



**AXELGAARD**  
MANUFACTURING CO., LTD.

## Frequently Asked Questions - AmGel® Hydrogels

### Can hydrogels be sterilized?

All our gels may be sterilized using the proper electron beam or gamma irradiation dose.

### What is the shelf life of hydrogels?

The "process by" shelf life is for roll goods prior to conversion. For master rolls this is 1 year and for slit rolls this is 6 months. Establishing the shelf life for finished goods is the responsibility of the converter.

### Where are AmGel hydrogels manufactured?

All AmGel hydrogels are manufactured in Fallbrook, California USA.

### Do AmGel hydrogels contain latex?

No. All of our gels are latex free.

### Can the hydrogels be slit to my specifications?

Yes, we can slit master rolls to almost any necessary width.

### What is the Minimum Order Quantity for gel?

Most standard hydrogels have a MOQ of only 1 roll.

### What is the lead time for hydrogel?

For standard hydrogels the lead time varies based on our production schedule and the quantity ordered, but a general timeline is 2-4 weeks for master rolls and 3-6 weeks for slit rolls.



**AXELGAARD**  
MANUFACTURING CO., LTD.

## Frequently Asked Questions - AmGel® Hydrogels

### What kind of manufacturing dies should be used when converting the hydrogel?

For easy release, plasma/non-stick coated dies should be used to convert hydrogel. Deep cavity dies should be considered for hydrogels thicker than 35 mil.

### What are the proper storage conditions for unconverted hydrogel?

Hydrogel should remain in its shipping plastic bag and kept in a temperature controlled environment. Short term temperature recommendation is 32° - 104°F (0° - 40°C). Long term and optimal temperature recommendation is 41° - 81°F (5° - 27°C).

### What are the proper storage conditions for finished goods using AmGel hydrogel?

The proper storage and packaging of products using AmGel Hydrogel are dependent on several factors, including the hydrogel type, product type and packaging type. It is the converter's responsibility to determine the storage conditions of finished goods.

### Is it okay to cool the hydrogel?

Some converters find that cooling the hydrogel makes for easier converting. A hydrogel is a viscoelastic material which is dependent on temperature. The lower the temperature will exhibit more elastic behavior and the higher the temperature will exhibit more viscous behavior. It will be firmer at the colder temperature and softer/more adhesive at the higher temperature. Cold does not have a negative impact on converting.

### What type of package should be used for finished products using AmGel hydrogels?

A high moisture barrier foil package is recommended for sensing hydrogels (small surface area), however it is the converter's responsibility to determine finished product packaging requirements. Hydrogels can lose and gain water depending on environmental conditions, which can affect its performance. It's recommended to keep the hydrogel on the protective liner. Also, if planning to reuse the product, a re-sealable package is recommended.



**AXELGAARD**  
MANUFACTURING CO., LTD.

## Frequently Asked Questions - AmGel® Hydrogels

### How many times can the hydrogel be applied to the skin or other surface?

The re-stick capabilities depends on the hydrogel series. For most gels, the number of times the hydrogel can be applied to skin depends on the proper preparation of the skin prior to application. Skin should be cleaned with water and soap to remove any lotions, skin oils, make-up and dead skin. Any debris on the skin will be transferred to the gel thereby compromising the integrity of the gel's adhesiveness. When the skin is properly prepared, the hydrogel will perform well for repeated application or wear.

### What are the proper temperatures for aging or temperature tests?

The converter is responsible for aging parameters. A hydrogel is a viscoelastic material which is dependent on temperature. The lower the temperature will exhibit more elastic behavior and the higher the temperature will exhibit more viscous behavior. It will be firmer at the colder temperature and softer/more adhesive at the higher temperature. The conductivity of a hydrogel is dependent on the temperature. The hydrogel should be conditioned prior to testing to have accurate and reproducible data.

### What are the steps for a custom formula hydrogel?

Our Engineering/R&D team will work with you regarding volumes, specifications, cost, and prototypes.

### What type of conductive film or liner is compatible with the hydrogel?

The converter is responsible for determining the compatibility of any materials used in conjunction with the hydrogel. We can supply a stimulating gel already laminated with a conductive film. We also offer quality liners for purchase.

### Have AmGel hydrogels gone through biocompatibility testing?

Yes, our hydrogels have passed all the ISO 10993-1 biocompatibility tests for intact skin contact. Samples were tested by NAMSA.



**AXELGAARD**  
MANUFACTURING CO., LTD.

## Frequently Asked Questions - AmGel® Hydrogels

### What is the 510(k) for AmGel hydrogels?

AmGel hydrogels are a component, not a finished device. The gel by itself does not require a 510(k) pre-market approval.

### What does water activity mean?

Water activity basically describes the amount of water available for hydration. It represents the ratio of the water vapor pressure of a substance (i.e. hydrogel) to the water vapor pressure of pure water. The scale is from 0 to 1.0 (pure water).

### How is the stainless steel (skin side) adhesion tested?

Axelgaard's testing is modeled after the American Society for Testing and Materials (ASTM) Standard D3330/D3330M "Standard Test Method for Peel Adhesion of Pressure-Sensitive Tape", Test Method A. Our adhesive and release tester operates on gel level based on the distance traveled to collect adhesion force data needed to obtain the average value. Our Stainless Steel (Skin Side) Adhesion specification is based on 180° peel, with the unit of measure being grams per inch of width.