DREUMEX OMNICARE HAND SANITIZER- alcohol spray
Dreumex 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.

Active Ingredient

Ethyl Alcohol, 80%

Purpose

Antibacterial

Uses

For hand cleaning to decrease bacteria on the skin.

Recommended for repeated use.

Warnings

For external use only.

Flammable. Keep away from fire or flame. No Smoking.

When using this product

avoid contact with face, eyes and broken skin. If eye contact occurs, rinse eyes thoroughly with water and seek medical advice.

Stop use and ask a doctor

if irritation or redness develops.

Contents under pressure.

Do not puncture or incinerate. Do not store at temperatures above 120°F (50°C).

Keep out of reach of children.

If swallowed get medical help, or contact a poison control center immediately.

Directions

- apply a palmful to hands
- scrub thoroughly until dry

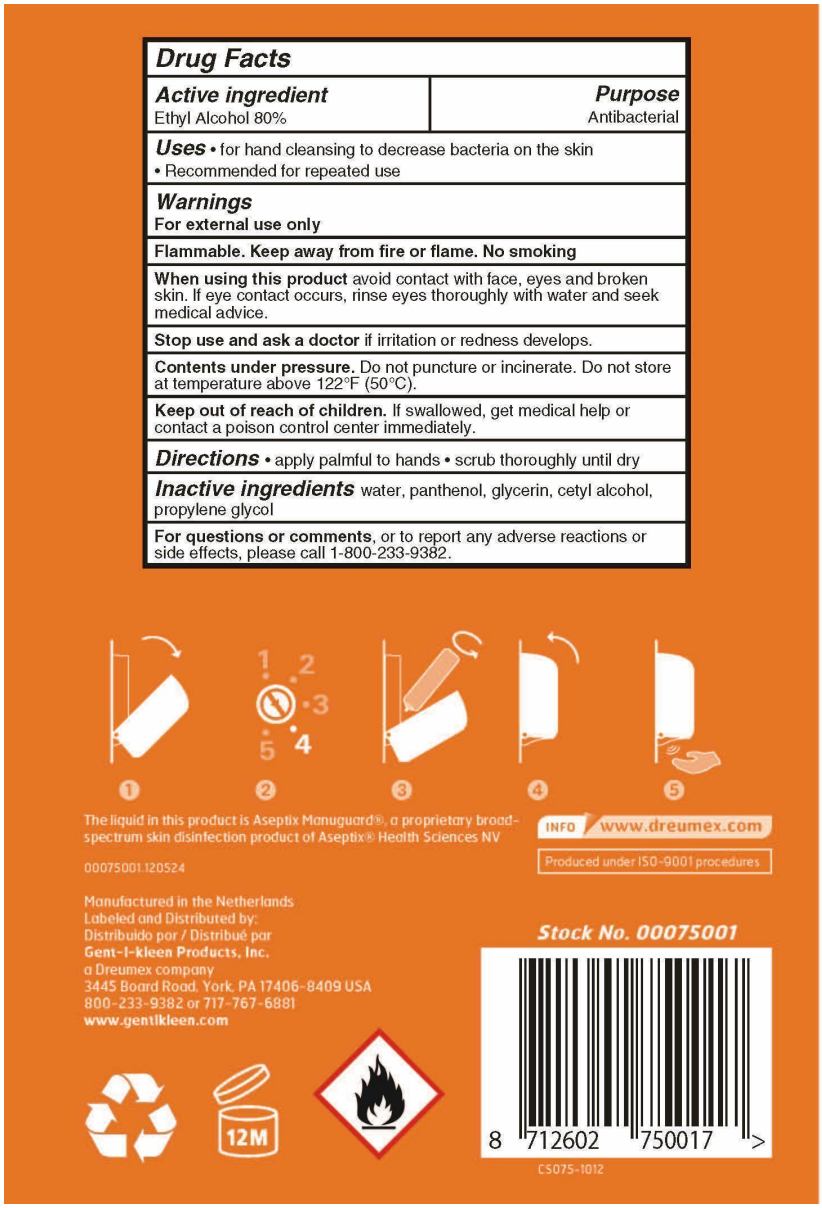
Inactive Ingredients

water panthenol, glycerin, cetyl alcohol, propylene glycol.

For questions or comments

or to report any adverse reactions or side effects, please call 1-800-233-9382.

Principal Display Panel -- Label on individual unit can



Carton Label -- package of 6 cans

DREUMEX OMNICARE HAND SANITIZER

alcohol spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:53305-065
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	800 mg in 1.2 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	400 mg in 1.2 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:53305-065-02	6 in 1 CASE	12/15/2016	
1	NDC:53305-065-01	400 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	part333E	12/01/2012	

Labeler - Dreumex USA, Inc. (003003118)

Establishment

Name	Address	ID/FEI	Business Operations
Dreumex USA, Inc.		003003118	label(53305-065)

Establishment

Name	Address	ID/FEI	Business Operations
BiB Production and Packaging B.V.		409606985	manufacture(53305-065)

Revised: 9/2018 Dreumex USA, Inc.