

## **HAND SANITIZER- ethyl alcohol liquid**

**Hand Sanitizer Company 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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### **The Hand Sanitizer**

#### ***Drug Facts***

#### ***Active Ingredients***

Ethyl Alcohol 70%

#### ***Purpose***

Antimicrobial

**Uses** ■ to decrease bacteria on the skin that could cause disease ■ recommended for repeated use

#### ***Warnings***

**For external use only: hands**

**Flammable, keep away from fire or flame**

**When using this product** ■ keep out of eyes. In case of contact with eyes, flush thoroughly with water. ■ avoid contact with broken skin ■ do not inhale or ingest.

**Stop use and ask a doctor if** ■ irritation and redness develop ■ 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** ■ wet hands thoroughly with product and allow to dry without wiping ■ for children under 6, use only under adult supervision ■ not recommended for infants

**Other information** ■ do not store above 85°F ■ may discolor some fabrics ■ harmful to wood finishes and plastics

**Inactive ingredients** water, sodium acrylates/C10-30 alkyl acrylate crosspolymer, sodium PCA, hyaluronic acid

Made in the USA

Kills more than 99% of infectious agents\*

Moisturizers leave hands smooth

**CLEAN YOUR DANG HANDS!**

Show us how you clean your hands on Instagram when you tag #cleanyourdanghands for the potential to

win free sanitizer product!

\*Effective at eliminating more than 99.98% of many harmful germs and bacteria in as little as 15 seconds.

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Distributed by: Sanitizer Company

4445 W 77th ST

Edina, MN 55435

Manufactured by: The Bottling Company, LLC

FDA Registered Facility

cleanyourdanghands.com

IG: @thehandsanitizercompany

#CLEANYOURDANGHANDS

OPEN SQUEEZE SANITIZE!

USE FOR YOUR REFILLABLE HAND SANITIZER PRODUCTS!

## Packaging

**The HAND SANITIZER**

Made in the USA

**Kills more than 99% of infectious agents\***

Moisturizers leave hands smooth

**CLEAN YOUR DANG HANDS!**

4 FL OZ (118mL)

**Drug Facts**

| Active Ingredients | Purpose       |
|--------------------|---------------|
| Ethyl Alcohol 70%  | Antimicrobial |

**Uses** ■ to decrease bacteria on the skin that could cause disease ■ recommended for repeated use

**Warnings**  
**For external use only: hands**  
**Flammable, keep away from fire or flame**

**When using this product** ■ keep out of eyes, ■ in case of contact with eyes, flush thoroughly with water, ■ avoid contact with broken skin, ■ do not inhale or ingest.

**Stop use and ask a doctor if** ■ irritation and redness develop ■ 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** ■ wet hands thoroughly with product and ■ allow to dry without wiping ■ for children under 6, use only under adult supervision ■ not recommended for infants

**Drug Facts (continued)**

**Other information** ■ do not store above 85° ■ may discolor some fabrics ■ harmful to wood finished and plastics

**Inactive ingredients** Water, Sodium Carbomer Poly Acrylate Crosspolymer, v Sodium PCA, Hyaluronic Acid

\*Efficacy at eliminating more than 99.98% of many harmful germs and bacteria in as little as 15 seconds.

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cleanyourdanghands.com  
IG: @thehandsanitizercompany

FDA NDC Code: 8005 76916-161-04  
BUNS 11-750-1453

8 60003 77940 8

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USE FOR YOUR REFILLABLE HAND SANITIZER PRODUCTS!

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# The HAND SANITIZER



Kills more than 99% of infectious agents\*

Moisturizers leave hands smooth

CLEAN YOUR DANG HANDS!



8 FL. OZ. (236mL)

| Drug Facts  |                                 |
|---|---------------------------------|
| <b>Active Ingredients</b><br>Ethyl Alcohol 70%  | <b>Purpose</b><br>Antimicrobial |
| <b>Uses</b> ■ to decrease bacteria on the skin that could cause disease ■ recommended for repeated use  |                                 |
| <b>Warnings</b><br><b>For external use only; hands</b><br>■ <b>Flammable, keep away from fire or flame</b><br>■ <b>When using this product</b> ■ keep out of eyes, ■ in case of contact with eyes, flush thoroughly with water, ■ avoid contact with broken skin ■ do not inhale or ingest.<br>■ <b>Stop use and ask a doctor if</b> ■ irritation and redness develop ■ condition persists for more than 72 hours<br>■ <b>Keep out of reach of children, if swallowed, get medical help or contact a Poison Control Center right away</b> |                                 |
| <b>Directions</b> ■ wet hands thoroughly with product and ■ allow to dry without wiping ■ for children under 6, use only under adult supervision ■ not recommended for infants  |                                 |

| Drug Facts (continued)  |  |
|---|--|
| <b>Other information</b> ■ do not store above 85° ■ may discolor some fabrics ■ harmful to wood finished and plastics   |  |
| <b>Inactive ingredients</b> Water, Sodium Carbomer, Poly Acrylate Crosspolymer, Sodium PCA, Hyaluronic Acid   |  |
| *Kills 99% of germs and more than 99.99% of many harmful germs and bacteria in as little as 15 seconds.<br>Copyright ©2019 The Hand Sanitizer Company, LLC. All rights reserved. "The Hand Sanitizer" and logo are trademarks of The Hand Sanitizer Company LLC and/or of its affiliates.<br>Distributed by: Hand Sanitizer Company<br>4445 W 77th ST<br>Edina, MN 55415<br>Manufactured by: The Hand Sanitizer Company, LLC<br>PMA Registered Facility<br>#cleanyourdanghands.com<br>@thehandsanitizercompany<br>FDA NDC Code 11-700-0453<br>24119-10-10 11-700-0453 |  |

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# The HAND SANITIZER



Kills more than 99% of infectious agents\*

Moisturizers leave hands smooth

CLEAN YOUR DANG HANDS!



1 Gallon (3.785L)

| Drug Facts  |                                 |
|---|---------------------------------|
| <b>Active Ingredients</b><br>Ethyl Alcohol 70%  | <b>Purpose</b><br>Antimicrobial |
| <b>Uses</b> ■ to decrease bacteria on the skin that could cause disease ■ recommended for repeated use  |                                 |
| <b>Warnings</b><br><b>For external use only; hands</b><br>■ <b>Flammable, keep away from fire or flame</b><br>■ <b>When using this product</b> ■ keep out of eyes, ■ in case of contact with eyes, flush thoroughly with water, ■ avoid contact with broken skin ■ do not inhale or ingest.<br>■ <b>Stop use and ask a doctor if</b> ■ irritation and redness develop ■ condition persists for more than 72 hours<br>■ <b>Keep out of reach of children, if swallowed, get medical help or contact a Poison Control Center right away</b> |                                 |
| <b>Directions</b> ■ wet hands thoroughly with product and ■ allow to dry without wiping ■ for children under 6, use only under adult supervision ■ not recommended for infants  |                                 |

| Drug Facts (continued)  |  |
|---|--|
| <b>Other information</b> ■ do not store above 85° ■ may discolor some fabrics ■ harmful to wood finished and plastics   |  |
| <b>Inactive ingredients</b> water, sodium acrylates/C10-30 acrylate crosspolymer, sodium PCA, hyaluronic acid   |  |
| *Kills 99% of germs and more than 99.99% of many harmful germs and bacteria in as little as 15 seconds.<br>Copyright ©2019 The Hand Sanitizer Company, LLC. All rights reserved. "The Hand Sanitizer" and logo are trademarks of The Hand Sanitizer Company LLC and/or of its affiliates.<br>Distributed by:<br>Hand Sanitizer Company<br>4445 W 77th ST<br>Edina, MN 55415<br>Manufactured by:<br>The Hand Sanitizer Company, LLC<br>PMA Registered Facility<br>#cleanyourdanghands.com<br>@thehandsanitizercompany<br>FDA NDC Code 11-700-0453<br>18170-10-10 11-700-0453 |  |

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# HAND SANITIZER

Made in the USA

**Kills more than 99% of infectious agents\***

Moisturizers leave hands smooth

**CLEAN YOUR DANG HANDS!**

16 FL OZ (473mL)

to win free sanitizer product!

|  |                |  |  |
|--|----------------|--|--|
| <b>Drug Facts</b>  |                | <b>Drug Facts (continued)</b>  |  |
| <b>Active Ingredients</b>  | <b>Purpose</b> | <b>Other information</b> ■ do not store above 85° ■ may discolor some fabrics ■ harmful to wood finished and plastics  |  |
| Ethyl Alcohol 70%.....   | Antimicrobial  | <b>Inactive ingredients</b> water, acrylates/C10-30 alkyl acrylate crosspolymer, sodium PCA, hyaluronic acid   |  |
| <b>Uses</b> ■ to decrease bacteria on the skin that could cause disease ■ recommended for repeated use   |                | *Effective at eliminating more than 99.98% of many harmful germs and bacteria in as little as 15 seconds.  |  |
| <b>Warnings</b>  |                | Copyright 2020 The Bottling Company, LLC. All rights reserved. "The Hand Sanitizer" and logos are trademarks of The Bottling Company LLC and/or of its affiliates. |  |
| <b>For external use only: hands</b>  |                | Distributed by:<br>Hand Sanitizer Company<br>4445 W 77th ST<br>Edina, MN 55435   |  |
| <b>Flammable, keep away from fire or flame</b>   |                | Manufactured by:<br>The Bottling Company, LLC<br>FDA Registered Facility   |  |
| <b>When using this product</b> ■ keep out of eyes. In case of contact with eyes, flush thoroughly with water. ■ avoid contact with broken skin ■ do not inhale or ingest.    |                | cleanyourdanghands.com<br>IG: @thehandsanitizercompany   |  |
| <b>Stop use and ask a doctor if</b> ■ irritation and redness develop ■ condition persists for more than 72 hours   |                | FDA NDC Code: DUNS<br>76810-101-52 11-750-2453   |  |
| <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away   |                |  |  |
| <b>Directions</b> ■ wet hands thoroughly with product and allow to dry without wiping ■ for children under 6, use only under adult supervision ■ not recommended for infants |                | 8 60003 77942 2  |  |

**#CLEANYOURDANGHANDS**

## DRUG FACTS LABEL

|   |                |
|---|----------------|
| <b>Drug Facts</b>   |                |
| <b>Active Ingredients</b>   | <b>Purpose</b> |
| Ethyl Alcohol 70%.....  | Antimicrobial  |
| <b>Uses</b> ■ to decrease bacteria on the skin that could cause disease ■ recommended for repeated use  |                |
| <b>Warnings</b>   |                |
| <b>For external use only: hands</b>   |                |
| <b>Flammable, keep away from fire or flame</b>  |                |
| <b>When using this product</b> ■ keep out of eyes. In case of contact with eyes, flush thoroughly with water. ■ avoid contact with broken skin ■ do not inhale or ingest. |                |
| <b>Stop use and ask a doctor if</b> ■ irritation and redness develop ■ condition persists for more than 72 hours  |                |
| <b>Keep out of reach of children.</b> If  |                |

|  |
|--|
| <b>Drug Facts (continued)</b>  |
| <b>Other information</b> ■ do not store above 85° ■ may discolor some fabrics ■ harmful to wood finished and plastics  |
| <b>Inactive ingredients</b> water, sodium acrylates/C10-30 alkyl acrylate crosspolymer, sodium PCA, hyaluronic acid  |
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| Manufactured by:<br>The Bottling Company, LLC<br>FDA Registered Facility   |
| cleanyourdanghands.com<br>IG: @thehandsanitizercompany   |
|  |

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

**Directions** ■ wet hands thoroughly with product and allow to dry without wiping  
 ■ for children under 6, use only under adult supervision ■ not recommended for infants

FDA NDC Code 76810-101-70 DUNS 11-750-2453



**Drug Facts**

| Active Ingredients | Purpose       |
|--------------------|---------------|
| Ethyl Alcohol 70%  | Antimicrobial |

**Uses** ■ to decrease bacteria on the skin that could cause disease ■ recommended for repeated use

**Warnings**  
**For external use only; hands**  
**Flammable, keep away from fire or flame**  
**When using this product** ■ keep out of eyes. In case of contact with eyes, flush thoroughly with water. ■ avoid contact with broken skin ■ do not inhale or ingest.  
**Stop use and ask a doctor if** ■ irritation and redness develop ■ 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** ■ wet hands thoroughly with product and allow to dry without wiping  
 ■ for children under 6, use only under adult supervision ■ not recommended for infants

**Drug Facts (continued)**

**Other information** ■ do not store above 85° ■ may discolor some fabrics ■ harmful to wood finished and plastics

**Inactive ingredients** water, acrylates/C10-30 alkyl acrylate crosspolymer, sodium PCA, hyaluronic acid

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FDA NDC Code 76810-101-04 DUNS 11-750-2453





## HAND SANITIZER

ethyl alcohol liquid

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:76810-101 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL           | 70 mL in 100 mL |

### Inactive Ingredients

| Ingredient Name                                   | Strength |
|---|----------|
| WATER (UNII: 059QF0K00R)                          |          |
| SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)  |          |
| SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2) |          |
| HYALURONIC ACID (UNII: S270N0TRQY)                |          |

## Packaging

| # | Item Code        | Package Description  | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:76810-101-04 | 118 mL in 1 POUCH; Type 0: Not a Combination Product           | 04/28/2020           |                    |
| 2 | NDC:76810-101-08 | 236 mL in 1 POUCH; Type 0: Not a Combination Product           | 04/28/2020           |                    |
| 3 | NDC:76810-101-52 | 473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 05/15/2020           |                    |
| 4 | NDC:76810-101-70 | 3785 mL in 1 JUG; Type 0: Not a Combination Product            | 04/28/2020           |                    |
| 5 | NDC:76810-101-42 | 51 mL in 1 POUCH; Type 0: Not a Combination Product            | 07/01/2020           |                    |
| 6 | NDC:76810-101-44 | 118 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product    | 07/15/2020           |                    |
| 7 | NDC:76810-101-80 | 208198 mL in 1 CONTAINER; Type 0: Not a Combination Product    | 07/01/2020           |                    |

## Marketing Information

| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A                                 | 04/28/2020           |                    |

**Labeler** - Hand Sanitizer Company LLC (117502453)

## Establishment

| Name                       | Address | ID/FEI    | Business Operations    |
|----------------------------|---------|-----------|------------------------|
| Hand Sanitizer Company LLC |         | 117502453 | manufacture(76810-101) |

Revised: 8/2020

Hand Sanitizer Company LLC