SANI- alcohol gel
AIS Specialty 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.

Sani-Gel 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

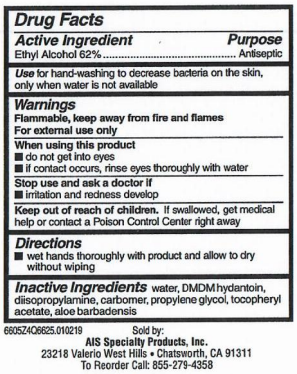
Drug Facts Box OTC-Dosage & Administration Section

wet hands thoroughly with product and allow to dry without wiping

Drug Facts Box OTC-Inactive Ingredient Section

water, diisopropylamine, carbomer, propylene glycol, DMDM hydantoin, tocopheryl acetate, aloe barbadensis

Sani-Gel 6605 5oz



Sani-Gel 5oz

SANI

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50522-221
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: 6DC9Q167V3)	

DMDM HYDANTOIN (UNII: BYR0546TOW)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
DIISOPROPYLAMINE (UNII: BR9JLI40NO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50522-221-17	532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/24/2012	
2	NDC:50522-221-24	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/24/2012	
3	NDC:50522-221-05	540 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/24/2012	
4	NDC:50522-221-28	149 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/24/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/24/2012	

Labeler - AIS Specialty Products, Inc. (003662885)

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

Establishment

Name	Address	ID/FEI	Business Operations
ABC Compounding Co., Inc.		003284353	manufacture(50522-221)

Revised: 1/2019 AIS Specialty Products, Inc.