# HAND SANITIZER- hand sanitizer gel TRI-COASTAL DESIGN GROUP 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.

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### TricstlFrtressPrplHndSntzrAlch62

#### Active ingredient

Alcohol 62%

### Purpose

Antiseptic

#### Use

■ For handwashing to decrease bacteria on the skin ■ Recommended for repeated use

#### **Warnings**

- For external use only
- **Flammable**, keep away from open flame and sources of heat
- Does not contain grain alcohol; do not drink. If taken internally will produce gastric distrubances.

#### When using this product

- Avoid the eyes and mucoous membranes
- In the case of eyes or mucous membranes contacr, rinse area thoroughly with water

### Stop use and ask a doctor if

- Condition worsens
- Redness or irritation develops
- Condition persists for more than 3 days

## Keep out of reach of children

■ If swallowed, contact a doctor or Poison Control Center immediately

#### Directions

- Rub dime sized amount between hands until dry.
- Supervise children in the use of this product.
- In the case of eye contact, rinse eyes thoroughly with water.

#### Other information

- Store below 105°F
- May discolor some fabrics.

# **Inactive ingredients**

Water, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Triethanolamine, Fragrance, PEG-40 Hydrogenated Castor Oil, D&C RED N0.33, FD&C BLUE NO.1, FD&C YELLOW NO.5

# Questions?

**■** 1-800-278-9218

# **Package Label**



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This product has been granted the Good Housekeeping Seal.

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#### Drug Facts

Active Ingredient Alcohol 62%

**Purpose** Antiseptic

Use ■ For handwashing to decrease bacteria on the skin ■ Recommended for repeated use

#### Drug Facts (continued)

#### Warnings

- For external use only
- Flammable, keep away from fire and flame
- Does not contain grain alcohol; do not drink. If taken internally will produce serious gastric disturbances.

#### When using this product

■ Avoid the eyes and mucous membranes

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#### Drug Facts (continued)

■ In the case of eyes or mucous membranes contact, rinse area thoroughly with water

#### Stop use and ask a doctor if

- Condition worsens
   Redness or irritation develops
- Condition persists for more than 3 days

Keep out of reach of children

#### Drug Facts (continued)

■If swallowed contact a doctor or Poison Control Center immediately.

#### **Directions**

- Rub dime sized amount
- between hands until dry.

  Supervise children in the use of this product.
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#### Drug Facts (continued)

■ May discolor some fabrics.

#### Inactive ingredients Water, Acrylates/C10-30 Alkyl

Acrylate Crosspolymer, Triethanolamine, Fragrance,PEG-40 Hydrogenated Castor Oil, D&C RED NO.33,FD&C BLUE NO.1,FD&C YELLOW NO.5.

#### **Questions?**

**■**1-800-278-9218

#### HAND SANITIZER

hand sanitizer gel

# **Product Information**

HUMAN OTC DRUG Product Type Item Code (Source) NDC:49852-704

TOPICAL **Route of Administration** 

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL		

Inactive Ingredients			
Ingredient Name	Strength		
D&C RED NO. 33 (UNII: 9DBA0SBB0L)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)			
WATER (UNII: 059QF0KO0R)			
TROLAMINE (UNII: 903K93S3TK)			
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)			
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)			

l	Pac	Packaging					
l	#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>		
l	1 NI	OC:49852-704-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/30/2020			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333A	07/30/2020			

# **Labeler** - TRI-COASTAL DESIGN GROUP INC. (609734900)

Revised: 8/2020 TRI-COASTAL DESIGN GROUP INC.