



MATERIAL SAFETY DATA SHEET

National Fire Protection Association (NFPA) Rating: Health: 1 Flammability: 3 Reactivity: 0 Special: 0

TELEPHONE CONTACTS:

Product Technical and Medical Information: (800) 433-8871
Transportation Emergency 24_Hour Response: (800) 424-9300

SECTION 1: PRODUCT IDENTIFICATION

Compound Name: **M.D. FORTE® Perfection Gel – Acne Medication (092)**
Chemical Class: N/A
Manufacturer's Name: Allergan, Inc.
Address: 2525 Dupont Drive
Irvine, CA 92612
Preparation Date: June 20, 2001 (*Supersedes May 27, 1999*)

SECTION 2: COMPOSITION/HAZARDOUS INGREDIENTS

Chemical Name	CAS Number	Percent (by weight)	Exposure Limits in Air	
			OSHA PEL	ACGIH - TLV
Ethyl Alcohol	64-17-5	35.0	1000 ppm	1000 ppm

SECTION 3: HAZARDS IDENTIFICATION

Emergency Overview: M.D. FORTE® Perfection Gel – Acne Medication may cause moderate to severe irritation to eyes. Do not allow contact with eyes. Product is flammable. Keep away from flames or other ignition sources.

Potential Health Effects

Eye Contact: Contact with the eyes may result in moderate to severe irritation.
Skin Contact: Prolonged contact with skin may result in moderate irritation.
Inhalation: Not likely to occur under normal conditions of use.
Ingestion: May cause irritation, nausea and vomiting if swallowed.

Chronic Effects: M.D. FORTE® Perfection Gel – Acne Medication has been shown to be non-sensitizing, non-phototoxic and non-photoallergic, and non-comedogenic in humans.

No ingredient in this product is regulated or listed as a carcinogen by OSHA, IARC, or NTP.

Conditions Which May Aggravate Exposure: None known.

SECTION 4: FIRST AID MEASURES

Eye Contact: If contact occurs, immediately flush eyes with plenty of water for at least 15 minutes. Obtain medical attention immediately if irritation develops.

Skin Contact: Wash skin with soap and water. If irritation or other symptoms develop, consult a physician.

Inhalation: Not likely to occur under normal conditions of use.

Ingestion: Consult a physician or poison control center immediately.

SECTION 5: FIRE FIGHTING MEASURES

Flash Point and (Method): 82°F (Pensky Martens Closed Cup)

Flammable Limits: Not determined

Autoignition Temperature: No data for this product

Fire-Extinguishing Materials: Use extinguishing media suitable for materials supporting combustion such as water fog, CO₂, foam or dry chemical.

Firefighting Procedures: Use self-contained breathing apparatus in enclosed or confined spaces or as otherwise needed.

Unusual Fire and Explosion Hazards: Product is flammable. Keep away from flames or other ignition sources.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Sweep up or take up with absorbent material and wash with water. If large quantities are spilled, flush spill area with water.

SECTION 7: HANDLING AND STORAGE

Handling: Avoid unintentional contact with skin surfaces. Do not allow contact with eyes. Wash thoroughly after handling. Observe all labeling precautions and protective equipment recommendations.

Storage: Store in a cool, dry location out of direct sunlight. Keep container closed when not in use.

SECTION 8: EXPOSURE CONTROLS AND PERSONAL PROTECTION

Engineering Controls:	None necessary for normal product handling.
Respiratory Protection:	None necessary for normal product handling.
Eye Protection:	None necessary for normal product handling. Avoid eye contact.
Protective Clothing:	None necessary for normal product handling. Clinicians repeatedly applying the product to patients should wear latex gloves when handling M.D. FORTE® Perfection Gel – Acne Medication .
Hygienic Work Practices:	Wash hands thoroughly after handling. No eating, drinking, or smoking in area.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Vapor Density (Air = 1):	No data on this product
Boiling Point:	80°C (Ethyl Alcohol)
Solubility in Water:	Dispersible
Specific Gravity	0.95 – 0.97 @ 25°C
pH:	3.6 – 3.9 @ 25°C
Vapor Pressure (mm Hg at 20° C):	30 mm @ 25°C (Ethyl Alcohol)
Appearance and Odor:	Clear to Slightly Hazy Gel With a Mild Alcohol Odor

SECTION 10: STABILITY AND REACTIVITY

General:	This product is stable and hazardous polymerization will not occur.
Incompatible Materials and Conditions to Avoid:	Store away from oxidizers and heat. Store below 30°C.
Hazardous Decomposition :	Carbon Dioxide and/or Carbon Monoxide.

SECTION 11: TOXICOLOGICAL INFORMATION

Oral:	The oral LD ₅₀ for M.D. FORTE® Perfection Gel – Acne Medication , based on its alcohol content, can be calculated to be between 7.06 and 10.6 g/Kg when tested in rats.
Reproduction:	Not Tested
Mutagenicity:	Not Tested

Skin:

Cumulative Irritation Testing: Twenty-three subjects participated in the study and were patch tested, on the upper back, with each of the test products daily for 14 days. Approximately 0.2 ml of each test material was applied onto a 2 cm x 2 cm semi-occlusive patch which was left in place for 24 hours Monday through Friday and 48 hours on Saturday for two consecutive weeks. Test sites were evaluated daily for erythema on a 0 (none) to 4 (severe) scale directly after patch removal and the scores were calculated via summation of the irritation values for each day. Maximum score per product was 1176.

Results/Conclusion: Table 1 depicts the cumulative irritation data curve for the experimental formulas tested. Based on the data obtained and the product's pH level of 3.8, **M.D. FORTE® Perfection Gel – Acne Medication** can be considered practically non-irritating and suitable for consumer use.

Table 1

<u>Conc.</u>	<u>pH</u>	<u>Cumulative Value</u>
10.0%	2.00	768/1176
10.0%	2.50	746/1176
10.0%	3.00	631/1176
10.0%	3.25	404/1176
10.0%	3.80	38/1176
15.0%	3.80	14/1176
20.0%	3.80	37/1176
10.0%	4.40	18/1176

Ocular:

In Vitro Acute Ocular Irritation Assay **M.D. FORTE® Perfection Gel – Acne Medication** was applied to a semi-permeable cellulose membrane and placed into a cubette filled with a protein reagent. The sample reacts with the reagent producing turbidity, the turbidity measured, and the irritancy potential projected based on a correlation of a standard set of known points produced by the positive control.

Results/Conclusion: Due to the sensitivity of the assay to acid based products, **M.D. FORTE® Perfection Gel – Acne Medication** produced a mild to moderate amount of irritation. However, in comparison to other commercially available products containing Glycolic Acid (with a known history of safe use in the market place) this product's irritation potential was considered either equal to or less than those currently being marketed.

Sensitization:

200 Subject Repeat Insult Patch Test: Induction Period - Approximately 0.2 ml of M.D. Formulations® Vit-A-Plus Hydr-A-Firming Masque was applied to a 2 cm x 2 cm square of Webril cotton fabric (affixed to Scanpor semi-occlusive surgical tape) and placed on the back of each subject between the scapulae and waist, adjacent to the spinal mid-line. The first induction patch was worn for a 48 hour period and was removed by a technician just prior to application of the second induction patch. Induction patches 2 through 9 were removed 24 hours after each application and the test site was allowed to rest for an additional 24 hours prior to repatching. All test sites were graded for erythema and edema prior to reapplication of the next patch. *Rest Period -* After the last induction reading, no patches were applied for 10 - 14 days. *Challenge Period -* After the rest period, subjects were patched with **M.D. FORTE® Perfection Gel – Acne Medication**, as outlined above, at a naive site; Patches were removed by a technician after 48 hours; Erythema/edema were evaluated upon removal and at 96 hours post application.

Results/Conclusion: Scattered, transient, barely perceptible to moderate non-specific irritation was observed in approximately 5% (11/207) of the subjects during the induction and/or challenge periods. None of these non-specific responses was considered to be irritant or allergic in nature

SECTION 12: ECOLOGICAL INFORMATION

Persistence and Degradability: Readily and rapidly degradable.

Aquatic Toxicity: No data available on this product.

SECTION 13: DISPOSAL CONSIDERATIONS

For small amounts of **M.D. FORTE® Perfection Gel – Acne Medication**, discard as ordinary trash. For large quantities, contact Allergan for information on disposal options.

SECTION 14: TRANSPORT INFORMATION

Domestic (Land, D.O.T.)

Consumer Commodity (containing flammable solution), ORM-D

International (Air, I.C.A.O.)

ID 8000 Consumer Commodity (containing flammable solution), Class 9

International (Water, I.M.O.)

UN 1993 Flammable Liquid, N.O.S. (Ethyl Alcohol Solution), Class 3.3, Pkg. Group III
(Flash pt. 82°F), Limited Quantity

SECTION 15: REGULATORY INFORMATION

TSCA (Toxic Substances Control Act):

Components of this product are listed on the TSCA Inventory.

CERCLA (Comprehensive Environmental Response, Compensation, and Liability Act):

This product contains no components subject to reporting or notification requirements.

SARA Title III (Superfund Amendments and Reauthorization Act):

311/312 Hazard Categories: Immediate Health, Fire

313 Reportable Ingredients: None

WHMIS (Workplace Hazardous Materials Information System - Canada):

Not Regulated (Product is regulated by the Food and Drugs Act)

SECTION 16: OTHER INFORMATION

The preceding information is based on available data and is believed to be correct. However, no warranty is expressed or to be implied regarding the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Since the information contained herein may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use. This information is furnished upon the condition that the persons receiving it shall make their own determinations of the effects, properties, and protections which pertain to their particular conditions.