

## **HAND SANITIZING GREEN APPLE- alcohol gel**

**Sigan Industries**

*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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**time&again™**

**HAND SANITIZING GEL**

**GREEN APPLE**

### ***Drug Facts***

#### **Active ingredient**

Alcohol 62%

#### **Purpose**

Antiseptic

#### **Uses**

To decrease bacteria on hands.

#### **Warnings**

**For external use only.**

**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 skin irritation develops.

**Keep out of reach of children.** In case of accidental ingestion, seek professional assistance or contact Poison Control Center immediately.

#### **Directions**

Wet hands thoroughly with product and allow to dry without wiping.

#### **Other information**

- Do not store above 105°F.
- May discolor some fabrics.
- Harmful to wood finishes and plastics.
- You may report a serious adverse reaction to this product to: Ganz U.S.A., LLC #043, 60 Industrial Parkway, Cheektowaga, New York, 14227-9903

## Inactive ingredients

Water, Fragrance, Glycerin, Triethanolamine, PEG-7 Glyceryl Cocoate, Hydrolyzed Jojoba Esters, Chamomilla Recutita (Matricaria) Flower Extract, Salvia Officinalis (Sage) Leaf Extract, Urtica Dioica (Nettle) Extract, Rosmarinus Officinalis (Rosemary) Leaf Extract, Aloe Barbadensis Leaf Extract, Aloe Barbadensis Leaf Juice, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Blue 1, Yellow 5.

## PRINCIPAL DISPLAY PANEL - 232 mL Bottle Label

*time&again*<sup>TM</sup>

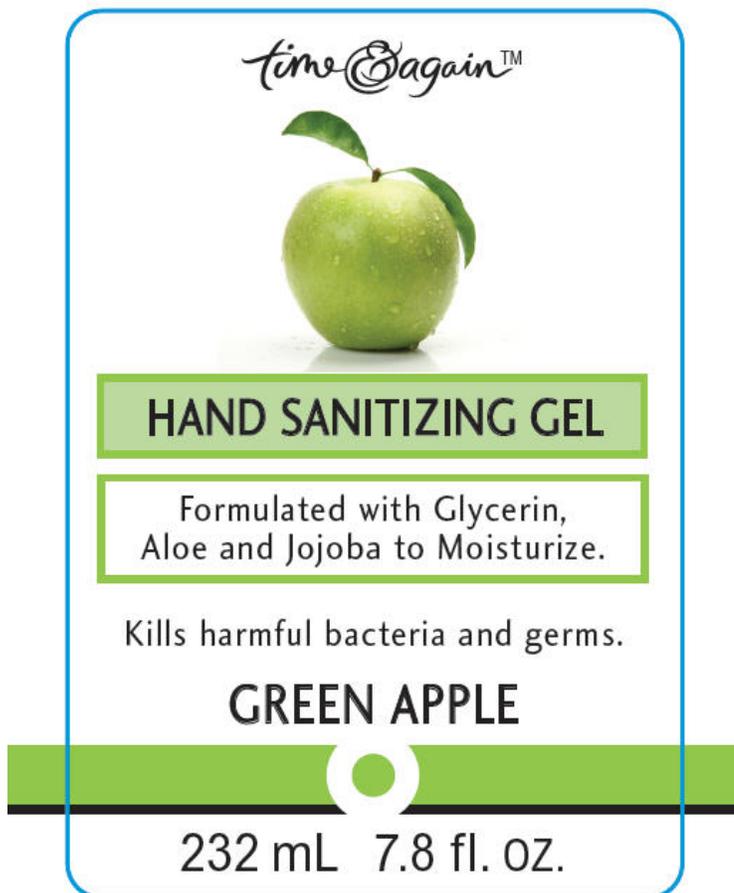
### HAND SANITIZING GEL

Formulated with Glycerin,  
Aloe and Jojoba to Moisturize.

Kills harmful bacteria and germs.

### GREEN APPLE

232 mL 7.8 fl. OZ.



The label design features the *time&again*<sup>TM</sup> logo at the top, followed by a photograph of a green apple. Below the apple, the text reads: "HAND SANITIZING GEL", "Formulated with Glycerin, Aloe and Jojoba to Moisturize.", "Kills harmful bacteria and germs.", "GREEN APPLE", and "232 mL 7.8 fl. OZ." at the bottom. The design uses green and white colors with a blue border.



The Drug Facts label is enclosed in a black border and contains the following information:

Drug Facts	
Active ingredient	Purpose
Alcohol 62%.....	Antiseptic
<b>Uses</b> To decrease bacteria on hands.	
<b>Warnings</b> For external use only.	
<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</b> if skin irritation develops.	
<b>Keep out of reach of children.</b> In case of accidental ingestion, seek professional assistance or contact Poison Control Center immediately.	
<b>Directions</b> Wet hands thoroughly with product and allow to dry without wiping.	
<b>Other information</b> ■ Do not store above 105°F. ■ May discolor some fabrics. ■ Harmful to wood finishes and plastics. ■ You may report a serious adverse reaction to this product to: Ganz U.S.A., LLC #043, 60 Industrial Parkway, Cheektowaga, New York, 14227-9903	
<b>Inactive ingredients</b> Water, Fragrance, Glycerin, Triethanolamine, PEG-7 Glyceryl Cocoate, Hydrolyzed Jojoba Esters, Chamomilla Recutita (Matricaria) Flower Extract, Salvia Officinalis (Sage) Leaf Extract, Urtica Dioica (Nettle) Extract, Rosmarinus Officinalis (Rosemary) Leaf Extract, Aloe Barbadensis Leaf Extract, Aloe Barbadensis Leaf Juice, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Blue 1, Yellow 5.	

At the bottom of the label, it says "GANZ Cheektowaga, N.Y. 14227-9903 www.timeandagain.com MADE IN CANADA" and includes a barcode with the number "6 61371 49543 9" and the product code "TA397327 Green Apple".

## HAND SANITIZING GREEN APPLE

alcohol gel

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:65365-001

Route of Administration TOPICAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
GLYCERYL COCOATE (UNII: WVK1CT5994)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
JOJOBA OIL (UNII: 724GKU717M)	
CHAMAEMELUM NOBILE FLOWER (UNII: O2T154T6OG)	
SAGE (UNII: 065C5D077J)	
URTICA DIOICA LEAF (UNII: X6M0DRN46Q)	
ROSEMARY (UNII: IJ67X351P9)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65365-001-01	232 mL in 1 BOTTLE, PUMP		
2	NDC:65365-001-02	59 mL in 1 BOTTLE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part333E	01/01/2011	

**Labeler** - Sigan Industries (255106239)