APPLAUSE- instant hand sanitizer gel QuestSpecialty Corporation

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.

Active Ingredient

Ethyl Alcohol 60%......Antiseptic

purpose

Antiseptic

Uses

- Handwash to help decrease bacterial on the skin.
- Recommended for repeated use.

Warnings

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

do not use

• In the eyes

When Using

- Do not use in or near the eyes.
- If contact occurs, flush eyes with water for 15 minutes. Consult physician if irritation persists.
- If swallowed, seek medical assitance or consult a poison control cener immediately.

Stop Use

- Stop use and ask a doctor if: Irritation develops. If condtion persists for more than 72 hours consult a doctor
- Keep out of reach of children.
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Directions for Use

- Place a palmful (5 grams) of product in one hand,.
- Spread on both hands and rub into the skin until dry (approximately 1 to 2 minutes).
- Place a smaller amolunt (2.5 grams) into one hand, spread over both hands to wrist and rub into the skin until dry (approximately 30 seconds).
- Will air dry in 15 seconds.
- Store below 95 ° F.
- Close spout to avoid evaporation.

Water, triethanolamine, fragrance, acrylic polymer



Drug Facts

Purpose Antiseptic

Uses

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Stop use and ask a doctor if • Irritation develops. If condition persists for more than 72 hours consult a doctor. Keep out of reach of children.

Directions

Place a 'palmful' (5 grams) of product in one hand.

• Spread on both hands and rub into the skin until dry (approximately 1 to 2 minutes).

• Place a smaller amount (2.5 grams) into one hand, spread over both hands to wrist, and rub into the skin until dry (approximately 30 seconds).

• Will air dry in 15 seconds.

Other information

Store below 95°F. • Close spout to avoid evaporation.

Inactive ingredients

Water, Triethanolamine, Fragrance, Acrylic Polymer.



ITEM 693000001-040Z

Made in USA

600006693



APPLAUSE

instant hand sanitizer gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:67858-693

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient NameBasis of StrengthStrengthALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)ALCOHOL3 g in 5 g

Inactive Ingredients Ingredient Name Strength WATER (UNII: 059QF0KO0R) TROLAMINE (UNII: 9O3K93S3TK) CARBOMER 940 (UNII: 4Q93RCW27E)

Packaging

# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:67858-693-24	12 in 1 CARTON	10/02/2018	
1 NDC:67858-693-04	107 g in 1 BOTTLE; Type 0: Not a Combination Product		
Marketing Info	ormation		
Marketing Info		Marketing Start Date	Marketing End Date
	y Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

Labeler - QuestSpecialty Corporation (103840377)

Registrant - QuestSpecialty Corporation (103840377)

Establishment						
Name	Address	ID/FEI	Business Operations			
QuestSpecialty Corporation		103840377	manufacture(67858-693)			

Revised: 10/2018 QuestSpecialty Corporation