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(54) Title: STERILIZATION CHAMBER MADE OF A POLYMERIC MATERIAL, PROCESS FOR ITS MANUFACTURE AND STERILIZATION APPARATUS COMPRISING THIS CHAMBER

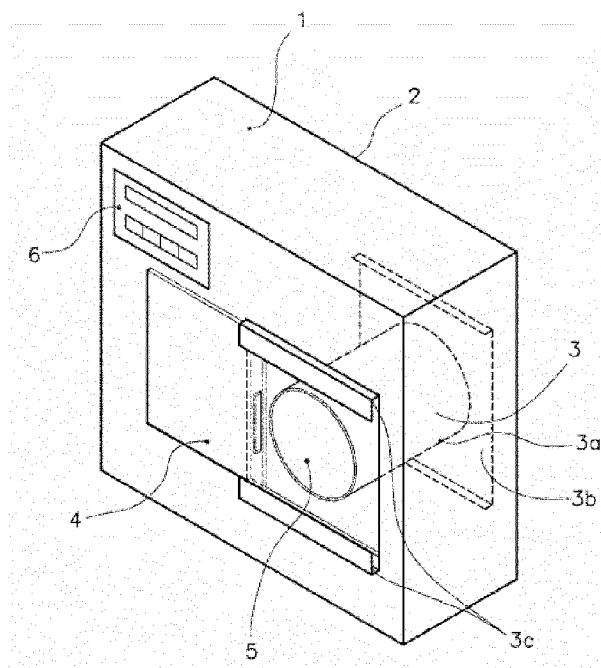


Figure 1

(57) Abstract: Sterilization chamber made of a polymeric material, process for its manufacture and sterilization apparatus comprising this chamber. The invention relates to a sterilization chamber (3) made of a polymeric material comprising a poly(aryl ether sulfone), to a process for its manufacture, and to a sterilization apparatus comprising it. In a special embodiment, the polymeric material further comprises a poly(aryl ether ketone) (P*).



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- 1 -

Sterilization chamber made of a polymeric material, process for its
manufacture and sterilization apparatus comprising this chamber

REFERENCE TO RELATED APPLICATIONS

This application claims priority to U.S. provisional application 12/977387 filed on December 23, 2010, whose disclosures are incorporated herein by reference.

5 FIELD OF THE INVENTION

The present invention relates to a sterilization chamber made of a polymeric material, a process for its manufacture and a sterilization apparatus comprising this sterilization chamber.

BACKGROUND OF THE INVENTION

10 Sterilization apparatuses are commonly used in health care and medicine. Sterilization apparatuses as they are commonly used in small variants in medical and dental clinics, and in large variants in pharmaceutical plants may largely vary in size, but usually have in common that they comprise a sterilization chamber in which goods to be sterilized are placed. In the sterilization chamber
15 there may be several inlets/outlets for steam, water or the like, depending on the kind of sterilization that is to be performed in it. Furthermore, means for pressurizing and heating the interior space of said chamber are provided.

Sterilization chambers are quite often made out of stainless metal material. Stainless metal material one has been so far “*the*” material of choice for this
20 application, because it exhibits high strength, high toughness and high fatigue resistance. High toughness and high fatigue resistance are obviously key properties for sterilization chambers, because these ones see pressures over 2 bars, and also steam.

However, there are some drawbacks associated with sterilization chambers
25 made of stainless metal material. For example, their manufacture may be somewhat time-consuming, since it requires welding or the like. Furthermore, a lot of energy is lost when heating such chambers, since some of the added energy is used for heating the chamber material, resulting in a somewhat ineffective sterilization process.

30 It has already been attempted to overcome these drawbacks, by proposing sterilization chambers made of certain polymeric materials, in vain.

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For example, WO 02/100446 A (to GETINGE) relates to a sterilization chamber for use in a sterilization device or the like. The chamber is adapted to enclose goods to be sterilized during a sterilization process and has a self supported structure being essentially manufactured from a polymeric material.

5 As polymeric material, WO 02/100446 A discloses the use of a polyamide material or of a composite material, wherein the composite material preferably comprises a carbon fiber rowing weave and a concatenating polymer material.

WO 02/10047 A (also to GETINGE) discloses a disinfection chamber for use in a disinfection device for health care goods, such as bed pans, urine bottles
10 and the like, the chamber in use being intended to receive the goods which are to be disinfected. The chamber has a self supported structure which is substantially made of a polymer material. The polymeric material is preferably a propylene plastic material.

Finally, WO 04/20001 (still to GETINGE) discloses a sterilization
15 apparatus comprising a sterilization unit and a processing unit which are mechanically separated from each other, wherein the sterilization unit comprises a sterilization chamber may be manufactured from a polymeric material.

The prior art plastic-made sterilization chambers (wherein the plastic material may be a polyamide, a composite or a polypropylene, as above detailed)
20 do not exhibit the high toughness and the high fatigue resistance as desired for the application. As a result thereof, they have been essentially unable so far to replace efficiently stainless steel metal-based sterilization chambers.

On the other hand, poly(aryl ether sulfone)s have already been proposed for various sterile applications in the medical field, including membrane filters, transfer bags, autoclavable containers and trays, and lids thereof. For example,
25 DE 197 28 217 A discloses the use of for example polysulfone membrane filters for the separation of gaseous components in the water supply of sterilizers. US 2004/0081601 A1 discloses an integrity testable autoclavable sterile transfer bag having section formed from a plastic, possibly a polyethersulfone or polyphenylsulfone. US 5,326,834 describes an autoclavable container or storage
30 tray made out of certain poly(aryl ether sulfone)s, which exhibit excellent environmental stress-cracking resistance when exposed to various chemicals. US 2007/0212277 A1 relates to a medical instrument container system comprising trays molded entirely of a rigid plastic able to withstand cleaning and
35 sterilization processes, e.g. polyphenylsulfone. US 2004/02566268 A1 describes a sterile container, in particular for the holding and sterile storage of surgical

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instruments or material, which comprises a lid (for closing the holding space) which may be made out of a plastic material such as polyphenylene sulfone.

None of the sterile medical applications of the prior art using poly(aryl ether sulfone)s have requirements similar to the sterilization chambers of present concern. For example, medical trays, which are used for cleaning of medical equipment, have actual contact with cleaning chemicals ; that's why environmental stress cracking resistance is critical for this first application. Medical trays do not see pressure. Sterilization chambers, on the other hand, see pressures over 2 bars, in addition to steam ; that's why fatigue and toughness properties are so important for this other application.

There is a need for sterilization chambers that would present the advantages of the known plastic-made sterilization chambers, while exhibiting a high toughness and high fatigue resistance, as can be achieved by the known stainless steel metal-made sterilization chambers.

These sterilization chambers would thus desirably be easy and quick to manufacture, since they would require no welding. Furthermore, the energy losses when heating the chambers would be low, since the heating energy for heating the chamber materials would be low. In addition, the goods to be sterilized would be easily heated since the heating of the chamber material would not consume much energy. Thus, fast and energy efficient sterilization cycles could be realized. The sterilization chambers would also desirably exhibit a high toughness and a high fatigue resistance, and provide long-term stability under high temperature and hydrolytic conditions as are encountered during the typical use of sterilization chambers.

SUMMARY OF THE INVENTION

An object of the present invention is to provide a sterilization chamber which overcomes the problems of the prior art.

In particular, it is an object of the present invention to provide a sterilization chamber which meets the above addressed needs.

The present invention thus relates to a sterilization chamber made of a polymeric material, wherein the polymeric material comprises at least one poly(aryl ether sulfone) (P).

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view of a sterilization apparatus, comprising a sterilization chamber in accordance with the present invention.

- 4 -

Figure 2 shows an enlarged view of the sterilization chamber 3 of the present invention as used in the sterilization apparatus 1 shown in Fig. 1.

DETAILED DESCRIPTION OF THE INVENTION

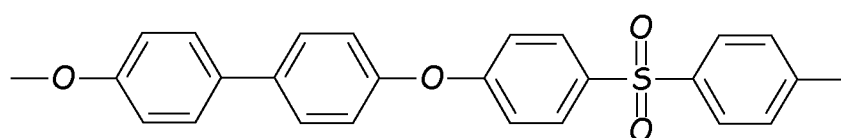
The present invention relates to a sterilization chamber made of a polymeric material, wherein the polymeric material comprises at least one poly(aryl ether sulfone) (P).

In general, above 50 wt. % of the sterilization chamber, based on its total weight, is composed of the polymeric material. Preferably, above 75 wt. % of the sterilization chamber is composed of the polymeric material. More preferably, above 90 wt. % of the sterilization chamber is composed of the polymeric material. Still more preferably, the sterilization chamber consists essentially of the polymeric material. The most preferably, the sterilization chamber consists of the polymeric material.

The polymeric material may comprise the poly(aryl ether sulfone) (P) in a weight amount of at least 10 %, at least 30 % or at least 50 %, based on the total weight of the polymeric material. Preferably, the polymeric material comprises the poly(aryl ether sulfone) (P) in a weight amount of at least 70 %, based on the total weight of the polymeric material. More preferably, the polymeric material comprises the poly(aryl ether sulfone) (P) in a weight amount of at least 90 %, if not at least 95 %, based on the total weight of the polymeric material. Still more preferably, the polymeric material consists essentially of the poly(aryl ether sulfone) (P). The most preferably, it consists essentially of the poly(aryl ether sulfone) (P).

The poly(aryl ether sulfone) (P) has advantageously a weight average molecular weight in the range of from 20,000 to 100,000. Preferably, the poly(aryl ether sulfone) (P) has a weight average molecular weight in the range of from 40,000 to 70,000. The weight average molecular weight can be determined by Gel Permeation Chromatography using conventional polystyrene calibration standards.

As detailed hereinafter, excellent results are obtained when essentially all (preferably, all) the recurring units of the poly(aryl ether sulfone) (P) are of formula (C) :



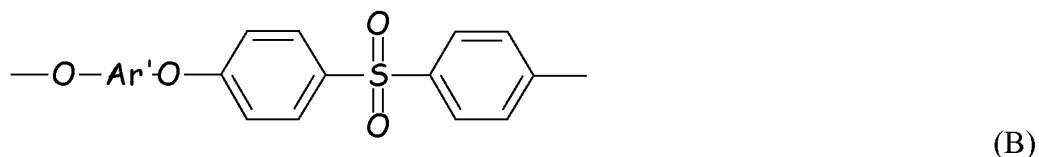
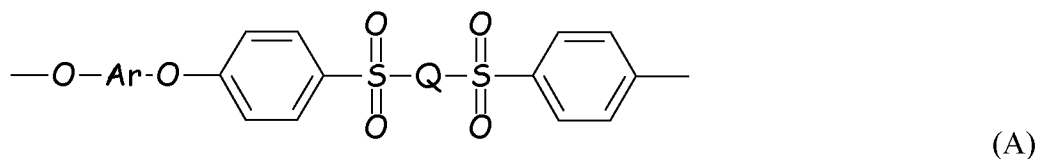
(C)

- 5 -

For the purpose of the invention, a poly(aryl ether sulfone) (P) (in short, PAES) is intended to denote any polymer (P), generally a polycondensate, of which more than 50 wt. % of the recurring units are recurring units (R) of one or more formulae containing at least one arylene group, at least one ether group (-O-) and at least one sulfone group [-S(=O)₂-].

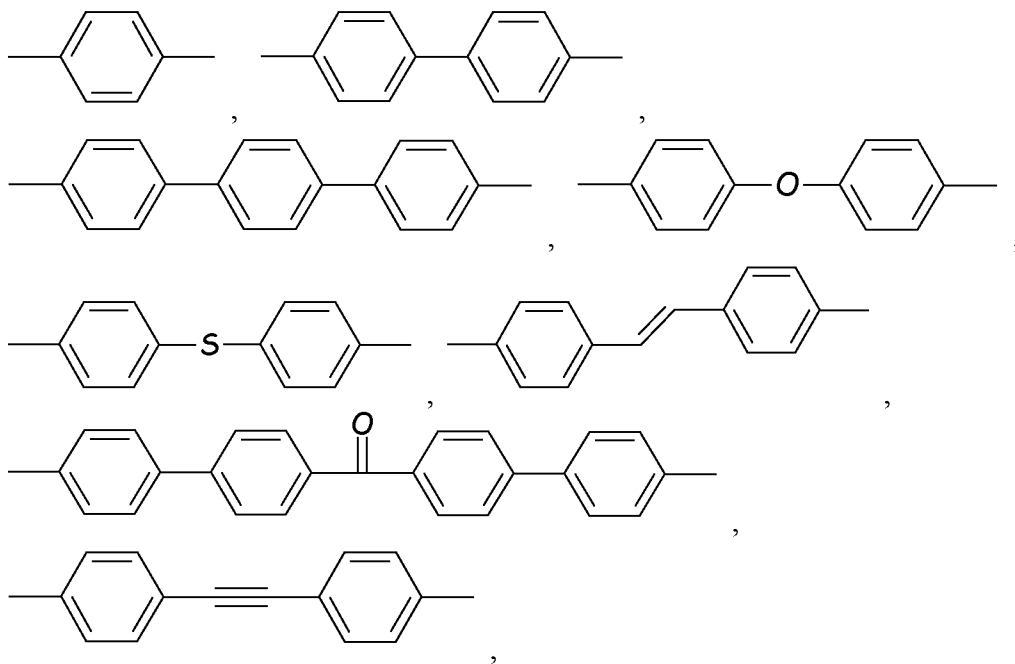
Preferably more than 90 wt. %, and more preferably more than 95 wt. % of the recurring units of the poly(aryl ether sulfone) (P) are recurring units (R). Still more preferably, essentially all the recurring units of the poly(aryl ether sulfone) (P) are recurring units (R). The most preferably, all the recurring units of the poly(aryl ether sulfone) (P) are recurring units (R).

The recurring units (R) are advantageously recurring units of formula (A) and/or formula (B), as shown below :

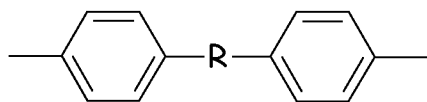
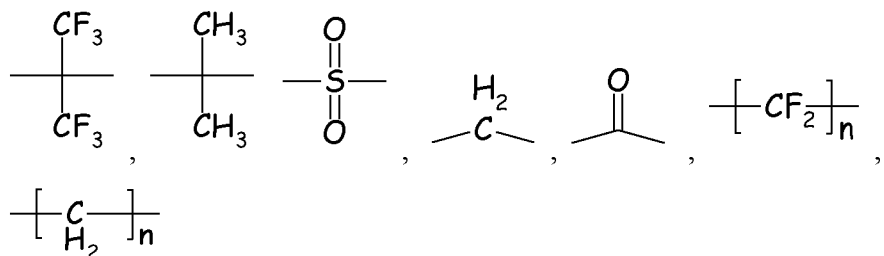


wherein :

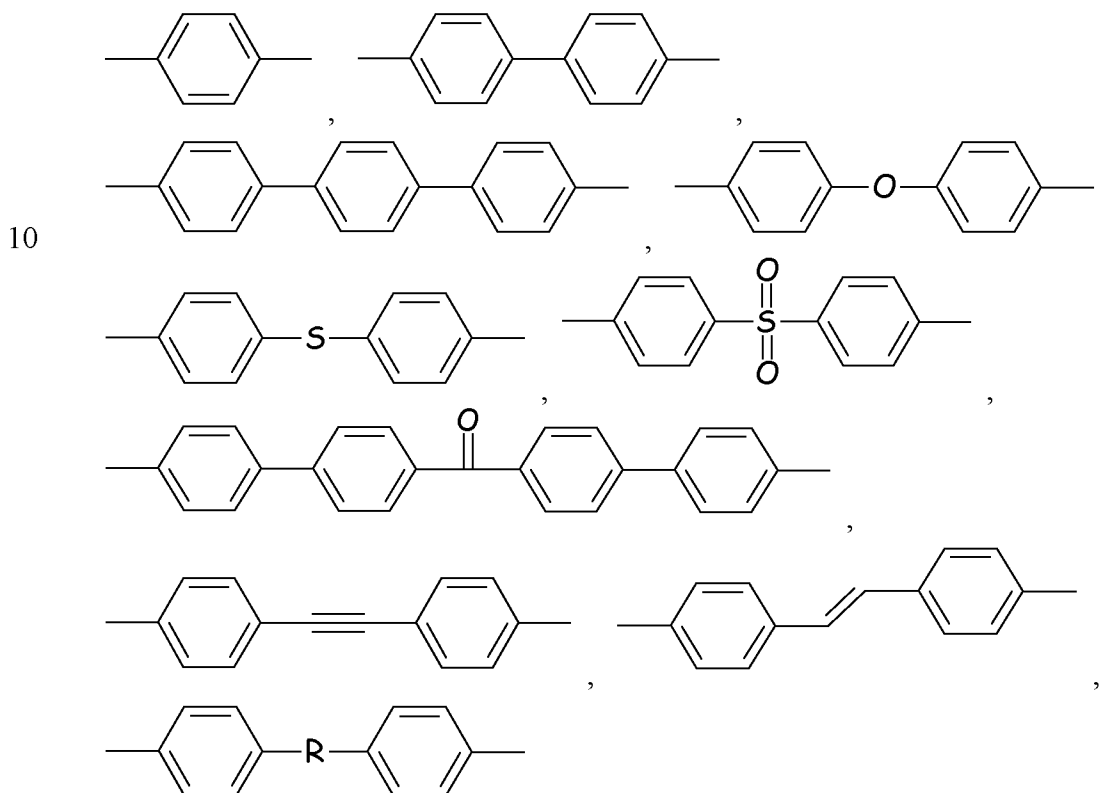
– Q is a group chosen among the following structures :



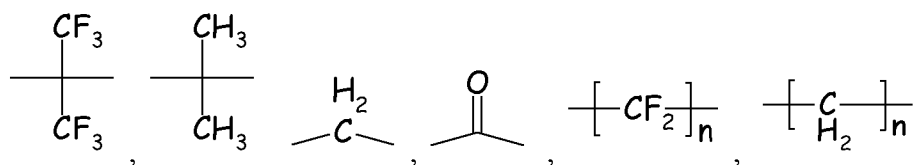
- 6 -

with **R** being :

- 5 with n = integer from 1 to 6, or an aliphatic divalent group, linear or branched, of up to 6 carbon atoms ;
and mixtures thereof ;

– **Ar** is a group chosen among the following structures :

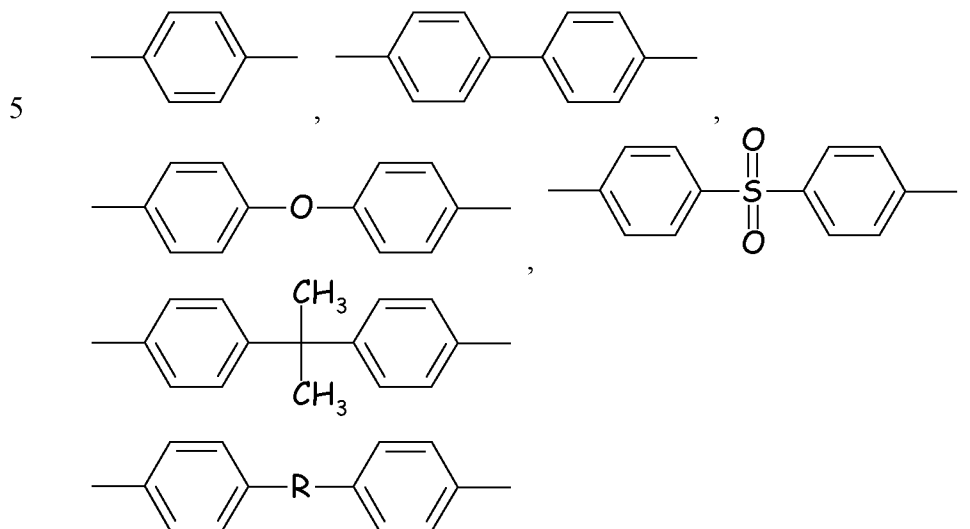
- 15 with **R** being :



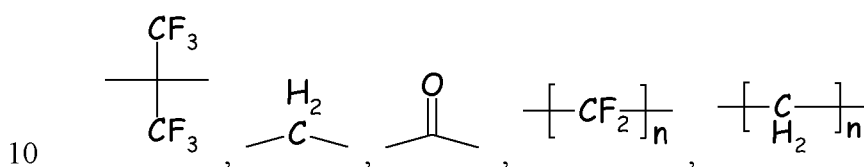
- 7 -

with n = integer from 1 to 6, or an aliphatic divalent group, linear or branched, of up to 6 carbon atoms ;
and mixtures thereof ;

- Ar' is a group chosen among the following structures :



with R being :

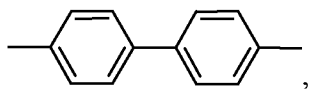


with n = integer from 1 to 6, or an aliphatic divalent group, linear or branched, of up to 6 carbon atoms ;
and mixtures thereof.

Embodiment (E1)

15 In a certain embodiment (E1) of the present invention, the poly(aryl ether sulfone) (P) is a poly(biphenyl ether sulfone) (P1).

For the purpose of the present invention,
a poly(biphenyl ether sulfone) (P1) is intended to denote any polymer of which more than 50 wt. % of the recurring units are recurring units (R1) of one or more
20 formulae containing at least one p-phenylene group :

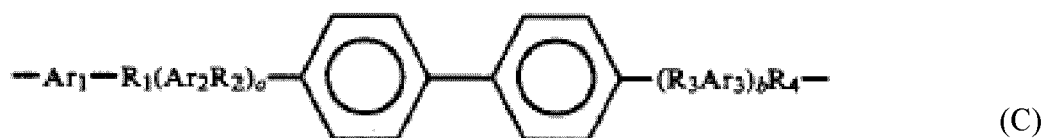


at least one ether group (—O—) and at least one sulfone group [$\text{—S(=O)}_2\text{—}$].

Recurring units (R1) are preferably of one ore more formulae of the general type :

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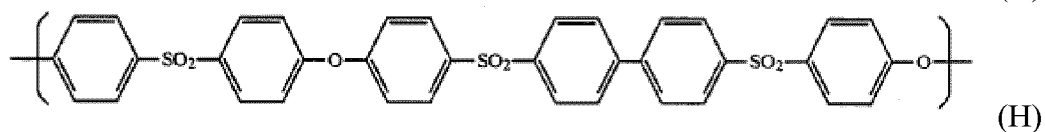
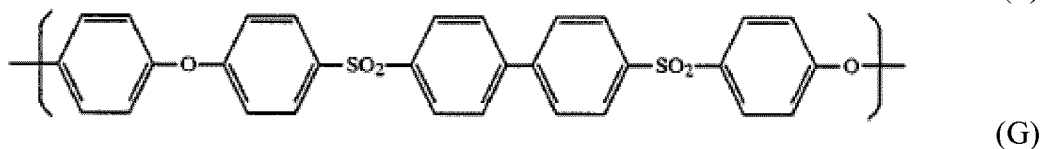
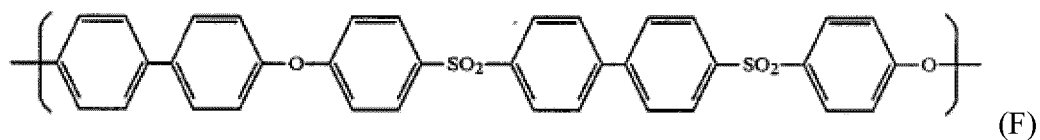
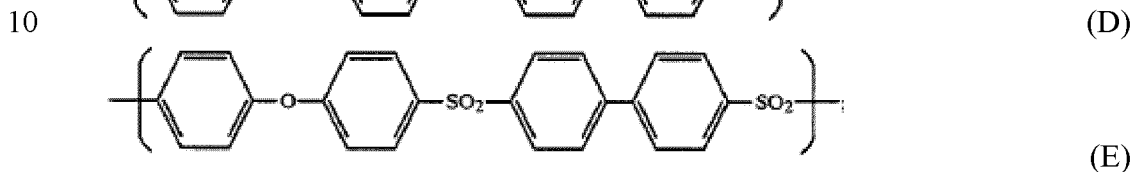
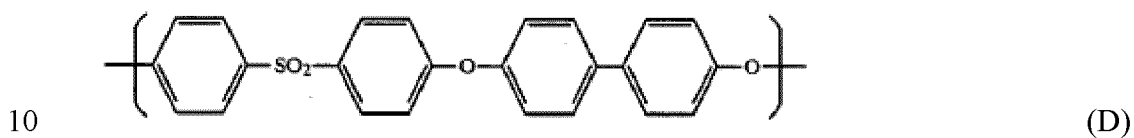
- 8 -



wherein R₁ through R₄ are -O-, -SO₂-, -S-, -CO-,

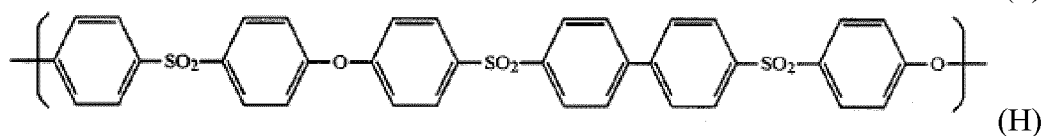
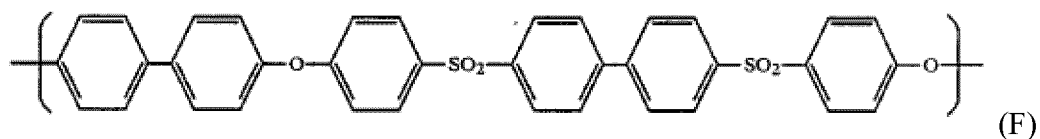
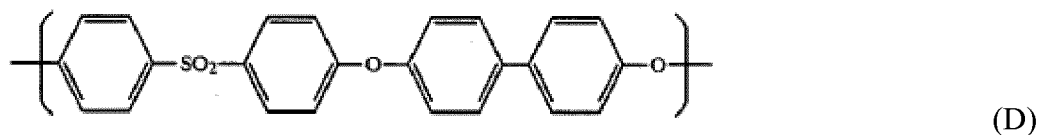
- 5 with the proviso that at least one of R₁ through R₄ is -SO₂- and at least one of R₁ through R₄ is -O-; Ar₁, Ar₂ and Ar₃ are arylene groups containing 6 to 24 carbon atoms, and are preferably phenylene or p-biphenylene; and a and b are either 0 or 1.

More preferably, recurring units (R1) are chosen from



- 15 and mixtures thereof.

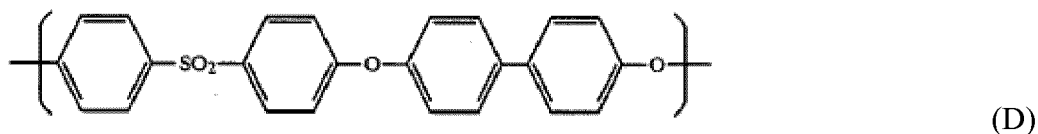
Still more preferably, recurring units (R1) are chosen from



- 20 and mixtures thereof.

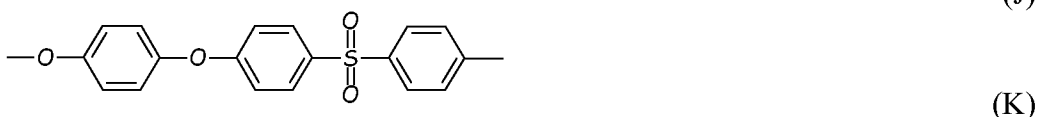
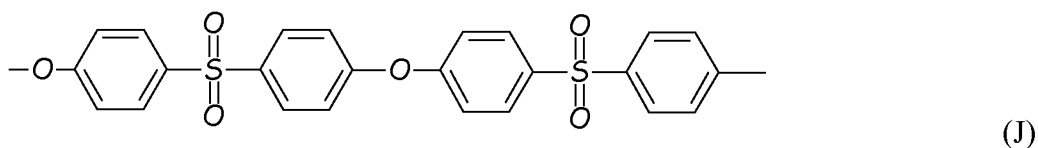
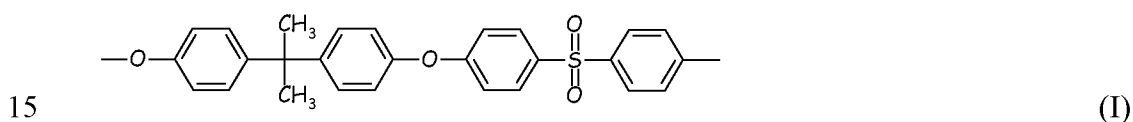
- 9 -

The most preferably, recurring units (R1) are



For the purpose of the present invention, a polyphenylsulfone (in short, PPSU) is intended to denote any polymer of which more than 50 wt. % of the recurring units are recurring units (R1) of formula (D), while a PPSU homopolymer is intended to denote any polymer of which essentially all (and, preferably, all) the recurring units are recurring units (R1) of formula (D).

The poly(biphenyl ether sulfone) (P1) may be notably a homopolymer or a copolymer such as a random or block copolymer. When the poly(biphenyl ether sulfone) (P1) is a copolymer, its recurring units may notably be composed essentially of (or composed of) (i) recurring units (R1) of at least two different formulae chosen from formulae (D) to (H), or (ii) recurring units (R1) of one or more formulae (D) to (H) and recurring units (R1*), different from recurring units (R1), such as :



and mixtures thereof.

Preferably more than 90 wt. %, and more preferably more than 95 wt. % of the recurring units of the poly(biphenyl ether sulfone) (P1) are recurring units (R1). Still more preferably, essentially all the recurring units of the poly(biphenyl ether sulfone) are recurring units (R1). The most preferably, all the recurring units of the poly(biphenyl ether sulfone) are recurring units (R1).

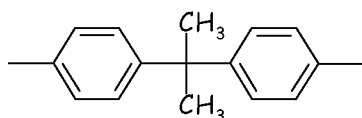
Excellent results are obtained when the poly(biphenyl ether sulfone) (P1) is a polyphenylsulfone homopolymer, i.e. a polymer of which essentially (and, preferably, all) the recurring units are of formula (H). RADEL[®] R polyphenylsulfone from SOLVAY ADVANCED POLYMERS, L.L.C. is an example of a polyphenylsulfone homopolymer.

- 10 -

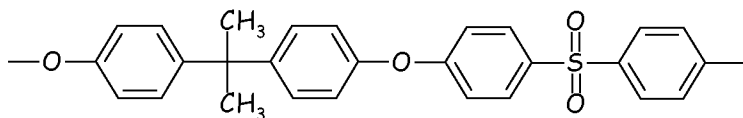
The poly(biphenyl ether sulfone) (P1) can be prepared by any method. Methods well known in the art are those described in U.S. Pat. Nos. 3,634,355 ; 4,008,203 ; 4,108,837 and 4,175,175, the whole contents of which is herein incorporated by reference.

5 *Embodiment (E2)*

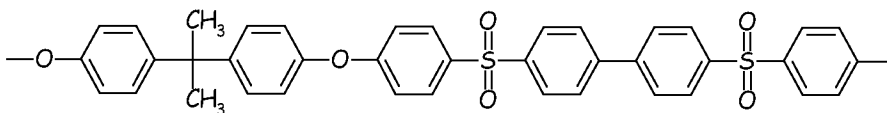
In a certain embodiment (E2) of the present invention, the poly(aryl ether sulfone) (P) is a polysulfone (P2). For the purpose of the present invention, a polysulfone (P2) is intended to denote any polymer of which more than 50 wt. % of the recurring units are recurring units (R2) of one or more
 10 formulae containing at least one ether group (—O—), at least one sulfone group (—SO₂—) and at least one group as shown hereafter :



Preferably, recurring units (R2) are chosen from



(I)

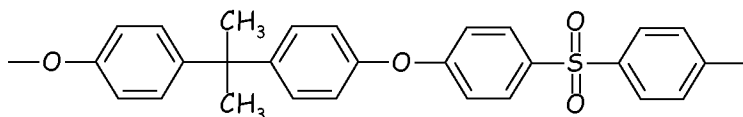


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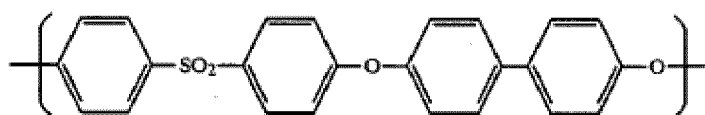
and mixtures thereof.

Very preferably, recurring units (R2) are



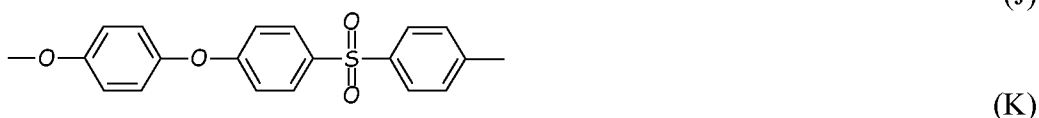
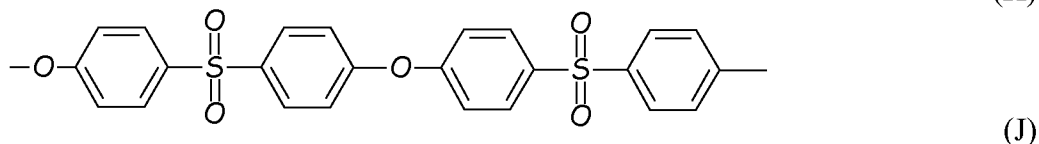
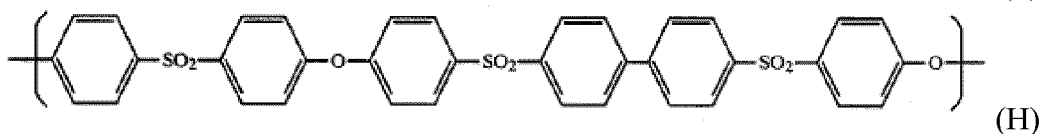
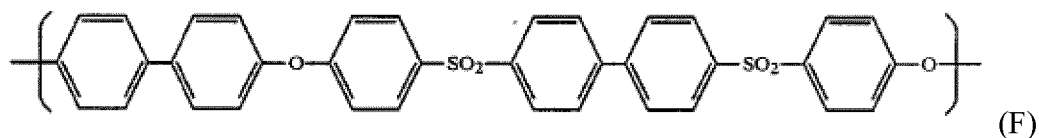
(I).

The polysulfone (P2) may notably be a homopolymer, a copolymer such as
 20 a random or block copolymer. When the polysulfone is a copolymer, its recurring units may notably be composed essentially of (or composed of) (i) recurring units (R2) of formulae (I) and (L), or (ii) on one hand, recurring units (R2) of at least one of formulae (I) and (L), and, on the other hand, recurring units (R2*), different from recurring units (R2), such
 25 as :



(D)

- 11 -

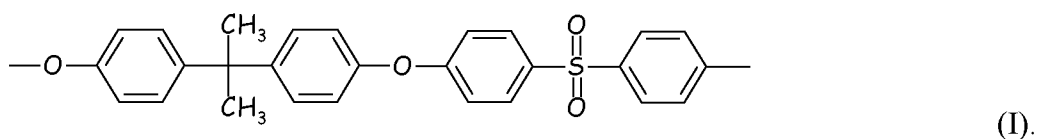


5 and mixtures thereof.

Preferably more than 90 wt. %, and more preferably more than 95 wt. % of the recurring units of the polysulfone (P2) are recurring units (R2). Still more preferably, essentially all the recurring units of the polysulfone are recurring units (R2). The most preferably, all the recurring units of the polysulfone are recurring units (R2).

10

The most preferred polysulfone (P2) is a homopolymer of which essentially all (and, preferably, all) the recurring units are recurring units (R2) of formula



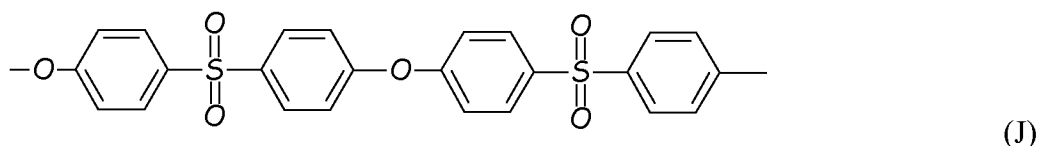
15

Such a polysulfone homopolymer is notably commercialized by SOLVAY ADVANCED POLYMERS, L.L.C. under the trademark UDEL[®].
Embodiment (E3)

In a certain embodiment (E3) of the present invention, the poly(aryl ether sulfone) (P) is a polyethersulfone (P3).

20

To the purpose of the present invention, a polyethersulfone is intended to denote any polymer of which more than 50 wt. % of the recurring units are recurring units (R3) of formula

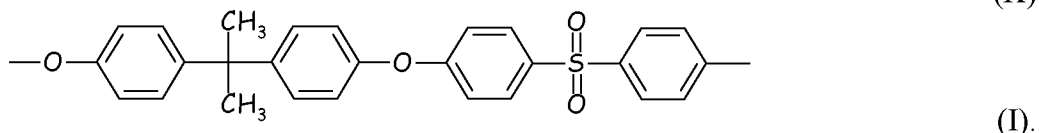
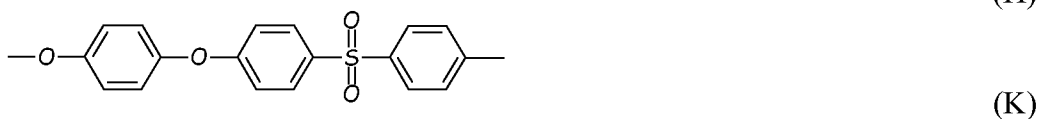
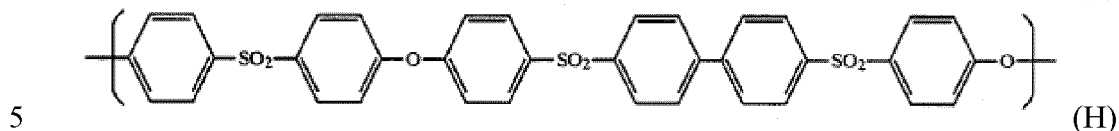
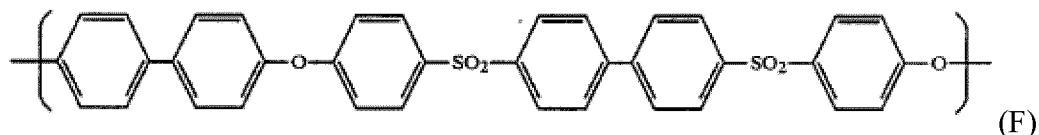
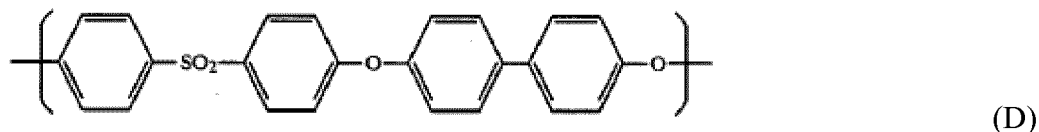


The polyethersulfone may be notably a homopolymer, or a copolymer such as a random or a block copolymer. When the polyethersulfone is a copolymer,

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- 12 -

its recurring units are advantageously a mix of recurring units (R3) of formula (J) and of recurring units (R3*), different from recurring units (R3), such as :



and mixtures thereof.

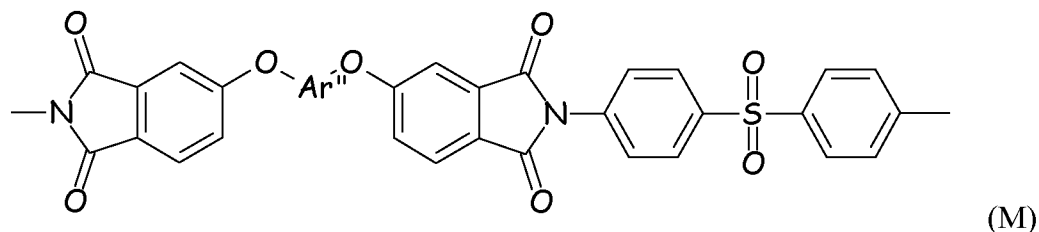
Preferably, the polyethersulfone is a homopolymer of which essentially all (and, preferably all, the recurring units) are of formula (J), or it is a copolymer the recurring units of which are essentially (and, preferably, are) a mix composed of recurring units (R3) of formula (J) and of recurring units (R3*) of formula (K), or it can also be a mix of the previously cited homopolymer and copolymer.

SOLVAY ADVANCED POLYMERS, L.L.C. commercializes various polyethersulfones under the trademark RADEL[®] A.

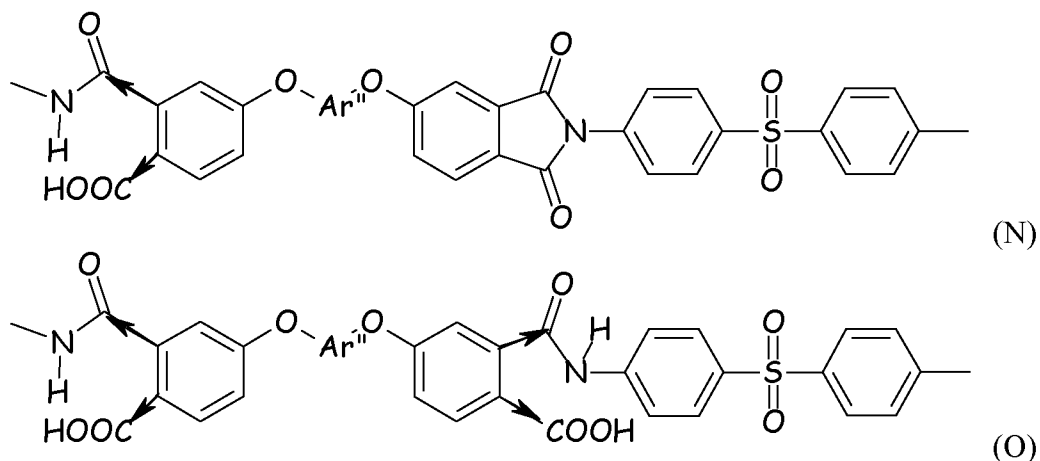
Embodiment (E4)

In a specific embodiment (E4) of the present invention, the poly(aryl ether sulfone) (P) is a polyimidoethersulfone (P4).

For the purpose of the present invention, a polyimidoethersulfone (P4) is intended to denote a polymer of which at least 5 wt. % of the recurring units are recurring units (R4) of formula (M), (N) and/or (O), as represented below :

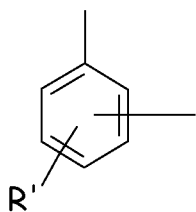


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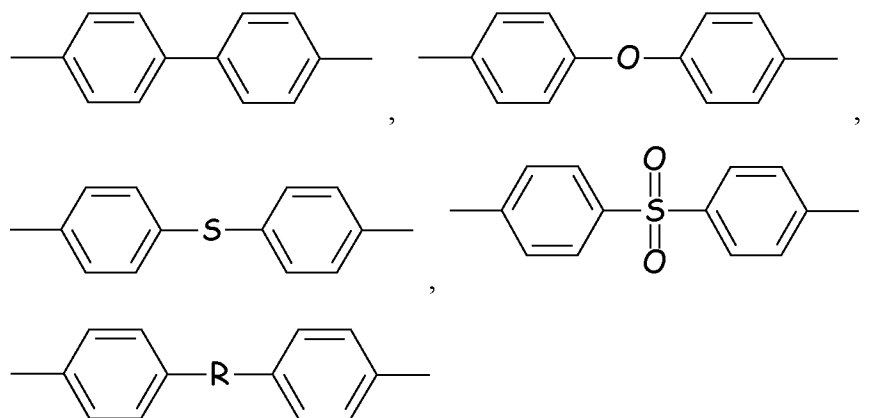


wherein :

- (N) and (O) are the amic acid forms corresponding to the imide form (M) ;
- 5 – the $\rightarrow$ denotes isomerism so that in any recurring unit the groups to which the arrows point may exist as shown or in an interchanged position ;
- Ar'' is chosen among the following structures :



- 10 with the linking groups being in ortho, meta or para position and **R'** being a hydrogen atom or an alkyl radical comprising from 1 to 6 carbon atoms ,



- 15 with R being an aliphatic divalent group of up to 6 carbon atoms, such as methylene, ethylene, isopropylene and the like, and mixtures thereof.

Preferably more than 50 wt. %, and more preferably more than 90 wt. % of the recurring units of the polyimidoethersulfone (P4) are recurring units (R4). Still more preferably, essentially all the recurring units of the

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polyimidoethersulfone are recurring units (R4). The most preferably, all the recurring units of the polyimidoethersulfone are recurring units (R4).

The poly(aryl ether sulfone) (P) is advantageously a poly(biphenyl ether sulfone) (P1), a polysulfone (P2), a polyethersulfone (P3),
5 a polyimidoethersulfone (P4), or a mixture thereof. Preferably, the poly(aryl ether sulfone) (P) is a poly(biphenyl ether sulfone) (P1). More preferably, the poly(aryl ether sulfone) (P) is a polyphenylsulfone. Still more preferably, the poly(aryl ether sulfone) (P) is a polyphenylsulfone homopolymer.

The polymeric material may contain one and only one
10 poly(aryl ether sulfone) (P). Alternatively, the polymeric material may contain two or more poly(aryl ether sulfone)s (P) ; for example, it may contain two or more poly(biphenyl ether sulfone)s (P1) (in particular, two or more polyphenylsulfone homopolymers), or it may contain at least one poly(biphenyl ether sulfone) (P1) and at least one polyethersulfone (P3).

15 The poly(aryl ether sulfone) (P) which is used according to the present invention may be prepared by various methods, for example by the so-called carbonate method. Generally described, the process is conducted by contacting substantially equimolar amounts of at least one aromatic bishydroxy monomer, e.g. 4-4' bisphenol A, 4-4' bisphenol S, or 4,4'-biphenol and at least one
20 dihalodiarylsulfone, e.g., 4,4'-dichlorodiphenyl sulfone, 4,4'-difluorodiphenyl sulfone or the like, with from about 0.5 to about 1.1 mole, preferably from about 1.01 to about 1.1 mole, more preferably from about 1.05 to about 1.1 mole of an alkali metal carbonate, preferably potassium carbonate, per mole of hydroxyl group.

25 The components are generally dissolved or dispersed in a solvent mixture comprising a polar aprotic solvent together with a solvent which forms an azeotrope with water, whereby water formed as a byproduct during the polymerization may be removed by azeotropic distillation continuously throughout the polymerization.

30 The polar aprotic solvents employed are those generally known in the art and widely used for the manufacture of poly(aryl ether sulfone)s. For example, the sulfur-containing solvents known and generically described in the art as dialkyl sulfoxides and dialkylsulfones wherein the alkyl groups may contain from 1 to 8 carbon atoms, including cyclic alkylidene analogs thereof, are
35 disclosed in the art for use in the manufacture of poly(aryl ether sulfone)s. Specifically, among the sulfur-containing solvents that may be suitable for the

- 15 -

purposes of this invention are dimethylsulfoxide, dimethylsulfone, diphenylsulfone, diethylsulfoxide, diethylsulfone, diisopropylsulfone, tetrahydrothiophene-1,1-dioxide (commonly called tetramethylene sulfone or sulfolane) and tetrahydrothiophene-1-monoxide. Nitrogen-containing polar aprotic solvents, including dimethylacetamide, dimethylformamide and N-methyl-pyrrolidinone pyrrolidinone and the like have been disclosed in the art for use in these processes, and may also be found useful in the practice of the present invention.

The solvent that forms an azeotrope with water will necessarily be selected to be inert with respect to the monomer components and polar aprotic solvent. Those disclosed and described in the art as suitable for use in such polymerization processes include aromatic hydrocarbons such as benzene, toluene, xylene, ethylbenzene, chlorobenzene and the like.

The azeotrope-forming solvent and polar aprotic solvent are typically employed in a weight ratio of from about 1:10 to about 1:1, preferably from about 1:5 to about 1:1.

Generally, after an initial heat-up period, the temperature of the reaction mixture will be maintained in a range of from about 160°C to about 250°C, preferably from about 200°C to about 230°C, still more preferably from about 200°C to about 225°C for about 0.5 to 3 hours. Typically, if the reaction is conducted at atmospheric pressure, the boiling temperature of the solvent selected usually limits the temperature of the reaction.

The reaction may be conveniently carried out in an inert atmosphere, e.g., nitrogen, at atmospheric pressure, although higher or lower pressures may also be used.

It is essential that the reaction medium be maintained substantially anhydrous during the polycondensation. While amounts of water up to about one percent, preferably no more than 0.5 percent by weight, can be tolerated, and are somewhat beneficial when employed with fluorinated dihalobenzenoid compounds, amounts of water substantially greater than this are desirably avoided as the reaction of water with the halo compound leads to formation of phenolic species and low molecular weight products are obtained. Substantially anhydrous conditions may be conveniently maintained during the polymerization by removing water continuously from the reaction mass with the azeotrope-forming solvent as an azeotrope. In the preferred procedure, substantially all of the azeotrope-forming solvent, for example, chlorobenzene, will be removed by

distillation as an azeotrope with the water formed in the reaction, leaving a solution comprising the poly(aryl ether sulfone) product dissolved in the polar aprotic solvent.

Sometimes, after the desired molecular weight has been attained, the polymer is endcapped to improve melt and oxidative stability. Generally, the endcapping is accomplished by adding a reactive aromatic halide or an aliphatic halide such as methyl chloride, benzyl chloride or the like to the polymerization mixture, converting any terminal hydroxyl groups into ether groups. In some instances, the polymer is intentionally left with excess hydroxyl groups to produce a reactive polymer. For the present invention it is preferred to use a reactive polymer.

The poly(aryl ether sulfone) is subsequently recovered by methods well known and widely employed in the art such as, for example, coagulation, solvent evaporation and the like. In the particular case of a reactive polymer, the recovery method must avoid reaching temperatures where the polymer will react. Frequently, in case a high excess of hydroxyl endgroups is desired, the polymer reaction is conducted with an excess of the bishydroxy monomer.

Poly(aryl ether sulfone), in particular polyphenylsulfone, has the advantage that it is especially durable with respect to heat and pressure. Moreover it isolates against heat as well as noise. In traditional sterilization apparatuses, a large amount of energy is consumed for heating the material in the metal or plastic sterilization chamber for each sterilization cycle (sometimes referred to also as "autoclaving cycle"). This heating of material is considerably reduced in the sterilization chamber according to the present invention.

A further problem with the heating of the sterilization chamber in a common sterilization apparatus is that the heat may be transported through the chamber walls to the housing, resulting in a risk of burning for the users when the sterilization apparatus housing is touched. Consequently, in a prior art sterilization apparatus, an extra isolation is a prerequisite. This problem is avoided in the sterilization chamber of the present invention.

Furthermore, the sterilization process, when vapour, water and so on is fed into the sterilization chamber in a known meander, tends to create noise within the chamber. By using the sterilization chamber of the present invention, this kind of noise does not leave the chamber due to the good sound isolating properties of poly(aryl ether sulfone), in particular polyphenylsulfone, resulting in an improved work environment for the users.

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The sterilization chamber is preferably releasably mountable in a sterilization apparatus, whereby the sterilization device, whereby the chamber may be mounted in the sterilization device as an easily exchangeable component.

5 In a preferred embodiment of the invention, the sterilization chamber is manufactured in one continuous piece. In this embodiment, the mounting of the chamber in the sterilization apparatus as well as any exchange of it is simplified.

Further, it is possible to manufacture the sterilization chamber without joints or the like. The risk of bacterial build-up is thus reduced, and clean and hygienic surfaces within the sterilization chamber are easily achieved.

10 Furthermore, the lack of joints in the chamber reduces wear.

Preferably, components such as inlets and outlets for steam, moisture and the like, are integrally formed with the sterilization chamber of the present invention. This reduces the number of required components and facilitates the mounting of the chamber in the sterilization apparatus. Also, the risk of
15 mounting a component incorrectly is reduced.

In a preferred embodiment, the sterilization chamber is provided with (preferably integrally formed) tracks in which a sealing chamber door may be slidably mounted. Thereby, no hinges or the like are necessary, and associated stress on the chamber door material at the attachment points is avoided.

20 Furthermore, the number of joints in the interface between the chamber and the sealing chamber door may be kept at a minimum.

The sterilization chamber of the present invention has preferably an inner volume of up to 50 liters, more preferably 5 to 40 liters, even more preferably 10 to 30 liters.

25 In the sterilization chamber of the present invention, an insert, preferably also made of a poly(aryl ether sulfone), more preferably made of polyphenylsulfone, for holding trays or the like comprising the matters to be disinfected may be arranged within the chamber in a known manner.

According to a preferred embodiment of the invention, the sterilization
30 chamber is manufactured in one piece using injection molding of a polyphenylsulfone material. A reinforcing material such as glass fibres or the like may be added to the polyphenylsulfone material in order to create a strong chamber structure.

The aforementioned advantages and objects of the inventions are moreover
35 achieved in accordance with the present invention by a sterilization apparatus, comprising the aforementioned chamber sterilization.

The sterilization apparatus of the present invention may be fed from the front, rear, side or from the top with articles to be sterilized. In addition, feed-through apparatuses are conceived. Moreover, the sterilization apparatus may be adapted to different kinds of uses, from small clinic apparatuses to large
5 apparatuses as used in industry. The adjustment of the sterilization apparatus and the sterilization chamber used therein will depend for example on the demands regarding temperature and pressure stability.

Namely, the sterilization chamber may have different shapes, with a rounded or rectangular cross-section. It is however preferred with the present
10 invention that the sterilization chamber has a rounded cross-section (cylindrical, ellipsoidal etc.) i.e., oval or essentially rectangular shapes are possible and may be chosen for specific applications. Corners and edges will however in general be avoided when the applied pressure is significant (i.e. around 2 bars).

The sterilization chamber may be produced in several pieces that are
15 mounted thereafter together to the desired sterilization chamber. However, a single piece chamber is preferred in most applications. In order to form a sterilization chamber from several separate pieces, the pieces may be put together by plastic welding.

The sterilization chamber according to the present invention may comprise
20 a filter, which is preferably made from polyphenylsulfone. Namely, a sterile file is required in order to prevent germs from penetrating into the holding space of the sterilization chamber following the sterilization operation. This filter has to be replaced from time to time and is thus preferably detachable from the sterilization chamber.

25 The invention is moreover directed to a process for the manufacture of a sterilization chamber of the present invention, comprising the step of injection moulding a polymer comprising at least 90 wt. % poly(aryl ether sulfone) (P) into a mould which is adapted to provide said sterilization chamber.

The sterilization chamber and apparatus, and the process for the
30 manufacture of the present sterilization chamber have a number of advantages. It was found that the sterilization chamber of the present invention retains the impact properties after steam sterilizations (for example 100 cycles) significantly better when compared to sterilization chambers that are made from other polymers, including polyetherimides and polyetherketones. In particular, the
35 change in maximum load is significantly lower with the sterilization chamber of the present invention.

In the following, the invention is described in more detail with reference to Figs. 1 and 2 wherein non-limiting examples for the sterilization chamber and sterilization apparatus according to the present invention are shown.

Fig. 1 is a perspective view of a sterilization apparatus, comprising a sterilization chamber in accordance with the present invention. The sterilization apparatus 1 comprises a housing 2, in which a sterilization chamber 3 according to the invention is placed. The sterilization apparatus 1 also comprises customarily used pressurization means, vaporization means etc. (not shown here).

In the embodiment of the invention shown in Fig. 1, the sterilization chamber 3 comprises a cylindrical portion 3a having a back wall 3b, 3a and 3b together forming a container having a front opening 5 through which goods to be sterilized may be entered. The sterilization apparatus 1 moreover comprises a chamber door 4 that can be moved between a first position (opening 5 is closed) and a second position (opening 5 accessible). The chamber door 4 thus creates together with the inside of the sterilization chamber 3 (i.e. the cylindrical portion and the back wall) a sterilization enclosure. In this position, the door 4 is in sealing contact with the sterilization chamber 3. In the second position, the door 4 is removed from front opening 5, leaving the sterilization chamber 3 open for entering or removing goods. In the embodiment shown in Fig. 1, the door is slidably arranged between the first and the second position.

In accordance with the invention, the sterilization chamber 3 is manufactured from a poly(aryl ether sulfone). The chamber may be formed by injection moulding, casting or the like.

The sterilization chamber 3 is manufactured in one piece using injection molding of a poly(aryl ether sulfone), in particular a polyphenylsulfone material. A reinforcing material may be added to the poly(aryl ether sulfone) material in order to create a strong chamber structure. Said reinforcement material may be glass fibres or the like.

Moreover, sterilization chamber 3 shown in this embodiment is detachable from the sterilization apparatus 1.

The sterilization apparatus 1, in particular the sterilization chamber 3, from Fig. 1 is fed from the front side with articles to be sterilized. The sterilization chamber 3 has a cylindrical shape in order to resist especially good to high pressure.

- 20 -

As seen in Figure 1, sterilization chamber 3 comprises fastening portions, formed in integration with the remainder of the chamber. The fastening portions 3c are intended to be used for releasable mounting of the chamber in the sterilization device by means of fasteners (not shown herein). In the present case, the fastening portions are flat front and back surfaces 3c, provided with openings, through which a fastening means like a screw may be introduced and thereafter fastened in the housing 2. Other ways of mounting the sterilization chamber 3 in the sterilization apparatus are possible and may be selected according to need. Consequently, sterilization chamber 3 may easily be removed from sterilization apparatus 1, for example for replacement in case of wear or altered user needs.

In order to facilitate mounting, inlets for vapour, water and the like, and outlets for excess fluids, are integrally formed in the sterilization chamber of the embodiment shown in Fig. 1. Thereby the mounting and the exchange of the sterilization chamber are further facilitated. The placement and configuration of inlets and outlets in the chamber depend on the desires of the person skilled in the art.

As shown in Fig. 1, the chamber door 4 is slidably mounted in a pair of parallel tracks 3c, being formed in integration with sterilization chamber 3. Said tracks 3c encompass the door 4 on two opposite edges. Further, sealing means are provided on door 4 in order to provide for the creation of a sealed pressure chamber when door 4 is closed. By arranging door 4 as a slidable component, no hinges or the like need to be attached to the sterilization chamber that could result in high wear in the hinge fastening points. By utilizing this track approach, wear is avoided, resulting in a longer lifetime of the sterilization chamber.

In the shown embodiment of the invention, the sterilization chamber 3 is manufactured in one piece, i.e. without joints. This results in a clean and smooth inner surface of the chamber, resulting in a decreased risk for bacterial buildups. Furthermore, due to the used material's properties, condensation is less likely to appear on the poly(aryl ether sulfone) material than on other materials. Consequently, it is easier to obtain dry goods in the chamber, since there is less condensation of moisture, whereby the added energy may be used in the sterilization process instead of vaporizing condensate.

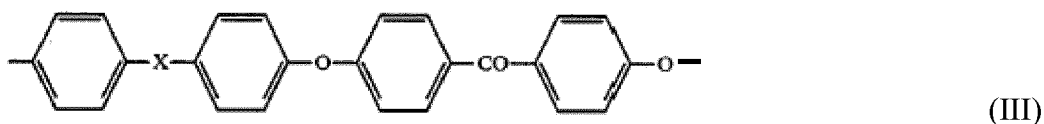
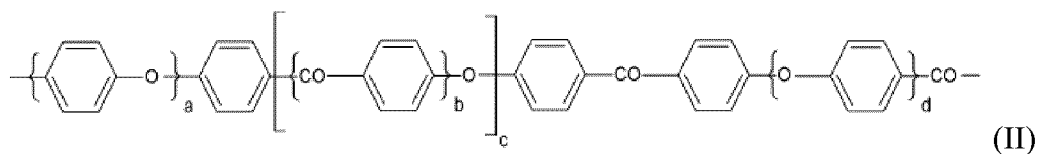
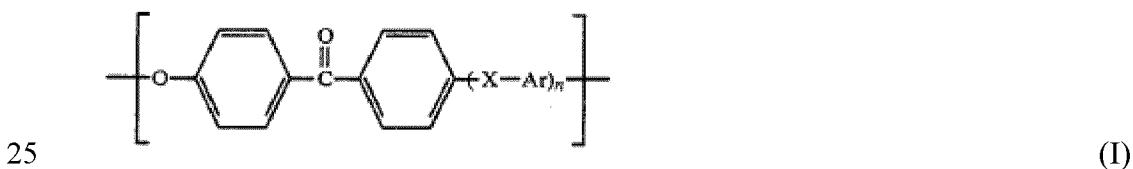
Fig. 2 shows an enlarged view of the sterilization chamber 3 of the present invention as used in the sterilization apparatus 1 shown in Fig. 1. 3a is the cylindrical portion of the sterilization chamber 3.

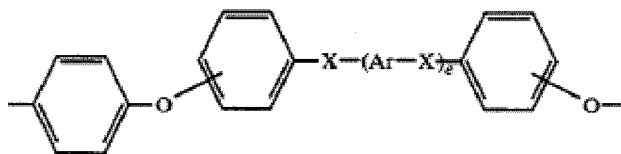
Embodiment (S)*

5 In a certain special embodiment [hereinafter, embodiment (S*)], the polymeric material further comprises at least one poly(aryl ether ketone) (P*). Sterilization chambers in accordance with embodiment (S*), i.e. sterilization chambers made of a polymeric material comprising at least one poly(aryl ether sulfone) (P) and at least one poly(aryl ether ketone) (P*) are especially useful
 10 when the sterilization chamber must comply with severe requirements in terms of chemical resistance. In such cases, the additional presence of the poly(aryl ether ketone) (P*) can provide the requested high level of chemical resistance, while the poly(aryl ether sulfone) (P) still provides high durability with respect to heat and pressure, good isolation against heat as well as noise, low energy
 15 consumption for achieving autoclaving cycle and absence of noise creation when vapour, water and so on are fed into the sterilization chamber. Also, when the poly(aryl ether sulfone) (P) and the poly(aryl ether ketone) (P*) are used in combination, extra isolating of the chamber to avoid risks of burning for the users can be avoided.

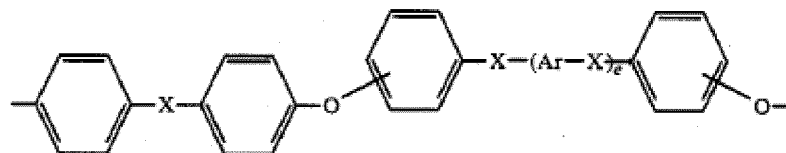
20 The term “poly(aryl ether ketone)” (PAEK) as used herein includes any polymer of which more than 50 wt. % of the recurring units are recurring units (R*) of one or more formulae containing at least one arylene group, at least one ether group (–O–) and at least one ketone group [–C(=O)–].

Preferably, recurring units (R*) are chosen from :





(IV)



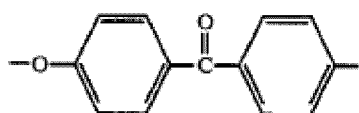
(V)

and mixtures thereof,

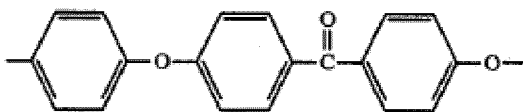
wherein :

- 5 Ar is independently a divalent aromatic radical selected from phenylene, biphenylene or naphthylene,
- X is independently O, C(=O) or a direct bond,
- n is an integer of from 0 to 3,
- b, c, d and e are 0 or 1,
- 10 a is an integer of 1 to 4, and preferably, d is 0 when b is 1.

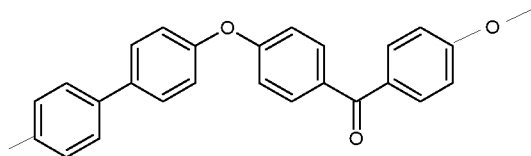
More preferably, recurring units (R*) are chosen from :



(VI)

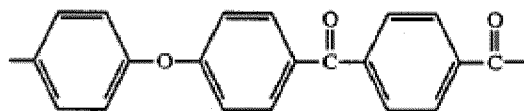


(VII)



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(VIII)



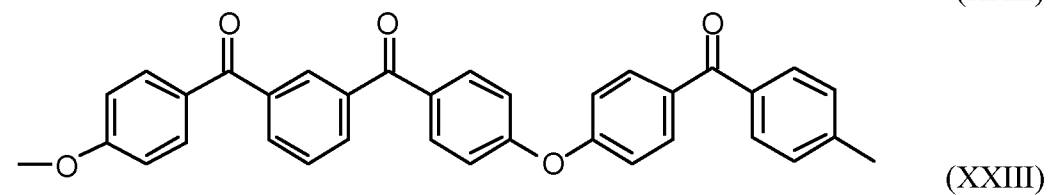
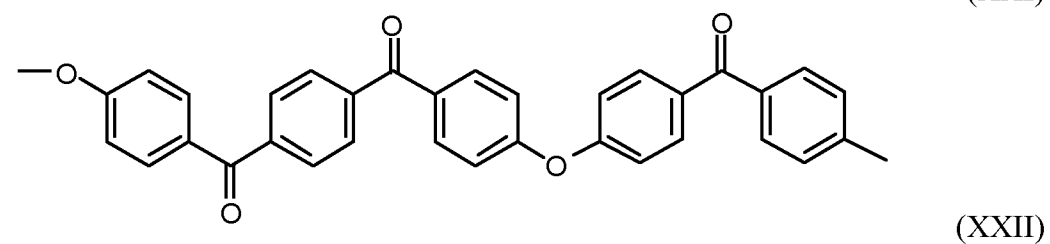
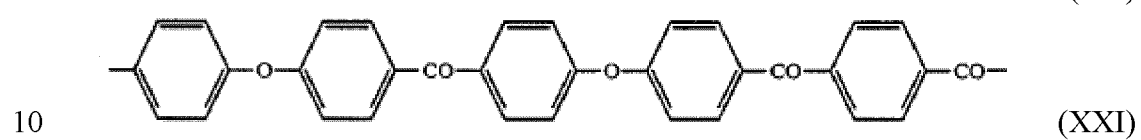
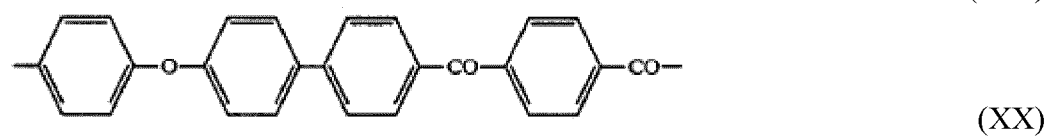
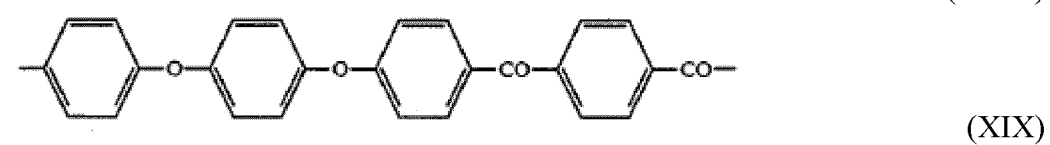
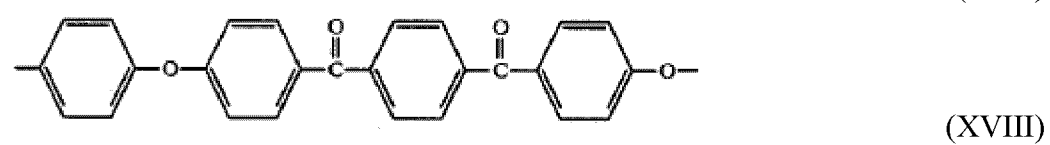
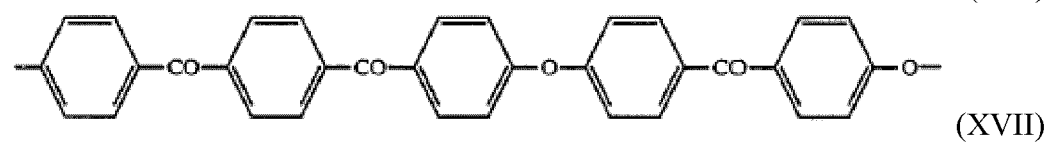
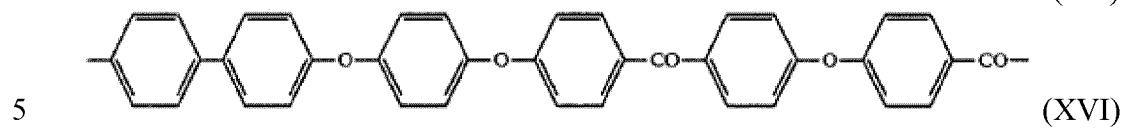
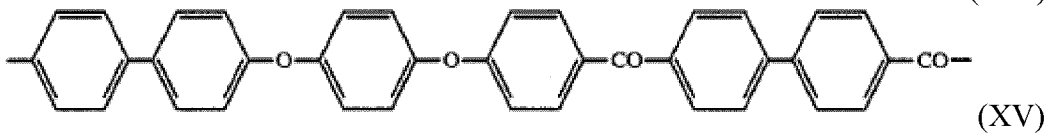
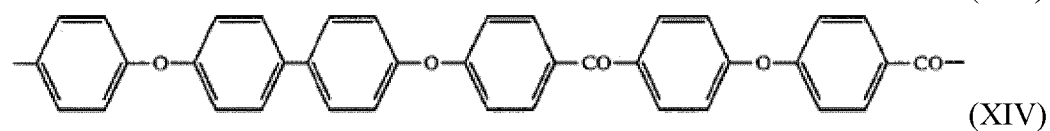
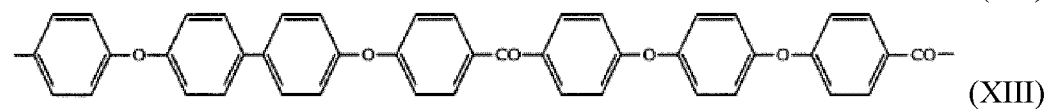
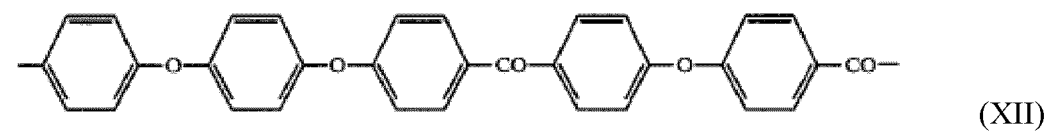
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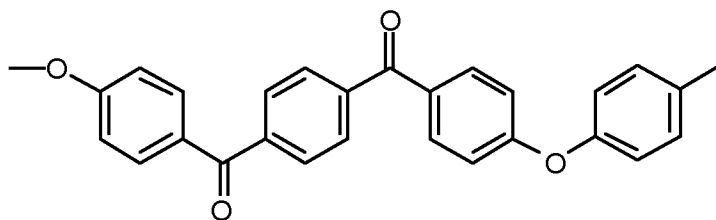
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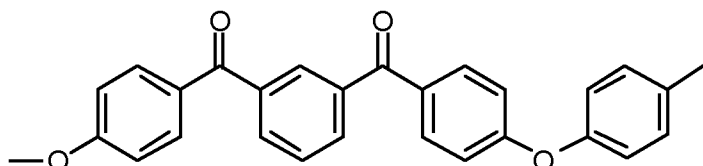
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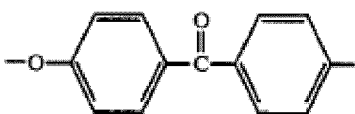
(XXIV)



(XXV)

and mixtures thereof.

Still more preferably, recurring (R^*) are chosen from :

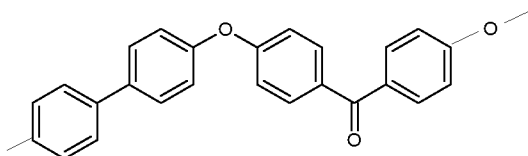


5

(VI)



(VII)



(VIII)

and mixtures thereof.

The most preferably, recurring units (R^*) are :



10

(VII)

The poly(aryl ether ketone) (P^*) may be notably a homopolymer, a random, alternate or block copolymer.

When the poly(aryl ether ketone) (P^*) is a copolymer, it may notably contain (i) recurring units (R^*) of at least two different formulae chosen from formulae (VI) to (XXI), or (ii) recurring units (R^*) of one or more formulae (VI) to (XXI) and recurring units different from recurring units (R^*) such as recurring units (R), (R_1), (R_2), (R_3) and (R_4) as above defined and any subset thereof.

Preferably more than 70 wt. %, more preferably more than 85 wt. % of the recurring units of the poly(aryl ether ketone) (P^*) are recurring units (R^*). Still more preferably, essentially all the recurring units of the poly(aryl ether

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ketone) (P*) are recurring units (R*). The most preferably, all the recurring units of the poly(aryl ether ketone) (P*) are recurring units (R*).

The poly(aryl ether ketone) (P*) has generally a reduced viscosity (RV) measured at 25°C with 1 wt./vol. % in conc. sulfuric acid of greater than or equal to 0.3 dl/g RV, including at least 0.5, at least 0.7, at least 0.9, at least 1.1, at least 1.3 or at least 1.5 ; besides, it has generally a RV of at most 2.5 dl/g, including at most 2, at most 1.8, at most 1.6, at most 1.4 or at most 1.2. The reduced Viscosity (RV) is measured according ASTM D2857-95 (2007), and as already said, at 25°C in concentrated sulfuric acid (1 wt. %/vol.). The viscometer tube can be a number 50 Cannon Fenske. The solution can be prepared by dissolving 1.0000 ± 0.0004 g of resin in $100 \text{ ml} \pm 0.3 \text{ ml}$ concentrated sulfuric acid (95-98 %, density=1.84). In order to facilitate the dissolution, ground powder (approx mean particle size 200-600 μm) can be used. The sample can generally be dissolved at room temperature (no heating). The solution is advantageously filtered on glass frit (medium porosity) before use.

The RV is calculated as $RV = \frac{t_{\text{soln}} - t_{\text{solvent}}}{t_{\text{solvent}} * C}$ wherein t_{soln} and t_{solvent} are the efflux times measured for the solution and the blank solvent, respectively.

A polyetheretherketone (in short, PEEK) is intended to denote any polymer of which more than 50 wt. % of the recurring units are recurring units (R*) of formula (VII). A PEEK homopolymer is a polymer of which essentially (and, preferably, all) the recurring units are of formula (VII). KetaSpire[®] polyetheretherketone from SOLVAY ADVANCED POLYMERS, L.L.C. is an example of a polyetheretherketone homopolymer.

Good results are obtained when the poly(aryl ether ketone) (P*) is a PEEK homopolymer, especially when the poly(aryl ether sulfone) (P) is a PPSU homopolymer.

U.S. Pat. Nos. 3,953,400, 3,956,240, 3,928,295, and 4,176,222, and RE 34085, all incorporated herein by reference, also disclose PAEKs and methods for their preparation. As noted above, PAEK polymers are generally prepared by aromatic nucleophilic substitution. For example, a bisphenol can be deprotonated with a base such as NaOH, Na₂CO₃ or K₂CO₃ and the resultant bisphenolate may then react with a bishalogenated monomer, e.g., a dihalobenzophenone via nucleophilic substitution, to form a PAEK via nucleophilic substitution. Such PAEK reactions are typically carried out in a solvent that is, or that contains, diphenyl sulfone.

In accordance with embodiment (S*), the polymeric material may comprise the poly(aryl ether sulfone) (P) and the poly(aryl ether ketone) (P*) in a combined weight amount of at least 10 %, at least 30 % or at least 60 %, based on the total weight of the polymeric material. In accordance with

5 embodiment (S*), the polymeric material comprises preferably the poly(aryl ether sulfone) (P) and the poly(aryl ether ketone) (P*) in a combined weight amount of at least 90 %, based on the total weight of the polymeric material ; more preferably, the polymeric material of embodiment (S*) consists essentially of the poly(aryl ether sulfone) (P) and the poly(aryl ether ketone) (P*) and, still
10 more preferably, the polymeric material of embodiment (S*) consists of the poly(aryl ether sulfone) (P) and the poly(aryl ether ketone) (P*). When the combined weight amount of the poly(aryl ether sulfone) (P) and the poly(aryl ether ketone) (P*) does not reach 100 %, the polymeric material of embodiment (S*) may further comprise, among other ingredients, at least one
15 polymer other than the poly(aryl ether sulfone) (P) and the poly(aryl ether ketone) (P*) ; said polymer other than the poly(aryl ether sulfone) (P) and the poly(aryl ether ketone) (P*) may be selected from the group consisting of polyimides, polyetherimides, polyamideimides, polyamides, polyesters, polytetrafluoroethylenes and mixtures thereof.

20 The polymeric material of embodiment (S*) comprises the poly(aryl ether sulfone) (P) in a weight amount ranging usually from 10 % to 99 %, based on the total weight of the polymeric material ; besides, it comprises the poly(aryl ether ketone) (P*) in a weight amount ranging usually from 1 % to 90 %, based on the total weight of the polymeric material. The polymeric material may comprise
25 the poly(aryl ether sulfone) (P) and the poly(aryl ether ketone) (P*) in a weight ratio (P):(P*) of at least 0.1, at least 0.2, at least 0.3, at least 0.4, at least 0.5, at least 0.6, at least 0.7, at least 0.8, at least 0.9 or at least 0.95 ; besides, the weight ratio (P):(P*) may be of at most 0.99, at most 0.95, at most 0.9, at most 0.8, at most 0.7, at most 0.6, at most 0.5, at most 0.4, at most 0.3 or at most 0.2.

30 As it appears from the above, the poly(aryl ether sulfone) (P) and poly(aryl ether ketone) (P*) contents may vary to a large extent while still providing a highly useful polymeric material. The skilled in the art will easily determine which poly(aryl ether sulfone) (P) and poly(aryl ether ketone) (P*) contents best fits the requirements to be achieved by the invented sterilization chamber. For
35 example, when an extremely high chemical resistance is desirable, preference will rather be given to a polymeric material having a high poly(aryl ether ketone)

content, hence sub-embodiment (sub-1) below ; on the other hand, notably when heat and pressure working conditions are especially harsh, and/or when extremely high isolation against noise is needed, preference will rather be given to a polymeric material having a high poly(aryl ether sulfone) content, hence sub-embodiment (sub-2) below.

Thus, in a first preferred sub-embodiment (sub-1), the weight amount of the poly(aryl ether ketone) (P*) comprised in the polymeric material is preferably of at least 30 %, more preferably of at least 50 % and still more preferably of at least 60 % on one hand, and it is preferably of at most 90 %, more preferably of at most 80 % and still more preferably of at most 70 % on the other hand. Besides, in accordance with (sub-1), the weight amount of the poly(aryl ether sulfone) (P) comprised in the polymeric material is preferably of at most 70 %, more preferably of at most 50 % and still more preferably of at most 40 % on one hand, and it is preferably of at least 10 %, more preferably of at least 20 % and still more preferably of at least 30 % on the other hand.

In a second preferred sub-embodiment (sub-2), the weight amount of the poly(aryl ether sulfone) (P) comprised in the polymeric material is preferably of at least 30 %, more preferably of at least 50 % and still more preferably of at least 60 % on one hand, and it is preferably of at most 90 %, more preferably of at most 80 % and still more preferably of at most 70 % on the other hand. Besides, in accordance with (sub-1), the weight amount of the poly(aryl ether ketone) (P*) comprised in the polymeric material is preferably of at most 70 %, more preferably of at most 50 % and still more preferably of at most 40 % on one hand, and it is preferably of at least 10 %, more preferably of at least 20 % and still more preferably of at least 30 % on the other hand.

As examples of polymeric materials suitable for use in accordance with present embodiment (S*), it can be cited blends consisting of 35 pbw (parts by weight) of PPSU and 65 pbw of PEEK, 50 pbw of PPSU and 50 pbw of PEEK, 65 pbw of PPSU and 35 pbw of PEEK.

Polymeric materials suitable for use in accordance with present embodiment (S*) can be easily prepared by the skilled person using a wide variety of well-known, conventional methods of mixing. A preferred method comprises dry mixing the poly(aryl ether sulfone) (P) with the poly(aryl ether ketone) (P*) in powder or granular form, using e.g. a mechanical blender, so as to form a mixture, then melt extruding the mixture into strands and chopping the strands into pellets. An alternative method comprises forming a solution

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including the poly(aryl ether sulfone) (P), the poly(aryl ether ketone) (P*) and a solvent, then evaporating the solvent to recover the polymeric material at solid state.

5 All references, patents, applications, tests, standards, documents, publications, brochures, texts, articles, etc. which may be mentioned herein are incorporated herein by reference. Where a numerical limit or range is stated, all values and subranges within the numerical limit or range are specifically included as if explicitly written out.

10 The above description is presented to enable a person skilled in the art to make and use the invention, and is provided in the context of a particular application and its requirements. Various modifications to the preferred embodiments will be readily apparent to those skilled in the art, and the generic principles defined herein may be applied to other embodiments and applications without departing from the spirit and scope of the invention. Thus, this invention
15 is not intended to be limited to the embodiments shown, but is to be accorded the widest scope consistent with the principles and features disclosed herein. In this regard, certain embodiments within the invention may not show every benefit of the invention, considered broadly.

20 Should the disclosure of any patents, patent applications, and publications which are incorporated herein by reference conflict with the description of the present application to the extent that it may render a term unclear, the present description shall take precedence.

C L A I M S

1. A sterilization chamber (3) made of a polymeric material, wherein the polymeric material comprises at least one poly(aryl ether sulfone) (P) and at least one poly(aryl ether ketone) (P*).
- 5 2. The sterilization chamber (3) according to claim 1, wherein the poly(aryl ether sulfone) (P) is a PPSU homopolymer.
3. The sterilization chamber (3) according to claim 1, wherein the poly(aryl ether sulfone) (P) has a weight average molecular weight in the range of from 20,000 to 100,000, as determined by Gel Permeation Chromatography
10 using conventional polystyrene calibration standards.
4. The sterilization chamber (3) according to claim 1, wherein the poly(aryl ether ketone) (P*) is a PEEK homopolymer.
5. The sterilization chamber (3) according to claim 1, wherein the poly(aryl ether ketone) (P*) has a reduced viscosity (RV) measured at 25°C
15 with 1 wt./vol. % in conc. sulfuric acid ranging from 0.5 to 2 dl/g RV.
6. The sterilization chamber (3) according to claim 1, wherein the poly(biphenyl ether sulfone) (P) is a PPSU homopolymer and the poly(aryl ether ketone) (P*) is a PEEK homopolymer.
7. The sterilization chamber (3) according to claim 1, wherein the
20 polymeric material consists essentially of the poly(aryl ether sulfone) (P) and of the poly(aryl ether ketone) (P*).
8. The sterilization chamber (3) according to claim 1, wherein said chamber is essentially manufactured in one continuous piece.
9. The sterilization chamber (3) according to claim 1, wherein inlets and
25 outlets for steam, moisture and the like, are integrally formed with said chamber (3).
10. A sterilization apparatus (1) comprising the sterilization chamber (3) of claim 1.

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11. A process for the manufacture of the sterilization chamber (3) as defined in claim 1, which comprises the step of injection moulding the polymeric material into a mould which is adapted to provide said sterilization chamber (3).

12. A sterilization chamber (3) made of a polymeric material, wherein the polymeric material comprises at least one poly(aryl ether sulfone) (P).

13. The sterilization chamber (3) according to claim 12, wherein the poly(aryl ether sulfone) (P) is a poly(biphenyl ether sulfone) (P1).

14. The sterilization chamber (3) according to claim 13, wherein the poly(biphenyl ether sulfone) (P1) is a polyphenylsulfone homopolymer.

15. The sterilization chamber (3) according to claim 14, wherein the poly(aryl ether sulfone) (P) has a weight average molecular weight in the range of from 40,000 to 70,000, as determined by Gel Permeation Chromatography using conventional polystyrene calibration standards.

16. The sterilization chamber (3) according to claim 12, wherein the polymeric material comprises the poly(aryl ether sulfone) (P) in a weight amount of at least 90 wt. %, based on the total weight of the polymeric material.

17. The sterilization chamber (3) according to claim 16, wherein the polymeric material consists essentially of the poly(aryl ether sulfone) (P).

18. The sterilization chamber (3) according to claim 12, wherein said chamber is essentially manufactured in one continuous piece.

19. The sterilization chamber (3) according to claim 12, wherein inlets and outlets for steam, moisture and the like, are integrally formed with said chamber (3).

20. A sterilization apparatus (1) comprising the sterilization chamber (3) of claim 12.

21. A process for the manufacture of the sterilization chamber (3) as defined in claim 12, which comprises the step of injection moulding the polymeric material into a mould which is adapted to provide said sterilization chamber (3).

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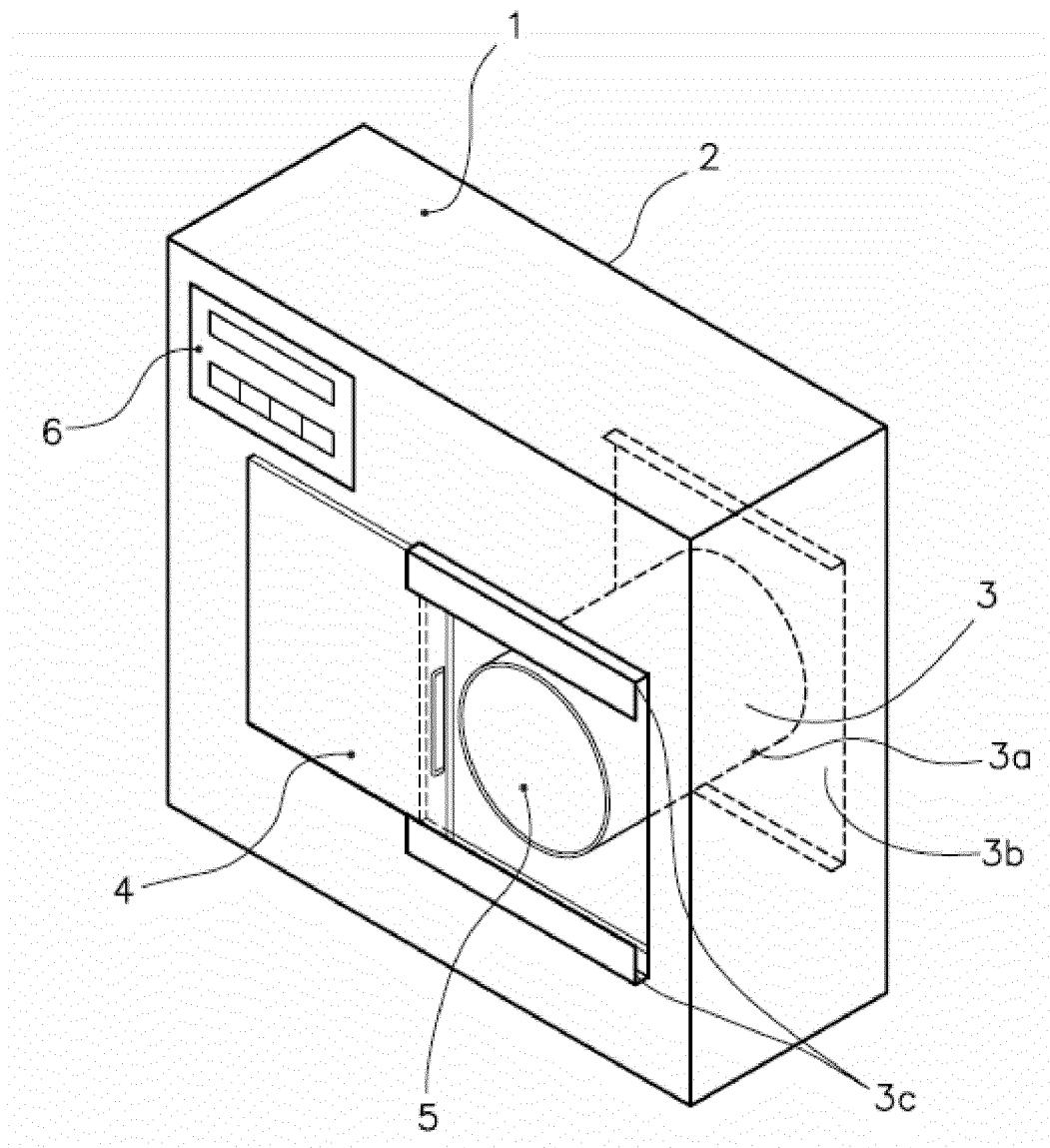


Figure 1

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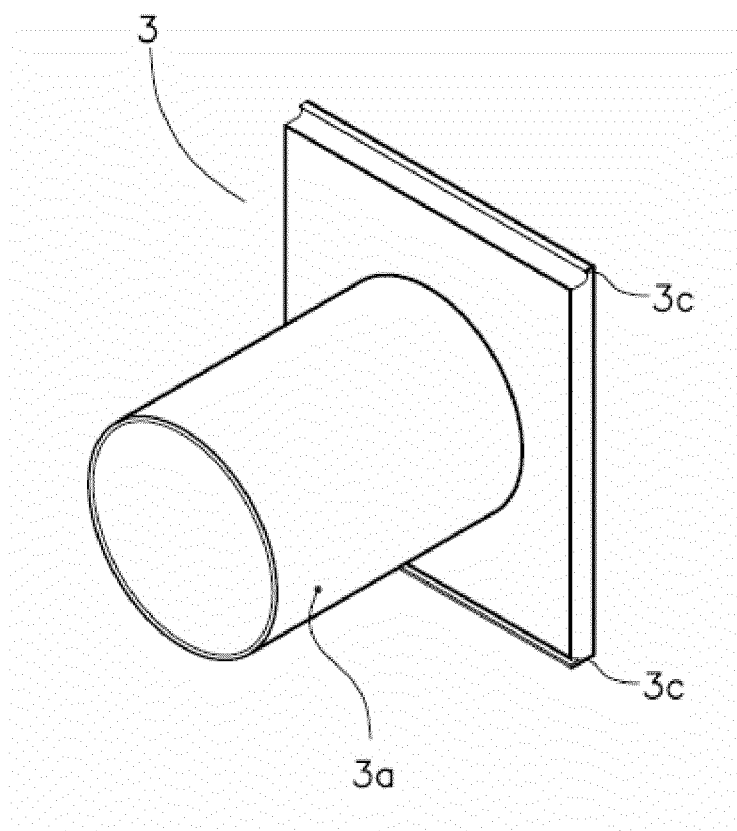


Figure 2