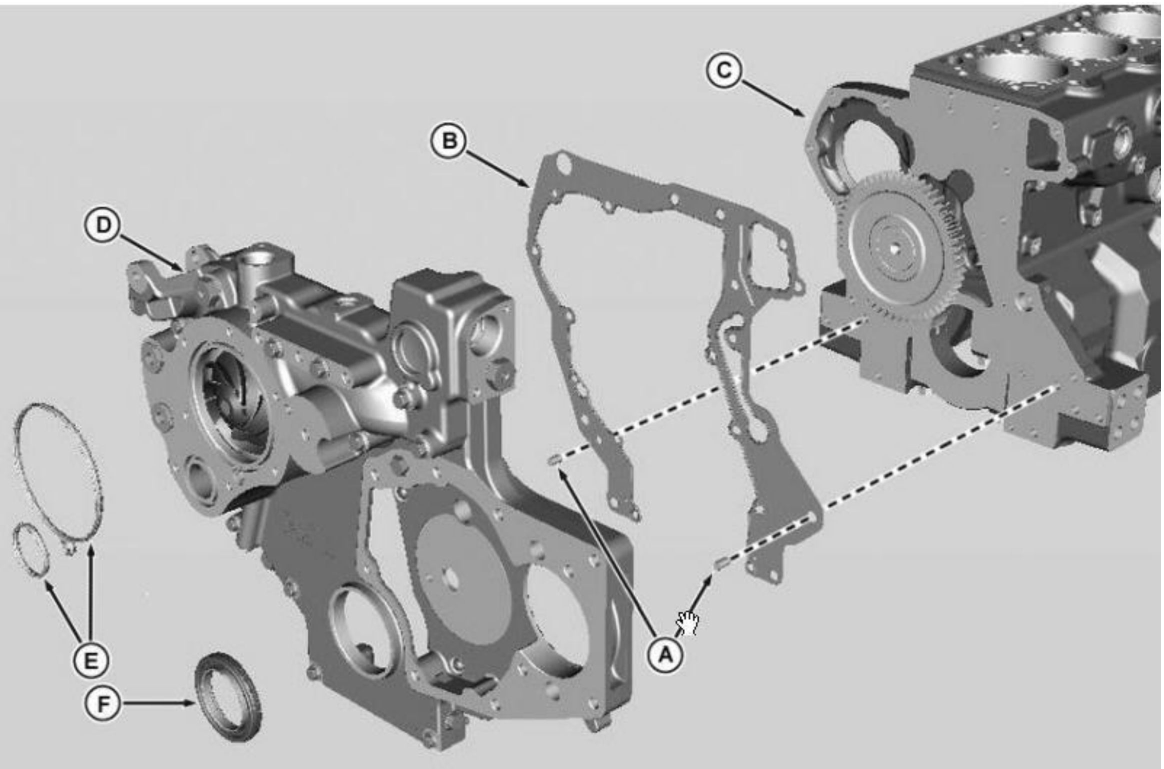

Figure 4. Typical example of locations of engine gaskets

- **Seals** are used as a barrier to oil and other engine fluids and also to exhaust gases. For example, oil seals are used at the ends of camshafts to prevent oil that lubricates these shafts from leaking out of the engine. These seals are round with a central hole into which is placed a shaft that turns. Plasticised rubbers are ideal for these seals as they remain flexible and stiff for long periods preventing leakage but allowing the shaft to turn without the rubber surface wearing away. Rings of rubber that resemble O-rings are also used as seals between parts of engine exhausts. The two parts are clamped together so that the rubber acts as a seal to prevent exhaust gas leakage. These are used at the cooler ends of exhausts as rubber is not able to withstand the temperatures at the hottest parts of engine exhausts. Flexible rubber has the advantage over rigid materials in that it remains flexible and maintains the seal even when there is expansion and contraction of metal parts as the temperature fluctuates. Long term reliability is dependent upon the retention of elastomeric properties and the ability of the rubber to recover during extreme environments.

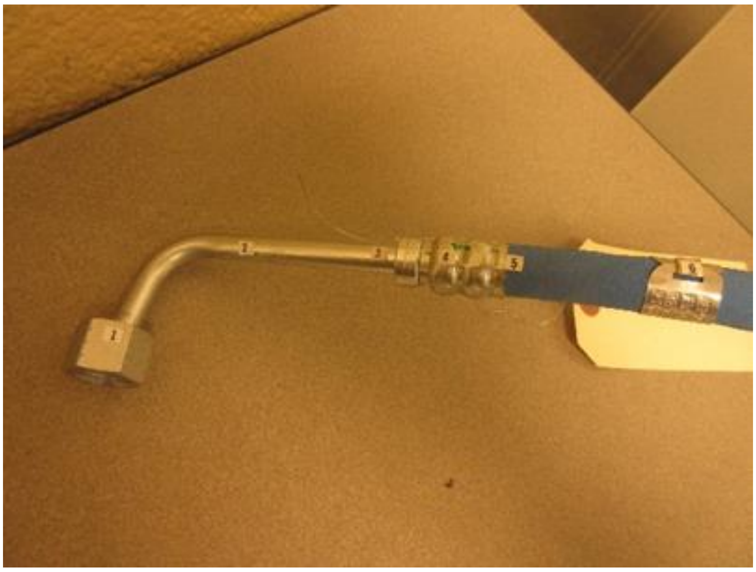

Figure 5. Example use of seals in turbochargers

Seals are used on the housing of a turbocharger; one side is an exhaust driven turbine wheel which recycles the heat and airflow to spin the other side of the turbocharger’s compressor wheel to pull in air and pressurize to force more air into the engine intake which allows for the ability of the engine to create more power with less fuel then a normally aspirated design. The compressor side of the turbo is much cooler and to keep the pressure contained, rubber seals are utilized to separate the sections of the turbo.

- **O-rings** are in appearance similar to seals in that they are round with a central hole. They are used for creating a seal between two parts, such as where a pipe or tube is connected to another part. Sometimes they are slotted into a recess in the exterior of a tubular part that is inserted into another tubular parts so that the O-ring forms a seal. The O-ring material is compressed by the connection, usually by tightening a nut on a screw-thread, so that fluid or gas cannot pass the O-ring seal. Long term reliability requires that the stiffness and resilience of the O-ring material do not change during the expected lifetime. If the material were to soften by absorption of engine fluid the force applied by the O-ring material onto the mating surface would decrease and a leak could occur. Also, if plasticiser were to migrate out into the engine fluid, the material would harden and could crack causing leakage to occur. One of the more significant uses of O-rings are what is known as O-ring face seal connections. These fittings allow for pressurized fluids to flow where needed and offer reliable leak free assembly processes. These have replaced tapered threaded fittings where the number of turns into a threaded hole are what allows the taper to seal the connection. If due to location a fitting need to be a 45 or 90 degree connection, the orientation is critical and can leave fittings loose and prone to leaks or over tight and prone to breaking. O-ring seals are therefore more reliable.

- **Grommets and cap plugs** are used as types of seals to prevent dirt and engine fluids from reaching electrical connections. All machinery that has an engine includes a wiring loom that connects to sensors and other electrical components. Each type of equipment is available with additional options and these are available by use of electrical connections from the wiring loom. Some end-users will select certain options and not others, depending on their requirements. When a connection is not used, the electrical contacts of the connector must be protected to prevent contamination as this will cause an electrical short-circuit and the equipment to malfunction. This is achieved by inserting flexible rubber grommets or cap-plugs that act as seals. These must remain in place for the lifetime of the equipment and so the properties of the rubber must not change despite contact with engine fluids, large temperature fluctuations, vibration, etc.

In reality, the terms seals, O-rings and gaskets can be interchangeable as O-rings and gaskets are usually used as seals. Also, seals are usually a similar shape to O-rings and gaskets which can also be round in shape. Also, seals are usually a similar shape to O-rings and gaskets can also be round in shape. Below is an example of a custom moulded O-ring seal for an actuator cover; while it is round in cross section, it is custom made to fit into a channel in the cover.)

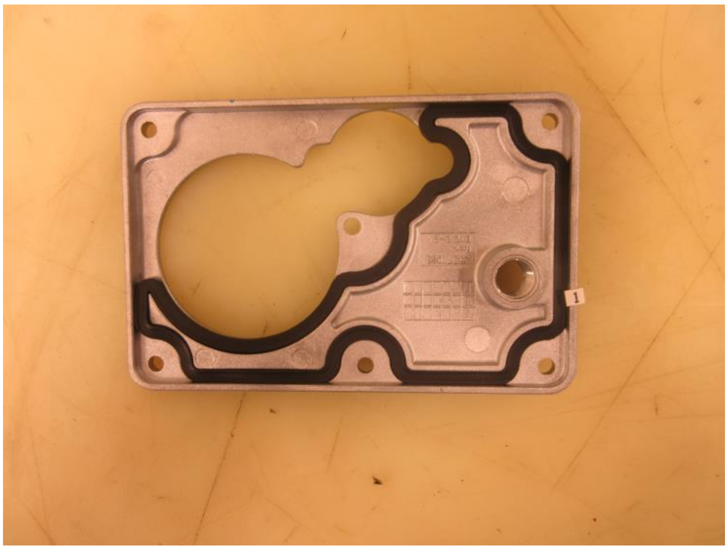

Figure 6. Custom moulded seal for actuator cover (black material in above image)

- **Vibration isolators or dampers** – These are used to attach the engine, cooling components and other components to the equipment. There will be vibration, mainly due to the engine, but also due to external sources such as when moved over rough ground. Anti-vibration isolators are used to prevent the movement of the engine or of components being transferred to the rest of the equipment. These are often made of rubber that contains DEHP plasticiser. These are intended to survive the lifetime of the engine (over 10 years) and the physical properties must not significantly change during this time. They will be exposed to extremes of temperature as well as water spray (e.g. rain) and engine fluids that accidentally leak. They can experience severe conditions, but the reliability when changing to a different material cannot be assured. One vibration isolator manufacturer has reported that replacement of DEHP is proving to be very difficult as alternative plasticisers give different tensile properties, making the material unsuitable. Reformulation of the rubber to achieve suitable tensile properties for these components is proving to be difficult[2].

Engines in end-user equipment

Most engines are used in applications that are excluded from the scope of the RoHS directive. The RoHS directive excludes forms of transport such as road vehicles and also professional-use Non-Road Mobile Machinery (NRMM) as defined by the RoHS Directive. This leaves a small proportion of engines that are used in types of equipment that are in scope of RoHS which includes stationary equipment and those types of machinery that can be moved from location to location, so are not permanently fixed at one location, but are stationary when in use, which can be for long periods and so are not covered by the RoHS Directive's NRMM exclusion which only excludes equipment defined by RoHS as "*mobility or continuous or semi-continuous movement between a succession of fixed working locations while working*"[3]. The RoHS definition of NRMM is different to the definition of the NRMM Emissions Regulation 2016/1628 so that some equipment is in scope of the NRMM Emissions Regulation are not excluded by RoHS[4].

Examples of types of equipment that are in-scope of RoHS that require this exemption include:

- Fixed and mobile generators
- Fixed and mobile compressors
- Agricultural irrigation pumps. These are standalone equipment which may be moved from one field to another, but are stationary when in use.
- Drilling machines
- Rock crushers
- Welding sets that are mounted onto trailers.
- Commercial types of equipment that are may be sold to leasing companies[5], so could

[2] Private confidential communication.

[3] Taken from, Article 2(28) of the RoHS Directive

[4] This was reviewed in 2015 by the Oeko Institut for the European Commission and the report is available from http://bookshop.europa.eu/en/study-for-the-analysis-of-impacts-from-rohs2-on-non-road-mobile-machinery-without-an-on-board-power-source-on-windows-and-doors-with-electric-functions-and-on-the-refurbishment-of-medical-devices-pbKH0415180/

[5] For example, https://www.hss.com/hire . Some leased equipment has a petrol or diesel engine and will be leased to professionals as well as consumers. As a result these products do not meet the RoHS Directive's

be used by both professionals and consumers. These would include chain saws, leaf blowers, some types of mowers, small-size diggers, etc.

The above are illustrative examples of types of equipment that are in scope of the RoHS Directive which are types of equipment that are not excluded from the RoHS Directive

Reliability of equipment that is powered by an engine that is used over extreme temperature and vibration operating conditions, especially if in continuous operation, depends on all of the component parts being reliable and functioning correctly in all conditions. This will include all of the plasticised rubber parts that are used. Reliability cannot be assured until extensive testing is completed satisfactorily with the finished equipment made using engines with all of the parts that contained restricted phthalates being replaced. This is discussed in answer to Q7.

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

The phthalate plasticisers are required to modify the flexibility of the polymeric material. The physical properties of the plasticised polymers depend on the application, but important properties include:

- Suitable hardness and flexibility of polymer at all temperatures of use of equipment that contains an engine
- Suitable tensile properties including the modulus of the polymer at all temperatures of use. This affects the stiffness of the material which is especially important when used as a seal or gasket to prevent leaks of engine fluids.
- Resistance to damage during normal use, such as abrasion resistance of the polymer
- Stability of properties including flexibility, stiffness, abrasion resistance and chemical resistance over the lifetime of engines (at least 10 years). This is dependent on many variable.
- Resistance to loss of plasticiser into engine fluids, into adjacent polymers or to the external surface of the part. This property is related to solubility of the plasticiser in the applicable fluids as well as migration rates from the bulk to the surface and from the surface into the fluid. The plasticised polymer must also be resistant to absorption of fluids by the polymer when exposed to engine fluids and environmental liquids, e.g. rain water, salt-spray, engine coolant (anti-freeze), lubricants (oils), brake fluids, etc. This is one of the most essential properties of the material. Variables that can affect the rate of loss of plasticiser include plasticiser volatility to air and rates of migration into fluids and also into other polymers that are in contact. These rates should be low in all of the conditions experienced by the equipment that contains an engine. It is

---

definition of professional Non-Road Mobile Machinery. The exact scope is not clear because some leased equipment is designed for and intended for professionals only.

known that these rates can be strongly affected by temperature, production conditions of the polymer and other variables (see section 6).

- Processability and compatibility – incorporation of the plasticiser must be straightforward so that the quality of the material can be maintained and does not vary. Some substitute plasticisers are more difficult to incorporate than phthalates and some are less compatible so that they slowly exude out of the polymer to leave a sticky fluid on the surface. Compatibility is related to the polarity of the plasticiser and polymer, which must be similar for both to achieve maximum compatibility. Molecular weight of the plasticiser can also influence compatibility, although low molecular weight polymers are often more easily soluble in polymers, high molecular weight plasticisers tend to have superior "permanence"[6]. Therefore, finding the correct balance is often difficult and requires application-specific testing of the material. High carbon number adipate esters, sebacate esters and azelate esters are reported to have incompatibility problems[7]. Trimellitates have some good properties such as low vapour pressure, but these are more difficult to incorporate into the polymer because of their higher viscosity and a lower fusion rate (this affects the time taken for the polymer blend to melt in the extruder).
- Permanence is the property of a plasticiser to remain in the polymer during its lifetime. Phthalates have high permanence in rubbers, but some alternatives such as diethylhexyl terephthalate are reported to have inferior permanence performance.

A further complication is the need for some types of engines also have to comply with the Non Road Mobile Machinery Emissions Regulation (due to the different definitions used by these two pieces of legislation). The EU NRMM Emissions Regulation controls the emissions of hazardous substances; CO, SO_2, NO_x and particulates. The requirements of the EU NRMM Emissions Regulation have been amended five times so far so that "stage V" will apply from 2019 – 2021, depending on the type and power rating of the engine.

Changes to materials used in these engines will require that they are revalidated for compliance with the NRMM Emissions Regulation and this is almost as much work and takes as long as gaining approval of a new engine design. Meeting the 2019 – 2021 NRMM Emissions Regulation stage V requirements and also those of the RoHS Directive will not be possible for two reasons:

1. Because reliability testing cannot be completed by these dates and so reliability cannot be assured by the RoHS 22 July 2019 deadline.
2. Because engines, which are constructed with rubber parts containing substitute plasticisers, must not negatively impact on the emissions regulated by the NRMM

[6] PVC: Compounds, Processing and Applications, J. Leadbitter, J. A. Day and J. L. Ryan, RAPRA Review Report 78, 1994. see section 3.3.

[7] Piezoelectric Polymers, volume 3, plasticisers, downloaded from https://www.researchgate.net/file.PostFileLoader.html?id=5754625d96b7e4f3677c4471&assetKey=AS%3A369671648890881%401465147997417

Emissions Regulation (where this is applicable). Substitutes are not now available and so will not be available in time to carry out the required tests and meet the 2019 – 2021 NRMM deadlines.

Reliability and durability testing cannot be assumed to be straightforward as engine manufacturers have found that emissions and reliability can only be assessed by extensive testing of engines in finished equipment, such as in generators or compressors. Laboratory tests of materials are not sufficient and can give misleading test results as they cannot accurately reproduce the conditions in a real engine. This testing is described below in section 7.

---

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.)**

No

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

Equipment with engines is usually collected for recycling. Although some parts are reused, most rubber parts become waste and so are disposed of via landfill or for energy recovery, the proportions of each depend on the processes that are used in EU Member States[8]. Eurostat data shows that 40.7% of all EU waste is landfilled and 6% is incinerated, with 4.7% for energy recovery. These figures are used below:

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

☐ In articles which are refurbished 0
☒ In articles which are recycled A few hoses may be reused, but the quantity is not known.

[8] Data from http://ec.europa.eu/eurostat/web/environment/waste/database

☒ In articles which are sent for energy return 47 kg

☒ In articles which are landfilled 407 kg

---

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

In 2008, DEHP and DBP and BBP were added to the Candidate List of Substances of Very High Concern (SVHC) under the EU REACH Regulation. Although this is not a restriction, it prompted manufacturers to start replacing these substances where this was technically possible in PVC and some other types of material. The phthalates DEHP and DBP were until 2010, very widely used as plasticisers in many applications including in cable insulation and adhesives, but since 2010, they have gradually been replaced in cables and electronic components such as capacitors by electrical equipment manufacturers. However replacement by other industry sectors such as automotive and NRMM has been slower because of the need to ensure reliability of substitutes and so many manufacturers have not yet replaced these phthalates.

Where the phthalate is used to plasticise or soften a polymer, the most commonly used substitute is an alternative plasticiser, but alternative flexible polymers are another option. There are many types of plasticiser on the market but these all have very varied physical and chemical properties and so for each application, usually only a few can be considered as being potentially suitable as substitutes. For example, in the cable industry, DEHP has mainly been replaced by di-isodecylphthalate (DiDP) and a few manufacturers have switched to the non-phthalate plasticiser Tris (2-Ethylhexyl) Trimellitate (TOTM), but most types of plasticiser on the market are not used as they are unsuitable. It appears that only a few alternative phthalates and TOTM are suitable in cables to replace DEHP, despite there being many other types of plasticiser available that are used by other industries such as in food contact materials, flooring, etc. The physical properties of the plasticisers on the market vary considerably so that most will be incompatible as substitutes for DEHP in engine applications, due to the temperature, flexibility, modulus and chemical resistance property balance that is needed.

For the applications covered by this exemption request, research is still underway to identify alternative materials and to determine whether the finished equipment that is constructed using these materials will be reliable. The technical suitability and reliability of potential alternatives is discussed below.

Properties of alternative plasticisers

Each application has a combination of essential requirements that must be met to assure reliability as well as technical suitability. These requirements are discussed below:

The required level of softness, stiffness and flexibility within the temperature range that will be experienced by the equipment. Types of equipment with engines are used at very low temperatures, as low as -40°C in some parts of northern Europe and it can also experience relatively high temperatures, up to 150°C, where the material is close to or inside the engine. The material must not become too brittle at low temperatures, otherwise it could fracture and fail and also, they should not be too soft at high temperatures as they could be damaged or distort and this could cause leaks of engine fluids (i.e. when used as a seal, gasket or hose)

Softening properties of plasticisers are very variable. Small molecules such as DBP (4 carbons in alkyl chain) tend to have a superior softening performance than larger molecules such as tridecyl phthalate (13 carbons in alkyl chain) and this is because the viscosity of DBP is lower than the viscosity of larger molecules. This property however has to be balanced by other essential requirements such as low volatility, where small molecules are usually more volatile than large molecules. The hardness of the plasticised polymer can be reduced by increasing the plasticiser content but there is a limit to which this is possible. Plasticisers are flammable and so flame retardants may need to be added. Flexibility can be improved only to a limited extent by adding more plasticiser as this affects all other properties of the material and this limits which substitutes can be used to replace DEHP.

Stability (or permanence) of plasticiser – the plasticiser must remain within the polymer during the expected lifetime. DEHP is very stable in rubbers and does not exude from the bulk to leak sticky material onto outer surfaces. It is known that some non-phthalate plasticisers can be lost by migrating to the polymer surface forming a sticky surface layer and in general, plasticisers with higher molecular weight tend to be more "permanent", this is discussed in more detail below.

Volatility of plasticisers

Low volatility is important for long lifetime in applications where the polymer is exposed to air for at least some of its lifetime, especially if exposed to elevated temperatures such as in engines. Loss of plasticiser will negatively affect reliability and is more likely to be an issue if the plasticiser is relatively volatile, as it slowly evaporates from the polymer and the polymer becomes harder and brittle and so could fail. DBP is more volatile than DEHP and so is not used in applications such as cables or rubber seals, but it is suitable where evaporation cannot occur such as in adhesives or potting materials. Some of the non-phthalate substitutes are more volatile than DEHP and this is shown in the data below.

Table 1. Vapour pressures of plasticisers, data from various published sources.

Plasticiser	Vapour pressure	Comments
Diethylhexyl phthalate (DEHP)	3.4×10^{-5} Pa at 25˚C	For comparison
Di-isononyl phthalate (DiNP)	6×10^{-5} Pa at 20˚C	
Diethylhexyl adipate (DEHA)	0.011 Pa	Relatively high vapour pressure
Dioctyl sebacate (DOS)	1.46×10^{-4} Pa, 1.3×10^{-5} Pa	Values differ from different published sources
Dioctyl azealate (DOZ)	5.1×10^{-4} Pa	
Dinonyl 1,2-Cyclohexanedicarboxylate (DINCH)	1.4×10^{-4} Pa	At 50˚C, from BASF datasheet (no data at lower temperature)
Triethylhexyl trimellitate (TETM)	5.25×10^{-10} Pa	Very much lower than DEHP and DBP
Acetyl tributyl citrate (ATBC)	6.1×10^{-4} Pa	5 x more volatile than DEHP
Dipropyleneglycol dibenzoate	6.2×10^{-5} Pa	
Diethylhexyl terephthalate (DEHT)[9]	2.86×10^{-3} Pa	Much more volatile than DEHP
Di(2-ethylhexyl) phosphate (DEHPA)	4.65×10^{-8} mm Hg 6.2×10^{-6} Pa	Lower than DEHP

Vapour pressure is very dependent on temperature and most values in the table above are measured at 20 - 25 ˚C, but the published data for DINCH is available only at the lowest temperature of 50 ˚C. Some plasticisers are much more volatile that DEHP and so could be lost more rapidly giving shorter lifetimes.

Water solubility

Water solubility of plasticisers is one variable that could affect reliability when the plasticised part is in contact with water, such as hoses that carry water-based coolant and parts that are exposure to rain. Clearly water solubility values that are significantly higher than DEHP would indicate that reliability could be inferior in these applications.

Table 2. Published water solubility data for DEHP, DBP and other plasticisers

Plasticiser	Water solubility	Data source

[9] „Review of exposure and toxicity data for phthalate substitutes", M. A. Babich, 2010. Downloaded from: http://www.cpsc.gov/PageFiles/126546/phthalsub.pdf

DEHP	0.27 to 0.285 mg/l	References 9 and 10
Di-isononyl phthalate (DiNP)	0.2 mg/l	Reference 9
Dibutyl phthalate (DBP)	11.4mg/l	Sigma Aldrich SDS
Acetyl tributyl citrate (ATBC)	Up to 5mg/l	COWI study[11]
Di(2-ethylhexyl) phosphate (DEHPA)	100mg/l	Reference 11
TETM and TOTM (Trioctyl trimellitate)	100mg/l	References 9 and 11
Dioctyl sebacate (DOS)	0.35 µg/l	Reference 11
Dinonyl 1,2-Cyclohexanedicarboxylate (DINCH)	<0.02 mg/l	Reference 9
Diethylhexyl terephthalate (DEHT)	4.0 mg/l	Reference 9

The data in the table above clearly shows that the water solubility of many of the listed plasticisers is higher and in some cases much higher than DEHP.

Viscosity and plasticising efficiency

The viscosity of the pure plasticiser gives an indication of the effect on the flexibility of a plasticised polymer. A low viscosity plasticiser will usually give a more flexible plastic than the same weight percent addition of a higher viscosity plasticiser, although plasticising efficiency is also a factor and so plasticiser viscosity is only an indication. Polymer formulators have some scope to adjust for plasticiser viscosity by increasing the amount of higher viscosity plasticiser that they add, but this usually means that the plastic or rubber 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. For the engine equipment sectors, these changes can result in changes that could affect long term reliability, not only because a different plasticiser is used, but also because the concentrations of most other additives have also had to be modified.

Table 3. Published data on viscosity of plasticisers

Plasticiser	Viscosity	Data source

[10] http://chemicalland21.com/industrialchem/plasticizer/DOP.htm

[11] Environmental and Health Assesment of Alternatives to Phthalates and to flexible PVC, Environmental Project No. 590 2001, funded by the Danish Environmental Protection Agency.

Dibutyl phthalate (DBP)	12 – 14 mPa.s (20°C)	Agar Scientific SDS
DEHP	56.6 mPa.s (25°C)	Eastman SDS
Dibutyl terephthalate	16 mPa.s (25°C)	Eastman datasheet for “Effusion” plasticiser
Dipropyleneglycol dibenzoate	70 mPa.s (25°C)	Eastman datasheet for “Versabond” plasticiser
Di-isononyl phthalate (DiNP)	85 – 100 mPa.s (20°C)	ExxonMobil datasheet
Di-isodecyl phthalate (DiDP)	110 – 125 mPa.s (20°C)	ExxonMobil datasheet
Di-isoundecyl phthalate (DiUP)	135 – 165 mPa.s (20°C)	ExxonMobil datasheet
Dinonyl 1,2-Cyclohexanedicarboxylate (DINCH)	52 mPa.s (20°C)	BASF datasheet
Trioctyl trimellitate (TOTM)	220 mPa.s	Reference 7
Epoxidised soybean oil (ESBO)	Performs poorly at low temperature	Reference 11

The most commonly used substitutes for DEHP are DiNP and DiDP, because these are chemically and physically similar to DEHP. The only structural difference between these compounds is the lengths of the alkyl chains of the phthalate molecule, with DEHP having eight carbon atoms, DiNP having nine and DiDP having ten. However, this apparently small difference makes a distinct difference to viscosity so that higher concentrations of DiNP or DiDP must be used to replace DEHP and this requires reformulation. Trimellitate plasticisers are less efficient plasticisers than phthalates (TOTM is also more viscous) and so significantly higher loadings will be needed if they are used to replace phthalates[16]. Substitution of hazardous substances is not straightforward because the manufacturer must choose a replacement substance that itself will not be restricted in the future. Many of the newer plasticisers are still be evaluated for hazard properties and some may be discovered to have undesirable toxicity and so would be a poor choice. Selection of substitutes is therefore very time-consuming and so great care must be made in choosing a suitable substance.

Migration rate

Migration rate is important in engine applications where the polymer is used as a hose, gasket, vibration damper or seal in contact with engine fluids. Plasticisers will slowly migrate out of polymers into other materials including water (e.g. used for coolants and also rain spray) and into oils used as lubricants and glycols used for anti-freeze. If this were to occur to a significant extent, the polymer would become too brittle and will fail. Therefore substitute plasticisers must not migrate out into the fluids that they will come into contact faster than the plasticiser they replace. Published data on migration rates is mainly limited to rates into food (e.g. olive oil), artificial sweat or saliva and so are not directly comparable with engine fluids. More importantly, it is not possible to compare data between publications or sometimes even within a publication. This is because migration rates depend on many variables, as explained in a study by the Danish Ministry of Environment and Food[12]. These variables include:

- Fluid in which the polymer is in contact, for example, water is very different to oil and both will be different to anti-freeze. Tests with food simulants show that migration rates of some plasticisers into olive oil are much faster than into aqueous fluids.
- Temperature very significantly affects migration rates
- Composition, molecular weight and production method of polymer
- Time of exposure, this is because plasticiser at the surface can be leached out into the fluid faster than material within the bulk structure that needs first to migrate through the polymer to the outer surface before it is in contact with the fluid
- Plasticiser concentration. Research is often carried out using commercial products where the plasticiser content varies significantly as well as the properties of the polymer.
- Agitation rate – the mild conditions of a static test will extract much less plasticiser than a harsh test using for example rapid stirring or ultrasonic agitation. This is very relevant to conditions in engines as fluids can be pumped through or past polymers that contain plasticisers at a wide range of different velocities.

Selected data from the Danish study shown below illustrates the large variability of migration rates from commercial PVC products that can result from differences in experimental conditions. However note that the variability is also affected by the way that the polymer was processed and this will vary considerably as these tests were all carried out using commercial products.

[12] Determination of Migration Rates for Certain Phthalates, Survey of chemical substances in consumer products No. 149, 2016, downloaded from http://www2.mst.dk/Udgiv/publications/2016/08/978-87-93529-01-4.pdf

Table 4. Ranges of migration rates determined using different samples and test conditions for three phthalate plasticisers

Plasticiser (in PVC)	Test condition severity	Minimum migration rate (µg/cm²/h)	Maximum migration rate (µg/cm²/h)
DEHP	Mild	0.002	3.31
DEHP	Harsh	4.4	118
DiNP	Mild	0.09	13.3
DiNP	Harsh	7.8	124.8
DBP	Harsh	1.17	144.8

It is therefore not possible to make accurate predictions on migration rates into engine fluids as the available published data is so variable and also are not applicable to engine fluids, engine conditions or the types of rubbers used. Measurements with the types of rubbers used in engines are not published and do not appear to have been carried out. As a result, engine manufacturers are having to determine the reliability of substitutes in engines as described below in section 7. A selection of the limited available migration rate data (for PVC only) is illustrated below.

Table 5. Selected published migration rate data for DEHP, DBP and poptential alternative plasticisers

Plasticiser	Migration potential	Comments
Diethylhexyl phthalate (DEHP) for comparison	Data very variable, 0.002 to 120 µg/cm²/h into simulated saliva and sweat	Rate depends on test conditions
Dibutyl phthalate (DBP) for comparison	0.2-1.1 mg/dm² from PVC to olive oil[14].	
Di-isononyl phthalate	Data very variable, 0.09 to 124.8 µg/cm²/h into simulated saliva and sweat	Research inconclusive[13]

[13] http://www.verbraucherrat.at/content/02-projekte/03-chemische-gefahren/01-weichmacher-im-spielzeug/phthalates2.pdf

Diethylhexyl adipate (DEHA)	2.6-41.3 mg/dm2 from PVC into olive oil[14].	One of the highest rates. Considerably higher than DBP so would be lost faster when in contact with oils
Dioctyl sebacate (DOS)	A study showed that migration from PVC into food (76-137 mg/kg of food) was much higher than from PVC containing DEHP (<10 mg/kg) [14].	Considerably higher than phthalates
Dinonyl 1,2-Cyclohexanedicarboxylate (DINCH)	29mg/dm^2 from "cling wrap" into sunflower oil PVC (with 37% DINCH) into aqueous fluids was low at 10 – 30 µg/dm^2.	Higher rate into oil than into water. Evidence from research with medical tubing is that migration rate is lower than for DEHP
Triethyl hexylyl trimellitate (TETM)	From PVC to sunflower oil, isooctane and ethanol was 1,280; 1,220 and 450 mg/dm2 respectively in studies over 1-3 days	High migration rate when in contact with oils and alcohols (cf. antifreeze). Migration rate into aqueous media is believed to be much lower.
Acetyl tributyl citrate (ATBC)	2.8-4.7 mg/dm^2 from PVC into olive oil[14].	Migration in oils is fairly high and faster than into aqueous media
Dipropyleneglycol dibenzoate	No data	No migration rate data available[14].
Diethylhexyl terephthalate (DEHT)[15]	No data found	-
Di(2-ethylhexyl) phosphate (DEHPA)	0.1 – 0.5 mg/dm^2 from food film (probably PVC) into a range of fats[14].	Water solubiulity is relatively high at 100mg/litre so this may not be suitable in contact with aqueous media

[14] http://www2.mst.dk/udgiv/publications/2001/87-7944-407-5/pdf/87-7944-408-3.pdf

[15] http://www.cpsc.gov/PageFiles/126546/phthalsub.pdf

Epoxidised soybean oil (ESBO)	306 mg/dm^2 or 3,492 mg/kg from PVC (bottles) into diethyl ether in 10 days 0.23 to 0.3 mg/kg from PVC into water, 50% ethanol and 3% acetic acid[14].	Migration rate into diethyl ether is very high and much higher than into water-based fluids. The limited data indicates that migration into oils may be relatively low but more research is needed.

Permanence

Permanence or transience is an important characteristic of plasticisers in polymers. Most plasticisers do not react chemically with the polymer and so are chosen because they have an affinity for the material and are able to form a stable mixture. Transience or permanency is the tendency for the polymer to loose plasticiser and depends on the rate of loss from the surface as well as the diffusion rate of plasticiser within the bulk polymer. Loss of volatile plasticisers is governed by the rate of diffusion from the bulk to the surface and loss also occurs when in contact with oils or other fluids in which the plasticiser has a high solubility.

Polymers such as PVC can also be degraded by hydrolysis when exposed to moisture and some plasticisers (phthalates, trimellitates and dicarboxylates) retard hydrolysis giving improved stability. However tests have shown that trimellitates in PVC have an inferior oil extraction resistance than phthalates, which will be an important limitation for these materials in applications when materials are in contact with engine oils[16]. The Polymer Handbook also states[16]:

> *The greater the plasticizer viscosity, or molecular weight, the greater its permanence. Polymeric plasticizers composed of branched structures are more resistant to diffusivity losses than those based on linear isomeric structures; on the other hand they are more susceptible to oxidative attack. The polarity, or the oxygen-to-carbon ratio, also impacts extraction resistance of the polymerics. Lower polarity materials exhibit better extraction resistance towards polar extraction fluids such as soapy water.*

Clearly, substitution is not straightforward as changes to molecular weight or polarity influence stability and permanence.

Plasticisers will be more compatible and therefore permanent if their polarity matches that of the polymer. Nitrile (NBR) rubber with high acrylonitrile content has a high polarity whereas EPDM rubber has a lower polarity. DEHP also has a relatively high polarity and so is compatible especially with high polarity polymers such as nitrile rubbers (with high acrylonitrile content)[17].

---

[16] PVC Handbook, C. Wilkes, J. Summers, C. Daniels, downloaded from http://www.hanserpublications.com/SampleChapters/9781569903797_9781569903797_PVC%20Handbook_Wilkes%20et%20al.pdf

[17] http://www.struktol.com/pdfs/Pg%2046-49%20-%20Plasticizers.pdf

Substitute polymers

Polymers that do not require plasticisers could be regarded as an alternative if they meet all of the essential requirements. There are several types of synthetic rubbers as well as natural rubber available although it should be pointed out that many of these may also contain plasticisers including DEHP. One publication indicates that natural rubber may have phthalate plasticisers added when it is used for engine seals, plasticisers in EPDM rubber are less common but DBP and DEHP have been used (and DEHP is still used) for certain applications and it is reported that polyvinylidene fluoride may contain DBP[18]. Flexible polyurethanes and acrylic resins may also contain plasticisers. Other types of rubber that are known to contain plasticisers such as DEHP include epichlorohydrin (ECO) rubber (used for coatings on gaskets), chloroprene and all types of nitrile (NBR) rubbers. DEHP use in chloroprene and nitrile rubbers is widespread and common.

Each type of rubber has different properties whereas each component used in an engine must meet all essential requirements, such as suitability within a specific temperature range, stiffness (modulus) and flexibility, resistance to oils, water etc. and of course long term reliability[19].

Chloroprene rubbers are notable for their sealing properties and so are a good choice for seals and gaskets in engines. Nitrile rubbers are also used in engines and have good resistance to oils, water and other fluids used in engines. Both nitrile and chloroprene rubbers are commonly plasticised with DEHP. The limitations and potential disadvantages of substitute rubbers are listed below (from references 17, 18 and 19):

- Fluoropolymers seldom require plasticisers and fluoropolymer rubbers have very good resistance to oils and chemicals. They are reported however to be relatively poor at low temperature when they can become quite hard and so cannot be used for applications where low temperatures may be experienced such as in northern Europe in winter.
- Ethylene propylene polymers (EPM and EPDM rubbers) have poor chemical resistance to hydrocarbon and lubricating oils and so cannot be considered as suitable alternatives in these applications, although they are used in some engine applications; DEHP is used as a plasticiser.
- Polyacrylate rubbers have been used for automatic transmission seals, but have poor "compression set resistance", poor resistance to water and perform poorly at low temperatures so are unsuitable for most other uses in engines.
- Ethylene-acrylic rubbers – has been used as engine seals but have poor resistance to fuels, brake fluids, aromatic hydrocarbons (usually present in lubricating oils) and to phosphate esters (common additives in lubricating oils and in hydraulic fluids)

[18] Handbook of Plasticiser, chapter 11 "Plasticizers Use and Selection for Specific Polymers", George Wypych. 2012. Download from http://www.sciencemadness.org/talk/files.php?pid=247355&aid=18568

[19] Data sources include http://www.columbiaerd.com/materials.html

- Styrene-butadiene rubber (SBR) – poor resistance to hydrocarbons and lubricating oils
- Polyurethane rubber – poor water resistance and a too low maximum temperature of <80°C, makes these unsuitable for most engine applications
- Silicone – lower physical strength. Typically not good for dynamic seals or most other engine applications due to friction properties and poor abrasion resistance
- Epichlorohydrin (ECO) rubber – similar to nitrile with good resistance to heat, oil and petrol, but has inferior compression set performance which limits its use in seals and gaskets. It can also cause metals to corrode and DEHP is used as a plasticiser.
- Natural rubber – poor resistance to hydrocarbon oils

In conclusion, although there are many alternative types of flexible polymer (rubbers), none are suitable as drop-in replacements. Many soft polymers such as polyethylene (used for plastic bags) have unsuitable tensile properties and modulus properties for applications such as seals and gaskets, where higher modulus values are needed for stiffness properties. Some of the other types of rubbers that are discussed above are used as seals and O-rings, but these have limitations in engines, particularly due to their inferior chemical resistance to engine fluids. Finally, several of the alternative rubbers contain plasticisers which include DEHP. For engine manufacturers, if they were to change to a different type of rubber in order to avoid restricted phthalates, they would need to carry out the same testing as is required when DEHP is replaced in order to determine whether the finished equipment will be reliable and also, if needed, whether the engine meets NRMM Emissions Regulation requirements. This is described in section 7.

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

This exemption request is being submitted because for the applications described above, reliability cannot be assured. Substitute plasticisers are increasingly used in PVC that is used in cables and in electrical components that are used by the electronics industry and which appear to be sufficiently reliable for these types of products. However, the conditions experienced by alternative plasticisers in rubber materials in engine equipment is very different and the polymeric materials (rubbers) used in engines are also different but there is no published data available that can be used to assess reliability. Engine manufacturers will therefore need to carry out reliability assessments of potential substitutes before using these substitute materials in engine equipment. This testing must be extensive and comprehensive and for some engines will also require validation of compliance with the Non-Road Mobile Machinery Emissions Regulation for which third party approval by a Notified Body is required before the engines can be placed on the EU market. This testing is described below in section 7.

A similar situation exist with potential alternative flexible polymers, if any are identified as suitable candidates for evaluation, until these are tested under realistic conditions, conditions replicating the extreme temperature and vibration conditions as well as chemical exposure in engine equipment (see section 7), as their reliability cannot be assured.

---

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.

Manufacturers of PVC and adhesives have carried extensive research into substitute plasticisers for DEHP and DBP, but manufacturers of the types of rubber components that are used in engines have carried very little research and none appears to be published. Furthermore, Universities and research organisations have published research on plasticisers in PVC as can be seen above in section 6A, but no equivalent work appears to have been carried out using rubbers of the types of materials and use conditions in internal combustion engines. The results obtained with PVC and its exposure to artificial saliva, sweat and foods such as olive oil have very limited value as it is not possible to predict from this data how substitutes to restricted phthalates in rubbers will behave in engines.

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

The work needed to establish suitable substitutes and determine reliability in engine equipment will require several stages of assessment and testing. These are described here:

a) Identification of substitute materials:

b) Assessment of components to determine if they have the combination of required essential physical and chemical properties for use in engines:

c) Long term testing of components:

d) Long term reliability testing of components in engines:

e) Long term reliability testing of engines containing substitute components in finished equipment:

Substitute materials identification

The first stage is to identify suitable materials. These are most likely to be the same types of rubber but with different plasticisers because different types of rubber will have different properties and so are unlikely to meet all of the essential requirements. The timescale depends on the activities of suppliers and is outside of the control of engine manufacturers. Engine manufacturers have identified many parts that contain DEHP and are in discussion with part suppliers to obtain suitable alternatives. However, substitutes for all rubber parts that contain DEHP are not yet available for assessment and testing. It is not possible to determine how long this will take, but it is expected to be at least one year and may be longer to find suitable substitutes with the correct ranges of essential properties.

Assessment of components

Components such as O-rings, seals, gaskets etc. made with substitute materials will be needed and must meet all of the essential physical and chemical properties that are required for each specific applications. Only if all of these appear to be met will it be worthwhile carrying out extensive reliability and durability testing.

Component testing

The O-rings, seals, gaskets, etc. have to be able to maintain their essential physical properties for at least 10 years in use and so these are tested to determine whether the components' properties remain within acceptable values when exposed to the conditions that they will experience in an engine. Each engine manufacturer has their own range of test conditions and one example of the range of tests that need to be carried out is listed below.

- Low temperature performance, down to -40°C
- High temperature performance: Long term at 85 to 200°C
  Short term at 150 to 250°C
- Flexibility and resistance to cracking (note that this can be affected by exposure to engine fluids)
- Low temperature impact which can cause cracks or fracture if too brittle
- Abrasion resistance, especially important for seals around rotating parts such as camshafts
- Indentation at high temperature – will be softer at high temperature, but must retain strength and modulus value so not be damaged
- Fire resistance
- Hydrolysis – especially important when exposed to rain, condensation or water-based engine fluids such as coolant
- Shrinkage during use should be negligible
- Chemical resistance to all types of engine fluid, including brake fluid, engine oil, greases, antifreeze, battery acid and washer fluids). Some may also need to be resistant to environmental contaminants (such as within chemical plant or oil refineries)

This testing typically takes one year to complete all of the required tests.

Engine reliability

When all of the DEHP-free rubber parts have been tested and confirmed to meet the required specifications, these will be tested in engines. This will be possible only when all rubber parts are available as RoHS-compliant versions as there is no point in starting these tests until all parts comply. Engine testing is likely to use up to 50 engines which will run for long periods to assess the reliability of rubber components. These engine tests are carried out in controlled laboratory conditions and so may not be as severe as conditions experienced in the field. This work typically takes 2 years.

Reliability in finished equipment

Field testing in finished equipment is the last stage of parts substitution. The reliability of rubber parts will be assessed in engines in a variety of types of equipment that are used in a variety of conditions and environments. These tests are intended to be severe and assess reliability under the extreme conditions that the equipment will be exposed. Engines in finished equipment may be exposed to a variety of chemicals that could affect rubber components, be exposed to extremes of temperature, be exposed to dirt that could be abrasive and corrosive and experience non-ideal maintenance conditions that may influence reliability. These tests typically take two years to complete including dismantling engines at the end of tests to assess the condition of the rubber parts in order to estimate if they will be reliable over at least a 10 year lifetime.

The total elapsed time per engine type once suitable RoHS compliant rubber parts are available will be about 5 years. However each engine manufacturer has many engines types, each using different ranges of rubber parts. It is not possible to assess and test all engines simultaneously as the availability of trained engineers is limited and so manufacturers estimate that about eight years will be needed to complete this work assuming that suitable substitutes are identified (this is not yet possible) and that these prove to be suitable and reliable , which is not a certainty. If any parts are found to be not suitable or are not reliable during engine or equipment tests, this would delay this wok by two or more years as testing would need to start again with alternatives.

As explained above, there is no published data on the performance of substitutes for DEHP in rubbers and so it is not possible to predict whether substitutes will be reliable and so this will not be known until testing is complete.

---

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 – yes, DEHP is a SVHC

☒ Candidate list

☐ Proposal inclusion Annex XIV

☐ Annex XIV – although DEHP is listed in Annex XIV, the substances are used as chemicals outside of the EU only and only articles are imported into the EU, Annex XIV is not applicable to import of articles

☐ Restriction

☐ Annex XVII – although a restrictions for DEHP is listed in Annex XVII, these apply only to children's and childcare products which is not applicable

☒ Registry of intentions Restriction intentions have been submitted but do not include the uses in engines described in this exemption request[20].

☒ Registration DEHP is registered[21]

2) Provide REACH-relevant information received through the supply chain.
Name of document: ______

(B) Elimination/substitution:

1. Can the substance named under 4.(A)1 be eliminated?

☐ Yes. Consequences?

☒ No. Justification: Reliability is not assured and could be significantly inferior

2. Can the substance named under 4.(A)1 be substituted?

☐ Yes.

☐ Design changes:

☐ Other materials:

☐ Other substance:

☒ No.

Justification: Reliability is not assured and could be significantly inferior

3. Give details on the reliability of substitutes (technical data + information): See section 6

---

[20] https://echa.europa.eu/registry-of-submitted-restriction-proposal-intentions

[21] http://www.plasticisers.org/regulation/reach/

4. Describe environmental assessment of substance from 4.(A)1 and possible substitutes with regard to

Not considered as not applicable to this exemption request

1) Environmental impacts: _____
2) Health impacts: _____
3) Consumer safety impacts: _____

⇨ Do impacts of substitution outweigh benefits thereof?
Please provide third-party verified assessment on this: _____

(C) Availability of substitutes:

a) Describe supply sources for substitutes: Alternative plasticisers are readily available but the reliability of engines that use these is not assured and may be very inferior.
b) Have you encountered problems with the availability? Describe: _____
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? _____

(D) Socio-economic impact of substitution:

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

Not applicable to this exemption request

☐ Increase in direct production costs
☐ Increase in fixed costs
☐ Increase in overhead
☐ Possible social impacts within the EU
☐ Possible social impacts external to the EU
☐ 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:
