

**PURESAN OCEAN BREEZE- alcohol gel**  
**Inopak, 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.*

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**Puresan Ocean Breeze Hand sanitizer 141**

**Active ingredient**

Ethyl Alcohol 70% v/v

**Purpose**

Antiseptic

**Keep away from children**

**Keep out of reach of children.** If swallowed. Get medical help or contact a Poison Control Center right away. Children should be supervised by an adult when using this product.

**Uses**

To decrease bacteria on the skin that potentially can cause disease. Recommended for repeated use

**Warnings**

**Flammable**, keep away from heat or flame. For external use only. Keep out of eyes, ears or mouth. In case of eye contact, flush eyes with water. **Stop use and ask a doctor** if irritation and redness develop or if 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. Children should be supervised by an adult when using this product.

**other information**

May discolor certain fabrics and surfaces.

**Stop use**

**Stop use and ask a doctor** if irritation and redness develop or if condition persists for more than 72 hours.

**Directions**

Apply sufficient amount of product to your palm to cover both hands. Rub until dry.

**Inactive ingredients**

Acrylates/C 10/30 Alkyl Acrylate Crosspolymer, Aloe Barbadosensis Leaf Juice, FD&C Blue 1, FD&C Yellow 5, Fragrance, Isopropyl Alcohol, PEG/PPG-18/18 Dimethicone, Triethanolamine, Vitamin E, Water

**Puresan Ocean Breeze front label**

puresan

Cleaning innovations

Kills 99.9%

of germs

Ocean Breeze Scented

Hand

Sanitizer

√ Ultimate protection

√ Ultra moisturizing

√ Leaves hands feeling ultra soft

Net. Wt. 18 fl. Oz.

AVR0-307 Rev. 1.1



*Ocean Breeze Scented*

# Hand Sanitizer

Kills  
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- ✓ *Ultra moisturizing*
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<b>Drug Facts</b>		
<b>Active Ingredient</b>	<b>Purpose</b>	
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		NOT TESTED ON ANIMALS
Got a question? 1-855-500-8080 puresanusa.com	puresan cleaning innovations	Puresan USA Sparta, NJ 07871

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Puresan USA  
Sparta, NJ 07871

#### **Case label**

puresan puresanusa.com

cleaning innovations (855) 500-8080

ITEM # 307

PURESAN Instant Hand Sanitizer Gel

18oz pump bottles OB case of 16 bottles

QTY 16

Bottles

AVRO-307-CS Rev: 1.0

BAR CODE

37654 23425



puresanusa.com

(855) 500-8080

# ITEM # 307

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18oz pump bottles OB case of 16 bottles

**QTY 16**  
**Bottles**

AVRO-307-CS

Rev: 1.0



## PURESAN OCEAN BREEZE

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58575-141
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	42 mL in 60 mL

### Inactive Ingredients

Ingredient Name	Strength
PERFLUOROALKYLETHYL ACRYLATES (C6-C14) (UNII: TKA54G588X)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
WATER (UNII: 059QF0K00R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58575-141-01	1080 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/01/2018	
2	NDC:58575-141-02	17280 mL in 1 CASE; Type 0: Not a Combination Product	01/01/2018	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	01/01/2018	

**Labeler** - Inopak, Ltd (194718243)

## Establishment

Name	Address	ID/FEI	Business Operations
Inopak, Ltd		194718243	manufacture(58575-141)

Revised: 2/2020

Inopak, Ltd