

**HAND GUARD FOAMING INSTANT HAND SANITIZER- alcohol liquid
Wechem, 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.

Hand Guard Foaming Instant Hand Sanitizer 6585 Drug Facts and Label

Drug Facts Box OTC-Active Ingredient Section

Ethyl Alcohol 62%

Drug Facts Box OTC-Purpose Section

Antiseptic

Drug Facts Box OTC-Indications & Usage Section

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

Drug Facts Box OTC-Warnings Section

FLAMMABLE, keep away from fire and flames

For external use only

Drug Facts Box OTC-When Using Section

do not get into eyes

if contact occurs, rinse eyes thoroughly with water

Drug Facts Box OTC-Stop Use Section

irritation and redness develop

Drug Facts Box OTC-Keep Out of Reach of Children Section

if swallowed, get medical help or contact a Poison Control Center right away

Drug Facts Box OTC-Dosage & Administration Section

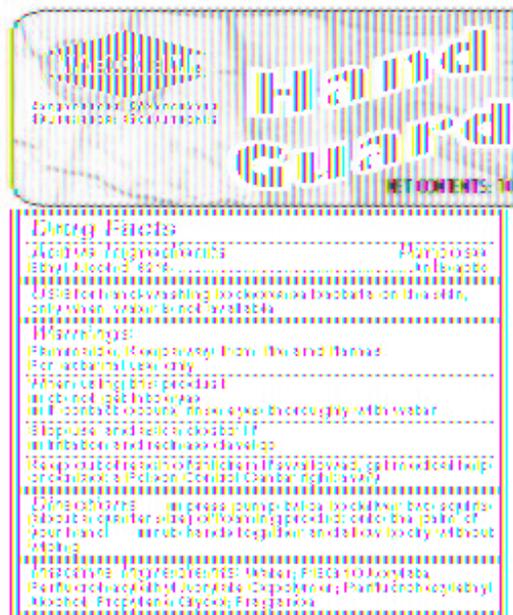
press pump twice to deliver two squirts (about a quarter size) of foaming product onto the palm of your hand

rub hands together and allow to dry without wiping

Drug Facts Box OTC-Inactive Ingredient Section

water, PEG-10 acrylate, perfluorohexylethyl acrylate copolymer, propylene glycol, fragrance

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Hand Guard Foaming Instant Hand Sanitizer

HAND GUARD FOAMING INSTANT HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:31507-585
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	0.62 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PEG-10 ACRYLATE/PERFLUOROHXYLETHYL ACRYLATE COPOLYMER (UNII: D76 Z8 79 28 N)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:31507-585-10	1000 mL in 1 CARTRIDGE; Type 0: Not a Combination Product	07/11/20 19	
2	NDC:31507-585-08	1 in 1 BOX	07/11/20 19	
2		1000 mL in 1 BAG; 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	part333E	07/11/2019	

Labeler - Wechem, Inc. (010397446)

Registrant - ABC Compounding Co., Inc. (010397446)

Establishment

Name	Address	ID/FEI	Business Operations
ABC Compounding Co., Inc.		003284353	manufacture(31507-585)

Revised: 7/2019

Wechem, Inc.