

HAND-E XL- 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-E XL 6605 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, diisopropylamine, carbomer, propylene glycol, tocopheryl acetate, aloe barbadensis

Hand-E XL 6605 Drug Facts and Label



Hand-E XL

**Alcohol Based
Waterless
Hand Cleaner**



**● Kills 99.99% of
E. coli, Salmonella enterica and
Staphylococcus aureus (MRSA)
in 15 seconds.**

DANGER: FLAMMABLE
KEEP OUT OF REACH OF CHILDREN
KEEP AWAY FROM FIRE OR FLAME. FOR EXTERNAL USE ONLY.
See other cautions on opposite panel of label.

NET CONTENTS: 16 OZ. (473 ml)

Hand-E XL is a thick, rich, alcohol based waterless hand cleaner, for use in areas where water is unavailable.

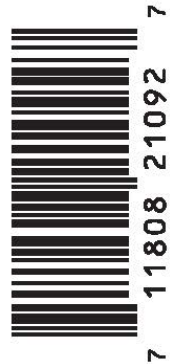
Hand-E XL is ideally suited for use prior to handling animals or handling equipment that may come into contact with animals.

Hand-E XL dries quickly, provides excellent cleaning and leaves no sticky residues on skin.

Drug Facts	
Active Ingredient	Purpose
Ethyl Alcohol 62%	Antiseptic
Use for hand-washing to decrease bacteria on the skin, only when water is not available	
Warnings	
Flammable, keep away from fire and flames For external use only	
When using this product	
<ul style="list-style-type: none"> ■ do not get into eyes ■ if contact occurs, rinse eyes thoroughly with water 	
Stop use and ask a doctor if	
<ul style="list-style-type: none"> ■ irritation and redness develop 	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away	
Directions	
<ul style="list-style-type: none"> ■ wet hands thoroughly with product and allow to dry without wiping 	
Inactive Ingredients water, DMDM hydantoin, diisopropylamine, carbomer, propylene glycol, tocopheryl acetate, aloe barbadensis	

Sold By:
Bio-Tek
Division of
ABC Compounding Co., Inc.
PO Box 16247
Atlanta, GA 30321-0247
Toll Free 800-795-9222

660516PTEK.123118



Hand-E XL 16 oz Label

HAND-E XL		
alcohol gel		
Product Information		
Product Type	HUMAN OTC DRUG	Item Code (Source) NDC:62257-606
Route of Administration	TOPICAL	
Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CARBOMER 934 (UNII: Z135WT9208)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
DIISOPROPYLAMINE (UNII: BR9JLI40NO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62257-606-17	532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/01/2005	
2	NDC:62257-606-24	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/01/2005	
3	NDC:62257-606-28	149 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/01/2005	
4	NDC:62257-606-30	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/01/2005	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/01/2005	

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(62257-606)

Revised: 12/2018

ABC Compounding Co., Inc.