SECURO 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.

Securo 6370 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

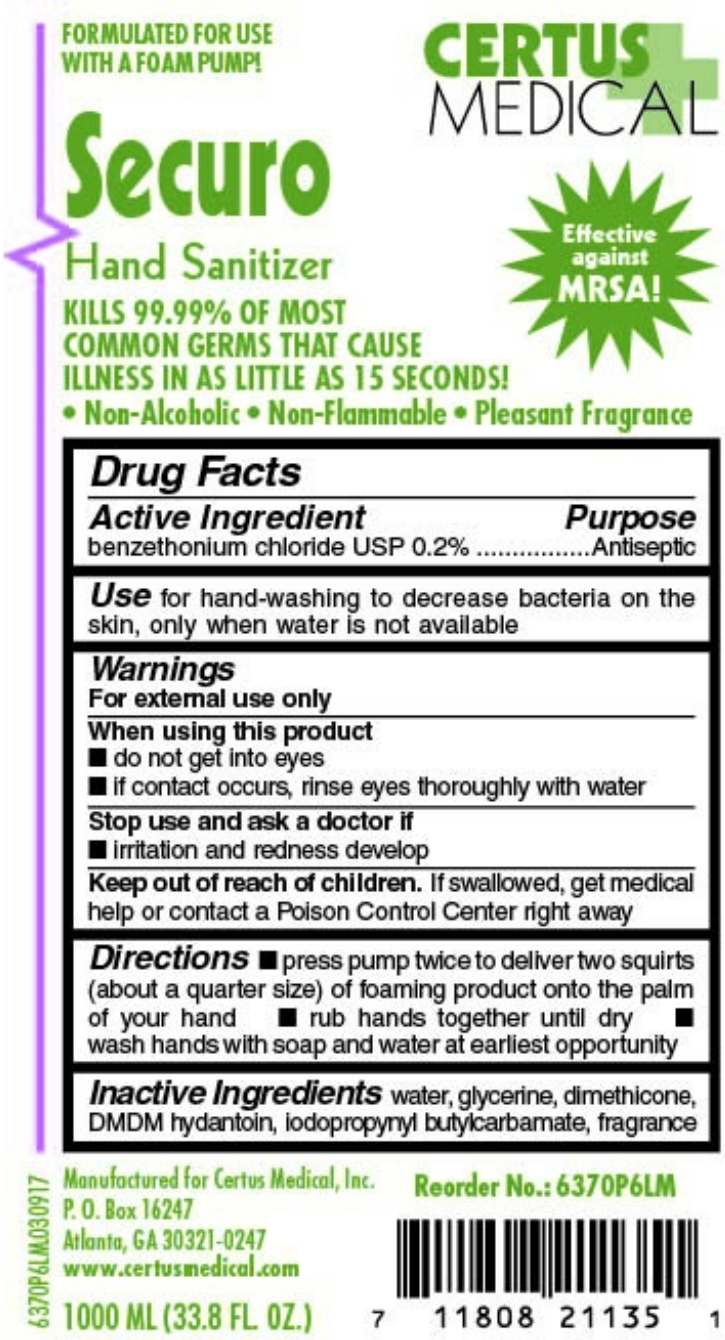
rub hands together until dry

wash hands with soap and water at earliest opportunity

Drug Facts Box OTC-Inactive Ingredient Section

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

6370 Securo Hand Sanitizer



6370 Securo

Hand Sanitizer

SECURO HAND SANITIZER

benzethonium chloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:75990-370
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		

Ingredient Name	Basis of Strength	Strength
BENZETHONIUM CHLORIDE (UNII: PH41D05744) (BENZETHONIUM - UNII:1VU15B70BP)	BENZETHONIUM CHLORIDE	2 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)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75990-370-06	1 in 1 BOX	03/14/2017	
1		800 mL in 1 BAG; Type 0: Not a Combination Product		
2	NDC:75990-370-17	532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/14/2017	
3	NDC:75990-370-24	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/14/2017	
4	NDC:75990-370-01	1200 mL in 1 CARTRIDGE; Type 0: Not a Combination Product	03/14/2017	
5	NDC:75990-370-03	350 mL in 1 CARTRIDGE; Type 0: Not a Combination Product	03/14/2017	
6	NDC:75990-370-05	540 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/14/2017	
7	NDC:75990-370-07	700 mL in 1 BAG; Type 0: Not a Combination Product	03/14/2017	
8	NDC:75990-370-09	2000 mL in 1 CARTRIDGE; Type 0: Not a Combination Product	03/14/2017	
9	NDC:75990-370-10	1000 mL in 1 CARTRIDGE; Type 0: Not a Combination Product	03/14/2017	
10	NDC:75990-370-11	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/14/2017	
11	NDC:75990-370-12	1000 mL in 1 BAG; Type 0: Not a Combination Product	03/14/2017	
12	NDC:75990-370-13	800 mL in 1 BAG; Type 0: Not a Combination Product	03/14/2017	
13	NDC:75990-370-14	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/14/2017	
14	NDC:75990-370-15	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/14/2017	
15	NDC:75990-370-28	149 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/14/2017	
16	NDC:75990-370-27	800 mL in 1 CARTRIDGE; Type 0: Not a Combination Product	03/14/2017	
17	NDC:75990-370-55	208200 mL in 1 DRUM; Type 0: Not a Combination Product	03/14/2017	
18	NDC:75990-370-08	1 in 1 BOX	03/14/2017	
18		1000 mL in 1 BAG; Type 0: Not a Combination Product		
	NDC:75990-370	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination		

19	NDC:75990-370-16	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/14/2017	
20	NDC:75990-370-18	50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/14/2017	
21	NDC:75990-370-19	18900 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/14/2017	
22	NDC:75990-370-20	75600 mL in 1 DRUM; Type 0: Not a Combination Product	03/14/2017	
23	NDC:75990-370-35	132500 mL in 1 DRUM; Type 0: Not a Combination Product	03/14/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	03/14/2017	

Labeler - Certus Medical, Inc. (966433653)

Establishment

Name	Address	ID/FEI	Business Operations
ABC Compounding Co., Inc.		003284353	manufacture(75990-370)

Revised: 3/2017 Certus Medical, Inc.