



ArmorFlex® 110 Film FAQ's

At ILC Dover we are always “*creating what’s next*” by listening carefully to our customers. In response to customer input and emerging regulations we’ve developed a robust new film to support our DoverPac® Containment Solutions line. This revolutionary product, ArmorFlex® 110, delivers permanent static dissipative properties while meeting FDA and 2002/72/EC requirements for food contact.



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<p>Q: <i>What are the food contact, USP, European Pharmacopeia compliance data that the film meets?</i></p>	<p>A: Compliant to FDA and European (2002/72/EC & Amendments) requirements. Pass USP <661> Physicochemical Tests For Plastics. Pass USP <88>, Class VI (7 day implant). European Pharmacopoeia (EP) Film per section 3.1.5 test protocols (Polyethylene with additives for containers for preparations for parenteral use and for ophthalmic preparations).</p>
<p><i>Have you/or are you planning to have the material tested to USP and European Pharmacopeia (as you have for your other grades of film)?</i></p>	<p>Yes, this revolutionary film has passed the testing shown in the table below.</p> <p>Regulatory Requirements</p> <p>FDA Food Grade: All ingredients must meet the applicable sections of 21 CFR</p> <p>EEC Food Grade: All ingredients must be listed and used IAW 2002/72/EC Pass applicable migration testing</p> <p>European Pharmacopoeia (EP) Film per section 3.1.5 test protocols (Polyethylene with additives for containers for preparations for parenteral use and for ophthalmic preparations)</p> <p>Meet the CPMP/QWP/4359/03 EMeA Section 3 of the Guideline on Plastics Immediate Packaging Materials.</p> <p>Pass USP <661> Physicochemical Tests For Plastics</p> <p>Pass USP <88>, Class VI (7 day implant)</p> <p>No animal sourced ingredients may be used</p> <p>Heavy Metals: Pass tests per 94/62/EC and CONEG</p>
<p><i>Does ArmorFlex 110 comply with the new European Medicines Agency (EMeA) Guidelines?</i></p>	<p>While the majority of this guideline refers to conducting compatibility tests of films with actual pharmaceutical products, the film was formulated in accordance with section 3 of the CPMP/QWP/4359/03 guideline which refers to the data submitted for EP, food contact, and the monographs of the EP or member states.</p>
<p><i>How are the anti-static properties achieved? What is the mode of action?</i></p>	<p>Static dissipative properties are achieved by the thorough blending of the antistatic compound in the base polymer. This creates a conductive network yielding the antistatic properties.</p>
<p><i>Are there any other components in the liners that may migrate into product?</i></p>	<p>As with most films, other components are used to help produce the film and provide desired characteristics. Only components that meet the materials of contact test protocol requirements as stated above are used in this product. European Food Contact testing (Overall Migration) shows this film complies with the allowable limits that have been set by the regulatory bodies.</p>

Q:

A:

<i>Does the film contain any anti-oxidants?</i>	Yes. The film contains only the antioxidants accepted by the regulatory agencies in the base resin as added by the resin manufacturer during polymerization.
<i>What is the minimum/maximum thickness of liners available?</i>	Typical thicknesses of film for use in DoverPacs and Continuous Liners will continue to be 4 mil (0.004 inch/100 micron nominal). Thicker film, up to 10 mil (0.010 inch/250 micron nominal), will be used in some flexible enclosures.
<i>Are anti-static properties affected by thickness?</i>	No.
<i>Is the mix ratio of permanent antistat agents always the same?</i>	Yes, the antistatic compound level is a weight percentage.
<i>I realize anti-stat properties are permanent, however, do you assign a shelf life to the product?</i>	Yes. The antistatic properties are expected to be permanent due to the manner in which this film is compounded. However, as the shelf life is for a completed product, a shelf life of 5 years has been established which is a typical standard based on similar resins.
<i>Have you set film down on stability trials?</i>	In terms of shelf life stability, yes. We do have supply bags available for customer testing as is the industry norm.
<i>Is the film manufactured in a similar way to your existing non-permanent versions? Are you still using film manufactured by your existing film manufacturers?</i>	Yes, the film is a monolayer blown film. Our same existing, qualified film manufacturers are supplying this product to us.
<i>Can the permanent anti-stat film be used for all types of applications e.g. drum liners, containment systems, liners with sampling sleeves etc.</i>	Yes. ArmorFlex 110 is available for all these applications.
<i>Will your containment products work with my existing ILC supplied hardware?</i>	Yes. Extrusion dimensions support current ILC Dover fabrication methods (gauge / width / tolerance) and this is carried into the systems we supply to allow you to use our current hardware designs.
<i>Do the crimps work on this film?</i>	Yes.
<i>Do you have a drug master file (DMF) for this material?</i>	Yes. Letters of Authorization are available upon request.

Q:

Is this film as rugged as ArmorFlex 104?

A:

Yes. A complete list of the physical attributes required of this film are listed in the table below.

Application & Physical Requirements

Electrical Static Dissipation (PASS INCENDIVITY at 0.12mJ MIE)

Shelf Life of 5 years

Temperature Range: Material should show minimal degradation at temperatures from -20C to 40C.

Heat Sealable Material

Tensile Strength of 4500 PSI (typical)

Tear Strength of 600 lbf/in (typical)

Elongation of 600% (typical)

Clear Film allowing product levels to be distinguished

Ability to stretch over Drum Transfer canisters, and able to function with DoverPac O-ring groove systems

Liner able to stabilize for an inflation dwell test at 3 inches water gauge

Ability to use crimps with the final product (4", 14", 23")

Solvent resistance – resistant to a wide range of solvents used in the pharmaceutical industry

Will you supply a Material Data Book for ArmorFlex 110 like you do for your other films?

Yes.

Is ArmorFlex 110 safe for incineration?

Yes. It contains no halogenated compounds.



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Providing Flexible Containment Solutions to the Pharmaceutical Industry since 1997

To “create what’s next” ILC Dover listens to its customers. Our skilled engineering staff, building on years of experience with NASA and commercial customers, translates those needs into high performance products. ArmorFlex®110 Film is a result of this process. We look forward to hearing from you so we can continue to “create what’s next”.