

HAND SANITIZER- alcohol gel
VANILLA SUGAR PTY 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.

Active Ingredient(s)

Alcohol 70%. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help reduce bacteria on the skin that potentially can cause disease.

Warnings

For external use only. Flammable. Keep away from heat or flame

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Avoid freezing and store below above 40°C (104°F)
- May discolor some fabrics or surfaces

Inactive ingredients

Water, Carbomer, Triethanolamine, Honey Extract, Menthol, Cymbopogon Citratus (Lemongrass) Extract, Anthemis Nobilis (Chamomile) Flower Extract, Melaleuca Alternifolia (Tea Tree) Leaf

Extract.

Package Label - Principal Display Panel

150 mL NDC: 74443-010-15



THE AUSTRALIAN WELLNESS CO.

INSTANT HAND SANITIZER

with natural extracts of

- HONEY
- LEMONGRASS
- TEATREE
- CHAMOMILE

KILLS 99.9% OF BACTERIA

PROFESSIONAL STRENGTH
QUICK DRYING
NO WATER NECESSARY

150mL e 5.07fl oz

NOT TESTED ON ANIMALS

The Australian Wellness Co Instant Hand Sanitizer kills 99.9% of germs without the need for water. Our kind to skin, non-sticky formula leaves you cleansed and refreshed with natural extracts of honey, lemongrass, teatree and chamomile. Use alongside your regular hand washing routine for optimal results.

Batch No.:
Expiry Date:

MADE IN SOUTH KOREA
DESIGNED IN AUSTRALIA

DISTRIBUTED BY
THE AUSTRALIAN WELLNESS CO.
4 PROHASKY STREET,
PORT MELBOURNE
VIC 3207 AUSTRALIA

8 10253 03825 1

Drug Facts	
Active ingredient Alcohol 70%.....	Purpose Antiseptic
Uses Hand sanitizer to help reduce bacteria on the skin that potentially can cause disease.	
Warnings For external use only. Flammable, keep away from fire or flame.	
Do not use on children less than 2 months of age on open skin wounds	
When using this product keep out of eyes, ears and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
Stop use and ask a doctor if irritation or rash occurs.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
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Inactive ingredients Water, Carbomer, Triethanolamine, Honey Extract, Menthol, Cymbopogon Citratus (Lemongrass) Extract, Anthesis Nobilis (Chamomile) Flower Extract, Melaleuca Alternifolia (Tea Tree) Leaf Extract.	

500 mL NDC: 74443-010-50



THE AUSTRALIAN WELLNESS CO.

INSTANT HAND SANITIZER

with natural extracts of

-  HONEY
-  LEMONGRASS
-  TEATREE
-  CHAMOMILE

KILLS 99.9% OF BACTERIA

PROFESSIONAL STRENGTH
QUICK DRYING
NO WATER NECESSARY

500mL e 16.90fl oz



The Australian Wellness Co Instant Hand Sanitizer kills 99.9% of germs without the need for water. Our kind to skin, non-sticky formula leaves you cleansed and refreshed with natural extracts of honey, lemongrass, teatree and chamomile. Use alongside your regular hand washing routine for optimal results.

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HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74443-0 10
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
MELALEUCA ALTERNIFOLIA LEAF (UNII: G43C57162K)	
CARBOMER 934 (UNII: Z135WT9208)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0K00R)	
CYMBOGON CITRATUS WHOLE (UNII: 6AE8LT94NG)	
HONEY (UNII: Y9H1V576FH)	

CHAMOMILE (UNII: FGL3685T2X)

MENTHOL (UNII: L7T10EIP3A)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74443-010-15	150 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:74443-010-50	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - VANILLA SUGAR PTY LTD (962303587)

Establishment

Name	Address	ID/FEI	Business Operations
Mirfeel Korea		695004258	manufacture(74443-010)

Revised: 4/2020

VANILLA SUGAR PTY LTD