SANI-CARE- alcohol gel
Pro Chem, 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-Care 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, DMDM hydantoin, diisopropylamine, carbomer, propylene glycol, tocopheryl acetate, aloe barbadensis

Sani-Care 6605

Single Use

Net Contents:
2.5 mL (0.08 fl. oz.)

PRO CHEM®

Sani-Care Sanitizing Gel

Kills 99.99% of E. coli and Salmonella enterica 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 OTHER CAUTIONS ON OPPOSITE PANEL OF LABEL.

Sold by: **PRO CHEM, INC.**
1475 Bluegrass Lakes Parkway • Alpharetta, GA 30004
TO REORDER CALL: 1-800-241-8180 • www.procheminc.com

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

Drug Facts (Continued)

Warnings

Flammable, keep away from fire and flames
For external use only

When using this product
- do not get into eyes
- if contact occurs, rinse eyes thoroughly with water

Stop use and ask a doctor if
- irritation and redness develop

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

Directions ■ wet hands thoroughly with product and allow to dry without wiping

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

660525L984.071620

Sani-Care doze pack label

SANI-CARE

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63830-221
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:63830-221-17	532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/16/2020	
2	NDC:63830-221-14	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/16/2020	
3	NDC:63830-221-28	149 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/16/2020	
4	NDC:63830-221-21	2.5 mL in 1 DOSE PACK; Type 0: Not a Combination Product	07/16/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	07/16/2020	

Labeler - Pro Chem, Inc. (061396065)

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

Establishment

Name	Address	ID/FEI	Business Operations
ABC Compounding Co., Inc.		003284353	manufacture(63830-221)

Revised: 7/2020 Pro Chem, Inc.