SANMED HEALTHCARE HAND SANITIZING HANDRUB- ethyl alcohol liquid
Sanmed Healthcare Private Limited

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.

SANMED HEALTHCARE HAND SANITIZING HANDRUB

DRUG FACTS

Active ingredients

Ethyl Alcohol 80.0% v/v

Purpose

Antiseptic Handrub

Uses:

* A hand rub to decrease microbial load on the skin

Warnings:

* For external use only
* Flammable. Keep away from fire or flame, heat sparks and sources of static discharge

When using this product:
* Keep out of Eyes, Ears and Mouth.
* In case of contact with eyes, rinse promptly & thoroughly with water.
* Discontinue use if irritation and redness develop.

Stop use and ask a doctor if skin irritation or redness occurs for more than 72 hours.

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

Directions:

* Apply product onto hands, spread thoroughly & rub until dry.

Other information:

* Store below 30°C
* See Safety Data Sheet (SDS)

* For emergency medical information in USA, call

Inactive ingredients:

Hydrogen Peroxide 0.125% v/v, Water (aqua), Glycerin, Carbomer 940, Aminomethyl Propanol, Dettol Frag.

Questions or comments?

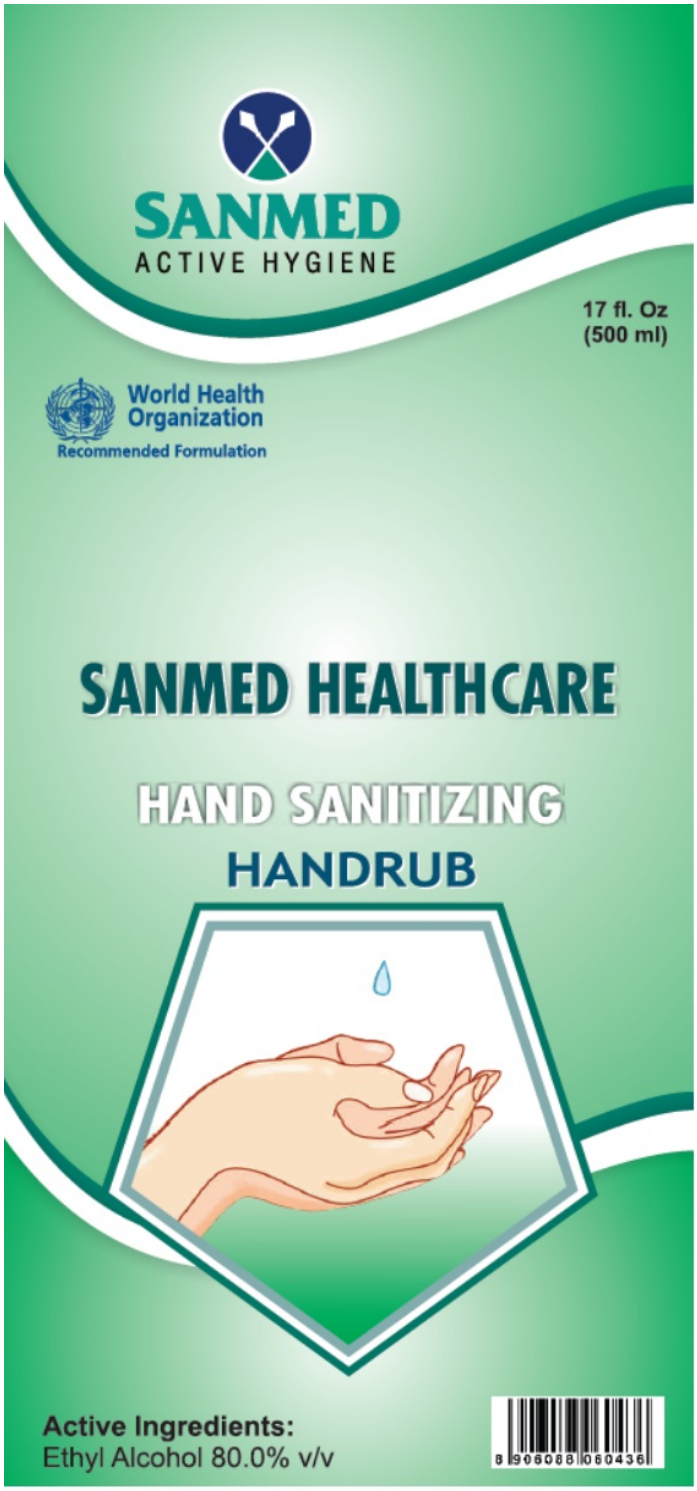
* Call: +91 40 4221 2432 / 33
* Email: info@sanmed.in

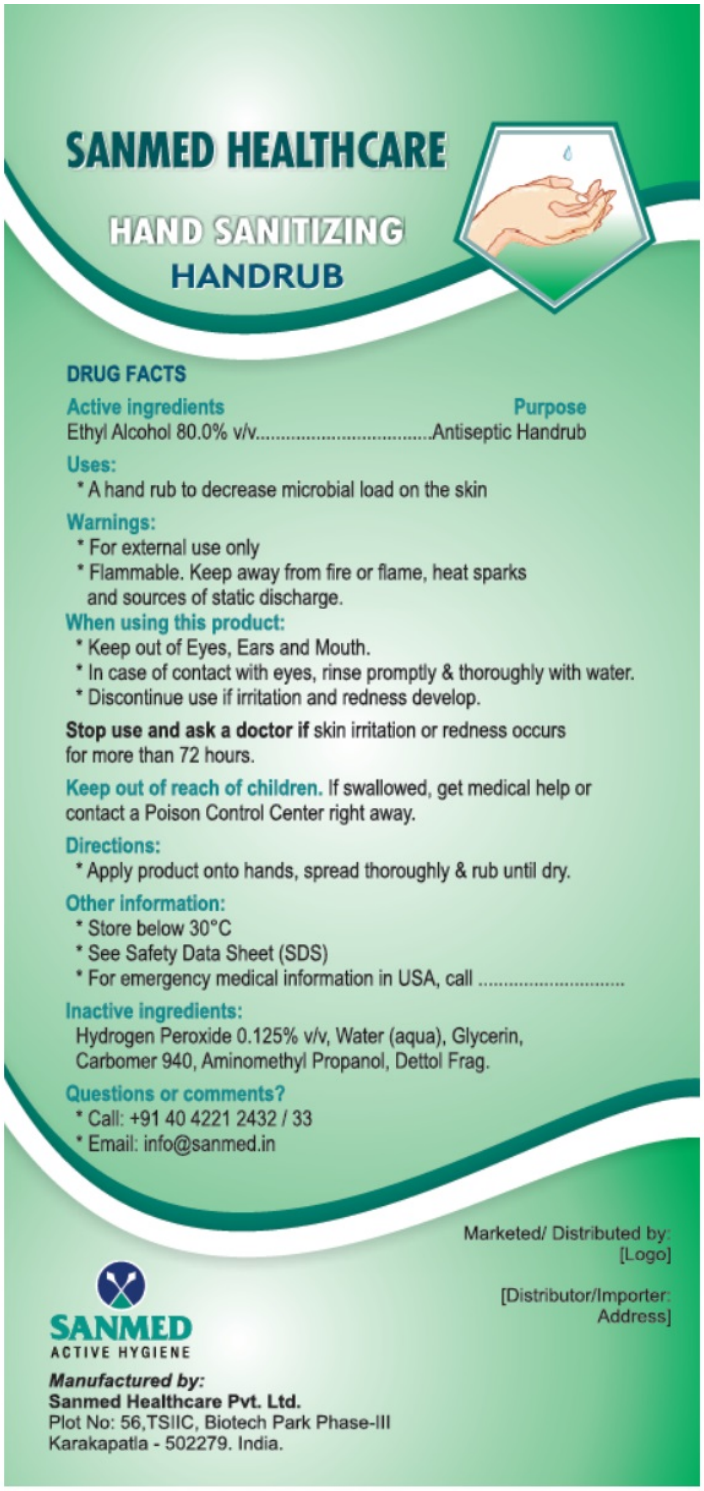
World Health Organization Recommended Formulation

SANMED ACTIVE HYGIENE

Manufactured by:
Sanmed Healthcare Pvt. Ltd.
Plot No: 56, TSIIC, Biotech Park Phase-III
Karakapatla - 502279. India.

Packaging





SANMED HEALTHCARE HAND SANITIZING HANDRUB

ethyl alcohol liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:81357-103
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81357-103-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/19/2021	
2	NDC:81357-103-02	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/19/2021	
3	NDC:81357-103-03	240 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/19/2021	
4	NDC:81357-103-04	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/19/2021	
5	NDC:81357-103-05	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/19/2021	
6	NDC:81357-103-06	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/19/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/19/2021	

Labeler - Sanmed Healthcare Private Limited (854248431)

Establishment

Name	Address	ID/FEI	Business Operations
Sanmed Healthcare Private Limited		854248431	manufacture(81357-103)

Revised: 5/2021 Sanmed Healthcare Private Limited