TONKA HAND SANITIZER (TNK 100)- alcohol gel
Gold Orient International Limited

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.

Tonka(TNK 100)Hand Sanitizer

Active Ingredient(s)

Alcohol 62% v/v.

Purpose

Antiseptic

Use

For hand-washing to decrease bacteria on the skin, only when water is not available

Warnings

For external use only. Flammable. Keep away from heat or flame

Do not use

- in children less than 2 months of age
- on open skin wounds

Do not get into eyes.

if contact occurs, rinse eyes thoroughly with water

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

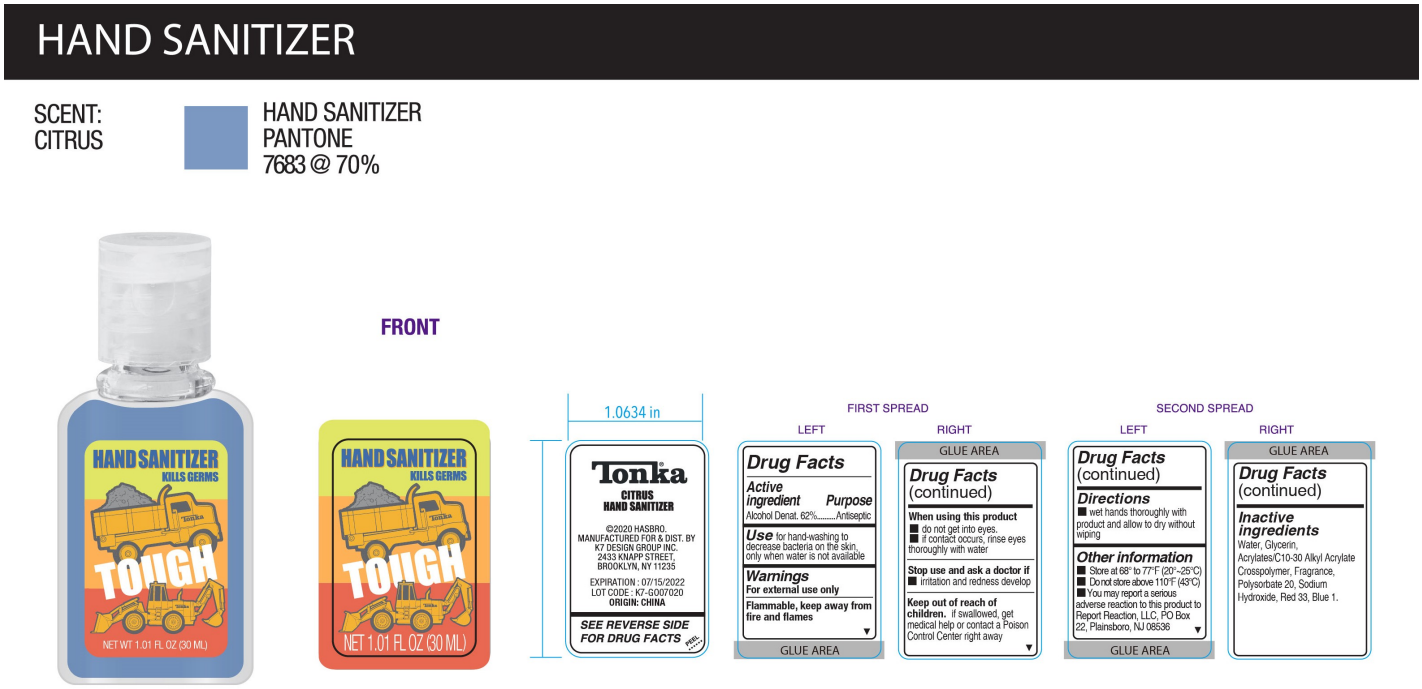
Other information

- Store between 66 to 77F (20-25C)
- Do not store above 110F (43C)
- You may report a serious adverse reaction to this product to Report Reaction, LLC, PO Box 22 Plainsboro, NJ 08536

Inactive ingredients

Water, Glycerin, Acrylates/ C10-30 Alkyl Acrylates Crosspolymer, Fragrance, Polysorbate 20, Sodium Hydroxide, Red 33, Blue 1

Package Label - Principal Display Panel



TONKA HAND SANITIZER (TNK 100)

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51522-034
Route of Administration	TOPICAL		

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**
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
WATER (UNII: 059QF0KO0R)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	

Packaging				
			Marketing Start	Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51522-034-01	1 in 1 POUCH	03/30/2020	
1		30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Gold Orient International Limited (679905914)

Establishment

Name	Address	ID/FEI	Business Operations
Gold Orient International Limited		679905914	manufacture(51522-034)

Revised: 7/2020 Gold Orient International Limited