CERTUS SECURE HAND SANITIZER- benzethonium 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.

Certus Secure Hand Sanitizer drug facts and label

Drug Facts Box OTC-Active Ingredient Section

BENZETHONIUM CHLORIDE 0.2%

Drug Facts Box OTC-Purpose Section

Antiseptic

Drug Facts Box OTC-Indications & Usage Section

For hand-washing to decrease bacteria on the skin

Drug Facts Box OTC-Warnings Section

For external use only

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, fragrance

Certus Secure Hand Sanitizer



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CERTUS SECURE HAND SANITIZER

benzethonium chloride liquid

Route of Administration

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:75990-637

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZETHO NIUM CHLO RIDE (UNII: PH41D05744) (BENZETHONIUM - UNII:1VU15B70BP)	BENZETHONIUM CHLORIDE	2 mg in 1 mL

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
GLYCERIN (UNII: PDC6A3C0OX)			
DIMETHICO NE (UNII: 92RU3N3Y1O)			
DMDM HYDANTO IN (UNII: BYR0546 TOW)			
IODO PRO PYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)			

Packaging			
Item Code	Package Description	Marketing Start Date	Marketing End Date
NDC:75990-637- 06	1 in 1 BOX	03/27/2017	
	800 mL in 1 BAG; Type 0: Not a Combination Product		
NDC:75990-637- 17	532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/27/2017	
NDC:75990-637- 24	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/27/2017	
NDC:75990-637- 01	1200 mL in 1 CARTRIDGE; Type 0: Not a Combination Product	03/27/2017	
NDC:75990-637- 03	350 mL in 1 CARTRIDGE; Type 0: Not a Combination Product	03/27/2017	
NDC:75990-637- 05	540 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/27/2017	
NDC:75990-637- 07	700 mL in 1 BAG; Type 0: Not a Combination Product	03/27/2017	
NDC:75990-637- 09	2000 mL in 1 CARTRIDGE; Type 0: Not a Combination Product	03/27/2017	
NDC:75990-637- 10	1000 mL in 1 CARTRIDGE; Type 0: Not a Combination Product	03/27/2017	
NDC:75990-637- 11	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/27/2017	
NDC:75990-637- 12	1000 mL in 1 BAG; Type 0: Not a Combination Product	03/27/2017	
NDC:75990-637- 13	800 mL in 1 BAG; Type 0: Not a Combination Product	03/27/2017	
NDC:75990-637- 14	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/27/2017	
NDC:75990-637- 15	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/27/2017	
NDC:75990-637- 28	149 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/27/2017	
NDC:75990-637- 27	800 mL in 1 CARTRIDGE; Type 0: Not a Combination Product	03/27/2017	
NDC:75990-637- 55	208200 mL in 1 DRUM; Type 0: Not a Combination Product	03/27/2017	
NDC:75990-637- 08	1 in 1 BOX	03/27/2017	
	1000 mL in 1 BAG; Type 0: Not a Combination Product		
	Item Code NDC:75990-637- 17 NDC:75990-637- 24 NDC:75990-637- 01 NDC:75990-637- 05 NDC:75990-637- 07 NDC:75990-637- 10 NDC:75990-637- 10 NDC:75990-637- 11 NDC:75990-637- 12 NDC:75990-637- 13 NDC:75990-637- 14 NDC:75990-637- 15 NDC:75990-637- 28 NDC:75990-637- 28 NDC:75990-637- 27 NDC:75990-637- 28 NDC:75990-637- 27 NDC:75990-637- 28 NDC:75990-637- 27 NDC:75990-637- 27 NDC:75990-637- 27	NDC:75990-637- NDC:75	Item Code Package Description Marketing Start Date NDC:75990-637- 06 1 in 1 BOX 03/27/20 17 800 mL in 1 BAG; Type 0: Not a Combination Product 03/27/20 17 NDC:75990-637- 17 532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product 03/27/20 17 NDC:75990-637- 24 118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product 03/27/20 17 NDC:75990-637- 30 1200 mL in 1 CARTRIDGE; Type 0: Not a Combination Product 03/27/20 17 NDC:75990-637- 30 350 mL in 1 CARTRIDGE; Type 0: Not a Combination Product 03/27/20 17 NDC:75990-637- 30 700 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product 03/27/20 17 NDC:75990-637- 30 2000 mL in 1 CARTRIDGE; Type 0: Not a Combination Product 03/27/20 17 NDC:75990-637- 10 1000 mL in 1 CARTRIDGE; Type 0: Not a Combination Product 03/27/20 17 NDC:75990-637- 10 1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product 03/27/20 17 NDC:75990-637- 12 1000 mL in 1 BAG; Type 0: Not a Combination Product 03/27/20 17 NDC:75990-637- 12 800 mL in 1 BAG; Type 0: Not a Combination Product 03/27/20 17 NDC:75990-637- 28 946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combinatio

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20	NDC:75990-637- 18	50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/27/2017	
21	NDC:75990-637- 19	18900 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/27/2017	
22	NDC:75990-637- 20	75600 mL in 1 DRUM; Type 0: Not a Combination Product	03/27/2017	
23	NDC:75990-637- 35	132500 mL in 1 DRUM; Type 0: Not a Combination Product	03/27/2017	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	03/27/2017		

Labeler - Certus Medical, Inc. (966433653)

Establishment				
Name	Address	ID/FEI	Business Operations	
ABC Compounding Co., Inc.		003284353	manufacture (75990-637)	

Revised: 3/2017 Certus Medical, Inc.