

## **4 HOUR POWER HAND SANITIZER- benzalkonium chloride liquid**

### **Guide Energy Solutions 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.*

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## **4 Hour Power Hand Sanitizer**

### ***Drug Facts***

#### ***Active ingredient[s]***

Benzalkonium Chloride 0.13%

#### ***Purpose***

Antimicrobial

#### ***Use[s]***

Hand sanitizer to help reduce bacteria on the skin that could cause disease.

#### ***Warnings***

**FOR EXTERNAL USE ONLY.** Do not use in the eyes. In case of eye contact, flush thoroughly with water & seek medical attention.

**Stop use and ask a doctor** if irritation or redness develops, or if condition persists for more than 72 hours.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

#### ***Directions***

Place enough product on your palm to thoroughly cover your hands. Rub hands together until dry. Children under 6 years of age should be supervised when using this product.

#### ***Other information***

Skin cells may be shed naturally or by abrasion prior to 4 hours, exposing fresh, unprotected skin. Reapply as needed. Keep out of extreme temperatures.

#### ***Inactive ingredients***

Water (Aqua), Aloe Barbadensis Leaf Juice, Glycerin, Lauramine Oxide, Dimethyltetradecylamine Oxide, DMDM Hydantoin (preservative), Fragrance\*  
*\*may contain this ingredient*

KILLS 99.9% OF GERMS

ALCOHOL FREE

FRESH ALOE SCENT

NON-FLAMMABLE

DYE FREE

NON-IRRITATING

MOISTURIZING FORMULA

NO STING

Long Lasting, Kills 99.9% of Germs for Up to 4 Hours

Outlasts Alcohol-Based Sanitizers by Persisting on Skin

Alcohol Free Formula Won't Dry Hands, Sting, or Cause Cracking

Leaves Skin Feeling Nourished and Moisturized

Paraben-Free, Sulfate-Free, Phthalate-Free

Foaming Formula

## **Packaging**

**PACKAGE - 59 mL**

<b>Drug Facts</b>	
<b>Active ingredient[s]</b>	<b>Purpose</b>
Benzalkonium Chloride 0.13% .....	Antimicrobial
<b>Use[s]:</b> Hand sanitizer to help reduce bacteria on the skin that could cause disease.	
<b>Warnings:</b> For external use only. Do not use in the eyes. In case of eye contact, flush thoroughly with water & seek medical attention.	
<b>Stop use and ask a doctor</b> if irritation or redness develops, or if condition persists for more than 72 hours.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions:</b> Place enough product on your palm to thoroughly cover your hands. Rub hands together until dry. Children under 6 years of age should be supervised when using this product.	
<b>Other information:</b> Skin cells may be shed naturally or by abrasion prior to 4 hours, exposing fresh, unprotected skin. Reapply as needed. Keep out of extreme temperatures.	
<b>Inactive ingredients:</b> Water (Aqua), Aloe Barbadensis Leaf Juice, Glycerin, Lauramine Oxide, Dimethyltetradecylamine Oxide, DMDM Hydantoin (preservative), Fragrance* <i>*may contain this ingredient</i>	

**4 HOUR  
POWER**

**HAND SANITIZER**

**KILLS 99.9% OF GERMS**

**ALCOHOL FREE**

**FRESH ALOE SCENT**

2 fl oz (59 ml)

KILLS 99.9% OF GERMS

ALCOHOL FREE

**PACKAGE - 473 mL**

NON-IRRITATING

DYE FREE

NON-FLAMMABLE

**4 HOUR  
POWER**   
**HAND SANITIZER**

Long Lasting, Kills 99.9% of Germs for Up to 4 Hours

Outlasts Alcohol-Based Sanitizers by Persisting on Skin

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Paraben-Free, Sulfate-Free, Phthalate-Free

Foaming Formula

**4 HOUR  
POWER**

**HAND SANITIZER**

**KILLS 99.9% OF GERMS**

**ALCOHOL FREE**

**FRESH ALOE SCENT**

16 fl oz (473 ml)

<b>Drug Facts</b>	
<b>Active ingredient[s]</b>	<b>Purpose</b>
Benzalkonium Chloride 0.13% .....	Antimicrobial
<b>Use[s]</b> Hand sanitizer to help reduce bacteria on the skin that could cause disease.	
<b>Warnings</b> FOR EXTERNAL USE ONLY. Do not use in the eyes. In case of eye contact, flush thoroughly with water & seek medical attention.	
<b>Stop use and ask a doctor</b> if irritation or redness develops, or if condition persists for more than 72 hours.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> Place enough product on your palm to thoroughly cover your hands. Rub hands together until dry. Children under 6 years of age should be supervised when using this product.	
<b>Other information</b> Skin cells may be shed naturally or by abrasion prior to 4 hours, exposing fresh, unprotected skin. Reapply as needed. Keep out of extreme temperatures.	
<b>Inactive ingredients</b> Water (Aqua), Aloe Barbadensis Leaf Juice, Glycerin, Lauramine Oxide, Dimethyltetradecylamine Oxide, DMDM Hydantoin (preservative), Fragrance* <i>*may contain this ingredient</i>	

ALCOHOL FREE

NO STING

MOISTURIZING FORMULA

**PACKAGE- 3785 mL**

NON-FLAMMABLE DYE FREE NON-IRRITATING

**4 HOUR POWER**   
**HAND SANITIZER**

- Long Lasting, Kills 99.9% of Germs for Up to 4 Hours
- Outlasts Alcohol-Based Sanitizers by Persisting on Skin
- Alcohol Free Formula Won't Dry Hands, Sting, or Cause Cracking
- Leaves Skin Feeling Nourished and Moisturized
- Paraben-Free, Sulfate-Free, Phthalate-Free

**4 HOUR POWER**  
**HAND SANITIZER**

**KILLS 99.9% OF GERMS**

**ALCOHOL FREE**  
**FRESH ALOE SCENT**

128 fl oz (3785 mL)

Drug Facts	
<b>Active ingredient(s)</b> Benzalkonium Chloride 0.13%	<b>Purpose</b> Antimicrobial
<b>Use(s)</b> Hand sanitizer to help reduce bacteria on the skin that could cause disease.	
<b>Warnings</b> FOR EXTERNAL USE ONLY. Do not use in the eyes. In case of eye contact, flush thoroughly with water & seek medical attention.	
<b>Stop use and ask a doctor</b> if irritation or redness develops, or if condition persists for more than 72 hours.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> Place enough product on your palm to thoroughly cover your hands. Rub hands together until dry. Children under 6 years of age should be supervised when using this product.	
<b>Other information</b> Skin cells may be shed naturally or by abrasion prior to 4 hours, exposing fresh, unprotected skin. Reapply as needed. Keep out of extreme temperatures.	
<b>Inactive ingredients</b> Water (Aqua), Aloe Barbadiensis Leaf Juice, Glycerin, Lauramine Oxide, Dimethyltetradecylamine Oxide, DMDM Hydantoin (preservative), Fragrance* <small>*may contain this ingredient</small>	

MOISTURIZING FORMULA NO STING ALCOHOL FREE

**4 HOUR POWER HAND SANITIZER**

benzalkonium chloride liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:77042-440
<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	0.13 g in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>LAURAMINE OXIDE</b> (UNII: 4F6FC4MI8W)	
<b>MYRISTAMINE OXIDE</b> (UNII: J086PM3RRT)	
<b>DMDM HYDANTOIN</b> (UNII: BYR0546TOW)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77042-440-02	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/05/2021	
2	NDC:77042-440-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/05/2021	

<b>3</b>	NDC:77042-440-01	3785 mL in 1 JUG; Type 0: Not a Combination Product	04/05/2021	
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>		<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part333A		04/05/2021	

**Labeler -** Guide Energy Solutions LLC (117045830)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Guide Energy Solutions LLC		117045830	manufacture(77042-440) , pack(77042-440)

Revised: 4/2021

Guide Energy Solutions LLC