

E-2 CLEANSER SANITIZER 86 - hand sanitizer soap
Penco Products, 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.

Active Ingredient

Benzalkonium Chloride 2.5%

Purpose

Food Handlers Hand Wash

Uses

- Hand wash to help reduce bacteria that cause disease
- Repeated usage suggested

Warnings

For external use only.

Keep out of reach of children.

Avoid contact with eyes and mouth.

If redness develops, discontinue use immediately. If condition persists for more than 72 hours, consult a physician.

Not for use on children under 6 months of age.

Directions

- Hands do not require washing prior to use.
- Apply 5 mL of product to hands.
- Scrub well for 30 seconds.
- Rinse and repeat.

Inactive Ingredients

Water, Cocamidopropyl Betaine, Cocamidopropylamine Oxide, PEG-6 Cocamide, Hydroxypropyl Methylcellulose, Quaternium-15, Citric Acid, Sodium Hydroxide

In Case of Emergency

Call: (800) 228-5635 ext. 167

Drug Facts		E-2 Cleanser Sanitizer #86	
Active Ingredient Benzalkonium Chloride 2.5%		Directions	
Purpose Food Handlers Hand Wash		<ul style="list-style-type: none"> • Hands do not require washing prior to use. • Apply 5 mL of product to hands. • Scrub well for 30 seconds. • Rinse and repeat. 	
Uses		Inactive Ingredients	
<ul style="list-style-type: none"> • Hand Wash to help reduce bacteria that cause disease • Repeated usage suggested 		Water, Cocamidopropyl Betaine, Cocamidopropylamine Oxide, PEG-6 Cocamide, Hydroxypropyl Methylcellulose, Quaternium-15, Citric Acid, Sodium Hydroxide	
Warnings		In Case of Emergency	
For external use only.		Call: (800) 228-5635 ext. 167	
Keep out of reach of children.		Manufactured For:	
Avoid contact with eyes and mouth.		Penco Products, Inc.	
If redness or irritation develops, discontinue use immediately. If condition persists more than 72 hours, consult a physician.		Skippack, PA 19474	
Not for use on children under 6 months of age.		Tel: (800) 562-1000	
		Fax: (800) 248-1555	

500 mL

LBL0795-3.0

E-2 CLEANSER SANITIZER 86

hand sanitizer soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42497-086
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
Benzalkonium Chloride (UNII: F5UM2KM3W7) (Benzalkonium - UNII:7N6JUD5X6 Y)		Benzalkonium Chloride	2.5 g in 100 g	
Inactive Ingredients				
Ingredient Name		Strength		
Water (UNII: 059QF0KO0R)				
Cocamidopropyl Betaine (UNII: 5OCF3O11KX)				
Quaternium-15 (UNII: E40U03LEM0)				
Citric Acid Monohydrate (UNII: 2968PHW8QP)				
Sodium Hydroxide (UNII: 55X04QC32I)				
Hypromellose (UNII: 3NXW29V3WO)				
Product Characteristics				
Color	yellow (pale yellow to amber)	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42497-086-01	500 g in 1 BOTTLE, PLASTIC		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333	05/21/2010		

Labeler - Penco Products, Inc. (808679773)

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Penco Products, Inc.