# **3M Medical Specialties**

## Frequently Asked Questions

May 2008

## 3M Hydrophilic Polyester Films for Diagnostics No. 9960 and 9962

3M Medical Specialties is the trusted source for quality diagnostic device components. This technical bulletin is provided to enable a smooth transition from bench top evaluation to conversion of these films into final product.

What does "hydrophilic" mean?

The films are called "hydrophilic" because the surface treatment is "water loving". This characteristic enables liquids to spread out, not bead up, on the surface of the film.

What is the composition of the hydrophilic films?

The films consist of a 3M proprietary hydrophilic treatment, permanently bonded to a polyester film.

No. 9960 is a 7 mil (0.17 mm), two sides hydrophilic-treated polyester film. No. 9962 is a 4 mil (0.10 mm), two sides hydrophilic-treated polyester film.

How thick is the hydrophilic treatment?

The hydrophilic layer is less than 1 micron in thickness.

Can the hydrophilic treatment be removed from the polyester film?

The hydrophilic treatment is anchored well to the polyester film and therefore, difficult to remove. Using a caustic solution such as sodium hydroxide will partially remove this treatment from the polyester film. However, it does scratch easily and should be handled with care.

How do I know that the hydrophilic treatment is on the film?

A quick means of determining if the hydrophilic treatment is present and effective is to place a drop of colored water onto the film. If the drop spreads out, the hydrophilic treatment is present. If the drop beads up, the film surface is untreated or the hydrophilic property has been reduced. The water drop should not bead up on the film surface if the hydrophilic property is present and not compromised.

What is the shelf life of the Hydrophilic Polyester Films?

With proper storage and handling, 3M Hydrophilic Polyester Films will maintain their stated properties for a period of one year from the date stamped on the core. Beyond one year, the film may begin to block or stick to itself resulting in an uneven unwind.

How should the film be stored?

As the product is hydrophilic, storage conditions are critical. Reduction of the hydrophilic property is minimized if the product remains wrapped in the moisture impervious barrier provided with original packaging. The product must be stored between 50°F-80°F (10°C-27°C) and relative humidity between 40%-60% or less.

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What if the humidity level was higher than the recommended storage conditions?

High humidity will reduce the hydrophilic property primarily around the exposed edges and wrap of roll, resulting in roll blockage. Use a moisture impervious barrier and desiccant, if possible. Before use, remove the outer few wraps of the roll and ensure the hydrophilic property has not been reduced.

How stable is the hydrophilic property with age?

Based on customer feedback and real time aging, we have observed minimal to no reduction of the hydrophilic property beyond the stated one-year shelf life when handled and stored properly. However, we recommend conducting accelerated aging studies to assure the suitability of the film in its final use and form.

Can the hydrophilic property be reduced?

Yes, the hydrophilic property can be compromised usually due to mishandling and contamination. The following precautions and recommendations are to ensure proper use of these films.

#### **Handling Suggestions:**

Finger oils, scratches, and accidental liquid splashes onto the film are common culprits in the reduction of the hydrophilic property.

- 1. Remove the first few outer wraps before testing or processing to ensure that the hydrophilic property has not been compromised.
- 2. Wear cotton or cloth gloves during the evaluation, production, and packaging of this film to eliminate the potential for finger smudges and scratching.
- 3. It is best to hold the film at the edges and if possible, minimize the amount of handling.

#### **Converting Suggestions:**

Scratches and contamination will compromise the hydrophilic property of the film.

- 1. Clean and wipe down rollers and nips to eliminate the potential for film contamination. Residual debris and coatings used in previous processing runs may compromise the hydrophilic property.
- 2. Limit the number of rollers in direct contact with the film. Eliminate all unnecessary contact.
- 3. Wrap all rollers with a soft, non-adhering wrap to prevent scratches.
- 4. Check any tape wrapped around the rollers as the tape may scratch the film.
- 5. If a nip pull is used, the rubber or silicone roller may contaminate the surface due to pressure contact on the film. The film should be inspected after going through the nip roll to determine if there are marks, contamination or a reduction of hydrophilic property.
- 6. All rollers, whether driven or idle, must be moving at the same speed to minimize the potential for scratching.

Can the hydrophilic property be reduced after exposure to elevated temperatures?

Based on limited data, we have not observed a significant reduction of the hydrophilic property after exposure to 150°C for 15 minutes, 130°C for 60 minutes, or 120°F for 3 weeks. We recommend our customers conduct their own studies to assure the suitability of the film for its use and in its final form. These tests were under dry conditions with low humidity.

If the film becomes wet, can the hydrophilic property be revived?

No, once the film has become wet, the hydrophilic property is compromised and cannot be revived. Please use the precautions provided in this technical bulletin to <u>minimize the exposure to humidity</u> and moisture during converting, storage and shipment.

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## film be stored and shipped?

How should stacked sheets of the Stacked sheets of the hydrophilic film may block against one another after an extended period of time. It is recommended that a slip-sheet be placed between film layers. Typical slip-sheets used are polyethylene, polyethylene/ethylene vinyl acetate, and polypropylene films with a smooth surface. Be sure the slip-sheets are untreated as coatings and additives may affect the hydrophilic surface. Also, wrap the stacked sheets in a moisture impervious barrier to minimize the potential for reducing the hydrophilic property and reduce shifting during shipment that can cause scratches.

#### What interleafing materials are recommended for insertion into roll?

Appropriate materials that can be wound in the roll are polyethylene, polyethylene/ethylene vinyl acetate, and polypropylene films with a smooth surface. As above, be sure that the films are not corona treated and additives checked for compatibility for your application and shipping/storage conditions.

#### Does the product contain any leachables?

The hydrophilic treatment contains no leachable components. We have conducted several product safety tests that include In-vitro Cytotoxicity and Acute Eye Irritation. The summary results from these tests are available and can be used to assist in regulatory filings.

#### Can the films be printed?

No. 9960 and No. 9962 are hydrophilic treated on both sides of the polyester film. Our customers have successfully printed on each with a variety of inks.

As always, we recommend conducting studies to determine processing conditions that work best to combine the film and selected ink.

#### How is the product labeled for traceability?

An 11-digit lot/roll number (XXYJJJZZ $\alpha$ ###) is located below the bar code on the core label where:

XX = Input reference code

Y = Last digit of year

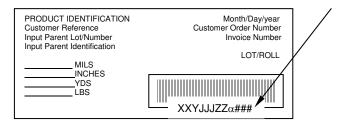
JJJ = Julian date

ZZ = Sequential roll number

 $\alpha$  = Sequential cut number

### = Roll position

Please reference this number to ensure proper trace-ability of the films.



If there are additional questions concerning 3M Hydrophilic Polyester Films, please contact your 3M Medical Specialties Account Representative or Customer Service at 1-800-228-3957 (U.S.) or 651-604-5599 (International).

**Product and Safety Information:** User is solely responsible for determining the suitability of 3M samples and products for the intended use including any necessary safety or toxicity assessment. 3M will provide Material Safety Data Sheets and results of toxicity testing upon request. In every case before using any product in full scale production users should conduct their own tests to determine to their own satisfaction whether the product is of acceptable quality and is suitable for their particular purposes under their own operating conditions.

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Call us at Customer Service to place an order: 800-742-1994 (U.S.). Visit our website: **www.3M.com/medicalspecialties** for product and services information, news about conferences we will be attending, new product highlights or to make a direct inquiry.

To have a sales representative contact you, to request samples or clinical and safety summaries, please contact us at 3M HELPLINE 800-228-3957 (U.S.) or for international inquiries, please contact your local country representative. Our 3M Medical Specialties subsidiary contacts are listed below

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