CLINICAL WORKS OCEAN BREEZE WATERLESS HAND SANITIZER - alcohol liquid
Taizhou Xinzhixuan Daily-Use Co., Ltd.

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.

Drug Fact

Active Ingredients
Ethyl Alcohol 62%

Purpose
Antisepic

Uses

- To decrease bacteria on the skin that could cause disease.
- Recommended for repeated use

Warnings

For external use only-hands.
Flammable. Keep away from heat and flame.
When using this product, Keep out of eyes. In case of contact with eyes, flush thoroughly with water.
Avoid contact with broken skin. Do not inhale or ingest.
Stop use and ask a doctor if skin irritation develops.
Keep out of reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

Directions

Wet hands thoroughly with product and allow to dry without wiping.
For children under 6,use only under adult supervision.
Not recommended for infants.

Other Information

Do not store above 105F
May discolor some fabrics.
Harmful to wood finishes and plastics

Inactive Ingredients

water(Aqua), Glycerin, Triethanolamine, Carbomer, Fragrance(parfum), PEG-40 Hydrogenated Castor Oil, DMDM Hydantoin, FD and C Yellow No. 5, FD and C Blue No. 1, FD and C Red No. 40

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CLINICAL WORKS OCEAN BREEZE WATERLESS HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50593-008
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62.000 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	35.39999 g in 100 g
GLYCERIN (UNII: PDC6A3C0OX)	1.0 g in 100 g
TROLAMINE (UNII: 9O3K93S3TK)	0.25 g in 100 g
CARBOMER 934 (UNII: Z135WT9208)	0.25 g in 100 g
DMDM HYDANTOIN (UNII: BYR0546TOW)	0.4 g in 100 g
POLYOXYL 40 CASTOR OIL (UNII: 4ERD2076EF)	0.5 g in 100 g
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	0.000002 g in 100 g
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	0.000006 g in 100 g
FD&C RED NO. 40 (UNII: WZB9127XOA)	0.000002 g in 100 g

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:50593-008-01	60 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333	06/10/2010	

Labeler - Taizhou Xinzhixuan Daily-Use Co., Ltd. (420438920)

Registrant - Taizhou Xinzhixuan Daily-Use Co., Ltd. (420438920)

Establishment

Name	Address	ID/FEI	Business Operations
Taizhou Xinzhixuan Daily-Use Co., Ltd.		420438920	manufacture

Revised: 6/2010 Taizhou Xinzhixuan Daily-Use Co., Ltd.