CAREONE AMBER- benzalkonium chloride soap
Retail Business Services, LLC

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.

72476-004- Careone Amber

Active Ingredient.

Benzalkonium Chloride (0.13%)

Purpose

Antibacterial

Uses

Helps eliminate bacteria on hands.

Warnings

For external use only

When using this product

Avoid contact with eyes. In case of contact, rinse thoroughly with water.

Stop use and ask a doctor.

If irritation or redness develops and lasts

Keep out of reach of children.

In case of accidental ingestion, get medical help or contact Poison Control Center immediately.

Directions

- apply onto wet hands (only for 222 ml and 333 ml)
- Lather and rinse thoroughly.(For all packages)
- From a pump bottle, apply onto wet hands (only for 1.66 L bottle)
- Use to refill a pump bottle (only for 1.66 L bottle)

Other Information

Store at Room Temperature

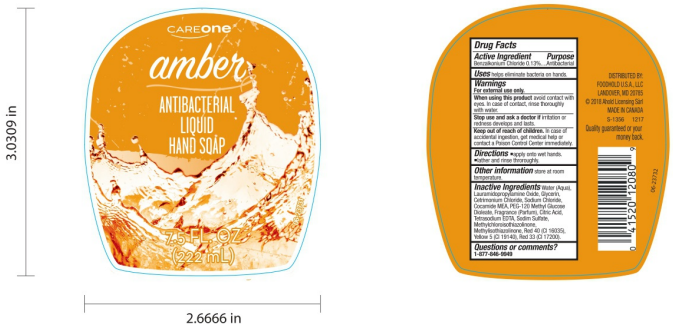
Inactive Ingredients

Water (Aqua), Lauramidopropylamine Oxide, Glycerin, Cetrimonium Chloride, Sodium Chloride, Cocamide MEA, PEG-120 Methyl Glucose Dioleate, Fragrance (Parfum), Citric Acid, Tetrasodium EDTA, Sodium Sulfate, Methylchloroisothiazolinone, Methylisothiazolinone, Red 40 (CI 16035), Yellow 5 (CI 19140), Red 33 (CI 17200).

Questions or comments?

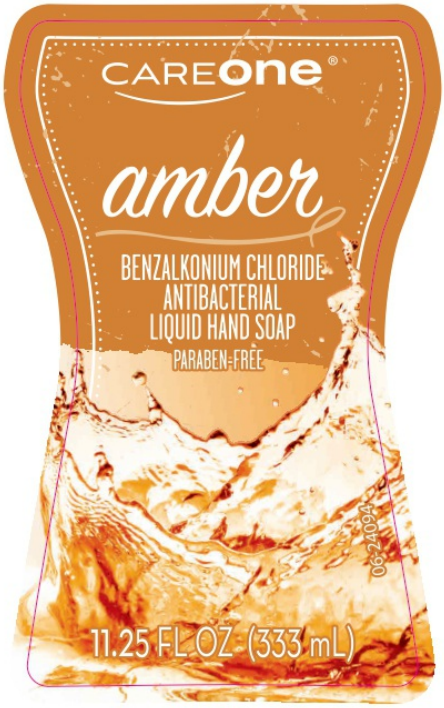
1-877-846-9949

PDP2

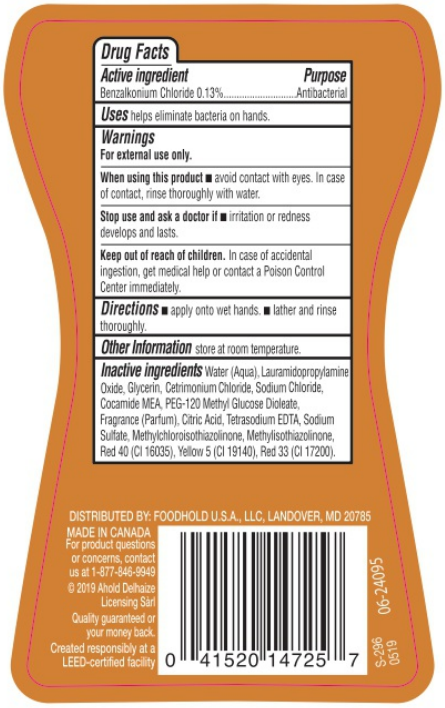


PDP3

Front Label



Back Label



ART #: 01596	DESIGNER #: KR	NOTE:

CLIENT: APOLLO | JOB DESCRIPTION: 06-24094-95 CAREONE AMBER | DATE: JUNE 13, 2019 | PROOF# 1

perFlex LABEL INC.

LABEL SIZE
4" X 2.4"
DIE# NEW
ROLL DIRECTION
3 FRONT 4 BACK

THIS IS NOT A COLOUR ACCURATE PROOF.
Please refer to process and pantone colour charts for accurate colour representation.
Every effort has been made to ensure the accuracy of this proof. However, the client is responsible for ensuring that label size, copy, graphics and colour separations are accurate, and to notify Perflex Label Inc. of any discrepancies prior to film, plate or label production. The client indemnifies Perflex Label Inc. against any liability related to costs incurred due to errors on a customer signed proof.

COLOURS
C M Y K
PMS 145

DIELINE
DOES NOT PRINT

THE CLIENT IS RESPONSIBLE FOR APPROVING THE FOLLOWING:
1. ALL COPY
2. LABEL DIMENSIONS
3. COLOURS USED
4. REWIND COPY DIRECTION
5. LOCAL, PROVINCIAL OR NATIONAL REGULATIONS ASSOCIATED WITH THIS LABEL(S)

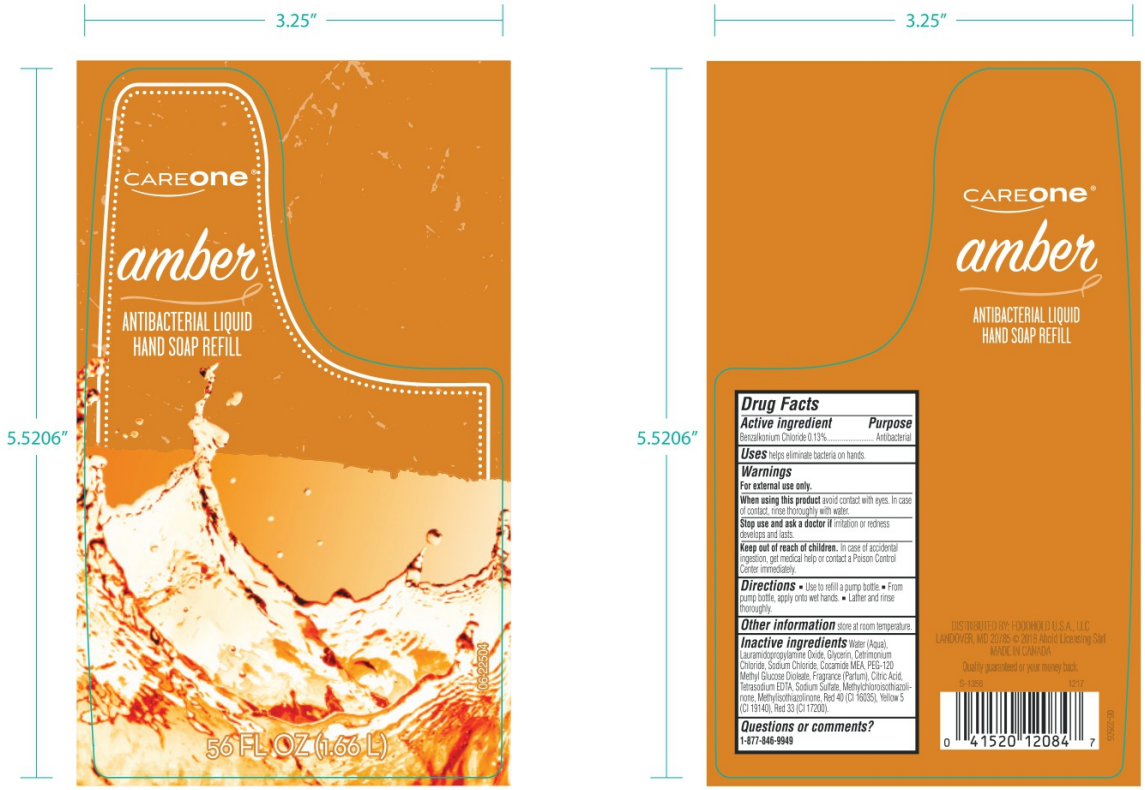
APPROVED AS IS : _____
APPROVED WITH CHANGES INDICATED : _____
RE-PROOF ◯ DATE : _____

MATERIAL: WHITE BOPP

COATING: GLOSS LAMINATE

PLEASE NOTE THAT THERE WILL BE NO LABEL PRODUCTION WITHOUT A SIGNED PROOF. FAX APPROVALS TO 416 321-2267. THANK YOU.

PDP4



CAREONE AMBER

benzalkonium chloride soap

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72476-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	130 mg in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
COCO MONOETHANOLAMIDE (UNII: C80684146D)	
LAURAMIDOPROPYLAMINE OXIDE (UNII: I6KX160QTV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

SODIUM SULFATE (UNII: 0YPR65R21J)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP)	
PEG-120 METHYL GLUCOSE DIOLEATE (UNII: YM0K64F20V)	
FRAGRANCE CLEAN ORC0600327 (UNII: 329LCV5BTF)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE SODIUM (UNII: MP1J8420LU)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72476-004-02	222 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/01/2021	
2	NDC:72476-004-03	333 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/01/2021	
3	NDC:72476-004-04	1660 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	09/01/2021	

Labeler - Retail Business Services, LLC (967989935)

Registrant - Apollo Health and Beauty Care (201901209)

Establishment

Name	Address	ID/FEI	Business Operations
Apollo Health and Beauty Care		201901209	manufacture(72476-004)

Revised: 11/2022 Retail Business Services, LLC