



U.S. Department  
of Transportation

Pipeline and Hazardous Materials  
Safety Administration

1200 New Jersey Ave., SE  
Washington, DC 20590

NOV 26 2008

Mr. Dennis Hernandez  
Wound Management  
Smith & Nephew Inc.  
2925 Shawnee Industrial Way  
Suite 100  
Suwanee, GA 30024

Ref. No: 08-0265

Dear Mr. Hernandez:

This is in response to your October 21, 2008 letter requesting clarification of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). Specifically, you ask if your products identified as "Remove Bottle" (UN1993 Flammable liquid, n.o.s. PG III) and "Skin Prep Pads" (UN3175 Solids containing flammable liquid, n.o.s., PG II) may be reclassified as Consumer commodity, ORM-D for highway transportation. You provide product descriptions and Material Safety Data Sheets for each of the products. The products are packaged as limited quantities and are in a form intended for sale or for consumption by individuals for the purposes of personal care or household use.

The answer is yes. Both products meet the definition of a Consumer commodity as defined in § 171.8. You may reclass the products as Consumer commodity, ORM-D provided the "Remove Bottle" is packaged and prepared for transportation in accordance with the limited quantity provisions specified in § 173.150(b) and the "Skin Prep Pads" are packaged in accordance with the limited quantity provisions specified in § 173.151(b).

I trust this satisfies your inquiry.

Sincerely,

Charles Betts  
Chief, Standards Development  
Office of Hazardous Materials Standards

Wound Management  
Smith & Nephew, Inc.  
c/o APL Logistics, Inc.  
2925 Shawnee Industrial Way  
Suite 100  
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 We are smith&nephew

Eichenlaub  
\$173.150  
Exceptions  
08-0265

October 21, 2008

Office of Hazardous Materials Standards  
U.S. Department of Transportation; Attn: PHH-52  
1200 New Jersey Avenue, SE East Bldg, 2<sup>nd</sup> Floor  
Washington, DC 20590

Re: Request for letters of interpretation concerning "Consumer Commodity, ORM-D"

Dear Sir(s),

Smith & Nephew, Inc. manufactures medical supplies that are sold to hospitals for the care of patients. Two of these products are currently classed as hazardous materials, however, both meet the limited quantity provision of 173.150 and are materials that (as defined in 171.8) are packaged and distributed in a form intended for sale or for consumption by individuals for purposes of personal care or household use.

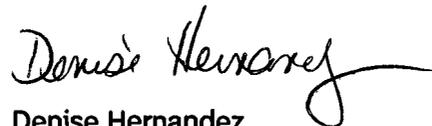
Please advise if these 2 items can be re-classed as "Consumer Commodity, ORM-D" for transport via truck. I've enclosed the MSDS sheets for both.

**Item 1:** Remove Bottle  
Current Class: 3 Flammable Liquid n.o.s. (Dipropylene) PG III  
Inner Vol / Wt: 8oz each / 3.5kg wt/case  
Package Wt: Typical package weight is less than 30kg.

**Item 2:** Skin Prep Swabs  
Current Class: 4.1 Solids containing Flammable Liquid n.o.s. (Isopropyl Alcohol) PG II  
Weight: 2kg wt/case  
Package Wt: Typical package weight is less than 30kg.

Feel free to call or email me with any questions regarding this request.

Regards,



**Denise Hernandez**  
Import/Export Coordinator  
[denise.hernandez@smith-nephew.com](mailto:denise.hernandez@smith-nephew.com)  
Direct 678.804-5260  
Cell 770.309.1541  
Fax 727.329.7668

# Material Safety Data Sheet

## Section 1 - Chemical Product and Company Identification

**Product/Chemical Name:** Remove™ without BHA Bottles

**Chemical Formula:** N/A

**CAS Number:** N/A

**Other Designations:** N/A

**General Use:** Topical

**Manufacturer:** Smith & Nephew, Inc. 11775 Starkey Road Largo, FL 33773-4727 **Phone:** 1 800 876-1261

**Date Reviewed:** April 27, 2007

## Section 2 - Composition Information on Ingredients

Ingredient Name	CAS Number	%wt or %Vol
Dipropylene Glycol Methyl Ether	34590-94-8	Proprietary
C10-11 Isoparaffin	64742-48-9	Proprietary
Aloe Extract	85507-69-3	Proprietary
Benzyl Alcohol	100-51-6	Proprietary
Fragrance	N/A	Proprietary

## Section 3 - Hazards Identification

★★★★★Emergency Overview★★★★★

HMIS	
H	1
F	2
R	1
PPE	0

### Potential Health Effects

**Primary Entry Routes:** Inhalation, Eyes, Skin, Ingestion

**Target Organs:** N/A

#### Acute Effects

**Inhalation:** Inhalation may cause respiratory tract irritation.

**Eye:** May cause temporary eye irritation or conjunctivitis.

**Skin:** None known

**Ingestion:** May cause gastrointestinal irritation.

**Carcinogenicity:** This material is not known to have carcinogenic properties.

**Medical Conditions Aggravated by Long-Term Exposure:** Significant skin irritation may occur if there is a pre-existing skin disorder.

**Chronic Effects:** None Known

## Section 4 - First Aid Measures

**Inhalation:** Remove to fresh air. Restore and/or support breathing as needed.

**Eye Contact:** Flush eyes with copious amounts of water for at least 15 minutes.

**Skin Contact:** Wash with soap and water, or shower.

**Ingestion:** If victim is conscious, give water or a few ounces of USP white mineral oil, but **do not** induce vomiting. Contact a physician immediately.

*After first aid, get appropriate in-plant, paramedic, or community medical support.*

**Special Precautions/Procedures:** None.

## Section 5 - Fire-Fighting

**Flash Point:** 114°F / 45.6°C

**Flash Point Method:** TCC

**Burning Rate:** Not determined

**Autoignition Temperature:** Not determined

**LFL (% vol. in air):** 0.6

**UFL (% vol. in air):** 6.5

**Flammability Classification:** Class II Combustible Liquid

**Extinguishing Media:** Water spray or fog, carbon dioxide, foam, dry chemical

**Unusual Fire or Explosion Hazards:** Vapors are heavier than air & may travel a long distance to an ignition source & flashback.

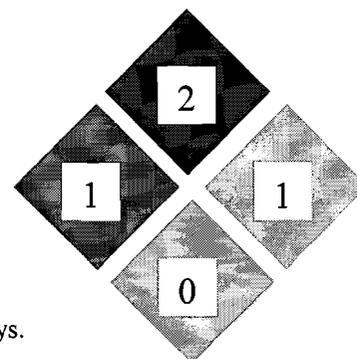
**Hazardous Combustion Products:** None Known

**Fire-Fighting Instructions:** Do not release runoff from fire control methods to sewers or waterways.

Water spray can be used to cool fire-exposed containers.

**Fire-Fighting Equipment:** Self Contained Breathing Apparatus and protective clothing should be worn.

**NFPA:**



## Section 6 - Accidental Release Measures

**Spill /Leak Procedures:**

**Small Spills:** Wipe up spill. Ventilate area.

**Large Spills**

**Containment:** Keep from entering sewers, lakes, or streams

**Cleanup:** Wearing appropriate protective clothing, soak up spills with sand or vermiculite, & place in a proper container for disposal. Provide adequate ventilation.

**Regulatory Requirements:** Follow applicable OSHA regulations (29 CFR 1910.120).

## Section 7 - Handling and Storage

**Handling Precautions:** Avoid prolonged skin & eye contact. Avoid breathing vapors. Keep from entering sewers, lakes, or streams.

**Storage Requirements:** Store in a cool dry place,  $\leq 77^{\circ}\text{F}$  /  $25^{\circ}\text{C}$  that is a well-ventilated area away from sources of heat, sparks, flames, & strong oxidizing agents.

**Regulatory Requirements:** None required for normal use

## Section 8 - Exposure Controls / Personal Protection

**Engineering Controls:** None required

**Ventilation:** General ventilation recommended

**Administrative Controls:** None required for normal use

**Respiratory Protection:** When working with small quantities in a well-ventilated area, respiratory protection may not be required.

**Protective Clothing/Equipment:** When working with small quantities in a well-ventilated area, protective clothing / equipment may not be required.

**Comments:** Never eat, drink, or smoke in work areas. Practice good personal hygiene after using this material, especially before eating, drinking, smoking, using the toilet, or applying cosmetics.

## Section 9 - Physical and Chemical Properties

**Physical State:** Liquid

**Appearance and Odor:** Clear, colorless liquid with a slight paraffinic odor.

**Odor Threshold:** Not determined

**Vapor Pressure (mm Hg):** < 10

**Vapor Density (Air=1):** > 1

**Formula Weight:** N/A

**Density:** Not determined

**Specific Gravity (H<sub>2</sub>O=1, at 25° C):** 0.83

**pH @ 20°C:** 3.8

**Water Solubility:** Appreciable

**Other Solubilities:** Not determined

**Boiling Point:** > 350°F / > 177°C

**Freezing/Melting Point:** Not determined Not determined

**Viscosity:** Not determined

**Refractive Index @ 25°C:** 1.416

**Surface Tension:** Not determined

**% Volatile:** Not determined

**Evaporation Rate (nBuAc=1):** < 1

## Section 10 - Stability and Reactivity

**Stability:** Stable

**Polymerization:** Hazardous polymerization will not occur.

**Chemical Incompatibilities:** Strong oxidizers & strong acids

**Conditions to Avoid:** Sources of heat, sparks, & flames

**Hazardous Decomposition Products:** Oxides of carbon & partially oxidized hydrocarbons

## Section 11 - Toxicological Information

### Toxicity Data:

**Eye Effects:** None known

**Skin Effects:** None

**Chronic Effects:** None known

**Mutagenicity:** None

**Acute Inhalation Effects:** None known

**Acute Oral Effects:** None known

**Carcinogenicity:** None known

**Teratogenicity:** None known

## Section 12 - Ecological Information

**Ecotoxicity:** Not determined

**Environmental Fate:** Not determined

**Environmental Degradation:** Not determined

**Soil Absorption/Mobility:** Not determined

## Section 13 - Disposal Considerations

**Disposal:** Contact your supplier or a licensed contractor for detailed recommendations. Follow applicable federal, state, and local regulations.

**Disposal Regulatory Requirements:** Contact your licensed waste disposal company for the disposal regulatory requirements.

**Container Cleaning and Disposal:** Burn waste in an approved incinerator or dispose of via licensed waste disposal company following all local, state and federal regulations.

## Section 14 - Transport Information

Flammable liquid n.o.s. UN1993

## Section - 15 Regulatory Information

**EPA Regulations:** None known for normal use

**OSHA Regulations:** None known for normal use

**State Regulations:** May vary from state to state

## Section 16 - Other Information

**Additional Hazard Rating Systems:** None Known

# Material Safety Data Sheet

## Section 1 - Chemical Product and Company Identification

**Product/Chemical Name:** *Skin Prep Swabs*

**Chemical Formula:** N/A

**CAS Number:** N/A

**Other Designations:** N/A

**General Use:** For external use only

**Manufacturer:** Smith & Nephew, Inc. 11775 Starkey Road Largo, FL 33773-4727 **Phone:** 1 800 876-1261

**Date Reviewed:** February 22, 2007

## Section 2 - Composition Information on Ingredients

Ingredient Name	CAS Number	%wt or % Vol
Isopropyl Alcohol	67-63-0	Proprietary
Butyl Ester of PVM/MA Copolymer Solution	25119-68-0	Proprietary
Acetyl Tributyl Citrate	77-90-7	Proprietary

## Section 3 - Hazards Identification

★★★★★Emergency Overview★★★★★

HMIS	
H	2
F	3
R	0
PPE	0

### Potential Health Effects

**Primary Entry Routes:** Inhalation, Eyes, Skin, Ingestion

**Target Organs:** N/A

#### Acute Effects

**Inhalation:** Exposure to high air concentrations may cause mild irritation to nose and throat. Drowsiness, headache, and mild narcosis can occur from inhalation.

**Eye:** Exposure to high air concentrations may cause mild irritation to eyes.

**Skin:** None Known

**Ingestion:** Ingestion may cause drowsiness, burning of the gastrointestinal tract, and death. Ingestion may cause gastrointestinal pain, cramps, nausea and vomiting.

**Carcinogenicity:** This material is not known to have carcinogenic properties.

**Medical Conditions Aggravated by Long-Term Exposure:** Pre-existing eye, skin and respiratory disorders may be aggravated by exposure to this product. Impaired function from pre-existing disorders may be aggravated by exposure to this product.

**Chronic Effects:** None Known

## Section 4 - First Aid Measures

**Inhalation:** Remove victim to fresh air. If victim is not breathing, give artificial respiration.

**Eye Contact:** Flush eyes (including under lids) with copious amounts of water for at least 15 minutes.

**Skin Contact:** No First Aid should be needed.

**Ingestion:** Do not induce vomiting. Contact the poison control center or a physician immediately for instructions.

*After first aid, get appropriate in-plant, paramedic, or community medical support.*

**Special Precautions/Procedures:** None.

## Section 5 - Fire-Fighting

**Flash Point:** 53°F / 11.7°C

**Flash Point Method:** TCC

**Burning Rate:** N/A

**Autoignition Temperature:** Not determined

**LFL (% vol. in air):** 2.5

**UFL (% vol. in air):** 12

**Flammability Classification:** Class IB Flammable Liquid

**Extinguishing Media:** Carbon Dioxide, Dry Chemical, Alcohol Foam

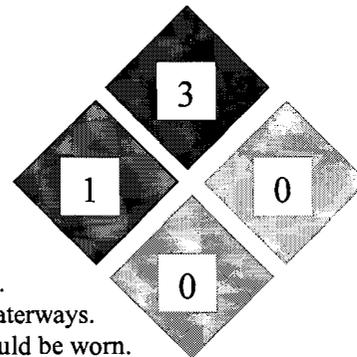
**Unusual Fire or Explosion Hazards:** Vapors are heavier than air and may travel a considerable distance to an ignition source and flashback.

**Hazardous Combustion Products:** Carbon Monoxide and unidentified organic compounds.

**Fire-Fighting Instructions:** Do not release runoff from fire control methods to sewers or waterways.

**Fire-Fighting Equipment:** Self Contained Breathing Apparatus and protective clothing should be worn.

**NFPA:**



## Section 6 - Accidental Release Measures

**Spill /Leak Procedures:**

**Small Spills:** Mop or wipe up

**Large Spills**

**Containment:** Not required

**Cleanup:** Remove all sources of heat and ignition. Absorb with sand or vermiculite. Ventilate area to dissipate vapors.

**Regulatory Requirements:** Follow applicable OSHA regulations (29 CFR 1910.120).

## Section 7 - Handling and Storage

**Handling Precautions:** Do not use with electrocautery procedures.

**Storage Requirements:** Store in a cool dry place ( $\leq 77^{\circ}\text{F}$  /  $25^{\circ}\text{C}$ ) that is away from oxidizers, heat, sparks, and open flames.

**Regulatory Requirements:** None known for normal use

## Section 8 - Exposure Controls / Personal Protection

**Engineering Controls:** None required

**Ventilation:** General ventilation recommended

**Administrative Controls:** None required for normal use

**Respiratory Protection:** None required for normal use

**Protective Clothing/Equipment:** None required for normal use

**Comments:** Never eat, drink, or smoke in work areas. Practice good personal hygiene after using this material, especially before eating, drinking, smoking, using the toilet, or applying cosmetics.

## Section 9 - Physical and Chemical Properties

**Physical State:** Liquid

**Appearance and Odor:** Clear, colorless liquid with an alcohol aroma.

**Water Solubility:** Miscible

**Odor Threshold:** Not determined

**Vapor Pressure (mm Hg):** 33

**Vapor Density (Air=1):** 2.1

**Formula Weight:** N/A

**Density:** Not determined

**Specific Gravity (H<sub>2</sub>O=1, at 25° C):** 0.85

**pH:** Not determined

**Other Solubilities:** Not determined

**Boiling Point:** 180°F

**Freezing/Melting Point:** Not determined / Not determined

**Viscosity:** Not determined

**Refractive Index @ 25°C:** 1.385

**Surface Tension:** Not determined

**% Volatile:** Not determined

**Evaporation Rate (nBuAc=1):** 2.83

## Section 10 - Stability and Reactivity

**Stability:** Stable

**Hazardous Decomposition Products:** Oxides of carbon

**Polymerization:** Hazardous polymerization will not occur. **Chemical Incompatibilities:** Strong oxidizing agents

**Conditions to Avoid:** Excessive heat, open flames and ignition sources. Do not use in conjunction with electrocautery equipment.

## Section 11 - Toxicological Information

### Toxicity Data

**Eye Effects:** None Known

**Chronic Effects:** None Known

**Skin Effects:** None

**Carcinogenicity:** None Known

**Acute Inhalation Effects:** None Known

**Mutagenicity:** None

**Acute Oral Effects:** None Known

**Teratogenicity:** None Known

## Section 12 - Ecological Information

**Ecotoxicity:** Not determined

**Environmental Fate:** Not determined

**Environmental Degradation:** Not determined

**Soil Absorption/Mobility:** Not determined

## Section 13 - Disposal Considerations

**Disposal:** Contact your supplier or a licensed contractor for detailed recommendations. Follow applicable federal, state, and local regulations.

**Disposal Regulatory Requirements:** None known for normal use

**Container Cleaning and Disposal:** Discard in suitable trash container

## Section 14 - Transport Information

DOT Transportation Data (49 CFR 172.101):

Not Regulated

## Section - 15 Regulatory Information

**EPA Regulations:** None known for normal use

**OSHA Regulations:** None known for normal use

**State Regulations:** May vary from state to state

## Section 16 - Other Information

**Additional Hazard Rating Systems:** None Known