

HAND SANITIZER WITH VITAMIN E- alcohol liquid
BBC GROUP 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.

Hand Sanitizer with VitE

Active ingredient

Alcohol Denat. 62%

Purpose

Antiseptic

Uses

■ to decrease bacteria on the skin that could cause disease ■ recommended for repeated use

Warnings

For external use only. Flammable, keep away from fire or 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

■ irritation and redness develop ■ condition persists for more than 72 hours

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 ■ for children under 6, use only under adult supervision ■ not recommended for infants

Other information

■ do not store above 105°F ■ may discolor some fabrics ■ harmful to wood finishes and plastics

Inactive ingredients

Water, PEG-40 Hydrogenated Castor Oil, Fragrance, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Sodium Hydroxide, Denatonium Benzoate, Tocopheryl Acetate

Questions?

1-888-287-1915

Package Label



HAND SANITIZER WITH VITAMIN E

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76383-014
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
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)	
WATER (UNII: 059QF0KO0R)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	

POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)

SODIUM HYDROXIDE (UNII: 55X04QC32I)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76383-014-01	50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/11/2020	
2	NDC:76383-014-03	89 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/11/2020	
3	NDC:76383-014-08	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/11/2020	
4	NDC:76383-014-12	354 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/11/2020	
5	NDC:76383-014-30	887 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/11/2020	
6	NDC:76383-014-34	1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/11/2020	
7	NDC:76383-014-28	3789 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/29/2020	
8	NDC:76383-014-02	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/29/2020	
9	NDC:76383-014-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/29/2020	
10	NDC:76383-014-50	50 in 1 BOX	09/07/2020	
10	NDC:76383-014-07	2 mL in 1 PACKET; 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	05/11/2020	

Labeler - BBC GROUP LIMITED (421270060)

Establishment

Name	Address	ID/FEI	Business Operations
BBC GROUP LIMITED		421270060	manufacture(76383-014)

Revised: 9/2020

BBC GROUP LIMITED