3M™ Cavilon™ Advanced Skin Protectant

General Description

3M™ Cavilon™ Advanced Skin Protectant (REF 5050G) is a polymeric-cyanoacrylate solution intended for the protection of intact or damaged skin. Upon application to skin, the liquid dries rapidly to form a primary long-lasting waterproof, highly durable film barrier. It is elastomeric, adhering to the contours of the skin and providing a uniform film. The film is transparent and possesses good oxygen and moisture vapor permeability. The polymer-cyanoacrylate is dispersed in a non-stinging solvent. The film is colorless, non-cytotoxic and has a low dermatitis potential. The film adheres to dry, moist or wet skin surfaces (i.e., superficial, partial thickness skin loss) and remains intact during conditions of continuous or repeated exposure to moisture or caustic irritants. It will wear off the skin and does not require removal. The applicator is sterilized by ethylene oxide. However, because ethylene oxide cannot penetrate the glass ampule, the solution inside the ampule is not sterile.

3M™ Cavilon™ Advanced Skin Protectant is CE marked as a Class IIa medical device and complies with the needs and requirements of the European Medical Device Directive 93/42/EEC. For other geographies the registration status should be confirmed.

Note: This Document is valid for the European Union only. The registration status in other geographies must be confirmed

Intended Use

Cavilon™ Advanced Skin Protectant forms a film barrier intended to cover and protect intact or damaged skin. It is effective in conditions where wet and/or dry skin is frequently or continuously exposed to moisture and caustic irritants such as feces, digestive fluids, wound drainage and urine. The protective film barrier reduces pain associated with Incontinence Associated Dermatitis (IAD) and prevents, stops, and/or reverses the effects of IAD. Cavilon™ Advanced Skin Protectant also can be used in areas exposed to friction and shear from bedding, clothing, shoes or any other material that would rub against the skin allowing/enabling the skin to heal.

Contraindications

Cavilon™ Advanced Skin Protectant is NOT to be used:

- as a wound dressing for full thickness wounds
- in or around the eyes

Precautions and Warnings

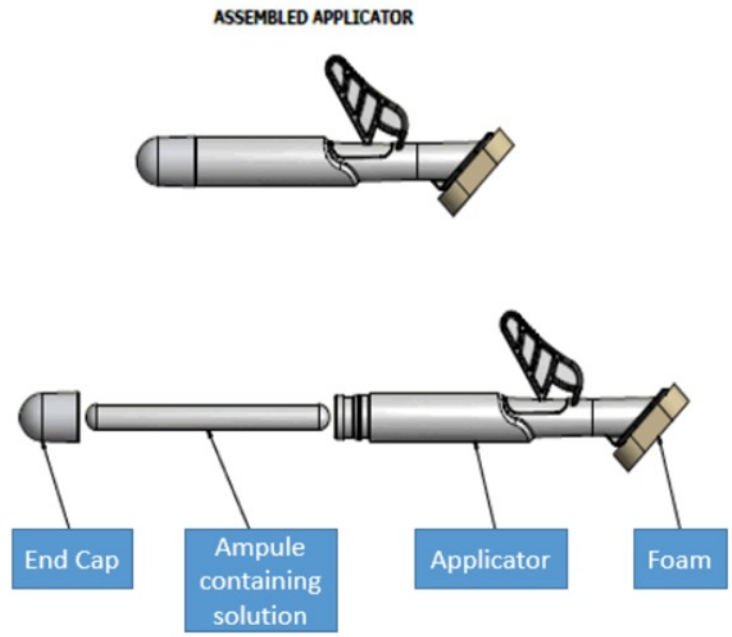
Warnings

1. **DANGER! HIGHLY FLAMMABLE!**
2. Cavilon™ Advanced Skin Protectant is highly flammable until it has completely dried on the skin.
3. The product should only be applied when no ignition sources or heat-producing devices are in use.
4. Avoid using the product around flames.
5. Use the product only in well ventilated areas.
6. Avoid use on individuals who are allergic to any of the ingredients.
7. The product is individually packaged for single use only. Reuse could result in increased risk of infection, or inadequate product performance.
8. The product is not intended for applications requiring sterile product (e.g. infusion catheter site protection and care, or surgical site protection).
9. Keep out of the reach of children.

Precautions

- Skin absorption and the effectiveness of topical medications (including: antimicrobials, antifungals, and analgesics) may be reduced or prevented by the presence of the Cavilon™ Advanced Skin Protectant.
- Use of other barrier products, ointments, creams or lotions may significantly reduce the effectiveness of the product.
- The product can increase the adhesion of some adhesive products (e.g. tape), particularly in the first few days of use. When removing an adhesive product, it is important to exercise care and follow the Directions for Use.

Product Composition



Materials

Applicator	Component	Material
	End Cap	High density polyethylene (HDPE)
	Ampule	Glass
	Solution	Cyanoacrylate-polymer
	Applicator	Low density polyethylene (LDPE)
	End Cap	High density polyethylene (HDPE)
	Foam	Polyurethane
Solution	**Component**	**Function**
	2-Octyl Cyanoacrylate	Adhesive/Resin - Adheres to skin
	Acrylic Tetrapolymer	Film-former - provides the barrier on skin
	Hexamethyldisiloxane (HMDS)	Solvent - enables film formation on skin

Packaging Composition

Each applicator is packaged into a pouch. Twenty pouches are packaged into a master carton.

Packaging Level	Material
Pouch	Heat-sealed, ethylene oxide permeable pouch (Tyvek/film)
Master Carton:	Corrugated box lined with perforated LDPE bag

Product Range

Name of Product / Description	Reference number	**Content** Items per box/case
3M™ Cavilon™ Advanced Skin Protectant	5050G	1 applicator / pouch 20 pouches / shipper

GENERAL CHARACTERISTICS

These results show that in majority of subjects with skin damage due to IAD, use of Cavilon Advanced Skin Protectant protects ski damaged by IAD from further deterioration and created an environment for the skin to improve and heal.

Parameter	Product Performance	Test Method	Results
Sterility	Applicator is sterile unless package is damaged or opened (The solution is non-sterile)	Ethylen Oxide Sterilization Validation	Complies ISO 11135-1 ISO 11737-1 ISO 11737-2 EN 556-1
Shelf Life	2 years	Stability Study	Pass
Skin Protection	Product forms a film barrier intended to cover and protect intact or damaged skin.	Clinical Study	Product protects skin damaged by Incontinence-Associated Dermatitis from further deterioration and creates an environment for the skin to improve and heal. No adverse events associated with the product application were reported during data collection of the clinical study.
Skin Protection	Product is effective in conditions where wet and/or dry skin is frequently or continuously exposed to moisture and caustic irritants such as feces, digestive fluids, wound drainage and urine.	Clinical Study	Study showed product forms a transparent, protective barrier in the presence of oozing exudate and blood and is effective as a protective barrier film in the presence of continued incontinence.
Skin Protection	Product reduces pain associated with Incontinence-	Clinical Study	All patients who reported pain associated with IAD experienced a

	Associated Dermatitis.		reduction in pain in the study.
Skin Protection	Product can be used in areas exposed to friction and shear from bedding, clothing, shoes or any other material that would rub against the skin allowing/enabling the skin to heal.	Laboratory Test Coefficient of Friction	Test showed the product helps to reduce frictional force.
Durability	Upon application to skin, the liquid dries rapidly to form a primary long-lasting waterproof, highly durable film barrier	Clinical Study	Healthy volunteers study showed the product forms a long-lasting barrier, protecting the skin for up to 7 days. It will wear off of the skin and does not require removal. Manufacturer's IFU recommends applying the product two to three times per week.
Waterproofness	Product forms a waterproof film barrier.	EN 20811 Testing Determination of resistance to water penetration. Hydrostatic pressure test.	Verified Product coated fabric demonstrated resistance to the passage of water through the coated fabric on average of 10.7 millibars.
Elastic Properties	Product is elastomeric, adhering to the contours of the skin and providing a uniform film.	3M Laboratory Test	Verified Elastomeric properties help prevent fracturing, cracking associated with cyanoacrylate films.
Breathability	Product is transparent and possesses good oxygen and moisture vapor permeability.	3M Laboratory Test	Verified Average moisture vapor transmission rate: 940 gm/m^2/24 hours

SAFETY AND SKIN TOLERABILITY (1)

All tests conducted according to GLP (good laboratory practice) as described by the FDA (21CFR Part 58) and according respective EU standards

Parameter	Product Performance	Test Method	Results
Biocompatibility – Safe for intended use	The biological safety of this product was evaluated in accordance with ISO 10993-1. Based on the overall assessment of the product composition, literature review, and biological test data, a toxicologist concluded that the product is biologically safe for its intended use as a surface device with permanent (> 30 days) contact of breached or compromised skin	EN ISO 10993-1 Evaluation and testing within a risk management process	In compliance (biocompatible)
Cytotoxicity	Product testing for the potential of leachable substances to damage cells *in vitro*	EN ISO 10993-5 Tests for *in vitro* cytotoxicity	Passed (Not cytotoxic)
Skin Irritation	Product testing for local skin responses to extracts of test materials in the rabbit	EN ISO 10993-10 Tests for irritation and skin sensitization	Passed (Not a skin irritant)
Maximization Sensitization	Product testing for the potential of delayed contact sensitization in the guinea pig	EN ISO 10993-10 Tests for irritation and skin sensitization	Passed (No potential of skin sensitization)
Genotoxicity	Product testing of the potential of genetic toxicity a) Bacterial reverse mutation study with a dose range finding test b) Mouse peripheral blood micronucleus study c) *In vitro* chromosomal aberration study in mammalian cells with a dose range finding assay	EN ISO 10993-3 Tests for genotoxicity, carcinogenicity, and reproductive toxicity	Passed (No genotoxic potential)

Parameter	Product Performance	Test Method	Results
Subchronic Systemic Toxicity	Product testing of the potential systemic toxicity in the rat	EN ISO 10993-11 Tests for systemic toxicity	Passed (No systemic toxicity potential)
Hypo-allergenic	Product testing of the potential of allergic reactions	Human Repeat Insult Patch Test (HRIPT)	Passed (no potential for dermal irritation or allergic contact sensitization)

SAFETY AND SKIN TOLERABILITY (2)

Parameter	Product Performance	Test Method	Results
Basic safety/ absence of toxic compounds	Free of: - PVC - Natural rubber latex - Colophony	Raw Material Information, Formulation, Composition, LCM	Confirmed
	No antimicrobial compounds intentionally added.	Raw Material Information, Formulation, Composition, LCM	Confirmed
Basic safety/ absence of Substances of Very High Concern	The substances of the REACH SVHC candidate list as of 15th January 2019 are not present at or above 0,1% in Tegaderm™ dressings	Raw Material Information, Formulation, Composition	confirmed

PACKAGING RELATED INFORMATION

Packaging standards

Parameter	Product Performance	Norm	Status
Labeling information supplied by manufacturer	Legally correct labeling	EN 1041	In compliance
Symbols used for labeling of medical devices	Legally correct symbols used	EN 980 and ISO 15223	In compliance
Sterile Barrier System (SBS)	Sterile unless package is damaged or opened	EN ISO 11607- Part 1&2	In compliance
Undesirable components of packaging	Free of substances of very high concern (SVHCs) in >0,1% in weight concentration	EC Regulation 1907/2006 (REACH) for any packaging article as described in directive 94/62/EC from the EU	Stated in supplier contracts
Undesirable components of packaging	Free of PVC (polyvinylchloride) Free of silica gel Totally Chlorine Free bleaching	3M internal standards	Stated in supplier contracts
Undesirable components of packaging	Sum concentration level of Lead, Cadmium, Mercury and Hexavalent Chromium not to exceed 100ppm (by weight)	Article 9 of EC directive 94/62/EC	Stated in supplier contracts

CERTIFICATIONS

Type of Certification	3M Company Certifications	Certifying Body	Certificate Number
ISO 13485:2003	3M Health Care 2510 Conway Ave. St. Paul, MN 55144 USA	Certified by BSI	FM 68740
93/42/EEC (MDD) Annex V	3M Health Care 2510 Conway Ave. St. Paul, MN 55144 USA	Certified by BSI	CE 00493

Additional information:

The information provided in this technical data sheet related to material content represents 3M's knowledge and belief as of the date it is provided, which may be based in whole or in part on information provided by suppliers to 3M.

This Technical Data Sheet is approved by 3M Regulatory Affairs:
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