

HANDS FIRST TM- benzalkonium chloride spray

Hands First, 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.

Drug Facts

Active Ingredient

Benzalkonium Chloride 0.13%

Purpose

Antimicrobial

Use

- For handwashing to decrease bacteria on the skin
- For temporary protection of minor cuts, scrapes, burns and chapped or cracked skin

Warnings

- For external use only.
- Keep out of the reach of children. If swallowed, get medical help, or contact a Poison Control Center right away.
- Do not use in the eyes.
- Do not use on deep or puncture wounds, animal bites or serious burns.
- Extended use may increase risk of sunburn.

Stop use and ask a doctor if:

- symptoms worsen, last for more than seven days, or new symptoms occur at any time

Direction

- Uses as needed.
- Remove cap and pump foam into palm of hands.
- Rub foam onto hands.
- Allow to air dry.

Other information

- save carton for full directions and warnings
- store between 20 to 25°C (68 to 77°F)

Inactive ingredients

water, cocamidopropyl betaine, allantoin, glycolic acid, dimethicone, aloe vera leaf, lavender extract, colloidal silver, tetrasodium EDTA, phenoxyethanol, ethylhexyl glycerine.

Questions?

Call 1-800-603-0589 between 9am and 5pm (EST) Monday through Friday or visit www.handsfirst.com

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Hands First

4 in 1 action

Alcohol Free Spray

Hand Sanitizer

Doctor created and hospital tested

Sanitize anytime, anywhere

Temporarily protect minor cuts and scrapes

Hydrate your skin

Clean without water

Kills 99.99% of germs

4 fl oz (118mL)

HANDS FIRST.
HAND SANITIZER

4-in-1 ACTION
CLEAN • SANITIZE • MOISTURIZE • PROTECT

PHYSICIAN DEVELOPED
NON TOXIC
INFANT SAFE
ALCOHOL FREE
KILLS 99.99% OF GERMS

PROTECT WHAT MATTERS

4.0 fl.oz. (118ml)
Made in USA

4-in-1 action alcohol-free mist hand sanitizer:

CLEAN - REMOVE DIRT AND OILS FROM THE SKIN ON THE GO.
SANITIZE - CONTAINS "BZK", WHICH KILLS 99.99% OF VIRUSES AND BACTERIA FOUND ON YOUR HANDS.
HYDRATE - MOISTURIZE SKIN WITH ALLANTOIN AND ALOE VERA.
PROTECT - CLINICALLY PROVEN TO DEFEND AGAINST RECONTAMINATION.

DRUG FACTS

ACTIVE INGREDIENTS
BENZALKONIUM CHLORIDE (0.13%)

INACTIVE INGREDIENTS
WATER, COCAMIDOPROPYL BETAINE, ALLANTOIN, GLYCOLIC ACID, DIMETHICONE, ALOE VERA LEAF, LAVENDER EXTRACT, COLLOIDAL SILVER, TETRASODIUM EDTA, PHENOXYETHANOL, ETHYLHEXYL GLYCERINE.

PURPOSE
ANTIMICROBIAL

USES
FOR HAND SANITIZING TO DECREASE BACTERIA ON THE SKIN. + FOR TEMPORARY PROTECTION OF MINOR CUTS, SCRAPES, CHAPPED OR CRACKED SKIN.

DIRECTIONS
APPLY THOROUGHLY AND RUB HANDS UNTIL DRY. + FOR RECONTAMINATION DEFENSE, REAPPLY EVERY 2-3 HOURS WHEN SOAP AND WATER ARE UNAVAILABLE. + SAFE FOR INFANTS AND CHILDREN, FOR INFANTS/CHILDREN UNDER 6 - USE ONLY UNDER ADULT SUPERVISION.

WARNINGS
FOR EXTERNAL USE ONLY. + KEEP OUT OF REACH OF CHILDREN. + DO NOT USE IN EYES OR ON DEEP OR PUNCTURE WOUNDS, ANIMAL BITES, OR SERIOUS BURNS. + STOP USE AND ASK A DOCTOR IF CONDITION WORSENS OR SYMPTOMS LAST MORE THAN SEVEN DAYS.

QUESTIONS:
800-603-0589 + M-F 8-5 p.m. + www.handsfirst.com

US Patent No. 6,814,737 B2
Manufactured by
Body-Merit, Inc.
Distributed by Hands First, LLC

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Contains over
400 applications
NDC 81858-042-04

HANDS FIRST™

benzalkonium chloride spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81858-042
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
ALLANTOIN (UNII: 344S277G0Z)	
GLYCOLIC ACID (UNII: 0WT12SX38S)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SILVER (UNII: 3M4G523W1G)	
ENGLISH LAVENDER OIL (UNII: ZBP1YXW0H8)	
EDETATE SODIUM (UNII: MP1J8420LU)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81858-042-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/07/2021	
2	NDC:81858-042-02	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/07/2021	
3	NDC:81858-042-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/07/2021	
4	NDC:81858-042-07	207 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/07/2021	
5	NDC:81858-042-08	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/07/2021	
6	NDC:81858-042-12	354 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/07/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/07/2021	

Labeler - Hands First, LLC. (117961848)

Registrant - Hands First, LLC. (117961848)

Establishment

Name	Address	ID/FEI	Business Operations
Hands First, LLC.		117961848	MANUFACTURE(81858-042)

Revised: 10/2021

Hands First, LLC.