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Germinario et al.

[54] **METHOD FOR REDUCING PEEL DEFECTS IN ADHESIVE BONDED PLASTICS**

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[51] **Int. Cl.**[7] **B27B 17/00**

[52] **U.S. Cl.** **264/130**; 264/134

[58] **Field of Search** 264/466, 130, 264/210.1, 210.2

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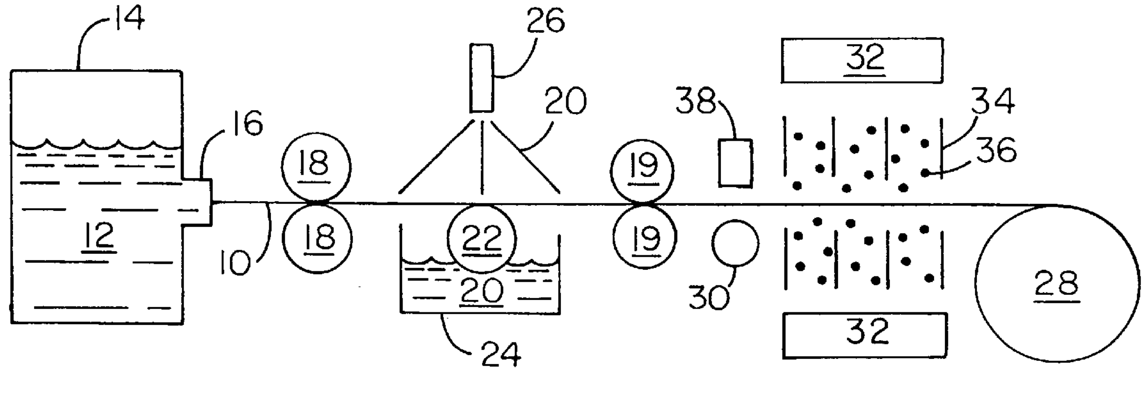
[57] **ABSTRACT**

A method for producing a processed polymeric sheet to be adhesively secured to a cover to form a seal, the sheet having properties such that the seal does not have branching peel defects when it is separated. A polymeric sheet is formed from a source of polymeric material, and at least one side of the polymeric sheet is coated with silicone. The polymeric sheet is further processed while implementing a static neutralization method to substantially eliminate electrostatic discharge across the polymeric sheet during such further fabrication, producing a processed polymeric sheet. Preferably the polymeric material is selected from the group consisting of polyethylene, polystyrene, polyester, polyvinyl chloride, polypropylene, acrylics, acrylonitrile, polycarbonates, polyimide, and cellulosics. The static neutralization method, in different preferred embodiments, may be impregnating the polymeric source with a conductive material to dissipate a static charge on the polymeric sheet, coating the polymeric sheet with a hygroscopic material to attract moisture and dissipate a static charge on the polymeric sheet, at least partially ionizing an air mass and passing the polymeric sheet through the air mass to neutralize a static charge on the polymeric sheet, or passing the polymeric sheet near static neutralization bars to neutralize a static charge on the polymeric sheet.

8 Claims, 1 Drawing Sheet



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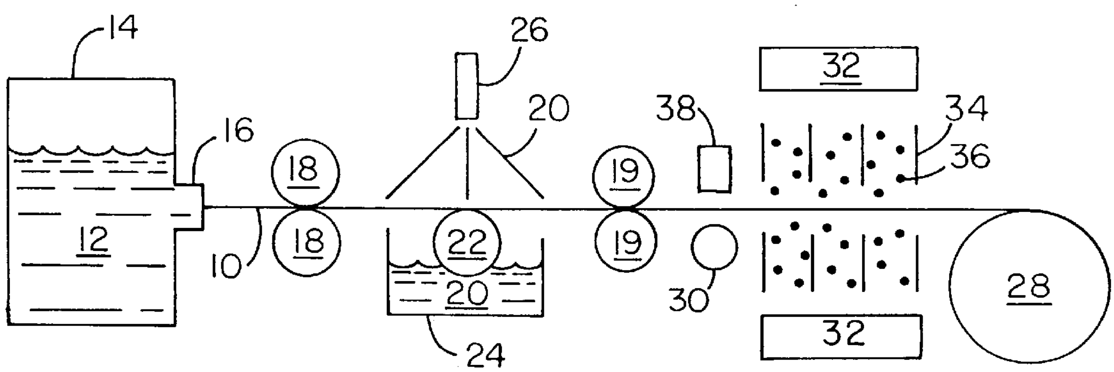

Fig. 1

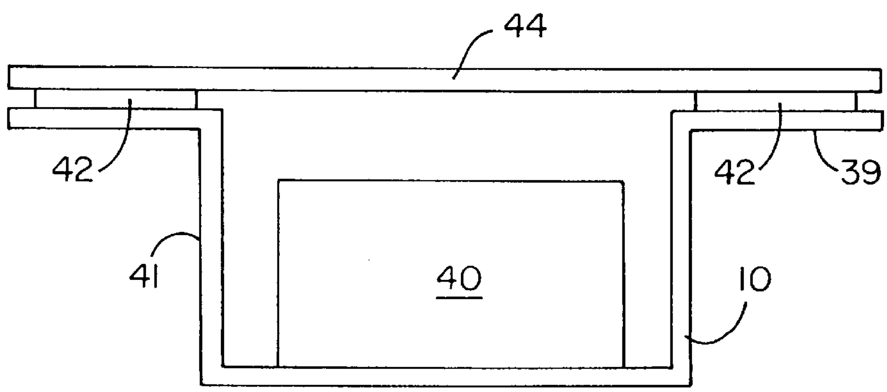

Fig. 2

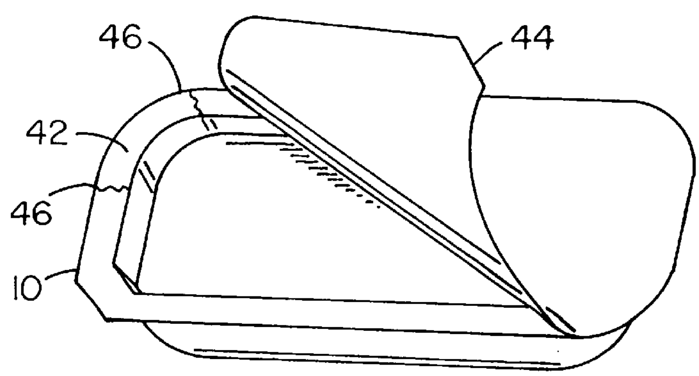

Fig. 3

METHOD FOR REDUCING PEEL DEFECTS IN ADHESIVE BONDED PLASTICS

CROSS REFERENCE TO RELATED APPLICATION

This application claims the benefit of provisional application Ser. No. 60/009,044, filed Dec. 21, 1995.

FIELD OF THE INVENTION

This invention relates to the field of bonding plastics with adhesives. More particularly the invention relates to the field of bonded plastic packaging for sterile items.

BACKGROUND OF THE INVENTION

Many industries, such as the pharmaceutical and medical packaging industries, require aseptic packaging of items that must remain sterile for as long as they are packaged. Therefore, the ability of the package material to act as an adequate bacterial (and other infectious organism) barrier, and the ability of the package seal to remain intact and continuous are important considerations.

The sterility of a package is typically evaluated by the medical professional prior to use by visual inspection of the package surfaces and the peeled sealing surfaces after the package is opened. A puncture in the package or a non-uniform peeled sealing surface indicates that the package contents may not be sterile and should be discarded. A uniform frosty appearance of the peeled sealing surfaces generally indicates a good seal.

The frosty appearance is typically the result of the adhesive, which is used to bond the packaging materials together, being left on both of the sealing surfaces after peeling. When the adhesive is left on both of the sealing surfaces in this manner, a cohesive separation has occurred within the adhesive layer during peeling. Alternately, an adhesive failure may occur between the adhesive and one of the sealing surfaces. When there is an adhesive failure, one of the peeled sealing surfaces has the frosty appearance of the adhesive, and the other sealing surface has the smooth appearance of the bare packaging material.

Thus, when the frosty appearance of a cohesive separation is observed, the person opening the package is assured that the adhesive seal was continuous and adequately bonded to both of the sealing surfaces. This provides confidence that the item within the package is still sterile. However, when the smooth appearance of an adhesive failure is observed, the person opening the package does not know whether the seal was good and that an adhesive failure occurred during peeling, or that the seal was bad and that an adhesive failure occurred prior to peeling the package open. If an adhesive failure occurred prior to peeling, then the package contents may not be sterile. Because it is typically not a simple matter to conclusively determine whether the adhesive failure occurred before or during peeling, it is most prudent to assume that the adhesive failure occurred prior to peeling, and discard the contents. This, of course, increases the cost associated with the use of the sterile items.

One type of adhesive peel defect is typically called "branching," or "channeling." The defect is called branching because there are smooth adhesive failure areas surrounded by frosty cohesive separation areas within the peeled areas. The smooth adhesive failure areas look like the branches of a tree. If the branches of the adhesive failure areas connect from the outside of the seal area to the inside of the seal area, then a channel has been formed through the seal. A single path of adhesive failure may be termed a channel defect. As used herein, "branching" refers to both branching and channeling type defects.

Branching defects have been observed on packaging made from a polyester of terephthalic acid, ethylene glycol, and 1,4-cyclohexanedimethanol (PETG), that has been coated on at least one side with silicone. Branching peel defects are not typically found on packages made from PETG that has not been coated with silicone. The silicone coating is useful as an anti-nesting agent, or in other words to keep stacked pieces of the PETG from sticking to each other. Therefore, it is desirable to continue using the silicone coating.

Contamination on the surface of the packaging material tends to create a defect that looks like branching, but which is actually quite different. Surface contamination inhibits a proper seal from ever forming between the adhesive and the surface of the package material. Thus, with surface contamination, a proper seal is typically never formed. By distinction, a branch defect looks like there may have been a gap between the adhesive and the packaging material, but in reality there was a good adhesive seal.

It has been thought that adhesive peel defects such as branching could be eliminated by increasing the adhesion between the PETG packaging and the adhesive. An electrostatic or corona discharge applied over a polymeric surface tends to oxidize the polymer surface, increasing the surface energy and polarity, and promoting adhesion to the polymer surface. Therefore, attempts have been made to treat packaging materials for sterile items with an electrostatic discharge, in an effort to eliminate branching peel defects. However, such treatment has typically not reduced branching peel defects effectively.

What is needed, therefore, is a method for achieving reduced branching peel defects in adhesive bonded plastics.

SUMMARY OF THE INVENTION

The above and other needs are provided by a method for producing a processed polymeric sheet to be adhesively secured to a cover to form a seal, the sheet having properties such that the seal does not have branching peel defects when it is separated. A polymeric sheet is formed from a source of polymeric material, and at least one side of the polymeric sheet is coated with silicone. The polymeric sheet is further processed while implementing a static neutralization method to substantially eliminate electrostatic discharge across the polymeric sheet during such further fabrication, producing a processed polymeric sheet.

Preferably the polymeric material is selected from the group consisting of polyethylene, polystyrene, polyester, polyvinyl chloride, polypropylene, acrylics, acrylonitrile, polycarbonates, polyimide, and cellulosics. The static neutralization method, in different preferred embodiments, may be impregnating the polymeric source with a conductive material to dissipate a static charge on the polymeric sheet, coating the polymeric sheet with a hygroscopic material to attract moisture and dissipate a static charge on the polymeric sheet, at least partially ionizing an air mass and passing the polymeric sheet through the air mass to neutralize a static charge on the polymeric sheet, or passing the polymeric sheet near static neutralization bars to neutralize a static charge on the polymeric sheet.

The above method may be used for packaging a sterile item into a package having an adhesive seal, which, when opened, does not have branching peel defects in the adhesive seal. A polymeric material is formed into a polymeric sheet,

and at least one side of the polymeric sheet is coated with silicone. A static neutralization method is implemented to substantially eliminate electrostatic discharge across the polymeric sheet. The polymeric sheet is formed into a polymeric receptacle, and the sterile item is placed within the polymeric receptacle, and a cover is attached to the polymeric receptacle by means of the adhesive, thereby forming a seal which does not have branching peel defects when opened.

BRIEF DESCRIPTION OF THE DRAWINGS

Further advantages of the invention will become apparent by reference to the detailed description of preferred embodiments when considered in conjunction with the following drawings, which are not to scale, in which like reference numerals denote like elements throughout the several views, and wherein:

FIG. **1** is a functional diagram of the fabrication process;

FIG. **2** is a cross-sectional view of a packaged sterile item; and

FIG. **3** is a partial view of a peeled sealing surface having branching peel defects.

DETAILED DESCRIPTION OF THE INVENTION

Referring now to the drawings, there is depicted in FIG. **1** a functional diagram of the fabrication process for a polymer sheet **10**. The polymer sheet **10** is initially produced with an extruder **14** that either melts or softens a source **12** of the polymer, which is then extruded through a nozzle **16**. In a preferred embodiment, the polymeric material used to form the sheet **10** is selected from the group consisting of polyethylene, polystyrene, polyester, polyvinyl chloride, polypropylene, acrylics, acrylonitrile, polycarbonates, polyimide, and cellulosics. Most preferably a polyester of terephthalic acid, ethylene glycol and 1,4-cyclohexanedimethanol (PETG) is used. This is commonly termed a glycol modified polyester, such as EASTAR PETG Copolyester 6763 manufactured by Eastman Chemical Company of Kingsport, Tenn.

The sheet **10** is drawn through a first series of rollers **18**. It will be appreciated that the rollers **18** as depicted are representative only. While the rollers **18** are depicted as a single pair, in actual use the rollers **18** may be used in pairs or individually, and in other ways well known in the art. Additionally, there will typically be more than just the single set of rollers **18** that are depicted. Therefore, it should be understood that rollers **18** diagrammatically represent any number and combination of rollers. Finally, the sheet **10** as depicted traverses a flat path, but this has only been done so as to not unduly complicate the drawing, or draw attention away from the more important aspects of the invention. In actual implementation, the sheet **10** would probably follow a non-planar path from one end of the fabrication process to the other. The rollers **18** help shape the physical characteristics of the sheet **10**, such as the thickness, surface texture, and width. The sheet **10** is preferably between about 5 mils and about 60 mils thick.

The sheet **10** is coated on at least one side with a silicone coating **20**. The silicone **20** is preferably a poly(dimethyl siloxane) such as SM 2128 Silicone Emulsion manufactured by General Electric Company, Waterford, N.Y., or most preferably DC 365 Silicone Emulsion, manufactured by Dow Corning of Midland, Mich. The silicone **20** is useful as a de-nesting agent, to inhibit items made from the sheet **10** from sticking to one another when they are stacked together.

The silicone **20** may be applied by any one or more of a variety of methods. For example, the silicone **20** may be roll coated onto the sheet **10** by means of a roller **22** which contacts the silicone **20** in a reservoir **24** at one portion of the roller **22**, and then rotates to dispense some of the silicone **20** onto the sheet **10** at another portion of the roller **22**. Alternately, the silicone **20** may be sprayed onto the sheet **10**, such as from a nozzle **26**. While FIG. **1** depicts both sides of the sheet **10** being coated with silicone **20**, using a different method to coat each side, it will be appreciated that only one side of the sheet **10** needs to be coated, and that any single method, or combination of methods may be used.

The sheet **10** will typically be drawn through a second set of rollers **19**. As described above, even though a single set of rollers **19** has been depicted, it will be appreciated that the rollers **19** may be used singularly or in sets or two or more, and there will typically be more than a single set. The sheet **10** is typically wound onto a wind-up roll **28** for staging prior to sale or further fabrication. Alternately, the sheet **10** could immediately be further processed.

At various points in the fabrication process of the sheet **10**, there is an opportunity for a static charge to develop on the sheet **10**. Commonly, the charge is developed at the rollers **18** and **19**, and the wind-up roll **28**. If a sufficient charge accumulates, then an electrostatic discharge will occur. Such a discharge, if sufficiently great, can ignite a combustible atmosphere, start a fire, or harm personnel.

As used herein, "electrostatic discharge," or just "discharge," refers to a localized accumulated charge that is reduced by one or more methods which are commonly called a "shock," and which include, without limitation, spark discharge, brush discharge, corona discharge, Lichtenberg discharge, and lightening-like discharge. Such discharges typically result in a luminous phenomenon, commonly called a spark.

There is depicted in FIG. **2** a packaged sterile item **40**. The package for the sterile item **40** is produced by fabricating the sheet **10** as described above, and then forming it into a receptacle **41**. The receptacle **41** may be formed by any one of a number of different methods well known in the art, such as thermoforming. The sterile item **40** is placed within the receptacle **41**.

A cover **44** is placed on the receptacle **41**, and is attached to the receptacle **41** by means of an adhesive **42**. The adhesive **42** is applied to at least portions of the cover **44**. The adhesive **42** is preferably a hot melt type adhesive, such as an ethylene vinyl acetate (EVA) rich copolymer adhesive. While the cover **44** may be fashioned from a variety of different materials, in the preferred embodiment a spun bonded polyolefin is used, such as TYVEK. The cover **44** is preferably not applied to the side **39** of the sheet **10** to which the silicone **20** was applied, if only one side of the sheet **10** was coated.

The process of forming the package for the sterile item **40** as described above specified an order of first forming the receptacle **41**, then placing the sterile item **40** within the receptacle **41**, then applying the adhesive **42** to the cover **44**, which is then attached to the receptacle **41**. It will be appreciated that this specified order is for illustration only, and that in actual implementation, any one of a number of different process orders may be employed without departing from the spirit of the invention. For example, the receptacle **41** may be formed and the sterile item **40** placed within it, the adhesive **42** may then be placed on the receptacle **41**, which is then attached to the cover **44**.

In a preferred embodiment, the entire package and its contents (sterile item **40**) are sterilized after the package has been completely assembled. A method such as ethylene oxide (ETO) sterilization or gamma irradiation may be used to sterilize the package and contents. In alternate embodiments the components of the package are sterilized individually and then assembled. Other methods of sterilization may be used in alternate embodiments.

As previously described, when the sterile item **40** is removed from the package, by removing the cover **44** from the receptacle **41**, the adhesive **42** is inspected to see that a portion of it remains on all the sealing surfaces of both the cover **44** and the receptacle **41**. If the adhesive **42** is not visible on all surfaces, then it is prudent to assume that the item **40** is no longer sterile, and to discard it in favor of another.

FIG. **3** depicts, in representative fashion, branching peel defects **46**, such as may be seen in the adhesive **42** on the sheet **10** which forms the receptacle **41**. As can be seen, there are branches **46** in the adhesive **42**. The branches **46** are areas where the adhesive **42** did not adhere to sheet **10** as the cover **44** was peeled away. Instead, as the cover **44** was peeled away, all of the adhesive **42** stuck to the cover **44**, and was removed with the cover **44**. In the other areas, a portion of the adhesive **42** was removed with the cover **44**, and a portion of the adhesive **42** remained on the sheet **10**. As previously mentioned, this latter separation mode, cohesive separation, is the generally desired separation mode for peeling.

The branches **46** tend to indicate that an adhesive failure occurred in these areas before a cohesive separation could occur. In other words, the adhesion between the adhesive **42** and the sheet **10** was less than the cohesion within the adhesive **42**. Using an adhesive **42** which is less cohesive is generally not a desired solution to the problem, as it would allow for the cover **44** to be too easily inadvertently removed from the receptacle **41**. Thus, a method for enhancing the surface of the sheet **10** to which the adhesive **42** is applied is desired.

As previously described, it is generally known to those skilled in the art that applying an electrostatic discharge to the sheet **10** during fabrication typically enhances the adhesive nature of the surface of the sheet **10**. Thus, the natural occurrence of electrostatic discharge during processing, as described above, would typically be thought of as beneficial to the bonding characteristics of sheet **10**. However, even intentionally employing electrostatic discharge, such as corona discharge, to the sheet **10** used to form receptacles **41** does not tend to reduce the incidence of branching peel defects **46**.

It has been discovered that, contrary to the conventional wisdom described above, eliminating any type of electrostatic discharge from occurring across the sheet **10** tends to reduce the frequency and degree of branching peel defects **46** in sterile packages made in this manner. Thus, the present invention goes against the common teaching of using corona discharge to increase adhesion, and further, displays the importance of reducing electrostatic discharge during the fabrication process of the sheet **10**, and not just those points at which explosion, fire, or harm to personnel could result. Indeed, one aspect of the invention is that the electrostatic discharge from the sheet **10** is not just detrimental to the environment in which the sheet **10** is produced, but to the sheet **10** itself.

Thus, to reduce branching peel defects **46** in these packages, an electrostatic discharge must be prevented from occurring after the time that the silicone **20** is applied to the sheet **10**. It does not appear to be important, from the standpoint of reducing branching peel defects **46**, to eliminate or reduce electrostatic discharge across the sheet **10** prior to applying the silicone **20** coating.

Any one of a number of different methods may be used to control electrostatic discharge across the sheet **10**. These methods are called neutralization, and they differ from electrostatic discharge in many important respects. One important difference is that neutralization tends to not be accompanied by the luminous phenomena, or spark, that is attendant with electrostatic discharge. Neutralization methods typically fall into one of two categories, conductivity or replacement.

To implement a conductivity method, for example, the sheet **10** may be impregnated with a conductive material, by incorporating the conductive material within the melt **12**. In this manner, static charges will tend to not accumulate on the sheet **10**, but will be conducted away by the conductive nature of the sheet **10**. Alternately, the surface of the sheet **10** may be treated with a hygroscopic material, such as by incorporating the hygroscopic material within the silicone **20** that is coated onto the surface of the sheet **10**. The hygroscopic material attracts moisture from the air to the surface of the sheet **10**. The moisture at the surface of the sheet **10** increases the conductivity of the sheet **10**, again allowing the static charge to be conducted away, rather than building up until an electrostatic discharge occurs.

Other neutralization methods of static control that may be employed do not involve changing the physical properties of the sheet **10** itself. The preferred embodiment implements one or more replacement methods, including a static bar **30**, which typically consists of a straight row of ionizing points contained in a metal casing. The sheet **10** may pass within an inch of the bar **30**, but preferably does not contact the bar **30**. Another preferred method is to use blowers **32** to blow air through a grid of ionizing points **34**, which create positive and negative ions **36** in the air. The ions **36** neutralize the static charges on the sheet **10**. Any one of a number of other neutralization methods may also be used.

The charge on the sheet **10** may be monitored at one or more locations throughout the fabrication process, such as by process monitor **38**. By reading the degree of static charge at different locations, additional antistatic procedures can be automatically implemented at times when the static charge on the sheet **10** generally increases, or in specific areas of the fabrication process where the charge is accumulating. By implementing neutralization methods to keep the surface voltage of the sheet **10** generally below about 3,000 volts, the probability of electrostatic discharge is substantially reduced, and with it the probability of branching peel defects **46** occurring.

While specific embodiments of the invention have been described with particularity above, it will be appreciated that the invention is equally applicable to numberless processes well known to those skilled in the art.

What is claimed is:

1. A method for producing a processed polymeric sheet to be adhesively secured to a surface to form a seal, comprising:

forming a polymeric sheet from a source of polymeric material, coating at least one side of the polymeric sheet with silicone, and thereafter processing the polymeric sheet while implementing a static neutralization method at a source of electrostatic charge accumulation to prevent an electrostatic charge accumulation of greater than 3000 volts across the polymeric sheet during processing, thereby producing a processed polymeric sheet that is resistant to peel defects when the processed polymeric sheet is adhesively secured to a surface and then peeled from the surface;

whereby the processed polymeric sheet is resistant to peel defects by the prevention of the electrostatic charge accumulation at the source of accumulation during processing.

2. The method of claim **1** wherein implementing the static neutralization method comprises impregnating the source of polymeric material with a sufficient quantity of conductive material to prevent electrostatic accumulation of greater than 3000 volts on the polymeric sheet.

3. The method of claim **1** wherein implementing the static neutralization method comprises coating the polymeric sheet with a sufficient quantity of hygroscopic material to attract moisture and prevent electrostatic accumulation of greater than 3000 volts on the polymeric sheet.

4. The method of claim **1** wherein implementing the static neutralization method comprises at least partially ionizing an air mass and passing the polymeric sheet through the air mass whereby electrostatic charge accumulation across the polymeric sheet is neutralized at the source of accumulation.

5. The method of claim **1** wherein implementing the static neutralization method comprises passing the polymeric sheet near static neutralization bars to prevent electrostatic accumulation of greater than 3000 volts on the polymeric sheet.

6. A method for producing a processed polymeric sheet to be adhesively secured to a cover to form a seal, the processed polymeric sheet having properties such that the seal is resistant to branching peel defects when the seal is separated, comprising:

extruding glycol modified polyester from a source of glycol modified polyester to produce a polymeric sheet, coating one side of the polymeric sheet with silicone, and thereafter passing the polymeric sheet through an at least partially ionized air mass at a source of electrostatic charge accumulation of the polymeric sheet to prevent an electrostatic charge accumulation of greater than 3000 volts on the polymeric sheet; whereby a processed polymeric sheet, having electrostatic charge accumulation of below about 3000 volts after application of silicone, is produced that has a seal resistant to branching peel defects when the processed polymeric sheet is adhesively secured to a cover and then peeled from the cover.

7. A method for fabricating packaging material for sterile items, the packaging material having a reduced number of branching peel defects, comprising the steps of:

(a) extruding a polymeric sheet,

(b) drawing the polymeric sheet through a first series of rollers, the first series of rollers acting to set physical characteristics of the polymeric sheet,

(c) coating at least one side of the polymeric sheet with silicone,

(d) drawing the coated polymeric sheet through a second series of rollers,

(e) winding the polymeric sheet onto a spool, and

(f) implementing a static neutralization method at steps (d) and (e) to prevent an electrostatic charge accumulation of greater than 3000 volts across the polymeric sheet by neutralizing any charge accumulation occurring at contact between the coated polymeric sheet and the second series of rollers and between the coated polymeric sheet and the spool.

8. A method for fabricating packaging material for sterile items, the packaging material having no branching peel defects, comprising the steps of:

(a) extruding glycol modified polyester into a polymeric sheet,

(b) drawing the polymeric sheet through a first series of rollers, the first series of rollers acting to set physical characteristics of the polymeric sheet,

(c) coating at least one side of the polymeric sheet with silicone,

(d) drawing the coated polymeric sheet through a second series of rollers,

(e) winding the polymeric sheet onto a spool, and

(f) implementing a static neutralization method at steps (d) and (e) to prevent an electrostatic charge accumulation of greater than 3000 volts across the polymeric sheet by neutralizing any charge accumulation occurring at contact between the coated polymeric sheet and the second series of rollers and between the coated polymeric sheet and the spool.

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