



# ArmorFlex® 110 Film FAQs



## SYSTEM DESCRIPTION

At ILC Dover we go “beyond boundaries” 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 EU Regulation 10/2011 requirements for food contact.

**Q:**

**A:**

*Have you or are you planning to have the material tested to prove AF110 meets the appropriate regulatory requirements?*

Yes, this revolutionary film has passed the testing shown in the table below.

**Regulatory Requirements**

FDA Food Grade: All ingredients must meet the applicable sections of 21 CFR

EEC Food Grade:

All ingredients must be listed and used IAW EU Regulation 10/2011  
Pass applicable migration testing

Pass ArmorFlex® 110 monograph (developed in accordance with EMeA guidelines)

Meets CPMP/QWP/4359/03 EMeA Section 3 of the Guideline on Plastics Immediate Packaging Materials

Pass USP <661> Physicochemical Tests For Plastics

Pass USP <87>, Biological reactivity, in vitro

Pass USP <88>, Class VI (7 day implant)

Heavy Metals: Pass tests per 94/62/EC and CONEG

*Does ArmorFlex® 110 comply with the new European Medicines Agency (EMeA) Guidelines?*

Yes. 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.

*Does ArmorFlex® 110 use surface treatments to obtain its static dissipative quality?*

No. While some suppliers offer that a base film without static dissipative additives can be used with an exterior surface treatment, we have elected not to accept that rationale. Coated films will not meet the intent of pharmacopoeia testing since test monographs require the composite cross section of the film be tested. This is done to assume that, in the event a piece of film should come in contact with the drug product, the film will not introduce a potential hazard to the patient.

*How are the antistatic properties achieved? What is the mode of action?*

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.

*Are there any other components in the liners that may migrate into product?*

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.

**Q:**

**A:**

<i>Does the film contain any antioxidants?</i>	Yes. The film contains only the antioxidants accepted by the regulatory agencies in the base resin as added 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), could be used in some applications.
<i>Are antistatic 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 antistat 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 films.
<i>Have you set film down on stability trials?</i>	In terms of shelf life stability, yes. We do have stability bags available for customer testing, as is the industry norm. Some customers have initiated this testing already.
<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 qualified film manufacturers are supplying this film to us.
<i>Can the permanent antistat 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:**

**A:**

<p><i>Is a certificate of analysis available?</i></p>	<p>Yes. The COA is provided as part of the film submittal, and a COC is provided on the end products.</p>													
<p><i>Is this film as rugged as ArmorFlex® 104?</i></p>	<p>Yes. A complete list of the physical attributes required of this film are listed in the table below.</p> <table border="1"> <tr> <td>Application &amp; Physical Requirements</td> </tr> <tr> <td>Electrical Static Dissipation (PASS INCENDIVITY at 0.12mJ MIE)</td> </tr> <tr> <td>Shelf Life of 5 years</td> </tr> <tr> <td>Temperature Range: Material should show minimal degradation at temperatures from -20C to 40C</td> </tr> <tr> <td>Heat Sealable Material</td> </tr> <tr> <td>Tensile Strength of 4500 PSI (typical)</td> </tr> <tr> <td>Tear Strength of 600 lb<sub>f</sub>/in (typical)</td> </tr> <tr> <td>Elongation of 600% (typical)</td> </tr> <tr> <td>Clear Film allowing product levels to be distinguished</td> </tr> <tr> <td>Ability to stretch over Drum Transfer canisters, and able to function with DoverPac O-ring groove systems</td> </tr> <tr> <td>Liner able to be stabilized for an inflation dwell test at 3 inches water gauge</td> </tr> <tr> <td>Ability to use crimps with the final product (4", 14", 23")</td> </tr> <tr> <td>Solvent resistance—resistant to a wide range of solvents used in the pharmaceutical industry</td> </tr> </table>	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 lb <sub>f</sub> /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 be stabilized 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
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<p><i>Will you supply a Material Data Book for ArmorFlex® 110 like you do for your other films?</i></p>	<p>Yes.</p>													
<p><i>Is ArmorFlex® 110 safe for incineration?</i></p>	<p>Yes. It contains no halogenated compounds.</p>													

ArmorFlex is a registered trademark of ILC Dover



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