

**BALMA SEPTIC ANTISEPTIC HAND WASH- benzalkonium chloride soap  
Rochester Midland Corporation**

*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.*

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**Balma Septic 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

**Balm Septic Antiseptic Handwash 6265**

Balma-Septic 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. It is exceptional for removing grease and fatty soils.

<b>Drug Facts</b>	
<b>Active Ingredients</b> Benzalkonium Chloride 2.5%	<b>Purpose</b> Antiseptic
<b>Use</b> for hand-washing to decrease bacteria on the skin	
<b>Warnings</b>	
For external use only	
When using this product	
<ul style="list-style-type: none"> <li>■ do not get into eyes</li> <li>■ if contact occurs, rinse eyes thoroughly with water</li> </ul>	
Stop use and ask a doctor if	
<ul style="list-style-type: none"> <li>■ irritation and redness develop</li> </ul>	
Keep out of reach of children	
If swallowed, get medical help or contact a Poison Control Center right away	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>■ wet hands and forearms</li> <li>■ apply 5 milliliters (teaspoonful) or palmful to hands and forearms</li> <li>■ scrub thoroughly for 1 minute and rinse</li> <li>■ this product must be dispensed from adequate dispensers located a sufficient distance from processing lines to prevent accidental product contamination</li> </ul>	
<b>Inactive Ingredients</b> water, glycerin, isopropyl alcohol, disodium cocoamphodipropionate, hydroxyethyl cellulose, lauramine oxide, PEG-75 lanolin, citric acid, FD & C red #4	

For external use only.

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Medical Emergency Telephone 1-800-535-5053 (U.S.).  
Outside The U.S. 1-352-323-3500.



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Form# 117650  
(REV. 11/01/19)

Food Safety Division

## Balma-Septic

Liquid Quaternary Hand Cleaner and Sanitizer  
Antiseptic Handwash

For Industrial and Institutional Use Only

**CAUTION/PRECAUCIÓN: KEEP OUT OF REACH OF CHILDREN/  
MANTENGA ESTE PRODUCTO FUERA DEL ALCANCE DE LOS NIÑOS**

NET CONTENTS: 1 Gallon (3.8 L)

Balma-Septic - LIMPIADOR Y SANITADOR DE MANO

**INSTRUCCIONES**

Lávese después de cada ausencia de su estación de trabajo o en forma especificada por la administración. No necesita lavarse las manos antes de usar Balma-Septic. Para lavarse y sanitarse las manos a la misma vez, coloque aproximadamente 5cc en la palma de la mano, añada 15cc de agua, haga espuma y lávese normalmente. Después de usarlo, tiene que enjuagarse bien las manos con agua potable. Repita cada vez que vuelva a entrar al área de producción. Balma-Septic tiene que ser colocado en un dispensador adecuado localizado una suficiente distancia de la línea de procesamiento para prevenir la contaminación accidental de la producción.

No contamine el agua, los alimentos o la comida al almacenarlo o al botarlo.

**PRECAUCION:** Puede causar irritación a los ojos. Dañino si se ingiere. No deje que caiga en los ojos. Evite la contaminación de los alimentos. Quitese y lave la ropa contaminada. En caso de contacto, lávese los ojos inmediatamente y llame a un médico. Número de Teléfono para Emergencia Médica (en los EE.UU.): 1-800-535-5053. Fuera de los Estados Unidos, llame 1-352-323-3500.

Para uso externo solamente.

Distributed By:

155 Paragon Drive  
Rochester, NY 14624 USA  
www.rochestermidland.com

For Technical Service  
Ordering Information (USA)  
1-800-762-4448 (Toll Free)

MADE IN USA

## Balm Septic Antiseptic Handwash 6265

### BALMA SEPTIC ANTISEPTIC HAND WASH

benzalkonium chloride soap

#### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59503-6265
<b>Route of Administration</b>	TOPICAL		

#### Active Ingredient/Active Moiety

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

#### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0K00R)	
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)	
<b>HYDROXYETHYL CELLULOSE (1500 MPAS AT 1%)</b> (UNII: L605B5892V)	
<b>DISODIUM COCOAMPHODIPROPIONATE</b> (UNII: 6K8PRP397M)	
<b>LAURAMINE OXIDE</b> (UNII: 4F6FC4MI8W)	
<b>PEG-75 LANOLIN</b> (UNII: 09179OX7TB)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>FD&amp;C RED NO. 4</b> (UNII: X3W0AM1JLX)	

#### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:59503-6265-2	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/09/2017	
2	NDC:59503-6265-6	2500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/09/2017	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/09/2017	

**Labeler** - Rochester Midland Corporation (002207041)

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

## Establishment

Name	Address	ID/FEI	Business Operations
ABC Compounding Co., Inc.		003284353	manufacture(59503-6265)

Revised: 10/2019

Rochester Midland Corporation