

1

MOLD MATERIAL WITH ADDITIVES**BACKGROUND OF THE INVENTION**

5

1. Field of the Invention

10

The present invention relates to a novel polymeric formulation containing an internal mold release additive or surfactant which assists in the release from each other of mold components from a multi-part mold employed in the molding of polymeric articles, such as soft contact lenses. The present invention is also directed to the molds made from such polymeric formulation as well as to a method of releasing the mold components from each other.

15

2. Background of the Invention

20

25

30

An extensive array of methods is currently utilized in the manufacture of hydrophilic polymer articles, such as soft contact lenses. A considerable variety of techniques have been employed, such as spin casting, static cast molding, lathing, and a combination of casting and lathing, and particularly through the use of two part molds. Generally, such mold parts for hydrophilic contact lenses consist of a curvilinear (concave/convex) center of front curve mold part adapted to form, in cooperation with a mating base mold curve part, a two part mold for the contact lenses. These hydrophilic contact lenses are usually constituted from a hydrophilic polymer, preferably a HEMA-based polymer (hydroxy-ethylmethacrylate), among numerous other materials.

The components of the mold within which the hydrophilic polymer contact lenses are molded may

35

REPLACED SHEETS		SG
☒	Description : paged 5,11,13,15 to paged 5	
☒	Claim(s) : paged 41 to paged 44	
☒	Drawing(s) : paged 34 to paged 5	
☒	Abstract : paged 46 to paged 5	
DATE OF RECEIPT		

1 consist of suitable pallets, each including a plurality
of cavities receiving mold parts having female and/or
male base surfaces or curvilinear mold portions for the
formation of the curved contact lenses. The molds, as
5 described, for instance in the molding technology, may
be constituted from suitably selected conventional
plastic materials, whereby the hydrophilic polymer
articles, i.e., the contact lenses, will be formed in
the cavity therebetween, and may possibly adhere to one
10 or both of the mold parts. In the utilization of
separable two part molds for the molding of hydrophilic
contact lenses, upon completing the molding step, it is
of critical importance to be able to release the
hydrophilic contact lenses from their surface engagement
15 without adherence to the mold parts or at least one of
the mold halves and to separate the mold part without
causing damage to the contact lenses which would render
the lenses unusable. Various means employed for
effectuating the release of hydrophilic contact lenses
20 from surfaces of molds, particularly two part molds
which are intended to be physically separated, are
through the employment of laser or infrared heat mold
separating devices, the use of external heat and/or the
application of heated gas, hot air or steam. However,
25 all too frequently, damage is sustained by the contact
lenses during the demolding operation. The potential
damage which generally renders the contact lenses unable
to meet necessary quality and/or inspection standards
may consist of edge tears and chips, nicks or other
30 surface defects formed in the contact lenses. Another
cause of rejected lenses are "holes", i.e., voids in the

1 center of the cast that are developed in the lenses
during the molding process.

U.S. Patent No. 4,159,292 to Neeffe discloses a
means for controlling the release of cast polymeric
5 optical lenses from a resinous optical mold by coating
the resinous mold material particles with a release
agent before forming the resinous material with a lens
mold. These release agents, e.g., silicone oil,
polyvinyl alcohol, steric acid, fluorocarbons and waxes,
10 are external additives to the mold resins. As such they
suffer from the disadvantage of being easily washed off
the surface of the mold resin and thus exhibit a
tendency to be retained on the lens material. In
addition, these additives are not distributed evenly in
15 the mold. Thus, the ease of separation of the lens
material from the mold resin varies depending upon the
distribution. In some areas of the mold, there may be
less resistance, while in others, there may still be
friction forces between the surfaces. Thus, using this
20 methodology, there may be a slight improvement, but even
so, the lenses frequently develop the defects described
herein.

As a result there is a need to find a new
formulation for the mold that would facilitate the
25 demolding process, so as to minimize the risk of damage
to the contact lenses upon demolding and also would
reduce the risk of holes in the lens.

The present invention accomplishes these goals by
utilizing an alternative material for one of the mold
30 parts. This new formulation has the advantage of
greatly reducing the adhesion forces between the lenses
and the mold part, thereby facilitating the release of

1 the mold material and minimizing the risk of developing
defects in the lens caused by and during the demolding
process. In addition, this new material has the added
5 advantage of reducing the tendency to form holes in the
contact lenses.

SUMMARY OF THE INVENTION

10 Accordingly, in order to improve upon the ability
of such hydrophilic polymeric articles, especially
hydrophilic polymeric contact lenses of being inherently
releasable in an undamaged state from its mold cavities
of two mold structures in which they are molded, the
present invention contemplates making one of the mold
15 structures of a new formulation. The present invention
provides for the formulation of a lens mold material
with an internal mold release agent or surfactant. This
provides improved and substantially uniform distribution
of the additive across the surface of the mold resin and
20 decreased probability that the additive would be
retained on the lens. Consequently, the adhesion forces
between the surfaces is greatly reduced, thereby
minimizing the risks for the defects described
hereinabove.

25 This formulation is a molding resinous
thermoplastic polymer of either polystyrene or
polypropylene. This additive is a surfactant or mold
release agent, such as waxes, and soaps and oil. More
particularly the additive is a propylene wax having a
30 molecular weight ranging from 5,000-200,000, a
polyethylene wax having a molecular weight of 5,000-
200,000, a fatty acid having 5-26 carbon atoms, a

1 hydrocarbyl carboxylic acid amide having a molecular
weight of 200-2,000, a glycerol ester having a molecular
weight of 200-2,000, salts of stearic acid, silicones
5 having a molecular weight of 2,000 to 100,000, Montan
wax, complex ester, oxidized waxes, or combinations
thereof.

This formation admixed with and impregnated with
at least 0.1% of an internal additive (w/w). When this
material was used to make one of the mold halves in the
10 mold assembly for making the contact lenses, it was
found that fewer lenses were formed having the defects
described hereinabove. Thus, an aspect of the present
invention is directed to the mold half comprised of this
new formulation. This mold half is part of the mold
15 assembly, and therefore another aspect of the present
invention is directed to the mold assembly comprising
said mold half comprised of the formulation of the
present invention.

The mold assembly comprises at least two pieces,
20 a female concave piece (front piece) and a male convex
piece (back piece), forming a cavity therebetween, and
when said pieces are mated, at least one piece having a
flange thereabout. More particularly the mold assembly
comprises a front mold half and a back mold half in
25 contact therewith, thereby defining and enclosing a
cavity therebetween, and a polymerizable composition in
said cavity in contact with said mold halves, the front
mold of which has a central curved section with a
concave surface, a convex surface and a circular
30 circumferential edge, wherein the portion of said
concave surface in contact with said polymerizable
composition has the curvature of the front curve of a

35

This Sheet Has Been Replaced



1 contact lens to be produced in said mold assembly and is
sufficiently smooth that the surface of a contact lens
formed by polymerization of said polymerizable
composition in contact with said surface is optically
5 acceptable, said front mold also having an annular
flange integral with and surrounding said circular
circumferential edge and extending therefrom in a plane
normal to the axis and extending from said flange, while
the back mold has a central curved section with a
10 concave surface, convex surface and circular
circumferential edge, wherein the portion of said convex
surface in contact with said polymerizable composition
has the curvature of the back curve of a contact lens to
be produced in said mold assembly and is sufficiently
15 smooth that the surface of a contact lens formed by
polymerization of the polymerizable composition in
contact with said surface is optically acceptable, said
back curve also having an annular flange integral with
and surrounding said circular circumferential edge and
20 extending therefrom in a plane normal to the axis of
said convex structure, and a generally triangular tab
situated in a plane normal to said axis and extending
from said flange, wherein the convex structure of said
back mold half contacts the circumferential edge of the
25 front mold half.

The inner concave surface of the front mold half
defines the outer surface of the contact lens, while the
outer convex surface of the base mold half defines the
inner surface of the contact lens which rests upon the
30 edge.

In this assembly, either the back mold or the
front mold half or both is comprised of the novel

1 formulation of the present invention. However, it is
the back mold half that is preferably comprised of the
novel formulation of the present invention, while the
front curve mold is comprised of a thermoplastic
5 material that does not contain the additive. Thus
another aspect of the present invention is directed to
the base mold comprised of said novel formulation.

The mold assembly with the base curve mold made
up of the polystyrene/additive or polypropylene/additive
10 formulations of the present invention are used in making
soft contact lenses. Thus, another aspect of the
present invention is directed to the process of making
soft contact lenses utilizing the mold assembly. As
described herein, the use of the polystyrene/additive
15 formulation facilitates the release of the mold from the
polymerized polymer comprising the contact lens and the
front mold.

Another aspect of the present invention is
directed to a process of minimizing and/or preventing
20 chips, holes or tears in the contact lens formed in the
molds by utilizing a lens mold comprised of the
polymeric formulation of the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS

25 The present invention may be more readily
understood by one skilled in the art with reference
being had to the following detailed description of
several preferred embodiments thereof, taken in
30 conjunction with the accompanying drawings wherein like
elements are designated by identical reference numerals
throughout the several views.

1 Figure 1 is a flow diagram of the continuous
process for contact lens production, including molding,
treatment and handling of the molds and contact lenses
in a low oxygen environment.

5 Figure 2 is a top elevational planar view of the
production line system.

 Figures 3 and 3(a) are respectively, a top or
planar view and an elevation of side view of one
embodiment of a first (female) or front curve mold half
10 molded pursuant to the present invention.

 Figure 3(b) is an enlarged detail of a portion of
Figure 3(a).

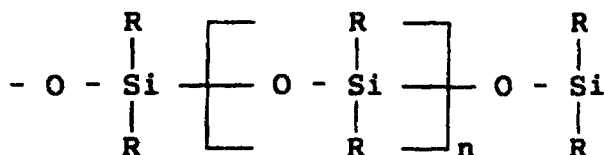
 Figures 4 and 4(a) are respectively a top or
planar view and an elevation or side view of one
15 embodiment of a second (male) or back curve mold half
molded pursuant to the present invention.

 Figure 5 is a base curve frame of 8 mold halves
(cavities) supported and registered in a pallet
comprised of various formulations, as described in
20 Example 2.

DETAILED DESCRIPTION OF THE PRESENT INVENTION

 The additives used in the present invention are
25 materials that are known or commercially available.

 As used herein, the term "silicones" is a term
applied to a range of materials based upon a silicon
oxygen polymer backbone with a carbon containing side
chain of hydrocarbyl groups containing 1-6 carbon atoms.
30 More specifically, it consists of a polymer having a
structure consisting of alternate silicon and oxygen
atoms of the formula:



wherein each R may be different, but preferably the same and are a hydrocarbyl group and n is an integer ranging from 20 to about 1500. The molecular weight of the silicone range from 2000 to 100,000 g/mole, inclusive. The silicone have very low surface tension, preferably 22-24 mN/m or dyn/cm. In addition, the silicones contemplated for use by the present invention are physiologically inert. They are stable, heat resistant, chemically inert, colorless and odorless. The term silicones includes among other things, silicone oil and silicone wax. Examples include ABILWAX 9800 and 9801, L-42, L-45, NM-1, VISC-10M, SF96, SF1080, SF18-850 DOW CORNING 200, 203, 230, KANTSTIK 406 NOO, KANTSTIK M-55, silicone wax (steroyldimethicone), dimethyl silicone, and the like.

Stearates are salts of stearic acid. They include ammonium salts and metal salts thereof. "Metal stearates" as used herein are the metal salts of stearic acid. These metals include alkali metals, alkaline earth metals, Group 13 metals, Group 14 metals and transition metals, such as Group 12. Example of the metals include zinc, sodium, calcium, lead, barium, cadmium, aluminum, lithium, and the like. Examples include HYTECH RSN 248D, PETRAC CP-11LS, PETRAC CP-115G, PETRAC 22, PLASTOLUBE, SYN PRO CALCIUM STEARATE PG, SYN PROTYPE 114-36, WITCO F, WITCO EXTRA DENSE G, WITCO FP, COMETALS SODIUM STEARATE, SYNPRO SODIUM STEARATE ST,

1 WITCO HEAT STABLE, INTERSTAB ZN-18-1, PETRAC ZN-4, MATHE
CALCIUM STEARATE, MILJAC CALCIUM STEARATE, WITCO CALCIUM
STEARATE, MATHE SODIUM STEARATE, WITCO SODIUM STEARATE,
WITCO T-1, COAD 20, 21, 23, 26 USP, 27B, 27D, 27F,
5 HYTECH RSN 1S31, MATHE ZINC STEARATE S, MATHE ZINC
STEARATE 25S, MILJAC ZINC STEARATE, WITCO ZINC STEARATE,
PLASTOLUBE, SYNPRO ACF, STNPRO 8, WITCO 42, WITCO 11,
and the like.

As used herein, amide waxes are waxes having the
10 formula $R_1\text{CONH}_2$ wherein R_1 is a hydrocarbyl radical and
 $R_1\text{CONH}_2$ has a molecular weight ranging from about 200
to about 2000 g/mole. There may be complete saturation
in R_1 or there may be at least one double bond between
the carbon atom in R_1 . The amide waxes preferably have
15 up to 40 carbon atoms, although it is preferred that the
amide waxes contain from 12-30 carbon atoms. The amide
waxes also include higher fatty acid amides, that is,
fatty acids having an even number of carbon atoms,
ranging from 12-30 carbon atoms. Examples include
20 CRODAMIDE ER, CRODAMIDE OR, CRODAMIDE SR, CRODAMIDE 203,
CRODAMIDE 212, EURESLIP 58, KEMAMIDE E, PARICIN 285,
PARICIN 220, PETRAC ERMIDE, PETRAC SLIP-EZE, PETRAC VIN-
EZE, PETRAC SLIP-QUICK, ACRAWAX C (1,2-
ethanediylbisoctadecanamide), ADWAX 280, EBS WAX,
25 HOSTALUB FA1, PARACIN 285, ROSSWAX 140, CRODAMIDE EBS,
BUSPENSE 047, ER, OR, 203, 212, KEMAMIDE B, S, U,
ethylene bis (stearamide), oleamide, erucamide, and the
like.

Examples of a fatty acid are CROD ACID, stearic
30 acid, and the like.

Polyethylene and propylene waxes as used herein
are waxes of low, medium or high density of polyethylene

1 and propylene respectively having a molecular weight
ranging from about 5000 to 200,000 g/mole. Examples of
polyethylene wax include EPOLENE C-13, C-14, C-15, C-17,
C-18, E-10, N-10, N-11, N-21, N-34, HOECHST WAX PE 190,
5 STANWAX, and the like. Examples of propylene wax are
EPOLENE N-15P, and EPOLENE E-43P, and the like.

Other waxes, such as mineral wax, e.g., Montan
wax can also be used. Montan wax contains three
portions, the wax portion, the resin portion and the
10 asphalt portion. The wax component of Montan is a
mixture of long-chain (C_{24} - C_{30}) esters (62-68 wt %),
long chain acids (22-26 wt %), and long-chain alcohols,
ketones and hydrocarbons (7-15 wt %). The resin portion
is approximately 70 wt % terpenes and polyterpenes and
15 30 wt % resinic acid and oxyresinic acid, while the
asphalt portion is believed to be polymerized esters of
oxyresinic acid.

Oxidized waxes are alkan hydrocarbons (paraffins)
having a molecular weight of 100 - 2000 g/mole. They
20 are capped at the ends with either ester, carboxylic or
hydroxy groups. Examples include carnauba wax and
Rosswax, such as Rosswax 100 and 1343 and the like.

As defined herein, glycerol esters are
hydrocarbyl esters of glycerol having a molecular weight
25 of 200 to 2000 g/mole. They include monoglycerides,
diglycerides and polyglycerides, including fatty acids
of triglycerides. Examples include PATIONIC 900, 901,
902, 907, 919, 1042 and 1042 K, and the like.

Alcohol esters contain 5-2000 carbon atoms, and
30 include such species as LUBE 106, and the like.

Complex esters are copolymers of organic
phosphate esters having a molecular weight of 200 - 2000

35

This Sheet Has Been Replaced



1 g/mole which contain glycerides, organic acid
derivatives and fatty acids. Examples include KANTSTIK
FX-9 and Q, and the like.

5 Combination of the additives listed hereinabove
or blends include MOLD EASE PCR, MOLD WIZ INT 33 PA, INT
38 H, INT 33 UDK, and the like. It is preferred that
the combination have a molecular weight ranging from 200
to 200,000 g/mole.

10 As defined herein, hydrocarbyl is an aliphatic,
cyclaliphatic, or aromatic moiety containing carbon and
hydrogen atoms, having 1 to 200 carbon atoms. The
hydrocarbyl moiety may be straight chain, or branched or
cyclic. If cyclic, the rings are preferably fused. The
hydrocarbyl group may be completely saturated or
15 partially saturated or completely aromatic or
conjugated. The hydrocarbyl moiety may contain at least
one double bond. It is preferred that the hydrocarbyl
group contains 1-100 carbon atoms.

20 As described hereinabove, the present invention
is directed to a new polymeric material containing an
additive admixed therewith. The polymeric material of
the present invention is a thermoplastic material, viz,
polystyrene or polypropylene. The polystyrene and
polypropylene that is utilized is transparent to
25 ultraviolet light. When the additive described
hereinabove is admixed with the polystyrene or
polypropylene, the new formulation maintains its ability
to transmit ultraviolet light. In a preferred
embodiment, the new formulation allows UV transmissions
30 of from 3 to 5 up to wavelengths of 300 nanometers.

The additive admixed with the thermoplastic
material is present in amounts of at least about 0.1% by



1 weight. As described hereinbelow, the additive is
thoroughly mixed with the thermoplastic material so as
to form a matrix. In other words, these are internal
5 stet additives and do not coat the thermoplastic
material. As such, the additive is relatively uniformly
distributed in the thermoplastic material.
Theoretically there is no upper limit to the amount of
additives added to the mold half, as long as one of the
mold halves maintains its transmission to UV light.
10 Typically, as a practical matter, additives up to about
20% are useable. In a preferred embodiment, the
additive should be present in amounts ranging from about
0.1% to about 5% by weight and more preferably from
about 0.1% to about 2% by weight.
15 The additive is basically an oil, soap, wax,
i.e., a mold release agent and/or surfactant. It is
preferably a silicone oil, stearates, e.g., zinc
stearates, or wax, but is not limited thereto. The
preferred additives are SF 1080 Silicone Oil, Int 38H
20 Ester Complex, Kantstik Q Ester Complex, FC 430 Ester
Complex, ABIL® Wax 9801, Silicone Wax (stearyl
dimethicone), SF 96-5 Silicone Oil, L-42, Calcium
Stearate, Sodium Stearate, Acrawax® C (1,2
ethanediylbis-octadecanamide), polystyrene 202, FC 4331
25 Ester Complex, SF 18-350 Silicone Oil, L-45 (dimethyl
silicone), Zinc stearate, ABIL® wax 9801 (cetyl
dimethicone), VSC-10M, Carnauba Wax and Ross Wax 100.
The more preferred additives are SF 1080 Silicone Oil,
Int. 38H Ester Complex, Kantstick Q Ester Complex, FC
30 430 Ester Complex and Abilwax 9801 Silicone Oil. The
most preferred additives are SF 1080 and Abilwax 9801.

35

This Sheet Has Been Replaced



1 Exemplary formulations include polystyrene or
polypropylene with the following additives in the
indicated amounts.

5

10

15

20

25

30

35

1	ADDITIVE	AMOUNT BY WEIGHT
	ABILWAX 9801	0.25%
	ABILWAX 9801	1.00%
	FC 430	0.25%
5	KANTSTICK Q	0.25%
	KANTSTICK Q	1.50%
	SF 1080	0.5%
	SF 1080	0.25%
	AXEL 33 P/A	0.25%
10	AXEL 33 P/A	2.50%
	AXEL 33-H	0.25%
	AXEL 38-H	2.5%
	GE 1080	0.5%
	GE 1080	0.25%
15	The polystyrene/additive and polypropylene/ additive compositions of the present invention are prepared by processes well known to those skilled in the art. The following procedure exemplifies the techniques used to make the composition of the present invention 20 using polystyrene. However, the techniques are just as applicable for making the polypropylene/additive composition.	
25	The procedure using polystyrene as the thermoplastic material is as follows. The polystyrene and the additive are mixed together by techniques known to one skilled in the art. In one methodology, the polystyrene is compounded with the additive. In other words, a predetermined amount of the additive and polystyrene are mixed together, the mixture is heated to 30 melt the polystyrene, the melted polystyrene and the additive are then again mixed together, such as with an extruder, which further intermixes the two components.	
35		

This Sheet Has Been Replaced



1 The mixture can then be repelletized in a pelletizer.
Alternatively, the polystyrene may first be melted to
form the molten polystyrene and the additive added to
the molten polystyrene in the mixer, e.g., extruder and
5 mixed together and then repelletized with the
pelletizer. Alternatively, the additive can be
compounded with the thermoplastic material directly in
the molding machine.

The composition of the present invention is
10 utilized to replace articles of manufacture wherein
polystyrene or polypropylene is normally utilized. In
one such application, the composition of the present
invention is employed to comprise a mold half of a
separable two part mold assembly utilized in the
15 preparation of soft contact lenses. The mold is
comprised of at least two pieces, a female, concave
piece and a male convex piece, forming a cavity
therebetween, when such pieces are mated, with at least
one flange thereabout. At least one of the pieces is
20 comprised of the composition of the present invention.
In other words, both mold halves or one mold half is
comprised of the composition of the present invention.
When only one mold half is comprised of the composition
of the present invention, the other mold half is
25 comprised of a thermoplastic polymer that is normally
used to make mold halves for contact lenses, as
described hereinbelow. It is preferred that the base
mold half be comprised of the composition of the present
invention.

30 A preferred mold assembly is depicted in Figures
3 and 3a, which illustrate respectively top elevational
and side views of one embodiment of a front mold half 10

1 useful in the production of a contact lens by the
polymerization of a polymerizable composition in a mold
assembly composed of two complementary front and base
mold halves. As indicated, the mold halves are useful
5 in the production of contact lenses in that lenses can
be made which are immediately ready to wear, and in that
unswelled lenses can be made which need to be swelled
(hydrated) to be ready to wear.

Although as indicated above, the front mold half
10 may be comprised of the present composition, it is
preferred that the front mold half 10 is formed of a
suitable thermoplastic polymer which is sufficiently
transparent to ultraviolet light to allow irradiation
therethrough with light to promote the subsequent
15 polymerization of a soft contact lens. Examples of
suitable materials include polyolefins such as low,
medium, and high density polyethylene, polypropylene,
including copolymers thereof; poly-4-methylpentene; and
polystyrene. Other suitable materials are polyacetal
20 resins, polyacrylethers, polyarylether sulfones, nylon
6, nylon 66 and nylon 11. Thermoplastic polyesters and
various fluorinated materials such as the fluorinated
ethylene propylene copolymers and ethylene
fluoroethylene copolymers may also be utilized. Other
25 materials that can be utilized for the front mold half
are described in U.S. Patent No. 4,565,348, the contents
of which are incorporated by reference. The most
preferred material for the front mold half is
polystyrene or polypropylene.

30 The front mold half 10 defines a central curved
section with an optical quality concave surface 15,
which has a circular circumferential parting edge 14

1 extending therearound. The parting edge 14, shown in
enlarged detail in Figure 3(b), is desirable to form a
sharp and uniform plastic radius parting line (edge) for
the subsequently molded soft contact lens. A generally
5 parallel convex surface 16 is spaced from the concave
surface 15, and an annular essentially uniplanar flange
18 is formed extending radially outwardly from the
surfaces 15 and 16 in a plane normal (perpendicular) to
the axis (of rotation) of the concave surface 15. The
10 concave surface 15 has the dimensions of the front curve
(power curve) of a contact lens to be produced by the
front mold half, and is sufficiently smooth such that
the surface of a contact lens formed by polymerization
of a polymerizable composition in contact with the
15 surface is of optically acceptable quality. The front
mold half is designed with a thinness (typically 0.8 mm)
and rigidity effective to transmit heat therethrough
rapidly and to withstand prying forces applied to
separate the mold half from the mold assembly during
20 demolding.

The front mold half or curve thickness was
reduced from 1.5 mm in prior designs to 0.8 mm. This
has a direct impact on cycle time reduction.

Figures 4 and 4(a) illustrate respectively top
25 elevational and side views of one embodiment of a
second, or back curve mold half 30. The back curve mold
half is designed with all of the same design
considerations mentioned hereinabove with respect to the
front curve mold half 10.

30 The back curve mold half 30 is formed of the
composition of the present invention (i.e., polystyrene
with additive or polypropylene with additive). The

1 composition of the present invention is preferably
transparent to visible or ultraviolet light. The back
curve mold half 30 defines a central curved section with
an optical quality convex surface 33, a generally
5 parallel concave surface 34 spaced from the convex
surface 33, and an annular essentially uniplanar flange
36 formed extending radially outwardly from the surfaces
33 and 34 in a plane normal to the axis (of rotation) of
concave surface 34. The convex surface 33 has the
10 dimensions of the rear curve (which rests upon the
cornea of the eye) of a contact lens to be produced by
the base mold half, and is sufficiently smooth such that
the surface of a contact lens formed by polymerization
of a polymerizable composition in contact with the
15 surface is of optically acceptable quality. The base
mold half is designed with a thinness (typically 0.6 mm)
to transmit heat therethrough rapidly and rigidity
effective to withstand prying forces applied to separate
the mold half from the mold assembly during demolding.
20 The mold halves 10,30 define generally triangular
tabs 26,37 integral with the flange which project from
one side of the flange. The tab 37 extends to the
injection hot tip which supplies molten thermoplastic to
the mold, and also defines therein an angled (e.g., 45°)
25 web sections 22,38 for smoothing the flow of the polymer
wave front and thus to avoid jetting, sink marks, weld
lines and other undesirable flows which would impair the
optical quality of the mold half. The mold halves 10,30
also define a small circular projections 25,35 which
30 serve as traps in the molding process to immobilize
small plugs of colder polymers that may form at the
injection hot tip between cycles.

1 The monomer and monomer mixtures to which this
process may be directed include copolymers based on 2-
hydroxyethylmethacrylate ("HEMA") and one or more
comonomers such as 2-hydroxyethyl acrylate, methyl
5 acrylate, methyl methacrylate, vinyl pyrrolidone, N-
vinyl acrylamide, hydroxypropyl methacrylate, isobutyl
methacrylate, styrene, ethoxyethyl methacrylate, methoxy
triethyleneglycol methacrylate, glycidyl methacrylate,
diacetone acrylamide, vinyl acetate, acrylamide,
10 hydroxytrimethylene acrylate, methoxyethyl methacrylate,
acrylic acid, methacryl acid, glyceryl methacrylate, and
dimethylamino ethyl acrylate.

 Preferred polymerizable compositions are
disclosed in U.S. Patent No. 4,495,313 to Larsen, U.S.
15 Patent No. 5,039,459 to Larsen et al. and U.S. Patent
No. 4,680,336 to Larsen et al., which include anhydrous
mixtures of a polymerizable hydrophilic hydroxy ester of
acrylic acid or methacrylic acid and a polyhydric
alcohol, and a water displaceable ester of boric acid
20 and a polyhydroxyl compound having preferably at least 3
hydroxyl groups. Polymerization of such compositions,
followed by displacement of the boric acid ester with
water, yields a hydrophilic contact lens. The mold
assembly of the present invention described herein may
25 be used to make hydrophobic or rigid contact lenses, but
the manufacture of hydrophilic lenses is preferred.

 The polymerizable compositions preferably contain
a small amount of a cross-linking agent, usually from
0.05 to 2% and most frequently from 0.05 to 1.0%, of a
30 diester or triester. Examples of representative cross
linking agents include: ethylene glycol diacrylate,
ethylene glycol dimethacrylate, 1,2-butylene

1 dimethacrylate, 1,3-butylene dimethacrylate, 1,4-
butylene dimethacrylate, propylene glycol diacrylate,
propylene glycol dimethacrylate, diethylglycol
dimethacrylate, dipropylene glycol dimethacrylate,
5 diethylene glycol diacrylate, dipropylene glycol
diacrylate, glycerine trimethacrylate, trimethylol
propane triacrylate, trimethylol propane
trimethacrylate, and the like. Typical cross-linking
agents usually, but not necessarily, have at least two
10 ethylenically unsaturated double bonds.

The polymerizable compositions generally also
include a catalyst, usually from about 0.05 to 1% of a
free radical catalyst. Typical examples of such
catalysts include lauroyl peroxide, benzoyl peroxide,
15 isopropyl percarbonate, azobisisobutyronitrile and known
redox systems such as the ammonium persulfate-sodium
metabisulfite combination and the like. Irradiation by
visible light, ultraviolet light, electron beam or a
radioactive source may also be employed to catalyze the
20 polymerization reaction, optionally with the addition of
a polymerization initiator. Representative initiators
include camphorquinone, ethyl-4-(N,N-dimethyl-
amino)benzoate, and 4-(2-hydroxyethoxy)phenyl-2-
hydroxyl-2-propyl ketone.

25 Polymerization of the monomer or monomer mixture
in the mold assembly is preferably carried out by
exposing the composition to polymerization initiating
conditions. The preferred technique is to include in
the composition, initiators which work upon exposure to
30 ultraviolet radiation; and exposing the composition to
ultraviolet radiation of an intensity and duration
effective to initiate polymerization and to allow it to

1 proceed. For this reason, the mold halves are
preferably transparent to ultraviolet radiation. After
the precure step, the monomer is again exposed to
ultraviolet radiation in a cure step in which the
5 polymerization is permitted to proceed to completion.
The required duration of the remainder of the reaction
can readily be ascertained experimentally for any
polymerizable composition.

As indicated at step 108 in Figure 1, the monomer
10 or monomer mixture is degassed prior to the filling of
the front curve mold half in order to remove dissolved
gases. O_2 is removed because of its deleterious effect
on polymerization as noted above. Other gases,
including N_2 , are removed to avoid the formation of gas
15 bubbles when the monomer is expelled from the relatively
high pressure of the pump line which supplies the fill
nozzle, to encounter the atmospheric or subatmospheric
 N_2 pressure of the filling and assembly chambers.

The contact lenses are made from the mold
20 assembly comprised of the present composition using
techniques known to one skilled in the art. The
following discussion is exemplary and is described in
more detail in a U.S. application assigned Serial No.
08/258,654 (Attorney Docket No. 9016) of Wallace Martin,
25 et al. for Consolidated Contact Lens Molding, the
contents of which are incorporated by reference. The
mold front curves and back curve molds described
hereinabove are prepared in accordance with the
description therein. An embodiment of the present
30 invention has both the front mold half and the back mold
half comprised of either the polystyrene/additive or the
polypropylene/additive formulations of the present

1 invention or a combination thereof. As described
hereinabove, the back curve is preferably comprised of
the polystyrene and additive, in accordance with the
present invention, while the front curve is preferably
5 made up of only the thermoplastic polymer, preferably
polystyrene or polypropylene. It is to be noted in a
preferred embodiment, that unlike the back curve mold,
the front curve mold does not contain any additive in
the thermoplastic polymer.

10 For efficiency, ease of operation and cycle
times, the front curve mold and back curve mold are made
using injection molding devices. It is preferred that
the thermoplastic material for the front lens and the
composition of the present invention for the back mold
15 is provided in the form of pellets or particles of
relatively high surface area which have equilibrated
fully with available oxygen available in the atmosphere.

Unlike prior practice as described in U.S. Patent
No. 4,565,348, the mold is designed to produce fully
20 formed lens mold parts directly, that is without
associated support structure such as a frame; there is
in consequence no need to dissociate the part from
unnneeded polymer material on demolding, and the lens
mold parts may be directly collected by automated
25 robotic means for delivery to the transport means. In
any given cycle, any number of mold parts may be
prepared but for convenience of handling, typically 8
lens mold parts of concave or convex configuration are
prepared in a given cycle and transferred by automated
30 robotic means to a pallet of aluminum or stainless steel
in which they are received and supported in a regular
spatial array adapted for further operations.

1 It should be understood that at most stages of
the continuous process, inspection means are operational
to effect rejection of parts against reference criteria;
hence, following injection molding, inspection,
5 generally visual, employing photoelectric means, for
example, for such defects as haze, mold defect as in
configuration due to improper material feed and the like
may lead to rejection of a part and thus disposal. To
maintain the continuity and consistency in line
10 operations generally a whole mold cycle or pallet of
lens mold parts will be expelled from the line following
discovery of a defect in any one lens mold part. Each
of the pallets contain a unique bar code number for use
in pallet tracking and quality control procedures
15 utilizing bar code scanners.

 The apparatus for removing and transporting lens
mold parts from the mold to the transport means includes
hand means for receiving the mold parts and a support
subassembly capable of sliding and pivotable movement
20 required for transfer of the mold parts to the
horizontally operating transport means.

 As illustrated in Figures 1 and 2 injection molds
#1 (101a) and #2 (102a), shown at steps 101 and 102 in
the flow diagram of Figure 1, mold respectively front
25 curve and back curve lens mold parts or sections; they
may be located in tandem as shown in Figure 2 or to
shorten exposure to the atmosphere still further, they
may be located in a common plane intersecting a
bifurcated transport line, even perpendicularly oriented
30 thereto in the same plane.

 Robotic means 103,104 are provided adjacent the
mold registry and engagement station for receiving

1 concave and convex lens molds respectively and
transferring said mold part to a low oxygen environment
at a high production cycle rate, as noted at step 105.

5 In the course of or following complete degassing
of the lens mold sections as indicated at 106 in Figure
1, the pallets containing concave and convex lens mold
sections are ordered into interleaved relation and
degassed on enclosed in feed conveyor such that
automated equipment may effect their operative
10 interengagement into molding relation.

The sequencing conveyor 32 including the
interleaving station 40 is enclosed and pressurized over
its entire length with an inert gas, conveniently
nitrogen. The amount of nitrogen is not critical, it
15 being suitable to use just enough nitrogen pressure to
effectively exclude the atmosphere under the operating
conditions experienced. In the nitrogen tunnel
surrounding sequencing conveyor 32 the freshly prepared
lens mold blanks are degassed as indicated at step 106
20 in Figure 1.

The concave lens molds are filled with the
reactive monomer composition at step 107 and the concave
and convex lens molds are placed into registry and urged
into complementary molding relation. The filling and
25 assembly zone 50 surrounds a portion of the conveying or
transport means 32, which delivers to the zone pallets
of concave and convex lens mold sections, respectively,
and at the terminus of the zone carries pallets of
paired and filled molds to the precure zone. The
30 filling and assembly zone illustrated in Figure 2 at 50
is defined by a geometrically appropriate, transparent
enclosure, generally of rectangular cross-section,

1 formed of any suitable thermoplastic or metal and
thermoplastic construction.

As illustrated at 107 in Figure 1, the concave
lens mold sections are filled with degassed monomer
5 composition from step 108, and then transported to an
assembly module having a vacuum chamber formed
intermittently within the nitrogen tunnel in which
filled concave lens molds are engaged with convex mold
sections in vertical alignment and in mating relation,
10 such that the reactive monomer composition is trapped
between the optical surfaces of the respective mold
sections and at least partially sealed by the engagement
of the parting edge formed peripherally in each of the
lens mold sections. The vacuum is released and the
15 mated mold is passed through nitrogen to the precure
station, an integral part of the nitrogen tunnel.

The vacuum chamber is formed upon and about a
single pallet by the periodic reciprocable motion of
apparatus also comprising means for alignment of the
20 seating of the convex mold sections upon the concave
mold sections so their axes of rotation are collinear
and their respective flanges are parallel. Upon sealing
engagement with the pallet the thus formed chamber is
evacuated in order to ensure that no gas bubbles are
25 entrapped between and upon the respective optical
molding surfaces. The degree of vacuum is selected for
the purpose of speeding the assembly of mold parts and
removing any gas bubbles at the monomer/mold interface
that might otherwise be entrapped in the course of
30 closure between the complementary mold sections.

Following assembly of the mold parts, the
incipient lens monomer is precured at step 109 in the

1 precure module 60 of the present invention. The process
of the precure involves clamping the mold halves in
registration and then precuring the monomer or monomer
mixture to a gel like state.

5 Following precure, the polymerization of the
monomer or monomer mixture is completed in curing tunnel
75 as indicated at step 110 with irradiation.

 In the cure zone (75), the monomer/diluent
mixture is then cured in a UV oven whereby
10 polymerization is completed in the monomer(s). This
irradiation with actinic visible or ultraviolet
radiation produces a polymer/solvent mixture in the
shape of the final desired hydrogel. In addition, the
cure zone also has a source of the polymerizable
15 composition to a temperature sufficient to assist the
propagation of the polymerization and to counteract the
tendency of the polymerizable composition to shrink
during the period that it is exposed to the ultraviolet
radiation.

20 After the polymerization process is completed,
the two halves of the mold are separated during a
demolding step of heating leaving the contact lens in
the first or front curve mold half 10, from which it is
subsequently removed. It should be mentioned that the
25 front and back curve mold halves are used for a single
molding and then discarded or disposed of.

 Heating the back curve lens mold creates
differential expansion of the heated mold polymer
relative to the cooler lens polymer which shifts one
30 surface with respect to the other. The resultant shear
force breaks the polymerized lens/polymer mold adhesion
and assists in the separation of mold portions. The

1 greater the temperature gradient between the surfaces of
the mold portions, the greater the shearing force and
the easier the mold portions separate. This effect is
greatest when there is maximum thermal gradient. As
5 time continues, heat is lost through conduction from the
back mold portion into the lens polymer and the front
mold portion, and then collectively into the surrounding
environment. The heated back mold portion is,
therefore, promptly removed so that very little energy
10 is transferred to the polymer lens, avoiding the
possibility of thermal decomposition of the lens. The
heating may be accomplished by techniques known to one
skilled in the art such as by steam, hot air, laser,
infrared and the like. The process of laser demolding
15 is described in U.S. Patent No. 5,294,379 to Ross et al,
the contents of which are incorporated by reference.

If the heating step is hot air or steam, after
the heating step, the back curve is pryed from the front
curve and mold in the mold assembly, as indicated at
20 Step 111. If on the other hand, the heating is by laser
or infrared, no prying is used and the back curve
separates spontaneously from the front curve.

The demolding assemblies of the mold separation
apparatus 90 each physically pry the back curve mold
25 half 30 from the front curve half 10 of each contact
lens mold to physically expose each contact lens
situated in the lens mold for conveyance to a hydration
station for hydration of the lenses. The prying process
occurs under carefully controlled conditions, so that
30 the back curve half 30 will be separated from the front
curve half 10 without destroying the integrity of the
lens formed in the lens mold.

1 After the mold assemblies have been separated in
the demold apparatus 90, each pallet containing the
front curve mold halves with an exposed polymerized
contact lens therein, is subsequently transported to a
5 hydration station for hydration and demolding from the
front curve lens mold, inspection and packaging, as
indicated at Step 112.

 In the processes described hereinabove, when the
base mold does not contain the additive therein, there
10 were many occasions when the lenses that were formed
were unusable because they contained defects, such as
chips or edge tears or holes, i.e., voids in the center
of the cast lenses. These defects were caused during
the demolding process and were noticed when the base
15 curve was separated from the front curve using the
prying mechanisms described hereinabove. However, when
the additive is present in the back curve, demolding is
facilitated and the back curve is more easily removed.
As a result, there are greatly reduced instances of lens
20 damage during the demolding step, in which the back
curve is separated from the front curve and the lens,
which stays in the front curve. Without wishing to be
bound, it is believed that the additive in the back
curve modifies the adhesion force between the lens and
25 the base curve. For example, when polystyrene alone is
used, it adheres very strongly to the polymeric material
of the lens; however, when the additive is added to the
polystyrene, the presence of the additive weakens the
friction forces between the polystyrene and the lens
30 material, making it easier to separate the back curve
from the lens and the front curve mold. Thus, there is
less stress on the lens surface during demolding, making

1 it easier to separate. Thus in a prying action between
the lens mold halves, as occurs during demolding, the
lens will slip more easily from the convex mold half.
Consequently, when the back curve is made up of the
5 formulation of the present invention, separating the
back curve from the front curve and the lens has become
facile. Consequently, less stringent conditions are
required for demolding than that used heretofore. In
fact, in certain embodiments such as with ABIL WAX 9801,
10 demolding occurs without the temperature gradient thus
eliminating the necessity of heat in the demolding step.
Thus, using the compositions of the present invention to
separate the back curve from the mold assembly, lenses
can be demolded in good yields right after the demold
15 tunnel at lower temperature, such as about 60 to 70°C.
For example, the coating of polystyrene with a 4% level
of ABIL Wax 9801, lower temperatures, such as 60°-75°C,
are used to demold the lenses in good yields.

However, the additive also serves a dual purpose,
20 it reduces the number of lenses that are produced having
holes in the lens. Without wishing to be bound, it is
believed that the additive is also acting as a
surfactant or wetting agent. In its absence, there may
be localized areas at the interface between the mold
25 surface and the polymerized monomer where the surface
tension therebetween may become so great that as a
result, a space would develop in the contact lens
between the polymerized mass and the mold surface.
These spaces allow air to be trapped between the back
30 curve and the monomer, resulting in an air bubble which
formed holes in the resulting contact lens upon curing.
However, the addition of the additive changes the

1 surface chemistry by improving the wetting of the
surface and reducing the surface tension sufficient to
allow intimate contact between the mold half and the
polymerized monomer. The improved wetting is readily
5 achieved by increasing the surface energy of the convex
mold half through modification of the base resin through
additive inclusion. No spaces are formed and after
curing, the lens do not develop any holes. The improved
wetting of the convex mold half by the lens material
10 greatly reduces holes.

Thus, the additive in the polystyrene forms two
functions, it acts as a surfactant and simultaneously
decreases the adhesion forces between the back curve
mold and the polymerized monomer and the front curve

15 Unless indicated to the contrary, the molecular
weights are in units of grams per mole. Moreover,
unless indicated to the contrary, the percentages are
given in weight percentages.

The present invention is more specifically
20 described by the following illustrative examples.
However, it is to be understood that these examples are
only described to illustrate the invention, but not to
limit the scope of the present invention.

25

30

35

1

EXAMPLE 1

5

Various soft contact lenses were prepared in accordance with the above procedures utilizing a back mold half made of either polystyrene or polystyrene and additive as described hereinabove. After the mold halves were pryed apart, the percentage of holes in the contact lens produced by that mold was determined. The results are tabulated hereinbelow.

10	Type of Material	% of Holes
	1. Polystyrene	5.4
	2. Polystyrene	3.8
	3. Polystyrene	1.8
15	4. Polystyrene	3.2
	5. Polystyrene + 1% Abilwax 9801	0.1
	6. Polystyrene + 1/2% SF1080	0.5
20	7. Polystyrene + 3% Axelwax 33 RD	0.9
	8. Polystyrene + 1% FC430	1.2
25	9. Polystyrene + 2.0% Axelwax 38H	0.4

30

As readily shown, there were significantly less holes in the contact lens when the back mold contained an internal additive.

35

1

EXAMPLE 2

5 Frames were molded on a 60 -ton Nestal from the
candidate formulations listed hereinbelow in Table 2, in
accordance with the procedure described herein. As
described herein, and shown in Figure 5, the pallet
contained 8 base mold halves (cavities) arranged as
depicted therein. The mold halves were comprised of the
various formulations described hereinbelow and contact
10 lens were prepared in accordance with the procedure
described herein.

The frame parameters are presented in the
following Table.

15

20

25

30

35

1

TABLE 1

5

FRAME ANALYSIS

10

HUNTSMAN 202
(Polystyrene)
FRAME #1 RADIUS
P/V

C-1	C-3	C-6	C-8
8.447	8.447	8.461	8.444
0.857	4.576	4.368	1.898

FRAME #2 RADIUS
P/V

8.448	8.457	8.417	8.419
0.891	3.742	4.511	0.986

FRAME #3 RADIUS
P/V

8.449	8.461	8.448	8.402
0.958	4.250	2.581	8.843

15

HUNTSMAN 202/PVDF (Polystyrene)

FRAME #1 RADIUS
P/V

8.872	8.881	8.879	8.875
0.653	0.557	0.595	0.653

FRAME #2 RADIUS
P/V

8.879	8.888	8.887	8.877
0.821	0.631	0.549	0.552

FRAME #3 RADIUS
P/V

8.859	8.816	8.879	8.872
0.545	2.796	1.323	2.297

20

HUNTSMAN 202/0.2225% SF1080 (Silicone Oil)

FRAME #1 RADIUS
P/V

7.855	7.861	7.871	7.858
0.561	0.677	0.396	0.859

FRAME #2 RADIUS
P/V

7.857	7.862	7.869	7.854
0.836	0.450	0.578	0.695

FRAME #3 RADIUS
P/V

7.855	7.861	7.870	7.858
0.579	0.724	0.214	0.900

25

30

35

1

TABLE 1 (CONT.)

FINAL ANALYSIS

5

HUNTSMAN 202/0.5% SF1080 (Silicone Oil)

		C-1	C-3	C-6	C-8
FRAME #1	RADIUS	7.858	7.857	7.865	7.853
	P/V	0.526	0.557	0.412	0.560
FRAME #2	RADIUS	7.856	7.859	7.867	7.854
	P/V	0.621	0.428	0.335	0.449
FRAME #3	RADIUS	7.856	7.862	7.867	7.854
	P/V	0.539	0.552	0.388	0.554

10

LEGEND:

15

C-1 cavity ONE of the pallet

C-3 cavity THREE of the pallet

C-6 cavity SIX of the pallet

C-8 cavity EIGHT of the pallet

P/V peak to valley roughness, an interferometric measurement

20

PVDF polyvinylidene fluoride

In Table 1, P/V is a roughness measurement, wherein a lower number is a better result. The C-legend refers to the cavity in a frame so that the data as presented eliminates cavity variations.

25

As can readily be seen from the data in Table 1, in all cases, when the additive, such as SF 1080 was present in the mold, the P/V value were significantly lower than in its absence. Thus, the data clearly show that the frames using a mold containing the additive produced smoother lenses.

30

35

1

EXAMPLE 3

5

Frames manufactured from sample candidate formulations plus a control, indicated in the key to Table 2, were prepared on the Acuvue Pilot lens to manufacture lenses in accordance with the procedure described in the present specification. The summaries are presented in Table 2.

10

15

20

25

30

35

TABLE 2

SET #	% of Edge Defects		TOTAL CHIPS AND TEARS
	CHIP	TEAR	
I	44.50	1.90	46.40
II	20.40	1.10	21.50
III	17.40	2.20	19.60
IV	13.80	0.00	13.80
V	14.10	2.20	16.30
VI	11.50	6.30	17.80
VII	22.50	15.00	37.50
VIII	32.50	5.00	37.50
IX	5.00	15.00	20.00
X	10.00	10.00	20.00
XI	21.60	5.40	27.00
XII	27.50	10.00	37.50

TABLE 2 (CONT.)

KEY	
I	HUNTSMAN 202 ps
II	0.5% GE SF1080
III	0.25% GE SF1080
IV	1.0% ABILWAX 9801
V	4.0% ABILWAX 9801
VI	0.25% 3M FC430
VII	2.5% AXEL 33
VIII	0.25% AXEL 33
IX	2.5% AXEL 33
X	0.25% AXEL 38
XI	1.50% KANTSTIK Q
XII	0.25% KANTSTIK Q

As can be readily seen by the data in Table 2, the total amount of edge defects (chips and tears) is the lower in all cases and significantly lower in many cases when the additive is present.

1

EXAMPLE 4

5

In this set of experiments, a study was conducted to evaluate the demolding of different compounds plus a standard polystyrene as base curves.

10

15

The lenses (14.0 Acuvue formulation) were processed on the WK Maximize lab line in accordance with the procedure described herein using vacuum deposition and 30 sec UV pre-cure under weight. They had additional four minutes of UV cure without weight at 60° in the simulated tunnel. The frames were kept thermostated in an oven with hot air circulation $\pm 1.5^{\circ}\text{C}$ prior to demold, transferred to an aluminum pallet kept at the same temperature and demolded immediately after the WK lab demolder mark 1 which simulates the movement of the mark 1 demolder at present installed in the Maximize pilot line at Vistakon.

20

No steam was applied.

Movement:	3.5 deg	0.5 sec	fast
	6.0 deg	3.0 sec	slow
	15 deg	4.4 sec	slow
			(end fast)

25

One side was pryed apart. The frames were inspected in a stereomicroscope at 10 x immediately after demold. Broken BC flanges, lens lift, missing lenses and tears were recorded. Results from this demold inspection are shown in Table 3.

30

All lenses, except those with broken flanges, were hydrated in simulated Maximize process: 5 mins at 70°C, 0.05% Tween 80 in DI-water, followed by 3 mins in DI-water + storage overnight in buffered saline.

35

1 The lenses were inspected for visual defects in a
DL2 using the Vistakon pilot line standards. The
conditions are indicated in Table 3.

5 TABLE 3

MATERIAL	% CH + TR ⁺	% HO
Polystyrene	20	3
Polystyrene/GE 1080 0.5%	20	3
Polystyrene/ABILWAX 9801, 1% ⁺⁺	8	2
Polystyrene/ABILWAX 9801, 4%	10	2

* Avg. valve of 3 runs
** only 1 run was performed

15 **Key**
 CH = Chips
 HO = Holes
 TR = Tears

As clearly shown by the data, a preferred embodiment in this run is the mold of polystyrene with ABILWAX, i.e., silicone wax which produced contact lenses having significantly less chips and tears therein than when the lenses were comprised of polystyrene alone.

25 The above preferred embodiments and examples are given to illustrate the scope and spirit of the present invention. The embodiments and examples described herein will make apparent to those skilled in the art other embodiments and examples. These other embodiments and examples are within the contemplation of the present invention. Therefore, the present invention should be limited only by the appended claims.

35



1 WHAT IS CLAIMED IS:

1. A mold material constituting a mold half for
use in the production of contact lenses, said mold
5 material comprising a thermoplastic polymer and an
internal additive which is impregnated into said
thermoplastic material and which is present in amounts
ranging from about 0.1% to about 20% by weight, said
thermoplastic material being polystyrene or
10 polypropylene and said additive being a polyethylene or
polypropylene wax having a molecular weight ranging from
about 5000 to about 200,000, stearate salt, a glycerol
ester having a molecular weight of about 200-2000, an
amide wax of the formula $R_1\text{CONH}_2$, wherein R_1 is a
15 hydrocarbyl group, and the amide wax has a molecular
weight of about 200-2000, silicone having a molecular
weight ranging from about 2000 to about 100,000, Montan
wax, oxidized wax, fatty acid having a molecular weight
of about 200 to about 2000, a complex ester or a
20 combination thereof.

2. The mold material of Claim 1 in which the
amide wax is a fatty acid amide wax.

3. The mold material of Claim 1 wherein the
thermoplastic polymer is polystyrene.

25 4. The mold material of Claim 1 wherein the
thermoplastic polymer is polypropylene.

5. The mold material of Claim 1 wherein the
additive is present in amounts ranging from 0.1 to 5% by
weight.

30 6. The mold material of Claim 5 wherein the
additive is present in amounts ranging from 0.1 to 2% by
weight.

35





-42-

1 7. The mold material of Claim 1 wherein the additive is stearate salt or silicone.

5 8. A mold half useful in the production of a contact lens by the polymerization of a polymerizable composition in a mold assembly comprised of said mold half and a second mold half, said mold half comprising an integral article having a central curved section defining a concave surface, a convex surface and a circumferential edge, at least the central portion of at least one of said concave surface and said convex surface having the dimensions of the back curve of the desired swelled or unswelled contact lens to be produced in said mold assembly and being sufficiently smooth and contoured so that the surface of said contact lens formed by polymerization of said polymerizable composition in contact with said surface is optically acceptable, said article having an annular flange integral width and surrounding said circular circumferential edge and extending therefrom in a plane normal to the axis of said concave surface, said article also having a generally triangular tab situated in a plane normal to said axis and extending from said flange, said article having a thinness and rigidity effective to transmit heat therethrough and to withstand prying forces applied to separate said mold half from said mold assembly, and said article being comprised of a composition comprising a thermoplastic polymer and an internal additive which is impregnated into said thermoplastic material and which is present in amounts ranging from about 0.1% to about 20% by weight, said thermoplastic material being polystyrene or polypropylene and said additive being a polyethylene or

35





-43-

1 polypropylene wax having a molecular weight ranging from
about 5000 to about 200,000, stearate salt, a glycerol
ester having a molecular weight of about 200-2000, an
amide wax of the formula $R_1\text{CONH}_2$, wherein R_1 is a
5 hydrocarbyl group, and the amide wax has a molecular
weight of about 200-2000, silicone having a molecular
weight ranging from about 2000 to about 100,000, Montan
wax, oxidized wax, fatty acid having a molecular weight
of about 200 to about 2,000, a complex ester or a
10 combination thereof.

9. The mold half of Claim 8 wherein the amide
wax is a fatty acid amide wax.

10. The mold half of Claim 8 wherein the
thermoplastic polymer is polystyrene.

15 11. The mold half of Claim 8 wherein the
thermoplastic polymer is polypropylene.

12. The mold half of Claim 8 wherein the
additive is present in amounts ranging from 0.1 to 5% by
weight.

20 13. The mold material of Claim 12 wherein the
additive is present in amounts ranging from 0.1 to 2% by
weight.

14. The mold half of Claim 8 wherein the
additive is stearate salt or silicone.

25 15. A mold assembly used in the production of a
contact lens by the polymerization of a polymerizable
composition in said mold assembly, said mold assembly
comprising a front mold half and a back mold half in
contact therewith thereby defining and enclosing a
30 cavity therebetween, and a polymerizable composition in
said cavity in contact with both mold halves, wherein

35



* C L M S *



1 said front mold half comprises a first article of
thermoplastic polymer transparent to ultraviolet light,
said article having a central curved section with a
5 circumferential edge, wherein the portion of said
concave surface in contact with said polymerizable
composition has the curvature of the front curve of a
contact lens to be produced in said mold assembly, and
is sufficiently smooth so that the surface of a contact
10 lens formed by polymerization of said polymerizable
composition in contact with said surface is optically
acceptable;

 said first article having an annular flange
integral with and surrounding said circular
15 circumferential edge and extending therefrom in a plane
normal to the axis of said concave surface, and
generally triangular tab situated in a plane normal to
said axis and extending from said flange;

 said back mold comprised of an integral article
20 having a central curved section with a concave surface,
a convex surface and a circular circumferential edge,
wherein the portion of said convex surface in contact
with said polymerizable composition has the curvature of
the back curve of a contact lens to be produced in said
25 mold assembly and is sufficiently smooth that the
surface of a contact lens formed by polymerization of
said polymerization composition in contact with said
surface is optically acceptable;

 said second article having an annular flange
30 integral with and surrounding said circular
circumferential edge with and surrounding said circular
circumferential edge and extending therefrom in a plane

35





- 1 normal to the axis of said convex surface, and a
generally triangular tab situated in a plane normal to
said axis and extending from said flange wherein the
convex surface of said back mold half contacts the
5 circumferential edge of said front mold half;

said back mold being comprised of a composition
comprising a thermoplastic polymer and an internal
additive which is impregnated into said thermoplastic
material and which is present in amounts ranging from
10 about 0.1% to about 20% by weight, said thermoplastic
material being polystyrene or polypropylene, and said
additive being a polyethylene or polypropylene wax
having a molecular weight ranging from about 5000 to
about 200,000, stearate salt, a glycerol ester having a
15 molecular weight of about 200-2000, an amide wax of the
formula $R_1\text{CONH}_2$, wherein R_1 is a hydrocarbyl group, and
the amide wax has a molecular weight of about 200-2000,
silicone having a molecular weight ranging from about
2000 to about 100,000, Montan wax, oxidized wax, fatty
20 acid having a molecular weight of about 200 to about
2000, a complex ester or a combination thereof.

16. The mold assembly of Claim 15 in which the
amide wax is a fatty acid amide wax.

17. The mold assembly of Claim 15 wherein the
25 thermoplastic polymer is polystyrene.

18. The mold assembly of Claim 15 wherein the
thermoplastic polymer is polypropylene.

19. The mold assembly of Claim 15 wherein the
additive is present in amounts ranging from 0.1 to 5% by
30 weight.





1 20. The mold assembly of Claim 19 wherein the
additive is present in amounts ranging from 0.1 to 2% by
weight.

5 21. The mold assembly of Claim 15 wherein the
additive is stearate salt or silicone.

22. In an improved process for forming a contact
lens from a mold assembly comprising a front mold half
and a back mold half in contact therewith thereby
defining and enclosing a cavity therebetween, and
10 containing in said cavity a polymerizable composition in
contact with said mold halves;

said front mold half comprising a first article
of thermoplastic polymer transparent to ultraviolet
light, said article having a central curved section with
15 a concave surface, a convex surface and a circular
circumferential edge, wherein the portion of said
concave surface in contact with said polymerizable
composition has the curvature of the front curve of a
contact lens to be produced in said mold assembly and is
20 sufficiently smooth so that the surface of a contact
lens formed by polymerization of said polymerizable
composition in contact with said surface is optically
acceptable;

said back mold half comprising a second article
25 of thermoplastic polymer transparent to ultraviolet
light, said article having a central curved section with
a concave surface, a convex surface and a circular
circumferential edge, wherein the portion of said convex
surface in contact with said polymerizable composition
30 has the curvature of the back curve of a contact lens to
be produced in said mold assembly and is sufficiently
smooth so that the surface of a contact lens formed by

35





1 polymerization of said polymerizable composition in
contact with said surface is optically acceptable,
wherein the convex surface of said back mold contacts
the circumferential edge of said front mold half;

5 and the front mold half is clamped against the
back mold half;

and the polymerizable composition undergoes
polymerization under precuring and curing conditions
with ultraviolet light and the back curve is separated
10 from the front curve and the contact lens during a
demolding process and the front curve is subsequently
separated from the contact lens, the improvement
comprising utilizing a back curve mold that is comprised
of a composition comprising a thermoplastic polymer and
15 an internal additive which is impregnated into said
thermoplastic material and which is present in amounts
ranging from about 0.1% to about 20% by weight, said
thermoplastic material being polystyrene or
polypropylene, and said additive being a polyethylene or
20 polypropylene wax having a molecular weight ranging from
about 5000 to about 200,000, stearate salt, a glycerol
ester having a molecular weight of about 200-2000, an
amide wax of the formula $R_1\text{CONH}_2$, wherein R_1 is a
hydrocarbyl group, and the amide wax has a molecular
25 weight of about 200-2000, silicone having a molecular
weight ranging from about 2000 to about 100,000, Montan
wax, oxidized wax, fatty acid having a molecular weight
of about 200 to about 2000, a complex ester or a
combination thereof.

30 23. The process of Claim 22 in which the amide
wax is a fatty acid amide wax.

35



1 24. The process of Claim 22 wherein the
thermoplastic polymer is polystyrene.

 25. The process of Claim 22 wherein the
thermoplastic polymer is polypropylene.

5 26. The process of Claim 22 wherein the additive
is present in amounts ranging from 0.1 to 5% by weight.

 27. The process of Claim 26 wherein the additive
is present in amounts ranging from 0.1 to 2% by weight.

10 28. The process of Claim 22 wherein the additive
is stearate salt or silicone.

15

This Sheet Has Been Replaced



20

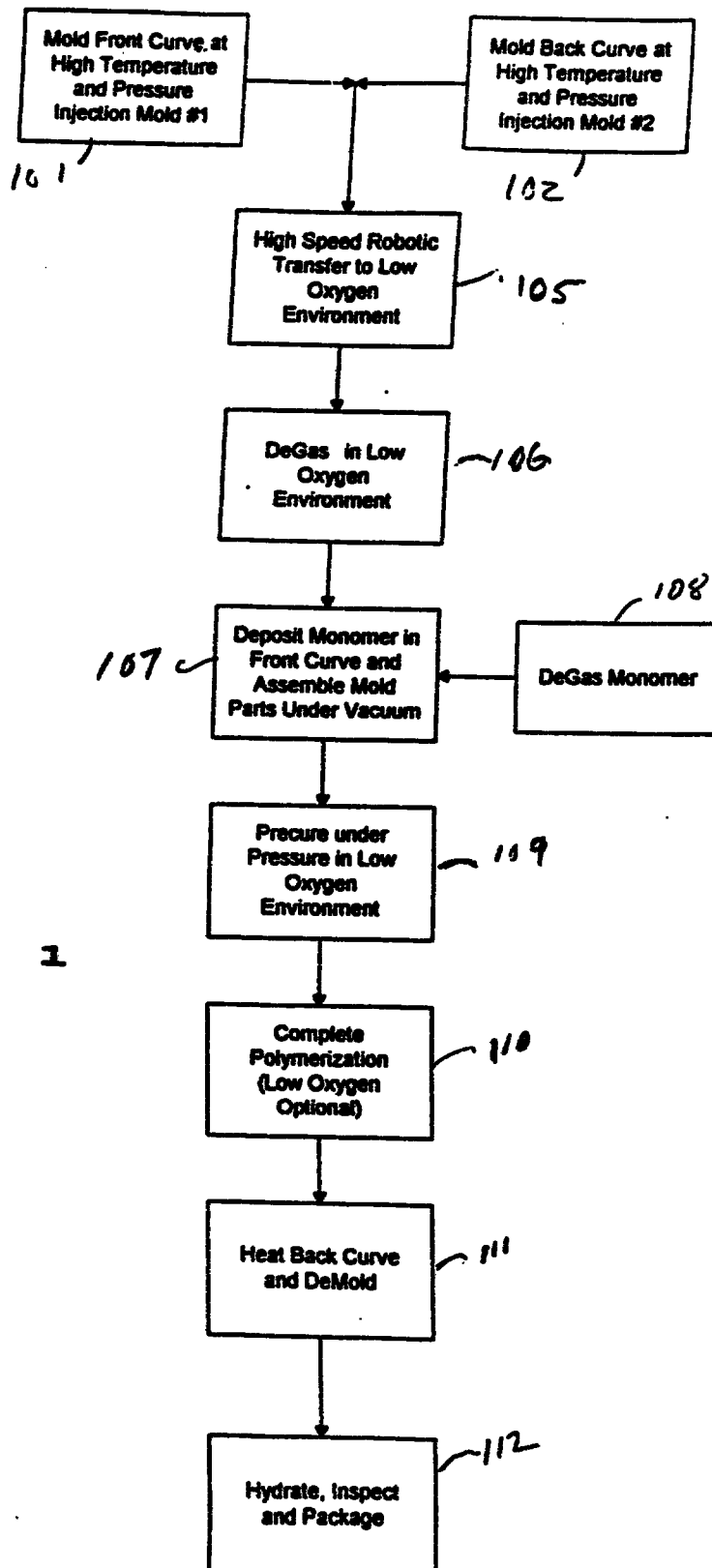
25

30

35



* C L M S *

**FIG. 1**

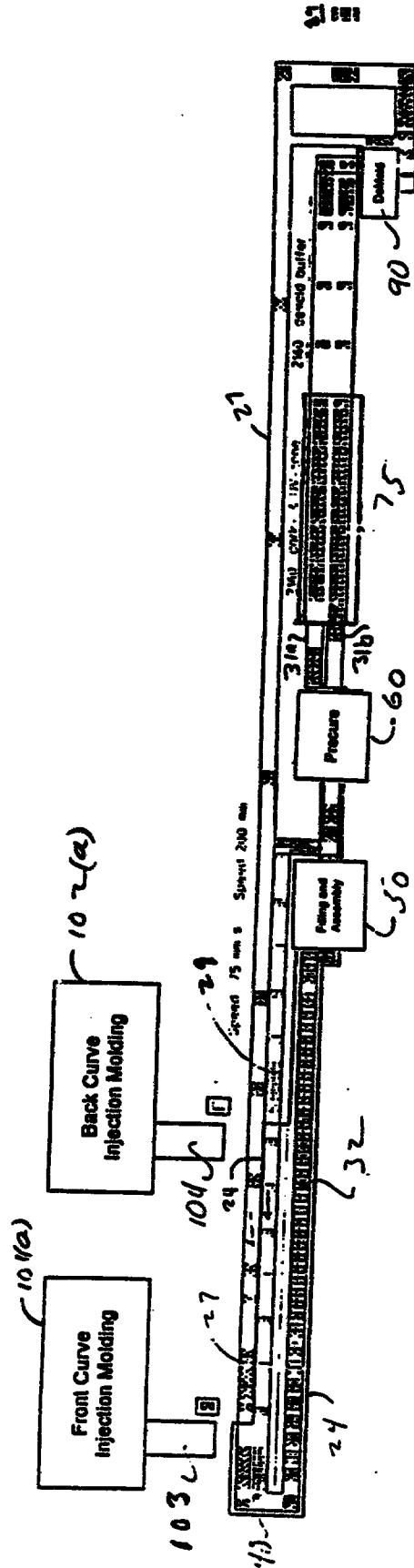
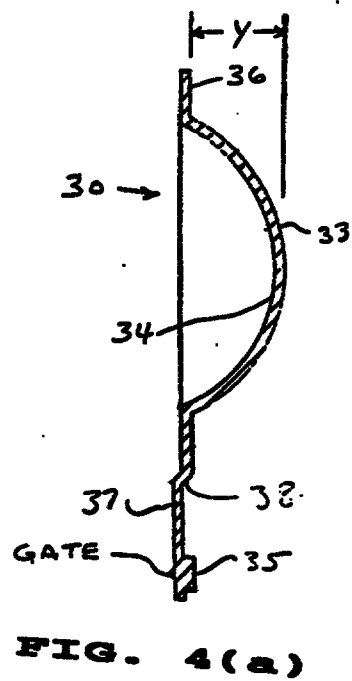
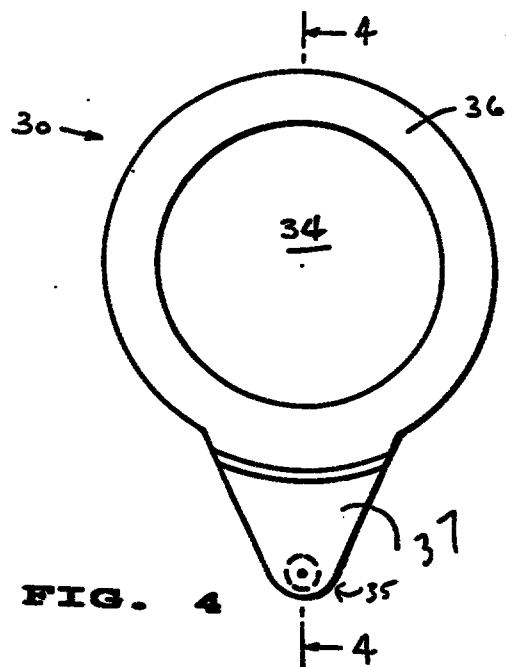
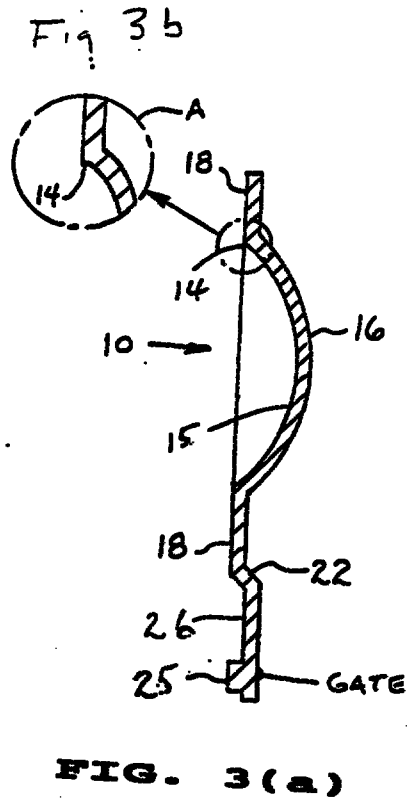
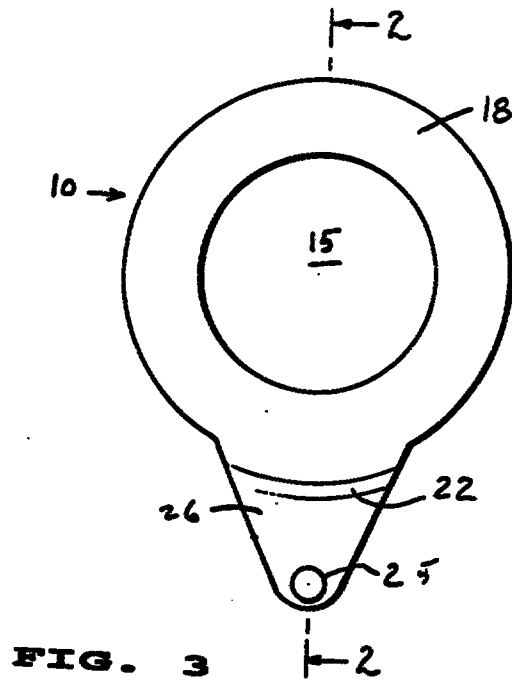
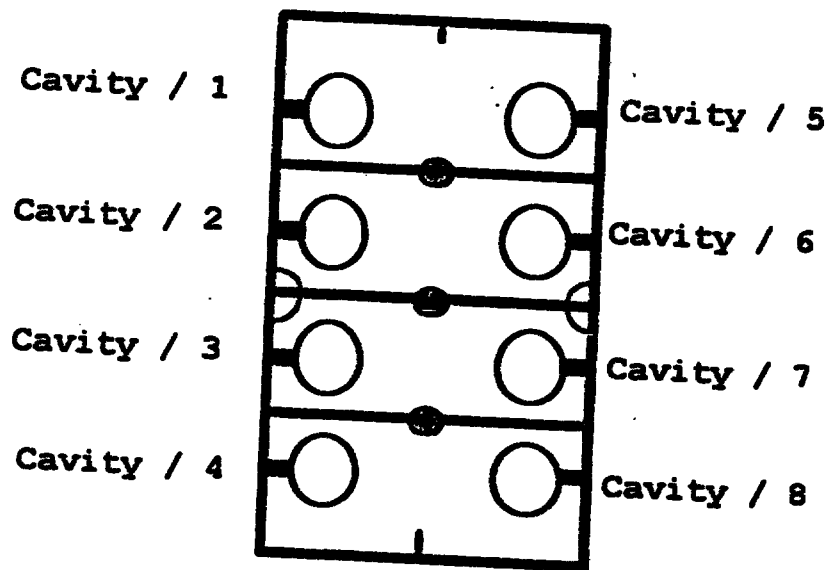


FIG. 2



This Sheet Has Been Replaced





Base Curve Frame

FIG. 5

MOLD MATERIAL WITH ADDITIVES

1

ABSTRACT

5 The present invention is directed to a
composition comprising polystyrene with at least 0.1%
10 (w/w) of an additive, the article of manufacture
comprised thereof, such as a mold for making contact
lenses and the mold assembly containing said mold, and
the use of such mold so to facilitate demolding from a
two mold assembly in the process of making contact lens.

10

15

20

25

This Sheet Has Been Replaced



30

35

MOLD MATERIAL WITH ADDITIVES

ABSTRACT

The present invention is directed to a composition comprising polystyrene with at least 0.1% (w/w) of an additive, the article of manufacture comprised thereof, such as a mold for making contact lenses and the mold assembly containing said mold, and the use of such mold so to facilitate demolding from a two mold assembly in the process of making contact lens.

Fig. 1

THIS SHEET HAS BEEN
REPLACED

REPLACEMENT SHEETS		SG
1. Introduction	pages 1 to page 1	
2. Summary	pages 1 to page 1	
✓ 3. Drawing(s)	pages 3/4 to page 1	
✓ 4. Abstract	pages 1/2 to page 1	
5. Comments		15/11/96

This Sheet Has Been Replaced



This is the replacement sheet

Date: 15 NOV 1996

2-2272000

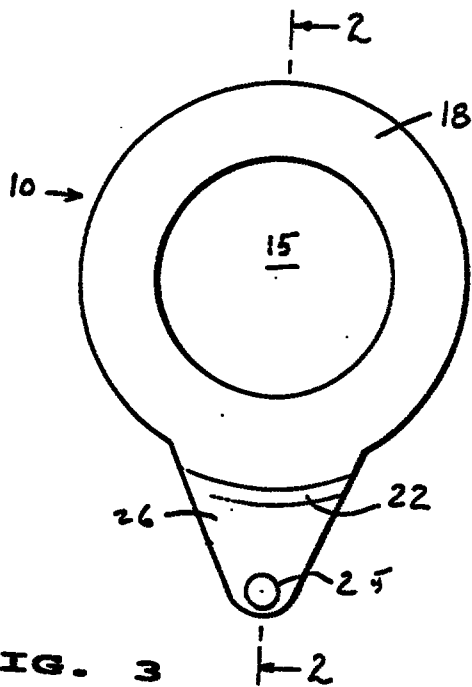


FIG. 3

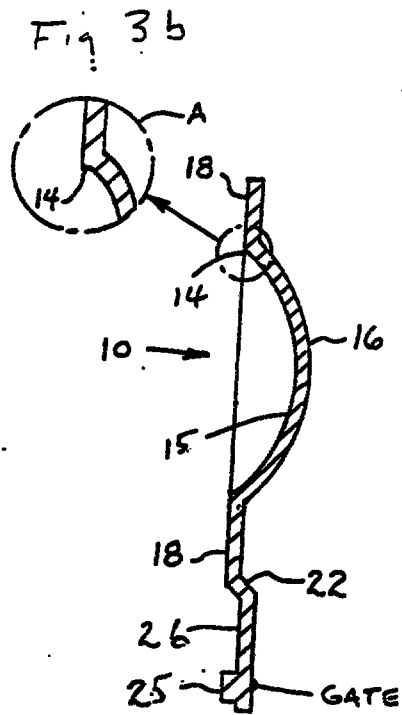


FIG. 3 a

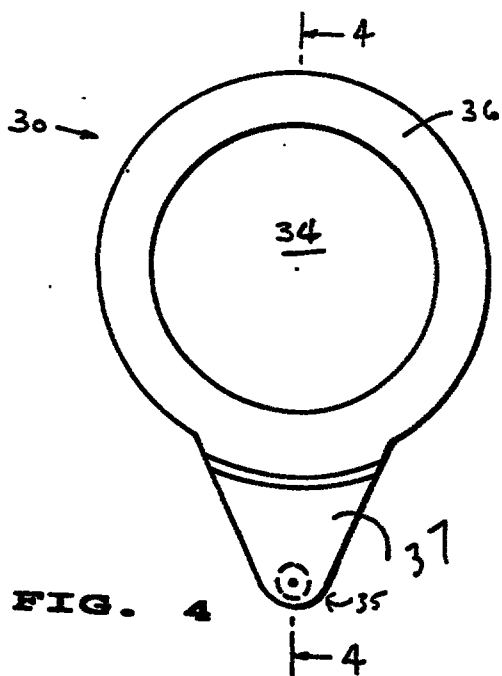


FIG. 4

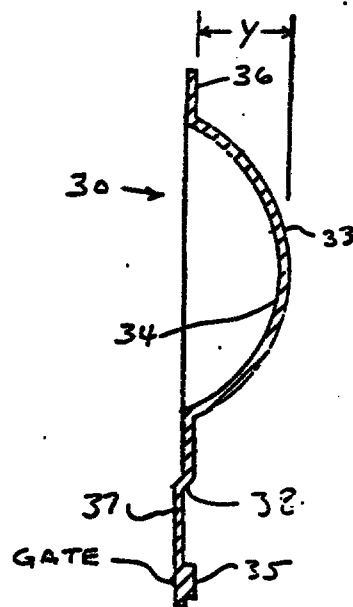


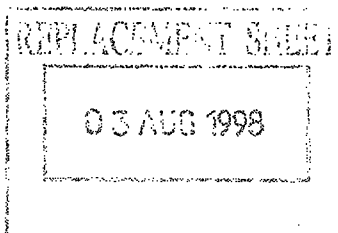
FIG. 4 a

This is the replacement sheet

Date: 15 NOV 1996

Box III TEXT OF THE ABSTRACT (Continuation of item 5 of the first sheet)

The present invention is directed to a mould material constituting a mould half for use in the production of contact lenses, said mould material comprising a thermoplastic polymer and an internal additive which is impregnated into said thermoplastic material and which is present in amounts ranging from about 0.1% to about 20% by weight, said thermoplastic material being polystyrene or polypropylene and said additive being a polyethylene or polypropylene wax having a molecular weight ranging from about 5000 to about 200000, stearate salt, a glycerol ester having a molecular weight of about 200-2000, an amide wax of the formula R_1CONH_2 , wherein R_1 is a hydrocarbyl group, and the amide wax has a molecular weight of about 200-2000, silicone having a molecular weight ranging from about 2000 to about 100000, Montan wax, oxidized wax, fatty acid having a molecular weight of about 200 to about 2000, a complex ester or a combination thereof.



-5-

hydrocarbyl carboxylic acid amide having a molecular weight of 200-2,000, a glycerol ester having a molecular weight of 200-2,000, salts of stearic acid, silicones having a molecular weight of 2,000 to 100,000, Montan wax, complex ester, oxidized waxes, or combinations thereof.

This formation is admixed with and impregnated with at least 0.1% of an internal additive (w/w). When this material was used to make one of the mold halves in the mold assembly for making the contact lenses, it was found that fewer lenses were formed having the defects described hereinabove. Thus, an aspect of the present invention is directed to the mold half comprised of this new formulation. This mold half is part of the mold assembly, and therefore another aspect of the present invention is directed to the mold assembly comprising said mold half comprised of the formulation of the present invention.

The mold assembly comprises at least two pieces, a female concave piece (front piece) and a male convex piece (back piece), forming a cavity therebetween, and when said pieces are mated, at least one piece having a flange thereabout. More particularly the mold assembly comprises a front mold half and a back mold half in contact therewith, thereby defining and enclosing a cavity therebetween, and a polymerizable composition in said cavity in contact with said mold halves, the front mold of which has a central curved section with a concave surface, a convex surface and a circular circumferential edge, wherein the portion of said concave surface in contact with said polymerizable composition has the curvature of the front curve of a

REPLACED SHEETS		SG
☐	Description : paged	to paged
☒	Claim(s) : paged	to paged
☐	Drawing(s) : paged	to paged
☐	Abstract : paged	to paged
DATE OF RECEIPT		

REPLACEMENT SHEETS		SG
☒	Description : paged 513 to paged 517	
☒	Abstract(s) : paged 41 to paged 41	
☐	Drawing(s) : paged to paged	
☐	Abstract : paged to paged	
DATE OF RECEIPT 23/2/99		

weight. As described hereinbelow, the additive is thoroughly mixed with the thermoplastic material so as to form a matrix. In other words, these are internal stet additives and do not coat the thermoplastic material. As such, the additive is relatively uniformly distributed in the thermoplastic material.

Theoretically there is no upper limit to the amount of additives added to the mold half, as long as one of the mold halves maintains its transmission to UV light. Typically, as a practical matter, additives up to about 20% are useable. In a preferred embodiment, the additive should be present in amounts ranging from about 0.1% to about 5% by weight and more preferably from about 0.1% to about 2% by weight.

The additive is basically an oil, soap, wax, i.e., a mold release agent and/or surfactant. It is preferably a silicone oil, stearates, e.g., zinc stearates, or wax, but is not limited thereto. The preferred additives are SF 1080 Silicone Oil, Int 38H Ester Complex, Kantstik Q Ester Complex, FC 430 Ester Complex, ABIL® Wax 9801, Silicone Wax (stearyl dimethicone), SF 96-5 Silicone Oil, L-42, Calcium Stearate, Sodium Stearate, Acrawax® C (1,2 ethanediylbis-octadecanamide), FC 4331 Ester Complex, SF 18-350 Silicone Oil, L-45 (dimethyl silicone), Zinc stearate, ABIL® wax 9801 (cetyl dimethicone), VSC-10M, Carnauba Wax and Ross Wax 100. The more preferred additives are SF 1080 Silicone Oil, Int. 38H Ester Complex, Kantstick Q Ester Complex, FC 430 Ester Complex and Abilwax 9801 Silicone Oil. The most preferred additives are SF 1080 and Abilwax 9801.

This is the replacement sheet

Date: 23 FEB 1999

**WHAT IS CLAIMED IS:**

1. A mold material constituting a mold half for use in the production of contact lenses, said mold material comprising a thermoplastic polymer and an internal additive which is impregnated into said thermoplastic material by compounding, said internal additive present in amounts ranging from about 0.1 % to about 20 % by weight, said thermoplastic material being polystyrene or polypropylene and said additive being a mold release agent or surfactant that is a polyethylene or polypropylene wax having a molecular weight ranging from about 5000 to about 200,000, stearate salt, a glycerol ester having molecular weight of about 200- 2000, an amide wax of the formula R_1CONH_2 , wherein R_1 is a hydrocarbonyl group, and the amide wax has a molecular weight of about 200-2000, silicone having a molecular weight ranging from about 2000 to about 100,000, Montan wax, oxidized wax, $C_5 - C_{26}$ fatty acid having a molecular weight of about 200 to about 2000, a complex ester or a combination thereof.
2. The mold material of Claim 1 in which the amide wax is a fatty acid amide wax.
3. The mold material of Claim 1 wherein the thermoplastic polymer is polystyrene.
4. The mold material of Claim 1 wherein the thermoplastic polymer is polypropylene.
5. The mold material of Claim 1 wherein the additive is present in amounts ranging from 0.1 to 5% by weight.
6. The mold material of Claim 5 wherein the additive is present in amounts ranging from 0.1 to 2% by weight.
7. The mold material of Claim 1 wherein the additive is stearate salt or silicone.



This is the replacement sheet

Date: 23 FEB 1999



8. A mold half useful in the production of a contact lens by the polymerization of a polymerizable composition in a mold assembly comprised of said mold half and a second mold half, said mold half comprising an integral article having a central curved section defining a concave surface, a convex surface and a circumferential edge, at least the central portion of at least one of said concave surface and said convex surface having the dimensions of the back curve of the desired swelled or unswelled contact lens to be produced in said mold assembly and being sufficiently smooth and contoured so that the surface of said contact lens formed by polymerization of said polymerizable composition in contact with said surface is optically acceptable, said article having an annular flange integral with and surrounding said circular circumferential edge and extending therefrom in a plane normal to the axis of said concave surface, said article also having a generally triangular tab situated in a plane normal to said axis and extending from said flange, said article having a thinness and rigidity effective to transmit heat therethrough and to withstand prying forces applied to separate said mold half from said mold assembly, and said article being comprised of a composition comprising a thermoplastic polymer and an internal additive which is impregnated into said thermoplastic material by compounding, said internal additive present in amounts ranging from about 0.1 % to about 20 % by weight, said thermoplastic material being polystyrene or polypropylene and said additive being a mold release agent or surfactant that is a polyethylene or polypropylene wax having a molecular weight ranging from about 5000 to about 200,000, stearate salt, a glycerol ester having molecular weight of about 200-2000, an amide wax of the formula R_1CONH_2 , wherein R_1 is a hydrocarbyl group, and the amide wax has a molecular weight of about 200-2000, silicone having a molecular weight ranging from about 2000 to about 100,000, Montan wax, oxidized wax, $C_5 - C_{26}$ fatty acid having a molecular weight of about 200 to about 2000, a complex ester or a combination thereof.

9. The mold half of Claim 8 wherein the amide wax is a fatty acid amide wax.

10. The mold half of Claim 8 wherein the thermoplastic polymer is polystyrene.

11. The mold half of Claim 8 wherein the thermoplastic polymer is polypropylene.

12. The mold half of Claim 8 wherein the additive is present in amounts ranging from 0.1 to 5% by weight.



This is the replacement sheet

23 FEB 1999

Date:



-43-

13. The mold material of Claim 12 wherein the additive is present in amounts ranging from 0.1 to 2% by weight.

14. The mold half of Claim 8 wherein the additive is stearate salt or silicone.

15. A mold assembly used in the production of a contact lens by the polymerization of a polymerizable composition in said mold assembly, said mold assembly comprising a front mold half and a back mold half in contact therewith thereby defining and enclosing a cavity therebetween, and a polymerizable composition in said cavity in contact with both mold halves, wherein

said front mold half comprises a first article of thermoplastic polymer transparent to ultraviolet light, said article having a central curved section with a concave surface, a convex surface and a circular circumferential edge, wherein the portion of said concave surface in contact with said polymerizable composition has the curvature of the front curve of a contact lens to be produced in said mold assembly, and is sufficiently smooth so that the surface of a contact lens formed by polymerization of said polymerizable composition in contact with said surface is optically acceptable;

said first article having an annular flange integral with and surrounding said circular circumferential edge and extending therefrom in a plane normal to the axis of said concave surface, and a generally triangular tab situated in a plane normal to said axis and extending from said flange;

said back mold comprised of an integral article having a central curved section with a concave surface, a convex surface and a circular circumferential edge, wherein the portion of said convex surface in contact with said polymerizable composition has the curvature of the back curve of a contact lens to be produced in said mold assembly and is sufficiently smooth that the surface of a contact lens formed by polymerization of said polymerizable composition in contact with said surface is optically acceptable;

said second article having an annular flange integral with and surrounding said circular circumferential edge with and surrounding said circular circumferential edge and extending therefrom in a plane normal to the axis of said convex surface, and a generally triangular tab situated in a plane normal to said axis and extending from said flange wherein the convex surface of said back mold contacts the circumferential edge of said front mold half;



This is the replacement sheet

Date: 23 FEB 1999



- 44 -

said back mold being comprised of a composition comprising a thermoplastic polymer and an internal additive which is impregnated into said thermoplastic material by compounding, said internal additive present in amounts ranging from about 0.1 % to about 20 % by weight, said thermoplastic material being polystyrene or polypropylene and said additive being a mold release agent or surfactant that is a polyethylene or polypropylene wax having a molecular weight ranging from about 5000 to about 200,000, stearate salt, a glycerol ester having molecular weight of about 200-2000, an amide wax of the formula R_1CONH_2 , wherein R_1 is a hydrocarbyl group, and the amide wax has a molecular weight of about 200-2000, silicone having a molecular weight ranging from about 2000 to about 100,000, Montan wax, oxidized wax, $C_5 - C_{26}$ fatty acid having a molecular weight of about 200 to about 2000, a complex ester or a combination thereof.

16. The mold assembly of Claim 15 in which the amide wax is a fatty acid amide wax.

17. The mold assembly of Claim 15 wherein the thermoplastic polymer is polystyrene.

18. The mold assembly of Claim 15 wherein the thermoplastic polymer is polypropylene.

19. The mold assembly of Claim 15 wherein the additive is present in amounts ranging from 0.1 to 5% by weight.

20. The mold assembly of Claim 19 wherein the additive is present in amounts ranging from 0.1 to 2% by weight.

21. The mold assembly of Claim 15 wherein the additive is stearate salt or silicone.

22. In an improved process for forming a contact lens from a mold assembly comprising a front mold half and a back mold half in contact therewith thereby defining and enclosing a cavity therebetween, and containing in said cavity a polymerizable composition in contact with said mold halves;



This is the replacement sheet

Date: 23 FEB 1969



-45-

said front mold half comprising a first article of thermoplastic polymer transparent to ultraviolet light, said article having a central curved section with a concave surface, a convex surface and a circular circumferential edge, wherein the portion of said concave surface in contact with said polymerizable composition has the curvature of the front mold curve of a contact lens to be produced in said mold assembly and is sufficiently smooth so that the surface of a contact lens formed by polymerization of said polymerizable composition in contact with said surface is optically acceptable;

said back mold half comprising a second article of thermoplastic polymer transparent to ultraviolet light, said article having a central curved section with a concave surface, a convex surface and a circular circumferential edge, wherein the portion of said convex surface in contact with said polymerizable composition has the curvature of the said back curve of a contact lens to be produced in said mold assembly and is sufficiently smooth so that the surface of a contact lens formed by polymerization of said polymerizable composition in contact with said surface is optically acceptable, wherein the convex surface of said back mold contacts the circumferential edge of said front mold half;

and the front mold half is clamped against the back mold half;

and the polymerizable composition undergoes polymerization under precuring and curing conditions with ultraviolet light and the back curve is separated from the front curve and the contact lens during a demolding process and the front curve is subsequently separated from the contact lens, the improvement comprising utilizing a back curve mold that is comprised of a composition comprising a thermoplastic polymer and an internal additive which is impregnated into said thermoplastic material by compounding, said internal additive present in amounts ranging from about 0.1 % to about 20 % by weight, said thermoplastic material being polystyrene or polypropylene and said additive being a mold release agent or surfactant that is a polyethylene or polypropylene wax having a molecular weight ranging from about 500 to about 200,000, stearate salt, a glycerol ester having molecular weight of about 200-2000, an amide wax of the formula R_1CONH_2 , wherein R_1 is a hydrocarbyl group, and the amide wax has a molecular weight of about 200-2000, silicone having a molecular weight ranging from about 2000 to about 100,000, Montan wax, oxidized wax, $C_5 - C_{26}$ fatty acid having a molecular weight of about 200 to about 2000, a complex ester or a combination thereof.

23. The process of Claim 22 in which the amide wax is a fatty acid amide wax.



This is the replacement sheet

Date: 23 FEB 1993

24. The process of Claim 22 wherein the thermoplastic polymer is polystyrene.

25. The process of Claim 22 wherein the thermoplastic polymer is polypropylene.

26. The process of Claim 22 wherein the additive is present in amounts ranging from 0.1 to 5% by weight.

27. The process of Claim 26 wherein the additive is present in amounts ranging from 0.1 to 2% by weight.

28. The process of Claim 22 wherein the additive is stearate salt or silicone.

This Sheet Has Been Replaced



* C L M S *

This is the replacement sheet

Date: 23 FEB 1998

-11-

and propylene respectively having a molecular weight ranging from about 5000 to 200,000 g/mole. Examples of polyethylene wax include EPOLENE C-13, C-14, C-15, C-17, C-18, E-10, N-10, N-11, N-21, N-34, HOECHST WAX PE 190, STANWAX, and the like. Examples of propylene wax are EPOLENE N-15P, and EPOLENE E-43P, and the like. Other waxes, such as mineral wax, e.g., Montan wax can also be used. Montan wax contains three portions, the wax portion, the resin portion and the asphalt portion. The wax component of Montan is a mixture of long-chain (C_{24} - C_{30}) esters (62-68 wt %), long chain acids (22-26 wt %), and long-chain alcohols, ketones and hydrocarbons (7-15 wt %). The resin portion is approximately 70 wt % terpenes and polyterpenes and 30 wt % resinic acid and oxyresinic acid, while the asphalt portion is believed to be polymerized esters of oxyresinic acid.

Oxidized waxes, as defined herein, are alkan hydrocarbons (paraffins) having a molecule weight of 100-2000 g/mole. They are capped at the ends with either ester, carboxylic or hydroxy groups. Examples include carnauba wax and Rosswax, such as Rosswax 100 and 1343 and the like.

As defined herein, glycerol esters are hydrocarbyl esters of glycerol having a molecular weight of 200 to 2000 g/mole. They include monoglycerides, diglycerides and polyglycerides, including fatty acids of triglycerides. Examples include PATIONIC 900, 901, 902, 907, 919, 1042 and 1042 K, and the like.

Alcohol esters contain 5-2000 carbon atoms, and include such species as LUBE 106, and the like. Complex esters, as defined herein, are copolymers of organic phosphate esters having a molecular weight of 200 - 2000

REPLACEMENT SHEET	30
✓ Description: page 11 to page 15	
✓ Title(s): page 11 to page 15	46
✓ Drawing(s): page 11 to page 15	
✓ Abstract: page 11 to page 15	
This is the replacement sheet	
Date: 25/1/99	25 JUN 1999

g/mole which contain glycerides, organic acid derivatives and fatty acids. Examples include KANTSTIK FX-9 and Q, and the like.

5 Combination of the additives listed hereinabove or blends include MOLD EASE PCR, MOLD WIZ INT 33 PA, INT 38 H, INT 33, UDK, and the like. It is preferred that the combination have a molecular weight ranging from 200 to 200,000 g/mole.

10 As defined herein, hydrocarbyl is an aliphatic, cyclaliphatic, or aromatic moiety containing carbon and hydrogen atoms, having 1 to 200 carbon atoms. The hydrocarbyl moiety may be straight chain, or branched or cyclic. If cyclic, the rings are preferably fused. The hydrocarbyl group may be completely saturated or partially saturated or
15 completely aromatic or conjugated. The hydrocarbyl moiety may contain at least one double bond. It is preferred that the hydrocarbyl group contains 1-100 carbon atoms.

20 As described hereinabove, the present invention is directed to a new polymeric material containing an additive admixed therewith. The polymeric material if the present invention is a thermoplastic material, viz, polystyrene or polypropylene. The polystyrene and polypropylene that is utilized is preferably transparent to ultraviolet light. When the additive described hereinabove is admixed with the
25 polystyrene or polypropylene, the new formulation maintains its ability to transmit ultraviolet light. In a preferred embodiment, the new formulation allows UV transmissions of from 3 to 5 up to wavelengths of 300 nanometers.

30 The additive admixed with the thermoplastic material is present in amounts of at least about 0.1% by

ADDITIVE	AMOUNT BY WEIGHT
ABILWAX 9801	0.25%
ABILWAX 9801	1.00%
FC 430	0.25%
KANTSTICK Q	0.25%
KANTSTICK Q	1.50%
SF 1080	0.5%
SF 1080	0.25%
AXEL 33 P/A	0.25%
AXEL 33 P/A	2.50%
AXEL 33-H	0.25%
AXEL 38-H	2.5%
GE 1080	0.5%
GE 1080	0.25%

The polystyrene/additive and polypropylene/additive composition of the present invention are prepared by processes well known to those skilled in the art. The following procedure exemplifies the techniques used to make the composition of the present invention using polystyrene. However, the techniques are just as applicable for making the polypropylene/additive composition.

The procedure using polystyrene as the thermoplastic material is as follows. The polystyrene thermoplastic material is as follows. The polystyrene and the additive are mixed together by techniques known to one skilled in the art. In one methodology, the polystyrene is compounded with the additive. In a preferred method, a predetermined amount of the additive and polystyrene are mixed together, the mixture is heated to melt the polystyrene, the melted polystyrene and the additive are then again mixed together, such as with an extruder, which further intermixes the two components.

This is the replacement sheet

Date: 25 JUN 1999

WHAT IS CLAIMED IS:

1. A mold material constituting a mold half for use in the production of contact
5 lenses, said mold material comprising a thermoplastic polymer and an internal additive which is
impregnated into said thermoplastic material by compounding, said internal additive present in
amounts ranging from about 0.1% to about 20% by weight, said thermoplastic material being
polystyrene or polypropylene and said additive being a mold release agent or surfactant that is a
polyethylene or polypropylene wax having a molecular weight ranging from about 5000 to
10 about 200,000, stearate salt, a glycerol ester having molecular weight of about 200-2000, an
amide wax of the formula R_1CONH_2 , wherein R_1 is a hydrocarbyl group, and the amide wax
has a molecular weight of about 200-2000, silicone having a molecular weight ranging from
about 2000 to about 100,000, Montan wax, oxidized wax, C_5 - C_{26} fatty acid having a molecular
weight of about 200 to about 2000, a complex ester or a combination thereof.
- 15 2. The mold material of Claim 1 in which the amide wax is a fatty acid amide wax.
3. The mold material of Claim 1 wherein the thermoplastic polymer is
polystyrene.
4. The mold material of Claim 1 wherein the thermoplastic polymer is
polypropylene.
- 20 5. The mold material of claim 1 wherein the additive is present in amounts ranging
from 0.1 to 5% by weight.
6. The mold material of Claim 5 wherein the additive is present in amounts
ranging from 0.1 to 2% by weight.
7. The mold material of claim 1 wherein the additive is stearate salt or silicone.

25

This is the replacement sheet



Date: 25 JUN 1999

8. A mold half useful in the production of a contact lens by the polymerization of a polymerizable composition in a mold assembly comprised of said mold half and a second mold half, said mold half comprising an integral article having a central curved section defining a concave surface, a convex surface and a circumferential edge, at least the central portion of at least one of said concave and said convex surface having the dimensions of the back curve of the desired swelled or unswelled contact lens to be produced in said mold assembly and being sufficiently smooth and contoured so that the surface of said contact lens formed by polymerization of said polymerizable composition in contact with said surface is optically acceptable, said article having an annular flange integral with and surrounding said circular circumferential edge and extending therefrom in a plane normal to the axis of said concave surface, said article also having a generally triangular tab situated in a plane normal to said axis and extending from said flange, said article having a thickness and rigidity effective to transmit heat therethrough and to withstand prying forces applied to separate said mold half from said mold assembly, and said article being comprised of a composition comprising a thermoplastic polymer and an internal additive which is impregnated into said thermoplastic material by compounding, said internal additive present in amounts ranging from about 0.1 % to about 20 % by weight, said thermoplastic material being polystyrene or polypropylene and said additive being a mold release agent or surfactant that is a polyethylene or polypropylene wax having a molecular weight ranging from about 5000 to about 200,000, stearate salt, a glycerol ester having a molecular weight of about 200-2000, an amide wax of the formula R_1CONH_2 , wherein R_1 is a hydrocarbyl group, and the amide wax has a molecular weight of about 200-2000, silicone having a molecular weight ranging from about 2000 to about 100,000, Montan wax, oxidized wax, $C_5 - C_{26}$ fatty acid having a molecular weight of about 200 to about 2000, a complex ester or a combination thereof.

9. The mold half of Claim 8, wherein the amide wax is a fatty acid amide wax.

10. The mold half of Claim 8, wherein the thermoplastic polymer is polystyrene.

11. The mold half of Claim 8, wherein the thermoplastic polymer is polypropylene.

12. The mold half of Claim 8, wherein the additive is present in amounts ranging from 0.5 to 5% by weight.

40



This is the replacement sheet

Date: 25 JUN 1990

13. The mold material of Claim 12 wherein the additive is present in amounts ranging from 0.1 to 2% by weight.

5 14. The mold half of claim 8 wherein the additive stearate salt or silicone.

15. A mold assembly used in the production of a contact lens by the polymerization of a polymerizable composition in said mold assembly, said mold assembly comprising a front mold half and a back mold half in contact therewith
10 thereby defining and enclosing a cavity therebetween, and a polymerizable composition in said cavity in contact with both mold halves, wherein said front mold half comprises a first article of thermoplastic polymer transparent to ultraviolet light, said article having a central curved section with a concave surface, a convex surface and a circular circumferential edge, wherein the portion of said
15 concave surface in contact with said polymerizable composition has the curvature of the front curve of a contact lens to be produced in said mold assembly, and is sufficiently smooth so that the surface of a contact lens formed by polymerization of said polymerizable composition in contact with said surface is optically acceptable;
20 said first article having an annular flange integral with and surrounding said circular circumferential edge and extending therefrom in a plane normal to the axis of said concave surface, and a generally triangular tab situated in a plane normal to said axis and extending from said flange;
25 said back mold comprised of an integral article having a central curved section with a concave surface, a convex surface and a circular circumferential edge, wherein the portion of said convex surface in contact with said polymerizable composition has the curvature of the back curve of a contact lens to be produced in said mold assembly and is sufficiently smooth that the surface of a contact lens formed by polymerization
30 of said polymerizable composition in contact with said surface is optically acceptable;
said second article having an annular flange integral with and surrounding said circular circumferential edge with and surrounding said circular circumferential edge and extending therefrom in a plane normal to the axis of said convex surface, and a
35 generally triangular tab situated in a plane normal to said axis and extending from said flange wherein the convex surface of said back mold contacts the circumferential edge of said front mold half;



This is the replacement sheet

Date: 25 JUN 1999

said back mold being comprised of a composition comprising a thermoplastic polymer and an internal additive which is impregnated into said thermoplastic material by compounding, said internal additive present in amounts ranging from about 0.1% to about 20% by weight, said thermoplastic material being polystyrene or polypropylene and said additive being a mold release agent or surfactant that is a polyethylene or polypropylene wax having a molecular weight ranging from about 5000 to about 200,000, stearate salt, a glycerol ester having a molecular weight of about 200-2000, an amide wax of the formula R_1COHN_2 , wherein R_1 is a hydrocarbyl group, and the amide wax has a molecular weight of about 200-2000, silicone having a molecular weight ranging from about 2000 to about 100,000 Montan wax, oxidized wax, C5-C26 fatty acid having a molecular weight of about 200 to about 2000, a complex ester or a combination thereof.

16. The mold assembly of Claim 15 in which the amide wax is a fatty acid amide wax.

17. The mold assembly of Claim 15 wherein the thermoplastic polymer is polystyrene.

18. The mold assembly of Claim 15 wherein the thermoplastic polymer is polypropylene.

19. The mold assembly of Claim 15 wherein the additive is present in amounts ranging from 0.1 to 2% by weight.

20. The mold assembly of Claim 19 wherein the additive is present in amounts ranging from 0.1 to 2% by weight.

21. The mold assembly of Claim 15 wherein the additive is stearate salt or silicone.

22. In an improved process for forming a contact lens from a mold assembly comprising a front mold half and a back mold half in contact therewith thereby defining and enclosing a cavity therebetween, and containing in said cavity a polymerizable composition in contact with said mold halves;

This is the replacement sheet



Date: 25 JUN 1999

said front mold half comprising a first article of thermoplastic polymer transparent to ultraviolet light, said article having a central curved section with a concave surface, a convex surface and a circular circumferential edge, wherein the portion of said concave surface in contact with said polymerizable composition has the curvature of the front mold curve of a contact lens to be produced in said mold assembly and is sufficiently smooth so that the surface of a contact lens formed by polymerization of said polymerizable composition in contact with said surface is optically acceptable;

said back mold half comprising a second article of thermoplastic polymer transparent to ultraviolet light, said article having a central curved section with a concave surface, a convex surface, and a circular circumferential edge, wherein the portion of said convex surface in contact with said polymerizable composition has the curvature of the said back curve of a contact lens to be produced in said mold assembly and is sufficiently smooth so that the surface of a contact lens formed by polymerization of said polymerizable composition in contact with said surface is optically acceptable, wherein the convex surface of said back mold contacts the circumferential edge of said front mold half;

and the front mold half is clamped against the back mold half,

and the polymerizable composition undergoes polymerization under precuring and curing conditions with ultraviolet light and the back curve is separated from the front curve and the contact lens during a demolding process and the front curve is subsequently separated from the contact lens, the improvement comprising utilizing a back curve mold that is comprised of a composition comprising a thermoplastic polymer and an internal additive which is impregnated into said thermoplastic material by compounding, said internal additive present in amounts ranging from about 0.1% to about 20% by weight, said thermoplastic material being polystyrene or polypropylene and said additive being a mold release agent or a surfactant that is a polyethylene or polypropylene wax having a molecular weight of about 200-2000, an amide wax of the formula R_1CONH_2 , wherein R_1 is a hydrocarbyl group, and the amide wax has a molecular weight of about 200-2000, silicone having a molecular weight ranging from about 2000 to about 100,000, Montan wax, oxidized wax, C5-C26 fatty acid having a molecular weight of about 200 to about 2000, a complex ester or a combination thereof.

23. The process of Claim 22 in which the amide wax is a fatty acid amide wax.

This is the replacement sheet



Date: 25 JUN 1998

24. The process of Claim 22 wherein the thermoplastic polymer is polystyrene.

5 25. The process of Claim 22 wherein the thermoplastic polymer is polypropylene.

10 26. The process of Claim 22 wherein the additive is present in amounts ranging from 0.1 to 5% by weight.

27. The process of Claim 26 wherein the additive is present in amounts ranging from 0.1 to 2% by weight.

28. The process of Claim 22 wherein the additive is stearate salt or silicone.



This is the replacement sheet

Date: 25 JUN 1999