

Claims:

1. A method of producing a moulded polyurethane hydrogel, the method comprising:
forming a first solution of at least one polyurethane having a molecular weight of between about 40000 to about 500000 in a water:organic polar solvent comprising less than about 40% (v/v) water;
applying a layer of the first solution to a mould;
drying the layer of the first solution to form a polyurethane film on the mould; and
contacting the polyurethane film with a swelling agent under conditions such that the film forms a polyurethane hydrogel with a swelling agent content of between about 1% to about 95%.
2. The method of claim 1 wherein the molecular weight of the polyurethane is about 40000 to about 200000, about 150000 to about 350000, or about 300000 to about 500000.
3. The method of claim 1 or 2 wherein the polyurethane is derived from polymerisation of 4,4'-dicyclohexylmethane diisocyanate.
4. The method of claim 1 or 2 wherein the polyurethane is a polyether- or polyester-based polyurethane.
5. The method of claim 4 wherein the polyether-based polyurethane is derived from polymerisation of 4,4'-dicyclohexylmethane diisocyanate and a polyether.
6. The method of claim 5 wherein the polyether comprises one to 35 ethyl ether groups.
7. The method of claim 6 wherein the polyester-based polyurethane derived from polymerisation of 4,4'-dicyclohexylmethane diisocyanate and a polyester.
8. The method of claim 7 wherein the polyester comprises one to 35 ethyl ester groups.
9. The method of any one of claims 1 to 8 wherein the organic polar solvent is selected from the group consisting of ethanol, methanol, isopropanol, butanol, tetrahydrofuran, dimethylformamide, dimethylsulfoxide, acetone, acetonitrile and any combination thereof.
10. The method of claim 9 wherein the organic polar solvent is ethanol.
11. The method of any one of claims 1 to 10 wherein the ratio of water:organic polar solvent is selected from about 5:95, about 10:90, about 15:85, about 20:80, about 25:75, about 30:70, about 35:65, or about 40:60.

12. The method of claim 11 wherein the ratio of water:organic polar solvent is about 10:90.
13. The method of any one of claims 1 to 12 wherein a swelling agent is selected from at least one of water, a glycol solution, a hydroxyethylcellulose solution, a paraben-based solution, a glycol-based solution, a glycerine based solution, an oil-based solution, or a silicone-based solution.
14. The method of claim 13 wherein the swelling agent comprises one or more of spermicide, lubricating agent, antiviral, antifungal, antimicrobial, prebiotic, probiotic, microbiome enhancer, flavour compound, aroma compound, sensation enhancing agent, sterilization agent, or disinfecting agent.
15. The method of any one of claims 1 to 14 wherein polyurethane film is contacted with the swelling agent for at least 1 second at ambient temperature.
16. The method of any one of claims 1 to 15 further comprising:
 - forming a second solution of at least one polyurethane having a molecular weight of between about 40000 to about 200000, about 150000 to about 350000, or about 300000 to about 500000 in a water:organic polar solvent comprising less than about 40% (v/v) water;
 - applying a layer of the second solution to the polyurethane film on the mould;
 - drying the layer of the second solution, wherein the layers form a polyurethane film on the mould; and
 - contacting the polyurethane film with a swelling agent under conditions such that the film forms a polyurethane hydrogel with a swelling agent content of between about 1% to about 95%.
17. The method of any one of claims 1 to 16 wherein the polyurethane comprises $-\text{CH}_2-(\text{CH}_2-\text{O}-\text{CH}_2)_n-\text{CH}_2-[\text{O}-\text{OCHN}(\text{C}_6\text{H}_{10})\text{CH}_2(\text{C}_6\text{H}_{10})\text{NHCO}-\text{O}-(\text{CH}_2\text{CH}_2-\text{O}-\text{CH}_2\text{CH}_2)-\text{O}-\text{OCHN}(\text{C}_6\text{H}_{10})\text{CH}_2(\text{C}_6\text{H}_{10})\text{NHCO}-\text{NH}-(\text{C}_6\text{H}_{10})\text{CH}_2(\text{C}_6\text{H}_{10})\text{NHCO}-\text{O}-\text{CH}_2\text{CH}_2-\text{O}-\text{CH}_2\text{CH}_2-\text{O}-\text{OCHN}(\text{C}_6\text{H}_{10})\text{CH}_2(\text{C}_6\text{H}_{10})\text{NHCO}-\text{O}]_m-\text{CH}_2-(\text{CH}_2-\text{O}-\text{CH}_2)_n-\text{CH}_2$, wherein
 - n is an average independently selected from any number from 1 to 35; and
 - m is an average independently selected from any number from 15 to 500.
18. The method of claim 17 wherein the ration of n:m is from about 1:0.1 to about 1:75.
19. The method of any one of claims 16 to 18, wherein the at least one polyurethane in the second solution is not the same as the at least one polyurethane in the first solution.

20. The method of any one of claims 1 to 19 further comprising applying a subsequent layer of the first or second solution to the polyurethane film on the mould to increase thickness, or to create a specific feature, of the polyurethane film.
21. The method of any one of claims 1 to 20 further comprising applying a subsequent layer of the first or second solution to a portion of the polyurethane film on the mould to increase thickness or to create a specific feature on a portion of the polyurethane film.
22. The method of claim 21, wherein the specific feature formed from the subsequent layer has a different modulus, tensile strength, and/or linear expansion range than the hydrogel formed from the layer to which it is applied.
23. The method of any one of claims 16 to 22 wherein either or both of the molecular weight and n:m ratio, of the at least one polyurethane in the first solution is different to the molecular weight and n:m ratio of the at least one polyurethane in the second solution.
24. The method of any one of claims 16 to 23, wherein additional subsequent layers are applied to increase the thickness to a predetermined value.
25. The method of any one of claims 1 to 24, wherein the moulded polyurethane hydrogel has a linear expansion range of about 1% to about 100%.
26. The method of any one of claims 1 to 25 wherein the moulded polyurethane hydrogel has a tensile strength of about 1 MPa to about 100 MPa; about 1 MPa to about 20 MPa, about 20 MPa to about 60 MPa, about 60 MPa to about 80 MPa, about 60 MPa to about 80 MPa.
27. The method of any one of claims 1 to 26 wherein the moulded polyurethane hydrogel has an elongation at break range of about 200% to about 2000%.
28. The method of any one of claims 1 to 27 wherein the moulded polyurethane hydrogel has at least one of a 50% modulus of about 80 kPa to about 15 MPa, a 100% modulus of about 200 kPa to about 15 MPa, and a 300% modulus of about 700 kPa to about 15 MPa.
29. A moulded polyurethane hydrogel condom produced by the method of any one of claims 1 to 28.
30. A moulded polyurethane hydrogel condom, wherein the polyurethane hydrogel comprises a polyurethane having a molecular weight of between about 40000 to about 500000 and a swelling agent content of between about 40% to about 70%.
31. The moulded polyurethane hydrogel condom of claim 30, having one or more of linear expansion range of about 1% to about 100%, tensile strength of about 1 MPa to

about 40 MPa, elongation at break range of about 200% to about 750%, and at least one of a 50% modulus of about 80 kPa to about 15 MPa, a 100% modulus of about 200 kPa to about 15 MPa, and a 300% modulus of about 700 kPa to about 15 MPa.

32. The condom of any one of claims 30 to 31, wherein the condom is substantially impervious to biological agents having an average diameter of 30 nm or greater.

33. The condom of any one of claims 30 to 32, wherein the condom is substantially impervious to biological agents having an average diameter of 30 nm or greater under simulated usage pressures from atmospheric pressure to about 5 kilopascals.

34. The moulded polyurethane hydrogel condom of any one of claims 30 to 33 having an airburst volume of about 5L to about 50L.

35. The moulded polyurethane hydrogel condom of claim 34 wherein the airburst volume is 5L to 40L.

36. The moulded polyurethane hydrogel condom of any one of claims 30 to 35 having an airburst pressure of about 0.75 kPa to about 5 kPa

37. The moulded polyurethane hydrogel condom of claim 36 wherein the airburst pressure is 1.6 kPa to 3.6 kPa.