DERMA STAT- ethyl alcohol aerosol, foam
Rosedale Therapeutics, LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Derma Stat

Active Ingredient:

65% Ethyl Alcohol by volume

Antiseptic

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

Use: For hand washing to decrease bacteria on the skin.

Warning: For external use only. Avoid contact with eyes. Contents under pressure. Do not puncture incinerate, use near fire, spark, flame, expose to heat or store above 120°F.

Stop use and ask a doctor if irritation and redness develop and persist for more than 72 hours.

When using this product do not get it in the eyes; this product causes eye irritation upon direct contact. In case of eye exposure, rinse thoroughly with water. If eye irritation persists, contact a physician.

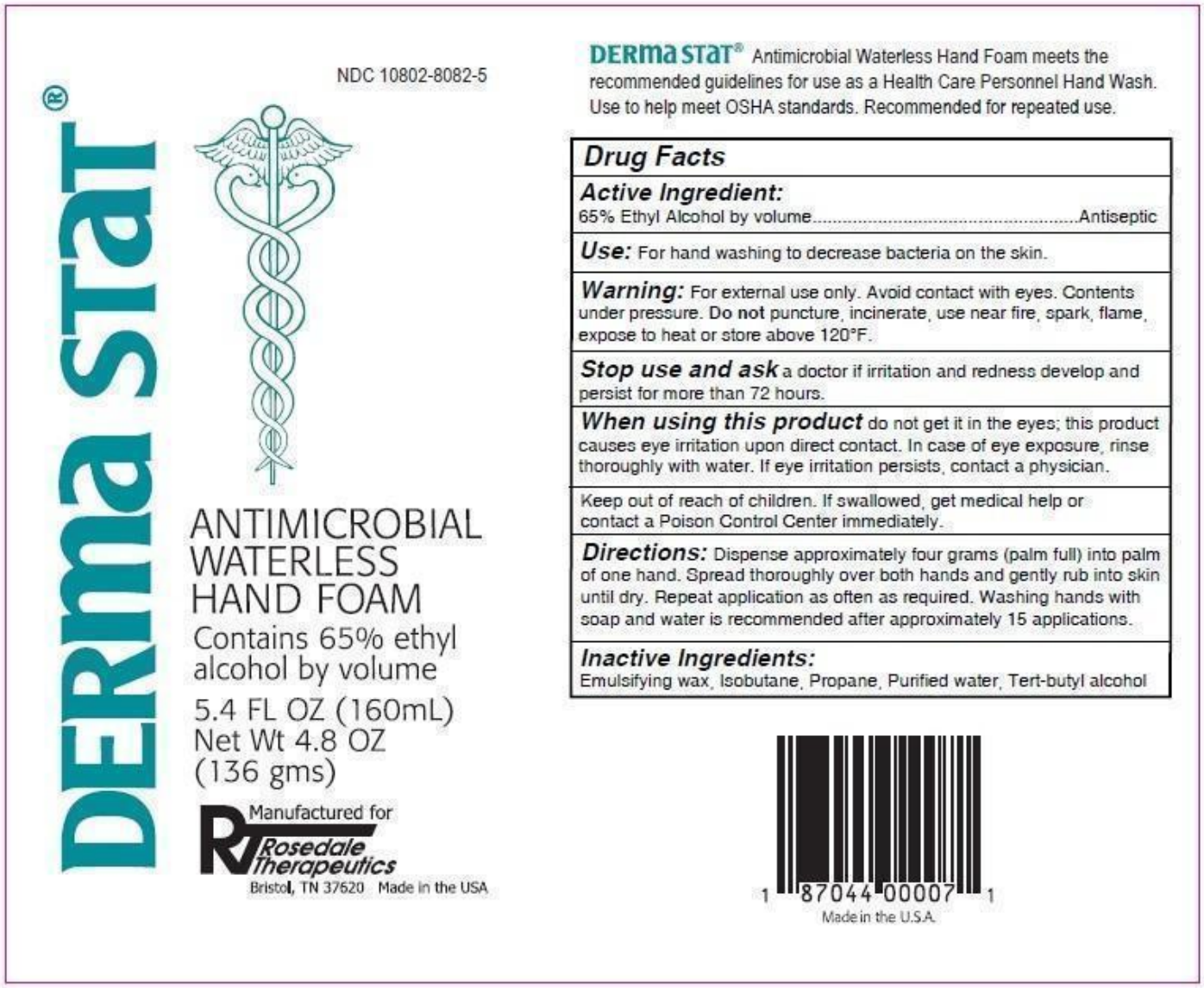
Directions: Dispense approximately four grams (palm full) into palm of one hand. Spread thoroughly over both hands and gently rub into skin until dry. Repeat application as often as required. Washing hands with soap and water is recommended after approximately 15 applications.

Inactive Ingredients:

Emulsifying wax, Isobutane, Propane, Purified water, Tert-butyl alcohol

DERMA STAT® Antimicrobial Waterless Hand Foam meets the recommended guidelines for use as a Health Care Personnel Hand Wash. Use to help meet OSHA standards. Recommended for repeated use.

Packaging



DERMA STAT

ethyl alcohol aerosol, foam

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:10802-8082
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	65 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	

ISOBUTANE (UNII: BXR49TP611)	
PROPANE (UNII: T75W9911L6)	
WATER (UNII: 059QF0KO0R)	
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	

Product Characteristics			
Color	white	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10802-8082-5	160 mL in 1 CAN; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	02/16/2015	

Labeler - Rosedale Therapeutics, LLC (161264622)

Establishment

Name	Address	ID/FEI	Business Operations
220 Laboratories Inc.		783247950	manufacture(10802-8082)

Revised: 2/2015 Rosedale Therapeutics, LLC