

MOLD MATERIAL MADE WITH ADDITIVES

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The present invention relates to a novel polymeric formulation containing an internal mold release additive which assists in the release of one mold component from another or an internal mold wetting agent which enhances the interfacial wetting between the reactive monomer mix and the mold surfaces, thereby reducing the amount of defects formed in the contact lens. The present invention is also directed to the molds made from such polymeric formulation as well as to a method of preparing contact lenses from these molds.

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 consist of suitable pallets, each including a plurality of cavities receiving mold parts having female and/or

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male base surfaces or curvilinear mold portions for the
1 formation of the curved contact lenses. The molds, as
described, for instance in the molding technology, may
be constituted from suitably selected conventional
plastic materials, whereby the hydrophilic polymer
5 articles, i.e., the contact lenses, will be formed in
the cavity therebetween, and may possibly adhere to one
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
10 of critical importance to be able to release the
hydrophilic contact lenses from their surface engagement
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
15 the lenses unusable.

Unfortunately, all too frequently, damage is
sustained during the preparation of contact lenses. The
potential damages which generally renders the contact
lenses unable to meet necessary quality and/or
20 inspection standards may consist of edge tears and
chips, nicks or other surface defects formed in the
contact lenses. Other causes of rejected lenses are
holes, voids in center of the cast that are developed in
the lenses during the molding process, pits, i.e. areas
25 on non-uniform thickness, and puddles.

As a result there is a need to find a new
formulation for the mold that would reduce the risk of
damage and defects.

Lens defects are major factors that causes low
30 production yield. There are two different types of

problems associated with contact lenses production which
1 the present invention is solving.

One such problem is the appearance of chips and
tears in the lens. These are caused during the
demolding step and are caused by adhesion of the mold to
5 the lenses. The present invention overcomes this
problem by utilizing an alternative material for one of
the mold parts. This new material contains an additive
that is added to the mold which greatly reduces the
adhesion forces between the lenses and the mold part,
10 thereby facilitating the release of the mold material
and minimizing the risk of developing defects in the
lens caused by and during the demolding step.

The second problem which is addressed by the
present invention is the prevention of the formation of
15 holes and puddles, which are developed in the lenses
during the molding process. Holes are usually found as
voids in the center of the lens, while puddles are
usually in random or in tree branch shapes, and are
usually found along the lens edge and are usually
20 associated with the concave or front curve mold.
According to the inventors, they are caused mainly by
poor wetting of the mold surface by the reactive monomer
mix at assembly of the mold surface. More specifically,
the poor wetting usually is due to either incompatible
25 chemistry or incompatible charges across the interface
of the mold and the reactive monomer mix or the
combination of both. More importantly, a heterogeneous
mold surface which causes uneven wetting by the reaction
monomer mix, results in many local unwetted voids, and
30 therefore lead to holes or puddles in the contact lens.

According to the inventors these holes and puddles
1 would be overcome if a prior wetting agent is added to
the polymer mold so as to increase the wettability power
of the mold. In order to understand the concept of
wetting, a brief digression will be made to discuss the
5 events occurring on the molecular level in a liquid. In
the body of a liquid, the time-averaged force exerted on
any given molecule by its neighboring molecule is zero.
Even though such a molecule may undergo diffusive
displacements due to random collisions within the
10 liquid, for any long duration, there exists no directed
forces upon it. There is equal probability to be
displaced in one direction as another. However, the
situation is quite different at the surface of the
liquid since there exist no molecules to counteract the
15 forces exerted by the molecules in the interior for
molecules on the surface. As a result, molecules on the
surface of a liquid experience a net attraction toward
the interior of a drop, thereby causing the droplet to
assume a spherical shape, minimizing both free energy
20 and surface area. This creates a surface tension, which
from a microscopic point of view is the reversible
isothermal work which must be done in bringing molecules
from the interior of the liquid to the surface, and
creating 1 unit of new surface thereby. The present
25 inventors believe that overcoming the surface tension
would remove the potential for forming "holes" in the
liquid, i.e., would make the liquid spreadable or
wetable on a solid.

In the wetting or nonwetting of solids by liquids,
30 the criteria employed is the contact angle between the

solid and the liquid (measured through the liquid).
1 Reference is made to Figure 6 which illustrates the
relationship between contact angle "a" and the
interfacial tensions that exist at the surface of a
liquid. As clearly shown, there are three interfaces
5 which exist when a droplet of liquid contacts a solid,
and thus there are three corresponding interfacial
tensions, γ_{SL} , γ_{SV} and γ_{LV} , wherein γ refers to the
interfacial tension, S, L and V refers to solid, liquid
and vapor, respectively. A liquid is said to wet a
10 solid if the contact angle "a" lies between 0 and 90°,
and not to wet the solid if the contact angle lies
between 90° and 180°. At equilibrium, a balance of
interfacial tensions exist at the line of common
contact, which intersects Figure 6 at point O. For a
15 liquid wetting the solid, this equilibrium is expressed
by the relation:

$$\gamma_{SV} = \gamma_{SL} + \gamma_{LV} \cos \theta$$

20 The present inventors have modified this concept
and utilized this modification to determine if a
particular substance could be used to reduce the
tendency of forming holes and puddles in making contact
lenses. Moreover, the present inventors have found a
25 trend and thus have found that particular compounds when
admixed with the polymeric mold material significantly
reduces the amount of holes and puddles in contact
lenses.

Their solution was based upon their understanding
30 of the thermodynamics of the situation. They calculated

that, the theoretical estimation of wetting, which is
1 the thermodynamic parameter called the spreading
coefficient, is defined as:

$$S = \gamma_s - \gamma_l - \gamma_{sl}$$

5 where S is the spreading coefficient, γ_s is the surface
energy of the mold material, γ_l is the surface tension of
the reactive monomer mix ("RMM") and the γ_{sl} is the
interfacial tension between reaction monomer mix and the
10 mold material. A positive "S" indicates spreading (or
wetting). Therefore, in order to spread or to wet, γ_l
and γ_{sl} should be made as small as possible or γ_s should
be made as large as possible. Practically, this means
that the surface energy of the mold is increased or the
15 surface tension of the reactive monomer mix is reduced
or both is effected in order to obtain the appropriate
wetting between reactive monomer mix and the mold. With
respect to increasing the mold surface energy, this
requires consideration of increasing not only the total
20 surface energy, but also increasing the portion of high
energy surface.

This can be accomplished by various techniques for
example, by coating the surface of one of the mold
halves with surfactant, or by transiently coating a the
25 mold surface with a wetting agent. Another method,
which is an embodiment of the present invention is the
incorporation of wetting agents into the mold material.

Obviously, not all wetting agents to the mold
material will be effective. The present inventors have
30 developed a methodology for determining which admixtures

will be useful for the composition of the mold material
1 for the manufacture of contact lenses having a reduced
number of holes or puddles. In consequence thereof, the
present inventors have developed a new mold material
which have the added advantage of reducing the tendency
5 to form holes or puddles.

Therefore, the present inventors have developed new
mold formulations improving the yield in and reducing
the defects in contact lenses. In one embodiment, the
formulation of the present invention reduces the
10 tendencies to form chips and tears. In another
embodiment, the present formulation reduces the
tendencies to form holes and puddles in contact lenses.

Accordingly, the present invention provides for a
mold for making contact lenses comprising thermoplastic
15 polymer of either polystyrene or polypropylene admixed
with an internal mold release agent (additive) or
wetting agent.

More specifically, the present invention is
directed to a mold material constituting a mold half for
20 use in the production of contact lenses, said mold
material comprising a thermoplastic polymer and a
internal additive which is impregnated into said
thermoplastic material and which is present in amounts
ranging from about 0.05% to about 5% by weight, said
25 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, an amide wax of the formula
 $R_1\text{CONH}_2$, wherein R_1 is a hydrocarbyl group, and the amide
30 wax has a molecular weight of about 200-2000, silicone

having a molecular weight ranging from about 2000 to
1 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.

The present invention is further directed to a mold
5 material constituting a mold half for use in the
production of contact lenses, said mold material
comprising polystyrene and an wetting effective amount
of a wetting agent admixed therewith, the wetting force
of said mold material being described by the equation:

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$$F = 2\gamma_1 p \cos \theta$$

where

F is the wetting force of the mold half

γ_1 is the surface tension of distilled water

15 p is the perimeter of the mold material at the
meniscus when the mold half is partially immersed in the
water and

θ is dynamic contact angle, wherein the contact
angle of said mold material is less than 100°.

20 When these materials were 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, the
present invention is further directed to the mold half
25 comprised of this new formulation. This mold half is
part of the mold assembly, and therefore the present
invention is still further directed to the mold assembly
comprising said mold half comprised of these
formulations of the present invention.

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More particularly, the present invention is
1 directed to 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
5 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
10 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
15 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
20 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 the
25 mold material comprised of a thermoplastic polymer
admixed with an additive or anti-wetting agent as
described above.

The mold assembly preferentially comprises at least
two pieces, a female concave piece (front piece) and a
30 male convex piece (back piece) forming a cavity

therebetween, and when said pieces are mated, at least
1 one piece having a flange thereabout. More
particularly, in a preferred embodiment, the mold
assembly comprises a front mold half and a back mold
half in contact therewith, thereby defining and
5 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
10 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 that the surface of a contact lens
formed by polymerization of said polymerizable
15 composition in contact with said surface is optically
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
20 the back mold has a central curved section with a
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
25 be produced in said mold assembly and is sufficiently
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
30 and surrounding said circular circumferential edge and

extending therefrom in a plane normal to the axis of
1 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
5 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
10 edge.

In this assembly, either the back mold or the front
mold half or both is comprised of the novel formulation
of the present invention. However, it is the back mold
half that is preferably comprised of the novel
15 formulation of the present invention, while the front
curve mold is comprised of a thermoplastic material that
does not contain the additive or wetting agent. Thus
the present invention is also directed to the base mold
comprised of said novel formulation.

20 More specifically, the present invention is
directed to 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
25 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,
30 said article having a central curved section with a

concave surface, a convex surface and a circular
1 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
5 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
10 integral with and surrounding said circular
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;

15 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
20 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 polymerization of
said polymerization composition in contact with said
surface is optically acceptable;

25 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
30 generally triangular tab situated in a plane normal to

said axis and extending from said flange wherein the
1 convex surface of said back mold half contacts the
circumferential edge of said front mold half;

said back mold being comprised of a mold material
comprised of a thermoplastic polymer admixed with an
5 additive as described above.

The mold assembly with the base curve mold made up
of the polystyrene/additive or polypropylene/additive,
polystyrene/wetting agent or polypropylene/wetting agent
formulations is used in making soft contact lenses.
10 Thus, the present invention is still further directed to
the process of making soft contact lenses utilizing this
mold assembly. That is, 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
15 thereby defining and enclosing a cavity therebetween,
and 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,
20 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
25 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;

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said back mold half comprising a second article of
1 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
5 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 so that the surface of a contact lens formed by
polymerization of said polymerizable composition in
10 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;

15 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
20 separated from the contact lens, the improvement
comprising utilizing a back curve mold that is comprised
of the mold material as described above.

As described herein, the use of the formulations of
the present invention modifies the surface chemistry of
25 the back mold by enhancing its wettability. In
addition, a formulation of the present invention
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
30 to a process of minimizing and/or preventing chips or

tears in the contact lens by utilizing a mold comprised
1 of polystyrene or polypropylene admixed with the
additive described hereinabove in mold releasing
effective amounts. Another aspect of the present
invention is directed to a process of minimizing and/or
5 preventing holes or puddles in the contact lens by
utilizing a mold half comprised of a thermoplastic
material admixed with an effective amount of a wetting
agent, said thermoplastic material being polystyrene or
polypropylene, and said mold half being sufficiently wet
10 to have a dynamic contact angle when immersed in water
of 100° or less.

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

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

Figure 2 is a top elevational planar view of the
production line system constructed according to the
25 present invention.

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
molded pursuant to the present invention.

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

Figures 4 and 4(a) are respectively a top or planar
view and an elevation or side view of one embodiment of
a second (male) or back curve mold half molded pursuant
5 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
Example 1.

10 Figure 6 is a schematic diagram of the contact
angle and the surface tension at the solid-vapor and
solid-liquid interfaces of a solid immersed in a probe
liquid.

Figure 7 is a schematic diagram of the methodology
15 of the present invention used to measure the contact
angle.

Figure 8 is a schematic of the various parameters
in determining the contact angle.

Figure 9 is a typical water wetting force trace.

20 As described hereinabove, the mold contains an
internal additive or wetting agent. In other words, the
additive or wetting agent is thoroughly admixed with the
thermoplastic polymer. This provides a substantially
uniform distribution of these internal additives or
25 wetting agents across the surface of the mold resin and
decreases the probability that they would be retained on
the lens. The polystyrene/additive,
polypropylene/additive, polystyrene/wetting agent or the
polypropylene/wetting agent compositions are prepared by
30 processes well known to those skilled in the art. The

following procedure exemplifies the techniques used to
1 make the formulations of the present invention, using
polystyrene and an additive as an example. However, it
is exemplary and is equally applicable for the
preparations of the other formulations of the present
5 invention.

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
10 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. The mixture can then be
15 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 mixed
together and then repelletized with the pelletizer.
20 Alternatively, the additive can be compounded with the
thermoplastic material directly in the molding machine.

The amount of additive added to the thermoplastic
material is a mold releasing effective amount, while the
amount of wetting agent added is a wetting effective
25 amount. The mold material comprised thereof is to be
transparent to UV transmission, especially of from 3 to
5 nm up to wavelengths of 300 nanometers. However
these amounts preferentially overlap. More
specifically, when present, the additive or wetting
30 agent is preferably present in an amount ranging from

about 0.05% to about 5% (w/w) relative to the
1 thermoplastic material, and more preferably ranging from
about 0.1% to about 2.5% (w/w).

These mold formulations solve two different
problems; thus, the mold formulation used is dependent
5 upon the objective. If the objective is to reduce
holes, the mold formulation utilized is the
thermoplastic material admixed with wetting agent. If
the objective is to reduce puddles, the front curve mold
is formed of the thermoplastic material with wetting
10 agent. On the other hand, if the objective is to
facilitate mold release from the lens, then the mold
formulation utilized for at least one of the molds,
preferably the back mold, is the thermoplastic material
with additive.

15 As used herein, reference to the "wetting
formulation" or "composition" refers to the mold
material comprised of the thermoplastic material (e.g.
polypropylene and more preferably polystyrene) and the
wetting agent, as defined herein. Alternatively
20 reference to the "mold release formulation" or
"composition" refers to the mold material comprised at
the thermoplastic material (e.g. polypropylene or
polystyrene) and the mold release agent. Reference to
the "formulations" or "compositions" of the present
25 invention or equivalent expression which does not
specify 'mold release' or 'wetting' refers to both
formulations.

The mold formulations of the present invention may
comprise either the backcurve mold, the front curve mold
30 or both. Because of their surface curative differences,

the wetting or adhesion force at the RMM/backcurve
1 interface is different from that of the RMM/front curve
interface. It is preferred that the backcurve be
comprised of the mold material of the present invention.

In the discussions that follow, reference will be
5 made to the backcurve, however, unless indicated to the
contrary, these discussions are equally applicable to
the front curve, and the use of the backcurve is for
illustrative purposes.

To determine the feasibility of a mold material for
10 use in the backcurve mold to reduce the tendency to form
holes in the contact lenses, the inventors developed a
modified wetting method to measure the wettability of
the backcurve mold. This method measures the wetting
forces between the probe wetting liquid (D.I. water) and
15 the backcurve mold surface defined by the relationship.

$$F = 2\gamma_1 p \cos \theta$$

20 wherein

F is the wetting force(mg) of the mold half being
measured;

γ_1 is the surface tension of the probe liquid, i.e.,
the water;

25 p is the perimeter of the mold half at the meniscus
(cm) when the mold half is partially immersed in the
water; and

θ is the dynamic contact angle in degrees.

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A schematic diagram of the experimental set-up is
1 given in Figure 7, while the various perimeters are
schematically depicted in Figure 8.

A sample (901), such as the backcurve, is suspended
vertically on a microbalance (902). The probe liquid
5 (903), such as water, is slowly raised to immerse the
backcurve. The wetting force between the probe liquid
and the backcurve as the probe liquid is being raised is
measured by the microbalance which is recorded on a
recorder 905. A trace of the wetting forces as a
10 function of distance travelled by the water meniscus
(904) over the backcurve surface is obtained. A typical
water (backcurve) wetting force trace is given in Figure
9. In this way, the value of γ can be measured.

The probe liquid that is used to make these tests
15 is a common liquid or solvent which has a known surface
tension. The preferred probe liquid is water, which has
a surface tension of 72.75 dynes/cm at 20°C.

From these measurements, the contact angle is
calculated.

20 The inventors have determined that a backcurve with
a water dynamic contact angle less than or equal to 100°
produces contact lenses with significantly less holes.
It is more preferred that the contact angle be less than
or equal to 90°. It is even more preferred that the
25 contact angle be less than or equal to about 75°.

Thus, mixing the appropriate wetting agent with the
polystyrene or polypropylene making the mold half
thereof and measuring the contact angle in accordance
with the above procedure is an easy test to determine
30 the feasibility of using the mold half in the process of

making contact lenses having a decreased tendency of
1 forming holes or puddles.

The wetting agents used in the present invention
are surface active chemicals, such as lubricants, anti-
static agents or surfactants which when mixed with the
5 mold material to form the backcurve, effectively changes
the mold surface chemistry and its surface properties.

Preferred wetting agents that are utilized are the
wetting agents, normally used in the plastic arts that
are not toxic to humans. They include the nonionic
10 surfactants, cationic surfactants and anionic
surfactants. Especially preferred are salts of fatty
acids containing 16-30 carbon atoms. The preferred
salts are stearates.

Stearates are salts of stearic acid. They include
15 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, ammonium salts, Group 13 metals, Group 14
metals and transition metals, such as Group 12.
20 Examples 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, SYN PRO CALCIUM STEARATE PG, SYN
PROTYPE 114-36, WITCO F, WITCO EXTRA DENSE G, WITCO FP,
25 COMETALS SODIUM STEARATE, SYNPRO SODIUM STEARATE ST,
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,
30 HYTECH RSN 1S31, MATHE ZINC STEARATE S, MATHE ZINC

STEARATE 25S, MILJAC ZINC STEARATE, WITCO ZINC STEARATE,
1 PLASTOLUBE, SYNPRO ACF, SYNPRO 8 (Synthetic Product Zinc
Stearate 8), WITCO 42, WITCO 11, and the like.

Other preferred wetting agents are oxygen
containing amines such as ethoxylated tertiary amines,
5 hydroxyalkyl tertiary amines (i.e., tertiary amine tri
substituted with alkyl groups containing 1-20 carbon
atoms which at least one of the alkyl groups substituted
by hydroxy) and quaternary ammonium compounds,
especially quaternary ammonium sulfates. Examples of
10 oxygen containing amines are described in Kirk-Othmer
"Encyclopedia of Chemical Technology," Vol. 22, p.379-
381, (1983), the contents of which are incorporated by
reference. Preferred hydroxalkyl tertiary amine are of
the formula



where R_{11} and R_{12} are alkyl of 1-20 carbon atoms
containing a hydroxy group and R_{10} is an alkyl group of
1-20 carbon atoms. Examples of quaternary ammonium
20 salts are described in Kirk-Othmer, Encyclopedia of
Chemical Technology, Vol. 22, pp. 383-384 (1983).
Examples include ARMOSTAT 410®, manufactured by AKZO,
(ethoxylated tertiary amine), ATMER 163®, manufactured
by ICI Americas (N,N-BIS-(2-hydroxyethyl)alkylamine),
25 CYASTAT LS, manufactured by CYTEC (3-Lauramidopropyl)
trimethylammonium methylsulfate, LAROSTATE 264A,
manufactured by PPG (Soy Dimethyl Ethyl ammonium
Ethosulfate), and the like.

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Other examples of preferred wetting agents are
 1 listed hereinbelow:

	<u>Surfactant</u>	<u>Supplier</u>
	Antistat A21750	Polyccm Huntsman
5	Armostat 310	Akzo, Ampacat
	Armostat 41 0	Akzo
	Armostat 475	Akzo
	Atmer 16	ICI Americas
	Chemstat 122	Chemax
10	Chemsat 122/60DC	Chemax
	Chemstat 182	Chemax
	Eurestat T22	Schering Berlin
	Kemamine AS650	Humko
	Antistatic KN	3-V Chemical
15	Atmer 1002	ICI Americas InL
	Cyastat 609	Am. Cyanamid
	Cyastat LS	Am. Cyanamid
	Cyastat SN	Am. Cyanamid
	Cyastat SP	Am. Cyanamid
20	Eurestat 66	Schering Bedin
	Larostat 96	PPG
	Larostat 451, 477	PPG
	Markstat AL-12	Argus
	Markstat AL-26, AL-48	Argus
25	Neutro-Stat A (Conc.)	Simco
	Addaroma IN	Merix
	Aristac M & 2M	CDC Infl.

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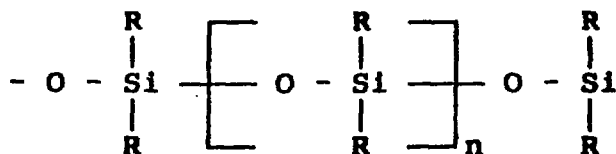
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	<u>Surfactant</u>	<u>Supplier</u>
1	Antffog/Antstatic MCG	Morix
	Antistat AS, 50059	Ferro
	Antistat AS50098	Ferro
	Antistat HTA	Hftech
5	Antistabc Agent 575	Houghton
	Angstatic Coating 1412	Coating Systems
	Aritistatc Spray	Price-Driscoll
	Atmer 1 90	ICI Americas
	Atmer 8505	ICI Americas
10	Atmos 150, Atmul 124	Humko
	Atmul 84	Humko

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

15 They are also known release agents. Preferred additives are silicones, amide waxes, fatty acids, polyethylene and propylene waxes, mineral wax, oxidized waxes and the like.

20 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. More specifically, it consists of a polymer having a structure consisting of alternate silicon and oxygen
 25 atoms of the formula:



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wherein each R may be different, but preferably the
1 same and are a hydrocarbyl group and n is an integer
ranging from 20 to about 1500. The molecular weight of
the silicone ranges from 2000 to 100,000 g/mole,
inclusive. The silicones have very low surface tension,
5 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
10 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.
15 As used herein, amide waxes are waxes having the
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 carbon-carbon double bond
20 in R_1 . The amide waxes preferably have 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-
25 30 carbon atoms. Examples include 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-
30 ethanediylbiscoctadecanamide), ADWAX 280, EBS WAX,

HOSTALUB FA1, PARACIN 285, ROSSWAX 140, CRODAMIDE EBS,
1 BUSPENSE 047, ER, OR, 203, 212 KEMAMIDE B, S, U,
ethylene bis (stearamide), oleamide, erucamide, and the
like.

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

Polyethylene and propylene waxes as used herein are
waxes of low, medium or high density of polyethylene or
polypropylene, respectively, having a molecular weight
ranging from about 5000 to 200,000 g/mole. Examples of
10 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
EPOLEN N-15P, and EPOLENE E-43P, and the like.

Other waxes such as mineral was, e.g., Montan wax
15 can also be used. Montan wax contains three portions,
the wax portion, the resin portion and the asphalt
portion. The wax component of Montan wax is a mixture
of long-chain (C_{24} - C_{30}) ester (62-68 wt%), long chain
acids (22-26 wt%), and long-chain alcohols, ketones and
20 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.

25 Oxidized waxes are alkane hydrocarbons (paraffins)
having a molecular 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.

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As defined herein, glycerol esters are hydrocarbyl
1 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,
5 907, 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 are copolymers of organic phosphate
esters having a molecular weight of 200-2000 g/mole
10 which contain glycerides, organic acid derivatives and
fatty acids. Examples include KANTSTIK FX-9 and Q, and
the like.

Combination of the additives listed hereinabove or
blends include MOLD EASE PCR, MOLD WIZ INT 33 PA, INT 38
15 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.

As defined herein, hydrocarbyl is an aliphatic,
cyclaliphatic, or aromatic moiety containing carbon and
20 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 completely aromatic or
25 conjugated. The hydrocarbyl moiety may contain at least
one double bond. It is preferred that the hydrocarbyl
group contains 1-100 carbon atoms.

The most preferred additives are SF 1080 Silicone
Oil, Int 38H Ester Complex, Kantstick Q Ester Complex,
30 FC 430 Ester Complex, ABIL® Wax 9801, Silicone Wax

(stearyl dimethicone), SF 96-5 Silicone Oil, L-42,
 1 Acrawax® C (1,2 ethanediylbis-octadecanamide),
 polystyrene 202, FC 4331 Ester Complex, SF 18-350
 Silicone Oil, L-45 (dimethyl silicone), ABIL® wax 9801
 (cetyl dimethicone), VSC-10M, Carnauba Wax and Ross Wax
 5 100. 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.

Exemplary formulations include polystyrene with the
 following additives or wetting agents in the indicated
 10 amounts.

	ADDITIVE	AMOUNT BY WEIGHT
	ABILWAX 9801	0.25%
	ABILWAX 9801	1.00%
15	FC 430	0.25%
	KANTSTICK Q	0.25%
	KANTSTICK Q	1.50%
	SF 1080	0.5%
	SF 1080	0.25%
20	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%
25	GE 1080	0.25%
	CYASTAT LS	0.05%
	CYASTAT LS	0.50%
	CYASTAT LS	1.00%
	ATMER 163	0.50%

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The composition of the present invention is
1 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
5 separable two part mold assembly utilized in the
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
10 one flange thereabout. At least one of the pieces is
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
15 of the present invention, the other mold half is
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
20 invention.

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
useful in the production of a contact lens by the
25 polymerization of a polymerizable composition in a mold
assembly comprised of two complementary front and base
mold halves. As indicated, the mold halves are useful
in the production of contact lenses in that lenses can
be made which are immediately ready to wear, and in that

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unswelled lenses can be made which need to be swelled
1 (hydrated) to be ready to wear.

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

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
25 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
parallel convex surface 16 is spaced from the concave
30 surface 15, and an annular essentially uniplanar flange

18 is formed extending radially outwardly from the
1 surfaces 15 and 16 in a plane normal (perpendicular) to
the axis (of rotation) of the concave surface 15. The
concave surface 15 has the dimensions of the front curve
(power curve) of a contact lens to be produced by the
5 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
surface is of optically acceptable quality. The front
mold half is designed with a thinness (typically 0.8 mm)
10 and rigidity effective to transmit heat therethrough
rapidly and to withstand prying forces applied to
separate the mold half from the mold assembly during
demolding.

Figures 4 and 4(a) illustrate respectively top,
15 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.

20 The back curve mold half 30 is preferably formed of
the composition of the present invention. The back
curve mold half 30 defines a central curved section with
an optical quality convex surface 33, a generally
parallel concave surface 34 spaced from the convex
25 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
dimensions of the rear curve (which rests upon the
30 cornea of the eye) of a contact lens to be produced by

the base mold half, and is sufficiently smooth such that
1 the surface of a contact lens formed by polymerization
of a polymerizable composition in contact with the
surface is of optically acceptable quality. The base
mold half is designed with a thinness (typically 0.6 mm)
5 to transmit heat therethrough rapidly and rigidity
effective to withstand prying forces applied to separate
the mold half from the mold assembly during demolding.

The mold halves 10,30 define generally triangular
tabs 26,37 integral with the flange which project from
10 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 angled (e.g., 45°)
web sections 22,38 for smoothing the flow of the polymer
wave front and thus to avoid jetting, sink marks, weld
15 lines and other undesirable flows which would impair the
optical quality of the mold half. The mold halves 10,30
also define small circular projections 25,35 which serve
as traps in the molding process to immobilize small
plugs of colder polymers that may form at the injection
20 hot tip between cycles.

The reactive monomer mixtures (polymerizable
composition) which are polymerized in the mold assembly
comprised of the two mold halves include copolymers
based on 2-hydroxyethylmethacrylate ("HEMA") and one or
25 more comonomers such as 2-hydroxyethyl acrylate, methyl
acrylate, methyl methacrylate, vinyl pyrrolidone, N-
vinyl acrylamide, hydroxypropyl methacrylate, isobutyl
methacrylate, styrene, ethoxyethyl methacrylate, methoxy
triethylene/glycol methacrylate, glycidyl methacrylate,
30 diacetone acrylamide, vinyl acetate, acrylamide,

hydroxytrimethylene acrylate, methoxyethyl methacrylate,
1 acrylic acid, methacrylic acid, glycerol methacrylate,
and dimethylamino ethyl acrylate.

Preferred polymerizable compositions are disclosed
in U.S. Patent No. 4,495,313 to Larsen, U.S. Patent No.
5 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 and a
10 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
15 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
20 diester or triester. Examples of representative cross
linking agents include: ethylene glycol diacrylate,
ethylene glycol dimethacrylate, 1,2-butylene
dimethacrylate, 1,3-butylene dimethacrylate, 1,4-
butylene dimethacrylate, propylene glycol diacrylate,
25 propylene glycol dimethacrylate, diethylglycol
dimethacrylate, dipropylene glycol dimethacrylate,
diethylene glycol diacrylate, dipropylene glycol
diacrylate, glycerine trimethacrylate, trimethylol
propane triacrylate, trimethylol propane
30 trimethacrylate, and the like. Typical cross-linking

agents usually, but not necessarily, have at least two
1 ethylenically unsaturated double bonds.

The polymerizable compositions generally also
include a catalyst, usually from about 0.05 to 1% (w/w)
of a free radical catalyst. Typical examples of such
5 catalysts include lauroyl peroxide, benzoyl peroxide,
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
10 radioactive source may also be employed to catalyze the
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-
15 hydroxyl-2-propyl ketone.

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
20 composition, initiators which work upon exposure to
ultraviolet radiation; and exposing the composition to
ultraviolet radiation of an intensity and duration
effective to initiate polymerization and to allow it to
proceed. For this reason, the mold halves are
25 preferably transparent to ultraviolet radiation. After
the procure step, the monomer is again exposed to
ultraviolet radiation in a cure step in which the
polymerization is permitted to proceed to completion.
The required duration of the remainder of the reaction

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can readily be ascertained experimentally for any
1 polymerizable composition.

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

The contact lens are prepared by various techniques
known to be skilled artisan, except at least one mold
half is comprised of a formulation of the present
15 invention. For example, they may be prepared by the
direct molding of hydrogel contact lenses, which is
disclosed in U.S. Patent Nos. 4,495,313 to Larsen,
4,565,348 to Larsen, 4,640,489 to Larsen et al.,
4,680,336 to Larsen et al., 4,889,664 to Larsen, et al.
20 and 5,039,459 to Larsen et al. Another method is
schematically depicted in Figures 1 and 2 as will be
hereinafter described in detail. Also see U.S. Patent
No. 5,540,410 to Lust et al.

In the description hereinbelow, the procedure is
25 described in which the backcurve mold is comprised of
the formulation of the present invention. This is just
exemplary as the front curve mold or both the backcurve
mold and the front curve mold may be comprised of the
instant formulation.

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For efficiency, ease of operation and cycle times,
1 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
5 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.

In this methodology the mold is designed to produce
fully formed lens mold parts directly, that is without
10 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
robotic means for delivery to the transport means. In
15 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
robotic means to a pallet of aluminum or stainless steel
20 in which they are received and supported in a regular
spatial array adapted for further operations.

It should be understood that at most stages of the
continuous process, inspection means are operational to
effect rejection of parts against reference criteria;
25 hence, following injection molding, inspection,
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
30 maintain the continuity and consistency in line

operations generally a whole mold cycle or pallet of
1 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
5 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
10 required for transfer of the mold parts to the
horizontally operating transport means.

As illustrated in Figures 1 and 2 injection molds
#1 and #2, shown at steps 101 and 102 in the flow
diagram of Figure 1, mold respectively front curve and
15 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 thereto in
20 the same plane.

Robotic means 103,104 are provided adjacent the
mold registry and engagement station for receiving
concave and convex lens molds, respectively and
transferring said mold part to a low oxygen environment
25 at a high production cycle rate, as noted at step 105.

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
30 degassed when enclosed in feed conveyor such that

automated equipment may effect their operative
1 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
5 nitrogen. The amount of nitrogen is not critical, it
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
10 lens mold blanks are degassed as indicated at step 106
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
15 into complementary molding relation. The filling and
assembly zone 50 surrounds a portion of the conveying or
transport means 32, which delivers to the zone pallets
concave and convex lens mold sections, respectively, and
at the terminus of the zone carries pallets of paired
20 and filled molds to the procure zone. The filling and
assembly zone illustrated in Figure 2 at 50 is defined
by a geometrically appropriate, transparent enclosure,
generally of rectangular cross-section, formed of any
suitable thermoplastic or metal and thermoplastic
25 construction.

As illustrated at 107 in Figure 1, the concave lens
mold sections are filled with degassed monomer
composition from step 108, and then transported to an
assembly module optionally having a vacuum chamber
30 formed intermittently within the nitrogen tunnel in

which filled concave lens molds are engaged with convex
1 mold sections in vertical alignment and in mating
relation, such that the reactive monomer composition is
trapped between the optical surfaces of the respective
mold sections and at least partially sealed by the
5 engagement of the parting edge formed peripherally in
each of the lens mold sections. If present, the vacuum
is released. Then, the mated mold is passed through
nitrogen to the precure station, an integral part of the
nitrogen tunnel.

10 Following assembly of the mold parts, the incipient
lens monomer is precured at step 109 in the precure
module 60 of the present invention. The process of the
procure involves clamping the mold halves in
registration and then precuring the monomer or monomer
15 mixture to a gel like state.

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

20 In the cure zone (75), the monomer/diluent mixture
is then cured in a UV oven whereby 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
25 source of heat which is effective to raise the
temperature of the polymerizable 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
30 that it is exposed to the ultraviolet radiation.

After the polymerization process is completed, the
1 two halves of the mold are separated during a demolding
step 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 front and back
5 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
10 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
greater the temperature gradient between the surfaces of
the mold portions, the greater the shearing force and
15 the easier the mold portions separate. This effect is
greatest when there is maximum thermal gradient. As
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
20 environment. The heated back mold portion is,
therefore, promptly removed so that very little energy
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
25 skilled in the art such as by steam, laser and the like.
The process of laser demolding is described in U.S.
Patent No. 5,294,379 to Ross et al.

If the heating step is hot air or steam, after the
heating step, the back curve is pried from the front
30 curve and mold in the mold assembly, as indicated at

Step 111. If on the other hand, the heating is by laser
1 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
5 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
10 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.

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

20 In the processes described hereinabove, when the
base mold does not contain the additive or wetting agent
therein, many 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
25 lenses. Without wishing to be bound, these defects are
caused by two different mechanisms. The chips are
caused during the demolding process and were noticed
when the base curve was separated from the front curve
using the prying mechanisms described hereinabove.
30 However, when the appropriate additive is present in the

back curve, demolding is facilitated and the back curve
1 is more easily removed. As a result, there are greatly
reduced instances of lens damage during the demolding
step, in which the back curve is separated from the
front curve and the lens, which stays in the front
5 curve. Without wishing to be bound, it is believed that
the additive in the back curve modifies the adhesion
forces between the lens and the base curve. For
example, when polystyrene alone is used, it adheres very
strongly to the polymeric material of the lens; however,
10 when the additive is added to the polystyrene, the
presence of the additive weakens the friction forces
between the polystyrene and the lens material, making it
easier to separate the back curve from the lens and the
front curve mold. Thus, there is less stress on the
15 lens surface during demolding, making 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 mold releasing
20 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,
25 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
30 tunnel at lower temperature, such as about 60 to 70°C,

The additives that are added to the mold material that
1 effectuate those changes are the mold release agents the
oils, soaps, waxes, and the like, describe herein.

Wetting agents, when added to the lens mold
increase the wetting of the mold material. These
5 wetting agents include the anti-static compounds, i.e.,
the alkoxyated amines and the quaternary ammonium
complexes and the stearic salts, described herein.

Without wishing to be bound, it is believed that
the original polystyrene or polypropylene mold (i.e.,
10 the mold without additional wetting agents) was a low
energy heterogeneous surface having a small portion of
high energy area. For example, the mold surface when
composed of polystyrene has a mold surface free energy
of 42 dynes/cm. A heterogeneous polystyrene or
15 polypropylene mold surface with small portions of high
energy surface area caused local non-wetting and voids,
which in turn led to lens holes. The lens hole problem
was a problem of prior wetting between the reactive
monomer mix and the mold surface.

20 When the wetting agent is added to the mold
surface, it significantly improved its wettability. The
surface became more homogenous and the high energy
surface area was significantly increased. As a result,
using the mold material wetting formulation of the
25 present invention instead of the typical formulation,
lens holes were reduced significantly. For example,
using zinc stearate, as the additive in a polystyrene
back curve mold, the lens holes were reduced from the
typical 10 to 15% to less than 2%.

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However, in many cases, even when the thermoplastic
1 material is admixed with either a wetting agent or
additive, the resulting contact lenses have not only a
minimum of holes or tears, respectively but
concomitantly therewith, the contact lenses have
5 improved yields. For example, when the contact lenses
were prepared utilizing a backcurve comprised of
polystyrene and 1% zinc stearate as the wetting agent,
as described hereinabove, the resulting contact lenses
had significantly less holes. Lens puddles are also
10 significantly reduced. Concomitant therewith, however,
the amount of chips and tears were decreased, with lens
yield improving 7 to 9%. Although such result may
indicate that zinc stearate may also act as a mold
releasing agent, further experiments show that the zinc
15 stearate is not acting in that capacity. In a study
measuring demold forces at various temperatures between
contact lens and the polystyrene mold, the results show
that there was little or no effect when zinc stearate
was used. The major effect on lens demold (or lens
20 release) was due to the higher temperature.
Observations of lens demold operation during production
did not show any de-mold difference between molds with
and without zinc stearate addition.

Similarly, a backcurve comprised of Abilwax, was
25 not wettable in accordance with the wetting test as
described hereinabove. It produced, as expected based
upon the teachings herein, contact lenses having
significantly less chips and tears. However, as shown
in Example 8, under the conditions therewith,

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concomitantly, contact lenses where produced having less
1 holes.

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

The present invention is more specifically
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
10 limit scope of the present invention.

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EXAMPLE 1

1 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
5 contained 8 base mold halves (cavities) arranged as
depicted therein. The mold halves were comprised of the
various formulations described hereinbelow and contact
lens were prepared in accordance with the procedure
described herein..
10 The frame parameters are presented in the following
Table.

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TABLE 1

1			FRAME ANALYSIS			
			C-1	C-3	C-6	C-8
5		HUNTSMAN 202 (Polystyrene)				
	FRAME #1	RADIUS P/V	8.447 0.857	8.447 4.576	8.461 4.368	8.444 1.898
	FRAME #2	RADIUS P/V	8.448 0.891	8.457 3.742	8.417 4.511	8.419 0.986
10	FRAME #3	RADIUS P/V	8.419 0.958	8.461 4.250	8.448 2.581	8.402 8.843
		HUNTSMAN 202/PVDF (Polystyrene)				
	FRAME #1	RADIUS P/V	8.872 0.653	8.881 0.557	8.879 0.595	8.875 0.653
15	FRAME #2	RADIUS P/V	8.879 0.821	8.888 0.631	8.887 0.549	8.877 0.552
	FRAME #3	RADIUS P/V	8.859 0.545	8.816 2.796	8.879 1.323	8.872 2.297
20		HUNTSMAN 202/0.2225% SF1080 (Silicone Oil)				
	FRAME #1	RADIUS P/V	7.855 0.561	7.861 0.677	7.871 0.396	7.858 0.859
	FRAME #2	RADIUS P/V	7.857 0.856	7.862 0.450	7.869 0.578	7.854 0.695
25	FRAME #3	RADIUS P/V	7.855 0.579	7.861 0.724	7.870 0.214	7.858 0.900

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FINAL ANALYSIS

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		C-1	C-3	C-6	C-8
		HUNTSMAN 202/0.5% SF1080 (Silicone Oil)			
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

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LEGEND:

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
PVDF polyvinylidene fluoride

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In table 1, P/V is a roughness measurement, wherein
1 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.

As can readily be seen from the data in Table 1, in
5 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.

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EXAMPLE 2

- 1 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
5 described in the present specification. The results are
presented in Table 2.

TABLE 2

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SET #	% of Edge Defects		TOTAL CHIPS AND TEARS
	CHIP	TEAR	
I	44.50	1.90	46.40
II	20.40	1.10	21.50
15 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
20 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
25 XII	27.50	10.00	37.50

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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 lower in all cases and significantly lower in many cases when the additives is present.

EXAMPLE 3

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

5 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
10 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
15 pilot line at Vistakon.

No steam was applied.

Movement:	3.5 deg	0.5 sec	fast
	6.0 deg	3.0 sec	slow
20	15 deg	4.4 sec	slow (end fast)

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

All lenses, except those with broken flanges, were
hydrated in simulated Maximize process: 5 mins at 70°C,
0.05% Tween 80 in D1-water, followed by 3 mins in D1-
30 water + storage overnight in buffered saline.

The lenses were inspected for visual defects in a
1 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

10

* Avg. value of 3 runs

** only 1 run was performed

Key

CH = Chips

HO = Holes

15

TR = Tears

20

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

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EXAMPLE 4

1% Zinc stearate (Znst) was mixed with polystyrene to produce backcurve molds. The contact lenses were prepared in accordance with the procedures described herein. The amount of holes and the overall yield were measured and compared with a control wherein no additive was added. Three trials were conducted, and the results are indicated hereinbelow.

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TRIAL	ADDITIVE	HOLES	YIELD
1	Control	23%	67%
	1% ZnSt added	2%	85%
5	Control	23%	58%
	1% ZnSt	<2%	84%
3	Control	62%	35%
	1% ZnSt	16%	78%

As clearly shown, the back curve mold comprised of polystyrene admixed with Zinc stearate showed significant reduction of holes and significant increase in lens yields compared to those of the control.

EXAMPLE 5

Various surface active anti-static agents indicated hereinbelow were admixed with polystyrene to produce backcurve molds. The contact lenses were prepared in accordance with the procedure described herein and the amount of holes measured and compared with the control wherein no additive is used. The results are indicated hereinbelow:

1	ANTISTATIC AGENTS	MANUFACTURER	COMPOUND	BACKCURVE MOLD MATERIAL ADDITIVE	HOLES
	-	-	-	NONE	13.5- 17.2%
5	LAROSTAT 264A®	PPG	Soy Dimethyl Ethyl Ammonium Etosulfate	0.5% LARSTAT 264A	5%
10	LAROSTAT 264®	PPG	Soy Dimethyl Ethyl Ammonium Etosulfate	1% LARSTAT 264A®	2.6- 3.6%
15	CYSTAT LN®	CYTEC	3-Lauramido- propyltri- methylul ammonium methylsulfate	0.5% LYSTAT LN®	2.3%
	CYSTAT LN®	CYTEC	3-Lauramido- propyltri- methylul ammonium methylsulfate	1% CYSTAT LN®	16.1- 21.6%
20	ARMOSTAT 410®	AK20	Ethoxylated Tertiary Amine	0.5% ARMOSTAT 410	10.7%
	ARMOSTAT 410®	AK20	Ethoxylated Tertiary Amine	1% ARMOSTAT 410	3.9%
	ATMER 163®	ICI AMERICA	N, N-Bis(2- hydroxyethyl) alkylamine	0.5% ATMER 163®	1.0- 1.3%
25	ATMER 163®	ICI AMERICA	N, N-Bis(2- hydroxyethyl) alkylamine	1% ATMER 163®	0.8%- 1.3%
	ZINC STERATE 8®	SYNPRO	ZINC STEARATE	1% ZINC STEARATE	0.7- 7.5%
	ZINC STERATE 8®	SYNPRO	ZINC STEARATE	2% ZINC STEARATE	2.8%

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EXAMPLE 6

1 Following the procedures of Examples 4 and 5, the
 following materials were used to make the backcurves and
 the lenses were produced in accordance with the
 description herein. The results are indicated
 5 hereinbelow.

Hole Counts of Lenses Made using Various Backcurve Material

	Backcurve Material used to Produce the Lenses	Visual Audits		Tunnel Audits	
		% Holes	95% CL	% Holes	95% CL
10	HCC202H1Y ^a (base resin; production)	9.8	2.4	15.7	4.5
	HCC204HON ^b (base resin)	8.6	2.3	7.0	3.1
	0.25% CYASTAT LS/HCC204HON	0.7	0.5	1.7	1.6
	0.5% CYASTAT LS/HCC204HON	0.2	0.4	0.7	1.0
15	1% ZnSt8/HCC204HON	0.3	0.5	2.0	1.7
	DOW666D ^c (base resin, production)	6.2	1.3	6.5	2.1
	DOW666APR ^d (base resin, production)	4.3	1.7	5.2	2.7
	0.05% CYASTAT LS/DOW666APR	0.5	0.6	1.7	1.6
	0.25% CYASTAT LS/DOW666APR	0.3	0.3	1.8	1.6
20	1% ZnSt8/DOW666APR	0.6	0.1		
	1% ZnSt8+0.05% LAROSTAT 264A/DOW666APR	0.7	0.7	0.3	0.7

^a Polystyrene base resin manufactured by Hunstman Chemicals Corp.

^b Polystyrene base resin manufactured by Hunstman Chemicals Corp.

^c Polystyrene base resin manufactured by Dow Chemicals.

^d Polystyrene base resin manufactured by Dow Chemicals.

EXAMPLE 7

1 1% Zinc stearate was mixed with polystyrene to
produce backcurve molds. The contact lens were prepared
in accordance with the procedures described herein,
except the curing temperatures were modified. The %
5 yields are indicated hereinbelow.

	Yields			
Curing Tunnel Zone I Temperature	43 (°C)	54 (°C) normal operating condition	62 (°C)	69 (°C)
10 Production/Control	31%	36%	34%	30%
1% ZnSt added	71%	73%	68%	72%

15 As shown hereinabove, the lenses made using 1% zinc
stearate molds under the above wide temperature range
gave about the same high yields. In addition, they gave
low holes. Thus, the zinc stearate modified molds
allows a wide range of variations in curing conditions
20 and do not affect the lens yields.

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EXAMPLE 8

- 1 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
5 halves were pried apart, the percentage of holes in the
contact lens produced by that mold was determined. The
results are tabulated hereinabove.

	Type of Material	% of Holes
10	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% 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

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

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The above preferred embodiments and examples are
1 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
5 and examples are within the contemplation of the present
invention. Therefore, the present invention should be
limited only by the appended claims.

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WHAT IS CLAIMED IS:

- 1 1. A mold material constituting a mold half for
 use in the production of contact lenses, said mold
 material comprising a thermoplastic polymer and a
 internal additive which is impregnated into said
5 thermoplastic material and which is present in amounts
 ranging from about 0.05% to about 5% by weight, said
 thermoplastic material being polystyrene or
 polypropylene and said additive being a polyethylene or
 polypropylene wax having a molecular weight ranging from
10 about 5000 to about 200,000, 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, fatty acid
15 having a molecular weight of about 200 to about 2000, a
 complex ester or a combination thereof.

2. A mold material constituting a mold half for
 use in the production of contact lenses, said mold
 material comprising polystyrene and an wetting effective
20 amount of a wetting agent admixed therewith, the wetting
 force of said mold material being described by the
 equation:

$$F = 2\gamma_1 p \cos \theta$$

where F is the wetting force of the mold half

- 25 γ_1 is the surface tension of distilled water

p is the perimeter of the mold material at the
meniscus when the mold half is partially immersed in the
water and

- θ is dynamic contact angle, wherein the contact
30 angle of said mold material is less than 100° .



3. The mold material of claim 1 in which the
1 amide wax is a fatty acid amide wax.

4. The mold material of claim 1 wherein the
thermoplastic polymer is polystyrene.

5. The mold material of claim 1 wherein the
5 thermoplastic polymer is polypropylene.

6. The mold material of claim 1 wherein the
additive is present in amounts ranging from about 0.1 to
about 2.5% by weight.

7. The mold material of claim 1 wherein the
10 additive is silicone.

8. The mold material of claim 2 wherein the
additive is an anti-static agent or lubricant.

9. The mold material of claim 2 in which the
wetting agent is an ethoxylated amine, hydroxy alkyl
15 tertiary amine or quaternary ammonium sulfate, stearic
acid or salt thereof.

10. The mold material of claim 9 wherein the
wetting agent is ethoxylated tertiary amine, N,-N-Bis(2-
hydroxyethyl) alkylamine, zinc stearate, (3-
20 Lauramidopropyl) trimethyl ammonium methyl sulfate, or
soy Dimethyl Ethyl Ammonium Ethosulfate.

11. 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
25 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
30 surface having the dimensions of the back curve of the



desired swelled or unswelled contact lens to be produced
1 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
5 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
10 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 the
15 mold material comprised of a thermoplastic polymer
admixed with an additive or anti-wetting agent in
accordance with claim 1.

12. The mold half of claim 11 wherein the additive
is a fatty acid amide wax.

20 13. The mold half of claim 11 wherein the
thermoplastic polymer is polystyrene.

14. The mold half of claim 11 wherein the
thermoplastic polymer is polypropylene.

25 15. The mold half of claim 11 wherein the additive
is present in amounts ranging from about 0.1 to about
2.5% by weight.

16. The mold half of claim 11 wherein the additive
is silicone.

30 17. 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
1 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
5 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
10 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
15 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
20 prying forces applied to separate said mold half from
said mold assembly, and said mold half being comprised
of a mold material comprised of a polystyrene admixed
with a wetting agent in accordance with claim 2.

18. The mold half of claim 17 wherein the contact
25 angle of the mold material is less than or equal to 90°.

19. The mold half of claim 17 wherein the wetting
agent is an ethoxylated amine, hydroxy alkyl tertiary
amine, or quaternary ammonium sulfate, stearic acid or
salt thereof.

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20. The mold half of Claim 17 wherein the contact
1 angle of the mold material is less than or equal to 75°.

21. The mold half of Claim 17 wherein the amount
of wetting agent present from 0.05% to 5% (w/w).

22. The mold half of Claim 21 wherein the amount
5 of wetting agent present range from 0.1% to 2.5% (w/w).

23. The mold half of claim 17 wherein the mold
material is ethoxylated tertiaryamine, N,N-Bis(2-
hydroxyethyl)alkylamine, zinc stearate, 3-
(Lauramidopropyl) trimethylulammonium methyl sulfate, or
10 soy dimethyl Ethyl Ammonium Ethosulfate.

24. 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
15 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,
20 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
25 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;

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said first article having an annular flange
1 integral with and surrounding said circular
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
5 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
10 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 so that the
surface of a contact lens formed by polymerization of
said polymerization composition in contact with said
15 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
20 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
circumferential edge of said front mold half;

25 said back mold being comprised of a mold material
comprised of a thermoplastic polymer admixed with an
additive in accordance with claim 1.

25. The mold assembly of claim 24 in which the
additive is a fatty acid amide wax.

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26. The mold assembly of claim 24 wherein the
1 thermoplastic polymer is polystyrene.

27. The mold assembly of claim 24 wherein the
thermoplastic polymer is polypropylene.

28. The mold assembly of claim 24 wherein the
5 additive or wetting agent is present in amounts ranging
from about 0.1 to about 2.5% by weight.

29. The mold assembly of claim 24 wherein the
additive is silicone.

30. A mold assembly used in the production of a
10 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
15 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
20 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
25 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
30 circumferential edge and extending therefrom in a plane



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normal to the axis of said concave surface, and
1 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,
5 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 so that the
10 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
integral with and surrounding said circular
15 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
20 convex surface of said back mold half contacts the
circumferential edge of said front mold half;

said back mold being comprised of a mold material
comprised of a polystyrene admixed with an wetting agent
in accordance with claim 2.

25 31. The mold assembly of claim 30 wherein the
contact angle is less than 90°.

32. The mold assembly of claim 30 wherein the
wetting agent is an ethoxylated amine hydroxy alkyl
tertiaryamine, quaternary ammonium sulfate, stearic acid
30 or salt thereof.



33. The mold assembly of claim 30 wherein the
1 wetting agent is ethoxylated tertiary amine, N,N-Bis(2-
hydroxyethyl)alkylamine, zinc stearate, 3-
(Lauramidopropyl) trimethylulammonium methyl sulfate, or
soy dimethyl Ethyl Ammonium Ethosulfate.

5 34. The mold assembly of Claim 30 wherein the
contact angle is less than or equal to about 75°.

35. The mold assembly of Claim 30 wherein the
wetting agent is present in amounts ranging from about
0.05% to 5% (w/w).

10 36. The mold assembly of Claim 35 wherein the
wetting agent is present in amounts ranging from about
0.1 to about 2.5% (w/w).

37. In an improved process for forming a contact
lens from a mold assembly comprising a front mold half
15 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;

said front mold half comprising a first article of
20 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
25 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
30 acceptable;



said back mold half comprising a second article of
1 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
5 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 so that the surface of a contact lens formed by
polymerization of said polymerizable composition in
10 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;

15 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
20 separated from the contact lens, the improvement
comprising utilizing a back curve mold that is comprised
of the mold material of claim 1.

38. The process of claim 37 wherein the
thermoplastic polymer is polystyrene.

25 39. The process of claim 37 wherein the
thermoplastic polymer is polypropylene.

40. The process of claim 37 wherein the additive
is present in amounts ranging from 0.1 to 2.5% by
weight.

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41. The process of claim 37 wherein the additive
1 is silicone.

42. 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
5 defining and enclosing a cavity therebetween, and
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,
10 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
15 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 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
25 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 so that the surface of a contact lens formed by
polymerization of said polymerizable composition in
30 contact with said surface is optically acceptable,



wherein the convex surface of said back mold contacts
1 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
5 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
10 comprising utilizing a back curve mold that is comprised
of the mold material of claim 2.

43. The process of Claim 42 wherein the contact
angle is less than or equal to 90° .

44. The process of Claim 42 wherein the contact
15 angle is less than or equal to 75° .

45. The process of Claim 42 wherein the wetting
agent is present in amounts ranging from about 0.05% to
about 5% (w/w).

46. The process of Claim 42 wherein the wetting
20 agent is present in amounts ranging from about 0.1% to
about 2.5% (w/w).

47. The process of claim 42 wherein the anti-
wetting agent is an ethoxylated amine, hydroxy alkyl
tertiary amine, or quaternary ammonium sulfate, or
25 stearic acid or salt thereof.

48. The process of claim 42 wherein the mold
material is ethoxylated tertiaryamine, N,N-Bis(2-
hydroxyethyl)alkylamine, zinc stearate, 3-
(Lauramidopropyl) trimethylul ammonium methyl sulfate, or
30 soy dimethyl Ethyl Ammonium Ethosulfate.



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49. The mold material of Claim 2 in which the
1 wetting agent is present in amounts ranging from about
0.05% to 5% (w/w).

50. The mold material of Claim 49 in which the
wetting agent is present in amounts ranging from 0.1% to
5 2.5% (w/w).

51. The mold material of Claim 2 in which the
dynamic contact angle is less than or equal to about
90°.

52. The mold material of Claim 51 in which the
10 dynamic contact angle is less than or equal to about
75°.

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ABSTRACT

1 The present invention is directed to a composition
comprising polystyrene or polypropylene with at least
0.05% (w/w) of an additive or wetting agent, the article
of manufacture comprised thereof, such as a mold for
5 making contact lenses and the mold assembly containing
said mold, and the use of such mold so to minimize
defects, such as holes, puddles, chips and tears in the
lens.

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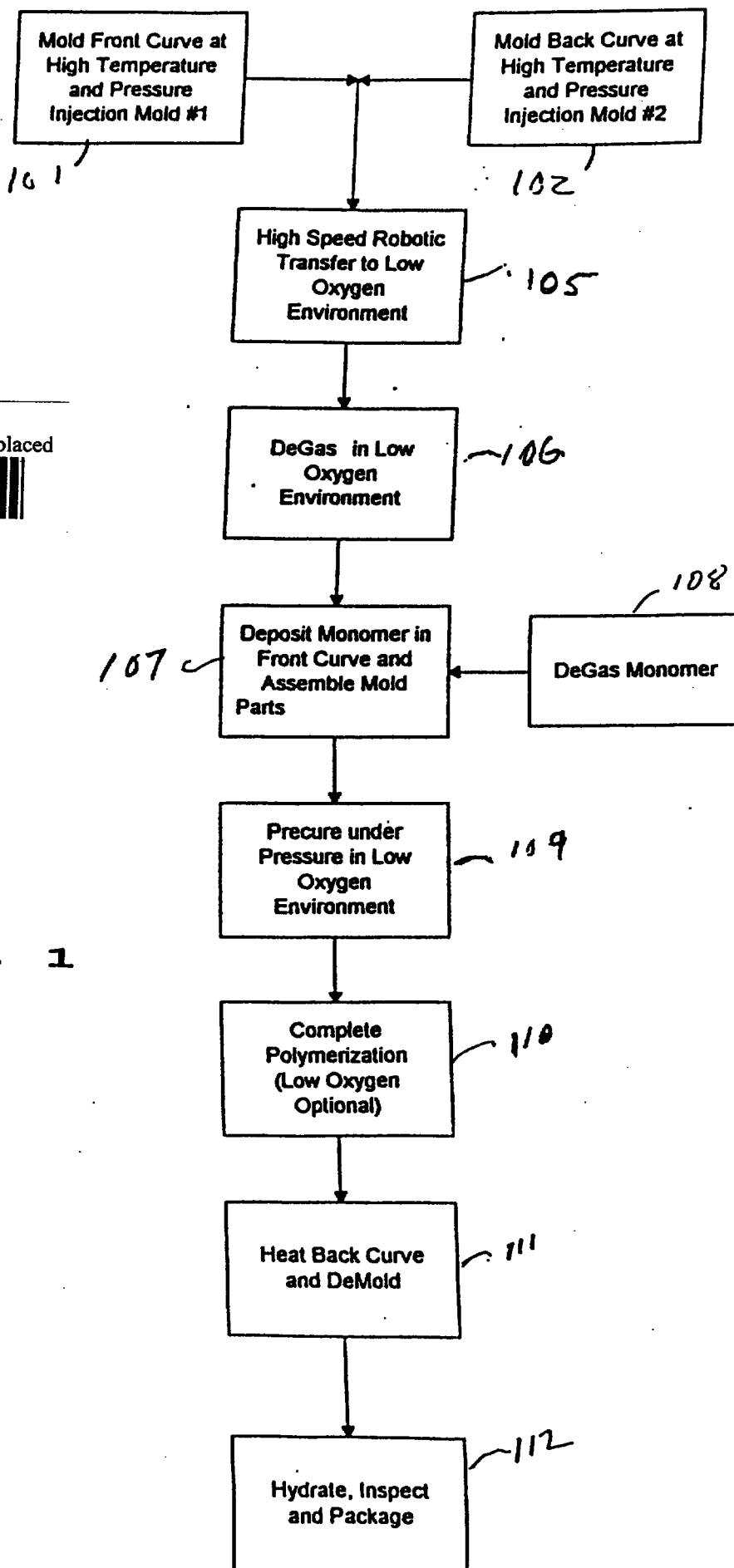


FIG. 1

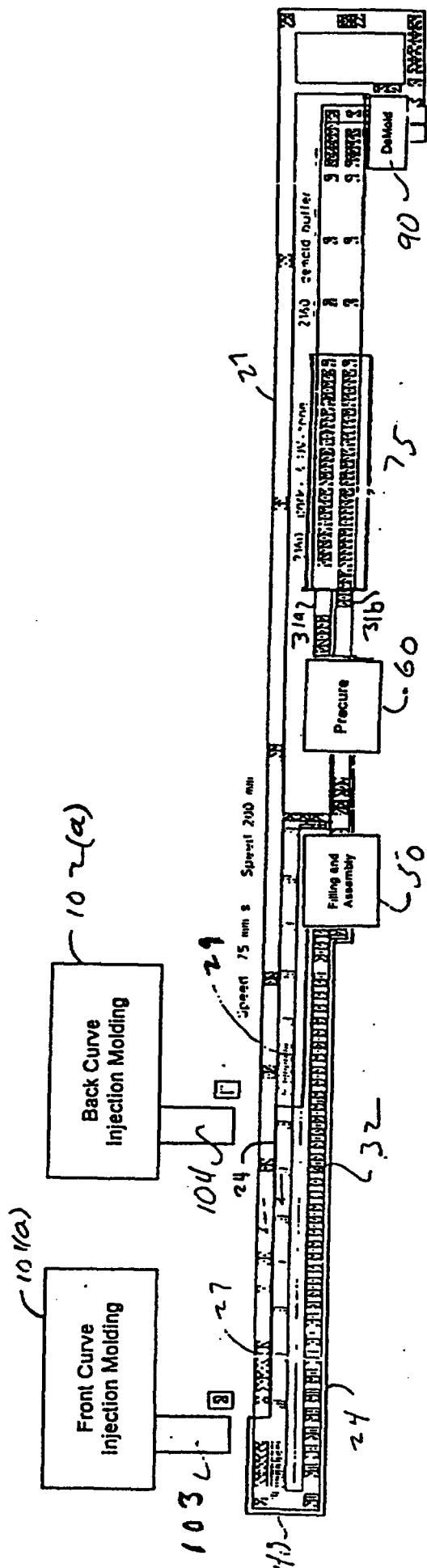
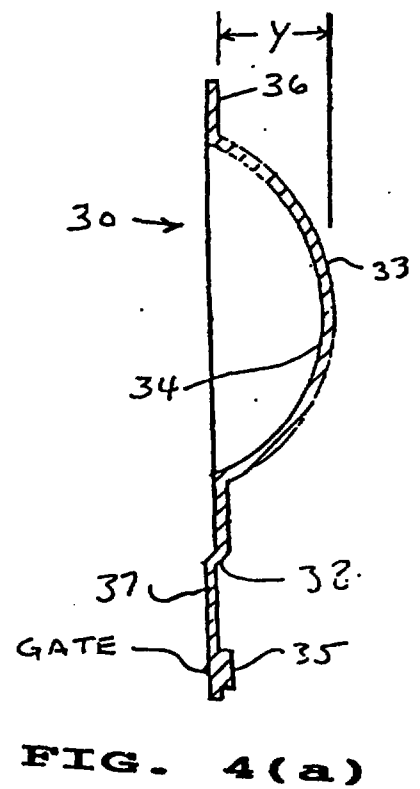
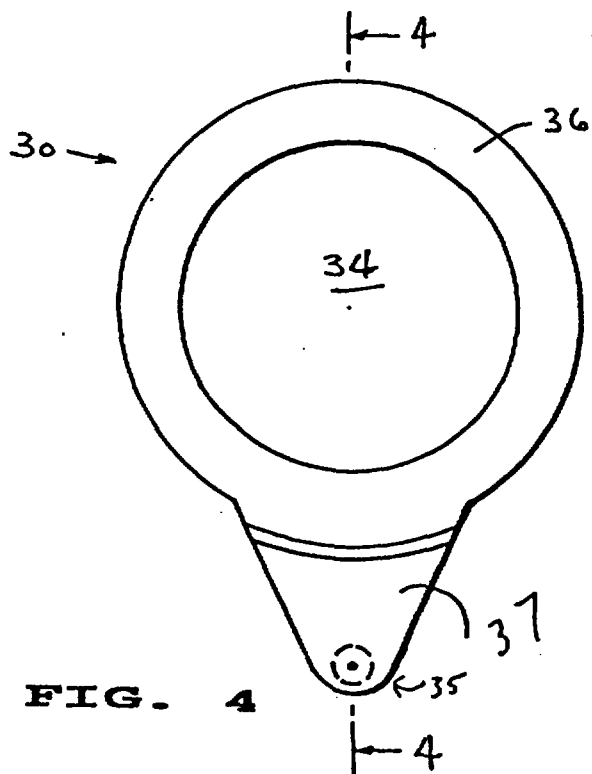
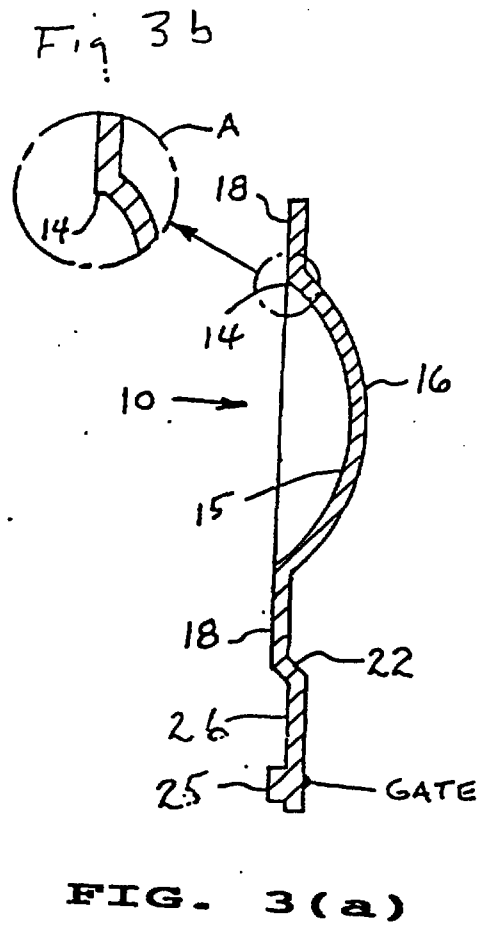
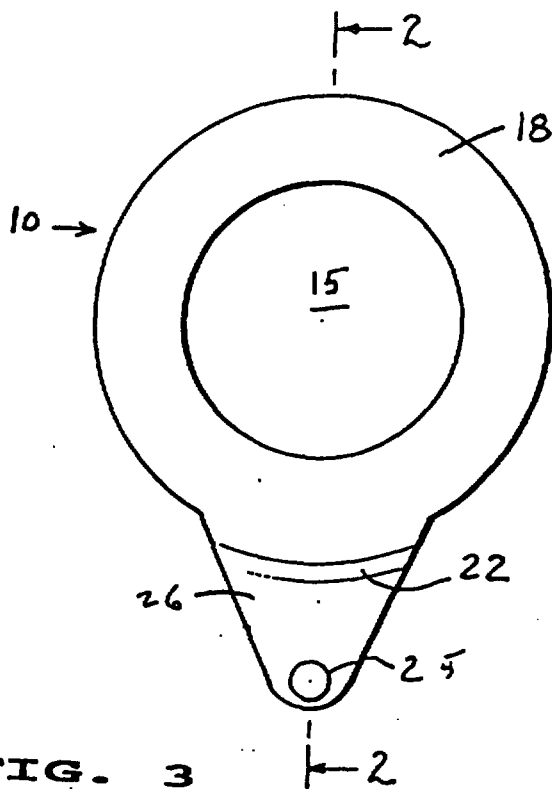


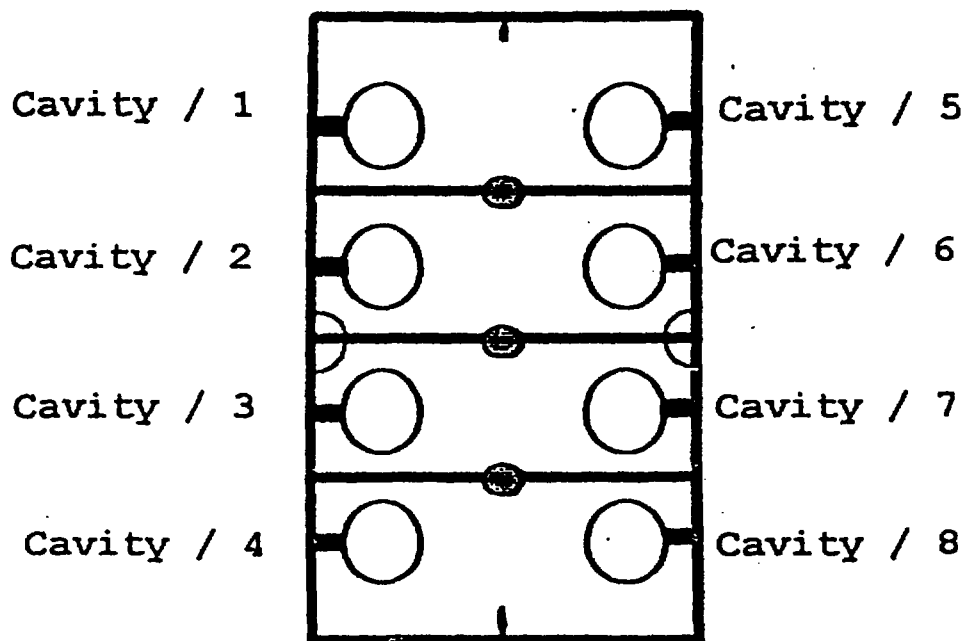
FIG. 2

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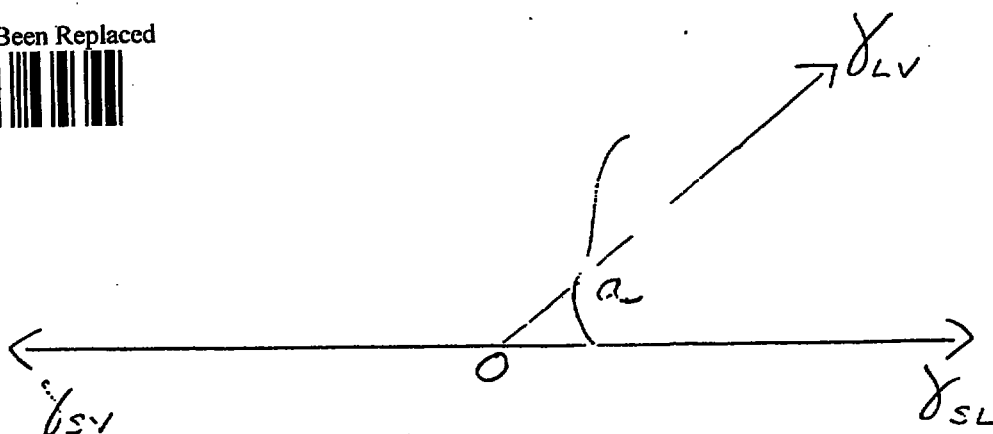
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Base Curve Frame

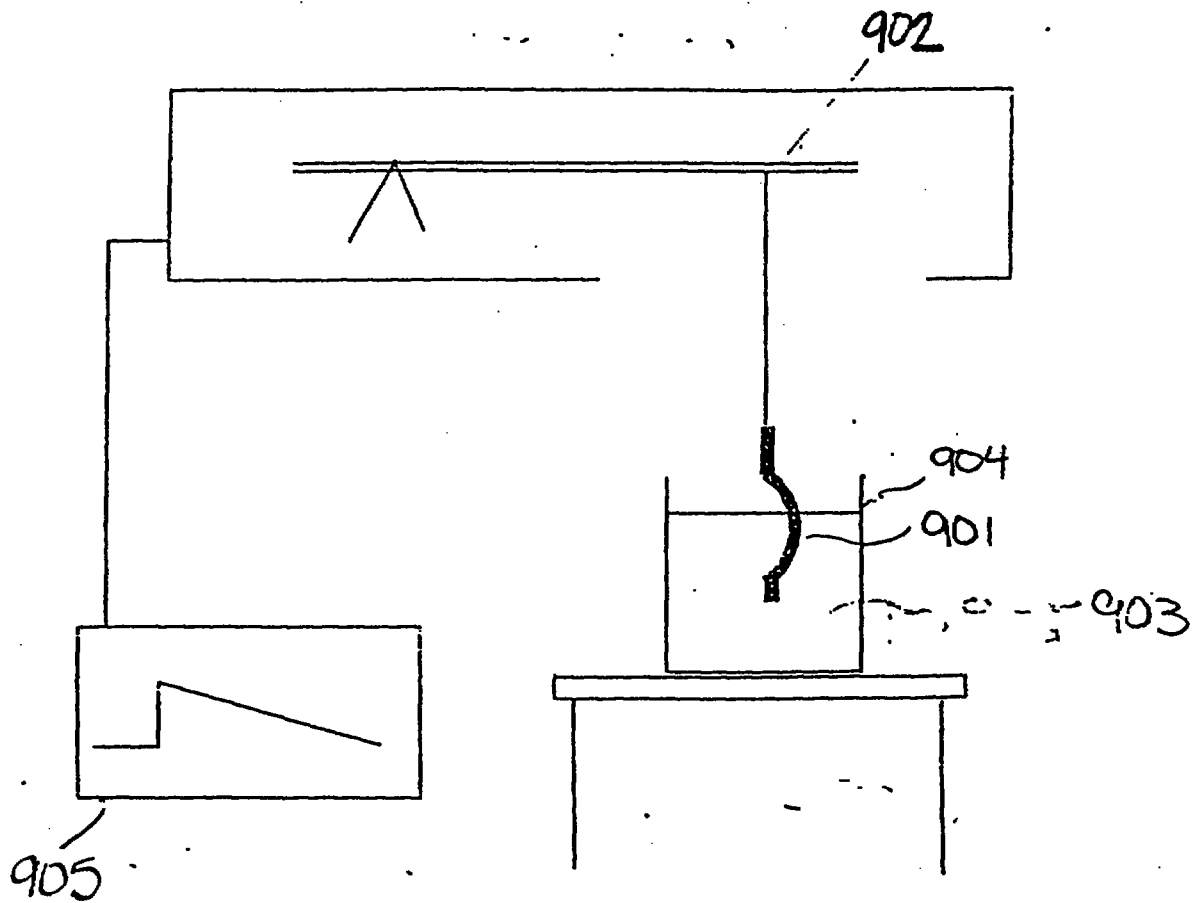
FIG. 5

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PRIOR ART

FIGURE 6

**FIGURE 7**

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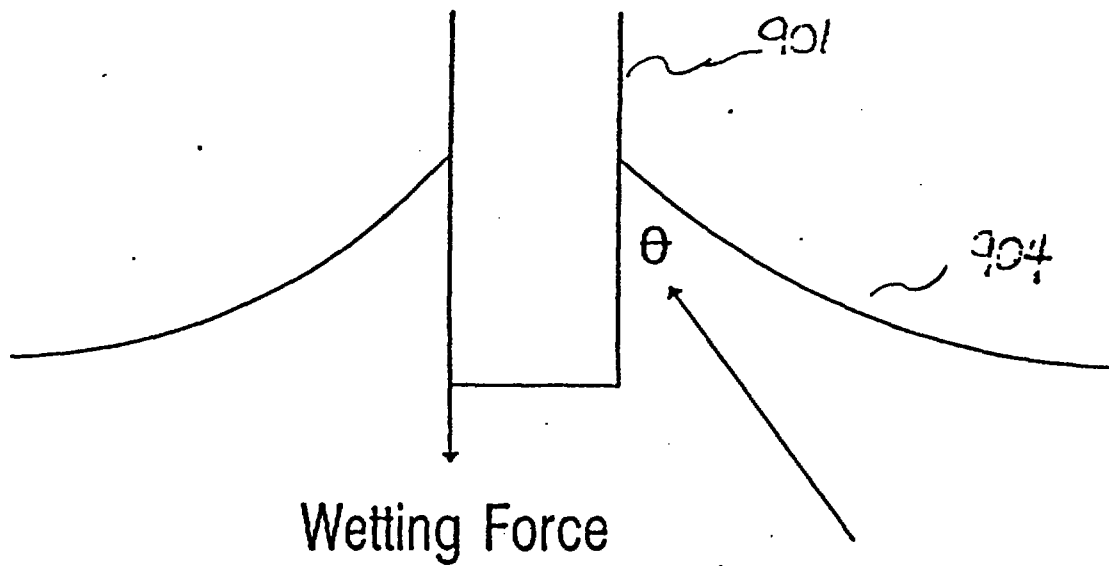


FIGURE 8

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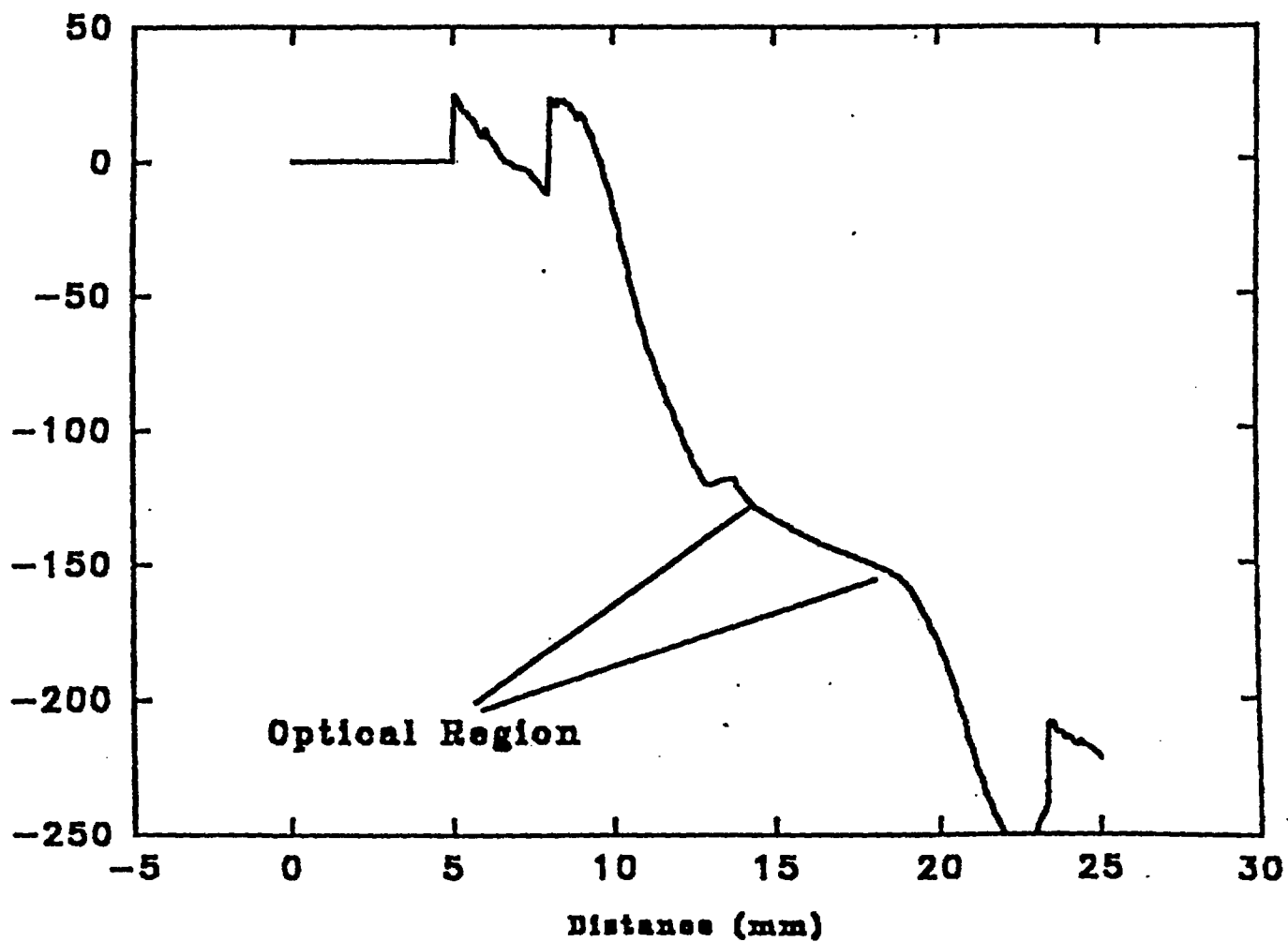


FIGURE 9

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MOLD MATERIAL MADE WITH ADDITIVES

ABSTRACT

- 1 The present invention is directed to a composition
comprising polystyrene or polypropylene with at least
0.05% (w/w) of an additive or wetting agent, the article
of manufacture comprised thereof, such as a mold for
5 making contact lenses and the mold assembly containing
said mold, and the use of such mold so to minimize
defects, such as holes, puddles, chips and tears in the
lens.

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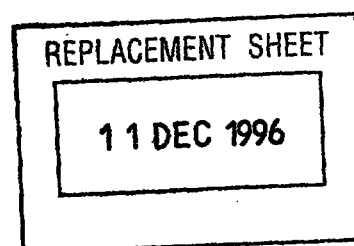
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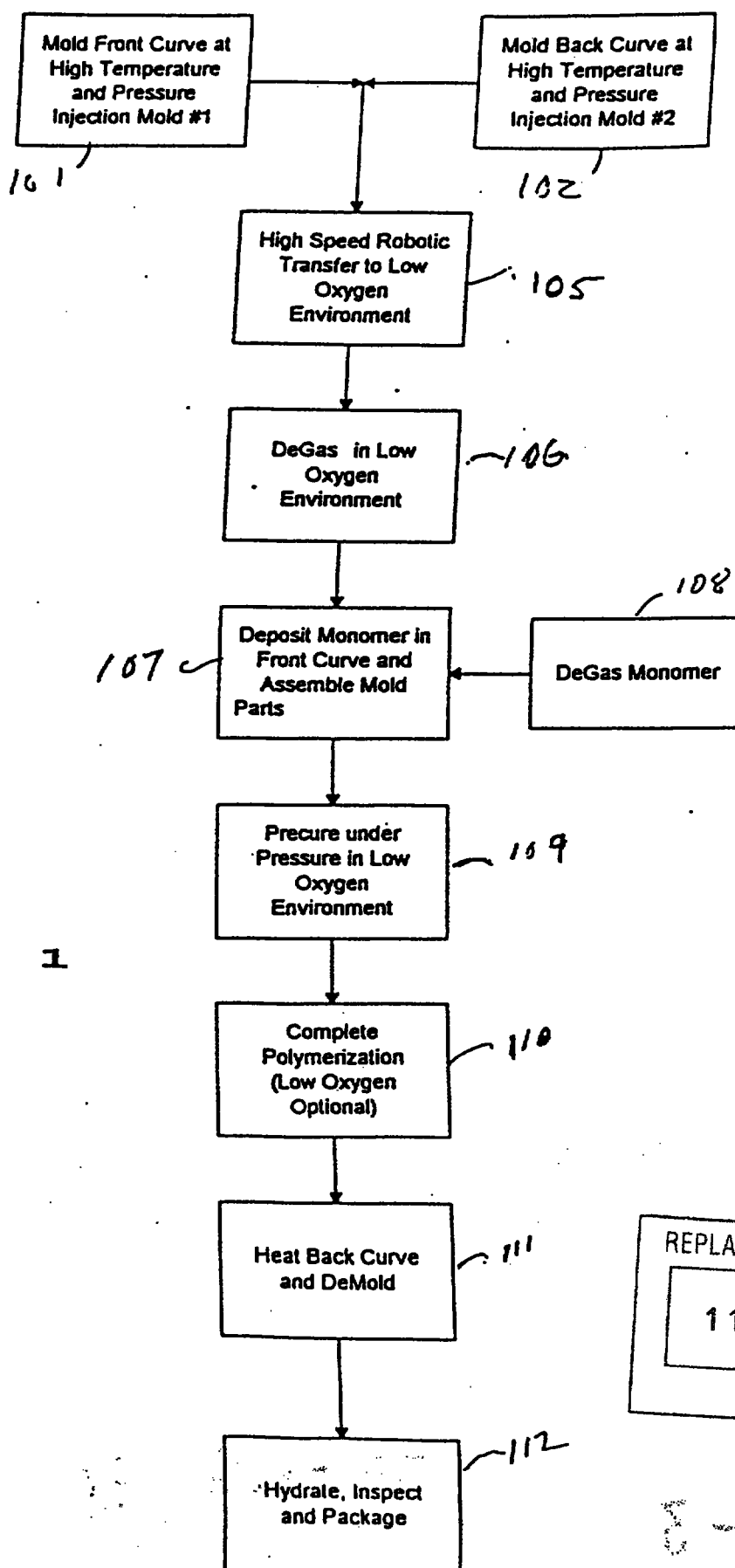


FIG. 1

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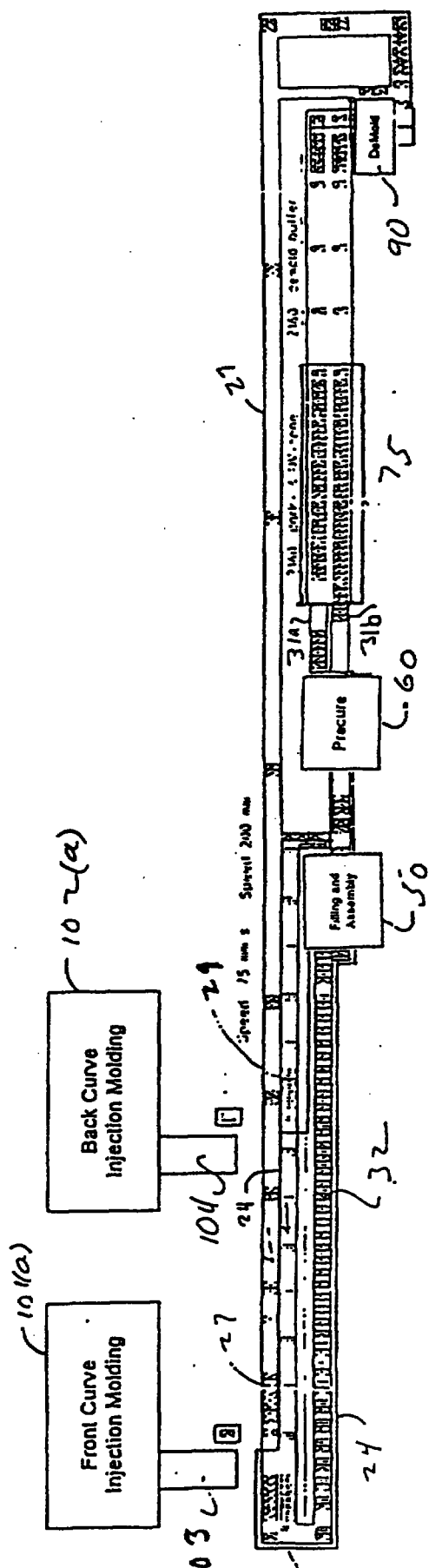


FIG. 2

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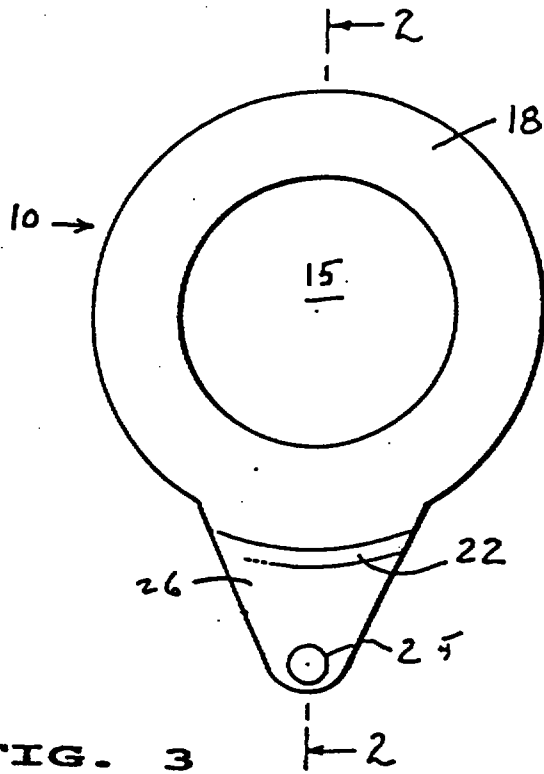


FIG. 3

Fig 3 b

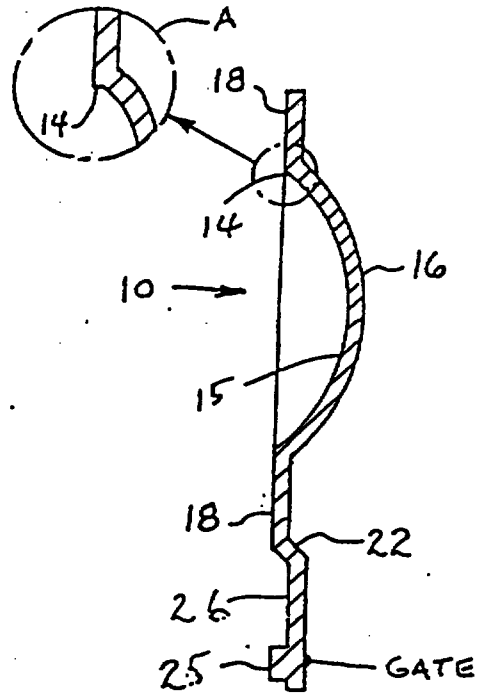


FIG. 3(a)

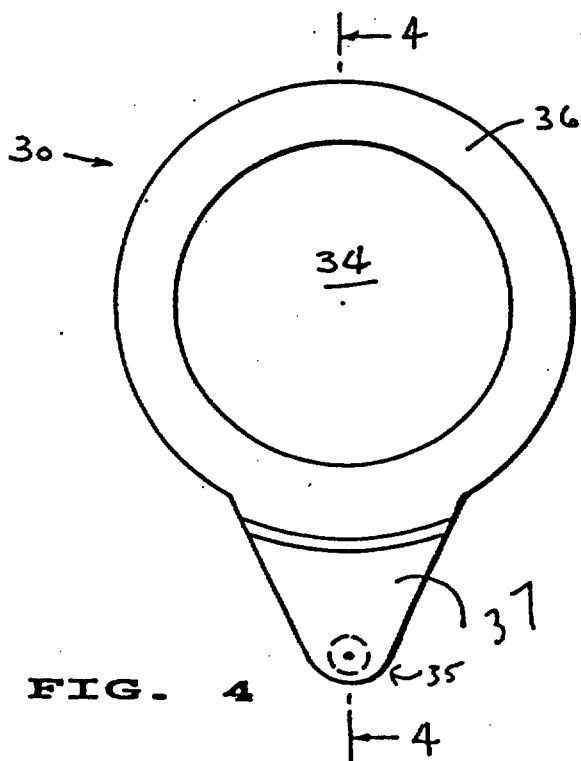


FIG. 4

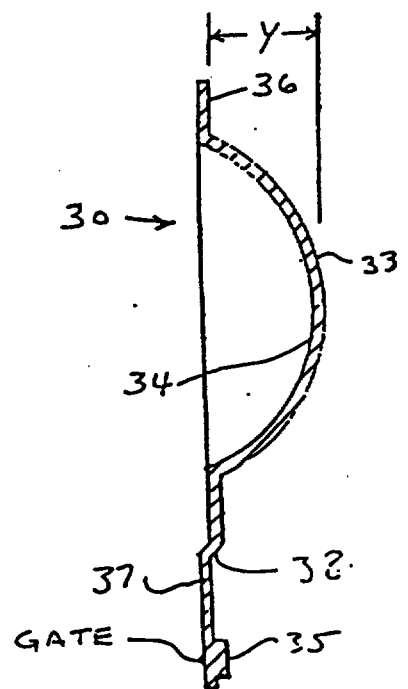
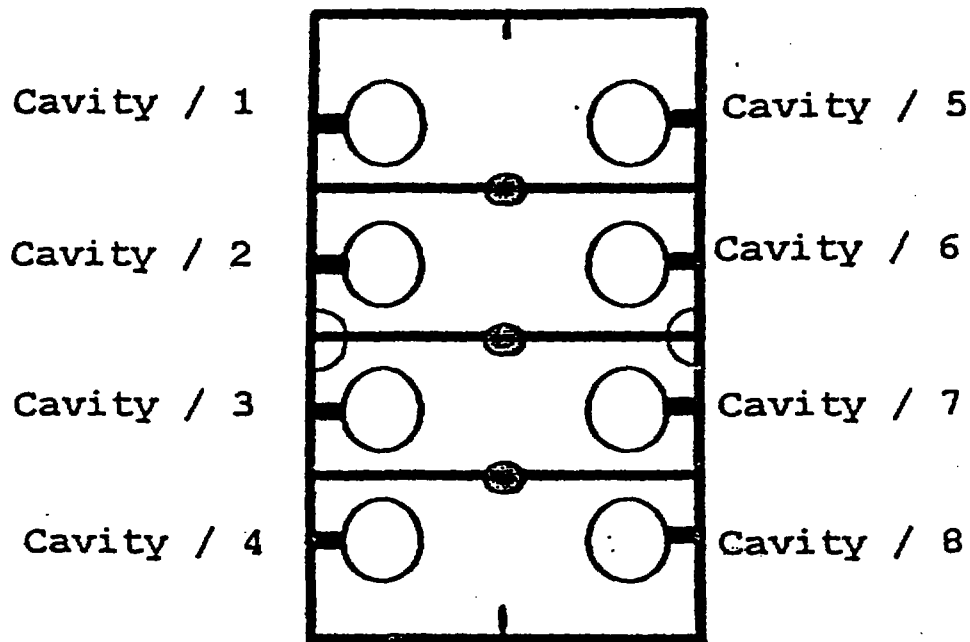
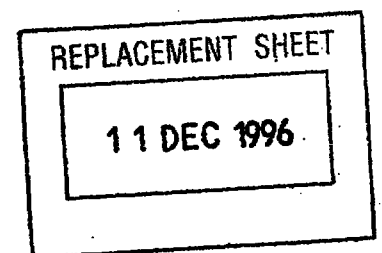


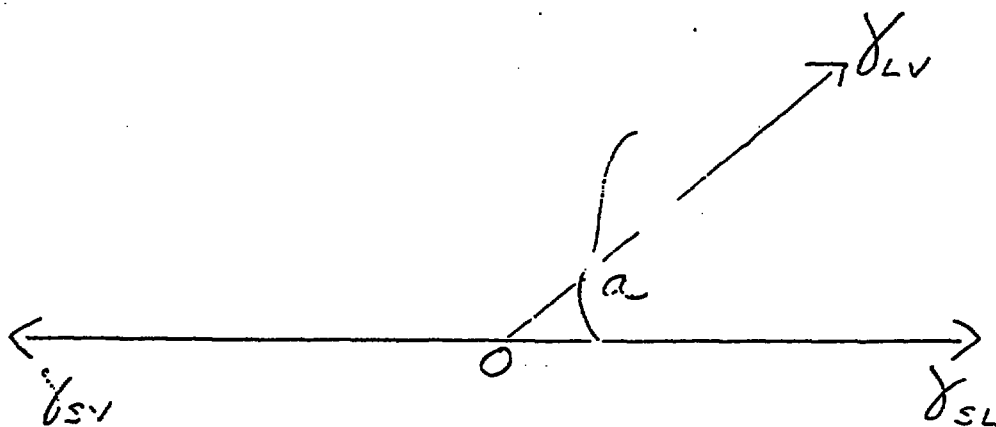
FIG. 4(a)



Base Curve Frame

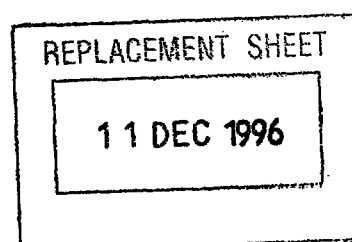
FIG. 5





PRIOR ART

FIGURE 6



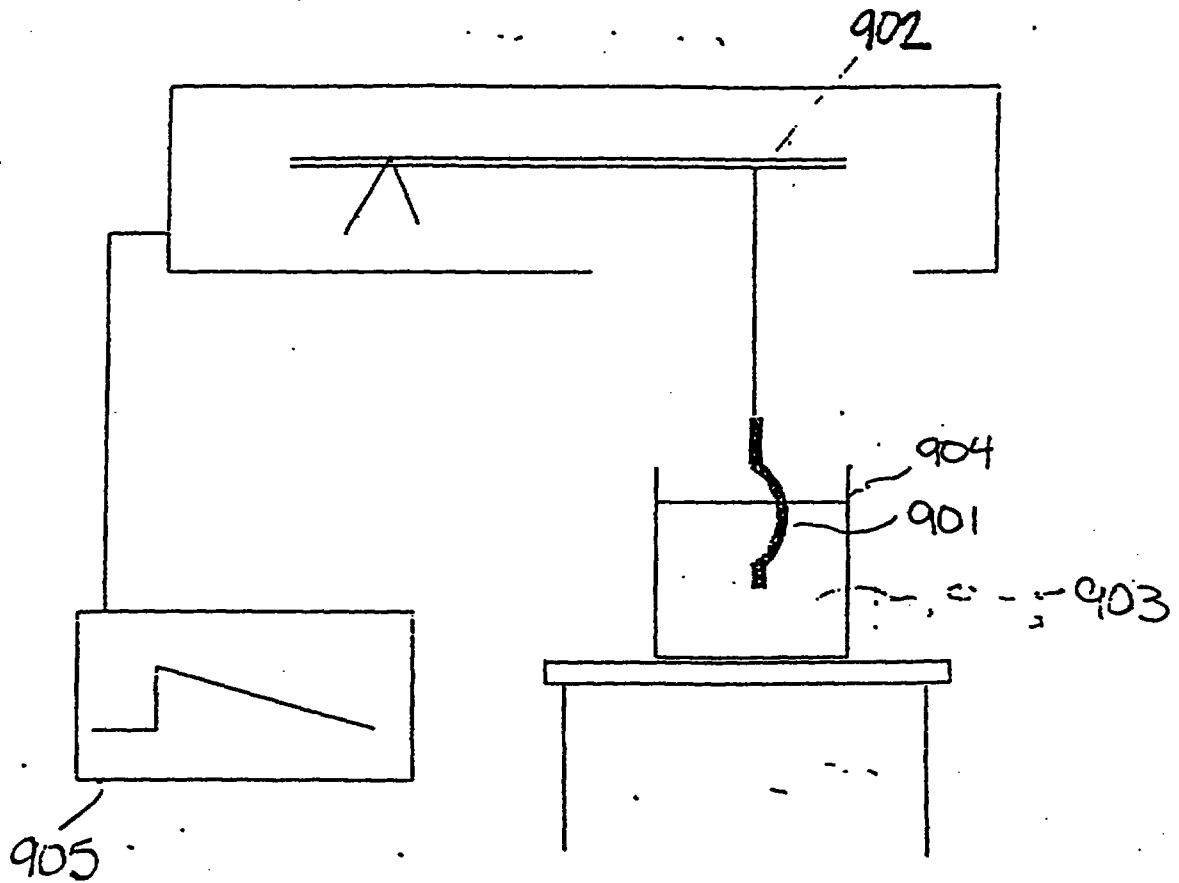
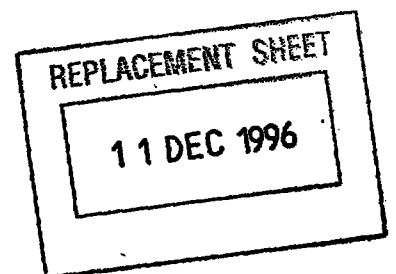


FIGURE 7



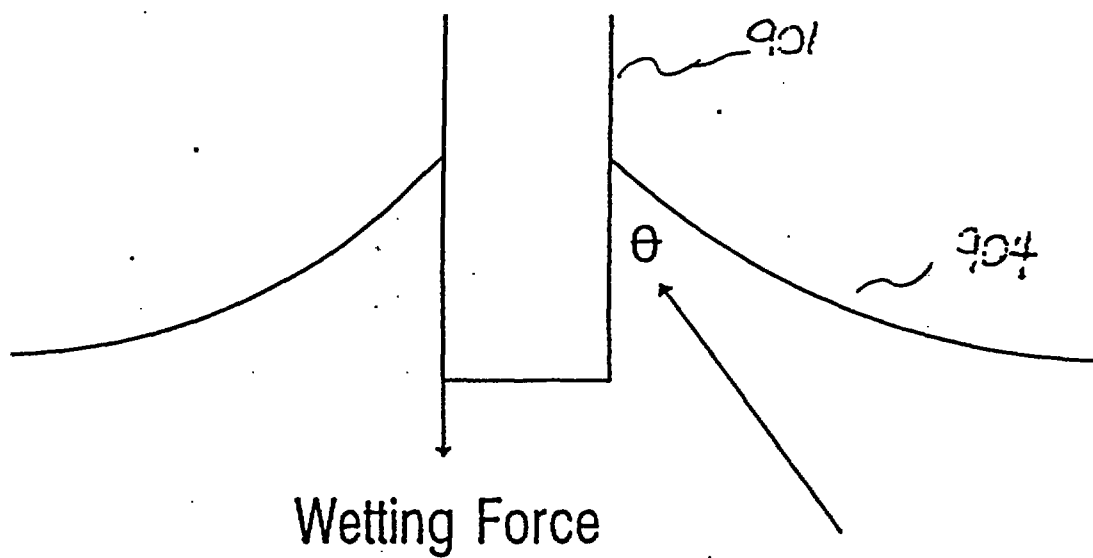


FIGURE 8

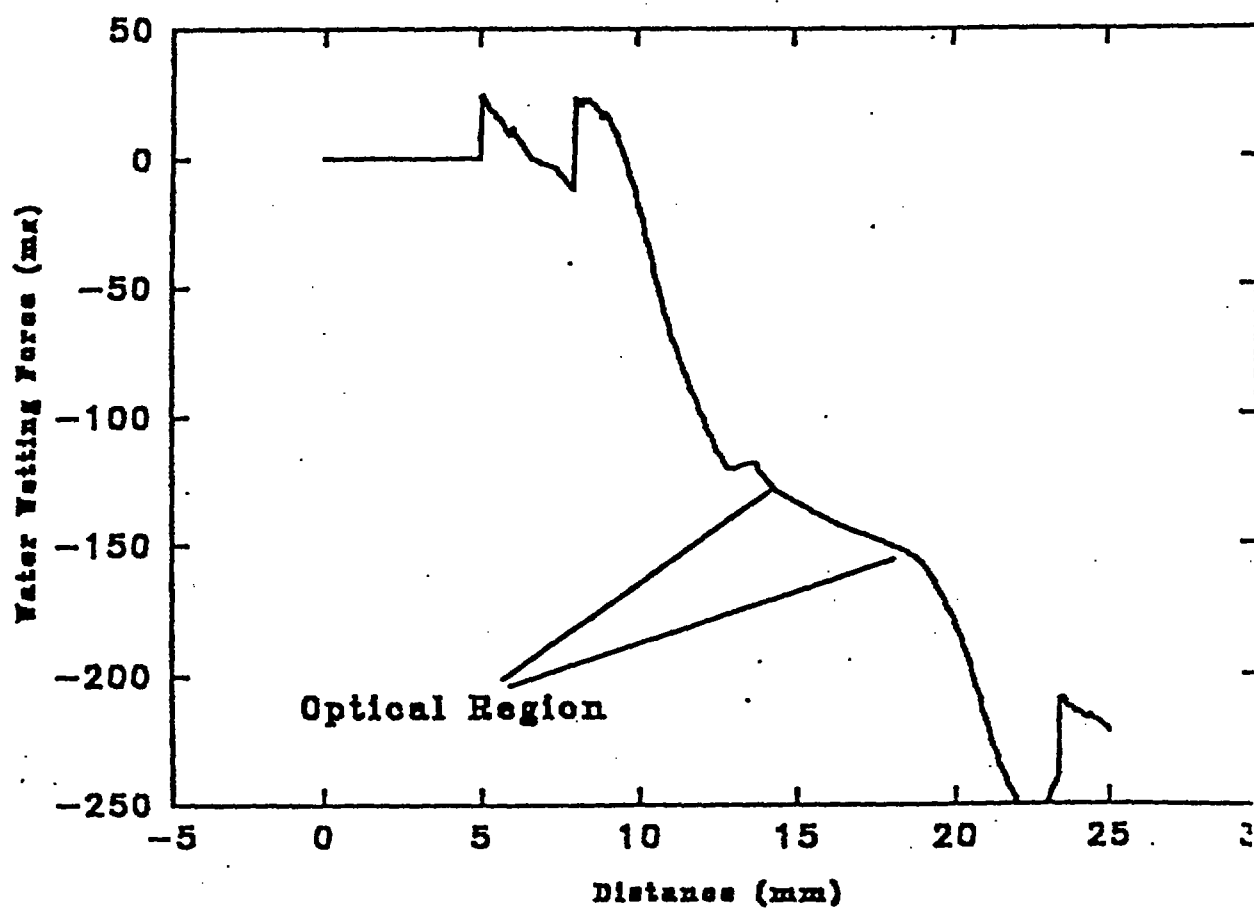


FIGURE 9

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MOLD MATERIAL MADE WITH ADDITIVES

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The present invention relates to a novel polymeric formulation containing an internal mold release additive which assists in the release of one mold component from another or an internal mold wetting agent which enhances the interfacial wetting between the reactive monomer mix and the mold surfaces, thereby reducing the amount of defects formed in the contact lens. The present invention is also directed to the molds made from such polymeric formulation as well as to a method of preparing contact lenses from these molds.

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 consist of suitable pallets, each including a plurality of cavities receiving mold parts having female and/or

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MOLD MATERIAL MADE WITH ADDITIVES

ABSTRACT

1 The present invention is directed to a composition
comprising polystyrene or polypropylene with at least
0.05% (w/w) of an additive or wetting agent, the article
of manufacture comprised thereof, such as a mold for
5 making contact lenses and the mold assembly containing
said mold, and the use of such mold so to minimize
defects, such as holes, puddles, chips and tears in the
lens.

Figure 1

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