SECURE HAND SANITIZER- benzealkonium chloride liquid
Certus Medical, 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.

Secure Hand Sanitizer 6475 Drug Facts and Label

Drug Facts Box OTC-Active Ingredient Section

benzalkonium chloride 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

Secure Hand Sanitizer

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SECURE HAND SANITIZER benzealkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:75990-457
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:75990-457-10	1000 mL in 1 CARTRIDGE; Type 0: Not a Combination Product	06/05/2020	
2	NDC:75990-457-18	50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/05/2020	
3	NDC:75990-457-14	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/05/2020	
4	NDC:75990-457-12	1000 mL in 1 BAG; Type 0: Not a Combination Product	06/05/2020	
5	NDC:75990-457-17	532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/05/2020	
6	NDC:75990-457-16	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/05/2020	
7	NDC:75990-457-24	115 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/05/2020	
8	NDC:75990-457-15	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/05/2020	
9	NDC:75990-457-55	208200 mL in 1 DRUM; Type 0: Not a Combination Product	06/05/2020	
10	NDC:75990-457-19	18900 mL in 1 PAIL; Type 0: Not a Combination Product	06/05/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/05/2020	

Labeler - Certus Medical, Inc. (118806847)

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

Establishment

Name	Address	ID/FEI	Business Operations
ABC Compounding Co., Inc.		003284353	manufacture(75990-457)

Revised: 11/2022 Certus Medical, Inc.