

**BIOMIRACLE STAYSAFE ANTIBACTERIAL HANDSOAP- chloroxylenol liquid**  
**MJM SOURCING, 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.*

**Labeler : MJM SOURCING, LLC**  
**NDC : 77978-525-01**

**BioMiracle staysafe ANTIBACTERIAL HAND SOAP**



**BIOMIRACLE STAYSAFE ANTIBACTERIAL HANDSOAP**

chloroxylenol liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:77978-525
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
CHLOROXYLENOL (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q)	CHLOROXYLENOL	1.25 g in 500 mL

**Inactive Ingredients**

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
GLYCOL STEARATE (UNII: 0324G66D0E)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	
COCO MONOETHANOLAMIDE (UNII: C80684146D)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	

<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	
<b>FD&amp;C RED NO. 4</b> (UNII: X3W0AM1JLX)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>PEG-150 DISTEARATE</b> (UNII: 6F36Q0I0AC)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>METHYLCHLOROISOTHIAZOLINONE</b> (UNII: DEL7T5QRPN)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77978-525-01	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/27/2020	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/27/2020	

**Labeler - MJM SOURCING, LLC (078861054)**

**Establishment**

Name	Address	ID/FEI	Business Operations
Panrosa Enterprises, Inc.		859957578	manufacture(77978-525)

Revised: 5/2020

MJM SOURCING, LLC