



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.

3M Hydrophilic Polyester Films

Frequently Asked Questions

May 2008

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 minimize the exposure to humidity and moisture during converting, storage and shipment.

3M Hydrophilic Polyester Films

Frequently Asked Questions

May 2008

How should stacked sheets of the film be stored and shipped?

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 interleaving 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 (XXYJJZZ α ###) 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
 α = Sequential cut number
= Roll position

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

PRODUCT IDENTIFICATION	Month/Day/year
Customer Reference	Customer Order Number
Input Parent Lot/Number	Invoice Number
Input Parent Identification	LOT/ROLL
_____ MILS	
_____ INCHES	
_____ YDS	
_____ LBS	
	
	XXYJJZZ α ###

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.

Notice: Nothing contained herein shall be construed to imply the nonexistence of any relevant patents or to constitute a permission, inducement or recommendations to practice any invention covered by any patent, without authority from the owners of this patent.

Warranty Information

All statements, technical information and recommendations herein are based on tests 3M believes to be reliable, but the accuracy or completeness thereof is not guaranteed. 3M warrants only that products will meet 3M's specifications at the time of shipment to the customer. 3M does not offer any other warranty and does not warrant the performance, safety or such other characteristics of Products in combination with other materials. 3M specifically DOES NOT warrant Products for any intended or unintended uses (whether or not foreseeable); for compatibility or suitability with other components or compatibility with any methods of manufacture or conversion. The foregoing warranty is made in lieu of all other warranties, expressed or implied, including the implied warranties of merchantability, fitness for a particular purpose and freedom from non-infringement.

Limitation of Remedies: If products are proven not to meet 3M's specifications, the sole and exclusive remedy available and 3M's only obligation shall be, at 3M's option, to replace such quantity of Products which are proven out of specification or to refund the purchase price paid for Products.

Limitations of Liabilities: The remedies provided herein are exclusive remedies against 3M for any alleged or actual nonconformance to specifications or defect or other failure in products or for 3M's performance of its supply obligations. Under no circumstances is 3M liable for any direct, indirect, incidental, special or consequential damages (including lost profits) in any way related to the product under any theory of law including, but not limited to, negligence and strict liability.

Ordering Information

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.

International Locations

Argentina

3M Argentina S.A.C.I.F.I.A.
Tel.: 54-11-4339-2400
Fax: 54-11-4339-2640

Dominican Republic

3M Dominicana
Tel: (809) 530-6560 X499
Fax: (809) 530-2960

Kazakhstan

3M Representation Office
Tel: +7 3272 509 944
Fax: +7 3272 509 573

Poland

3M Poland Sp.z o.o.
Tel: (48 22) 739 60 00
Fax: (48 22) 739 60 01

Thailand

3M Thailand Ltd.
Tel: (66)2 260 8577 Ext.175
Fax: (66)2 261 7535

Australia

3M Health Care
Tel: 1 300 363 878
Fax: 1 800 060 888

Finland

Suomen 3M Oy
Tel.: 358-9-52-521
Fax: 358-9-512-29-44

Korea

3M Korea Ltd.
Tel: 82-2-3771-4286
Fax: 82-2-786-2825

Portugal

3M Portugal
Tel: 351-21-3134500
Fax: 351-21-3134680

Taiwan

3M Taiwan Ltd.
Tel: 886-2-2704-9011
Fax: 886-2-2706-0355

Belgium

3M Belgium N.V./S.A.
Tel: 32-2-722-5111
Fax: 32-2-720-0225

France

Laboratoires 3M Santé
Tel: 33-1-3031-8376
Fax: 33-1-3031-8378

Malaysia

3M Malaysia Sdn. Bhd.
Tel: 6-03-7806 2888
Fax: 6-03-7806 2902

Russia

3M Russia
Tel: 7 (495) 784-74-74
Fax: 7 (495) 784-74-75

Turkey

3M Turkey
Tel: 9 (0212) 3507777
Fax: 9 (0212) 2821742

Brazil

3M DO Brasil Ltda.
Tel: 55-19-864-7171
Fax: 55-19-864-7848

Germany

3M Medica
Tel: 49 2131 14 40 00
Fax: 49 2131 14 49 99

Mexico

3M México, S.A. de C.V.
Tel: +52-55-5270-0400
Fax: +52-55-5270-0433

Singapore

3M Technologies (S) Pte. Ltd.
Tel: 65-6450-8866
Fax: 65-6455-2130

Ukraine

3M Ukraine
Tel: +380 44 490 57 77
Fax: +380 44 490 57 75

Canada

3M Canada
Tel: 800 364-3577
Fax: 800 341-4630

Hong Kong

3M Hong Kong Ltd.
Tel: (852) 2806 6111
Fax: (852) 2234 6044

Middle East

3M Gulf Ltd.
Tel: 971-4-3670-777
Fax: 971-4-3670-699

Sri Lanka

3M Lanka (Pvt.) Ltd.
Tel: (94) 11 2785701
Fax: (94) 11 4410083-4

United Kingdom & Ireland

3M Health Care Ltd.
Tel: 44-1509-611-611
Fax: 44-1509-237-288

Chile

3M Chile S.A.
Tel: (56-2) 4103000
Fax: (56-2) 4103400

Hungary

3M Hungária Kft.
Tel: (36-1) 270-7777
Fax: (36-1) 320-0951

The Netherlands

3M Nederland B.V.
Tel: 31-715-450-450
Fax: 31-715-450-212

Spain

3M España, S.A.
Tel: 34-91-321-6000
Fax: 34-91-321-6002

Venezuela

3M Manufacturera Venezuela
Tel: 58-241-8391911
Fax: 58-241-8391928

China

3M China Ltd.
Tel: 86-21-6275-3535
Fax: 86-21-5208-2205

India

3M India Ltd.
Tel: +91-80-2223 1414
Fax: +91-80-22231431

New Zealand

3M New Zealand
Tel: 64-9-444 4760
Fax: 64-9-443 7885

Sweden

3M Svenska AB
Tel: +46-8-92 21 00
Fax: +46-8-92 24 22

Viet Nam

3M Viet Nam Ltd.
Tel: 84 8 640986
Fax: 84 8 641024

Colombia

3M Colombia S.A.
Tel: 57-1 4108585
Fax: 57-1 4161677

Indonesia

PT 3M Indonesia
Tel: (62-21) 520 3401
Fax: (62-21) 520 3106

Peru

3M Peru S.A.
Tel: 511-224-2728
Fax: 511-224-3171

Switzerland & Eastern Europe

3M (Schweiz) AG
Tel: +41 44 724 92 44
Fax: +41 44 724 94 80

Czech Republic

3M Cesko s.r.o.
Tel: +420-261 380 111
Fax: +420-261 380 110

Italy

3M Italia SPA
Tel: +39 2 7035-2406
Fax: +39 2 7035-2484

Philippines

3M Philippines
Tel: (632) 8133781 to 95
Fax: (632) 8145873 to 74

Denmark

3M a/s
Tel: 45-43-48-0100
Fax: 45-43-96-8596

Japan

3M Health Care Ltd.
Tel: 81-3-3709-8289
Fax: 81-3-3709-8754



3M Medical Specialties
3M Center, Building 275-5W-05
St. Paul, MN 55144-1000 USA
Tel.: 800 228-3957

ISO 9001
ISO 13485
EN 46001
CERTIFIED



FM 14552