

**ONE STEP ANTISEPTIC HAND WASH- benzalkonium chloride soap
RECO Research Chemical Specialties Company, 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.

One Step Antiseptic Hand Wash 6265 Drug Facts and Label

Drug Facts Box OTC-Active Ingredient Section

Benzalkonium Chloride 2.5%

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, glycerin, isopropyl alcohol, disodium cocoamphodipropionate, hydroxyethylcellulose, lauramine oxide,

PEG-75 lanolin, citric acid, FD and C red no.4

One Step Antiseptic Hand Wash 6265 Drug Facts and Label

This product is an effective one-step cleaner/sanitizer for use in food processing plants and restaurants by personnel prior to handling food and/or food-processing equipment. Based on quaternary ammonium chlorides, this viscous formulation is more cost-efficient than traditional PCMX-based products.

This formulation effectively reduces the bacterial flora of the skin. When tested via the Modified Available Chlorine Germicidal Equivalent Concentration Test it demonstrates equal sanitizing activity to 50 ppm of free chlorine against *Staphylococcus aureus* and *Salmonella typhi*. 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.

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Drug Facts	
Active Ingredients	Purpose
Benzalkonium Chloride 2.5%.....	Antiseptic
Use for hand-washing to decrease bacteria on the skin	
Warnings	
For external use only	
When using this product	
<ul style="list-style-type: none"> ■ 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	
<ul style="list-style-type: none"> ■ wet hands and forearms ■ apply 5 milliliters (teaspoonful) or palmful to hands and forearms ■ scrub thoroughly for 1 minute and rinse ■ this product must be dispensed from adequate dispensers located a sufficient distance from processing lines to prevent accidental product contamination 	
Inactive Ingredients water, glycerin, isopropyl alcohol, disodium cocamidopropionate, hydroxyethyl cellulose, lauramine oxide, PEG-75 lanolin, citric acid, FD & C red #4	

HMS Ratings: Health: 0, Flammability: 0, Reactivity: 0, Personal Protection: A

Manufactured For:

 Research Chemical Specialties Co.
 505 N. Norwood Street, Wallace, NC 28466
 910-285-3004

One Step Antiseptic Hand Wash 6265 Drug Facts and Label

ONE STEP ANTISEPTIC HAND WASH

benzalkonium chloride soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62830-265
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	25.0 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
HYDROXYETHYL CELLULOSE (1500 MPAS AT 1%) (UNII: L605B5892V)	
DISODIUM COCOAMPHODIPROPIONATE (UNII: 6K8PRP397M)	
LAURAMINE OXIDE (UNII: 4F6FC4MI8W)	
PEG-75 LANOLIN (UNII: 09179OX7TB)	
GLYCERIN (UNII: PDC6A3C0OX)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62830-265-55	20820 mL in 1 DRUM; Type 0: Not a Combination Product	12/27/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	12/27/2017	

Labeler - RECO Research Chemical Specialties Company, Inc. (622536506)

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

Establishment

Name	Address	ID/FEI	Business Operations
ABC Compounding Co., Inc.		003284353	manufacture(62830-265)

Revised: 7/2019

RECO Research Chemical Specialties Company, Inc.