SUDS HAND SANITIZER- benzealkonium chloride liquid
Pro Chem, 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.

SUDS Hand Sanitizer Drug Facts and Label

Drug Facts Box OTC-Active Ingredient Section

benzalkonium chloride USP 0.13%

Drug Facts Box OTC-Indications & Usage Section

For hand-washing to decrease bacteria on the skin, only when water is not available

Drug Facts Box OTC-Warnings Section

For external use only

Drug Facts Box OTC-Purpose Section

Antiseptic

Drug Facts Box-OTC When Using Section

do not get into eyes

if contact occurs, rinse eyes thoroughly with water

Drug Facts Box-OTC Stop Use Section

irritation and redness develop

Drug Facts Box-OTC Keep Out Of Reach Of Children Section

If swallowed, get medical help or contact a Poison Control Center right away

Drug Facts Box-OTC Dosage & Administration Section

press pump twice to deliver two squirts (about a quarter size) of foaming product onto the palm of your hand

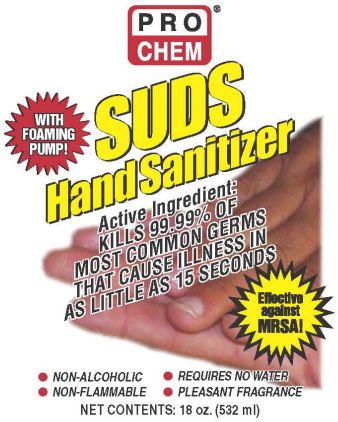
rub hands together until dry

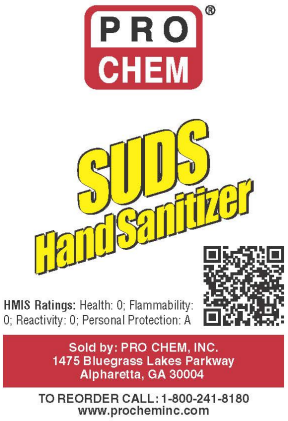
wash hands with soap and water at earliest opportunity

Drug Facts Box-OTC Inactive Ingredient Section

water, glycerine, dimethicone, DMDM hydantoin, iodopropynl butylcarbamate, methylchloroisothiazolinone, methylisothiazolinone, fragrance

SUDS Hand Sanitizer





SUDS Hand Sanitizer

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benzealkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63830-457
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63830-457-10	1000 mL in 1 CARTRIDGE; Type 0: Not a Combination Product	08/12/2019	
2	NDC:63830-457-18	50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/12/2019	
3	NDC:63830-457-14	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/12/2019	

4	NDC:63830-457-12	1000 mL in 1 BAG; Type 0: Not a Combination Product	08/12/2019	
5	NDC:63830-457-17	532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/12/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	08/12/2019	

Labeler - Pro Chem, Inc. (061396065)

Registrant - ABC Compounding Co., Inc. (003284353)

Establishment

Name	Address	ID/FEI	Business Operations
ABC Compounding Co., Inc.		003284353	manufacture(63830-457)

Revised: 8/2019 Pro Chem, Inc.