SURGENT ANTISEPTIC- chloroxylenol soap
SunCoast Paper 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.

Surgent Antiseptic Hand Soap 6544 Drug Facts and Label

Drug Facts Box OTC-Active Ingredient Section

Chloroxylenol 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, decyl glucoside, sodium laureth sulfate, cocamide MIPA, propylene glycol, sodium chloride, citric acid, DMDM hydantoin, fragrance, FD and C yellow no.5, food red 10

Surgent Antiseptic Hand Soap 800 mL

SunCoast™ Paper Inc.

Surgent

ANTISEPTIC HAND SOAP

CAUTION: KEEP OUT OF REACH OF CHILDREN

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
(If you do not understand this label, find someone to explain it to you in detail.)

This product is an effective antibacterial hand soap for use in food processing plants and restaurants by personnel prior to handling food and/or food processing equipment.

This formulation effectively reduces the bacterial flora of the skin. When tested via the Time Kill Test, it demonstrates 99% or greater kill against Staphylococcus aureus, E. Coli, and Pseudomonas aeruginosa. Formulated with skin conditioners for extra mildness.

This product is designed exclusively for industrial and institutional use by trained personnel. This product is sold as is and the manufacturer makes no warranty, express or implied, of merchantability, fitness for a particular purpose or otherwise.

Drug Facts

Active Ingredient — **Purpose**

Chloroxylenol 0.3% ..... Antiseptic

Uses 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, decyl gluccoside, sodium laureth sulfate, cocoamide MIPA, propylene glycol, DMDM hydantoin, sodium chloride, citric acid, fragrance, FD&C yellow no. 5, food red 10

NET CONTENTS: 800 ML 27 FL OZ 6544M4P10219.122618

Distributed by: **SunCoast Paper Inc.**
PO Box 1598 / Brunswick, GA 31521

Surgent Antiseptic Hand Soap 800 mL

SURGENT ANTISEPTIC

chloroxylenol soap

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:66155-544
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CHLOROXYLENOL (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q)	CHLOROXYLENOL	3 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
COCO MONOISOPROPANOLAMIDE (UNII: 21X4Y0VTB1)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:66155-544-06	1 in 1 BOX	10/12/2015	
1		800 mL in 1 BAG; Type 0: Not a Combination Product		
2	NDC:66155-544-17	532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/12/2015	
3	NDC:66155-544-24	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/12/2015	
4	NDC:66155-544-01	1200 mL in 1 CARTRIDGE; Type 0: Not a Combination Product	10/12/2015	
5	NDC:66155-544-03	350 mL in 1 CARTRIDGE; Type 0: Not a Combination Product	10/12/2015	
6	NDC:66155-544-05	540 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/12/2015	
7	NDC:66155-544-07	700 mL in 1 BAG; Type 0: Not a Combination Product	10/12/2015	
8	NDC:66155-544-09	2000 mL in 1 CARTRIDGE; Type 0: Not a Combination Product	10/12/2015	
9	NDC:66155-544-10	1000 mL in 1 CARTRIDGE; Type 0: Not a Combination Product	10/12/2015	
10	NDC:66155-544-11	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/12/2015	
11	NDC:66155-544-	1000 mL in 1 BAG; Type 0: Not a Combination Product	10/12/2015	

11	12	1000 mL in 1 BAG; Type 0: Not a Combination Product	10/12/2015	
12	NDC:66155-544-13	800 mL in 1 BAG; Type 0: Not a Combination Product	10/12/2015	
13	NDC:66155-544-14	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/12/2015	
14	NDC:66155-544-15	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/12/2015	
15	NDC:66155-544-28	149 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/12/2015	
16	NDC:66155-544-27	800 mL in 1 CARTRIDGE; Type 0: Not a Combination Product	10/12/2015	
17	NDC:66155-544-55	208200 mL in 1 DRUM; Type 0: Not a Combination Product	10/12/2015	
18	NDC:66155-544-08	1 in 1 BOX	10/12/2015	
18		1000 mL in 1 BAG; Type 0: Not a Combination Product		
19	NDC:66155-544-16	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/12/2015	
20	NDC:66155-544-18	50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/12/2015	
21	NDC:66155-544-19	18900 mL in 1 CONTAINER; Type 0: Not a Combination Product	10/12/2015	
22	NDC:66155-544-20	75600 mL in 1 DRUM; Type 0: Not a Combination Product	10/12/2015	
23	NDC:66155-544-35	132500 mL in 1 DRUM; Type 0: Not a Combination Product	10/12/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	03/01/2012	

Labeler - SunCoast Paper Inc. (031211089)

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

Establishment

Name	Address	ID/FEI	Business Operations
ABC Compounding Co., Inc.		003284353	manufacture(66155-544)

Revised: 12/2018 SunCoast Paper Inc.