SOFT N SURE ANTISEPTIC HAND- alcohol gel
Deb USA, Inc.

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.

Soft 'N Sure® Antiseptic Hand Gel

Drug Facts

Active ingredient

Ethyl alcohol 65%

Purpose

Antiseptic

Uses

- to decrease bacteria on the skin that could cause disease
- recommended for repeated use

Warnings

For external use only: hands

Flammable. Keep away from fire or flame.

When using this product

- keep out of eyes. In case of contact with eyes, flush thoroughly with water
- avoid contact with broken skin
- do not inhale or ingest

Stop use and ask a doctor if

- irritation and redness develop.
- condition persists more than 72 hours

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

Directions

- wet hands thoroughly with product and allow to dry without wiping
- for children under 6, use under adult supervision
- not recommended for infants

Other information

- do not store above 105°F
- may discolor some fabrics
- harmful to wood finishes and plastics

Inactive Ingredients

benzophenone-4, carbomer, fragrance, glycerin, isopropyl myristate, propylene glycol, tocopheryl acetate, water

Questions or comments?

1-866-783-0422

PRINCIPAL DISPLAY PANEL - 33.8 fl oz Bottle Label

Soft 'N Sure®

deb med®

NDC 11084-812-41

Hand Sanitizer
Antiseptic Hand Gel

Moisturizing

15
seconds
Fast-Acting*

REORDER #
1445-87

1 Liter SDS (33.8 fl oz) (1.05 qt)

Manufactured for:
Deb USA, Inc., Charlotte, NC 28217

1-866-783-0422

www.debmed.com

61874
1445-86H(F)(118)
L0000376FD
Made in USA with US and
foreign components

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SOFT N SURE ANTISEPTIC HAND

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11084-812
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**
SULISOBENZONE (UNII: 1W6L629B4K)	
Glycerin (UNII: PDC6A3C0OX)	
Isopropyl Myristate (UNII: 0RE8K4LNJS)	
Propylene Glycol (UNII: 6DC9Q167V3)	
ACETATE ION (UNII: 569DQM74SC)	
Water (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:11084-812-41	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2018	
2	NDC:11084-812-13	444 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2018	
3	NDC:11084-812-21	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2018	
4	NDC:11084-812-25	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC monograph not final	part333E	02/01/2018	

Labeler - Deb USA, Inc. (607378015)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon		088520668	MANUFACTURE(11084-812)

Revised: 2/2018 Deb USA, Inc.