# HYGIENE OF SWEDEN- pocket spray aerosol, spray Hygiene of Sweden AB

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.

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#### **Hand sanitizer**

#### **Active Ingredients**

Benzalkonium Chloride 0,495 g/l

Apply generously to hands and allow it to dry for 60 seconds.

Avoid contact with eyes. If contact occurs, rinse thoroughly with water.

Purified water, Biopolymer, Aloe Vera, Vitamin B5, Lactic Acid

Antibacterial. Spray on hands and rub, allow 60 seconds to dry.

Antibacterial

N/A

81274-001-01





### **HYGIENE OF SWEDEN**

pocket spray aerosol, spray

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81274-001	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM -	BENZALKONIUM	9.9 mg	

UNII:7N6JUD5X6Y)	CHLORIDE	in 100 mL
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Inactive Ingredients			
Ingredient Name	Strength		
LACTIC ACID (UNII: 33X04XA5AT)	0.03 mL in 100 mL		
CHITOSAN MEDIUM MOLECULAR WEIGHT (200-400 MPA.S) (UNII: 5GV09YM052)	0.02 mL in 100 mL		
POLYETHYLENIMINE HYDROCHLORIDE (20000 MW) (UNII: R1Q64CR5FF)	0.01 mL in 100 mL		
PHENOXYETHANOL (UNII: HIE492ZZ3T)	0.25 mL in 100 mL		
DEXPANTHENOL (UNII: 106C93RI7Z)	0.01 mL in 100 mL		
WATER (UNII: 059QF0KO0R)	99.48 mL in 100 mL		
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.1 mL in 100 mL		

l	Packaging				
	# Item Code Package Description		Marketing Start Date	Marketing End Date	
	1	NDC:81274- 001-01	20 mL in 1 BOTTLE, SPRAY; Type 6: Drug/Biologic Combination	01/01/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	01/01/2020		

## Labeler - Hygiene of Sweden AB (353008228)

## Registrant - Hygiene of Sweden AB (353008228)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Hygiene of Sweden USA LLC		117779651	label(81274-001)	

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Hygiene of Sweden AB		353008228	manufacture(81274-001)	

Revised: 3/2022 Hygiene of Sweden AB