

HAND SANITIZER- hand sanitizer gel
Tropical Enterprises International, Inc.

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.

Formula #1000-B-Bulk gel - 70% ethyl alcohol hand sanitizer

ACTIVE INGREDIENT

Ethyl Alcohol 70% v/v

DOSAGE AND ADMINISTRATION

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

INACTIVE INGREDIENT

InActive Ingredients: Water, Carbomer, Triethanolamine

INDICATIONS AND USAGE

Use Hand Sanitizer to help reduce bacteria that potentially can cause disease.

For use when soap and water are not available.

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children. If swallowed, seek prompt medical attention.

OTC PURPOSE

Purpose... Antiseptic

WARNING

WARNINGS: For external use only

When using this product avoid contact with eyes. If contact with eyes occurs, flush with water.

Stop use and ask a doctor if irritation or redness develops and persists. If swallowed, seek prompt medical attention.

Other information: Non-staining, may discolor certain fabrics.

Flammable: Keep away from open flame.

Avoid freezing and excessive heat above 40C (**104F**).

PACKAGE LABEL PRINCIPAL DISPLAY PANEL

Antibacterial Hand Sanitizer
Kills Germs Without Water - 1fl oz. (30mL)

Drug Facts

Active Ingredient	Purpose
Ethyl Alcohol 70% v/v.....	Antiseptic

Uses: Hand sanitizer to help reduce bacterial that potentially can cause disease. For use when soap and water are not available.

WARNINGS For external use only

When using this product avoid contact with eyes. If contact with eyes occurs, flush with water.

Stop use and ask a doctor if irritation or redness develops and persists.

Keep out of reach of children. If swallowed, seek prompt medical attention.

Flammable. Keep away from open flame. Avoid freezing and excessive heat above 40C (140F).

Directions: Wet hand thoroughly with product and allow to dry without wiping.

Other Information: Non-staining, may discolor certain fabrics.

Inactive Ingredients: Water, Carbomer, Triethanolamine.

Questions: 1-800-535-5053

Made in USA Distributed by:
 TMarketing Tampa, FL 33611
 asi/92243

Manufactured in a FDA registered facility.

HAND SANITIZER

hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58418-116
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	20.4 mL in 30 mL

Inactive Ingredients

Ingredient Name	Strength
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER 1342 (UNII: 809Y72KV36)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58418-116-00	10 mL in 1 PACKET; Type 0: Not a Combination Product	08/01/2012	
2	NDC:58418-116-05	15 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/01/2012	

3	NDC:58418-116-10	10 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	08/01/2012	
4	NDC:58418-116-01	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/01/2012	
5	NDC:58418-116-02	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/01/2012	
6	NDC:58418-116-04	120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/01/2012	
7	NDC:58418-116-08	240 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/01/2012	
8	NDC:58418-116-12	360 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/01/2012	
9	NDC:58418-116-16	480 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/01/2012	
10	NDC:58418-116-64	1920 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/01/2012	
11	NDC:58418-116-28	840 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/01/2012	
12	NDC:58418-116-70	211200 mL in 1 DRUM; Type 0: Not a Combination Product	02/02/2020	
13	NDC:58418-116-32	1228800 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	02/02/2020	
14	NDC:58418-116-15	45 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	02/02/2020	
15	NDC:58418-116-18	52 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	02/02/2020	
16	NDC:58418-116-55	30 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	08/01/2012	
17	NDC:58418-116-99	3840 mL in 1 JUG; Type 0: Not a Combination Product	02/02/2020	
18	NDC:58418-116-09	240 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	01/02/2017	
19	NDC:58418-116-25	960000 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	04/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	08/01/2012	

Labeler - Tropical Enterprises International, Inc. (091986179)

Registrant - Tropical Enterprises International, Inc. (091986179)

Revised: 2/2020

Tropical Enterprises International, Inc.