HANITIZER - alcohol gel Apple Products, 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.

Hanitizer 6920 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

Hanitizer 6920 18 oz

692018PE.jpg Hanitizer 18 oz bottle



HANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67147-221
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: 059QF0KO0R)		
CARBOMER 934 (UNII: Z135WT9208)		
PROPYLENE GLYCOL (UNII: 6 DC9 Q16 7 V3)		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		
.ALPHATO CO PHERO L ACETATE, DL- (UNII: WR1WPI7EW8)		
DIISO PRO PYLAMINE (UNII: BR9 JL 140 NO)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67147-221-06	1 in 1 BOX		
1		800 mL in 1BAG		
2	NDC:67147-221-17	532 mL in 1 BOTTLE, PLASTIC		
3	NDC:67147-221-24	118 mL in 1 BOTTLE, PLASTIC		
4	NDC:67147-221-01	1200 mL in 1 CARTRIDGE		
5	NDC:67147-221-03	350 mL in 1 CARTRIDGE		
6	NDC:67147-221-05	540 mL in 1 BOTTLE, PLASTIC		
7	NDC:67147-221-07	700 mL in 1 BAG		
8	NDC:67147-221-09	2000 mL in 1 CARTRIDGE		

9	NDC:67147-221-10	1000 mL in 1 CARTRIDGE
10	NDC:67147-221-11	1000 mL in 1 BOTTLE, PLASTIC
11	NDC:67147-221-12	1000 mL in 1 BAG
12	NDC:67147-221-13	800 mL in 1 BAG
13	NDC:67147-221-14	3785 mL in 1 BOTTLE, PLASTIC
14	NDC:67147-221-15	946 mL in 1 BOTTLE, PLASTIC
15	NDC:67147-221-28	149 mL in 1 BOTTLE, PLASTIC
16	NDC:67147-221-27	800 mL in 1 CARTRIDGE
17	NDC:67147-221-55	208200 mL in 1 DRUM
18	NDC:67147-221-08	1 in 1 BOX
18		1000 mL in 1 BAG

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	10/01/2010	

Labeler - Apple Products, Inc. (965982544)

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

Establishment			
Name	Address	ID/FEI	Business Operations
ABC Compounding Co., Inc.		003284353	manufacture

Revised: 3/2012 Apple Products, Inc.