

## **FIKES INSTANT HAND SANITIZER- alcohol gel**

**Fikes Northwest, Corp.**

*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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### **Fikes Instant Hand Sanitizer**

#### **Drug Facts**

##### **Active Ingredient**

Ethanol (60% v/v)

##### **Purpose**

Anti-Microbial Hand Sanitizer

##### **Uses**

- Helps reduce bacteria that potentially can cause disease
- Helps prevent cross contamination by hand contact
- Recommended for repeated use

##### **Warnings**

- **For external use only**
- **Flammable, keep away from fire, heat, or flame**
- **Keep out of reach of children.**
- Do not use near eyes
- In case of eye contact flush with water for 15 minutes
- If irritation persists stop use of product and get medical attention
- In case of accidental ingestion seek medical attention or contact a poison control center immediately.

##### **Directions**

- Use no water or towels
- Apply appropriate amount of product to palm of hand
- Rub until hands are completely covered
- Agitate lightly until dry
- Let air dry for 15 seconds
- Do not rinse or wipe with towel.

##### **Other Information**

- Store in a cool dry place below 104° F.

##### **Inactive Ingredients**

Water, Carbomer, Triethanolamine, PEG-75 Lanolin, Aloe Vera Gel, Fragrance.

##### **Principal Display Panel**

# FIKES

## Instant Hand Sanitizer

### (Gel-Type)

- Enhanced with Moisturizers
- Kills disease causing germs within seconds
- Effective against MRSA, VRE, E. coli (0157:H7) Staphylococcus, Streptococcus and other organisms
- Assists with OSHA Bloodborne Pathogen Standard Compliance

See Drug Facts panel for additional information

### For Hospital and Professional Use Only

Align the half moon ears (round side out) with the slots of the dispenser's lower docking area. Press top and bottom of tube firmly into place.

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515-001-100-401F

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Net Contents: 27 Fl. Oz. (800 mL)

<b>Drug Facts</b>	
<b>Active Ingredient:</b> Ethanol (60% v/v)	<b>Purpose:</b> Anti-Microbial Hand Sanitizer
<b>Uses</b> <ul style="list-style-type: none"><li>• Helps reduce bacteria that potentially can cause disease</li><li>• Helps prevent cross contamination by hand contact</li><li>• Recommended for repeated use</li></ul>	
<b>Warning</b> <ul style="list-style-type: none"><li>• For external use only</li><li>• Flammable, keep away from fire, heat or flame</li><li>• Keep out of reach of children.</li><li>• Do not use near eyes • In case of eye contact flush with water for 15 minutes</li><li>• If irritation persists stop use of product and get medical attention • In case of accidental ingestion seek medical attention or contact a poison control center immediately.</li></ul>	
<b>Directions</b> <ul style="list-style-type: none"><li>• Use no water or towels • Apply appropriate amount of product to palm of hand • Rub until hands are completely covered • Agitate lightly until dry</li><li>• Let air dry for 15 seconds • Do not rinse or wipe with towel.</li></ul>	
<b>Other information</b> <ul style="list-style-type: none"><li>• Store in a cool dry place below 104° F.</li></ul>	
<b>Inactive Ingredients</b> Water, Carbomer, Triethanolamine, PEG-75 Lanolin, Aloe Vera Gel, Fragrance.	
<b>Manufactured for:</b> <b>Fikes Northwest, Corp.</b> 13401 E. Trent Ave., Spokane Valley, WA 99216 (509) 926-0534 • (509) 755-0370 Fax fikesnw@att.net • www.fikesnorthwest.com	
515-001-100-401B	

## FIKES INSTANT HAND SANITIZER

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50036-515
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
alcohol (UNII: 3K9958V90M) (alcohol - UNII:3K9958V90M)	alcohol	600 mL in 1000 mL

**Inactive Ingredients**

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
carbomer homopolymer type c (UNII: 4Q93RCW27E)	
aloe (UNII: V5VD430YW9)	
trolamine (UNII: 9O3K93S3TK)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50036-515-80	800 mL in 1 BAG		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333	07/21/2010	

**Labeler** - Fikes Northwest, Corp. (167376284)**Establishment**

Name	Address	ID/FEI	Business Operations
Canberra Corporation		068080621	MANUFACTURE

Revised: 7/2010

Fikes Northwest, Corp.