3M™ DuraPrep™
Surgical Solution
(Iodine Povacrylex [0.7% available iodine] and Isopropyl Alcohol, 74% w/w)
Patient Preoperative Skin Preparation

3M™ Ioban™ 2
Antimicrobial Incise Film

Sterile Surface
Resource Guide
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Introduction

Because all of the most commonly used patient skin preps meet the FDA criteria for immediate microbial kill and persistent antimicrobial activity, it’s important to look at other factors that may affect performance when choosing a prep for surgical patients. In this guide, you will find several ways to compare patient skin preps based on factors that affect their application, performance and cost-effectiveness.

You will also find helpful information here about incise drapes, for this reason: studies show that patient skin preps cannot completely eradicate bacteria, especially on patients with high preoperative bacterial counts.\(^1\)\(^-\)\(^6\) That’s why an infection prevention program isn’t complete without an incise drape system that creates a sterile surface which is unachievable by using a patient prep alone.

To learn more, contact your 3M representative or call the 3M Health Care Helpline at 1-800-228-3957.

Skin flora is the leading cause of surgical site infection

Resident flora continues to regrow as a natural part of skin health.

The bacteria normally found on the skin are called “resident” bacteria. Resident bacteria exist on the skin of normal, healthy people, and are usually not harmful. This type of bacteria is always present and cannot be entirely removed from the skin surface. Even the best skin preparation prior to surgery will not completely remove all bacteria. Creating a barrier reduces the risk of bacteria from migrating into the surgical wound. A barrier can be created by the application of an incise drape.

Fig. 1
Bacteria can be a resourceful traveler.

Organisms that remain on the skin can potentially migrate into the surgical wound.

“Transient” bacteria can be transferred to the wound through contact with instruments, gloves or sponges.
3M™ DuraPrep™ Surgical Solution
(Iodine Povacrylex [0.7% available iodine] and Isopropyl Alcohol, 74% w/w)

Patient Preoperative Skin Preparation

Clarifying what’s important in selecting a patient prep for your facility.
Efficacy test requirements don’t match real O.R. conditions.

FDA Tentative Final Monograph (TFM)\(^1\) testing is based on small samples of clean, dry skin that do not replicate surgical conditions.

This *in vivo* test uses a cup scrub method on the abdomen and groin. Samples from the areas indicated in Figure 4 are taken and analyzed using the following:

- ASTM Designation: E 1173-01, Standard Test Method for Evaluation of Preoperative, Precatheterization, or Preinjection Skin Preparations

- ASTM Designation: E 1054-08, Standard Test Methods for Evaluation of Inactivators of Antimicrobial Agents – NEUTRALIZATION and baseline counts are required

This is important to note because although surgical patient preps may pass the TFM test, it does not mean they provide equal protection to patients in the operating room, when blood, saline and other fluids enter the scene.

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1. Health-Care Antiseptic Drug Product Tentative Final Monograph, Proposed Rule, 59 Federal Register, p. 31402-31452 (Friday, June 17, 1994)
Some O.R. Teams are painting when they should be scrubbing.

Only one surgical patient prep is designed to be applied in a single, painted coat with no scrubbing: 3M™ DuraPrep™ Surgical Solution (Iodine Povacrylex [0.7% available iodine] and Isopropyl Alcohol, 74% w/w) Patient Preoperative Skin Preparation. Chlorhexidine gluconate preps must be scrubbed on to be properly applied, according to the manufacturers’ application instructions.

Below are application instructions for DuraPrep solution and ChloraPrep® Patient Preoperative Skin Preparation 2% Chlorhexidine Gluconate (CHG) & 70% Isopropyl Alcohol (IPA).

<table>
<thead>
<tr>
<th>Instructions for Use</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DuraPrep Solution</strong></td>
</tr>
<tr>
<td><strong>Application</strong></td>
</tr>
<tr>
<td>Paint a single, uniform application and do not go back over areas already prepped.</td>
</tr>
<tr>
<td><strong>Moist Site (such as the inguinal fold)</strong></td>
</tr>
</tbody>
</table>

Fig. 5

* Per ChloraPrep label
Some surgical prep applicators cover a lot more ground than others.

With a 26 mL applicator of 3M™ DuraPrep™ Surgical Solution (Iodine Povacrylex [0.7% available iodine] and Isopropyl Alcohol, 74% w/w) Patient Preoperative Skin Preparation, you can cover more than twice the area of the 26 mL ChloraPrep® Patient Preoperative Skin Preparation 2% Chlorhexidine Gluconate (CHG) & 70% Isopropyl Alcohol (IPA).

According to labeling, a 26 mL applicator of ChloraPrep will cover an area 13.2 inches by 13.2 inches, or 174 square inches. In comparison, a 26 mL applicator of DuraPrep solution (8630) will cover 15 inches by 30 inches, or 450 square inches (Fig.6). This is more than twice the area, with a single applicator. For procedures that call for large coverage with a prep, this can be the difference between using one and using several applicators. A difference that, ultimately, can add to the cost of a procedure (Fig.7).

How much does it cost to cover 450 sq. in.?

<table>
<thead>
<tr>
<th>Description</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 26 mL applicator of 3M™ DuraPrep™ Surgical Solution (Iodine Povacrylex [0.7% available iodine] and Isopropyl Alcohol, 74% w/w) Patient Preoperative Skin Preparation</td>
<td>$4</td>
</tr>
<tr>
<td>2.58 26 mL applicators of ChloraPrep® Skin Preparation</td>
<td>$21</td>
</tr>
</tbody>
</table>

Fig. 6

Fig. 7
CDC Guidelines: There’s not just one.

Contrary to what some would have you believe, there are different CDC guidelines that address skin antisepsis.

CDC guidelines can help drive best practice. But even when two guidelines address a shared segment, they are not interchangeable. For example, both the CRBSI and SSI guidelines address patient skin prep. But the rationale and recommendation in each are not the same. Bottomline: make sure you are using the appropriate CDC guideline before you make decisions on product use.

CDC Guideline for the Prevention of Intravascular Catheter-Related Bloodstream Infection (CRBSI)
Focus: management of catheters in place for long-term monitoring or delivery of therapeutics.

CDC Guideline for the Prevention of Surgical Site Infection (SSI)
Focus: multi-disciplinary category approach to reducing the risk of surgical site infection.
Source: Guideline for the Prevention of Surgical Site Infection, Centers for Disease Control and Prevention, Infection Control and Hospital Epidemiology. 1999; vol.20; 247-278.
Before you standardize on a patient prep, remember this: CDC, AORN and NQF don’t.

**CDC** (Centers for Disease Control and Prevention, “Guideline for Prevention of Surgical Site Infections,” *Infection Control and Hospital Epidemiology*, Vol. 20, No 4, April 1999)

“Use an appropriate antiseptic agent for skin preparation.”

**AORN** (Perioperative Standards and Recommended Practice, Patient Skin Antisepsis. AORN, 2009)

“Preoperative skin antiseptic agents that have been FDA-approved or -cleared and approved by the health care organization’s infection control personnel should be used for all preoperative skin preparation.”

**NQF** (National Quality Forum, Safe Practice #22 on Surgical Site Infections (SSIs). NQF 2010)

“Preoperatively use solutions that contain isopropyl alcohol as skin antiseptic preparation until other alternatives have been proven as safe and effective, and allow appropriate drying time per product guidelines.”
Iodine Povacrylex does not contain one drop of Povidone Iodine.

In a recent study of skin preps, published by the *New England Journal of Medicine*¹, it was pointed out that povidone-iodine-based preps didn’t perform as well as CHG-based preps. What wasn’t pointed out is that DuraPrep solution was not included in this study, and its active ingredient is not povidone-iodine. **So any conclusions drawn about povidone-iodine cannot be attributed to 3M™ DuraPrep™ Surgical Solution (Iodine Povacrylex [0.7% available iodine] and Isopropyl Alcohol, 74% w/w) Patient Preoperative Skin Preparation.** Compare the differences between the two in the chart below.

<table>
<thead>
<tr>
<th>Description</th>
<th>Iodine Povacrylex</th>
<th>Povidone-Iodine Scrub and Paint</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effective in a single, painted coat²</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Resists removal by irrigation³</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Persistent</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>- At least 48 hours* against resident bacteria after a blood and saline (fluid) challenge⁴</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>- At least 12 hours against transient bacteria⁵</td>
<td></td>
<td>Unknown</td>
</tr>
<tr>
<td>Immobilizes bacteria remaining on the skin after prepping⁶</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Promotes drape adhesion³⁷⁸</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

Fig. 8

* Following ASTM E1173

2. Data on file (05-010214, LIMS 8304, LIMS 8918, LIMS 8058).
5. Data on file (SRFE 1513).
8. Data on file (LIMS 9567, 05-010210, 05-010262, 05-010212).
Unfortunately, when drape edges lift, microbes get a boost.

In clinical studies, 3M™ DuraPrep™ Surgical Solution (Iodine Povacrylex [0.7% available iodine] and Isopropyl Alcohol, 74% w/w) Patient Preoperative Skin Preparation provided significantly greater drape adhesion than ChloraPrep® Patient Preoperative Skin Preparation 2% Chlorhexidine Gluconate (CHG) & 70% Isopropyl Alcohol (IPA) and other water-soluble preps, when tested with 3M™ Ioban™ 2 Antimicrobial Incise Film.

Incise drapes are used to create a sterile surface in procedures where the consequence of infection can have serious morbidity or mortality, such as cardiothoracic, joint replacement and other implant surgeries, neurosurgery, and trauma. But when a drape lifts at the wound edge, the exposed skin allows for the potential of bacteria being transferred into the wound. In one study, drape lift was associated with a 6-fold increase in surgical site infections. Therefore, it is important to consider the effect of different preps on drape adhesion. In clinical studies, DuraPrep solution provided significantly greater drape adhesion than ChloraPrep® and other water-soluble preps (Fig. 9 and 10).

When blood and saline enter the scene, a good surgical prep doesn’t run away.

3M™ DuraPrep™ Surgical Solution (Iodine Povacrylex [0.7% available iodine] and Isopropyl Alcohol, 74% w/w) Patient Preoperative Skin Preparation contains a polymer that dries to a water-insoluble film and resists wash-off by blood and saline challenges. Studies show that blood and saline irrigation can significantly reduce the microbial effectiveness of some surgical patient preps. In fact, a published study\(^1\) showed that DuraPrep solution had greater log reduction than ChloraPrep® Patient Preoperative Skin Preparation 2% Chlorhexidine Gluconate (CHG) & 70% Isopropyl Alcohol (IPA) when challenged by saline irrigation or soak – and that difference was statistically significant with the saline soak (\(P=.006\)) (Fig. 11)\(^1\).

<table>
<thead>
<tr>
<th>3M™ DuraPrep™ Surgical Solution (Iodine Povacrylex [0.7% available iodine] and Isopropyl Alcohol, 74% w/w) Patient Preoperative Skin Preparation</th>
<th>ChloraPrep® Patient Preoperative Skin Preparation (2% Chlorhexidine Gluconate [CHG] &amp; 70% Isopropyl Alcohol)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Keeps resident bacteria counts low for at least 48 hours(^*) after a blood and saline (fluid) challenge(^2)</td>
<td>No fluid challenge data available(^3)</td>
</tr>
</tbody>
</table>

Table 1. Comparison of patient preoperative skin preparations

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Fig. 11

*Following ASTM E1173
2. Safety & Efficacy Data (http://multimedia.3m.com/mws/mediawebserver?66666UuZcFSLXItmXME48&cEVuQEuZqV5s8EvE6E66666)
3. Website: http://www.chloraprep.com

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When an operation is finished, a good surgical prep has only just begun.

3M™ DuraPrep™ Surgical Solution (Iodine Povacrylex [0.7% available iodine] and Isopropyl Alcohol, 74% w/w) Patient Preoperative Skin Preparation shows persistent activity for at least 48 hours* after simulated surgical conditions.

<table>
<thead>
<tr>
<th>3M™ DuraPrep™ Solution vs. ChloraPrep® Persistent Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Persistence</strong></td>
</tr>
<tr>
<td><strong>3M™ DuraPrep™ Surgical Solution</strong></td>
</tr>
<tr>
<td>(Iodine Povacrylex [0.7% available iodine] and Isopropyl Alcohol, 74% w/w) Patient Preoperative Skin Preparation</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Keeps resident bacteria counts low for at least 48* hours¹</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

Fig. 13

* Following ASTM E1173
1. Safety & Efficacy Data (http://multimedia.3m.com/mws/mediawebserver?666669JuZjcFSLXtmXME48&cEVuDEcuZgVs6EVs6E666666)
   Data on file 3M Health Care.
2. Website: http://www.chloraprep.com
Not all surgical preps match their quality with this quantity of documentation.

**3M™ DuraPrep™ Surgical Solution (Iodine Povacrylex [0.7% available iodine] and Isopropyl Alcohol, 74% w/w) Patient Preoperative Skin Preparation has substantial clinical documentation including data in simulated surgical conditions.**

This includes:
- 5 human safety studies
- 9 *in vitro* studies
- 8 *in vivo* studies
- 8 clinical in-use studies

Only five published clinical studies of common topical antiseptic products have a SSI primary outcome (Fig. 14).

<table>
<thead>
<tr>
<th>Antiseptic Prep Related Publications</th>
<th>Author</th>
<th>Journal</th>
<th>Preps Studied</th>
<th>Primary Outcome</th>
<th>Other Interventions</th>
<th>Hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlorhexidine-Alcohol versus Povidone-Iodine for Surgical-Site Antisepsis</td>
<td>Darouiche et al</td>
<td>New England Journal of Medicine, Jan 2010</td>
<td>2% CHG/IPA** (ChloraPrep®) vs. PVP-I (aqueous povidone-iodine)</td>
<td>SSI</td>
<td>Unknown</td>
<td>X</td>
</tr>
<tr>
<td>Effects of Preoperative Skin Preparation on Postoperative Wound Infection Rates: A Prospective Study of 3 Skin Preparation Protocols</td>
<td>Swenson et al</td>
<td>Infection Control &amp; Hospital Epidemiology, Oct 2009</td>
<td>Iodine Povacrylex/IPA (DuraPrep solution) vs. PVP-I/IPA (Betadine® solution) vs. 2% CHG/IPA (Chlora-Prep)</td>
<td>SSI</td>
<td>Unknown</td>
<td>X</td>
</tr>
<tr>
<td>Preoperative Skin Preparation of Cardiac Patients</td>
<td>Segal et al</td>
<td>Association of Operating Room Nurses Journal, Nov 2002</td>
<td>Iodine Povacrylex/IPA (DuraPrep solution) vs. PVP-I (aqueous povidone-iodine)</td>
<td>SSI</td>
<td>YES incise drapes</td>
<td>X</td>
</tr>
<tr>
<td>Skin Preparations in CABG Surgery: A Prospective Randomized Trial</td>
<td>Roberts et al</td>
<td>Complications in Surgery, Nov/Dec 1995</td>
<td>Iodine Povacrylex/IPA (DuraPrep solution) vs. PVP-I (aqueous povidone-iodine)</td>
<td>SSI</td>
<td>YES incise drapes</td>
<td>X</td>
</tr>
<tr>
<td>Cutting Surgical-site Infection Rates for Pacemakers and ICDs</td>
<td>Taylor</td>
<td>Nursing, Mar 2006</td>
<td>Only CHG with IPA</td>
<td>SSI</td>
<td>YES Timing of antibiotic prophylaxis, clipping instead of shaving</td>
<td>X</td>
</tr>
</tbody>
</table>

Fig. 14 **Isopropyl Alcohol**
The right surgical prep won’t create problems for the meninges.

3M™ DuraPrep™ Surgical Solution (Iodine Povacrylex [0.7% available iodine] and Isopropyl Alcohol, 74% w/w) Patient Preoperative Skin Preparation is not contraindicated for lumbar puncture and epidural access and procedures where a patient prep might come in contact with the meninges. ChloraPrep® Patient Preoperative Skin Preparation 2% Chlorhexidine Gluconate (CHG) & 70% Isopropyl Alcohol (IPA), product labeling contraindicates use in these areas.

Standardization of practice is a goal for healthcare facilities because it helps prevent error and assists in providing the same level of care for all patients. DuraPrep solution helps you standardize your practice: one solution for intact skin.*

* See DuraPrep solution drug facts at the end of this brochure.
3M™ Ioban™ 2 Antimicrobial Incise Drapes

Because skin cannot be sterilized, the use of an incise drape helps reduce the risk of wound contamination.
Only a drape does what a drape does.

Skin surface that has been prepped has only been disinfected, not sterilized. Patient Pre-operative preps are not enough. You need a drape.

By definition, a skin surface covered by a sterile incise drape creates a sterile barrier at the beginning of surgery, whereas a skin surface that has been prepped has only been disinfected, not sterilized.

- Skin preps cannot completely eradicate bacteria
- Skin preps are vulnerable to removal or neutralization during surgery by blood, exudate and irrigation fluids
- Bacterial regeneration occurs continuously on the skin even after prepping

Fig. 15 – Incise Drape/Bacterial Regeneration Stops at the Incise Drape/Bacterial Regeneration Emerges to the Skin’s Surface
Drape lift has been associated with a six-fold increase in surgical site infection.¹

A drape’s barrier is only effective when the drape is securely adhered to the patient’s skin all the way to the incision site.

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What separates one incise drape from all the rest is where its antimicrobial agent lives.

The antimicrobial in 3M™ Ioban™ 2 antimicrobial incise drapes is in the adhesive – so it’s in constant contact with the skin.

Ioban 2 antimicrobial incise drapes are made from a polymeric film coated with a pressure-sensitive adhesive. An iodophor complex is incorporated into the adhesive and provides antimicrobial properties (Fig. 17).

Ioban 2 antimicrobial incise drapes not only immobilize bacteria, their iodophor complex continues to come in contact with a patient’s skin. In an in vitro study, Ioban has been demonstrated to be effective in reducing microorganisms.\(^1\) Other clear incise drapes simply immobilize bacteria, but do not contain an antimicrobial agent.

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Not all antimicrobial incise drapes are created equal.

Test methods that directly apply the drape to the skin and measure skin flora are very difficult to correlate with real suppression at the skin surface. But a time-kill study clearly reveals the difference between drapes.

The objective of this study was to measure the antimicrobial activity of three different antimicrobial incise drapes, using an in vitro time-kill method. A 3M™ Steri-Drape™ Incise Drape, with no antimicrobial, was used as a control.

Conclusions:
• 3M™ Ioban™ 2 Anitmicrobial Incise Drapes were significantly better at reducing the microbial counts when compared with ISO Drape® Incise Drape featuring Microban® Antimicrobial Protection and MCD ACTI-Gard® for all microorganisms tested at 90 minutes.
• ACTI-Gard drape was not significantly better than Steri-Drape 2 in reducing any of the microorganism tested at all time points tested.
• Microban drape was not significantly better than Steri-Drape 2 in reducing any of the microorganism tested at all time points tested.

Fig. 18

**3M™ DuraPrep™ Surgical Solution Drug Facts**

**Active ingredients**

| Iodine povacrylex (0.7% available iodine) | Antiseptic |
| Isopropyl alcohol, 74% w/w | Antiseptic |

**Uses**

**patient preoperative skin preparation:**
- for preparation of the skin prior to surgery
- helps reduce bacteria that potentially can cause skin infection

**Warnings**

For external use only. Flammable, keep away from fire or flame.

To reduce the risk of fire, PREP CAREFULLY:
- do not use 26 mL applicator for head and neck surgery
- do not use on an area smaller than 8 in. x 10 in.
- Use a small applicator instead.
- solution contains alcohol and gives off flammable vapors
- do not drape or use ignition source (e.g., cautery, laser) until solution is completely dry (minimum of 3 minutes on hairless skin; up to 1 hour in hair).
- avoid getting solution into hairy areas. **Wet hair is flammable.** Hair may take up to 1 hour to dry. Do not allow solution to pool
- remove solution-stained material from prep area

Do not use:
- on patients with known allergies to iodine or any other ingredients in this product
- on open wounds, on mucous membranes, or as a general skin cleanser
- on infants less than 2 months old due to risk of excessive skin irritation and transient hypothyroidism

When using this product:
- keep out of eyes, ears, and mouth. May cause serious injury if permitted to enter and remain. If contact occurs, flush with cold water right away and contact a doctor.
- to avoid skin injury, care should be taken when removing drapes, tapes, etc. applied over film.
- use with caution in women who are breast-feeding due to the potential for transient hypothyroidism in the nursing newborn

Stop use and ask a doctor if irritation, sensitization or allergic reactions occur. These may be signs of a serious condition. On rare occasions, use of this product has been associated with skin blistering.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

**Directions (follow all directions for use)**

- At the end of the prep, discard any portion of the solution which is not required to cover the prep area. It is not necessary to use the entire amount available.

Getting Patient Ready for Solution:
- use in well-ventilated area
- do not microwave or heat the solution applicator
- apply to clean, completely dry, residue-free, intact skin
- when hair removal is necessary, use a surgical clipper on the morning of the surgery. If a wet shave is used, thoroughly remove all soap residues.

**Activating the Applicator:**

- For 8635 (6 mL) applicator: grasp product by wrapping hand and fingers around the labeled portion of the applicator. Place thumb on the lever.
- with sponge parallel to floor, snap lever. Allow all fluid to flow into sponge.

For 8630 (26 mL) applicator:
- with sponge parallel to the floor, press the cap end of the applicator. Solution will begin to flow into the sponge.
- wait for fluid level to reach indicator line of applicator barrel.

When Applying Solution:
- **DO NOT SCRUB.** Paint a single, uniform application and do not reprep area.
- do not allow solution to pool. Use sponge applicator to absorb excess solution and continue to apply a uniform coating. If solution accidentally gets outside of prep area, remove excess with gauze.
- when using the 8630 (26 mL) applicator, clean umbilicus with enclosed swabs when applicable. (Moisten swabs by pressing against solution-soaked sponge applicator.)
- tuck prep towels as needed under both sides of the neck to absorb excess solution. Remove towels before draping.
- avoid getting solution into hairy areas. **Wet hair is flammable.** Hair may take up to 1 hour to dry.
- when prepping skin folds, toes, or fingers, use a sterile-gloved hand to hold skin apart until completely dry. Otherwise, skin may adhere to itself.

After Applying Solution:
- to reduce the risk of fire, wait until solution is completely dry (minimum of 3 minutes on hairless skin; up to 1 hour in hair).

Solution will turn from a shiny to a dull appearance on skin alerting the user that the solution is completely dry and no longer flammable.

While Waiting for Solution to Completely Dry:
- do not drape or use ignition source (e.g., cautery, laser)
- check for pooled solution. Use sterile gauze to soak up pooled solution. Do not blot because it may remove solution from skin.
- remove solution-stained materials. Replace if necessary.

After Solution is Completely Dry:
- remove solution-stained materials. Replace if necessary.
- do not drape or use ignition source (e.g., cautery, laser)
- apply dressings following standard practices

Other Information:
- store between 20–25°C (68–77°F) • avoid excessive heat above 40°C (104°F) • solution is not water soluble and may stain. Therefore, avoid contact with reusable items (basins, instruments).

Inactive Ingredients:
- ethyl alcohol, water

Questions?
- call 1-800-228-3957 (Monday to Friday, 7AM – 6PM, CST), www.3M.com.

Effective as of February 2010.