

HAND SANITIZER ISLAND ESCAPE- alcohol gel
ABC Compounding Co., 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.

Hand Sanitizer Island Escape 6416 Drug Facts and Label

Drug Facts Box OTC-Active Ingredient Section

Ethyl Alcohol 62%

Drug Facts Box OTC-Purpose Section

Antiseptic

Drug Facts Box OTC-Indications & Usage Section

for hand-washing to decrease bacteria on the skin, only when water is not available

Drug Facts Box OTC-Warnings Section

FLAMMABLE, keep away from fire and flames

For external use only

Drug Facts Box OTC-When Using Section

do not get into eyes

if contact occurs, rinse eyes thoroughly with water

Drug Facts Box OTC-Stop Use Section

irritation and redness develop

Drug Facts Box OTC-Keep Out of Reach of Children Section

if swallowed, get medical help or contact a Poison Control Center right away

Drug Facts Box OTC-Dosage & Administration Section

wet hands thoroughly with product and allow to dry without wiping

Drug Facts Box OTC-Inactive Ingredient Section

water, triethanolamine, carbomer, propylene glycol, tocopheryl acetate, aloe barbadensis, dmdm hydantoin, fragrance

Hand Sanitizer Island Escape 6416 Drug Facts and Label

aero[®] instant hand sanitizer island escape

- KILLS 99.99% of E. COLI, SALMONELLA ENTERICA and STAPHYLOCOCCUS AUREUS (MRSA) in 15 SECONDS
- CONTAINS VITAMIN E and ALOE VERA

DANGER: FLAMMABLE
KEEP OUT OF REACH OF CHILDREN
KEEP AWAY FROM FIRE OR FLAME. FOR EXTERNAL USE ONLY.
SEE OPPOSITE PANEL FOR ADDITIONAL PRECAUTIONS.
Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand this label, find someone to explain it to you in detail.)

NET CONTENTS: 16 FL. OZ. (473 ML)

Drug Facts

Active Ingredient

Ethyl Alcohol 62%

Use for hand-washing to decrease bacteria when water is not available

Warnings

Flammable, keep away from fire and for external use only

When using this product

- do not get into eyes
 - if contact occurs, rinse eyes thoroughly
- Stop use and ask a doctor if
- irritation and redness develop

Keep out of reach of children. If swallowed or contact a Poison Control Center right away.

Directions

- wet hands thoroughly with product and rub for 20 seconds
- Inactive Ingredients** water, D-isopropylamine, carbomer, propylene glycol, aloe barbadensis, fragrance

Manufactured by: ABC COMPOUNDING CO., INC.
P.O. Box 16247 • Atlanta, GA 30321-0247

Hand Sanitizer Island Escape 6416 Label

HAND SANITIZER ISLAND ESCAPE

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62257-416
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
CARBOMER 934 (UNII: Z135WT9208)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
DIISOPROPYLAMINE (UNII: BR9JLI40NO)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62257-416-17	532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/21/2020	
2	NDC:62257-416-24	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/21/2020	
3	NDC:62257-416-01	1200 mL in 1 CARTRIDGE; Type 0: Not a Combination Product	04/21/2020	

4	NDC:62257-416-28	149 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/21/2020	
5	NDC:62257-416-14	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/21/2020	
6	NDC:62257-416-13	800 mL in 1 BAG; Type 0: Not a Combination Product	04/21/2020	
7	NDC:62257-416-47	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/21/2020	
8	NDC:62257-416-17	532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/21/2020	
9	NDC:62257-416-55	208200 mL in 1 DRUM; Type 0: Not a Combination Product	04/21/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/21/2020	

Labeler - ABC Compounding Co., Inc. (003284353)

Registrant - ABC Compounding Co., Inc. (003284353)

Establishment

Name	Address	ID/FEI	Business Operations
ABC Compounding Co., Inc.		003284353	manufacture(62257-416)

Revised: 4/2020

ABC Compounding Co., Inc.