

WASHING-FREE DISINFECTION GEL- washing-free disinfection gel gel
Hangzhou Changing Time Biotechnology 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.

Washing-free disinfection gel

ACTIVE INGREDIENT

Alcohol 72%v/v.

PURPOSE

Antimicrobial

USES

Washing-free disinfection gel to help reduce bacteria that potentially can cause disease.

For use when soap and water are not available.

WARNINGS

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

When using this product

do not use in or near the eyes.In case of contact,rinse eyes thoroughly with water.Stop use and ask doctor if irritation or rash appears and lasts.Keep out of reach for children.If swallowed,get medical help or contact a Poison Control Center right away.

Stop use and ask a doctor if irritation or rash occurs.These may be signs of a serious condition.

Keep out of reach of children

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

DIRECTIONS

Place enough Product in your palm to thoroughly spread on both hands and rub into the skin until dry.

Children under 6 years of age should be supervised when using this product.

OTHER INFORMATION

Store below 106°F.(40°C)

May discolor certain fabrics or surfaces.

INACTIVE INGREDIENTS

Aqua, Glycerin, Trolamine, Polyacrylic Acid.

Package Label - Principal Display Panel





WASHING-FREE DISINFECTION GEL

washing-free disinfection gel gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75153-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	72 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6 A3C0 OX)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

Marketing Start Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75153-001-01	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2020	
2	NDC:75153-001-02	280 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2020	
3	NDC:75153-001-03	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2020	
4	NDC:75153-001-04	208.198 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/24/2020	

Labeler - Hangzhou Changing Time Biotechnology Co., Ltd. (554529093)

Registrant - Hangzhou Changing Time Biotechnology Co., Ltd. (554529093)

Establishment

Name	Address	ID/FEI	Business Operations
Hangzhou Changing Time Biotechnology Co., Ltd.		554529093	manufacture(75153-001)

Revised: 4/2020

Hangzhou Changing Time Biotechnology Co., Ltd.