

CORAL - triclosan soap
ABC Compounding Co., 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.

Coral 6576 Drug Facts and Label

Drug Facts Box OTC-Active Ingredient Section

Triclosan 0.3%

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

wet hands and forearms

apply 5 milliliters (teaspoonful) or palmful to hands and forearms

scrub thoroughly for 1 minute and rinse

Drug Facts Box OTC-Inactive Ingredient Section

water, sodium laureth sulfate, sodium lauryl sulfate, cocamidopropyl betaine, alcohol denat., propylene glycol, tetrasodium EDTA, PEG-75 lanolin, boric acid, lauramine oxide, chloroxylenol, methylparaben, propylparaben, fragrance, aloe barbadensis, acid red 1, reactive green 12

Coral 6576 8 oz

6367Z3PS.jpg Coral 8 oz

abc

SkinCare

Luxury Foaming



Coral

Antibacterial Hand & Body Wash

Health-Care Personnel Handwash

Contains Lanolin & Aloe Vera

NET CONTENTS: 8 FL OZ (236ML)



7 11808 20497 1

Mfd. by: ABC Compounding Co., Inc. P. O. Box 16247 Atlanta, GA 30321

Drug Facts

<i>Active Ingredient</i>	<i>Purpose</i>
Triclosan 0.3%	Antiseptic

Use for hand-washing to decrease bacteria on the skin

Warnings

For external use only

When using this product

- do not get into eyes
- if contact occurs, rinse eyes thoroughly with water

Stop use and ask a doctor if

- irritation and redness develop

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

Directions ■ wet hands and forearms ■ apply 5 milliliters (teaspoonful) or palmful to hands and forearms ■ scrub thoroughly for 1 minute and rinse

Inactive Ingredients water, sodium laureth sulfate, sodium lauryl sulfate, cocamidopropyl betaine, alcohol denat., propylene glycol, tetrasodium EDTA, PEG-75 lanolin, boric acid, lauramine oxide, chloroxylenol, methylparaben, propylparaben, fragrance, aloe barbadensis, acid red 1, reactive green 12

63673PS 1008

CORAL

triclosan soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62257-367
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	0.003 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	
BORIC ACID (UNII: R57ZHV85D4)	
ALCOHOL (UNII: 3K9958V90M)	
CHLOROXYLENOL (UNII: 0F32U78V2Q)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62257-367-06	1 in 1 BOX		
1		800 mL in 1 BAG		
2	NDC:62257-367-17	532 mL in 1 BOTTLE, PLASTIC		
3	NDC:62257-367-24	118 mL in 1 BOTTLE, PLASTIC		
4	NDC:62257-367-01	1200 mL in 1 CARTRIDGE		
5	NDC:62257-367-03	350 mL in 1 CARTRIDGE		
6	NDC:62257-367-05	540 mL in 1 BOTTLE, PLASTIC		
7	NDC:62257-367-07	700 mL in 1 BAG		
8	NDC:62257-367-09	2000 mL in 1 CARTRIDGE		
9	NDC:62257-367-10	1000 mL in 1 CARTRIDGE		
10	NDC:62257-367-11	1000 mL in 1 BOTTLE, PLASTIC		
11	NDC:62257-367-12	1000 mL in 1 BAG		
12	NDC:62257-367-13	800 mL in 1 BAG		
13	NDC:62257-367-14	3785 mL in 1 BOTTLE, PLASTIC		
14	NDC:62257-367-15	946 mL in 1 BOTTLE, PLASTIC		
15	NDC:62257-367-28	149 mL in 1 BOTTLE, PLASTIC		
16	NDC:62257-367-27	800 mL in 1 CARTRIDGE		
17	NDC:62257-367-55	208200 mL in 1 DRUM		
18	NDC:62257-367-08	1 in 1 BOX		

18		1000 mL in 1 BAG		
19	NDC:62257-367-16	236 mL in 1 BOTTLE, PLASTIC		
20	NDC:62257-367-18	50 mL in 1 BOTTLE, PLASTIC		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph not final	part333E		11/01/2010	

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

Establishment			
Name	Address	ID/FEI	Business Operations
ABC Compounding Co., Inc.		003284353	manufacture

Revised: 11/2010

ABC Compounding Co., Inc.